



**Consumer Healthcare
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To Whom it May Concern

RE: Sports supplements. Proposed clarification that certain sports supplements are therapeutic goods

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include **improving health literacy, growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

Overview

CHP Australia is supportive of the effective and appropriate regulation of healthcare products to ensure the safety of consumers. In this regard, CHP Australia recognises that there is a gap in enforcement that potentially exposes consumers to safety risks in the sports supplements space, either due to misinterpretation of Food Standard 2.9.4 or lack of clear enforcement pathways of the current standard. There also appears to be a range of products available on the Australian market that would be better regulated as medicines with the associated safety and quality controls given the nature of some of the ingredients and claims. CHP Australia does not oppose the development of a Declared Goods Order in principle as a mechanism to address this enforcement gap however we do not support the current drafting of the Order due to the anticipated impacts on products that are compliant with the Food Standards and that should continue to be regulated as foods.



Comments regarding the process

CHP Australia is disappointed with the approach taken by the TGA to this consultation, including:

- The short consultation period provided. To consider the implications of the drafted Declared Goods Order on a wide range of products, including potential unintended consequences, during a 6-week consultation presents difficulties for industry in developing a comprehensive and considered response;
- The provision of additional consultation details, e.g. further background information missing from the consultation paper and suggested transition arrangements, only a week before the closure of the consultation period coupled with refusal to provide any additional time to incorporate these details, is unreasonable; and
- Regulation of sports supplements has been identified as a potential public health issue for an extended period, since at least [July 2018](#), with a review of Standard 2.9.4 – Formulated Supplementary Sports Foods flagged as a high priority by Food Standards Australia New Zealand (FSANZ). While resolution of this enforcement gap is desirable, this public consultation is rushed and does not provide a proportionate period for the impacted industry and consumers to prepare considered input.

CHP Australia aim to provide high quality, representative responses to consultations, incorporating a broad array of industry views into a cohesive narrative. The short consultation period with incomplete and changing information does not facilitate an effective consultation environment.

Comments regarding the proposal

CHP Australia acknowledges the difficulties in drafting appropriate regulation to address issues in the interface areas, such as the interface between foods and medicines. CHP Australia do not believe that the TGA has established this line effectively in this instance and we hold significant concerns about potential unintended impacts and the risk of regulatory over-reach. The intention of the Order is to improve the clarity of requirements at the food/medicine interface however this proposal inappropriately redefines a range of foods as medicines and creates confusion over the jurisdictional boundaries. This response will include some of the issues that CHP Australia has identified; noting the comments on process and timing identified above, we do not claim that this is an exhaustive list and we stress the importance of further consultation before a final Declared Goods Order is enacted.

The mechanisms used to define which supplementary sports foods are to be classified as therapeutic goods in this instance appear problematic:

1. The World Anti-Doping Agency (WADA) Prohibited List is developed outside the jurisdiction of the TGA.



2. Content limits set by the 26BB instrument are established specifically for listed medicines, not foods.
3. The Poisons Standard provides a general exemption for foods under appendix A.
4. References to “a substance with equivalent pharmacological action” is poorly defined.

The WADA list is maintained and updated outside of the jurisdiction of the TGA, and therefore raises questions over the appropriateness of using this list as a decision tool by the TGA, particularly in the absence of ongoing transition arrangements. Further complicating the adoption of the WADA list are the references to amines and hormonal compounds that may be present in plant species or other naturally derived materials. Although at sub-therapeutic or insignificant amounts, this will risk capturing a range of food products inappropriately due to the absence of allowable limits.

The utilisation of the 26BB legislative instrument to underpin the definition of what is or is not a food is not supported by CHP Australia. This is not the purpose of the 26BB limits; this instrument is designed to consider the use of substances in listed medicines only. In many ways it is more appropriate to defer to the Poisons Standard (which underpins the majority of the limits in the 26BB instrument), as there are clear decision-making processes that take into account all relevant considerations. That said, the Poisons Standard generally exempts application of the schedules to foods, so the integration of this tool will create a conflict of definition. The schedules of the Poisons Standard also describe particular uses and conditions, and the extension of these requirements to foods may not be logical or appropriate.

Common food ingredients that may be unnecessarily impacted by the reference to the 26BB instrument include:

- Whey protein concentrate (content limit of 5%)
- Prune juice concentrate (content limit of 5%)
- Soybean flour (content limit of 5%)
- Spray dried liquid glucose (content limit of 5%)
- Molasses (content limit of 5%)
- Milk fat (content limit of 5%)

CHP Australia also holds concerns about the TGA proposal that a substance with equivalent pharmacological properties to those in (i), (ii) or (iii) (presented in Column 2) to be declared as therapeutic goods. Caffeine has stimulant properties – does this mean it is equivalent to the prohibited stimulants and could this make all caffeine containing products therapeutic goods? The current provision is not clearly defined by function or composition, allowing TGA to interpret this condition in an inconsistent manner and creating uncertainty for industry over the correct regulatory pathway for products.



The assertion that all of the claims presented in Column 3 are therapeutic claims is not appropriate. Many of these claims can be functional, rather than therapeutic, and therefore would fit within the definitions of Standard 2.9.4 – Formulated Supplementary Sports Foods. It is inappropriate for the TGA to determine that these are all exclusively therapeutic goods without giving adequate consideration to the context and presentation of the goods. It should be noted that while section 2.9.4 – 7 refers to prohibited representations for Supplementary Sports Foods based on physiological benefit, this excludes representations in Division 3 of Standard 2.9.4 that allows for pre- and post- workout representations and the benefits of supplementing protein for muscle bulking, which are claims captured in Column 3.

The current drafting of the Order oversteps the regulatory bounds of the TGA and determines that products that are currently adhering to the definition of Standard 2.9.4 – Formulated Supplementary Sports Foods would become therapeutic goods. There are also potential impacts on foods that comply with other Food Standards as well e.g. Standard 2.6.4 Formulated caffeinated beverages. The intention and application of a Declared Goods Order to clarify this difficult interface area should only be to capture products that do not comply with the Food Standards Code, rather than redefining compliant foods as therapeutic goods.

CHP Australia believe that the definition in Column 2 of the Declared Goods Order should not include “or any other recreational activity” as this is too broad to be appropriate for the intended use of the mechanism. Additionally, CHP Australia hold concerns over the inclusion of specified dosage forms, as the description of a product as a ‘tablet’ can have varying intentions and applications, which don’t necessarily equate to being therapeutic in nature.

Some products inappropriately impacted by this proposed Order include:

- Glucose tablets
- Whey protein powders that contain more than 5% whey protein concentrate
- Protein bars that contain more than 5% whey protein concentrate or other ingredients that are inconsistent with the limits in the 26BB instrument
- Energy drinks containing more than 100mg caffeine per can, despite these being compliant with the recently consulted FSANZ proposal P1054 Pure and highly concentrated caffeine products
- Energy cubes e.g. chewable chocolate tablets

CHP Australia opposes the Declared Goods Order in its current form due to the approach the TGA has taken to creating an ingredient list and how the TGA has determined therapeutic claims.



Conflicting transition arrangements

While the recent [FAQs](#) published assure that there is no intent to introduce new requirements 'overnight' and that transition arrangements will be provided, this is not reflected in the drafting of the Declared Goods Order. The TGA has provided assurances that there will be a 2-3 year transition provided, however it is also noted that all decisions about the Order will be made by the Minister. In this regard, the TGA should ensure that the draft Order presented to the Minister accurately reflects the transition arrangements that the TGA has committed to in the FAQ.

Conclusion

CHP Australia does not oppose the intention of this proposal; however we note that the proposed Declared Goods Order is likely to have unintended impacts on legitimate food products, such that products that are currently complying with Standard 2.9.4 – Formulated Supplementary Sports Foods could be inappropriately captured.

CHP Australia call on the TGA not to implement the proposed Declared Goods Order in its current form and to undertake further industry consultation to address the adverse impacts of this proposal.

CHP Australia remains available to assist in the design of a revised mechanism to address the intended issues without inappropriate capture of legitimate food products. We have unfortunately had insufficient time to consider alternate approaches to provide a suitable proposal at this time.

Regards,