

Human And Supplement Testing Australia (HASTA) submission to the TGA Consultation on Sports Supplements

29 November 2019

Responses to TGA Consultation questions for "Proposed clarification that certain sports supplements are therapeutic goods"
[Version 1.0, October 2019]

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

What are the reasons for your answer?

Strongly Support

There is significant confusion in relation to the classification of sports supplements at the Food Medicine Interface (FMI) and clearer guidelines would assist in ensuring that the "*Formulated Supplementary Sports Foods (Std 2.9.4)*" category is made up of products that the average consumer would recognise as food. A significant proportion of products in this category are powders, and we believe that the average consumer considers powders used to prepare drinks, or added to other foods to provide additional nutrients, to be foods.

However, we agree with the proposition that if these sport supplement powders contain a substance that is in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)- the *Poisons Standard* or on the WADA banned list that it should be re-classified as a therapeutic, and the substance should be clearly identifiable on the label.

We agree with the proposition that products that otherwise meet the existing compositional requirements of Standard 2.9.4, but which are presented in a tablet/capsule/pill format would not be considered as food by the average consumer and require dosage rather than consumption instructions, as would be expected for therapeutic goods (medicines).

The increase in novel ingredients and increasingly broad health claims being made by some sports supplements should disqualify them from being marketed as foods, they should be considered and regulated as complimentary medicines.

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

What are the reasons for your answer?

Somewhat negative impact

In the short to medium term we would expect to see a decrease in the availability and choice of sports supplements, as we believe a quite significant percentage of products may require re-classification.

Food manufacturers, who are unfamiliar with the TGA requirements, may decide to cease supply, rather than invest the time and money required in listing their product with the TGA and moving production to a TGA Licenced manufacturer, or obtaining a

TGA Licence for their manufacturing facility. Products would also require actual evidence of efficacy, which may be problematic for a number of existing products, considering the broad health and performance claims that they are currently making.

There is a risk that both consumers and sport supplement retailers will resort to imported products to fill this gap, thereby re-introducing a risk to athletes and consumers from even less regulated imports. Consumer education regarding the reasons for changes in the Australian regulations and the benefits in buying compliant Australian brands, will be required to support the local supplement industry. There should also be a fair and reasonable grandfather provision for stock in trade and implementation period for compliance with the new TGO.

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

What are the reasons for your answer?

Somewhat agree

The proposed declaration, with the support of educational material such as the Decision tree should increase clarity for industry to better determine the category that their product fits into for the Australian marketplace.

Our reservation is based on the use of the two key references, the Poisons Schedule and the WADA Prohibited List, both of which are complex technical documents which use a range of different chemical naming conventions, and which are regularly updated by authorities other than the TGA. Consideration should be given to providing a readily searchable version of each to facilitate compliance.

As a general rule though, supplement companies should already be well aware of the addition of ingredients that are not standard in food and are likely to fall into a therapeutic classification. The area that has more uncertainty will be the accurate determination of levels of ingredients that exceed the Food Standard Code limits, such as amino acids and permitted nutritive substances such as creatine. Manufacturers may underrepresent these on pack to avoid being classified as therapeutic goods, and the consultation paper does not discuss any possible independent testing to verify active levels in sports supplements.

In relation to the use of the claims described in Column 3 of Schedule 1, Part 2, to assist in the determination of classification of these products, in the case that a product is reclassified as therapeutic, will these products be able to rely on the “traditional use” description used so liberally by complimentary medicines, in the event that they are unable to provide reliable efficacy data?

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

What are the reasons for your answer? Please provide specific details and the rationale for why these products should be therapeutic goods.

No - if a sports supplement manufacturer does a thorough compliance review of their formulation against both the Food Standard 2.9.4 and the TGO order, then it should be clear whether their product is a food or a medicine.

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

Yes

Currently electrolyte products fall on both sides of the FMI, with some electrolyte products labelled as *Formulated Supplementary Sports Foods*, some as electrolyte drinks or electrolyte drink bases under *Std 2.6.2 Non-alcoholic beverages and brewed soft drinks*, and others as Listed medicines.

Electrolyte drinks formulated for rehydration after sport and recreational activities (as opposed to those used in clinically dehydrated patients including children) would appear to be relatively low risk and should stay within Std 2.6.2, not be classified as formulated supplementary sports foods under Std 2.9.4, where their formulation and/or proposed use may have them classified as a potential therapeutic.

Products currently being seen as possible “sports supplements” by athletes now include almost any food with “added protein” eg. muesli bars, energy bars etc. The addition of whey protein should not automatically re-classify a food as a sports supplement, especially considering the widespread use of milk powder in so much processed food.

What impact would the proposed declaration, if made, have on your business?

HASTA is a division of Racing Analytical Services Ltd (RASL), a leading drug testing laboratory in Australia. We are NATA accredited to ISO 17025; and we perform independent testing and certification of sports supplements. Our sport supplement screening test covers over 200 WADA prohibited substances.

Passing of the proposed declaration and the significant industry discussion it has generated will once again highlight to athletes the risk of taking sports supplements, which may lead to additional pressure for manufacturers to perform independent testing.

There is a risk though, that during the implementation phase fewer new products will come to market and legacy products that require re-classification are phased out, disrupting the local industry and our ability to market both our testing and Certification scheme. Those manufacturers having to factor in the costs of a Therapeutic Listing may not have the budget to spend on independent testing, and instead rely on GMP systems.

Please provide any other comments related to the consultation

We understand that the consultation paper is primarily focused on health and safety of all consumers, but sports supplements are a particular issue for competing athletes, due to the risk of an anti-doping violation from a supplement containing a WADA Prohibited substance.

As per the example illustrated in Case study 1, some supplements contain banned substances that are not on the label, but this is true of supplements in both the food and therapeutic categories, and in the absence of independent testing, the re-classification of this supplement would not necessarily decrease the risk.

There is a risk though, that athletes in particular, will view any TGA listed product as safer than a food product, whereas the reality is that despite the additional regulatory framework and GMP requirements, being a Listed Medicine does not guarantee that a product will not contain a WADA banned substance.

Prior to establishing our Certification Scheme in 2016, HASTA also performed a market survey and found that of 63 samples analysed; 6 (10%) were positive for contamination with one or more stimulants and 4 (6%) positive for one or more steroids; overall 10 (16%) products tested were found to contain WADA prohibited substances not declared on the label. *[data available to TGA on request]*. According to their labels, several of the positive samples were manufactured in TGA Licenced or cGMP (US) facilities, leading us to conclude that inadvertent contamination of raw ingredients may continue to be a factor in the presence of banned substances.

In over 4 years of commercial testing we have continued to find WADA banned drugs in both food and therapeutic products, which emphasises the need for actively monitoring products through testing for the enforcement of the classification requirements for products.

We agree that the more rigorous disclosure, verification and GMP requirements for gaining an Aust-L number provide a far more significant barrier to entry than the current food regulations, particularly for products clearly at the FMI. However, considering the size of the local industry and the lightning fast-pace of new product development in response to the latest “wellness” trends, a key issue for the TGA will be enforcement of the new regulations in an industry with a reputation for pushing the boundaries.

For further information or queries in relation to our Sport Supplement survey and testing results, please contact HASTA on 03 9376 6760.

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