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Sports Supplements Consultation
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
Department of Health
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To whom it may concern,

Consultation: Proposed clarification that certain sports supplements are therapeutic goods

About SDA

Sports Dietitians Australia (SDA) is the peak body for evidence-based sports nutrition in Australia. Our members are Accredited Practising Dietitians (APDs) who undertake further study and professional development to become Accredited Sports Dietitians (AccSDs) and specialise in the practice of sports nutrition. AccSDs work across a range of settings including private practice, team sports (grass roots through to professional levels), elite/Olympic level sports and industry.

Consumers who seek SDA professional services (i.e. everyday active Australians, both recreational and competitive) deserve safe, efficacious and reliable sports supplements, as recommended by AccSDs. Our sports dietitians need to have confidence that the sports supplements they recommend are safe for both:

1. Recreational and competitive consumers seeking the benefits of sports supplements;
2. Elite, high performance athletes, whose competitive careers may be significantly affected (e.g. by suspension, loss of competitive achievements, disqualification from future competitions) if they return a positive anti-doping rule violation (ADRV) from incorrectly classified supplements.

As such, AccSDs and sports supplement consumers need confidence that Australian supplementary sports foods are compliant with the Food Standards Code and:

1. will not contain substances which are not permitted as food ingredients and not listed on the packaging;
2. will not contain substances in excess of permitted levels;
3. will not contain any prohibited substances.

Overview

SDA welcomes the Therapeutic Goods Administrations (TGA's) '*Consultation: Sports Supplements Proposed Clarification that Certain Sports Supplements are Therapeutic Goods*', hereafter referred to as 'The Proposal'. This is particularly timely in view of the risks to consumers posed by some sports supplements on the Australian market (as described in The Proposal) and given there are sports supplement products sold in Australia that are currently classified as food but would be more appropriately classified as therapeutic goods.

We note this TGA Proposal seeks to resolve much of the uncertainty around the regulatory status of sports supplements, to ensure such products are regulated appropriately to safeguard public health and safety.

While SDA supports this resolution, we also seek to highlight the importance of readily available and affordable supplements for active Australians.

This submission comprises three main sections:

1. To outline overlap between The Proposal's Draft Therapeutic Goods (Declared Goods) Order 2020 (known hereafter as the Draft Order) and the Food Standards Code (FSC) permitted health claims for sports supplements under Standard 2.9.4;
2. To highlight that sports supplements which go beyond the FSC and become a therapeutic good via compositional compounds and/or therapeutic claims, should require TGA registration;
3. To discuss the requirement for safe, readily available and affordable sports supplements for active Australians.

1. Proposed 'Therapeutic Use' definition overlaps with FSC health claims

Presently, Australian producers of sports supplement products are responsible for deciding whether their products fall under Australia's food or therapeutic goods regulatory frameworks. As a result, some types of sports supplements can be categorised as "food" and comply with the relevant Australian & New Zealand Food Standards Code (FSC) (Std 2.9.4 - Formulated Supplementary Sports Foods and relevant schedules), while others should be registered on the Australian Register of Therapeutic Goods (ARTG), which falls under the jurisdiction of the Therapeutic Goods Act and is administered by the Therapeutic Goods Administration (TGA).

The Food Standards Code (Std 2.9.4) defines a sports food as "*a product that is specifically formulated to assist sports people in achieving specific nutrition or performance goals*". Division 3 of Std 2.9.4 permits certain performance claims associated with supplementary sports food, including benefits to muscle gain and pre-workout, during-workout and post-workout claims.

The Therapeutic Goods Act defines a therapeutic good as a product that is represented for therapeutic use. Here, 'therapeutic use' includes: (a) *preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons*; or (b) *influencing, inhibiting or modifying a physiological process in persons*.

The Proposal's Draft Order suggests a wider definition of **therapeutic use** for sports supplements, including representations about gaining muscle, increasing mental focus, metabolism or stamina and losing weight or fat. As such, there appears to be a strong risk of significant overlap between the two definitions. Given 'The Proposal' also states that goods are not therapeutic goods under the TGA if there is an existing Food Standard for these goods (page 8), we suggest the potential confusion which may result from the draft order's expanded 'therapeutic use' definition may cause confusion and so further ongoing compliance problems.

For example, the Draft Order identifies 'therapeutic uses' that overlap with permitted 'health effect' claims under the FSC, such as 'gaining muscle', 'increasing mental focus' and 'preparing and/or recovering from a workout' as therapeutic uses.

As the FSC expressly prohibits claims of therapeutic nature and defines these as claims which 'refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition' (Std 1.2.7-8), we suggest the permitted health claims under the FSC are not therapeutic claims.

SDA recommendation: SDA largely supports the Draft Order insofar as it proposes a product will be regulated as a therapeutic good where the following applies:

- It contains a substance in an amount that exceeds a limit for sports foods in Schedule 29 of the Food Standards Code, if the manufacturer prefers not to reformulate to become compliant
- It contains a substance included in the Poisons Standard
- It contains a substance on the World Anti-Doping Agency (WADA) Prohibited List
- It contains β -methylphenylethylamine, dendrobium, methyllicberine or N-phenethyl dimethylamine
- It contains an ingredient in an amount that exceeds the limit in the Permissible Ingredients Determination.

However, SDA suggests the Draft Order definition of 'therapeutic use' is revised, so it does not include performance and health effects permitted under the FSC. This will ensure greater alignment with the FSC and will further support clarity between the Food-Medicine-Interface.

SDA further supports that enforcement capacity of regulators be increased to better deal with non-compliant sports supplement products.

2. Sports Supplements that go Beyond the FSC Should Require TGA Listing

Products marketed as Supplementary Sports Foods, but which are non-compliant with the Food Standards Code (Std 2.9.4) or other relevant Food Standards Codes, should be included in the ARTG as medicines or removed from the market.

The potential risks to consumer safety posed by non-compliance with the Food Standards Code and/or non-inclusion in the ARTG as medicines, but instead sit ambiguously at the Food-Medicine-Interface, is highlighted by the tragic death of 21-year-old Australian man [Mr. Lachlan Foote](#), who died from caffeine toxicity when he ingested one teaspoon of pure caffeine powder added to his protein shake ¹.

SDA is also aware of another case in Western Australia in 2014, where a combination of a pre-workout and weight loss supplement purchased online was linked to liver failure with urgent, life-saving transplant surgery needed in a then 27-year-old man. This case was outlined in the Medical Journal of Australia ².

SDA recommendation: Case studies 1 and 3 in The Proposal clearly demonstrate that the products are intended for therapeutic use. All Sports Supplements which clearly demonstrate they are intended for therapeutic use by the inclusion of therapeutic ingredients thereof, are manufactured and marketed beyond the intentions of the Food Standards Code and are unsafe or unsuitable for consumer use should:

- 1) be listed as a medicine: or
- 2) become unavailable, via the TGA's regulatory action to remove them from supply.

Non-compliance detections require reliable audit and enforcement procedures, which was highlighted by delegates who attended the Department of Health's Sports Supplement Roundtable discussions in 2018 ³.

3. Accessibility to Safe Supplementary Sports Foods Remains Important

Active Australian consumers need safe, affordable sports food supplements, with relevant claims that clearly articulate consumer benefits. As such, it's important that where there is no real health risk to consumers, that manufacturers be given an opportunity to meet FSC regulations when modifiable non-compliance issues are detected, to avoid driving up TGA regulatory compliance requirements and costs.

SDA recommendation: Case study 2 in The Proposal

The manufacturer should be asked to conform with Std 2.9.4, Sch 29. The claims are largely consistent with health claim permissions under Std 2.9.4.

This product should remain an affordable Supplementary Sports Food product which may be audited for compliance by relevant enforcement agencies, to ensure:

- It does not contain a substance in an amount that exceeds a limit for sports foods in Schedule 29 of the Food Standards Code
- It does not contain a substance included in the Poisons Standard
- It does not contain a substance on the World Anti-Doping Agency Prohibited List
- It does not contain β -methylphenylethylamine, dendrobium, methyllicberine or N-phenethyl dimethylamine
- It does not contain an ingredient in an amount that exceeds the limit in the Permissible Ingredients Determination

Concluding remarks

Consumer safety is rightly the priority for regulatory change under The Proposal. SDA welcomes The Proposal drafted by the TGA. However, SDA recommends consideration of the following:

1. SDA recommends stronger auditing and compliance action from non-compliant manufacturers by increasing the capacity of relevant enforcement agencies. This also applies to imported products.
2. The Draft Order be revised to remove definitions of *'gaining muscle'*, *'increasing mental focus'* and *'preparing and/or recovering from a workout'* etc. (Column 3) as therapeutic uses, as the FSC defines these as 'health effects. Clarifying this definition reduces risk of confusion.
3. SDA supports a full review and update of Std 2.9.4 (FSC) to better define a 'sports supplement'. This should be done in consultation with key stakeholders at the Australian Institute of Sport, to align with their definitions of sports supplements outlined in the AIS Sports Supplement Framework.
4. All sports supplements which clearly demonstrate they are intended for therapeutic use by the inclusion of therapeutic ingredients thereof, are manufactured and marketed beyond the intentions of the FSC and are unsafe or unsuitable for consumers use should:
 - a) be listed as a medicine: or
 - b) become unavailable, via the TGA's regulatory action to remove them from supply.
5. Further consultation, review and consideration needs to be given to those sports supplements that can be presented in multiple forms (liquid, solid, powder, capsule, gum etc.) to avoid driving up the cost and regulatory complexity of Sports Supplements otherwise compliant with the Food Standards Code, simply because they are presented in a certain form.
6. SDA advocates that any advice on sports supplementation, based on individual circumstances and health considerations, is conducted under the guidance of an appropriately trained Sports Dietitian or other appropriately qualified medical professional.

If you require any clarification or information, please contact Marie Walters at marie@sportsdietitians.com.au or 03 9699 8634 or mobile 0416 188 246.

Yours sincerely,

Marie Walters
Executive Officer

References

1. <https://www.smh.com.au/national/nsw/a-teaspoon-will-kill-you-grieving-father-warns-of-caffeine-powder-20190709-p525oy.html>
2. Smith, R.J., Bertilone, C., & Robertson, A.G. (2016). Fulminant liver failure and transplantation after use of dietary supplements. *Med J Aust*, 204(1): 30-32
3. Deloitte, Department of Health Sports Supplements Roundtable: Reports on Discussions and Next Steps (August 2018).