

ATP Science: TGA Submission

Thank you for providing this opportunity to comment on the proposed clarification regarding sports supplements and therapeutic goods.

At the outset, we welcome the intention shown by the TGA to improve the safety in the sports supplement industry. Both the regulators, and the industry, not to mention the Australian public welcome this.

The consultation process

This consultation was brought to our attention from [REDACTED] whom also provided excellent statistics on the sports supplement industry. They have also highlighted the huge unintentional financial consequences if the proposed changes become legislation, which we will not repeat here as it forms part of their submission. We were advised through third parties of this consultation sometime after the consultation commences, and feel that as an Australian manufacturer of these specialised products we would have expected targeted notification from the TGA and/or FSANZ. Also, we note that the consultation period of only 6 weeks is very short, and due to the timeframe we have not been able to prepare an in-depth submission, but would welcome any opportunity to be involved in discussion around changes to these regulations.

Two separate documents

There were two documents presented for consultation. The first of the two documents called "*Consultation: Proposed clarification that certain sports supplements are therapeutic goods*" mostly made common sense, and we support the intention. While there were some points we would disagree with (noted below), the entirety of the document seemed reasonable. However; the second document "*Consultation: Attachment A: DRAFT Therapeutic Goods (Declared Goods) Order 2020*" seemed to contradict the first document. For example, the first document suggested that whey protein would probably not become a therapeutic good yet, the second document (page 4) states that if the product is used for muscle building, then it would become a therapeutic good. Most individuals consume whey protein for muscle building or as a meal replacement for weight loss.

Either way, whey protein would likely be deemed a therapeutic good by the TGA when the goods are used, advertised, or presented for supply for a therapeutic use (i.e., gaining muscle, losing weight or fat) or in a way that is likely to be taken to be for therapeutic use.

World Anti-Doping Agency banned substance list

We don't believe the World Anti-Doping Agency (WADA) banned substance list should be used to discern whether the good is a therapeutic good or a food. Firstly, the WADA list is changeable as individual sports have different lists, there are on-season and off-season lists and the banned substances are added or removed annually. Furthermore, WADA does not specify ingredients, but only chemical compounds but that may be present in foods naturally. For example, simple cow's milk would become a therapeutic good because it contains naturally occurring hormones such as testosterone and Insulin Like Growth Factor-1 (IGF-1)¹. Both of these hormones are on the WADA banned list. IGF-1 is found in the casein and whey proteins, meaning the naturally occurring IGF-1 present in protein powders would indicate these proteins should be therapeutic goods, according to both documents released by the TGA. We also note that in randomized controlled studies show that whey protein supplementation does increase IGF-1 levels when consumed at normal levels (30g per day).²

¹ Hassan MALEKINEJAD and Aysa REZABAKHSH. Iran J Public Health. 2015 Hormones in Dairy Foods and Their Impact on Public Health - A Narrative Review Article. Jun; 44(6): 742–758.

² Zhu K1, Meng X, Kerr DA, Devine A, Solah V, Binns CW, Prince RL. The effects of a two-year randomized, controlled trial of whey protein supplementation on bone structure, IGF-1, and urinary calcium excretion in older postmenopausal women. J Bone Miner Res. 2011 Sep;26(9):2298-306. doi: 10.1002/jbmr.429.

Capsules and Tablets

We don't believe that placing the food into a capsule, or making the food into a tablet makes it a therapeutic good. One example is spirulina, which is a popular food consumed, however, spirulina is an algae and unfortunately tastes like algae. Wisely, spirulina is often put into tablet form³ to facilitate user consumption. Even if suppliers wanted to 'list' spirulina, they would not be able to because spirulina is not listable with the TGA as an active ingredient.

Sweeteners, often consumed to reduce weight, commonly come in tablet form⁴. These proposed changes could (unintentionally) include these sweeteners because they not only come in tablet form, but make therapeutic claims like 'helps with weight management/cutting calories'.

With regards to safety, putting foods into tablets or capsules does nothing to improve the safety of foods. The two deaths highlighted in the discussion paper, resulting from excessive consumption of caffeine and protein, would not be prevented by encapsulation or tableting of foods. Conversely, a 2018 publication found that *"despite the recent policy of sale restrictions of caffeine tablets, which was introduced in 2004 in several countries, we have identified an increase in caffeine-related deaths in the last years."* The publication continued to identify that there was a higher rate of accidental deaths as the caffeine was hidden in other products or users were confused about the levels they were taking, either via inaccurate measuring, unregulated dosages or use of multiple products containing caffeine.⁵

Food Standards Australia and New Zealand (FSANZ) are undergoing a 2-year review

The draft order 2020 references the FSANZ Standard which is currently under review. Food Standards Australia and New Zealand (FSANZ) are currently undergoing a 2-year review on sport foods, which was initiated by Health Minister Hunt about 18 months ago. The TGA discussion papers refer back to the food standards, which are currently actively undergoing change, and will likely change. We believe that this review, running at the request of the Health Minister, should run its course as the outcomes may deal with the concerns raised by the discussion papers.

Australian products found to be safe

The regulatory instrument (Attachment A) document has specifically targeted pre-workout supplements and post-workout supplements (Page 4) and suggests these supplements should be therapeutic goods in Australia only. The consumer will simply go on-line and purchase their supplements from elsewhere in the world where safety isn't as well regulated as in Australia, if this is the only way the consumer can have access to their desired ingredients. A study, in one of the discussion papers highlighted contaminants that were all from overseas (mainly the USA) suppliers.⁶ Interestingly, this paper also stated that there were no contaminants found in any Australian made product.

The net unintentional result is that consumers would shop from overseas/on-line (USA) suppliers and increase risking their health by consuming potentially contaminated products. This would also result in huge job losses as Australian products would not be manufactured or purchased.

⁵ Nutrients. 2018 May 14;10(5). pii: E611. doi: 10.3390/nu10050611. Caffeine-Related Deaths: Manner of Deaths and Categories at Risk. Cappelletti S1, Piacentino D2, Fineschi V3, Frati P4, Cipolloni L5, Aromatario M6.

⁶ Elliot R. Cooper et al. Androgen Bioassay for the Detection of Non-labeled Androgenic Compounds in Nutritional Supplements Volume 28: Issue 1 Pages: 10–18. International Journal of Sport Nutrition and Exercise Metabolism 2017.

The possible contamination of foods made in TGA plants

Australian standards of manufacturing are world class. As previously mentioned, no Australian made products were found with contaminations. However; if sports foods become listable medicines, these 'foods' would need to be manufactured in TGA plants where medicines are made. Whilst these plants presumably have extremely good processes in place to avoid contamination, there is a slim possibility that some medicines may end up in some food products. Again, this risk is small, but currently, food manufacturers do not have medicines on site and thus the contamination risk is virtually zero. For example, ██████████ had to recall their all-natural products due to potential contamination by pharmaceuticals into these products.

2 in 3 Australians are overweight.

The best way an individual can lose weight is to change their diet and exercise more. We feel that if weight loss products are going to be listed as a therapeutic good, discussion surrounding weight loss in this country may be stifled. In 2017-18, the Australian Bureau of Statistics' National Health Survey showed that two thirds (67.0%) of Australian adults were overweight or obese (12.5 million people), an increase from 63.4% in 2014-15. The National Health Survey also indicated that almost one quarter (24.9%) of children aged 5-17 years were overweight or obese in 2017-18 (17% overweight and 8.1% obese).⁷ More discussion surrounding diet and exercise should be encouraged. Sports supplements, which may aid in the difficult task of losing weight, should be available for individuals who may require this kind of help and making these products therapeutic goods could severely restrict the supply of these goods.

Going forward

If there are to be any future discussions surrounding legislative changes surrounding sports foods or any other supplement issues, we would gladly be a participant in round table discussions about creating new systems. We believe in round table discussions with all aspects of the industry, along with health professionals and the regulators to produce better draft/discussion papers and to ensure due process is followed. This method is used by FSANZ with great success because once the discussion papers are released input has been sought by all parties and agreement from that point on is easier to achieve.

ATP Science, throughout 2019 and into 2020, is on a journey to position our company to be the epitome of a successful interface between TGA, FSANZ and FDA, with a clear delineation of therapeutic goods, supplementary sports foods and FMCG.

Thank you again for this opportunity to participate in this process.

⁷ <https://www1.health.gov.au/internet/main/publishing.nsf/Content/Overweight-and-Obesity>