

# Response ID ANON-WP81-BN4E-S

Submitted to Product Labelling Review  
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## Introduction

1 What is your name?

Name:  
Samantha Gray

2 What is your role title?

Role title:  
Government Affairs Director

3 What is your phone number? (optional)

Phone number:  
0211197226

4 What is your email address?

Email:  
govtaffairs@naturalhealthproducts.nz

5 What is the name of your organisation?

Organisation:  
Natural Health Products NZ

6 Are you happy for us to contact you if we have questions about your submission?

Yes

## About Your Organisation

7 What sector(s) does your business operate in?

Manufacturing, Other Services

If other, which sector?:

We are the peak industry body for the natural health products sector [www.naturalhealthproducts.co.nz](http://www.naturalhealthproducts.co.nz)

8 How many people work at your organisation?

Large business – 50 or more FTE employee

9 What best describes your organisations interest in this review?

Industry Body

If other, please describe::

10 What region(s) does your business operate in?

Countrywide

11 If you are an importer what country/s do you import from?

Other country

If other, please state which country:

Some of our members import products from a range of countries across the world

12 If you are an exporter, which country/s do you export to?

China, Australia, United States, Japan, South Korea, United Kingdom, Germany, Indonesia, Singapore, Malaysia, Other country

If other, please state which country:

Our members also export to other SE Asian, Middle Eastern, North American and Oceanian countries

## Experience with Product Labelling

13 Which types of products does your business handle?

Agricultural Products & Veterinary Medicines, Food & Beverages, Organic Products, Medicines & Therapeutic Products, Cosmetics, Other

If other, please describe:

We have checked "other" because a large proportion of our products are Dietary Supplements

Tell us the relevant product labelling requirements your business needs to comply with (Domestic & International) where appropriate:

Internationally, dietary supplements labels must comply with the labelling regulations for each country. These regulations diverge markedly per country. At present in practice exported dietary supplements must comply with the domestic Dietary Supplements Regulations (1985). These regulations are markedly out of date and not fit for purpose. The Regulations and the Medicines Act prevent dietary supplements from making health benefit claims that are permitted in export markets and that consumers demand. Consumers make purchasing decisions for a dietary supplement based on the health benefits that are communicated on the product label.

Other export product classes such as Foods, Cosmetics, Animal Health Products all need to comply with the labelling requirements of each country also. Domestic products are required to comply with the labelling requirements of each product class.

14 For the following product types, how easy is it to comply with the relevant product labelling regulations for your business?

Ease of Compliance - Clothes, Shoes, Fabrics & Furnishings:

Ease of Compliance - Exported Products:

Very Difficult

Ease of Compliance - Imported Products:

Ease of Compliance - Electronic Products:

Ease of Compliance - Vehicles:

Ease of Compliance - Building Materials:

Ease of Compliance - Chemicals & Hazardous Substances:

Ease of Compliance - Agricultural Products & Veterinary Medicines:

Ease of Compliance - Food & Beverages:

Ease of Compliance - Wine:

Ease of Compliance - Organic Products:

Ease of Compliance - Medicines & Therapeutic Products:

Ease of Compliance - Cosmetics:

Ease of Compliance - Cigarettes, Tobacco & Products that contain Nicotine:

Ease of Compliance - Media & Film:

Ease of Compliance - Other:

Tell us about your selection(s) above and if you selected difficult or very difficult, please tell us why.:

Although our members products do fit into a range of categories, the most important category for our association is Dietary Supplements. It is impossible for our members to comply with export requirements where the importing countries regulations differ from NZ's. As every country has their own labelling regulations for these products, NZ exporters often find themselves in an impossible situation.

15 What aspects of product labelling regulations work well for your business?

Tell us what aspects of labelling requirements in regulation work well for your business.:

Focused on Dietary Supplements, the requirements for declaration of quantities or proportions of active ingredients and identification of non-active ingredients by class or name for domestic labelling works well because it provides consumers with the information they need to make informed decisions.

16 What are the regulatory challenges you face with product labelling?

Tell us how the challenge/s affect you: In your response, please include relevant detail, for example the specific requirements & associated regulation that you find challenging and why you find this challenging for your business.:

Exported products cannot comply with importing countries regulations including labelling. We have provided the detail of amendments required to regulations that sit under the Food Act - Dietary Supplements Regulations (1985) and the Medicines Regulations (1984) to fix this issue so that Dietary Supplements can access and compete in export markets. These amendments will open up \$500 million in exports for NZ. This information has been provided already and we will also provide this to you as follow up.

17 How do product labelling regulations affect your business operations?

If yes, please explain what you would like to do and how current requirements have affected this:

The restrictions on exported products described above has severely constrained business operations for our members. There are multiple examples of our members turning away business opportunities presented to them because they cannot access the markets because dietary supplements must comply with NZ domestic regulations. Our members cannot participate in opportunities in emerging and high growth markets such as in SE Asian and Middle Eastern countries. Some of our members have shifted manufacturing to contract manufacturing in countries that provide export exemptions so that they export products from those countries. This has constrained industry growth with consequential impacts on high value manufacturing capability and capacity in NZ and jobs. Additionally, because health benefit claims cannot be made, our members are extremely cautious about investing in R&D in NZ as there is no ROI. Due to tight economic conditions our association has real concerns that members may move further manufacturing operations offshore if the situation is not resolved urgently. As an association we are extremely concerned that our sector is unpalatable for overseas investment because the opportunities for export are so severely constrained. Furthermore the flow on effect to innovation in the nutraceutical product and ingredient sector is obvious, because innovation of these high value products relies on export channels to market for success. There is significant lost opportunity for volume to value growth from primary sector products and the bio-actives discovery ecosystem.

18 How difficult is it for you to meet current international and/ or domestic regulations?

Current requirements difficulty - Domestic Requirements:

Difficult or costly to meet and have prevented me entering new markets or growing my business

Current requirements difficulty - International Requirements:

Difficult or costly to meet and have prevented me entering new markets or growing my business

Tell us about the domestic regulations you find difficult, if any::

It is difficult to compete with products purchased by consumers from e commerce because the NZ regulations prohibit health benefit claims on label.

Tell us about the international regulations you find difficult, if any::

As already detailed in our response, because dietary supplements must comply with NZ regulations, and other countries' regulations diverge markedly, it is extremely difficult for NZ products to comply with international regulations.

19 Do you consider labelling regulations impose unnecessary compliance costs on your business?

Yes

If yes, what specifically that you consider unnecessary adds to your compliance costs?:

It is necessary for exported dietary supplement to have to comply with NZ regulations when the importing country's regulations are in place.

Please estimate the time and/or financial costs and how this occurs.:

This is a lost opportunity of \$500 million per annum to the NZ economy in direct export sales, with further consequential impact to the sector where export manufacturing has moved overseas.

## Opportunities for improvement

20 What changes would make product labelling regulation more efficient or effective from your perspective?

Tell us what changes would make product labelling regulation more efficient or effective::

As soon as the government implements the amendments to the Dietary Supplements (1985) and the Medicines Regulations (1984) to enable export exemptions for dietary supplements, the export issue will be resolved. We have provided the detail for these amendments and will follow up directly to ensure your group also receives a copy of this work.

21 Would aligning New Zealand's product labelling standards more closely with international standards benefit your business?

No

If yes, Please note the standards you would like to follow:

This is an impossible question to answer for dietary supplements because the labelling standards for this class of products diverges markedly from country to country. The benefit to NZ will be gained by enabling the workable export exemption process we have proposed so NZ products can access

and compete in international markets.

If yes, please tell us how following international standards will help::

## Experience with Regulators

22 Which Government Agency/s do you get product labelling guidance from?

Ministry for Primary Industries (MPI), MedSafe, Environmental Protection Authority (EPA), Industry Association, Other

If other, please describe:

ANZA/TAPS (Therapeutic Advertising Pre-Vetting Service) provides industry self-regulatory guidance on certain aspects of dietary supplement product labelling including claims, although their service is not a comprehensive labelling review service.

Professional Regulatory Consultants are also available in the market to assist

No

Please tell us why you said yes or no:

Member feedback is that it is very difficult to understand and comply with export regulations because products must comply with NZ domestic regulations.

For domestic regulations, member feedback is that the out of date domestic regulations are also difficult to comply with, particularly for health benefit claims where the regulator's interpretation of compliance varies and varies over time.

23 Have you been contacted by, or made contact with the agency or agencies?

Yes

Information, Guidance, Compliance & Monitoring (Including Exemptions where appropriate), Enforcement

If the contact was for some other reason, please describe:

24 In your contact with the agency or agencies, what went well and what didn't?

Experience with the agency - The information provided by the agency was clear and easy to understand.:

I don't know

Experience with the agency - The guidance provided by the agency was helpful.:

I don't know

Experience with the agency - The agency responded to my query in a timely fashion:

I don't know

Experience with the agency - The agency is fair - I see the agency applying the rules consistently and taking enforcement action/s when necessary:

I don't know

In relation to your answer above, if you had contact with more than one agency, please specify which agency you are referring to.:

We have checked "don't know" because as the industry association we cannot comment on individual member interactions and these interactions vary depending on the matter and the agency. We do have interactions with agencies ourselves and welcome an opportunity to discuss these in the interests of continuous improvement and good regulatory stewardship. We feel that this matter is too complex to be addressed in this questionnaire

Please share any examples of practices or interactions that have supported your business.:

We feel that this matter is too complex to be addressed in this questionnaire. and welcome an opportunity to discuss these in the interests of continuous improvement and good regulatory stewardship

Please share any suggestions for improvement.:

We feel that this matter is too complex to be addressed in this questionnaire. and welcome an opportunity to discuss these in the interests of continuous improvement and good regulatory stewardship

25 Based on your previous answer, overall, how would you rate that experience?

Experience with the agency - Please rate your experience of engaging with the agency:

Anything else

26 Is there anything else you would like to tell us in relation to product labelling regulation?

Yes

Anything else to tell us?:

There are industry concerns about permitting dietary supplements imports where the product labelling does not comply with NZ regulations as follows:

- Products from Australia – there is no requirement to include excipients (even functional class names). NZ requires at least functional class names and consumers have a right to know what non-actives are in the dietary supplements they purchase
- USA/UK/EU - use of NRV/DV that are not related to NZ RDI/AI values so give a different view of nutrient levels. Gives NZ consumers incorrect information about nutrient intake requirements and contribution to diet.
- USA - aligning with USA will permit use of FDA disclaimer statement which has no relevance here and could cause confusion. We appreciate there are already a multitude of labels with this being sold in NZ but it certainly does cause confusion.
- USA - proprietary blends are permitted in dietary supplements where the consumer does not receive complete information about the quantities or proportions of all active ingredients. NZ regulations require this declaration and we believe consumers have a right to know this information, so they can make informed choices about the ingredients and dosages of ingredients they take.

• If products with labels (that do not comply with NZ regulations) from a variety of countries or even select countries are permitted, there is a risk that these products could be noncompliant with the originating country. Who will provide assurance that this is not the case? NZ regulators are not equipped to determine compliance with overseas regulations. There is a real risk of non compliant and even counterfeit and adulterated products entering NZ with consequential risk for NZ consumers

• Imported Dietary Supplements that make health benefit claims that are not permitted by NZ regulations would fall into the class of an unapproved medicine.

In terms of the Terms of Reference for the labelling review, for dietary supplements the benefit to NZ is overwhelmingly in moving forward with urgency to enact the required amendments to enable export exemptions for dietary supplements. This can be achieved very quickly because the consultation has happened and the detail of the required amendments is well understood. We encourage the government to move forward with this program of work first, as it does not require further review.

We welcome and encourage further engagement with us because we represent an sector that contributes \$2.3 billion to the NZ economy per annum. We look forward to hearing from you to engage further on this important work.