


Industry Alert (public)

Is my Sports Supplement or other product, a Food or Therapeutic Good?

The TGA's Sports Supplement declaration was made on 23 September 2020[1]. The declaration has been incorporated into the *Therapeutic Goods (Declared Goods) Order 2019* ('Declared Goods Order'), which can be found here. This Declared Goods Order clearly describes certain products, including a category of sports supplements, that are 'declared' to be therapeutic goods under Section 5 and Schedule 1 (Part 2, item 1A) of that Order. Those described in this item 1A sports supplements category need to be entered onto the ARTG on or before **30 November 2023** to be supplied or imported, or exported from Australia:

Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way	
Column 2	**Column 3**
Goods or classes of goods	**Use, advertising or presentation**
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 recreational activity, and that: (a) contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named): (i) a substance included in a schedule to the current Poisons Standard; or (ii) a substance expressly identified on the Prohibited List that is added as an ingredient to the goods; or (iii) a relevant substance that is added as an ingredient to the goods; or (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 (b) on or after 30 November 2023, are supplied in the dosage form of a tablet, capsule or pill, other than those goods containing glucose only	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

What if I have a product which is not described in the Declared Goods Order (such as a sports supplement) as a therapeutic good? Does that mean it is a food and doesn't have to be on the ARTG?

Not necessarily. The Declared Goods Order is used for special circumstances where extra clarification is needed.

- An interface product is *definitively* 'not a therapeutic good' if it is declared not to be one under Section 6 and Schedule 2 of the Declared Goods Order. For example, unmedicated chewing gum whose only claimed benefit is improvement to oral hygiene, is declared not to be a therapeutic good under the Order.

For *other supplements* not described by the Declared Goods Order, as either a therapeutic good, or not a therapeutic good, there is no simple answer as there many different products on the market. To answer this question, products are assessed case-by-case using a range of questions in the **Food-Medicine Interface Guidance Tool** (FMIGT).

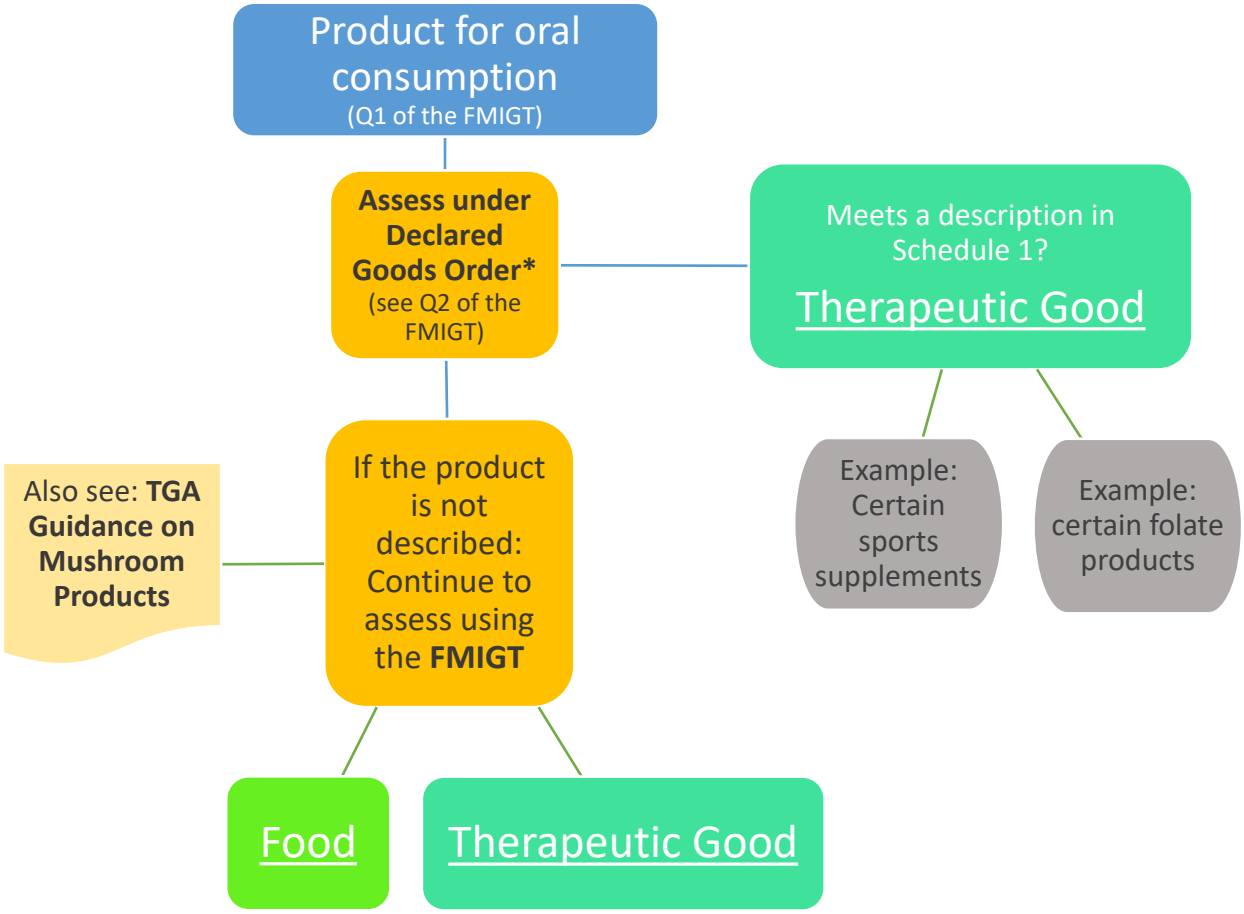
[1] Note: In 2023, no changes to the content or meaning of the legislation declaring sports supplements made in 2020 or to the food-medicine interface have occurred, and CMA has not made any representations to this effect to members or the public.

What is the Food-Medicine Interface Guidance Tool (FMIGT)?

Many products for oral consumption have characteristics that may resemble either a food *or* a therapeutic good, these products are considered 'interface' or 'boundary' products. The Government take an approach that: foods are regulated as foods, and medicines are regulated as therapeutic goods. This makes it necessary to have a way for both industry and Government to determine which category a product should fall into.

The Food-Medicine Interface Guidance Tool was developed, taking into account Australian legislation such as the *Therapeutic Goods Act 1989* and legal principles, to provide questions to help determine a product's regulatory status. In some cases especially more difficult cases, legal advice may assist a company in making a decision that they believe would be defendable under the law if questioned by a Government regulator about compliance of a product.

Assessing whether goods for oral consumption are a food or therapeutic good



*At the time of writing, the Declared Goods Order captured all existing s7 declarations in Q2 of the FMIGT however this may change from time to time. For information on s7 declarations see the TGA website here and here.

FMIGT – Interactive version

FMIGT – Diagram version

FMIGT – Explanation and information about answering questions

For example, whether a *capsule or tablet without claims* is a therapeutic good – see Questions 5, 6 and 7.

Finding further information

If, after reviewing the FMIGT and related information such as the TGA mushroom guidance, you are still unsure of whether your product is a food or a therapeutic good, there are various avenues to seek more information:

- CMA's list of regulatory consultants https://www.cmaustralia.org.au/Consultants-List
- Legal advice
- Email the TGA with questions at complementary.medicines@health.gov.au

What happens if I accidentally list a food as a therapeutic good on the ARTG, or do not list or register a therapeutic good on the ARTG?

If a food has been accidentally listed on the ARTG, the sponsor can voluntarily cancel an ARTG listing. In addition, a delegate of the Secretary (certain TGA employees) has the power to cancel listings that are not therapeutic goods.

If a product that is a therapeutic good and required to be entered on the ARTG, but is not entered on the ARTG, compliance actions can be taken against these products by the TGA when the products are imported or supplied in Australia; or if the advertising does not comply with therapeutic goods advertising requirements.

Compliance actions range in nature based on perceived severity based on the TGA's Compliance Framework and approach to managing advertising compliance. They can include warnings, enforceable undertakings, or infringement notices, and in some more severe cases commencement of court proceedings, for example, here and here.

The TGA's 2023 Compliance Priorities, include unlawful advertising of unapproved and high-risk medicines and medical devices used in the wellness and beauty industries, including sports supplements.

Products that are foods

Foods can be compliant or non-compliant foods, under relevant requirements of the Australia New Zealand Food Standards Code. The TGA may refer cases about non-compliant foods to the relevant state and territory regulator.

The requirements of Standard for Sports Foods (Formulated Supplementary Sports Foods Standard 2.9.4.) are currently under review by FSANZ with a view to expanded permissions. CMA has provided responses to the ongoing consultation process to advocate for an expanded scope of compliant sports foods, including through addressing aspects of the Standard such as nutrition, labelling and claims for sports foods; we encourage all companies who supply sports foods to follow the P1010 FSANZ consultations and to also respond to consultations individually.

Products that are therapeutic goods

Paragraph (a) of item 1A describing sports supplements in the Declared Goods Order refer to certain *higher risk* ingredients which would in most cases be required to be **registered** onto the ARTG (AUST R), which is considered difficult to achieve and may not be possible for some. A supplement contains a higher-risk ingredient if there are:

- substances present that are 'scheduled' in the Poisons Standard (e.g. S4 prescription medicine ingredients);
- ingredients intentionally added to the product that are classified as a substance banned for use in sport by the World Anti-Doping Agency;
- ingredients intentionally added to the product that are substances included in a list of 'Relevant Substances' specified in the Declared Goods Order for sports supplements.

Sports supplements that are now declared therapeutic goods under paragraph (b) of item 1A, or other products under the FMIGT that are considered therapeutic goods, can be **listed** onto the ARTG (AUST L or LA) if they comply with all regulatory requirements, including a requirement to contain *lower risk* ingredients included in the Permissible Ingredients Determination and lower risk indications for use in the Permissible Indications Determination. If an ingredient is likely to be lower risk and therefore safe to be in listed medicines, but isn't yet included on the Permissible Ingredients list, an application for a new ingredient can be made.

Information about listing (or registering) a product in the ARTG can be found on the TGA website including:

- General guidance for listed medicines
- Listed and assessed listed medicines: Application and submission user guide
- Australian Regulatory Guidelines for Listed Medicines and Registered Complementary Medicines

Manufacturers of therapeutic goods, unless exempt, need TGA GMP licensing or clearance for manufacturing:

- Manufacturing therapeutic goods
- Manufacturing medicines

All advertisers of therapeutic goods need to consider compliance with all advertising requirements, including:

- TGA Advertising hub: Advertising therapeutic goods
- The Therapeutic Goods Advertising Code
- Complying with any requirements for restricted and prohibited representations
- The Act prohibits advertising to the general public for a substance or a therapeutic good containing a substance included in Schedule 4 or Schedule 8 of the Poisons Standard.

Retailer considerations

Retailers should be aware of their responsibilities under relevant State and Territory laws for sale of products that are foods and therapeutic goods:

- Department of Agriculture: regulation of the importation of food
- NSW Food Authority
- Victorian Department of Health
- Queensland Department of Health
- Western Australian Department of Health
- South Australian Department of Health
- Tasmanian Department of Health and Human Services
- Australian Capital Territory Health Directorate
- Northern Territory Department of Health

Additional Resources

- TGA web page: Changes to the regulation of sports supplements in Australia
- TGA Food-Medicine Interface Guidance Tool (FMIGT)
- TGA Guidance on mushroom products
- CMA Professional Industry Consultants List
- *Therapeutic Goods (Declared Goods) Order 2019*
- *Therapeutic Goods Act 1989*