

November 2019.

Submission re TGA Consultation – Sports Supplements

1. Do you support the proposal for certain sports supplements to be declared therapeutic goods?

No, while the interface between foods and therapeutic goods, when it comes to sports supplements deserves further consideration; it is critical that this is done on an evidence basis after considering all types of regulatory options that would be available under a full and proper coordination with industry members and other Government bodies.

It is most important for all stakeholders involved to sit together and discuss the total industry, not just selective parts.

As the stated aim of the TGA is to clarify the Food/Therapeutic Interface how can this be possible while Standard 2.9.4.-Formulated Supplementary Sports Food is currently being reviewed by FSANZ? No decisions should be made until this review is complete as it affects any decision made at this stage.

FSANZ, the TGA and stake holders should use this time now to produce a total outcome, not piecemeal and knee jerk reactions. The fact that Regulation 2.9.4. dates back to the late 1980's and early 1990's (30 plus years ago) makes it clear it is up for review, as are all the other parts of the sports supplement industry.

Not reviewing in total is analogous to the Government having a review of Telecommunications in Australia and only including landline and facsimile. A lot; mobile phones, internet, social media has changed in 30 years; and must be included in any Telecommunication consultation. The same with Sports Nutrition.

A lot has changed, the introduction of high-level performance coaches for Olympic level teams and other intense sports participants such as Triathletes, has placed demands on the human body with intense training and the need for faster recovery, more than ever.

This is the time to discuss and correct Food Standard 2.9.4, but most importantly set up a ***register of allowable sports supplements with correct dose levels for elite athletes***. This would allow those that need such products simple access and assist with education that is an important part of sports supplementation.

2. Would the proposed declaration have an impact on the availability and choice of supplements for consumers?

Yes, many commonly used products that can only assist athletes would be wrongly caught up. E.g. The Recovery amino acids – commonly called Branch Chain Amino Acids – Leucine, Iso Leucine
Page 1.

and Valine – are very important in the removal of lactic acid from an exercised muscle, which then allows the athlete to train at a higher level next session. The doses allowed in 2.9.4. are too low – higher doses should be discussed and allowed. This also applies to Glutamine which apart from recovery is also very important in gut health. There are other examples.

3. Would the proposed declaration provide greater clarity for industry as to whether their products should be marketed as foods or medicines?

No, as some products should be foods with higher doses, some products will be medicines (discussed later in points 5 and 6), but the third and missing category of Sports Supplements that are neither, should be addressed and setup as permissible in this category – with all stakeholders in a discussion to arrive at this range of products.

As the current Standard 2.9.4. is under review, no clarity is possible and further confusion and grey areas will open up. Nothing will be achieved.

4. Are you aware of products on the market that would not be captured by the proposed declaration but should be?

No.

5. Are you aware of products on the market that would be captured by the proposed declaration but should not be?

There appears to be confusion within the proposed clarification legislation between illegal steroid compounds and general sports supplements.

(a). All steroid and related products must remain as prescription only, as they have always been. As stated in the discussion, previous studies have shown that 1 in 20 Sports Supplement products contain steroids or derivatives. It does not say whether these are imported or manufactured in Australia. The presumption would be the vast majority of these illegal products are imported. This is an issue for Australian Border Force to police and control, not change our TGA regulations. The reality is 19 out of 20 products do not contain such ingredients.

It is essential that all WADA rules are followed, and that is why bodies such as [REDACTED] in Australia and [REDACTED] are essential testing grounds as well.

(b) All products on the potential new Sports Supplement list should have an annual testing regime.

(c) Many consumers use Sports Supplements to keep themselves healthy, active and as they age continue to be active. This has enormous benefits on their weight and cardiovascular systems, which reduces the number of diabetes cases and heart disease, the largest killer in Australia. These people also use supplements to ward off the tightness and often pain associated with various exercise and competitive events, in turn saving the Australian health system millions of dollars in Medicare, Hospital and Pharmaceutical costs. This alone is enough reason to keep products available in the Sports Supplement category which otherwise may disappear off the market.

(d) Placing Sports Nutrition in the same category as Pharmaceuticals is not the answer; many pharmaceuticals have side effects, which only taking another pharmaceutical can counter. Sports Nutrition should be in its own category.

Page 2.

6. What impact would the proposed declaration have on your business?

This is not my major concern. My concern is that the consumer should be protected from illegal products but should still have available products they wish to use for their health and sport regimes.

Should this proposal be followed through, consumers will turn to the internet and order the products they require from overseas websites. This is fraught with problems, as many sites sell adulterated

products or straight forgeries. This puts the Australian consumer at far greater risk than purchasing products they require, either made in Australia or imported products direct from the manufacturer.

When one considers that Alcohol remains available to anyone over 18 years of age, and the damage that causes to the individual as well as to other members of society in the form of car accidents and drunken violence; when one considers the high fat and high sugar products that are available and promoted to children, let alone adults; and the health damage and cost to the community that all this causes; having a range of sports supplement products available for the correct reason seems a very reasonable proposition and one worth exploring.

Caffeine is an example used in the discussion, yet everyone can purchase 4 or 5 short black coffees anywhere and have caffeine doses far exceeding any in sports nutrition.

7. a. I would ask that the submission date be moved forward from 3 December 2019 to 31 March 2020. This is because many of the manufacturers I have spoken to have not had the time to prepare submissions; as before the end of the year they are busy making sure they have enough product manufactured to last till the new year and factories begin production late January.

One cannot change regulations affecting so many businesses and so many employees without full notification to all affected, giving the time to prepare a submission.

b. Calling for submissions is one part, as the process is called a consultation, all stake holders should be invited to sit with FSANZ and the TGA to come up with a plan and legislation that is for the benefit for the whole community for years to come. This proposal does not offer that outcome, a truly consultative process.

c. The potential loss of retailers will also put manufacturers and distributors at grave risk of closing due to lack of volume. The number of staff that will become unemployed is a huge issue for the community to deal with.

d. Encouraging people into sports, with products , in doses that work, to stop them being sore after their exercise, as well as for faster recovery, encourages them to continue with their training.

Page 3.

e. This also leads to better food and drink intake, which is also very healthy. Apart from this sports people are less likely to drink alcohol and smoke cigarettes. All of this vastly reduces the cost of Medicare and the Pharmaceutical Benefits Scheme to the Government.

f. Another area that may prove difficult under the proposed Legislation is products for Triathletes. This is the Swim, Bike, Run people or any one or two of these. They need products that are readily available, sold by people with knowledge who can offer advice and compare formulas. (Pharmacy does not offer this in most cases and especially not in the large self service model which dominates the Australian Pharmacy market).

These formula are put together scientifically, and affect the performance of the athlete dramatically. They need the higher doses, as they train and compete at a different level to the general public.

g. I have looked after Olympic athletes, Commonwealth Games Athletes as well as AFL footballers and they also required products that are WADA approved – tested by [REDACTED], but in doses higher than available under 2.9.4. Elite athletes need Elite products that vary according to their sports and their size.

This is why 2.9.4. is inadequate and was 15 years ago when change was first mooted

h. For the general public, if products are removed from Australian shelves, they will simply purchase from overseas websites, putting them at far greater risk of taking either contaminated or adulterated products

. This would be a retrograde step for the health and safety of the Australian consumer. Australian Border Force cannot check every product that enters Australia,

Ian Collins.
(Director).