Natural Health Products NZ

Submission on Proposed Amendments to the Dietary Supplements Regulations 1985

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CONTENTS

1. INTRODUCTION 1
2. INTERNATIONAL REGULATORY REGIME 1
3. OBJECTIVES AND CRITERIA OF THE REVIEW 2
    - Objectives and policy approach 2
    - Criteria 2
    - Impacts and additional issues to resolve 3
4. PROPOSED AMENDMENTS TO THE DIETARY SUPPLEMENTS REGULATIONS 1985 3
    - Regulation 2 – Interpretation 3
    - Regulation 2A – Meaning of dietary supplement 5
    - Regulation 3 – Maximum daily doses 7
    - Regulation 5 – General requirements for labelling of dietary supplements 10
    - Regulation 7 – Size of letters 11
    - Regulation 9 – Consumer information panel 11
    - Regulation 11 – Therapeutic claims 11
    - Regulations 12-16 – Non-active substances 11
    - Regulation 18 – Vitamins 12
    - Regulation 19 – Minerals 13
    - Regulation 20 – Enzymes 13
5. CONSEQUENTIAL AMENDMENTS TO THE MEDICINES REGULATIONS 1984 14
6. TRANSITION PERIOD AND NEXT STEPS 15
    - Transition period 15
    - Next steps 15

1. INTRODUCTION

1.1 Natural Health Products NZ ("**NHPNZ**") is the peak industry body representing the natural health products sector, which contributes $2.3 billion annually to New Zealand's GDP and plays a critical role in the country's value-added economy. Natural health products include dietary supplements, nutraceuticals, functional foods, and some topical consumer products available for general sale. These products are sold through groceries, pharmacies, health food stores, other retail outlets, and e-commerce platforms.

1.2 Around 70% of our members are exporters, generating more than $600 million in export revenue each year. Globally, vitamin and dietary supplement sales exceed $218 billion annually and continue to grow strongly, according to Euromonitor data. Our members span the entire value chain, from raw material and ingredient supply through to branded goods, contract manufacturing, and service providers.

1.3 Our manufacturers are internationally trusted partners, operating state-of-the-art facilities that meet global compliance standards and the sector employs over 4,000 New Zealanders. The sector also commercialises New Zealand research and innovation through partnerships with research institutes and universities, creating high-value, evidence-based products and ingredients.

1.4 NHPNZ supports the Government's goal to double the value of all exports by 2034. As a rising star in New Zealand's value-added economy, our sector is ready to grow exports and contribute to this goal through enabling regulations.

2. INTERNATIONAL REGULATORY REGIME

2.1 NHPNZ has briefly set out some of the significant parts of the international regulatory regime to provide further background on these regimes and provide context to our proposed amendments.

2.2 The vast majority of the world (by country, sales volume and range of individual products) regulates products marketed as dietary supplements in New Zealand within food regulatory frameworks.

2.3 The New Zealand nomenclature "dietary supplement" is shared by some markets, including the USA, the largest global market. In other markets these products are named health foods or health supplements, or functional foods, food supplements, nutraceutical or other similar names.

2.4 Cross-Border E-Commerce ("**CBEC**") markets (notably China) rely on originating country regulations and recognise dietary supplements as an important product class because the largest exporter of these products via CBEC to China is the USA.

2.5 The countries that name these products dietary supplements (e.g. the USA and Singapore) permit non-culinary herbs as active ingredients.

2.6 There is significant divergence in the detail of regulations for these products across the world, making it imperative that New Zealand exporters can utilise all ingredients and make all health claims that are permitted in all export markets

2.7 For example, in some markets the use of some ingredients may move the product into its own categorisation in between foods and medicines. This is similar in many ways to the distinct

regulatory approach in New Zealand where the Dietary Supplements Regulations 1985 ("**Regulations**") sit outside of the Food Standards Code for conventional foods, in between foods and medicines.

2.8 There are a small number of countries who are outliers, where supplement-type products are regulated as medicines – notably, Australia, Canada, Qatar and South Africa. South Africa's government made a relatively recent move to a medicines regulatory model. This has now been the subject of legal action for regulatory overreach and, the South African Supreme Court of Appeal has since declared the 2017 regulations for complementary medicines and health supplements unlawful and an overreach by the Minister of Health. This has rendered those medicines-type regulations unenforceable.

2.9 CODEX uses the term "food supplements" because the CODEX Standard is only for vitamin and mineral supplements whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

2.10 It is against this backdrop that NHPNZ provides insights into the significance of these reforms for industry and provides suggested amendments for a workable regime that is consistent with international regimes.

3. OBJECTIVES AND CRITERIA OF THE REVIEW

Objectives and policy approach

3.1 NHPNZ strongly supports the objectives and policy approach of the Ministry for Primary Industries' ("**MPI**") review and proposed changes, as:

(a) facilitating the export of dietary supplements is vital for sector growth and competitiveness;

(b) removing restrictions on therapeutic claims for export-only products will enable alignment with importing country requirements and reduce trade barriers;

(c) updating labelling and composition rules ensures the Dietary Supplements Regulations 1985 ("**Regulations**") remain risk-proportional while protecting consumer safety; and

(d) clarifying the food and medicine interface and aligning additive permissions with CODEX standards will strengthen compliance and global market access.

3.2 We suggest an additional key objective is to align with New Zealand's waste minimisation strategy, as reducing waste supports national sustainability goals and meets growing consumer expectations for environmentally responsible products.

Criteria

3.3 NHPNZ agrees with MPI's proposed criteria. In particular, NPHNZ considers that the changes must:

(a) protect public health, ensuring products are consistently safe and appropriate for consumers;

(b) facilitate trade and maintain New Zealand's reputation as a trusted supplier of food, by providing comprehensive composition export exemptions;

(c) maintain international consistency for food regulation; and

(d) ensure the efficiency, transparency, clarity and risk-appropriateness of the Regulations.

3.4 In addition, as in paragraph 3.2, NHPNZ suggests adding as a criterion "aligning with New Zealand's waste minimisation strategy".

Impacts and additional issues to resolve

3.5 Overall, NHPNZ agrees with the rationale and need to change the Regulations. Current challenges impeding export are clear and significant, and the proposed amendments to the Regulations represent a major opportunity to remove these barriers. This reform will strengthen New Zealand's competitiveness in international markets, support the Government's export growth objectives, and ensure that safety and substantiation standards remain robust.

3.6 Other issues we consider should be resolved as part of this update are:

(a) general sale classification issues;

(b) export exemptions regarding maximum daily doses for products that meet the importing country requirements; and

(c) further opportunities for alignment with international standards and nomenclature.

3.7 However, NHPNZ considers that amendments to the Regulations alone will not resolve all challenges facing the natural health products sector and we look forward to the further regulatory reform for the industry, to unlock the full potential of New Zealand's natural health products industry.

4. PROPOSED AMENDMENTS TO THE DIETARY SUPPLEMENTS REGULATIONS 1985

Regulation 2 – Interpretation

Meaning of controlled dosage form

4.1 NHPNZ supports the inclusion of a definition of controlled dose form, with the following modified definition:

> **Controlled dosage form** means a form described as a liquid, powder, tablet, capsule, lozenge, pastille or cachet, or other solid dose form designed to deliver a specific ~~small unit~~ quantity of active ingredients per dose over a specified time period.

4.2 The proposed modification removes unnecessary, repeated and ambiguous text, in line with the intention of the proposed amendment to provide clarification both to industry and regulators.

4.3 A dose is already understood as a small unit quantity. The inclusion of the explicit use of the terminology "small unit", therefore overcomplicates the definition and gives scope for misinterpretation, as "small unit" can be interpreted as meaning an individual unit sachet for a powder or a liquid. This is of particular concern given it has already been misinterpreted as such by regulators, creating unnecessary costs and productivity issues for manufacturers. The term "small"

is also ambiguous, often defined as less than normal or insignificant, and is problematic on its own because it relies on subjective judgement. Therefore, we propose that "small unit" is removed from the definition of controlled dosage form.

4.4 We suggest the definition and any guidance for controlled dosage also ensures that calibrated spoons, individual unit sachets or dropper bottles are not specifically required for the following reasons:

(a) major jurisdictions (including the EU[1], US[2] and Japan[3]) and the CODEX[4] satisfy "controlled/measurable dose" requirements through clear labelling, not dosing devices;

(b) where regulators do require or strongly recommend dosing devices, it is almost always in the context of medicines or medicine-like products with narrow therapeutic windows. These are clearly described as guidance for higher-risk health products, not as conditions for defining a dietary or food supplement;

(c) therefore, re-classifying or restricting New Zealand dietary supplements based on whether a device is included would:

(i) blur the conceptual line between foods and medicines (contrary to the "food umbrella" positioning of dietary supplements); and

(ii) create non-tariff barriers and re-packaging requirements that do not exist in major markets and are not supported by CODEX;

(d) the additional requirements would create unnecessary cost and capability burden on industry, including:

(i) requiring product packaging to be changed, resulting in many packing lines not being able to deliver these requirements; and

(ii) requiring stability programs to be restarted, and stability requirements may not be able to be met (e.g. dropper bottle requirements may not be able to be met under environmental specifications); and

(e) this would create additional packaging waste at a time when businesses are actively reducing packaging locally and globally, and it is inconsistent with the Ministry for the Environment's Waste Minimisation Strategy.[5]

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1 Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements.

2 Dietary Supplement Health and Education Act of 1994 (US).

3 Food with Nutrient Function Claims (FNFC), Foods with Function Claims (FFC) and Food for Specified Health Uses (FOHSU) (Japan).

4 CODEX Guidelines for Vitamin and Mineral Food Supplements (CAC/GL 55-2005).

5 Single-use plastics, laminated sachets, polystyrene, LDPE soft plastics, and small PP items are all identified as problematic under waste reform initiatives. New Zealand's Waste Minimisation Act and the Plastic Packaging Product Stewardship Scheme aim to eliminate unnecessary packaging, particularly components that cannot be recycled, use multi-layer materials, or are small-format consumables such as scoops and syringes. Globally, regulations like the EU Packaging and Packaging Waste Regulation are driving reductions in non-recyclable plastics, mandating recyclability, and banning certain single-use formats. Many countries already restrict polystyrene and single-use plastics, and Extended Producer Responsibility fees penalise non-recyclable packaging, making mandated measuring devices an unnecessary compliance cost.

Additional definitions

4.5 NHPNZ supports the addition of MPI's proposed definition of "dose or dosage".

4.6 NHPNZ recommends that the following definitions are added to regulation 2:

> **active pharmaceutical ingredient** means any substance or mixture of substances intended to be used in the manufacture of a medicine and that, when used in the production of a medicine, becomes an active ingredient of the medicine intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.[6]
>
> **food** has the same meaning as in section 9 of the Food Act 2014.

4.7 Our submission points below provide additional context for these proposed definition insertions.

Regulation 2A – Meaning of dietary supplement

4.8 It is important that regulation 2A ensures that there is a consistent and clear definition of dietary supplements, which reflects industry practice, is aligned with the empowering legislation and has clear parameters.

4.9 NHPNZ is concerned that the proposed change to regulation 2A does not meet these objectives. We have identified additional amendments to the definition that are required for consistency and clarity.

4.10 NHPNZ does not support MPI's proposed amendment to regulation 2A to add "is safe and suitable for the intended purpose" to the definition of dietary supplement.

4.11 The Food Act 2014, which is the primary legislation under which the Dietary Supplement Regulations 1985 ("**Regulations**") are deemed to be made, already imposes requirements to this effect. Specifically, the Food Act 2014 requires that foods (including dietary supplements) must be used, capable of being used, or represented as being for use, for human consumption,[7] and be safe and suitable for their intended use.[8]

4.12 It is unnecessary and inappropriate for regulation 2A to "align and reinforce the expectations in the Food Act 2014". Regulation 2A is concerned with defining what a dietary supplement is – not what safety standards they must meet. The proposed amendment would merely duplicate existing obligations that apply to all food under the Act, which means the definition in the Regulations becomes convoluted and circular. Given that one of the intentions of the proposed amendments is to provide clarity, this amendment is against that purpose.

Amendments for consistency and clarity

4.13 NHPNZ recommends that further amendments to regulation 2A are made for clarity and to achieve alignment with the New Zealand Food (Supplemented Food) Standard 2016 ("**SF Standard**") and international practice.

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6 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use *ICH Harmonised Tripartite Guideline: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients Q7* (2000) at [20].

7 Food Act 2014, s 9.

8 Food Act 2014, ss 12, 14.

4.14 Namely, regulation 2A(6) currently provides that a dietary supplement must be "intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food." While we support the intent of this requirement, which is to ensure that dietary supplements are within the broader definition of food under the Act, we have concerns with the way that it is being interpreted.

4.15 The provision can be interpreted as requiring something to be normally found in another food before it can be included in a dietary supplement. This makes little sense when the focus should be on ensuring that the dietary supplement itself is a food. For example, a wide range of non-culinary herbal ingredients such as St John's Wort and black cohosh are not normally found in foods other than dietary supplements, but there is no doubt that they should be classified as a dietary supplement (which, by definition, makes them a food).[9]

4.16 If the current definition is interpreted in an unduly narrow way, then it would have the effect of excluding many substances that have long been accepted as safe and suitable for use in dietary supplements and permitted in dietary supplements internationally.

4.17 Furthermore, these types of non-culinary herbal ingredients have been recognised as safe for human consumption as they are allowed in supplemented foods ("**SFs**"),[10] all of which demonstrates that these substances can be safely incorporated into food products without compromising consumer safety. It also highlights the need for regulatory alignment to ensure that different regulators are not taking inconsistent approaches to the regulation of food products.

4.18 We recommend a two-fold solution to resolve this issue, which also has the effect of reinforcing that dietary supplements are subject to the Food Act 2014:

(a) removing subsection (6); and

(b) amending subsection (5) to state "It is intended to be ingested orally **as a food**."

4.19 This proposal would provide clarity on what is considered a dietary supplement and reduce the grey areas that have arisen from the current requirements set out in regulation 2A(6), while also not compromising on safety and the purpose of the Regulations. By making it explicitly clear in the Regulations that dietary supplements are food for the purposes of the Food Act 2014, it clarifies that the substance must be:

(a) safe for human consumption;

(b) safe and suitable for its intended purposes; and

(c) not a medicine as any food product cannot also be a medicine.[11]

4.20 All of this will assist with MPI's intention of removing outdated requirements and ensure a clear and consistent definition of dietary supplements.

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9 For example, Medsafe stated in 2009 that "products containing black cohosh are generally regarded as dietary supplements and regulated as foods": Medsafe "Minutes of the 138th Medicines Adverse Reactions Committee Meeting" (11 June 2009) at [2.1.23].

10 St John's Wort can be included in supplemented foods: New Zealand Food (Supplemented Food) Standard 2016 at [1.10].

11 Food Act 2014, s 9(1)(c)(iii)(A).

Regulation 3 – Maximum daily doses

4.21 MPI proposes the following amendments to regulation 3:

(a) increasing the maximum daily dose of zinc from 15mg to 20mg (as permitted in supplemented foods);

(b) amending subsection (2) to link to the Nutrient Reference Values for Australia and New Zealand ("**NRV**") and reference daily doses for a specific life stage and gender;

(c) including a list of food standards that mean the product is not a dietary supplement;

(d) adding a requirement that a dietary supplement may not contain any substance scheduled under the Misuse of Drugs Act 1975; and

(e) adding a requirement that a dietary supplement may not contain any substance classified as prescription, restricted, or pharmacy-only medicine.

4.22 We address each proposal in turn, as well as further issues that these proposals do not address relating to general sales medicine classification.

Alignment with Supplemented Foods Standard

4.23 NHPNZ supports the proposed amendment to increase the maximum daily dose ("**MDD**") of zinc from 15mg to 20mg, as permitted in SF under the SF Standard.

4.24 Under the same rationale, we also propose increasing the MDD of Vitamin D from 25mcg to 40mcg to align with the MDD permitted in SF under the SF Standard. This will ensure consistency between the SF Standard and the Regulations.

Nutrient Reference Values for Australia and New Zealand

4.25 NHPNZ supports adding reference to the NRV and the replacement of the reference to *Recommended Dietary Allowances*, published by the Food and Nutrition Board of the National Academy of Science and National Research Council, Washington DC, USA, with the current edition of the "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements issued by the Food and Nutrition Board of the Institute of Medicine in the USA".

4.26 However, we consider that issues arise where substances contained in these references, when used in medicines, are classified as prescription, restricted, or pharmacy-only medicine under Schedule 1 of the Medicines Regulations 1984. We address these issues below.

4.27 More generally, NHPNZ also strongly recommends that the upper limits for vitamins and minerals stated in the NRV and / or Dietary Reference Intakes are the MDDs for all vitamins and minerals. This will ensure consistency with standards, and reflects best practice given that these upper limits are determined by scientific research, to confirm what the levels of vitamins and minerals are that are still for a nutrient value.

4.28 NHPNZ also considers the amendments to reference daily doses for a specific life stage and gender to be appropriate.

List of food standards that mean the product is not a dietary supplement

4.29 While NHPNZ supports providing that "a food for which there is a food standard in the food code" is not a dietary supplement in the Regulations, we do not support including the list of specific standards. The list of relevant standards will change over time, and having a specific list will make the Regulations confusing and require further amendments in future. Instead, the proposed catch-all should be amended slightly, and then guidance and support can be provided by MPI to the industry to assist with understanding what may or may not be relevant for particular products. We suggest that this provision should state that:

> a food for which there is a joint standard in the food code **or a New Zealand only food standard**

4.30 This addition would ensure that both the joint standards and New Zealand only standards are appropriately captured.

Prohibition of Misuse of Drugs Act 1975 scheduled substances

4.31 NHPNZ considers that it should already be the case that dietary supplements are prohibited from containing any substance scheduled under the Misuse of Drugs Act 1975 but sees no harm including an additional provision in the Regulations to this effect.

Prohibition of Medicines Regulations scheduled substances

4.32 NHPNZ considers that the proposal to require that a dietary supplement may not contain any substance classified as prescription, restricted, or pharmacy-only medicine, as defined in Schedule 1 of the Medicines Regulations 1984 is unworkable and would have a number of unintended consequences.

4.33 Currently, there are a number of substances commonly used in dietary supplements (including those expressly permitted in the Regulations[12] and in the NRV table) that, when used above certain amounts in medicine, are classified as prescription, restricted, or pharmacy-only medicine, including Vitamin A,[13] Vitamin D,[14] iodine,[15] iron,[16] selenium,[17] zinc,[18] and other substances like tryptophan.

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12 Dietary Supplements Regulations 1985, regulation 3.

13 Vitamin A is classified as a prescription medicine, except for internal use in medicines containing 3 mg or less of retinol equivalents per recommended daily dose, in parenteral nutrition replacement preparations, or for external use in medicines containing 1% or less.

14 Vitamin D is classified as a prescription medicine, except for external use, for internal use in medicines containing 25 mcg or less per recommended daily dose, or in parenteral nutrition replacement preparations.

15 Iodine is classified as a pharmacy-only medicine, except for external use in medicines containing 2.5% or less or for internal use in medicines containing less than 300 mcg per recommended daily dose

16 Iron is classified as a prescription medicine, or a pharmacy-only medicine where it is for oral use either in medicines containing more than 24 mg per recommended daily dose or in medicines containing more than 5 mg per dose unit and more than 750 mg of iron per pack, except for oral use in medicines containing 24 mg or less per recommended daily dose in medicines containing not more than 5 mg per dose unit; except for oral use in medicines containing 24 mg or less per recommended daily dose in medicines containing more than 5 milligrams per dose unit in packs containing not more than 750 mg of iron.

17 Selenium is classified as a prescription medicine, or a pharmacy-only medicine where it is for oral use in medicines containing 300 mcg or less and more than 150 mcg per recommended daily dose or for external use except in medicines containing 3.5% or less of selenium sulphide.

18 Zinc is classified as a prescription medicine, except for internal use in medicines containing 25 mg or less per recommended daily dose, for internal use in medicines containing 50 mg or less and more than 25 mg per recommended daily dose in packs that have received the consent of the Minister or the Director-General to their distribution as general sale medicines, when sold in the manufacturer's original pack and when labelled with a statement that the product may be dangerous if taken in large amounts or for long periods, for external use when in medicines containing 5% or less, or in parenteral nutrition replacement preparations.

4.34 As MPI is aware, the mere fact that a substance appears in Schedule 1 does not automatically make it a medicine. To be a medicine, a substance must also meet the definition of a medicine under the Medicines Act 1981, which expressly excludes food. As discussed above, dietary supplements are a special type of food under the Food Act 2014 and thus are not medicines.

4.35 Overall, whether or not a product is a medicine or dietary supplement will depend on a comprehensive assessment of its principal purpose. The assessment of purpose may be informed by whether a substance appears on Schedule 1, but that cannot be determinative, particularly for substances that can have different uses.

4.36 Therefore, simply prohibiting Schedule 1 substances from being used in dietary supplements does not properly and fully reflect how the boundary between medicines and dietary supplements actually works.

4.37 The proposed amendment would be unworkable because it would have the unintended consequence of not allowing the vitamins and minerals noted above to be used in *any* dietary supplement. This is clearly not the intention of the amendment, given regulation 3 explicitly allows those substances in dietary supplements. Such a change would be a significant departure from the current practice and would have severe adverse impacts on the sector.

4.38 Therefore, NHPNZ strongly recommends that this proposal is not included in the Regulations, as it is unnecessary (with a dietary supplement by its very nature not being a medicine) and due to the unintended consequences that would occur.

4.39 If despite our strong views to the contrary it is decided that the proposal must be included in the Regulations, then it is essential that the following amendments are made to reduce the unintended consequences discussed above:

> A dietary supplement may not contain any substance in Schedule 1 of the Medicines Regulations 1984 **unless:**
>
> **(a)** **the substance is not an active pharmaceutical ingredient; or**
>
> **(b)** **each daily dose of the substance does not contain more than the maximum specified in regulation 3(1) or (2).**

4.40 NHPNZ would ask that this option is only used as a last resort, as it creates more complexity in the regime.

General sale classification issues

4.41 MPI's current proposal does not address the issue of the inclusion in dietary supplements of substances used in general sale medicines. NHPNZ understands that Medsafe's position is that ingredients classified as general sale medicines have been assessed as therapeutic and therefore are not suitable for inclusion in a dietary supplement, unless specifically authorised under regulation 3 of the Regulations.

4.42 As discussed above, we consider that the proper interpretation of the boundary between medicines and dietary supplements does not exclude the use of these substances in dietary supplements. As with Schedule 1 substances, many substances that appear under the general sale classification in the Medicines Classification Database are suitable for dietary supplements and are widely accepted for

use in dietary supplements and food.[19] It is essential for the sector to be able to include these ingredients in dietary supplements, as limiting their use would significantly reduce competitiveness and business viability in both domestic and export markets. However, we acknowledge that there are also many substances classified as general sale medicines that are generally understood to not be appropriate for inclusion in dietary supplements.

4.43 We propose the following solution could assist with clarifying the interpretation of the boundary between general medicines and dietary supplements:

(a) an amendment to regulation 3 to allow substances classified as general sale medicines to be included in dietary supplements, provided that the substance is not commonly associated with therapeutic claims as an active pharmaceutical ingredient in medicines.

4.44 By way of illustration, ibuprofen would not meet this test because it is an API commonly associated with therapeutic claims as an active pharmaceutical ingredient in medicines. On the other hand, substances classified as general medicines that are currently used in dietary supplements would meet this test for the opposite reason.

Export exemption regarding maximum daily doses for products that meet the importing country requirements

4.45 As is the position for the proposed export exemption for therapeutic claims, it is essential for the industry to be able to export dietary supplements that are tailored to the importing market. The export exemption is only effective if the products are exempt from compositional, labelling and claim requirements.

4.46 NHPNZ proposes that regulation 3 is amended to have the following inserted:

> The maximum daily doses for vitamins and minerals set out in this regulation do not apply to dietary supplements containing those vitamins and minerals, provided that they are manufactured and packed solely for export.

4.47 The Regulations should also specify, as will be required for the therapeutic claims exemption, that there are certain recordkeeping requirements. This is a critical issue, that is vital for the unlocking of the economic potential of the dietary supplements market. Products will still be required to meet the importing country regulatory requirements, which will ensure that they are safe and effective products.

Regulation 5 – General requirements for labelling of dietary supplements

4.48 NHPNZ supports all MPI's proposed amendments to regulation 5, which support consumer safety and clarity for industry and regulators.

[19] For example, acetylcysteine, aescin, aloes, benzoic acid, berberine, beta carotene, blood, borax, boric acid, boron, bromelains, capsicum oleo-resin, cardamom compound, chromium, colecalciferol, copper, crocus sativus (saffron), cyanocobalamin, ergocalciferol (a form of Vitamin D), fluorides, folic acid, folinic acid, galactose, glutathione, guar gum, hydroxocobalamin, iodine, iron, jaborandi, liquorice deglycyrrhinized, magenta, nicotinic acid, nicotinamide, pancreatic enzymes, phytomenadione, pomegranate, potassium, pyridoxal, pyridoxamine, quinine, selenium, sodium bitartrate, sodium nitrite, sodium phosphate, tannic acid, tryptophan, Vitamin A, Vitamin D and zinc.

Regulation 7 – Size of letters

4.49 NHPNZ supports MPI's proposed amendments to regulation 7, which reflect modern international industry practice.

Regulation 9 – Consumer information panel

4.50 NHPNZ supports MPI's proposed amendment to regulation 9, which supports consumer safety.

Regulation 11 – Therapeutic claims

4.51 NHPNZ supports MPI's proposed amendments to regulation 11, as removing restrictions on therapeutic claims for export-only products will enable alignment with importing country requirements and significantly reduce trade barriers.

Regulations 12-16 – Non-active substances

4.52 NHPNZ supports the proposed amendments to regulations 13-16, and recommends the following further amendments:

Tabletting aids

(a) Adding regulation 12, relating to tabletting aids, to the list of regulations that will be amended. Substances that meet the definition in regulation 12(1) are included in CODEX STAN 192-1995 and Part 1.3 of the Food Standards Code, and ensures additional substances permitted in these standards can be used as tabletting aids in dietary supplements. This change ensures alignment with proposed permissions for other non-active substances, such as preservatives, antioxidants, colouring agents, and artificial sweeteners.

(b) Replacing all references to "tabletting aid(s)" in the Regulations with "formulation aid(s)". Clarifying the terminology to “formulation aid” modernises the regulations and enhances clarity, as it is broader and more accurate, covering substances used to create all forms of dietary supplements, not just tablets.

Artificial sweeteners

(c) Replacing all references to "artificial sweetener(s)" in the Regulations with "sweetener" and removing from the definition in regulation 16(1) "and that is not a saccharide, polyhydric alcohol, or honey." These amendments align with international standard nomenclature (including the CODEX).

Usage conditions

(d) Adding that the usage conditions described in CODEX STAN 192-1995 and Part 1.3 of the Food Standards Code do not apply to dietary supplements, as these refer specifically to conventional foods and are not suitable conditions for dietary supplements.

Either Standard Applies

(e) Replacing “and” with "or" so it is clear that a substance is permitted if it appears in either CODEX STAN 192-1995 *or* Part 1.3 of the Food Standards Code. This will ensure that there

are no issues if there is a conflict between the CODEX and Food Standards Code, while ensuring that proper standards are met.

Additional Substance Permissions

(f) Adding to regulations 12 - 16 that substances that are permitted in CODEX or the Food Standards Code as conventional food ingredients are permitted in dietary supplements regulations 12-16. This would ensure that ingredients like rice flour can be used as a processing aid and cacao can be used as a natural colour. These types of ingredients are widely accepted for use in dietary supplements, however the proposed amendment would prevent the use of such ingredients as they are not "food additives". This would be harmful to the industry as it would stifle innovation and exports and is also unnecessary, given there is no harm associated with these ingredients as they will still be required to be permitted by CODEX or Food Standards Code.

4.53 These proposed amendments strengthen public health protections, align with international standards, facilitate trade, and uphold good regulatory practice by confirming the permissibility of these substances for their intended use in dietary supplements.

Regulation 18 – Vitamins

4.54 The current list of vitamins is outdated and does not include forms that are recognised as suitable for human consumption internationally. This prevents dietary supplements from containing internationally accepted safe and suitable forms of vitamins for both the domestic market and for export. NHPNZ considers the New Zealand market and export markets would benefit from alignment with international nomenclature and standards, particularly with the Food and Agriculture Organization of the United Nations ("**FAO**") and World Health Organization ("**WHO**").

4.55 NHPNZ recommends replacing the list of "Dietary supplement described as vitamins or containing vitamins" with the following, in line with FAO nomenclature:

Vitamin A
Thiamin
Riboflavin
Niacin
Pantothenate
Vitamin B6
Vitamin B12
Vitamin C
Vitamin D
Vitamin E
Biotin
Vitamin K
Folate

4.56 Consequential amendments would need to be made to the column headed "Calculated as".

4.57 NHPNZ also recommends amending regulation 18(1) to link to CODEX CAC/GL55 Part 3.1, which states that:

> Vitamin and mineral food supplements should contain vitamins/provitamins and minerals whose nutritional value for human beings has been proven by scientific data and whose status as vitamins and minerals is recognised by FAO and WHO.

4.58 Our proposed amendments would align with vitamins recognised by the FAO and WHO, with regulation 18(1) revised to state:

> The dietary supplements specified in the first column of the table of this subclause, **and any vitamins or provitamins whose status as vitamins is recognised by the Food and Agriculture Organization of the United Nations and World Health Organization**, or any compound of those supplements, and no others, may be described as vitamins, and the quantity of vitamins in those dietary supplements shall be calculated in accordance with the second column of that table.

Regulation 19 – Minerals

4.59 We note that MPI's proposed amendment to regulation 3(2) states that:

> Every dietary supplement described as or containing any mineral, other than a mineral specified in regulation 19(1), shall be so manufactured that each daily dose (for a specific life stage and gender) does not contain more than the Upper Limit specified in the current edition of the Nutrient Reference Values for Australia and New Zealand or the maximum specified in the current edition of the "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements" issued by the Food and Nutrition Board of the Institute of Medicine in the US.

4.60 However, regulation 19 currently provides that the only dietary supplements that can be described as minerals are those listed in subsection (1). Therefore, there is a conflict between regulations 3 and 19, which could lead to inconsistency in interpretation and application, limiting the ability to include other internationally permitted minerals in dietary supplements.

4.61 We propose the following addition to regulation 19(1) to make the intention of regulation 3 clear, namely that minerals listed in the NRV and/or Dietary Reference Intakes can be included in dietary supplements:

> any other mineral listed in the Nutrient Reference Values for Australia and New Zealand or the maximum specified in the current edition of the "Dietary Reference Intakes: The Essential Guide to Nutrient Requirements" issued by the Food and Nutrition Board of the Institute of Medicine in the US.

Regulation 20 – Enzymes

4.62 NHPNZ recommends amending regulation 20 as follows to modernise the Regulations and use the internationally recognised nomenclature for enzymes, supporting international alignment and trade:

> The following enzymes may be added to dietary supplements:

(a) digestive enzymes that are Class EC 3 Hydrolases in the International Union of Biochemistry and Molecular Biology Enzyme Nomenclature List that function as:[20]

(i) carbohydrases:

(ii) proteases:

(iii) lipases:

(iv) nucleases:

(v) phytases:

(b) catalase (Class EC 1.11.1.6 in the International Union of Biochemistry and Molecular Biology Enzyme Nomenclature List):

(c) superoxide dismutase (Class EC 1.15.1.1 in the International Union of Biochemistry and Molecular Biology Enzyme Nomenclature List).

4.63 We also recommend adding that enzymes for the purpose of additives may be used in the manufacturing of dietary supplements if they are described in CODEX STAN 192-1995 or Part 1.3 of the Food Standards Code, to align with the proposed amendments to regulations 12-16.

5. CONSEQUENTIAL AMENDMENTS TO THE MEDICINES REGULATIONS 1984

5.1 MPI's current proposal is to provide an exemption in the Regulations that allows therapeutic claims to be made in respect of dietary supplements intended for export (subject to certain conditions). Consequential amendments to the Medicines Regulations 1984 would confirm that a dietary supplement is not a related product under the Medicines Act 1981 if it is exempt from the restriction on therapeutic claims in the Regulations.

5.2 NHPNZ is concerned that this amendment could create interpretation issues, particularly as Medsafe's approach to the general sale classification issue has highlighted that it may deem a product to be a medicine (ie not a related product) solely because it makes a therapeutic claim. That is, Medsafe could determine that a therapeutic claim means that the product is used *wholly or principally* for a therapeutic purpose. This compares to a related product, which is a food (or other product) where any therapeutic claim is made, but the claim is not sufficient to mean that the product is used wholly or principally for a therapeutic purpose.

5.3 Therefore, in order to give full effect to the intent of the proposal, and to account for our additional compositional requirements exemption, to ensure that dietary supplements for export only can make therapeutic claims and use importing countries maximum daily doses, we propose the following wording for the consequential amendment to the Medicines Regulations 1984:

> A dietary supplement is not a **medicine or** related product for the purposes of the Medicines Act 1981 provided that it is exempt from the restriction on therapeutic claims **and maximum daily doses** in the Dietary Supplements Regulations 1985.

[20] International Union of Biochemistry and Molecular Biology *IUBMB Enzyme Nomenclature List* available here: ExplorEnz: Search the Official IUBMB Enzyme List.

6. TRANSITION PERIOD AND NEXT STEPS

Transition period

6.1 NHPNZ supports an adequate transition period to protect public health and minimise the impact of these new requirements on businesses.

6.2 NHPNZ proposes a five-year transition period, comprising:

(a) a three-year transition phase; and

(b) a two-year sell-through period for stock-in-trade.

6.3 The proposed transition period would provide sufficient time for:

(a) sell-through of existing product, noting that product shelf life is generally 24–48 months;

(b) sourcing allergen statements and/or conducting analytical testing for inputs;

(c) development of substantiated warning statements; and

(d) relabelling requirements, including sell-through of existing label stock.

6.4 A five-year transition period would also provide consistency with the implementation approach for similar labelling changes. For example, when FSANZ introduced plain English allergen labelling, a three-year transition period plus a two-year stock-in-trade period was provided, resulting in a five-year implementation timeframe.[21]

Next steps

6.5 NHPNZ are at MPI's disposal to respond to any follow-up questions regarding the proposed amendments outlined in this consultation, as well as any future amendments under consideration. We are also willing to assist and contribute to the development of any industry guidance that may be required to support the implementation of these amendments.

6.6 While these amendments represent an important step forward, NHPNZ considers that changes to the Regulations alone will not resolve all challenges facing the natural health products sector. Legislative reform is essential to clarify the interface between food and medicines and to unlock the full potential of New Zealand's natural health products industry.

6.7 We look forward to continuing to work collaboratively with MPI to achieve a regulatory environment that enables innovation, safeguards consumers, and strengthens New Zealand's position in the global natural health products market.

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[21] Food Standards Australia New Zealand *Approval Report – Proposal P1044: Plain English Allergen Labelling* (2020) at [4.1]: This provided that businesses had a 3-year transitional period to comply with the new requirements. During this period, importers could comply with the old declaration requirements or new requirements. Following this, a 2-year stock-in-trade period provided that food packaged and labelled in accordance with the old requirements could be sold for up to 2 years.