# Response to Consultation:

## Sports supplements - Proposed clarification that certain sports supplements are therapeutic goods

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**Introduction**

Vitaco Health (AU) Pty Ltd is a food and complementary medicines company. Our sports brands include Musashi, Aussie Bodies, and Balance. The majority of products sold in Australia are manufactured by Vitaco Health (NZ) Limited in New Zealand and imported into Australia for sale.

Vitaco have built a reputation for world-class manufacturing and products based on decades of industry experience and knowledge. Vitaco exports and distributes products internationally, and contract manufactures and packs for private label clients worldwide; as well as having a strong presence in the New Zealand and Australian markets.

**Vitaco Response to Consultation**

Vitaco values opportunities to make submissions regarding proposed legislation. We support the examination of issues related to product safety, efficacy and quality and these areas should be subject to the appropriate levels of regulation. However, we oppose TGA's current proposal to declare that certain sports products/supplements are therapeutic goods.

Vitaco currently manufactures and sells some products as Supplemented Foods, which are covered under the *New Zealand Food (Supplemented Food) Standard* 2016. The *Standard 2.9.4 - Formulated Supplementary Sports Foods* is distinctly separate and does not apply to Supplemented Foods. Supplemented Foods are a separate regulatory category compared to Formulated Supplementary Sports Foods or Listed complementary medicines and it is important that this distinction is retained. As the TGA's proposed declaration takes legal hierarchy over any food standard, this consultation affects many New Zealand products that are currently sold under the Trans-Tasman Free Trade Agreement under the *New Zealand Food (Supplemented Food) Standard* 2016. The sports foods sold under the Supplemented Foods category should not be captured by the proposed declaration.

We disagree with the premise that the consultation is a clarification of the current requirements as it will affect the regulatory status of a number of products. Moreover, the proposed declaration would not provide greater clarity for industry as to whether their goods should be marketed as foods or medicines. It will add unnecessary regulatory complexity, confusion and uncertainty. For example:

- The consultation is confusing as it mixes up policy issues of products that are already illegal to be sold as food (such as prescription medicines), athletes' requirements, as well as changes to the way products are interpreted as being either foods or therapeutic goods.

- Any substance with equivalent pharmacological action to a substance on the WADA Prohibited List, Poisons Standard, or other relevant substance 'including those characterised

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as an active principle, precursor, derivative, salt, ester, ether or stereoisomer' would automatically trigger the product to become a therapeutic good. This definition is open-ended and it is unclear what 'equivalent pharmacological action' means.

- The declaration refers to a substance that 'exceeds any limit in the Permissible Ingredients Determination'. The Permissible Ingredients Determination was designed to set limits for ingredients used in Listed complementary medicines. It was not designed to differentiate whether a product is a food or a therapeutic good.

- On the draft Therapeutic Goods Order, for a product to be declared a therapeutic good the TGA have left it open to include any other 'relevant' substance as decided by the TGA. We are uncertain as to what other 'relevant' substances would likely to be added in the future.

**Summary of Vitaco Response**

The proposed declaration would have a negative impact on our business as it introduces new regulatory requirements and increases regulatory time and operational costs to our business.

We are aware that there goods on the market that do not comply with the current regulations, particularly imported products from the United States. People would continue to import many of these products as dietary supplements from international countries with potentially non-compliant advertising and claims, and at a low cost. They are easily ordered and delivered rapidly under modern e-commerce platforms that compete aggressively for consumers' attention. Border Force cannot prevent this personal importation of products. We would support increased enforcement of the current regulations in preference to introducing the proposed declaration.

Moreover, if this consultation does proceed, then we would support that this consultation is delayed given that the FSANZ *Standard 2.9.4 - Formulated Supplementary Sports Foods* standard has not yet been released for consultation. It would be logical that both consultations proceed under the same timeframe. The *Standard 2.9.4* was planned to be open for consultation in June 2019. To date, no consultation has been released.

We urge you to reconsider the impact of the proposed Therapeutic Goods Order to the sports products industry before progressing further.

Yours sincerely,

[redacted]

Michael Syme
Regulatory Affairs Manager