Australian Government
Department of Health
Therapeutic Goods Administration

Regulation of sports supplements- proposal and consultation

Stakeholder workshops

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Presentation overview

- What is the problem?
- Are sports supplements foods or medicine?
- Why does it matter whether if it is a food or medicine?
- Why is there legal uncertainty?
- What are we doing about it?
- Proposed declaration
- Issues raised in the public consultation
- Clarifications made
- What products are in? What products are out?
- Next steps

What is the problem with sports supplements?

- Some sports supplements sold in Australia have **undeclared ingredients that are not appropriate for food** and/or are **presented as medicines rather than as a food.**
- There have been **serious adverse events** in Australia and internationally associated with use of sports supplements – including deaths, liver transplants, kidney transplants.
- 2016 LGC survey of **Australian supplements** found 1 in 5 contained one or more substances banned in sport and in virtually all cases these had not been declared on the label.
- A recent university study found that over 5% of 116 sports supplements in **Australia** contained banned substances.

In Australia supplements are regulated as either foods or medicines

- **Medicines** (therapeutic goods) if they are “represented … or in the way in which the goods are presented … likely to be taken to be for **therapeutic use**”
- **Foods** if:
  - there is an Australian NZ **Food Standard** relating to the product (e.g. standard 2.9.4 for Formulated Supplementary Sports Foods) or
  - they have a tradition of use as foods for humans in the **form in which they are presented**

If a food standard applies, making therapeutic claims (beyond the health claims allowed for foods) or presenting as a medicine does NOT make a product a medicine in law – it is an unlawful food

Whether a product is regulated as a food or medicine will determine:

- **Who regulates it**
  - the TGA **or** State and Territory food regulators
- **And therefore..**
  - who oversees adverse reactions, packaging, tampering, illegal ingredients or advertising issues
- **What ingredients** the product can contain
- **How the product has to be made**
- **What claims** the product can make, including in advertising
- **What information** the product owner is required to hold
- **How the product is** presented, e.g. labelling

Why is there regulatory uncertainty?

- **Food Standard 2.9.4** – Formulated Supplementary Sports Foods can mean that a product that is '*specifically formulated to assist sports people in achieving specific nutrition or performance goals'* and is compliant with the standard, is a food.
- However, there is **currently significant uncertainty** as 2.9.4 does **not** expressly exclude certain products from being foods:
  - products with ingredients included in the WADA Prohibited Substance List
  - products with ingredients included as substances in a schedule to the Poisons Standard
  - products presented in a form such as a capsule
- This means these products, while clearly medicines, **could be argued in court to be outside the remit of the TGA.**

The work complements the review of Food Standard 2.9.4

- Working together with other bodies for a **joined up cross government approach**
  - FSANZ
  - ASADA/NISU
  - State and Government Health authorities / Food regulators
- **Review of FSANZ - Food Standard 2.9.4**
  - Commenced by FSANZ
  - Will focus on “food” aspects of nutrition and performance
  - Requires agreement by all state and territories to finalise
- **Section 7 declaration** under the *Therapeutic Goods Act 1989*

Consultation - issues raised by industry

- Some stakeholders perceived that the **scope of the affected products was broader than intended.**
- Concerns **some foods may be captured by the following criteria** in the proposed declaration:
  - substances in excess of the limits provided in Schedule 29-18 and 29-19 of the Food Standards Code
  - ingredients exceeding the limits specified in the Permissible Ingredients determination
- Concerns that the **World Anti-Doping Agency (WADA) Prohibited Substance List:**
  - may be subject to change, creating uncertainty
  - some food ingredients in sports supplements naturally contain substances banned by WADA

How the draft declaration should be read

For products to be considered therapeutic goods, they must meet

BOTH

- *column 2 criteria* ***(ingredients or presentation)***

AND

- *column 3 criteria* ***(indications)***

Part 2—Therapeutic goods when used, advertised, or presented for supply in a particular way

Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way		
Column 1	Column 2	Column 3
Item	Goods or classes of goods	Use, advertising or presentation
1	goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or any other recreational activity, and which: (a) contain, or are represented (expressly or by implication) to contain, one or more of the following (however described or named): (i) a substance included in a schedule to the current Poisons Standard; (ii) a substance expressly identified on the WADA Prohibited List; (iii) a relevant substance; (iv) a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer;	when the goods are used, advertised, or presented for supply: (a) for therapeutic use; or (b) in a way that is likely to be taken to be for therapeutic use; including, but not limited to, one or more of the following therapeutic uses: (c) gaining muscle; (d) increasing mental focus; (e) increasing metabolism; (f) increasing stamina; (g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels; (h) losing weight or fat; (i) preparing for workout; (j) recovering from workout

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Clarification – what is proposed to be declared as medicines

Products that are used, advertised or presented for supply to **improve or maintain physical or mental performance** in sport, exercise or other recreational activity

AND

(A) **contain ingredients** that are not appropriate for a sports supplement food i.e. a substance above the restrictions provided in a schedule to the Poisons Standard; a substance that is banned by the WADA; or a substance identified in the Imported Food Notices; **or**

(B) are presented **in a form associated with medicines** rather than foods (i.e. a tablet, capsule or pill)

Clarifications to the proposed declaration

Goods for oral administration that are represented (expressly or by implication) as being for the **improvement or maintenance of physical or mental performance in sport, exercise or any other recreational activity** and which:

a) contain, or are represented (expressly or by implication) to contain, one or more of the following:

(i) a**n** ~~substance~~ **ingredient** included as a substance in a schedule to the current **Poisons Standard**; (*i.e. it does not meet the restrictions specified in the Poison Standard*)
(ii) a**n** ~~substance~~ **ingredient** expressly identified on the **WADA Prohibited Substance List**;
(iii) a **relevant** ~~substance~~ **ingredient;**
(iv) a substance with **equivalent pharmacological action** to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; **or**
~~(v) an ingredient in an amount that exceeds any limit for the ingredient specified in the Permissible Ingredients Determination when used in accordance with the directions for use in relation to the goods;~~
~~(vi) an amino acid in an amount that exceeds any limit for the amino acid specified in section S29—18 of the Food Standards Schedule 29 when used in accordance with the directions for use in relation to the goods;~~
~~(vii) a substance in an amount that exceeds any limit for the substance specified in section S29—19 of the Food Standards Schedule 29 when used in accordance with the directions of use in relation to the goods; or~~
(viii) are manufactured in **the dosage form of a tablet, capsule or pill.**

Clarifications to the proposed declaration

Column 3: Goods stipulated in column 2 are therapeutic goods when used, advertised or presented for supply

when the goods are used, advertised, or presented for supply:

(a) for therapeutic use; or

(b) in a way that is likely to be taken to be for therapeutic use

including, but not limited to, one or more of the following therapeutic uses:

(c) gaining muscle

(d) increasing mental focus

(e) increasing metabolism

(f) increasing stamina

(g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels

(h) losing weight or fat

(i) preparing for workout

(j) recovering from workout

Terms used in the declaration

'Sports' and 'Exercise' covers professional sports people and 'non-athlete' individual activities

'Other recreational activity' covers non-physical (mental) sports such as gaming

Changing 'substance' to 'ingredient'- *avoids capturing naturally occurring substances e.g IGF-1 in milk*

Relevant ingredient means **any of the following substances** (where the substance is **not** included in a schedule to the current Poisons Standard **or expressly identified** on the WADA Prohibited Substance List) identified in the Imported Food Notices:

(a) β-methylphenylethylamine (BMPEA) (*Acacia rigidula*)

(b) dendrobium (*Dendrobium nobile*)

(c) methylliberine

(d) N-phenethyl dimethylamine (*Eria jarensis* extract)

WADA prohibited list vs Poisons Standard?

Many WADA substances belong to classes of drugs that are already scheduled

WADA Prohibited lists	Substances	Poisons Standard	Where sold
Prohibited at all times	• Non approved substances for human use • Anabolic agents e.g. testosterone • Peptide hormones, growth factors • Beta-2 agonists • Hormone and metabolic modulators • Diuretic and masking agents	Schedules 3/4/8	Pharmacy only/ prescription
Prohibited in competition	• Stimulants • Narcotics • Cannabinoids • Glucocorticoids	Schedules 4/8 Schedules 9/10	Prescription Not permitted to be sold, even on prescription
Prohibited in particular sports	• Beta-blockers	Schedule 4	Pharmacy on prescription

BUT some WADA prohibited substances are not currently scheduled and would require determination of appropriate access – listed/unscheduled OTC/scheduled OTC/prescription medicines

Why are some tablets, pills and capsules in scope?

They will only be captured by the proposed declaration

IF they make/imply a therapeutic claim relating to sports performance

- **WHY ?** The average consumer would assume that a product presented as a capsule, tablet or pill **AND** making therapeutic claims is a medicine.
- **SO:** If there is NO sports performance related therapeutic claim **they are a FOOD** e.g. spirulina, pectin, fermented soy, artificial sweeteners ….
- We also don't want to capture foods in capsules that do provide nutritional value - e.g. pure glucose tablet with energy claims; others?
- Tablets/capsules with a low concentration of the claimed beneficial ingredient and a high amount of 'filler' (sugars) may not meet nutritional requirements to make compliant claims under the relevant Food Standard and could be **non-compliant foods**.

Other issues raised by industry

Interface with 'Australian NZ trade agreement'

- Sports supplements that are declared to be therapeutic goods will not be able to be lawfully imported or supplied as foods in Australia, as therapeutic goods sit outside this agreement.

Interaction with food standard 2.9.4

- TGA and FSANZ have been working together for 18 months to ensure the proposed declaration does not duplicate planned reforms to 2.9.4

Health claims permitted under FSANZ

- The food health claims scheme is legally separate to the permitted indications scheme under the *Therapeutic Goods Act 1989.*

Health care professionals, consumers and governments were generally highly supportive of the proposed declaration.

What products would be unaffected?

Sports supplements presented as foods

- with **ingredients** that are appropriate for foods; and
- which only make **health claims** compliant with health claims permitted by FSANZ ***will NOT*** *be affected by the proposal*

A product in the form of a tablet or capsule

- that **does NOT make any claims** regarding improving physical or mental performance in sport, exercise or other recreational activity ***would NOT*** *be affected by this proposal (e.g. artificial sweeteners)*

What products would be affected?

Products that claim to **improve or maintain physical or mental performance** in sport, exercise or other recreational activity

AND

(A) contain **ingredients that are not appropriate** for food:

- a substance included in a schedule to the Poisons Standard
- a substance that is banned by the WADA
- a substance identified in an Imported Food Notice

(B) are presented in a tablet, capsule or pill

What products in scope would need to do

- **Products within the scope of the proposed declaration** would not automatically be 'banned' from sale except if they have quite dangerous ingredients (e.g. S4/8/9/10 substances)
- **Owners of affected products** would usually have the choice to either:
  - **make changes to their product** to remove them from the scope of therapeutic goods regulation and allow them to remain subject to food regulation
    - e.g. removal of ingredients included in the WADA Prohibited Substance List; changing dosage form from pills, capsules or tablets
  - **apply for the product to be included** in the Australian Register of Therapeutic Goods as a listed or registered medicine

What are the next steps?

- A **Regulatory Impact Statement** (RIS) is being developed to determine impact on industry.
- **Regulatory costings** are being calculated by an independent economics organisation including targeted industry consultation.
- The RIS will be provided to government before any decision is made.
- It is anticipated that a decision will be made in April-May 2020.
- **Submissions** to the public consultation, the RIS and the government's decision will be published on the TGA website.
- There will be **sufficient transition arrangements** for companies who may be required to reformulate products and/or seek listing or registration of their products by the TGA.
- More immediate action would be required for products providing a major safety risk.