Australian Government
Department of Health
Therapeutic Goods Administration

Proposal to clarify that certain sports supplements should be regulated as therapeutic goods

Regulation Impact Statement for the Minister for Health

Office of Best Practice Regulation (OBPR) ID number: 25664

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TGA Health Safety Regulation

Contents

Executive Summary

The Australian Government is concerned about the safety risks of some sports supplement that are readily available for sale as foods in Australia. There have been serious adverse events reported domestically and internationally associated with the use of certain sports supplements, including deaths and liver transplants. These events are not only tragic for the individuals concerned; they represent a significant cost to society as a whole - affecting the individuals' family, friends, their immediate and broader communities, as well as posing a significant cost to the Australian healthcare system. In addition, in general, these events occur in otherwise healthy, predominantly younger people, for whom there is usually no medical reason to take the product that caused them harm.

The Minister for Health, the Hon. Greg Hunt MP, instigated a national roundtable in 2018 to identify measures to improve the safe use of sports supplements. Following the forum, the Minister asked the Therapeutic Goods Administration (TGA) and Food Standards Australia New Zealand (FSANZ) to investigate options to provide clarity on the regulatory status of these products to improve their safe use.

In Australia, food and medicines are regulated under separate legislative frameworks, commensurate with the intended use and potential risks that those products pose to public health and safety. Within the regulatory frameworks, there are different requirements for foods and medicines in relation to their manufacturing, labelling, advertising and evidence required to substantiate any claims made for the products.

'Sports supplements' is a broad category of products that carry claims relating to sport, fitness or recreational performance. A sports supplement, like many other products for oral consumption, can be either food or a medicine in law depending on the specific combination of ingredients, claims and overall presentation. For instance, two products with the same formulation may be characterised differently—one as a food and the other as a medicine—depending on their claims, label artwork and other aspects of their packaging and advertising. However, a product cannot simultaneously be both a food and a medicine in law. Sports supplement products are at the interface between the food and medicine regulatory frameworks—the 'food-medicine interface' ('FMI').

An increasing number of sports supplements are being brought to market in Australia as foods. While this is appropriate for many of these products, some are:

- not appropriate for food [for example: include substances such as prescription medicine ingredients included in a schedule to the Standard for the Uniform Scheduling of Poisons and Drugs (the Poisons Standard) or substances in the World Anti-Doping Code Prohibited List (WADC Prohibited List)]; and/or
- presented as a medicine (with respect to their health claims and dosage forms such as tablet, capsule or pills)

Currently there is a lack of legal clarity in food and therapeutic goods legislation to determine the regulatory status of these products as foods or medicines. This means that it is not clear if it is the national medicine regulator or the individual state and territory food regulators that have jurisdictional responsibility for these goods. Where significant safety concerns have arisen that require urgent enforcement activity to protect consumer safety (for example a product marketed as a food is found to contain an illegal drug) this lack of legal clarity can, and has, resulted in lengthy and costly court proceedings with lawyers arguing that (under the current legislation) these products fall outside therapeutic goods legislation. The consequence of this legal uncertainty is continued risk of consumer exposure to unsafe products and a significant waste of Government resources and taxpayer's money in pursuing protracted legal proceedings.

There are two categories of sports supplements, currently being marketed as foods, which pose actual and potential safety concerns for consumers:

- products which are either non-compliant or illegal (in relation to the ingredients they contain) but are not being sufficiently regulated (due to lack of clarity on their legal status as a food or medicine in current legislation)
- other products which may not be illegal under current legislation, but present a level of risk to consumers (in relation to their ingredients or presentation as medicines) such that it is appropriate to mitigate these risks through regulation

Some companies may knowingly market supplements as food products, rather than therapeutic goods, to avoid appropriate regulatory scrutiny, even though they contain ingredients that may cause harm. Similarly, some consumers knowingly consume products containing high-risk ingredients for their purported performance enhancement, in spite of known health risks.

Conversely, other consumers are unaware of the ingredients that certain food sports supplements contain (due to the ingredients not being declared on the label or listed under different names). This is a not only a concern relating to potential adverse events, it is also of particular relevance to amateur and professional athletes who unwittingly consume WADC prohibited substances and suffer lengthy bans from their sport resulting in personal hardship, reputational damage and delayed or ruined careers.

In relation to food products presented in a medicinal form, a product presented as a tablet, capsule or pill and making therapeutic claims implies that the product is for therapeutic use and, is therefore a therapeutic good under current legislation. A reasonable consumer would assume that such a product is a medicine and that it is subject to an appropriate level of regulatory oversight to ensure its safety, quality and efficacy. Dosage forms such as tablets, capsules, and pills would generally provide a more concentrated version of an ingredient compared to presentation in forms traditionally aligned with foods, such as powders or bars. Manufacturing requirements for foods are not as stringent as for therapeutic goods [the latter being required to be made in accordance with good manufacturing practice (GMP) principles], which can lead to variability in dosing and an altered safety profile of the products.

The therapeutic goods framework provides a national system of controls to ensure consumer safety. It is in the interest of the Australian public that products, which may pose actual and potential risks to consumer health and safety, are subject to the national system of controls relating to the quality, safety and efficacy of therapeutic goods. If the therapeutic goods framework applied to certain sports supplement products (that pose actual and potential risks), it would assist industry in ensuring they meet the high levels of safety, quality and efficacy that Australian consumers expect from products marketed in Australia. Most importantly, it will enable swift action by the regulator when products pose an elevated risk to public safety.

In response to the Minister's request to investigate options to provide clarity on the regulatory status of these products to improve their safe use, the TGA developed an initial proposal to declare that certain sports supplements are therapeutic goods under the existing authority provided by section 7 of the *Therapeutic Goods Act 1989* ('TG Act'). In developing this proposal, the TGA collaborated with other government departments/agencies, including state and territory health departments, FSANZ, the Australian Institute of Sport (AIS), the former Australian Sports Anti-Doping Agency (ASADA) and the former National Integrity Sports Unit (NICU) (now Sport Integrity Australia). The TGA then conducted a public stakeholder consultation, receiving an extensive number of submissions from consumers, retailers, manufacturers, industry bodies and health professionals.

The insights gained from stakeholder consultation submissions led to a refinement of the initial proposal by the TGA in order to address stakeholder concerns, while still mitigating the risks of the products of concern. Further targeted stakeholder consultation (in the form of two

workshops) was then conducted on the refined proposal with retailers, manufacturers, consumer representative bodies, sporting associations, regulatory consultants and government bodies/ agencies. In addition, nine face-to-face interviews were conducted with key stakeholders by the Noetic Group (Noetic) to inform regulatory burden costings (refer to the Noetic Report at Appendix 1).

This extensive consultation process has been used to inform the number of options and alternative approaches examined in this RIS. The final options proposed include taking no action and three separate proposals to declare (under the authority of section 7 of the TG Act) that certain sports supplements are therapeutic goods, based on the ingredients they contain and/or their presentation in medicinal form. The initial proposed declaration, which was the subject of the 2019 public consultation, is presented in the RIS as an alternative approach that was not pursued. The key options explored in the RIS are provided in Table 1.

Table 1: Key options explored in this RIS:

Option	Elements
Option 1	Maintain the status quo (no change)
Option 2A	Declare that sports supplements are therapeutic goods if they: • contain ingredients that are not appropriate for a sports supplement food: – a substance above the restrictions provided in the Poisons Standard – a substance that is included in the WADC Prohibited List – a Relevant substance as declared by the Secretary of the Department of Health (the Secretary) • and/or are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill)
Option 2B	Declare that sports supplements are therapeutic goods if they: • contain ingredients that are not appropriate for a sports supplement food: – a substance above the restrictions provided in the Poisons Standard – a Relevant substance as declared by the Secretary • and/or are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill)
Option 3	Declare that sports supplements are therapeutic goods if they contain ingredients that are not appropriate for a sports supplement food: • a substance above the restrictions provided in the Poisons Standard • a substance that is included in the WADC Prohibited List • a Relevant substance as declared by the Secretary

Option 1 (status quo) would fail to address the actual and potential safety concerns for consumers and fail to resolve the issues relating to product classification (i.e. as either a food or

a therapeutic good) that make regulatory enforcement actions inefficient and cause prolonged legal proceedings.

Option 2A proposes to declare that sports supplements containing certain ingredients (i.e. substances in the Poisons Standard, WADC Prohibited list or in the Relevant substance list) and/or that are presented in the form of a tablet, capsule or pill are therapeutic goods. This option has been extensively consulted on and is considered to address many of the safety concerns surrounding the use of sports supplements.

Option 2A will not affect those sports supplements that contain only appropriate food ingredients and that are presented for sale in the manner of food products, for example: meal replacement shakes, muesli bars, protein powders. These will continue to be regulated as foods.

If Option 2A is implemented, manufacturers/ suppliers of sports supplements in scope of the proposal who wish their products to be marketed as foods, will need to consider changing, as applicable, the product's claims; and/or ingredients; and/or dosage forms. Alternatively, if the products are to be maintained on the market as medicines, the products would need to be entered in the Australian Register of Therapeutic Goods (ARTG) and the sponsor of the medicine will need to ensure that the products meet the applicable legislative requirements for manufacturing, formulation, labelling, evidence and/or advertising.

If sports supplements are regulated as lower risk listed medicines in the ARTG, those supplements may be self-selected by consumers without the restrictions required for higher risk over-the-counter or prescription medicines. For sports supplements that include high-risk substances and require registration in the ARTG, these supplements would undergo a full TGA pre-market evaluation of safety, quality and efficacy.

However, if sports supplements (in scope of the proposal) cannot be reformulated to be marketed as foods or the manufacturer/supplier does not want the products to be regulated as therapeutic goods, then these products would have to be removed from the marketplace.

While Option 2A will pose a regulatory burden to affected stakeholders, it is considered the minimal necessary regulatory burden to reduce the risk posed to consumers by these products. Regulating such products as medicines is expected to significantly reduce the risk to public health in relation to sports supplements and provide consumers with greater confidence in the safety of the products they are using. This will be enabled by swift compliance and enforcement action by the relevant authorities when safety concerns are identified (which is not currently possible, given the present legal ambiguity around the regulatory status of such products) and ensure that sports supplements that are on the market are being subject to controls commensurate with their level of risk. In addition, by being subject to the labelling and advertising standards for therapeutic goods, consumers would also be aided in making informed decisions when self-selecting these goods.

Option 2B is similar to Option 2A, but the criterion of the WADC Prohibited List has been removed, in consideration of feedback from a small number of stakeholders. However, Option 2B is not preferred due to the potential safety concerns associated with these substances. There is a high correlation between substances included in the WADC Prohibited List and those in a schedule to the Poisons Standard. Many, but not all, WADC prohibited substances are included in a schedule to the Poisons Standard either explicitly or under scheduled drug classes (such as 'androgenic steroidal agents'). Those substances in the WADC Prohibited List that are not included in a schedule to the Poisons Standard appear to possess similar characteristics to other scheduled substances and therefore may meet the requirements to be included in the Poisons Standard (but inclusion of a substance is not automatic – it requires an application to amend the Poisons Standard).

Option 2B would, in effect, equate to the same level of regulatory burden as Option 2A, given that substances from the WADC Prohibited List identified with a significant health risk (that are not

already expressly included in a schedule to the Poisons Standard) may be included in the Relevant substance list by the Secretary of the Department of Health (the Secretary) or included in the Poisons Standard (via an amendment application). It would however, require significantly more Government resources to complete either of these processes and the likely delays may result in a continued risk of exposure to consumers to potentially hazardous substances. There may also be some substances that are prohibited by the WADC that are not considered appropriate for inclusion in the Poisons Standard, however, it would seem inconsistent that if a substance is considered by WADC to be inappropriate for use in athletes that it should be available in sports food supplements designed for use by athletes.

In addition to the safety risks to consumers, the presence of a WADC prohibited substance in a supplement may result in an anti-doping rule violation for an athlete, whether its use was intentional or unintentional, resulting in bans of up to four years from their sport and ensuing personal hardship. In addition, Australia is a state party to the United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention against Doping in Sport and has an obligation to limit the availability of prohibited substances in order to restrict their use in sport. Option 2B may be seen as failing to meet this obligation.

Option 3 is similar Option 2A, but the criterion of product presentation in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill) has been removed in consideration of feedback from some stakeholders. However, Option 3 is not preferred due to the potential of risk that sports supplements presented in a medicinal form may pose to consumers.

An analysis of the presentation of sports supplement products by the Noetic Group (Noetic) (Appendix 1) shows that the product category known as 'fat burners' represents the largest portion of sports supplement products being presented as tablets, capsules or pills in Australia. Noetic estimate that 51% of fat burner products are in the presentation of tablets, capsules or pills, compared to 6% post-workout products and 3% of pre-workout products (the basis for the calculation of these figures is explained further within the Noetic Report at Appendix 1). The significance of this analysis is that, the product category of 'fat burners' (the largest portion of products presented as tablets, capsules or pills,) has been linked to serious events in Australia. In 2018, the NSW Ministry of Health advised of significant adverse events from the category of products known as 'fat burners' or 'shredders' and urged the public to avoid any product from an unverified source being promoted as a weight-loss agent (24). It is also of interest to note that there are a number of 'fat burner' products presented in tablet, capsule or pill dosage forms already included in the ARTG by sponsors who consider that their products are appropriately regulated as therapeutic goods.

Option 3 is not preferred as it is considered that products making therapeutic indications, with a potential for having higher risk ingredients (i.e. that require accurate dosage forms) and presented in a medicinal form (i.e. a tablet, capsule or pill) more closely align with being regulated under the therapeutic goods framework.

This Regulation Impact Statement (RIS) is intended to assist the Australian Government in reaching a decision to address the issues relating to the safe use of sports supplements in Australia. The evidence presented in this RIS does not support the wholesale removal of all food sports supplement products from sale (which is, in any event, is not the intent of any of the options proposed), but does support a greater degree of regulatory oversight for higher-risk products in relation to their product formulation, presentation, manufacture and post-market surveillance.

Background

In 2018, a roundtable on the 'Regulation of Sport Supplements' was convened by the Australian Government Department of Health, on behalf of the Food Regulation Standing Committee (1). This was at the request of the Australian Government Minister for Health, the Hon. Greg Hunt MP, following the death of a woman in Western Australia in 2018, attributed to her use of sports supplements. The woman had an underlying metabolic disorder - Urea Cycle Disorder - where her body was unable to metabolise her high protein diet (including protein rich foods and various sports supplement protein powders).

Attendees at the roundtable included representatives from Australian Government agencies, state and territory governments, public health organisations and industry. The purpose of the roundtable, which was broader than a consideration of issues relating to high protein sports supplements, was to investigate opportunities at the Commonwealth and/or state and territory levels to enhance the safety of consumers who choose to use all types of sports supplements.

Following the roundtable, the Minister tasked the TGA to investigate options under the therapeutic goods regulatory framework to provide clarity on the regulatory status of these goods with the aim of improving their safe use.

Section 7 of the *Therapeutic Goods Act 1989* (the TG Act) provides the Secretary of the Department of Health (the Secretary) or his/her delegate, the power to declare that goods are or, are not, therapeutic goods generally or when used, advertised or presented for supply in a particular manner. Section 7 declarations are made to provide clarity for consumers, industry and regulators about whether a product is a therapeutic good.

A draft proposal to declare (via a section 7 declaration under the TG Act) that certain sports supplements are therapeutic goods, was presented for discussion to the July 2019 meeting of the Food Regulation Standing Committee's Implementation Subcommittee for Food Regulation (ISFR). A subsequent September 2019 workshop was held by TGA with representatives from other government organisations and state and territory health departments.

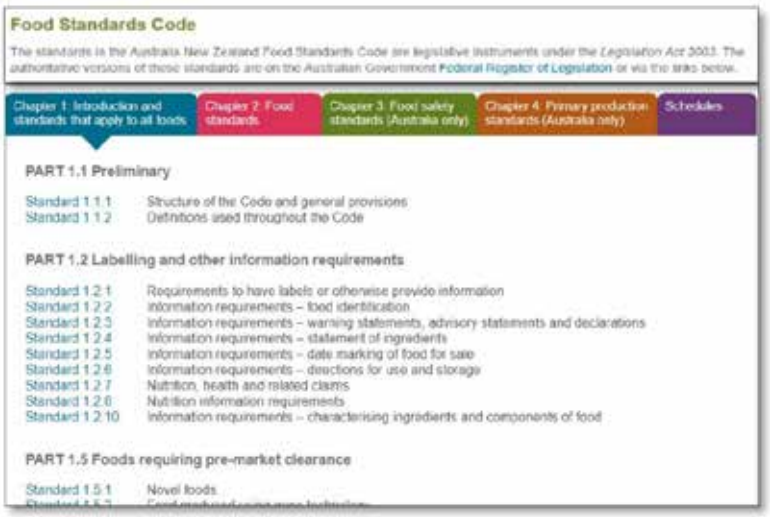
A consultation paper on a Proposed clarification that certain sports supplements are therapeutic goods (by way of a declaration) was released for public comment on 22 October 2019. The consultation received a significant amount of stakeholder feedback (for details refer to Consultation). In consideration of stakeholder feedback, the proposed declaration was refined and clarified and was the subject of additional targeted stakeholder consultations (in the form of two workshops) in early 2020. In addition, nine face-to-face interviews were conducted with key stakeholders by the Noetic Group (Noetic) to inform regulatory burden costings (refer to the Noetic Report at Appendix 1).

The consultation process has informed the options proposed in this RIS to address the safety concerns surrounding the use of sports supplements, while imposing the minimal necessary regulatory burden.

Current regulatory systems for food and therapeutic goods

Regulation of food in Australia

The regulation of food in Australia is a joint responsibility of the Commonwealth and the states and territories.


Food Standards Code

The standards in the Australia New Zealand Food Standards Code are legislative instruments under the *Legislation Act 2003*. The authoritative versions of these standards are on the Australian Government Federal Register of Legislation or via the links below.

Chapter 1: Introduction and standards that apply to all foods | Chapter 2: Food standards | Chapter 3: Food safety standards (Australia only) | Chapter 4: Primary production standards (Australia only) | Schedules

PART 1.1 Preliminary

Standard 1.1.1 Structure of the Code and general provisions
Standard 1.1.2 Definitions used throughout the Code

PART 1.2 Labelling and other information requirements

Standard 1.2.1 Requirements to have labels or otherwise provide information
Standard 1.2.2 Information requirements – food identification
Standard 1.2.3 Information requirements – warning statements, advisory statements and declarations
Standard 1.2.4 Information requirements – statement of ingredients
Standard 1.2.5 Information requirements – date marking of food for sale
Standard 1.2.6 Information requirements – directions for use and storage
Standard 1.2.7 Nutrition, health and related claims
Standard 1.2.8 Nutrition information requirements
Standard 1.2.10 Information requirements – characterising ingredients and components of food

PART 1.5 Foods requiring pre-market clearance

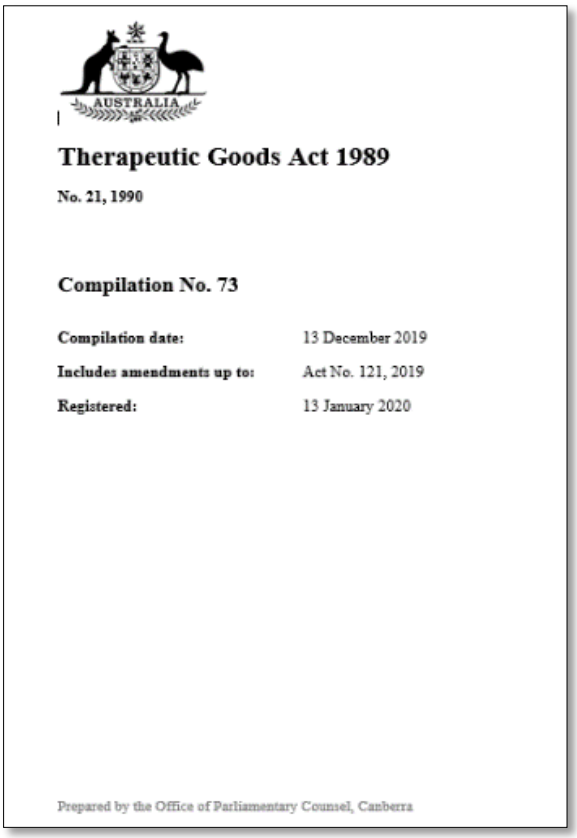
Standard 1.5.1 Novel foods

FSANZ is responsible for the Australia New Zealand Food Standards Code (the Code), which is a set of bi-national standards for food made under the *Food Standards Australia New Zealand Act 1991*.

State and territory government food authorities and local councils enforce the Code, deal with complaints about food and investigate food safety issues through their respective legislation.

Regulation of therapeutic goods in Australia

The TGA, part of the Commonwealth Department of Health, is responsible for regulating therapeutic goods (including medicines, medical devices and biological products) under the TG Act and relevant regulations to ensure those goods are of acceptable quality, safety and efficacy.


AUSTRALIA

Therapeutic Goods Act 1989

No. 21, 1990

Compilation No. 73

Compilation date: 13 December 2019

Includes amendments up to: Act No. 121, 2019

Registered: 13 January 2020

Prepared by the Office of Parliamentary Counsel, Canberra

Therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) to be lawfully supplied in, imported into, or exported from Australia, unless those goods are otherwise the subject of an exemption, approval or authority under the TG Act.

There are two tiers of regulatory requirements that medicines must meet in order to be included in the ARTG, corresponding with the degree of risk based on a product's ingredients, therapeutic indications (claimed health benefits) and presentation:

- Lower risk medicines (for example most complementary medicines such as vitamin and mineral supplements) are listed in the ARTG. These are identified by an AUST L or AUST L(A) number on their label and are available for self-selection by consumers.
- Higher risk medicines (for example all prescription medicines) are *registered* in the ARTG. These are identified by an AUST R number on their label and may be accessed over-the- counter or with a prescription in pharmacies.

The regulatory requirements for medicines include:

- licensing or approval of manufacturing facilities to ensure medicines are manufactured in accordance with good manufacturing practice (GMP)
- restrictions over the types and amounts of ingredients to ensure medicines are acceptable in terms of safety and quality prior to marketing and supply, for example:
  - listed medicines are only permitted to contain certain low risk ingredients that are specified in a legislative instrument known as the Therapeutic Goods (Permissible Ingredients) Determination ('the Permissible Ingredients Determination')
  - only registered medicines may be permitted to contain a substance included in a Schedule to the Poisons Standard, a legislative instrument that consists of decisions regarding the classification of medicines and poisons into schedules for inclusion in the relevant legislation of the states and territories
- sponsors must have evidence to support the indications (specific therapeutic uses) and claims for the medicine (that it does what it says it does)
- labelling that supports safe and effective use of medicines by consumers
- advertising that is not misleading or suggests unsafe product use

The TG Act also provides for post-market monitoring of complaints about advertising, medicine defects and adverse events.

Further detail of the regulatory requirements for therapeutic goods and a comparison to those for foods are provided below.

Importation of food and medicines into Australia

The Department of Agriculture, Water and the Environment (DWE) administers the *Imported Food Control Act 1992* and enforces food laws at Australia's borders in relation to imported food. All imported food must meet the conditions imposed under the *Biosecurity Act 2015* to be allowed into the country. Once imported food has met these requirements, food is monitored for safety and compliance to the Code and the Country of Origin Food Labelling Information Standard 2016.

In relation to food imported from New Zealand, the Trans-Tasman Mutual Recognition Arrangement (TTMRA) is a non-treaty arrangement between New Zealand and Australian Commonwealth, state and territory governments, which allows for goods (excluding therapeutic goods) legally sold in New Zealand to be sold in Australia. This means that foods that are compliant with the supplementary food standards and dietary supplements regulation in NZ can legally enter Australia.

The Australian Border Force enforces the laws relating to the importation of medicines across Australia's borders.

There are limitations on the type, quantity and intended consumer of imported medicines. Some medicines can only be imported with a valid prescription, some medicines may only be imported by a medical professional and some substances may not be imported at all.

Under the Personal Importation Scheme a person may import a 3 month supply at the one time (at the maximum dose recommended by the manufacturer) of unapproved therapeutic goods into Australia without any approval required by the TGA provided they meet a number of requirements, including that:

- they do not supply (sell or give) the medicine to any other person

- the goods are not restricted under Australian Customs controls or quarantine rules and the goods do not contain a controlled substance
- if the goods are medicines in Schedule 4 or 8 of the Poisons Standard a prescription from an Australian-registered medical practitioner is held for the medicines

Persons cannot import more than a 3-month supply at the one time under the personal importation scheme. If more than 3 months' supply are to be imported at the one time into Australia, an Australian-registered doctor will first need to apply to the TGA for Special Access Scheme approval.

If an import of therapeutic goods is made that does not comply with the rules of the Personal Importation Scheme, and without any other relevant approval, the importation can be seized and destroyed at customs and the importer may be charged with an offence under the TG Act, which can carries significant fines, or even result in imprisonment.

Different regulatory requirements for food and medicines

There are different requirements for foods and medicines in relation to ingredients, health claims/indications, labelling, manufacturing and advertising.

In relation to claims made for the products, while specific health claims are allowed under the Code for foods, therapeutic goods can make claims relating to therapeutic use, which are higher-level claims than permitted for foods. A food can be considered an illegal food or illegal therapeutic good if it makes claims of therapeutic use.

With respect to manufacturing, there are more stringent requirements for medicines than foods. For example:

- Food products are only tested in the final form, but medicinal products require testing at multiple stages.
- Food products have food grade ingredients whereas medicines need to have pharmaceutical grade ingredients.
- The level of sanitisation is different for food and therapeutic goods, requiring different air supply; filters; operating procedures; staffing skill level; storage; product dispatch; equipment validation and calibration; manufacture process validation; and product testing.

Foods and medicines have different labelling requirements with respect to:

- label claims and warning statements
- product identification numbers
- nutritional information (food) or active ingredient information (medicines)

There are also different requirements for post market activity for food and medicines, such as:

- adverse event monitoring
- stability of product testing and monitoring
- pharmacovigilance

Advertising requirements for both food and medicine require advertising to be truthful and to not mislead. However, there are stricter advertising requirements for medicines, with higher risk medicines not being able to be advertised at all.

The different requirements for food and medicines are outlined below.

Health claims for foods and indications for medicines

Health claims for foods

A 'claim' is defined in Standard 1.1.2 of the Food Standards Code as an express or implied statement, representation, design or information in relation to a food or property of food which is not mandatory in the Code.


Standard 1.2.7 Nutrition, health and related claims

Division 1 Preliminary

1.2.7—1 Name

This Standard is Australia New Zealand Food Standards Code – Standard 1.2.7 – Nutrition, health and related claims.

1.2.7—2 Definitions

In Standard 1.2.7 and Standard 1.2.8:

fruit means the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole fruit (with or without the peel or water); and does not include nuts, spices, herbs, fungi, legumes and seeds.

vegetable means the edible portion of a plant or constituents of the edible portion that are present in the typical proportion of the whole vegetable (with or without the peel or water) and does not include nuts, spices, herbs, fungi, dried legumes (including dried legumes that have been cooked or rehydrated) and seeds.

Food Standard 1.2.7 regulates the following types of claims for general foods:

- nutrition content claims (claims that refer to a particular nutritional property of food being present or absent)
- health claims, which can be either:
  - high level health claims (claims that a food or a property of a food product, has or may have a health effect relating to a serious disease or biomarker of a serious disease)
  - general level health claims (claims that a food or a property of a food product, has or may have a health effect but are not a high level health claim)

Health claims are only permitted on foods that meet the Nutrient Profiling Scoring Criterion (NPSC). A food-health relationship is the relationship between a food or a property of the food and a health effect. All health claims are required to be supported by scientific evidence to the same degree of certainty, whether they are pre-approved by FSANZ or self-substantiated by food businesses[1].

Table 2 provides example of general and high-level health claims for general foods.

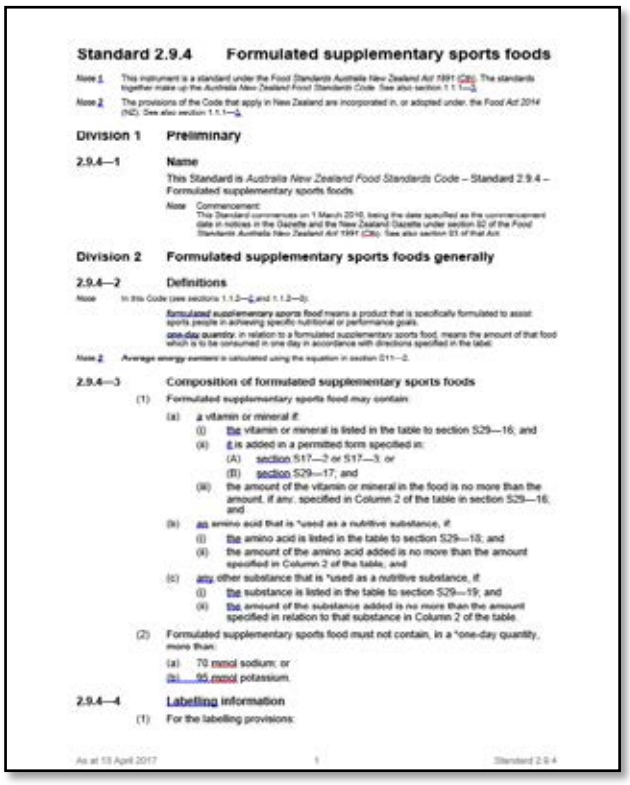
[1] Getting Your Claims Right - A guide to complying with the Nutrition, Health and Related Claims Standard of the Australia New Zealand Food Standards Code

Table 2: Food Standard 1.2.7 Food Health claims

Food Standard 1.2.7 permits the following health claims where specific nutrient or substance requirements are met in a food	
General level health claims refer to a nutrient or substance in a food, or the food itself, and its effect on health. They must not refer to a serious disease or to a biomarker of a serious disease. Food businesses making **general level health claims** are able to base their claims on one of the more than 200 pre-approved food-health relationships in the Standard or self-substantiate a food-health relationship in accordance with detailed requirements set out in the Standard, including notifying FSANZ.	For example: 'Calcium for healthy bones and teeth.'
High level health claims refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease **High-level health claims** must be based on a food-health relationship pre-approved by FSANZ. There are currently 13 pre-approved food-health relationships for high-level health claims listed in the Standard.	For example: 'Diets high in calcium may reduce the risk of osteoporosis in people 65 years and over.' 'Phytosterols may reduce blood cholesterol.'

Alternatively, Part 2.9 of the Code provides standards for 'special purpose foods' [including Food Standard 2.9.4 Formulated Supplementary Sports Foods (FSSF)] which allows products complying with the requirements of these standards to make specific health claims.

Table 3 provides examples of health claims allowed for FSSFs compliant with the requirements of Food Standard 2.9.4.



Standard 2.9.4 Formulated supplementary sports foods

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—4.

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—4.

Division 1 Preliminary

2.9.4—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Standard 2.9.4 – Formulated supplementary sports foods.

Note Commencement:
This Standard commences on 1 March 2010, being the date specified as the commencement date in notices in the Gazette and the New Zealand Gazette under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

Division 2 Formulated supplementary sports foods generally

2.9.4—2 Definitions

Note In this Code (see sections 1.1.2—5 and 1.1.2—6):

formulated supplementary sports food means a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals.

one-day quantity, in relation to a formulated supplementary sports food, means the amount of that food which is to be consumed in one day in accordance with directions specified in the label.

Note 2 Average energy content is calculated using the equation in section 01I—2.

2.9.4—3 Composition of formulated supplementary sports foods

(1) Formulated supplementary sports food may contain:

(a) a vitamin or mineral if:
(i) the vitamin or mineral is listed in the table to section S29—16; and
(ii) it is added in a permitted form specified in:
(A) section S17—2 or S17—3; or
(B) section S29—17; and
(iii) the amount of the vitamin or mineral in the food is no more than the amount, if any, specified in Column 2 of the table in section S29—16; and

(b) an amino acid that is "used as a nutritive substance, if:
(i) the amino acid is listed in the table to section S29—18; and
(ii) the amount of the amino acid added is no more than the amount specified in Column 2 of the table; and

(c) any other substance that is "used as a nutritive substance, if:
(i) the substance is listed in the table to section S29—19; and
(ii) the amount of the substance added is no more than the amount specified in relation to that substance in Column 2 of the table.

(2) Formulated supplementary sports food must not contain, in a "one-day quantity, more than:
(a) 70 mmol sodium; or
(b) 95 mmol potassium.

2.9.4—4 Labelling information

(1) For the labelling provisions:

As at 13 April 2017 1 Standard 2.9.4

Table 3: FSSF health claims

Food Standard 2.9.4 – Formulated Supplementary Sports Foods permits the following health claims where specific nutrient or substance requirements are met in a food	
Energy supplement	• 'May assist in supplementing the diet with an energy source as may be required during training.' • 'Useful before, during or after sustained strenuous exercise.'
Protein energy supplement	• 'May assist in providing a low-bulk diet as may be required during training.' • 'May assist in supplementing the diet with a high energy source as may be required during training.' • 'May assist in the development of muscle bulk.' • 'Useful before, during, or after sustained strenuous exercise.'
High carbohydrate supplement	• 'Useful before, during, or after sustained strenuous exercise.' • 'May assist in the provision of energy in the form of carbohydrates.'

Indications for medicines

"Indications" for a medicine means the therapeutic use for the product. For medicines, therapeutic use means 'preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or influencing, inhibiting or modifying a physiological process in persons'.

Indications for medicines vary depending on the risk of the product. The risk hierarchy for indications is shown in Table 4.

Sponsors must hold evidence to support their medicine's indications; however, this is only evaluated pre-market by the TGA for 'listed assessed' and registered medicines. In the case of listed medicines, this evidence may be evaluated as part of a post-market random or targeted compliance review.

Table 4: Indication risk hierarchy

	Listed medicines (AUST L)	Assessed listed medicines [AUST L(A)]	Registered medicines (AUST R)
Pre-market assessment by the TGA	Not pre-market assessed.	Pre-market assessed for efficacy.	Fully pre-market assessed – quality, safety and efficacy.
Indications able to be used	Low level indications that **only refer to**: • health enhancement • health maintenance • prevention of dietary deficiency • a non-serious[2] form of a disease, ailment, defect or injury	Indications that are not appropriate for permitted indications, but are not high level indications. Intermediate level indications **may refer to**: • the prevention, alleviation, or cure of a non-serious disease, ailment, defect or injury • restricted representations[3] (i.e. a serious form of a disease)	Indications that refer to the prevention, alleviation or cure of a serious form of a disease, ailment or injury (i.e. restricted representations).

All permitted indications for listed medicines and their requirements are contained in a legislative instrument called the Permissible Indications Determination. Table 5 provides examples of permitted indications referring to sports-related activity.

Table 5: Example of permitted indications that refer to maintenance or enhancement of sports related activity that may be selected for listed medicines

Permitted indications for sports related activity
Enhance/promote energy levels
Helps enhance/promote calorie burning
Maintain/support physical endurance/capacity/stamina
Maintain/support heat/energy production/thermogenesis
Helps enhance/promote/increase weight loss

[2] As defined in the Therapeutic Goods Advertising code
[3] As defined in the Therapeutic Goods Advertising code

Permitted indications for sports related activity
Maintain/support healthy body fat/muscle composition
Helps in the maintenance of lean body mass
Aid/assist/helps post exercise recovery
Helps enhance/improve/promote/increase physical/exercise performance

When selecting indications in the electronic application form, applicants can also select from a drop-down list of 'indication qualifiers' to add to the indication in order for the indication to align with the evidence they hold, for example:

- 'in athletes'
- 'after exercise'
- 'before exercise'

Ingredients for food and medicines

Ingredients in food

FSANZ develops standards that regulate the use of ingredients, processing aids, colourings, additives, vitamins and minerals. The Food Standards Code also covers the composition of some foods, for example: dairy, meat and beverages as well as foods developed by new technologies such as genetically modified foods.

Ingredients in medicines

Table 6 provides a comparison of the different ingredients in medicines.

Table 6: Comparison of ingredients in medicines

	Food	Listed medicines	Registered complementary medicines	Registered OTC medicines	Registered prescription medicines
Ingredient requirements	Compliant with the Food Standards Code	Cannot contain a substance included in a Schedule to the Poisons Standard. Can only use ingredients from a list of permitted ingredients	May include a substance included in Schedules 2 or 3 (not Schedules 4, 8 and 9) or an appendix of the Poisons Standard	May include a substance included in Schedules 2 or 3 (not Schedules 4, 8 and 9) or an appendix of the Poisons Standard	May include a substance included in Schedules 4, 8 and 9 of the Poisons Standard

Manufacturing requirements for foods and medicines

The Code provides standards for the processing of food. State and Territory food regulatory authorities enforce the Code within their own jurisdictions. The manufacturing principles for food are provided in:

- FSANZ 3.1.1, 3.2.1 - 3.2.3
- HACCP –Hazard Analysis Critical Control Points

In Australia, food manufacturers and retailers must comply with the food safety standards (of which standards 3.1.1. (Interpretation and Application), 3.2.2 (Food Safety Practices and General Requirements) and 3.2.3 (Food Premises and Equipment) are mandatory. These Standards are detailed in the 'Safe Food Australia' guide.

Food manufacturers may also seek to be certified under the Hazard Analysis Critical Control Point (HACCP) food safety program or ISO 22000, which sets out the requirements for a food safety management system. Additionally, those food manufacturers exporting products to the United States of America will need to be audited against the Food and Drug Administration (FDA) Current Good Manufacturing Practice (CGMP) regulation for food.

For therapeutic goods, Section 36 of the Act allows the Minister for Health to determine manufacturing principles that are to be applied in the manufacture of therapeutic goods. The current Therapeutic Goods (Manufacturing Principles) Determination specifies that medicinal products supplied in Australia have to meet the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme - PIC/S Guide to Good Manufacturing Practice (GMP) as adopted by Australia. Through the operation of section 36 and other provisions within the Act, the PIC/S Guide to GMP has legal force in Australia.

Good Manufacturing Practice (GMP) describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality. Table 7 provides a comparison of manufacturing requirements for foods and medicines.

Table 7: Comparison of manufacturing requirements for foods and medicines

Item	Food	Therapeutic Good
Responsible parts of Government	FSANZ	TGA
Regulators	State and Territories Food Regulators	TGA
Manufacturing standards/principles	FSANZ 3.1.1, 3.2.1- 3.2.3 and HACCP –Hazard Analysis Critical Control Points	GMP – Good Manufacturing Practice. Therapeutic Goods Manufacturing Principles). PIC/S PE009-13; Part I, II and Annexes.

Labelling requirements for food and medicines

Labelling requirements for food

FSANZ is responsible for labelling requirements for packaged and unpackaged food, for example: specific mandatory warnings or advisory labels and nutrition panels as provided in the Code.

Some of the standards require certain statements and others prohibit certain claims. In particular, a product can only be claimed to be a Formulated Supplementary Sports Food if it complies with the requirements specified in Standard 2.9.4.

Unless exempt under the Code, all food for retail sale must include a statement (list) of ingredients on the label. All ingredients in the food must be declared in the statement of ingredients for the food using one of the following:

1. The common name of the ingredient.
2. A name that describes the true nature of the ingredient.
3. A generic name for the ingredient.

The names of ingredients should be accurate and sufficiently detailed to ensure that they are not false, misleading or deceptive, or likely to mislead or deceive. The use of certain terms or ingredient names can be prohibited by the Code.

However, where an ingredient has separate, but valid, synonyms (for example oxedrine/synephrine) any of those synonyms can be used on the label as long as it is accurate and does not mislead. This means that two (or more) products can use different synonyms for the same ingredient and still be compliant and only a consumer aware of each synonym will be able to know that these refer to the same substance.

For substances which may be added as an individual ingredient but that also may be present within herbal sources (for example caffeine which may be present in '*Camellia sinensis*' or 'green coffee bean extract'), there is no requirement for the label to declare the amount of the ingredient present in the natural sources. Therefore, in this example, where caffeine has been added as an ingredient this amount must be declared, but inclusion of a natural source of caffeine can mean that the label is not required to state the total amount of caffeine present (and the same for other plant-derived compounds).

Labelling requirements for medicines

A product's 'label' includes the label attached to the container (for example bottle, tube, sachet or blister pack) and the primary pack (for example carton). Sponsors must ensure the product label and any printed information supplied with the medicine (for example a package insert) complies with all relevant legislation before it can be supplied in Australia, including advertising requirements.

Specific documents relating to medicine labelling requirements include:

- the Therapeutic Goods Labelling Order as current and in force
- Part 5-1 (Advertising and generic information) of the *Therapeutic Goods Act 1989*
- Therapeutic Goods Advertising Code
- Therapeutic Goods Regulations 1990
- Therapeutic Goods (Permissible Ingredients) Determination
- Therapeutic Goods (Permissible Indications) Determination

- Required Advisory Statements for medicine Labels (RASML)
- the Poisons Standard (note: Australian states and territories vary in the way they adopt the Poisons Standard)
- TGA approved terminology for medicines

For ingredients, all active ingredients must be declared on the medicine label and must use the names stipulated in the TGA approved terminology for medicines, for example: a herbal extract must use the botanical binomial, plant part and preparation on the medicine label. Similarly, where plant ingredients may contain certain substances, such as caffeine, the TGA can require that the total amount of that substance be provided on the label through restrictions placed on the herbal ingredient. This allows consumers to understand the total dose of such substances that they are consuming, which is in contrast to the presence of such substances not being required to be calculated for food labels.

Advertising requirements for foods and therapeutic goods

Advertising requirements for foods

Standard 1.2.7 –Nutrition, Health and Related Claims of the Code sets out the requirements for making nutrition content and health claims on food. These claims are voluntary statements made by food businesses on labels and in advertising about the content of certain nutrients or substances in a food, or the relationship between food and health.

Also, if a label on or relating to food is prohibited by the Code from including a statement, information, a design or a representation, an advertisement for that food must not include that statement, information, design or representation.

Australia has a self-regulatory system for food and beverage advertising. Self-regulatory Codes and Initiatives that apply to food and beverage advertising are:

- AANA Code of Ethics
- AANA Food and Beverages Advertising and Marketing Communications Code
- AANA Code for Advertising and Marketing Communications to Children
- AFGC Responsible Children's Marketing Initiative (RCMI) for of the Australian Food and Beverage Industry
- AFGC Australian Quick Service Restaurant Industry Initiative for Responsible Advertising and Marketing to Children (QSRI)

These Codes and Initiatives have been negotiated with government, industry and advertisers to ensure appropriate advertising of food choices.

Advertising requirements for therapeutic goods

Therapeutic Goods Advertising Code (the Code) sets the requirements advertisers must meet to ensure the marketing and advertising of their therapeutic goods is conducted in a manner that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer.

The problem

Summary:

- The Australian Government is concerned about safety risks to the Australian public posed by some sports supplements that are readily available as foods in Australia.
- Confusion regarding the legal status of sports supplements as foods or therapeutic goods significantly delays appropriate and timely action, even where there are significant health and safety concerns for consumers.
- There are two categories of sports supplements, currently being marketed as foods, which pose both actual and potential safety concerns for consumers:
  - products which are either non-compliant or unlawful (in relation to the ingredients they contain) but are not being sufficiently regulated (due to lack of clarity on their legal status as a food or medicine in current legislation)
  - other products which may not be unlawful under current legislation, but present a level of risk to consumers (in relation to their health claims, ingredients or presentation in medicinal forms such as tablets, capsules and pills,) such that it is appropriate to mitigate these risks through regulation

The consumer problem

In Australia, there is a diverse range of consumers that use sports supplement products, including those that research available information, assess personal risks and do not experience significant adverse events. Many sports supplements contain only food ingredients, are presented in the manner of food products (for example: meal replacement shakes, nutritional bars) and these are appropriate to be sold as foods, commensurate with their low risk profile.

However, many studies have found that this product category possesses a concerning rate of either intentional or unintentional adulteration, often with substances such as stimulants and anabolic steroids. A study on products within Australia have found that up to 19% of products containing substances banned in sport (2) which demonstrates the consumer health risk posed by some sports supplements available in Australia containing high-risk ingredients – for more information refer to Analysis of ingredients in sports supplements available in Australia.

A number of serious adverse events related to sports supplements have occurred in Australia and internationally – refer to Adverse events to sports supplements. In general, the products associated with serious adverse events have contained ingredients that are not appropriate for food, such as prescription medicine ingredients – for information on these ingredients refer to Substances included in a Schedule to the Poisons Standard.

There is a growing body of case reports and studies into adverse effects related to the use of sports supplements (3; 4; 5; 6; 7; 8; 9; 10; 11; 12) (13; 14; 15; 16). While there are many adverse events reported for sports supplements, there are also studies revealing that adverse events are often under reported for this category of products (17).

Case studies report instances of renal failure and exercise related rhabdomyolysis (damage and subsequent breakdown of skeletal muscle); liver damage and failure; lupus-like syndrome (an auto-immune syndrome with joint and muscle pain, fatigue and inflammation to the lining of the heart and lungs); interstitial nephritis (hindering the ability of the kidneys to work properly);

cardiac toxicities; compartment syndrome (muscle pressure build up resulting in severe pain and weakness); and haemorrhagic stroke among other sequelae (8; 10; 11; 12; 18; 19; 15; 16).

The range of products and substances implicated is diverse, including both commonly used and undeclared substances such as caffeine, ephedrine, other amphetamine-like stimulants, yohimbine and anabolic steroidal agents.

In general, these events occur in otherwise healthy, predominantly younger people, for whom there has usually been no medical reason to take the product that caused them harm. The popularity of sports supplements is prevalent and continuing to grow in younger generations (20; 21), putting this cohort at increasing risk to serious adverse events.

These events are not only tragic for the individuals; they represent a significant cost to society as a whole - affecting the individuals' family, friends, their immediate and broader communities, as well as posing a significant cost to the Australian healthcare system. Based on 2014/2015 data, the NSW Ministry of Health estimated the hospital cost of a liver transplant procedure (i.e. hospital costs) to be $153,200, the cost of a kidney transplant procedure to be $43,700, treatment of kidney failure $8,900 and a single session of haemodialysis to be $400 (22). These costs do not take into account other costs to the patient, such as: medication costs; medical consultations; pathology; loss of income; reduced quality of life; or impact on life expectancy. A 2019 article by ASADA (23) referred to 18 cases of liver damage in recent years, which would translate to $2.8 million in direct hospital costs. A case study of fulminant liver failure and transplantation after use of dietary supplements is described in more detail in the medical literature by Smith et al. (2016) (15).

In relation to the cost to society of an individual death associated with the use of sports supplements, the Office of Best Practice Regulation's advice to policy makers is to use estimates derived by Abelson (2007) (24), adjusted for current day costs, which equate to a Value of Statistical Life (VSL) of $4.9 million in 2019 dollars (25). The NSW Poisons Information Centre reports that since 2015, 4 people have died in Australia from taking supplements containing the 'fat shredder' ingredient 2,4-dinitrophenol (DNP). Extrapolating the VSL to these cases, the cost of the loss of these individuals' lives in the last 5 years is $19.6 million. For the regulatory options proposed in this RIS (to address safety concerns associated with certain sports supplements), Noetic (Appendix 1) estimates the average annual regulatory impact over a 10-year period for industry for the highest cost options to be $0.22 million. Therefore, if one single death was avoided (by the proposal to regulate certain sports supplements as medicines), this would save society $4.9 million compared to the potential highest regulatory burden to industry of $2.2 million (over 10 years).

It must be acknowledged that some individuals knowingly consume products containing high-risk ingredients (such as prescription medicine ingredients or substances in the WADC Prohibited List) for their purported performance enhancement, in spite of the known health risks. These consumers know which ingredients will provide the effect they are seeking as well as what food sports supplements contain these ingredients. These consumers believe it is their right to have access to these products because they have made their own personal assessment of their health risks compared to the potential benefit to their performance. This could also be compared to other consumers who consider it is their consumer right to consume psychoactive substances for recreational purposes, based on their own personal risk benefit assessment.

However, the costs of adverse events associated with consumption of these substances, including hospitalisation, are largely met by public monies. Government has a role to regulate, and does so, to control access to poisons in consideration of their detrimental effects at a community level even if that denies the individual consumer's right to consume them.

Some consumers are unaware of the ingredients that certain food sports supplements contain (due to the ingredients not being declared on the label or listed under different names) or the consequences of their consumption. This is a not only a concern relating to adverse events that

pose a risk to consumer health, but also to amateur and professional athletes who may unwittingly consume WADC prohibited substances and suffer lengthy bans from their sport resulting in personal hardship, reputational damage and ruined careers - see Substances in the WADC Prohibited List. The cost of this to an athlete is difficult to measure, as it is difficult to quantify the financial outlay, physical commitment and personal sacrifices an individual athlete has had to endure to reach an elite level in their sport. The subsequent costs of the loss of their career is also difficult to quantify in relation to the athlete's mental, physical and financial health for the many years following the incident.

In addition to the costs to the individual, , there are also societal impacts of unintentional dosing such as the undermining of the reputation of Australian sports and Australia's standing on the international stage, thereby diminishing potential economic gains (such as the wider economic benefits from being selected to host elite sporting events) that relies on Australia's pre-eminent sporting reputation.

It is apparent that the presence of high risk ingredients, whether declared or undeclared on the label of the product pose actual risks to consumers. There is also a potential risk to consumers from products marketed as foods that make therapeutic claims, contain active ingredients and are presented in a medicinal dosage form (such as tablets, capsules and pills), but have not been subject to the regulatory controls of therapeutic goods. This potential risk is posed, in part, by the lower sample testing requirements for foods and the potential for dose variability between product batches – see Presentation of concern in sports supplements. Where a substance requires a specific dose for both safety and efficacy, as can be assumed is the case for sport supplements presented in this dosage form, changes in the levels of those ingredients could have deleterious effects for consumer health.

While many manufacturers produce safe sports supplement products that are appropriately marketed as foods or medicines in Australia, some companies knowingly market supplements as food products, rather than therapeutic goods, to avoid appropriate regulatory scrutiny, even though they contain ingredients that may cause harm. A driver for this is the product revenue to be gained from increased consumer demand for products with a reputation for providing the desired performance enhancement. It is unlikely that a non-regulatory approach would have any effect on this behaviour. The TGA has published warnings about such products over the last decade as well as communicated the hazards associated with them through the mass media but with little effect on the behaviour of these companies.

There is a growing trend in Australia for improvement of health and wellbeing, with an increasing number of Australians attending fitness classes and weight training. This trend is particularly embraced by younger generations, which supports growing sales in sports nutrition products to support intensive training routines – see Consumer use of sports supplements in Australia. While many food sports supplements pose no safety concern, some contain ingredients of high risk to consumers, whether intentionally or unintentionally consumed by the consumer. As the use of sports supplements continues to increase, the actual and potential risks of these products to consumers could also correspondingly increase.

Consumer use of sports supplements in Australia

Euromonitor's 2019 Consumer Health in Australia report (21) states that in the last five years in Australia gym memberships have increased due to personal wellbeing trends and an increasing number of consumers participating in fitness classes and weight training. Younger generations of Australians are engaging the most in regular intensive fitness training. This trend supports growing sales in sports nutrition products to support intensive training routines.

The 2019 IBISWorld report (26) on vitamin and supplement manufacturing in Australia states that sports and nutrition supplements comprised 24.5% and weight loss products 11% of the $159.2m online sales of vitamin and supplements in Australia in 2019.

In the last five years there has also been a strong growth in the popularity of protein powders, which are used by consumers for muscle growth, muscle regeneration and weight management. In particular, there has been an increased demand for protein sports supplements linked to the 'keto diet', which involves a diet that is high in protein and low in carbohydrates to force the body into ketosis, the process through which the body begins to consume excess body fat (21).

Weight management products include appetite suppressants, energy boosters and various meal replacements, including low-carbohydrate and protein bar supplements. The IBISWorld October 2019 report stated that while sales of weight management products increased marginally in 2019, Australian consumers are shifting towards a more holistic approach to weight loss and weight management. In 2019, supplement nutrition drinks was the only weight management category to register sales growth (26).

In 2019, Baker et al. (3) conducted a survey on the use of dietary and nutritional supplements in 2162 Australian army personnel (1833 males and 296 females). 76.4% of males and 86.8% of females used more than one supplement per week. The most popular types of combination products were 'pre-workout'/'intra-workout' supplements (n = 602; 28%), 'fat burner'/'thermogenic' supplements (n = 252; 12%), and 'post-workout' supplements (n = 234; 11%). The authors stated that the highest use of dietary supplements was in those aged between 23 and 27yrs.

Yager et al. (2020) conducted a study on use of muscle building supplement by 237 Australian adolescent boys aged 14–16 years from an independent boy's school in Melbourne (20). The study found that:

- 50% of boys (n=118) currently used, and 62% (n=147) intended to use protein powder
- 8.4% (n=20) currently used, and 26% (n=61) intended to use creatinine
- 4.2% (n=10) currently used, and 10%(n=24) intended to use anabolic steroids

The authors state that gender is commonly accepted as a predictor of muscle building supplement use, in that males are much more likely to use supplements and steroids than females. Higher levels of drive for muscularity, participation in weight training, and playing a sports increased the desire to use sports supplements. Yager et al. concluded that the prevalence of muscle building supplement use was relatively high among this adolescent population and that their research has implications for prevention programs to educate young boys about muscle building supplements to reduce negative physical and psychological health effects of their use (20).

These studies and reports demonstrate the growing popularity of sports supplements in Australia, in line with the growth of personal wellbeing trends. The popularity of sports supplements is especially prevalent in younger generations.

Adverse events related to sports supplements

Adverse events related to sports supplements reported in Australia

NSW Poisons Information Centre warning (2020)

In a letter to the editor of the *Australian Medical Journal*, published May 2020, researchers from the NSW Poisons Information Centre warn that the banned 'fat shredder' 2,4-dinitrophenol (DNP) is experiencing a resurgence in Australia as an illicit body building supplement. The researchers state it is available in Australia and overseas, often being sold online and labelled as 'turmeric' (27).

From 2002 to 2016, the NSW Poisons Information Centre received 1- 4 annual calls concerning DNP exposures. In 2018, this number increased to 10 annual calls.

The authors advise that since 2015, four patients have died in Australia after using DNP. Two of the four deaths occurred after 2017, after DNP was included in schedule 10 of the Poisons Standard (banning its use in all circumstances, including clinical trials, which is a stricter control than for illicit drugs such as cocaine).

The authors suggest that awareness campaigns specifically targeting gyms and body building communities should be undertaken to stop people taking the drug.

NSW Health Authority warning (2018) (28)

In 2018, the New South Wales Health Authority also issued warnings about sports supplements containing DNP, advising it had contributed to deaths locally and overseas. The products containing the chemical were weight loss agents, commonly known as 'Shredders' marketed to fitness communities.

NSW Health advised that DNP prevents energy being stored as fat, causing the energy to instead be released as heat. This increases body temperature, which can damage the cells of organs such as muscles, kidneys and the brain. People can become seriously unwell within hours of ingesting DNP. There is no antidote for DNP and, even with the best medical care, people have died after using products containing this chemical. NSW Health urge the public to avoid products marketed online that name this chemical, or any product from an unverified source being promoted as a weight-loss agent.

Wang et al. study 2020 (9)

An Australian case study in 2020 reports of an otherwise healthy, 33-year old female who presented to the emergency department with acute cardiac ischaemia following the consumption of a pre-workout/weight loss supplement and a strenuous exercise session (9).

Baker et al study (2019) (3)

In 2019, Baker et al. conducted a survey on the use of dietary and nutritional supplements in 2162 Australian army personnel (1833 males and 296 females). Of these, 267 respondents reported suffering side effects from the use of supplements (approximately 16 of every 100 persons), with the most common adverse effects being palpitations (10.6%), tingling or numbness in the face, fingers, arms, or legs (5.5%), tremors or shaking (2.9%), flushing (2.3%), headache (2.0%), abdominal pain (1.6%), anxiety (1.4%), and dizziness or confusion (0.9%).

Smith et al. Study (2016) (15)

In 2016, Smith et al. reported the case of a 26 year-old man who required a liver transplant after consuming 2 weight loss supplements. One supplement was a whey protein powder with multiple ingredients, including *Camellia sinensis* and the other supplement contained 70% *Garcinia cambogia*, which were identified by the authors as the likely agents associated with hepatotoxicity. The man had no previous medical history, was healthy prior to consuming the supplements and the authors report there were no clinical features to suggest chronic liver impairment prior to the presentation. The man received a liver transplant 2 months after presentation and will require lifelong clinical management, including immunosuppression therapy to prevent transplant rejection.

Separate to the case study, in a statement to the media, the father of two stated: "I didn't think something you could buy online or just over the counter did the damage that it did to me. They didn't say anything about 'could cause liver failure'"[4].

[4] https://www.abc.net.au/news/2016-02-14/man-faced-death-after-taking-popular-weight-loss-product/7162378?nw=0

Other deaths reported in Australia

In 2018, a 21 year-old male died in NSW from caffeine toxicity after adding a pure caffeine powder to a protein shake. This tragic incident led to the recent inclusion of caffeine in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP or Poisons Standard) by the National Drugs and Poisons and Scheduling Committee[5].

Also in 2018, a woman's death in Western Australia was partially attributed to her use of sports supplements. The woman had an underlying metabolic disorder - Urea Cycle Disorder - where her body was unable to metabolise her high protein diet (including protein rich foods and various sports supplement protein powders).

Adverse events reported in the US

Amatto et al. case report (2020) (16)

Amatto et al. (2020) report a case study involving a previously healthy 24-year-old man, with no apparent risk factors, who presented with a haemorrhagic stroke the morning after he consumed pre-workout supplementation and participated in high intensity exercise. The authors state that this is the fourth report in the literature of haemorrhagic stroke associated with pre-workout supplementation. The authors considered that the supplements consumed by the patient included various potential causative agents, including: caffeine, creatine, taurine, tyrosine, hordenine and dendrobium extract.

Six months following presentation, the patient had persistent sensory deficits to his right thigh and trunk, but improved sensation to the feet and improving neuropathic pain. At this time, the patient was advised he could gradually return to exercise and the patient questioned which pre-workout supplements he could resume taking. The authors conclude with their recommendation that, for any individual planning to consume pre-workout supplementation, a thorough review of ingredients should be undertaken to avoid any sympathomimetic agent or other stimulants.

Geller et al. study (2015) (29)

Geller et al. (2015) calculated an average of 23,005 emergency department visits in the USA annually related to dietary supplement adverse events, which the authors estimated to result in an average of 2154 hospitalisations. The most common category of product implicated was weight loss products (25.5%) followed by energy supplements (10% - which may include pre-workout products). Specific body building products made up 2.2% of overall cases. The most common adverse events experienced resulting from weight loss or energy products were palpitations, chest pain or tachycardia (in 42% and 46% of cases respectively) followed by headache, dizziness, pre-syncope, or other acute sensory or motor impairment (32.1% and 34.3% respectively). 4.2% of weight loss product related adverse events were severe allergic reactions and another 4% were seizure, syncope or loss of consciousness (29).

United States Food and Drug Administration report 2016 (30; 31)

A review by the US Food and Drug Administration (FDA) of adverse event reports submitted to the FDA from 1 July 2009 to 31 December 2016, found 35 cases involving men (ages 20-48) presenting with serious liver injury (reported as hospitalisation/life-threatening) associated with body-building products that are labelled or suspected to contain steroids or steroid alternatives. The FDA states that drug-induced liver injury is a known possible harmful effect of using anabolic steroid-containing products. In addition, anabolic steroids may cause other serious adverse effects such as abnormal fat and cholesterol in the blood, mood disorders,

[5] https://www.tga.gov.au/consultation-invitation/consultation-proposed-amendments-poisons-standard-acms-and-joint-accsacms-meetings-november-2019

androgenic effects (acnes, baldness, excessive hair growth in females), gonadal suppression (decreased sperm count, testicular atrophy) and enlarged breasts.

Pascale et al. study 2016 (17)

A survey of US sports medicine medical practitioners investigated the practitioner's knowledge of dietary supplement adverse events and the likelihood of the practitioner to report these events to the FDA. The survey found that a high number of practitioners had encountered patient cases of adverse events associated dietary supplements (71% of respondents), with a concerning under-reporting of these events by the practitioners (less than 10% of those who had encountered them). The authors concluded that, given concerns relating to the lack of safety data for many products and substances, impediments to post-market surveillance (such as under-reporting) increases the risk of significant safety signals going unrecognised (17).

Or et al. study 2019 (32)

An observational study over an 11-year period on the relationship between supplement categories and adverse events in patients under 25 years of age found 977 single supplement-related adverse drug reactions with a mean patient age of 16.5 years. Of note, the study found that supplements sold for muscle building, energy and weight loss were associated with almost three time the risk for severe medical events in this age group when compared with vitamins (32).

Schmitz et al study (2018) (4)

Schmitz et al. (2018) reviewed 41,121 unique adverse event cases reported to two large, U.S.-based dietary supplement marketers from 1 March 2014 to 31 August 2016.

Of the 41,121 cases reported, 203 (0.48%) were classified as serious adverse events (SAE's). Thermogenic fat burners (35.5%) and non-thermogenic weight-loss agents (33.5%) were the most frequent types of dietary supplements reported with SAEs, followed by glucose control/insulin management agents (19.2%) and digestive aids. The serious adverse events occurred most commonly in the cardiovascular, gastrointestinal, and nervous systems.

Limitations of studies

The length of safety studies commonly performed was raised as a concern by Harty et al. (2018) in a study into multi-ingredient pre-workout supplements. The authors state that while the available evidence suggests a low occurrence of adverse events and apparent relative safety of consumption, most studies examining the effects of these products were considered short (less than 8 weeks), especially when compared to the often long-term usage by consumers, particularly gym enthusiasts (5). They also noted that many safety studies reviews often reported on mean changes across the entire sample in measures such as heart rate, blood pressure or haematological markers, an approach that may mask significant individual variations from these measures as a result of an adverse event (5).

While the evidence presented in this RIS would similarly benefit from larger sample sizes and longer-term studies, the aggregate results provide an evidence landscape that supposes this product category has the potential to pose a degree of safety and regulatory risk that is not fully commensurate with the risk profile that Australian consumers expect from a food. It is reasonable for consumers to expect that foods are safe for general consumption and that the safety risks from food are negligible for the whole population, and in particular, younger generations for whom the consumption of sports supplements is the most prevalent.

Ingredients of concern in sports supplements

The ingredients of concern for public health in sports supplements are substances included in a Schedule to the Poisons Standard and substances included in the World Anti-Doping Code Prohibited List (the WADC Prohibited List)[6].

Appendix 2 provides examples of different ingredients used in sports supplements in Australia and overseas. For information on ingredients of concern detected or that may be present in sports supplements available in Australia, refer to Analysis of ingredients in sports supplements available in Australia.

Substances included in a Schedule to the Poisons Standard

In Australia, the *Scheduling Policy Framework* (Scheduling Policy) sets out the national policy for applying access restrictions on all 'poisons' according to the risk of harm and the level of access control required to protect consumers. As defined in the Poisons Standard, poisons include medicines for human therapeutic use; veterinary medicines; and agricultural, domestic and industrial chemicals where there is a potential risk to public health and safety.

Scheduling is a national classification system that controls how medicines and poisons are available to the public. Medicines and poisons are classified into schedules according to the level of regulatory control over access to the poison required to protect public health and safety. The schedules are published in the Poisons Standard and are given legal effect through state and territory legislation. State and territory governments are responsible for imposing legislative controls on the supply of poisons.

Some of the substance restrictions in the schedules only apply above a certain quantity. For example, the stimulant oxedrine (or synephrine, a component of Bitter orange extract) is included in Schedule 4 of the Poisons Standard when the preparation has a recommended daily dose of more than 30mg of oxedrine.

An application to amend the Poisons Standard (for example to include a new entry or amend an existing entry) can be made to the Secretary of the Department of Health (the Secretary) under section 52EAA of the TG Act. Individuals, stakeholder organisations or Government bodies can submit applications. The Secretary also has the power under the TG Act to amend the Poisons Standard on his/her own initiative. For more information, refer to Scheduling handbook: Guidance for amending the Poisons Standard.

The schedules and some substance examples are provided in Table 8.

Table 8: Poisons Standard Schedules and examples

Schedule	Signal words required	Example
1	Not currently in use	
2	**Pharmacy medicine**	Bromhexine
3	**Pharmacist only medicine**	Doxylamine in oral preparations except: when included in Schedule 2; or for the treatment of children under 2 years of age

[6] The list of substances and methods prohibited in Sport under the World Anti-Doping Code and UNESCO International Convention against Doping in Sport

Schedule	Signal words required	Example
4	**Prescription only medicine**	Insulin
5	**Caution**	Cambendazole
6	**Poison**	Pindone
7	**Dangerous poison**	Fluoroacetic Acid
8	**Controlled drug**	Methadone
9	**Prohibited substances**	Heroin
10	**Substances of such danger to health as to warrant prohibition of sale, supply and use**	1,3-Dimethylamylamine (DMAA)

The access restrictions placed on poisons in the Poisons Standard are to protect public safety. It is therefore not appropriate for a food to contain an ingredient that is restricted in the Poisons Standard and not be legally compliant with the access restrictions for that substance. Substances such as prescription medicines require appropriate medical management and monitoring, as they pose significant risks to the individuals who take them. For example, Selective Androgen Receptor Modulators (SARMs) are included in Schedule 4 of the Poisons Standard and can only be accessed with a prescription from a medical doctor. SARMs are associated with serious safety concerns including liver toxicity and increased risk of heart attack and stroke (33).

Substances that are scheduled in the Poisons Standard have frequently been detected in sports supplements (2; 34). There have been instances of commonly used substances in sports supplements being scheduled based on safety concerns, such as was the case with 1,3-dimethylamylamine (DMAA) which was moved from being an unscheduled substance to being included in Schedule 10 (previously called Appendix C) of the Poisons Standard due to emerging safety concerns associated with its use.

It is illegal for supplements containing Schedule 4 substances to be supplied by supplement stores and illegal for consumers to possess these products without a prescription. It is also illegal for supplement stores to supply and consumers to possess Schedule 9 and 10 substances.

While it is clear that products including Scheduled substances require regulatory enforcement activity, the current legal uncertainty in relation to these goods makes it unclear who has jurisdictional responsibility for them and delays timely enforcement action (refer to The problem with current legislation).

Substances in the WADC Prohibited List

The World Anti-Doping Agency (WADA) is an international independent agency composed and funded equally by the sport movement and governments of the world. Its key activities include scientific research, education, development of anti-doping capacities, and monitoring of the World Anti-Doping Code (the WAD Code). The WAD Code is a collaborative and shared document that is developed with input from all anti-doping stakeholders in order to harmonise anti-doping policies in all sports and all countries. As part of the WAD Code, WADA maintains an annually updated World Anti-Doping Code Prohibited List (WADC Prohibited List).

Australia is a State Party to the United Nations Educational, Scientific and Cultural Organization (UNESCO) International Convention against Doping in Sport ('the Convention'). Australia's anti-doping obligations are derived from being a State Party to the Convention, which requires governments to adopt appropriate measures at the national and international levels, consistent with the principles of the WAD Code. The Convention places obligations on State Parties to limit the availability of prohibited substances and methods in order to restrict their use in sport (Article 8) and, to encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information about their composition and quality assurance (Article 10).

The WADC Prohibited List forms part of the Convention as Annexure 1. Australia formally recognises annual updates to Annexure 1 as a minor treaty action through the Joint Standing Committee on Treaties (JSCOT). There are currently two Australians, in the capacity of individual experts, on WADA's Prohibited List Expert Group, which provides expert advice, recommendations and guidance to the Health, Medical and Research Committee on the overall publication, management and maintenance of its annual International Standard of the WADC Prohibited List.

Article 4.3 of the WAD Code stipulates that a substance or method must satisfy at least two of three criteria to be included on the list. These criteria are:

4. It has the potential to enhance or enhances sport performance.

5. It represents an actual or potential health risk to the athlete.

6. It violates the spirit of sport.

Table 9 provides the substance categories in the WADC Prohibited list and examples of substances, with a comparison to the Poisons Standard.

Table 9: Categories of substances included in the WADC Prohibited list and comparison to Poisons Standard

Category	Substances	Presence in schedules of Poisons Standard	Where legally allowed to be sold
Prohibited at all times	Non approved substances for human use, for example: anabolic agents; 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	4/8: Prescription 9/10: Not permitted to be sold

Category	Substances	Presence in schedules of Poisons Standard	Where legally allowed to be sold
Prohibited in particular sports	Beta-blockers	Schedule 4	Pharmacy on prescription

As outlined in Table 9, many substances included in the WADC Prohibited List are already included in a schedule to the Poisons Standard either explicitly or under scheduled drug classes [such as 'androgenic steroidal agents' (Schedule 4) or 'alkoxyamfetamines' (Schedule 9)]. Those substances in the WADC Prohibited List that are not included in a schedule to the Poisons Standard appear to be from similar classes (or possess similar characteristics to other scheduled substances) and would likely meet the requirements to be a scheduled substance (but have not yet been the subject of an application to amend the Poisons standard – refer to Poisons Standard substances).

In addition to some prohibited substances posing serious health risks for athletes, the presence of a WADC prohibited substance in a supplement may result in an anti-doping rule violation for an athlete, whether its use was intentional or unintentional. Under the WAD Code's strict liability principle, athletes are ultimately responsible for any substance found in their body, regardless of how it got there. Products containing a WADC prohibited substance can result in bans for athletes of up to four years.

The TGA received numerous submissions to the October-December 2019 consultation on sports supplements from individual Australian athletes who had suffered severe reputational and career damage from unknowingly consuming WADC prohibited substances in the sports supplements they consumed.

In 2017, an Australian athlete competing at the World Roller Games tested positive for 1,3-Dimethylbutylamine (DMBA), a stimulant banned in competition under the WADA 2017 Prohibited List. The substance was detected in a sports supplement the athlete advised he was taking at the time of testing. DMBA was not explicitly named in the ingredients; however, it may have been in the supplement in the form of Pouchong Tea extract (AMP Citrate). The World Skate Doping Review Panel determined that the athlete did not intend to dope and therefore banned the athlete from competition for only one year, rather than the maximum penalty of 4 years (35).

Sport Integrity Australia [previously Australian Sports Anti-Doping Authority (ASADA)] administers the National Anti-Doping Scheme (NAD Scheme). They advise athletes that the sports supplement industry is poorly regulated and that the ingredient list of a product does not always match the product contents. Banned substances can be added deliberately during the manufacturing process, or added accidentally through contamination. It is for these reasons Sport Integrity Australia will not guarantee whether a specific supplement is safe to use.

ASADA's long standing advice has been that no supplement is safe to use and athletes should not risk their careers by taking one (36).

Sport Integrity Australia also advises athletes that athletes should be aware that supplement manufacturers might use alternate names for WADC prohibited substances. For example, the WADC banned substance higenamine is a beta 2 agonist and can be known by at least 15 different names including: *Tinospora crispa*, aconite root, Nelumbo nucifera. As discussed in 'Labelling requirements for food', use of different synonyms for ingredients is permissible under the Food Standards Code.

In routine drug testing in 2017, an Australian elite runner tested positive for higenamine. After investigation by ASADA (now Sports Integrity Australia), it was found that a supplement the athlete declared she was taking at the time of testing contained higenamine, which was labelled on the product as 'Nardinia fruit extract'. The athlete was banned from competition for 9 months and missed her opportunity to compete at the 2018 Commonwealth games. The athlete advises that, "A positive test affects more than just you. It affects your team, your coach, your family. It's not just the athlete that suffers, it's everyone around them"[7].

The Australian Institute of Sport (AIS) (37) advises that all athletes should be aware of the risks involved in taking supplements and provides an athlete guide to assist in their decision-making. The AIS's ABCD System ranks sports foods and supplement ingredients into four groups according to scientific evidence and other practical considerations that determine whether a product is safe, permitted and effective in improving sports performance.

The AIS advises that multi-ingredient supplements (for example, products commonly marketed as 'pre-workouts') raise specific concerns. These products contain a long list of individual ingredients and, in some cases, the quantity of these ingredients are not stated on the label because the formulation is claimed to be a 'proprietary blend' over which the manufacturer has ownership. AIS concerns about these products include: the lack of an effective dose of some active ingredients (for example, inadequate amounts or poor timing of intake relative to exercise); potential for harmful interactions between ingredients; and the increased risk of inadvertent contamination due to the sourcing of ingredients from various producers. The AIS advises that athletes should not take any supplements without first consulting their Sports Doctor or Accredited Sports Dietitian.

In 2018, the International Olympic Committee (IOC) (38) released a consensus statement on dietary supplements and high-performance athletes:

> *"Supplements intended to enhance performance should be thoroughly trialled in training or simulated competition before being used in competition. Inadvertent ingestion of substances prohibited under the anti-doping codes that govern elite sport is a known risk of taking some supplements. Protection of the athlete's health and awareness of the potential for harm must be paramount; expert professional opinion and assistance is strongly advised before an athlete embarks on supplement use".*

It is a common misconception that only elite level athletes are subject to the NAD Scheme. The NAD Scheme, as outlined in the Sport Integrity Australia Regulations, applies to a broad range of athletes. It captures any athlete who competes in a sport with an Anti-Doping policy. This includes recreational, national and international level athletes. Sport Integrity Australia has Anti-Doping policies with 122 sporting administration bodies; this includes National Sporting Organisations, Institutes of Sport and other sporting organisations. All athletes including

local/recreational and junior athletes who participate under these bodies are subject to the Anti-Doping policy of that sport and as such the NAD Scheme.

In addition, a number of professions in Australia have strict anti- doping policies, the violation of which can be grounds for dismissal. In some jobs, such as road and rail transport, maritime and mining occupations, the law may prohibit a worker from being affected by any drugs—legal or illegal (39). The Australian Defence Force has a Prohibited Substance Testing Program to deter Defence members from using prohibited substances, with testing conducted on a random and a targeted basis. If personnel test positive for a WADC prohibited substance this can be grounds for dismissal (3).

The high correlation between substances included in the WADC Prohibited List and those in a Schedule to the Poisons Standard, combined with the resulting increased risk posed by these

[7] https://www.sportintegrity.gov.au/what-we-do/supplements-sport

substances to all athletes and other consumers, supports that these products should be subjected to an appropriate level of regulatory control to ensure their safety and quality.

Analysis of ingredients in sports supplements available in Australia

There have been many studies into the presence of undeclared substances in food sports supplements, both within Australia and internationally. Many of these studies have found that this product category possesses a concerning rate of either intentional or unintentional adulteration, often with substances such as stimulants, oestrogenic agents, anabolic steroidal agents and diuretics (8; 10; 11; 12; 18; 19; 27). Studies into the potential safety of different compounds (such as BMPEA (40), SARMs (41) and others), as well as sports supplements more generally note the lack of safety data for many substances found to be commonly in use (4; 42; 43; 44; 5).

These studies (outlined below) demonstrate the actual risk to consumers of some food sports supplements containing undeclared high-risk ingredients, in particular, substances that are included in a schedule to the Poisons Standard. The availability of these substances in food means that consumers are exposed to such substances without the required medical management to monitor the significant risks they pose to the individual.

TGA Laboratory testing

The TGA laboratories tested 10 samples of seven different imported sports supplements in late 2018/early 2019. The products were all found to contain scheduled substances, including:

- Schedule 4 substances (prescription-only medicines):
  - synephrine (oxedrine)
  - 4-hydroxyephedrine
  - theophylline
  - yohimbine
  - deanol (diethylaminoethanol)
  - levodopa
  - 5-hydroxytryptophan (S4 as a derivative of tryptophan when present in >100mg per daily dose, calculated as equivalent weight of tryptophan).
- Schedule 9 prohibited substance:
  - phenibut
- Schedule 10 substance (dangerous/prohibited substances):
  - 1,3-dimethylamylamine (1,3-DMAA)
  - 1,4-dimethylbutylamine (1,4-DMBA)

Most, but not all, the scheduled ingredients were listed as ingredients on the product label, albeit sometimes as synonyms. Despite the presence of illegal substances, the ambiguity of the products' status in law as either food or therapeutic goods has protracted any potential legal action by the TGA.

Other studies on products within Australia have found rates of up to 19% of products containing substances banned in sport (2) and another study found 16% of products reviewed to contain WADC banned substances that were not declared on the product label (45). These studies (outlined below) demonstrate the consumer health risk posed by some sports available in Australia containing high-risk ingredients.

(outlined below) demonstrate the consumer health risk posed by some sports available in Australia containing high-risk ingredients.

LGC study (2016) (2)

In 2016, LGC, an international life sciences measurements and testing company, analysed 67 market-leading sports supplements available in Australia from a range of internet sites and retail stores. Products known to be part of an existing testing program were excluded from the survey. The products were selected from a range of categories and a variety of presentations such as bars, capsules, gels, liquids, powders and tablets.

Findings included:

- of the 67 products tested, 13 (19%) contained one or more substances which would be considered prohibited within sport
- the stimulant 1,3-dimethylbutylamine (AMP Citrate) was present in 7 products (10% of findings)
- anabolic steroids were present in 25% of products
- two products (pre-workout and weight management products) were found to contain the unlabelled stimulants 1,3-dimethylbutylamine and methylhexeanamine at such high levels that they were considered to pose a significant health risk to athletes and a significant risk of failing a doping test

The substances identified belonged to either stimulants (75% of findings) or anabolic agents (25% of findings). These substances are listed below:

Stimulants found in products tested:

- 1,3-dimethylbutylamine
- Methamphetamine
- Methylephedrine
- Methylhexaneamine
- Nopseudoephedrine
- Oxilofrine
- Selegiline
- Strychnine
- Anabolic agents found in products tested:
- 1,4-androstadiene-3,17-dione
- 5(6)-androstene-3,17-dione
- DHEA

Cooper et al. study (2018) (46)

In 2018, Cooper et al. analysed 112 sports supplements available for sale in Australia, either over the counter or via the internet, including protein powders, pre-workout formulations, fat metabolisers, vitamins and herbal extracts.

Six of the 112 supplements demonstrated strong androgenic activity and contained anabolic steroids that were not declared on the product labels. The report's authors state that while many supplements contain ingredients that may have useful properties, there are supplements that are contaminated with compounds that are banned for use in sport or have been deliberately adulterated to fortify a supplement with an ingredient that will produce the advertised effect.

The researchers concluded that there is a real health risk and doping violation risk for athletes consuming sports supplements.

HASTA study (2015) (45)

Human and Supplement Testing Australia (HASTA) conducted a survey of supplements in the Australian marketplace in October 2015. The survey included products targeted at athletes that were purchased from a variety of retail and online stores. Product categories included protein products (weight gainers, post-workout recovery, muscle builders); energy products (carbohydrate-based products, stimulants, energy gels); and others (including creatine, testosterone boosters, multivitamins, joint support formulations). Product presentations included powders, capsules, tablets, gels, bars and milk drinks.

Of 63 samples analysed: 16% (10 samples) were found to contain substances in the WADC Prohibited List that were not declared on the label; 10% (six samples) were positive for one or more stimulants; and 6% (four samples) were positive for one or more steroids.

Of the 10 samples that tested positive for substances in the WADC Prohibited List:

- the majority were made in the USA, however two were listed medicines in the ARTG
- the most common stimulant identified was methylhexanamine (DMAA) (banned for use in therapeutic and food products in both Australia and the US)
- the next most common stimulant was ephedrine
- the most frequently identified steroid was boldione, a precursor to boldenone
- one product that contained significant amounts of cyproheptadine, which is included in Schedule 3 of the Poisons Standard (pharmacist only medicine), which was not declared on the label
- a number of milk-based products (such as whey powders and high protein UHT milk drinks) tested positive for low levels (<10ng/g) of Androstenedione, a known factor in milk

The most common presentation for contamination in this study was powders, followed by capsules. This is in contrast to other studies, where it has been predominantly capsules. HASTA considered that this might be due to the substantial growth in the supplement industry over the last 10 years and the proliferation of powders for pre and post-workouts.

HASTA concluded that supplements that are readily available in store and online to Australian consumers continue to pose a significant threat to athletes, due to the presence of substances included in the WADC Prohibited List.

The Australian Capital Territory Health Protection Service (34)

The ACT Health Protection Service (HPS) published an information sheet in 2018 warning consumers that some sports supplements sold in the ACT through retail supplement stores were found to contain substances included in a Schedule to the Poisons Standard, including the

following SARMs: stenabolic; ibutamoren; cardarine; tadalafil; oxedrine; melatonin; and phenibut. Other substances found in some sports supplements sold in the ACT were:

- Stenabolic (Schedule 4: Prescription only)
- Ibutamoren (Schedule 4: Prescription only)
- Cardarine (Schedule 10: Substances of such danger to health as to warrant prohibition of sale, supply and use)
- Tadalafil (Schedule 4: Prescription only)
- Oxedrine (Schedule 4: Prescription only when daily dose is 30 mg or more)
- Melatonin (Schedule 4: Prescription only)
- Phenibut (Schedule 9: Prohibited)

Attipoe et al. study 2019 (47)

An Australian study that tested 15 pre-workout supplements for caffeine[8] content within and between batches found only six of the 15 products specified their caffeine content on their label and that the amount of caffeine present ranged from 59% to 176% of the stated amount. Of the 15 products, 14 had variations in caffeine content between batches of over 40mg per serve.

Given the caffeine content of all products was between 91mg to 387mg per serve, the authors stated that variations of greater than 40mg represent a significant change in dose. Similarly, another study looked at the variability of stimulant levels in nine sports supplements over a nine-month period. In five of the six caffeinated products assessed, the variation of caffeine content was from ~7% to 266% of the baseline measurement in subsequent batches.

The study also reported that other stimulants (synephrine, octopamine, cathine, ephedrine, pseudoephedrine, strychnine, and methylephedrine) occurred in variable amounts in eight of the nine products (47).

Presentations of concern in sports supplements

Tablets, capsules and pills,

In relation to food products presented in a medicinal form, a product with therapeutic claims and presented as a tablet, capsule or pill implies that the product is for therapeutic use and, is therefore a therapeutic good under current legislation. A reasonable consumer would assume that a product presented as a tablet, capsule or pill and making therapeutic claims is a medicine and is subject to an appropriate level of regulatory oversight to ensure their safety, quality and efficacy.

A search conducted by the TGA of sports supplements sold in tablets, capsules or pills from a prominent online Australian retail store revealed a number of products (not included in the ARTG) with claims such as: 'Thermogenic fat burner', 'Immune support', 'Burn subcutaneous fat molecules' and 'Boost testosterone'. These claims appear more aligned with therapeutic indications than the allowed health claims (as per Division 3 of Food Standard 2.9.4) for food products marketed as FSSF (refer to Health claims for foods and indications for medicines for more information). Claims made for foods outside of those allowed in the Food Standards are considered 'non-compliant labelling' by FSANZ.

[8] Note: As of 1 June 2020, caffeine is included in Schedules 4 and 6 of the Poisons Standard.

It should be noted that there are products with similar ingredients, similar claims and similar presentations (i.e. forms associated with medicines) as foods marketed as FSSFs that are already included in the ARTG as medicines.

Tablets, capsules, and pills would generally provide a more concentrated version of an ingredient compared to presentation in forms traditionally aligned with foods, such as powders or bars. The manufacturing requirements for foods are not as stringent as for therapeutic goods [the latter being required to be made in accordance with good manufacturing principles (GMP)]. Products manufactured as foods have lower sample testing requirements than products manufactured as therapeutic goods. This means that there is a potential for food products with an 'active' ingredient to have variability between batches. Where a substance requires a specific dose for both safety and efficacy, as can be assumed is the case for sport supplements presented as tablets, capsules or pills, changes in the levels of those ingredients could have deleterious effects for consumer health.

There have been a number of small-scale studies investigating batch consistency of different supplements that have found concerning rates of variability, particularly with some higher-risk ingredients (41; 48; 47). Attipoe et al. (2016) (47) tested three samples of nine popular sports supplements in the US over a 9-month period. The authors found that many supplements did not contain the same number and quantity of stimulants over the period studied. In five of the six caffeinated supplements caffeine content varied widely compared with the initial measurement (-7% to +266%). In addition, stimulants (including synephrine, octopamine, cathine, ephedrine, pseudoephedrine, strychnine, and methylephedrine) occurred in variable amounts in eight of the nine products.

Desbrow et al. (2019) (48) studied the caffeine content within and between batches of 15 pre-workout supplements commonly used by Australian consumers. The caffeine content of selected products ranged from 91 to 387 mg serve and the percent of caffeine present ranged from 59% to 176% of packaging claims. The authors concluded that consumers are likely to be exposed to large and variable caffeine doses if ingesting pre-workout supplements and that product information panels do little to improve consumer awareness of likely caffeine intakes.

An analysis of the presentation of sports supplement products in Australia by Noetic (see Appendix 1 for further details) shows that the product category known as 'fat burners' represents the largest portion of products being presented as tablets, capsules or pills. Noetic analysed the product range of the three top industry players in Australia, with a combined total of 630 unique products, representing 80% of total market share. These figures were then extrapolated across all Australian retailers (see Tables 3 and 4 of the Noetic Report at Appendix 1). The Noetic data (presented below in Table 10) demonstrates that 51% of fat burner products in Australia are in the presentation of tablet/capsules/pills, compared to 6% post workout products and 3% of pre-workout products. Note that the basis for the calculation of these figures (and any other Noetic figures referenced throughout the RIS) is explained further within the Noetic Report at Appendix 1.

Table 10: Presentation forms of product presentation across all Australian retailers[9]

Presentation	Fat Burner products	Post-workout products	Pre-workout products
Powders, liquids, novel foods	225	160	271
Tablets/capsules/pills	114	9	9

[9] Based on Noetic market analysis - see Appendix 1

Presentation	Fat Burner products	Post-workout products	Pre-workout products
Percentage of product category presented as tablets/capsules/pills	51%	6%	3%

The significance of the above information is that, not only is the product category of 'fat burners' the most common sports supplement product category presented as tablets, capsules and pills, this category has also been linked to serious events in Australia. In 2018, the NSW Ministry of Health advised of significant adverse events from the category of products known as 'fat burners' or 'shredders' and urged the public to avoid any product from an unverified source being promoted as a weight-loss agent (28).

Due to the potential safety concerns associated with products presented as tablets, capsules and pills, sports supplement products making therapeutic indications and presented in medicinal forms should be subjected to the same manufacturing requirements of therapeutic goods to ensure their safe use. These dosage forms are generally used to deliver concentrated amounts of 'active' ingredients which, combined with therapeutic indications, would more closely align with their being regulated under the therapeutic goods framework to ensure their quality, safety and efficacy and protect public health.

The problem with current legislation

'Sports supplements' is a broad category of products promoted to improve or maintain physical or mental performance in sport, exercise or other recreational activity that differ markedly in terms of ingredients, instructions for use, labelling and dosage forms (for example powder, drink, tablet or capsule). A sports supplement, like many other products for oral consumption, can be either food or a medicine in law depending on the specific combination of ingredients, claims and overall presentation. For instance, two products with the same formulation may be characterised differently—one as a food and the other as a medicine—depending on their claims, label artwork and other aspects of their packaging and advertising. However, a product cannot simultaneously be both a food and a medicine in law. Refer to Current regulatory frameworks for food and medicine for information on the different regulatory frameworks for food and medicines.

Ambiguity as to whether products are food or medicine gives rise to the notion of the **food-medicine interface** (FMI), requiring that a detailed technical assessment of their formulation, claims and presentation is conducted to determine the regulatory status of some goods under law. Minor changes to one or more of these attributes may result in a product changing from being a medicine to a food in law, or vice versa.

Currently there is a lack of legal clarity in food and therapeutic goods legislation to determine the regulatory status of sports supplements as foods or medicines. This delays regulatory action where safety concerns occur, as it is not clear in law whether the therapeutic good regulator or the food regulators have jurisdictional responsibility for these products.

Sub-section 3(1) of the TG Act provides that **therapeutic goods** are:

> *'goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use'*

with **therapeutic use** relevantly defined as:

> *'use in or in connection with … influencing, inhibiting or modifying a physiological process in persons'.*

However, the TG Act stipulates [under sub-section 3(1)(e)] that products are not therapeutic goods if there is an existing Food Standard for goods. The existence of Food Standard 2.9.4 – Formulated Supplementary Sports Foods can mean that a product (meeting the requirements of the Standard) that is '*specifically formulated to assist sports people in achieving specific nutrition or performance goals*' is a food and therefore, falls outside the scope of the therapeutic goods regulatory framework .

Why the problems with current legislation impede appropriate regulatory enforcement to address safety concerns

The existence of Food Standard 2.9.4 means that sports supplements, irrespective of the ingredients they contain or their presentation, can be argued to fall out of the remit of the TGA because they can claim to be specifically formulated to assist sports people in achieving specific nutrition or performance goals. The weakness in this argument is that many of the products that are claimed to be 'formulated supplementary sports foods' principally or solely contain active ingredients that have no proper or legitimate use in sports nutrition. Further, some of the products principally or solely contain active ingredients the use of which is prohibited in sport. Nevertheless, the issue is open to interpretation and therefore exposes regulatory actions to the risk of delay and obfuscation through vexatious legal argument.

Where, for example, safety concerns have arisen that require urgent enforcement activity to address significant safety risks to consumers (such as a product marketed as a food found to contain illegal drugs, such as substances in Schedules 4, 9 and 10 to the Poisons Standard), the lack of legal clarity can result in unnecessarily lengthy and costly preparation for court proceedings intended to enforce compliance with the TG Act, which causes significant delays in action to protect consumer safety.

This is the case because the definition used in Food Standard 2.9.4 to describe such foods, 'specifically formulated to assist sports people in achieving specific nutrition or performance goals' requires that the formulation of the sports supplement be analysed to decide whether it does fall within the terms of the standard. This analysis needs to be performed in relation to the formulation of the product as a whole, and involves consideration of the properties of each ingredient in the product. Where the goods may be directed towards meeting a performance goal (for example, because they have no potential nutritional benefit), this is assessed in accordance with the International Olympic Committee step-by-step assessment – relevantly:

- whether the product is safe for use
- whether there is evidence that the product is effective in delivering an outcome related to performance
- if the product is permitted to be used in sport

If, as is often the case, a product contains multiple active ingredients, this analysis is very time consuming, particularly if it needs to be undertaken by an independent expert witness for the purpose of litigation. Many substances used in such products may be subject to little to no reliable research, and this uncertainty increases where substances can interact in a variety of ways when consumed together, with outcomes including synergistic effects and negative effects. Burke and Peeling (2018) state that "the scientific literature, which has only just started to address supplement combinations, fails to provide evidence for an optimal protocol for combining the use of some or all of these supplements. Indeed, it would be almost impossible to conduct a study in which the independent and interactive effects of each of the combinations of these products could be tracked" (49).

The consequence of the above is a continued risk of consumer exposure to unsafe products, as well as a significant waste of Government resources and taxpayer's money in pursuing legal proceedings. Any legal ambiguity increases the risk that suppliers of unsafe products will refuse

to comply with TGA warnings to cease supplying those products, with the result that consumers may continue to be exposed to the risks of those products for an extended period of time while the necessary steps are taken to commence court proceedings or otherwise bring an end to the supply of those products.

In contrast, an appropriately worded instrument under section 7 of the TG Act would clearly and irrefutably settle the parameters by which a product at the FMI is a therapeutic good with resultant improvements for safety outcomes.

Problems with Food Standard 2.9.4

Food Standard 2.94 provides a number of requirements for a product to be marketed as a FSSF, for example: labelling, nutritional requirements. However, it does not expressly exclude certain products from being foods, namely:

- products with ingredients included as substances in a schedule to Poisons Standard
- products with ingredients included in the WADC Prohibited list
- products presented in a form associated with medicines, such as a capsule

This means that such products, while clearly medicines due to their higher risk ingredients and presentation, could be legally argued in court to be outside the remit of the TGA.

Food Standard 2.9.4 was introduced in 1998 and in the past 20 years, there have been significant changes in the sports food supplement marketplace, such as:

- expansion of the number and types of products available in the market
- increased consumer demand for these products, particularly products to assist workouts
- products now on the market are compositionally very different from those available 20 years ago
- internet sales are more prevalent- domestic and international
- imports being a common source of product supply
- proliferation of advertising for these products, particularly personal endorsements by media influencers in social media channels

This changing landscape means that these products are now far more easily available to a broader range of consumers than was the case when the Standard was first developed.

At the Department of Health Sports Supplements Roundtable, held in August 2018, it was broadly agreed by participants that Standard 2.9.4 was no longer fit for purpose (1). FSANZ has now commenced a review of the Standard (50). While a review of the Standard will be welcomed by industry and other stakeholders, the purpose of a food standard is to set the safety standards and labelling for a food, not to explicitly determine if a good is a food or a therapeutic good in law. That given, the review of the Standard provides an opportunity to further improve the legal clarity of these goods.

Problems with the Trans-Tasman Mutual Recognition Arrangement and sports supplements

Another problem with current legislation is associated with sports supplements and the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA is a non-treaty arrangement between New Zealand and Australia's Commonwealth, state and territory governments, which allows for goods (excluding therapeutic goods) legally sold in New Zealand to be sold in Australia and vice-versa.

New Zealand has a separate Supplemented Food Standard 2016 and Dietary Supplement Regulations 1985 that differ from the Code. The TTMRA enables food that are compliant with the NZ legislation to legally enter Australia, even if they are not compliant with the Code that is applicable in Australia. This means that while food sports supplements manufactured in Australia must comply with the Code, food sports supplements imported to Australia from New Zealand do not necessarily need to comply with the Code provided they comply with the New Zealand specific legislation.

However, therapeutic goods are exempt from TTMRA. This means that if certain sports supplements are declared to be therapeutic goods, these products will need to be included in the ARTG to be legally supplied in Australia, irrespective of whether they have been imported in to Australia from New Zealand or any other country.

It is difficult to estimate how many imported food products may be affected by a proposed declaration, however the number would be expected to be small for the following reasons:

- The *Food Act 2014* section 9 is the definition of food in New Zealand. A substance that is used only as a medicine, controlled drug or psychoactive substance cannot be presented as a food.
- The Dietary Supplement Regulations 1985 have been adopted into the NZ Food Act so also cannot contain medicines, controlled drugs or psychoactives. Similarly the NZ Food Act adopts the Food Code so anything specified in standards (e.g. sports supplements) cannot contain medicines etc.
- Substances that are 'only used as a medicine' are those that have been scheduled under the *Medicines Act 1981*. Scheduled medicines are further classified as pharmacy-only, pharmacist-only (restricted) or prescription. Similarly controlled drugs are those that are scheduled under the *Misuse of Drugs Act 1975* and psychoactive substances are those that are included in the *Psychoactive Substances Act 2013*.
- It is also likely that 'only used as a medicine' would extend to any substance that is only used for a therapeutic effect irrespective of whether it has been scheduled in New Zealand or the claims made for it. The NZ Medicines Act defines a medicine as anything that is administered to a person wholly or principally for a therapeutic purpose.

How a declaration made under section 7 of the Act will help address problems with the current legislation

Section 7 of the TG Act provides the Secretary the power to declare that goods are (or are not) therapeutic goods generally or when used, advertised or presented for supply in a particular manner, even if:

- they are also goods for which there is a standard in the Code; or
- have a tradition of use as food in the form in which they are presented in Australia or New Zealand

The effect is that goods that would otherwise be regulated as food, are regulated as therapeutic goods.

Section 7 declarations are made by the Secretary to provide clarity for consumers, industry and regulators about whether a product is a therapeutic good.

For example, the current Therapeutic Goods (Declared Goods) Order 2019 includes an entry under Part 1(3) declaring that Beta-hydroxy-beta-methylbutyrate (a metabolite of the amino acid leucine and used in sports supplements) is a therapeutic good when manufactured in the dosage form of a tablet, capsule, pill or powder.

Providing clarity on which sports supplements are medicines or food will allow regulators—the TGA or State and Territory food authorities—to ensure that these products are regulated commensurate with the potential risks that they pose to public safety. Whether these goods are a food or medicines determines:

- what ingredients the product can contain
- how the product is presented for example: labelling
- how the product is manufactured
- what claims the product can make, including in advertising
- what information the product owner is required to hold
- how the product is marketed for example: advertising
- who oversees adverse reactions, packaging, tampering, illegal ingredients or advertising issues

The clarification provided by the section 7 declaration will not only distinguish goods that are foods and medicines domestically, but also those that are imported into Australia. In relation to sports supplements, a declaration clarifying their legal status would complement the FSANZ review and update of Food Standard 2.9.4.

The sports supplement industry in Australia

A 2019 IBISWorld report (26) on vitamin and supplement manufacturing in Australia states that online sales of vitamin and supplements in Australia were worth $159.2m in 2019. Sports and nutrition supplements comprised 24.5% and fitness and weight loss products 11% of this figure (26).

The IBISWorld report predicts that the industry revenue in Australia for vitamins and supplements in 2020 would be $1.9bn (although the actual 2020 figures are likely to be affected by the COVID-19 pandemic).

Sports and active nutrition products comprised 23.9% and weight management products 10.2% of total industry revenue. Sports nutrition products makeup a sizeable segment of the industry, these products include:

- pre, post and intra-workout products
- performance enhancers
- fat burners
- energy boosters
- nutritional supplements, such as: amino acid supplements, glutamine, and creatine

Weight management products include appetite suppressants, energy boosters and various meal replacements, including low-carb and protein bar supplements. The IBISWorld October 2019 report stated that while sales of weight management products increased marginally in 2019, Australian consumers are shifting towards a more holistic approach to weight loss and weight management. In 2019, supplement nutrition drinks was the only weight management category to register sales growth (26). The IBISWorld 2019 report forecast the vitamins and supplement industry to grow at 3.2% per annum over the next five years, reaching an expected revenue of $2.2Bn in 2024-25 (26).

The predicted continued growth of the Australian sports supplement industry is supported by the growing consumer demand for these products, particularly by younger generations – see Consumer use of sports supplements in Australia.

International problems associated with sports supplements

The risks associated with some sports supplements is not unique to Australia, it is also a recognised problem internationally, with the US Food and Drug Administration (FDA) (51) and the UK Medicines and Healthcare products Regulatory Agency (MHRA) (52) urging consumers to exercise caution when using sports supplements.

The FDA regulates supplements for exercise performance enhancement as dietary supplements, which can be presented in forms such as tablets, capsules, soft gels, gel caps, powders, and liquids. The FDA does not test or approve dietary supplements pre-market, but unlike drugs, supplements are not intended to treat, diagnose, prevent, or cure diseases. That means claims such as 'reduces pain' or 'treats heart disease' can only be made legitimately for drugs, not dietary supplements[10].

In an International Olympic Committee Statement, Maughan et al. (2018) report that similar regulations as the FDA's apply to sports supplements in most other countries, where sports supplements are regulated in the same way as food ingredients and are not subject to the stringent regulations applied to the pharmaceutical industry. This means that there are liberal labelling requirements for these products and no requirements to prove claimed benefits, show safety or demonstrate quality. The authors state that "It is well-recognised that there are problems with some of the dietary supplements on sale, but the options open to those responsible for food safety are limited by the legislation that applies" (38).

The FDA warns that some products marketed as dietary supplements to improve athletic performance might contain inappropriate, unlabeled and unlawful stimulants, steroids, hormone-like ingredients, controlled substances, prescription medications or unapproved drugs. An FDA media release in October 2017 (33) stated:

> *We are extremely concerned about unscrupulous companies marketing body-building products with potentially dangerous ingredients. Body-building products that contain selective androgen receptor modulators, or SARMs (Selective Androgen Receptor Modulators), have not been approved by the FDA and are associated with serious safety concerns, including potential to increase the risk of heart attack or stroke and life threatening reactions like liver damage.*

The FDA Dietary Supplement Ingredient Advisory List is intended to alert the public when the FDA identifies ingredients unlawfully included in products marketed as dietary supplements. Information about other ingredients and dietary supplement products that have been the subject of FDA action and/or statements can be found on the FDA Dietary Supplement Products & Ingredients page. The FDA prohibits certain ingredients in dietary supplements, such as androstenedione, dimethylamylamine (DMAA) and ephedra.

The FDA can remove a supplement from the market and regularly uses its powers to recall products in breach of the regulations, although recalls generally occur only after people have been harmed (38). For example, a range of products containing hydroxycitric acid were withdrawn from sale, but only after they were linked with the death of one consumer and with a substantial number of other cases of liver toxicity, cardiovascular problems and seizures (31).

In contrast to the US and many other countries, in Canada, dietary supplements are regulated as non-prescription drugs, known as 'Natural Health Products' (NHP). All NHPs must have a

[10] https://www.tandfonline.com/doi/full/10.1080/19390211.2018.1513109

product licence before they can be sold in Canada, with varying assessment timeframes based on whether a Canadian monograph exists. There is a NHP monograph for sports supplements (53) which provides a list of what these products can contain to be eligible for a shorter assessment timeframe.

In spite of sports supplements being regulated as NHPs in Canada, there are the same safety concern for sports supplements in Canada as other countries, likely due to the ease of access for Canadians to US dietary sports supplements. The Canadian Department of National Defence advises:

> *Canadians cannot be sure of what they are actually buying in this vast array of performance-enhancing products. In fact, dietary supplements remain largely unregulated, particularly outside Canada. What you see is not always what you get when purchasing these dietary supplements; you can't be entirely sure what many of these products actually contain. Some companies maintain high quality standards while others are less professional, so you really don't know what you are putting into your body. Recent studies show some of these products do not always contain the ingredients listed on their content label, and often contain other ingredients that are not listed on the label. Some products have even been found to contain lead, anabolic steroids, animal faeces and other potentially harmful contaminants. The bottom line is that you really can't be sure what your dietary supplement contains.* (54)

For member states of the European Union, sports supplements can be regulated under food law or medicines law depending on their composition (55). There are also national laws in different member states defining food supplements and these may differ between countries.

Various European authorities have reported finding banned substances in sports supplements. The Hungarian National Food Chain Safety Agency found nutritional supplements aimed at athletes contained creatinine nitrate and teak (a caffeine-like purinase alkaloid) which are both novel food ingredients and unauthorised for sale in Europe (52; 56).

In 2016, the United Kingdom's Medicine (MRHA) (52) reviewed the product ranges of 33 UK based companies' product ranges and found 69 unauthorised medicines being sold as sports supplements with16 companies found to be selling one or more unauthorised medicines.

The MHRA subsequently took action to remove unauthorised medicinal products from the market.

To reduce the risk of the presence of WADC prohibited substances in food intended for sports people, the European Committee for Standardization have established a technical body, the 'Dietary supplements and sports food free of doping substances' which is currently developing a guidance document to provide the requirements for the development and manufacture of these goods. The guidance document, Good development and manufacturing practices aimed at preventing the presence of prohibited substances in food intended for sports people and food supplements, is scheduled for finalisation in October 2020.

It can be seen that many countries are experiencing similar safety concerns as Australia in relation to certain sports supplements that are marketed as foods and are endeavouring to use a number of measures in an attempt to address these concerns.

Need for government action

Why the Government should intervene

The TGA is committed to the Australian Government Department of Health's strategic priority of protecting the health and safety of the Australian community through effective, timely and risk proportionate regulation of therapeutic goods. The TGA is responsible for protecting the health and safety of the community by regulating therapeutic goods for safety, efficacy and quality. This applies to goods exported, imported, supplied and manufactured in Australia.

It is well recognised that there are safety risks associated with the use of some sports supplements by Australian consumers (from both domestic and overseas manufacturers) (see The consumer problem). There have been deaths and serious adverse events reported with the use of certain sports supplements, which, in general, have occurred in otherwise healthy, predominantly younger people, for whom there is usually no medical reason to take the product that caused them harm. Although the frequency of serious adverse events and deaths may be low (for example, the NSW Poisons Information Centre reports 4 people have died in Australia from 'fat shredder' supplements in the last 5 years) the cost associated with just one mortality is very high and far outweighs the regulatory impact of any of the proposed regulatory interventions. The Value of Statistical Life in 2019 dollars is $4.9 million (24) and Noetic (Appendix 1) estimates the average annual regulatory impact over a 10-year period for the highest cost options proposed in this RIS to be $0.22 million. Therefore, if one single death was avoided (by the proposal to regulate certain sports supplements as medicines), this would save society $4.9 million compared to the potential highest regulatory burden to industry of $2.2 million (over 10 years).

Similarly, while the frequency of serious adverse events may not be high, the costs of such individual events is high. Based on 2014/2015 data, the NSW Ministry of Health estimated the hospital cost of a liver transplant procedure (i.e. hospital costs) to be $153,200. This amount does not take into consideration other costs such as medication, pathology, ongoing monitoring, the costs of a potential organ rejection or the personal costs to the individual and their families.

There are two categories of sports supplements, currently being marketed as foods in Australia, which pose actual and potential safety risks to consumers:

- products which are either non-compliant or illegal (in relation to the ingredients they contain) but are not being sufficiently regulated (due to lack of clarity on their legal status as a food or medicine in current legislation)
- other products which may not be illegal under current legislation, but present a level of risk to consumers (in relation to their ingredients or presentation as medicines) such that it is appropriate to mitigate these risks through regulation

Complexity and a lack of clarity regarding the regulatory status of sports supplements as foods or medicines creates inefficiency and limits the ability of the TGA to instigate timely enforcement activities where safety concerns arise, or mitigate the potential for future safety concerns. Legal proceedings against manufacturers/importers of these products experience lengthy and costly delays due to the lack of legislative clarity - refer to (refer to The problem with current legislation). This poses an elevated risk to public health, given the nature and widespread use and expected continued growth of sports supplements by consumers.

It is in the interest of the Australian public that products, which may pose actual and potential risks to consumer health, are subject to a system of controls relating to the quality, safety and efficacy of these goods. Government action is required to provide clarity on which sports supplements are medicines or food which will enable regulators—the TGA or State and

Territory food authorities—to ensure that these products are regulated commensurate with the risks that they pose to public health.

The objective of the intervention

The objective of the intervention is to protect the health of the Australian community by enabling the effective, timely and risk proportionate regulation of sports supplements products that pose actual and potential safety risks to consumers.

The Government has the capacity to intervene

The therapeutic goods framework provides a national system of controls to ensure consumer safety. If the therapeutic goods framework applied to certain sports supplement products (as identified in the proposed options), it would assist industry in ensuring they meet the high levels of safety, quality and efficacy that Australian consumers expect from products available in Australia.

Section 7 of the TG Act provides the Secretary of the Department of Health (the Secretary) the power to declare that goods are (or are not) therapeutic goods generally or when used, advertised or presented for supply in a particular manner, even if:

- they are also goods for which there is a standard in the Code; or
- have a tradition of use as food in the form in which they are presented in Australia or New Zealand

The effect is that goods that would otherwise be regulated as food are regulated as therapeutic goods. Section 7 declarations are made by the Secretary to provide clarity for consumers, industry and regulators as to whether a product is a therapeutic good or a food.

Barriers or natural limits on what might be achieved by Government intervention

Even if legal clarification is provided on the status of certain sports supplements as therapeutic goods, consumers may still be exposed to higher risk goods if some companies continue to market certain supplements as food products to avoid appropriate regulatory scrutiny. This is a known issue with products from this category and there is a risk that businesses could continue this practice. However, the legal clarity will mean that timely and appropriate enforcement activity can be undertaken by the TGA against these products where they are identified. The TGA already has testing protocols in place for sports supplements, which will be increased if the regulatory clarification is implemented. It is also likely that the clarification of jurisdictional responsibility for these goods, and the resulting increased regulatory enforcement, will be a deterrent to such practices continuing in the future.

Consultation

This proposal has been consulted over an 18-month period. Following initial internal consultation in 2018, the proposal was discussed by the TGA and the Implementation Subcommittee for Food Regulation (ISFR) at its July 2019 meeting. ISFR members include senior officials of the Australian and New Zealand state and territory food authorities, the Australian Local Government Association and other Australian Government representatives (such as FSANZ and ASADA). Following ISFR consultation a workshop was held at the TGA in September 2019 with Commonwealth regulators and the Australian and New Zealand state and territory food regulatory bodies. This workshop aimed to generate technical input for the criteria for the proposed section 7 declaration to ensure it was appropriately scoped and fit for purpose.

A consultation paper on a proposed clarification that certain sports supplements are therapeutic goods was released for public comment on 22 October 2019. The consultation paper outlined

the regulatory complexities between foods and therapeutic goods and raised the emerging issues of consumer safety and jurisdictional responsibility associated with sports supplements. The consultation paper included a proposed declaration under the authority of section 7 of the TG Act that certain sports supplements are therapeutic goods. The precise terms of this proposal are the same as what is in this RIS referred to as Alternative approach 2.

In response to the public consultation, 43 written responses were received from a range of stakeholders including: consumers; manufacturers; industry representatives; regulatory affairs consultants; government bodies; and health professional associations. An online survey received over 5300 submissions, primarily from consumers. There was also an industry-initiated campaign 'Save Aussie Supplements' that received over 14,000 signatures. The list of responses is provided in Table 11.

Table 11: Stakeholder response to public consultation paper on sports supplements

Category	Representatives
Government representatives	Australian Sports Anti-Doping Authority Department of Agriculture Queensland Department of Health Sports Dieticians Australia
Consumers	Consumers Health Forum of Australia 5365 responses to TGA online survey
Industry consultants	MKK Consulting Ron Law
Industry bodies	Australian Traditional-Medicine Society Complementary Medicines Australia Consumer Healthcare Products Australia
Professional bodies	Australian College of Sport and Exercise Physicians Dieticians Association of Australia Exercise & Sports Science Australia Monash University School of Public Health and Preventative Medicine Pharmacy Guild Public Health Association Australia Royal Australian College of General Practitioners
Other	Human and Supplement Testing Australia
Health professionals	Evelyn Faye Nutrition

Category	Representatives
Manufacturers and Retailers	Amway of Australia ATP Science Bulk Nutrients Elite Supps Gelatine Manufacturers Association of Europe Healthcare Product Specialists High Performance Sport New Zealand HUT Group Morlife Nutrition Warehouse PharmaCare Laboratories Revvies Energy Spartansuppz Syn-Tec Nutriceuticals Vitaco Health
Anonymous submissions	8
'Save Aussie Supplements' campaign	14,063 signatures

Healthcare professionals, government bodies, regulatory bodies, athletes and sports associations strongly favoured the consultation proposal while many in the sports supplement industry opposed it. Consumers were mixed in their responses; many consumers who regularly use sports supplements products were opposed to the proposal while conversely, other consumers favoured stronger regulatory control for these products.

Almost no opposition was received to the aspects of the proposal relating to substances include in a schedule to the Poisons Standard, with many respondents believing products containing scheduled ingredients were already considered therapeutic goods (the issues related to this are discussed within the 'Problems with the current legislation' section of this document).

Several submissions from consumers, industry, healthcare professionals and consumer representative groups called for a broader approach and actions that would impose a greater regulatory burden than what was presented in the initial consultation proposal. This included adding other dosage forms to the criteria, such as gels and wafers.

Many of the responses opposing the proposal appeared to misunderstand the intent, scope and implementation for the proposal. Many believed that the proposal would affect all sports supplements (including protein powders and meal replacement shakes); that the proposal would not be subject to any further review or consultation; and that it would be implemented the day after the consultation closed, resulting in stores being raided and products physically removed from shelves. This misunderstanding was due, in part, to the industry-initiated campaign, as well as the lack of specificity provided for consumers and industry in the consultation paper.

The 'Save Aussie Supplements' campaign claimed that the proposal would lead to the withdrawal from sale of a large number of products ("70 000") from the Australian market with the potential loss of tens of thousands of jobs across the country. However, these claims were based on the stakeholder perception that the scope of products that would be affected was broader than intended.

Industry were alarmed that some legitimate foods would be captured by some of the criteria included in the initial proposed declaration. Issues raised by industry included:

- sports supplements containing naturally occurring appropriate food substances could be declared to be therapeutic goods due to the following criteria included in the initial proposal:
  - substances in excess of the limits provided in Schedules 29-18 and 29-19 of the Food Standards Code, for example: where L-carnitine is present at more than 2 grams per one-day quantity or L-taurine at more than 60mg per one day quantity
  - ingredients exceeding the limits specified in the Permissible Ingredients Determination for listed medicines, for example: glucose
  - substances banned by WADC, for example: naturally occurring hormones such as testosterone and Insulin Like Growth Factor-1 (IGF-1) in cow's milk
- the inclusion of the criteria that sports supplements with substances from the WADC Prohibited List would be therapeutic goods would create uncertainty for industry as the list is subject to change. Industry also questioned whether it was appropriate for Australia to include reference in our legislation to an 'international, non-Government body'
- industry also expressed concern that the examples of 'therapeutic use' provided in the draft declaration overlapped with permissible health claims made under the Food Standards Code

To address both public and industry concerns, the initial proposed declaration was refined and the criteria referring to the permissible indications list and the food standard schedules was removed (presented as Option 2A in this RIS).

Given that the initial public consultation received a large number of responses (a total of 19 470 responses including written responses, responses to the online survey and signees to the industry led campaign) it was considered that the submissions received had provided a good representation of public opinion and that further public consultation was unlikely to yield any additional information. Instead, further consultation was undertaken in the form of two targeted stakeholder workshops held in Sydney and Melbourne in February 2020. Invitees to the workshops consisted of: stakeholders who provided comprehensive responses to the consultation as well as those identified as major industry players; industry representative groups; healthcare professional representative groups; sporting associations; relevant government bodies; consumer representative groups; and independent sports supplement testing facilities. Table 12 provides a list of the different stakeholder representatives who attended the workshops.

Table 12: Stakeholder representation at February 2020 workshops

Stakeholder Category	Number of entities
Consumer Representative Groups	3
Contract Manufacturers	2
Government Agencies	6
Healthcare Professional Representative Groups	3
Independent Testing Agency	1
Industry Representative Groups	4
Manufacturers	23

Stakeholder Category	Number of entities
Regulatory Consultants	5
Retailers/Distributors	14
Sporting Body/Associations	7

Following consideration of stakeholder feedback from the targeted workshops, Noetic undertook nine additional face-to-face interviews with key manufacturers and retailers. The results of these interviews (discussed in the Noetic Report at Appendix 1) informed the assessment of the regulatory costing and other regulatory impacts considered in this RIS.

The revised proposal (presented as Option 2A in this RIS) was generally positively received by workshop participants and considered an improvement of the initial proposal. However, there remained industry concerns, primarily regarding the legitimacy of the WADC Prohibited List and the inclusion of the criteria of product presentation as tablets, capsules and pills (these industry concerns are given consideration in proposed Options 2B and 3 of this RIS).

Stakeholders expressed concern at the workshops that consumers would increasingly use the Personal Importation Scheme to access the sports supplements they want, which would cause increasing loss of the Australian market share to international competitors, which is recognised as a pre-existing issue for the industry across a range of products, not just sports supplements. Refer to Importation of food and medicines into Australia for more information. The use of the Personal Importation Scheme is separate from the wholesale import for retail sale of products. The Personal Importation Scheme applies to the import for use by a single person and has several limitations on what and how much can be imported, including that it can be for no more than 3 months' supply at a time. In the case of wholesale importation for sale made by either legitimate or illegitimate businesses, a clarification that certain sports supplements are therapeutic goods would assist the ABF in detecting such imports and referring them to the TGA for compliance actions against the importer, providing a more level playing field for the existing compliant Australian industry.

At one of the workshops, some industry stakeholders proposed that a separate listed medicine pathway should be created under therapeutic goods legislation for sports supplements to be included in the ARTG to address concerns that the Permissible Ingredients Determination for listed medicines does not contain many of the commonly used ingredients in sports supplements. The industry proposed pathway would enable sports supplements to contain ingredients that were not in the Permitted Ingredients Determination but not be required to meet the same evidence requirements of other listed medicine ingredients based on the claim that sports supplements were low-risk and therefore should remain available for self-selection and general sale. However, the standards set for listed medicines are considered the minimum requirements in order to ensure consumer safety for low-risk therapeutic goods available for self-selection and it would be inappropriate to provide a separate pathway for sports supplements, with lower standards of safety, quality and efficacy. The proposal was also based on the mistaken view that only ingredients satisfying a definition of a complementary medicine substance could be included in the Permissible Ingredients Determination. However, listed medicines can be any product type.

In relation to consumer concerns, it is considered that the refined proposal addresses many consumer concerns raised during consultation. The majority of consumer concerns were associated with the misconception that products such as protein powders, nutritional bars, meal replacements, creatine and branch chain amino acids would be removed from the market.

Consumers can be reassured that, providing these products have food ingredients and are presented as food, they will not be affected by the proposal, if implemented. Another common

consumer concern was that there would be less products on the market and some products may be more expensive. This issue is considered under impacts under Options 2A, 2B and 3.

In addition to the public and targeted consultation process described above, the TGA has also sought input from the Department of Industry, Science, Energy and Resources (DISER), the Department of Foreign Affairs and Trade (DFAT) and the Australian Small Business and Family Enterprise Ombudsman (ASBFEO) to assess the impact of the proposal on international and domestic trade. The TGA also contacted the New Zealand Ministry for Primary Industries (NZ MPI) in relation to the potential impacts on products currently imported under the TTMRA. The comments, concerns and information provided by these agencies have been considered in the development of this proposal.

The TGA has also notified members of the World Trade Organisation (WTO) of the proposal to clarify that certain sports supplements are therapeutic goods in Australia, in accordance with the Government's international obligations under the WTO Agreement on Technical Barriers to Trade. WTO member states have been given a reasonable time to respond.

Policy options considered

A number of approaches and options for addressing the problem were considered, based on internal and external consultations.

Four key options explored in this RIS:

- **Option 1**—Maintain the status quo (no change)
- **Option 2A**—Declare under authority of the TG Act that sports supplements are therapeutic goods if they:
  - contain ingredients that are not appropriate for a sports supplement food:
    - substance above the restrictions provided in the Poisons Standard
    - a substance that is included in the WADC Prohibited List
    - a Relevant substance as declared by the Secretary
  - and/or are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill)
- **Option 2B**— Declare under the authority of the TG Act that sports supplements are therapeutic goods if they:
  - contain ingredients that are not appropriate for a sports supplement food:
    - a substance above the restrictions provided in the Poisons Standard
    - a Relevant substance as declared by the Secretary
  - and/or are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill)
- **Option 3**—Declare under authority of the TG Act that sports supplements are therapeutic goods if they:
  - contain ingredients that are not appropriate for a sports supplement food:
    - substance above the restrictions provided in the Poisons Standard
    - a substance that is included in the WADC Prohibited List
    - a Relevant substance as declared by the Secretary

In addition to the four options explored in the RIS, **two alternative approaches** were considered – refer to Alternative approaches considered but rejected.

Criteria for assessing options

Some of the criteria used in assessing the various options are provided below:

- the degree by which the option would likely address the identified problem
- the benefits to be attained
- the overall regulatory burden
- impacts on businesses such as Australian manufacturers, suppliers and retailers
- impacts on availability of products for consumers and consumer choice
- impacts on competition and potential effect on price
- the potential for unintended loopholes and gaps (which could possibly then be exploited)

The criteria are not stand-alone and have been considered together in determining the option offering the highest overall net benefit. Higher emphasis has been placed on the degree by which the option would likely address the identified actual and potential safety risks associated with the use of certain sports supplements.

Option 1. Status Quo

The 'status quo' option would not implement any changes to the regulation of sports supplements in Australia. Manufacturers of sports supplements marketed as foods will not experience any additional regulatory burden. There will also be no change in the products available and the cost of these products to consumers.

Maintenance of the status quo would see continued consumer exposure to the actual and potential risks associated with sports supplements marketed as foods. The costs associated with serious adverse events for individuals, their families, their communities and the Australian healthcare system will continue. The 2019 Industry reports (21; 26) predict that this is a category of products with expected growth in Australia due to a growing fitness culture, which means that there is the potential for risks to compound over time with the increasing consumer use of sport supplements.

The lack of legal clarity relating to the categorisation of these products (i.e. as foods or as therapeutic goods) means that regulatory authorities will continue to be required to conduct complex food-medicine assessments to determine which authority should take action where a product poses a public health risk. The legal ambiguity for these products will continue to waste Government resources and taxpayer's money in the pursuit of legal proceedings against high-risk products, with continued exposure of these products to consumers while the necessary legal steps are taken to end their supply. There may also be a lack of consumer confidence in the food and medicine regulators due to their perceived inability to effectively regulate goods that pose a risk to the safety of consumers.

Industry has expressed frustration with the ambiguity they encounter when interpreting the Food Standards, including Standard 2.9.4 -Formulated Supplementary Sports Foods. The lack of clarity for these products incurs resource costs for businesses in trying to understand their legal obligations and puts a business at risk of unintended non-compliance. There would also be continued legal risk for industry, since there is the possibility that a court would determine a product to be a food or therapeutic good, irrespective of existing guidance that is intended to

resolve the uncertainty. The status quo would mean this ambiguity would continue and these industry concerns would not be addressed.

A summary of the impacts on various stakeholders from maintaining the status quo are provided in Table 13.

Table 13: Summary of impacts from maintaining the status quo

Stakeholder	Benefits	Negatives
Australian manufacturers	• No additional regulatory burden. • Reformulation of products not required. • Change in product presentation not required. • No requirement to list or register a medicine in the ARTG.	• Continued difficulty navigating the current legislation. • Continued legal risk for industry of unintended con-compliance due to the ambiguity of current legislation.
Overseas manufacturers	• No change to current importation requirements.	• Continued legal uncertainty for industry as to when a product could be determined to be a therapeutic good and seized at the Australian border.
Consumers	• No change in the availability, cost, formulation or presentation of the products available to consumers.	• Continued exposure to actual and potential risks from sports supplements marketed as foods. • Lack of consumer confidence in food and medicine regulators due to their perceived inability to effectively regulate goods that pose a potential risk to the safety of consumers.
Retailers	• No change in the availability, cost, formulation or presentation of the products available for retail sale. • No loss of revenue.	• Continued legal risk for retailers as to when a product they are selling could be determined to be a therapeutic good.

Stakeholder	Benefits	Negatives
Australian Government	• No detrimental effect to the Australian economy arising from potential job losses from decreased retailer and manufacturer revenue.	• Continued waste of Government resources and taxpayer's money in pursuing legal proceedings against high-risk products. • Continued individual, society and government costs arising from adverse events, in particular where these occur in young, otherwise healthy Australians.

Option 2A. Declare that sports supplements including substances (in the Poisons Standard, WADC or Relevant substance lists) and/or presented as medicines are therapeutic goods

Option 2A would declare under the existing authority of section 7 of the TG Act that certain sports supplements are therapeutic goods, with the effect that they are not foods. A declaration would complement the FSANZ pending update to Food Standard 2.9.4. The criteria for the proposed declaration are provided in the text box below.

Option 2A: Declare that following sports supplements are therapeutic goods

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

AND

- contain an ingredient that is 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 included in the **WADC Prohibited List**
  - a **Relevant substance** (as declared by the Secretary)
- and/or are presented in a **form associated with medicines** rather than foods (i.e. a tablet, capsule or pill)

Elements of Option 2A

Products will only fall within the scope of the declaration if they carry indications relating to the improvement or maintenance of performance in physical or mental activity in sports, exercise or any other recreational activity. If there is no sports performance related therapeutic claim, whether explicit or implied, they will not be affected by the proposed declaration and will remain food. For example, artificial sweeteners and pectin tablets.

Option 2A does not change the ability for sports supplements to be sold in stores other than pharmacies, a potential concern raised by industry during the consultations. Listed medicines

and some registered OTC medicines (that do not contain scheduled ingredients) can be sold from general retail stores such as sports supplement, health food and grocery stores.

Ingredients in scope in Option 2A

Option 2A would declare that a sports supplement product containing a substance above the restrictions provided in a schedule to the **Poisons Standard** (scheduled substance) is a therapeutic good and therefore subject to the same regulatory control as other medicines containing such substances.

Option 2A would also declare that products including substances in the **WADC Prohibited List** are therapeutic goods. Many (but not all) substances included in the WADC Prohibited List are already included in a schedule to the Poisons Standard either explicitly or under scheduled drug classes [such as 'androgenic steroidal agents' (Schedule 4) or 'alkoxyamfetamines' (Schedule 9)]. Those substances in the WADC Prohibited List that are not included in a schedule to the Poisons Standard appear to be from similar classes (or possess similar characteristics to other scheduled substances) and would likely meet the requirements to be a scheduled substance (but have not yet been the subject of an application to amend the Poisons Standard).

The third category of ingredients in scope of Option 2A is the '**Relevant substance**' list which will contain substances that the delegate of the Secretary considers to have a risk profile not appropriate for inclusion in foods but which are not already included in the Poisons Standard or the WADC Prohibited List. This provision in the declaration allows the Secretary to declare substances that are identified with a significant safety concern, but not yet subject to other regulatory controls, to be considered therapeutic goods, for example: prohibited food imports.

Option 2A will not affect those sports supplements that contain only appropriate food ingredients and that are presented for sale in the manner of food products. These will continue to be regulated as foods.

The inclusion of a substance in the proposed declaration will not 'ban' ingredients from use in Australia nor remove them from sale. Rather, it will mean that products containing these ingredients will be required to comply with the regulatory requirements for therapeutic goods particularly as they relate to the safety, quality and efficacy of the product.

Medicine presentation in scope for Option 2A

Option 2A would declare that sports supplements that are presented in a form commonly associated with medicines rather than foods (i.e. a tablet, capsule or pill) are therapeutic goods.

If Option 2A is implemented, sports supplement products making therapeutic indications and presented in medicinal forms would be subjected to the same manufacturing requirements of therapeutic goods to ensure their safe use.

Implementation of Option 2A

Implementation of Option 2A will mean that the manufacturer/owner of products in scope would need to undertake action for their product to either comply with regulations as a therapeutic good or modify their product in order for it to be regulated as a food- see Impacts on manufacturers of products in scope of Option 2A.

If Option 2A is implemented, sports supplements that are in scope of the proposed declaration and being supplied in Australia prior to the commencement date would, in general, have the benefit of 3-year transition period to comply with the legislative requirements for foods or medicines, as applicable. This transition period is anticipated to afford suppliers sufficient time for their stock in trade to be used up, thereby helping to minimise the disruption of the proposal on business.

Products in scope of the declaration that contain substances of significant safety concerns to consumers (for example, prescription medicine ingredients) will be affected from the date that the Section 7 declaration is made, enabling swift enforcement action by the regulator in the interest of protecting public safety.

How Option 2A will mitigate the risk associated with certain sports supplements

Effect of Option 2A on ensuring appropriate regulatory controls are applied to protect public health.

The products in scope of the proposed regulatory clarification contain higher risk ingredients that are not appropriate for food and/or are being presented as medicines rather than food.

In Australia, the Poisons Standard restricts access to poisons to protect public safety. Substances such as prescription medicines require appropriate medical management and monitoring, as they pose significant risks to the individuals who take them. It is not appropriate for a food to contain an ingredient that is restricted or prohibited by the Poisons Standard and be easily accessible to the general public with no medical oversight. Industry stakeholder response to the TGA consultation process provided no objection to products containing scheduled substance to be in scope of the declaration. In contrast, stakeholders were very surprised that enforcement measures could not be undertaken in a suitably prompt or efficient manner under the current legislation for such products. For information on why the lack of clarity in current legislation impedes timely and appropriate regulatory enforcement to address safety concern refer to The problems with current legislation.

The correlation between substances included in the WADC Prohibited List and those in a Schedule to the Poisons Standard, combined with the resulting increased risk posed by these substances to all athletes and other consumers, supports the implementation of Option 2A that will see these products subjected to an appropriate level of regulatory control to ensure their safety and quality.

Implementation of Option 2A will also ensure that medicinal dosage forms, which are generally used to deliver concentrated amounts of 'active' ingredients which, are made under the principles of good manufacturing process, ensuring their batch to batch consistency and reducing risks of potential overdosing. This aligns with the regulation of comparable goods under the therapeutic goods framework to ensure their quality, safety and efficacy. The rationale for including this criterion is provided in the section in this RIS entitled Presentations of concern in sports supplements.

Option 2A will enable timely and appropriate enforcement activity (such as removal of products from the market) by the TGA or State/Territory authorities where issues that pose a risk to public health are identified.

Option 2A will also assist consumers in making informed decisions and identifying potential risks or adverse events associated with products. This may also encourage consumers to discuss their supplement use with their health professionals, which was raised as a considerable benefit by health professionals who are concerned by the potential of some substances available in sports supplements to cause adverse effects, drug interactions and significant long-term health issues.

Effect of Option 2A on reducing the risk of athletes/consumers from WADC Prohibited substances

Implementation of Option 2A will mean that products containing WADC prohibited substances that are entered in the ARTG as medicines must comply with all applicable legislative requirements, including labelling requirements that all active ingredients are listed on the

product label in Australian approved terminology, which will give assurance to consumers in relation to the contents of these products. In addition, the timely and appropriate enforcement action by regulators that is enabled by the proposal will also reduce the risk to athletes.

In addition to WADC prohibited substances posing health risks for athletes, the presence of a WADC prohibited substance in a supplement may result in an anti-doping rule violation for an athlete, whether its use was intentional or unintentional. Under the WAD Code's strict liability principle, athletes are ultimately responsible for any substance found in their body, regardless of how it got there. The National Anti-Doping Scheme applies to a broad range of athletes, including national and international level athletes, as well as local/recreational and junior athletes who participate under sporting administration bodies that have an anti-doping agreement with ASADA. In addition, a number of professions in Australia, such as the Australian Defence Force, have strict anti- doping policies, the violation of which can be grounds for dismissal.

Any measure that may reduce the instances of inadvertent doping and the devastating effects on athlete's careers has been widely and heavily supported across the sporting community, including consumers, athletes, industry, sporting bodies and government agencies.

Some industry stakeholders expressed concern that inclusion of the WADC Prohibited List will create regulatory uncertainty for industry, as the list is subject to annual change and maintained by an entity external to the Australian Government. However, if implemented, Option 2A will adopt the WADC Prohibited List at a 'point in time'. Any changes made by to the WADC Prohibited List after that point in time would require a specific update to the declaration in order to incorporate the revised list. These updates, if made, would be communicated widely.

Limitations of Option 2A

Some manufacturers may choose to continue marketing their product with substances of concern (declared, or undeclared, on the label) and/or in medicinal dosage forms. However, the legal clarity provided by Option 2A, will mean that timely and appropriate enforcement activity can be undertaken by the TGA against these products. The TGA already has testing protocols in place for sports supplements and its own, in-house testing laboratories, and testing will be increased if Option 2A is implemented. While undeclared ingredients in supplements may continue to be a risk under any option discussed in this RIS, the clarified enforcement pathway and compliance actions under Option 2A will assist in providing a disincentive for such practices by manufacturers of products in Australia and encourage the development of a compliant industry in the long-term.

It is possible that consumers may purchase products no longer available in Australia online (under the Personal Importation Scheme) and thereby continue to be exposed to products with potential risks, as the safety of unregulated imported products is not known (refer to Importation of food and medicines into Australia for information on this scheme). Further, products with Schedule 4 or 8 substances require a prescription from an Australian registered medical practitioner in order for lawful import under the Personal Importation Scheme. If an import of therapeutic goods is made that does not comply with legislative requirements, the importation can be seized and destroyed and the importer may be charged.

Impacts of Option 2A

Impacts on manufacturers of products in scope of Option 2A

As there is not a national register for food products, it is difficult to determine how many products available in the Australian market may be affected by the proposal.

Only a small number of industry submissions to the public consultation provided quantitative estimates of the impacts of the proposal and, unfortunately, many of these were based on some of the misconceptions encountered with the public consultation paper (namely that over 70,000

products lines, including protein powders and nutrition bars, would be impacted and an assumption that products would be 'banned').

In developing their report (Appendix 1), Noetic conducted targeted stakeholder consultation to determine the extent of products that may be affected by the proposal. In their analysis of the sports supplement industry, Noetic determined that there were 3 major retailers in Australia (Nutrition warehouse, Elite Supplements and Australian Sports Nutrition), with a combined market share of 80% of the national proportion of sports supplements. Noetic visited each retailer's website and collected details for all products listed under the categories of 'pre-workout', 'fat burner' and 'post-workout'/'recovery' products. Noetic removed duplicate products and then extrapolated the figures to represent all Australian retailers (that is, to include the remaining 20% market share). Table 14 provides the Noetic product datasets and the total number of products in each category.

Table 14: Sports supplement product dataset extrapolated across all Australia retailers *

Presentation	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders, liquids and novel foods#	225	160	271	656
Capsule/tablet/pill	114	9	9	132
Total products				788

*extrapolated from table 4 of Noetic Report (Appendix 1)
#liquids, novel foods represent only 7% of product total

From the Noetic Report product dataset (Table 14 above), 132 sports supplement products presented as tablets/capsules/pills may be in scope of the proposal, however, a number of these products may already be included in the ARTG. Of the 656 products presented in forms other than tablets/capsules/pills, these will only be in scope of the proposal if they contain ingredients of concern. The number of potential products affected, based on likely action undertaken by manufacturers is explored further below.

Potential action for manufacturers/owner of products in scope

If Option 2A is implemented, manufacturers/owners of affected products can choose from the following pathways to establish that their product would be regulated as a food or a therapeutic good, as applicable:

- modify their product, as required, to be regulated as a food:
  - by changing the product claims to not refer to performance in sport, exercise or other recreational activity
  - by changing the product formulation to remove ingredients in scope
  - by changing the product dosage form from tablet, capsules or pills to more traditional food presentations
- list or register their product in the ARTG and comply with all relevant regulatory requirements for therapeutic goods
- withdraw their product from the market

Reformulation of a product in scope would mean a product avoids being affected by this proposal. The intent of this proposal is not to include as many products as possible, rather it is to make clear that products that contain an ingredient that is not appropriate for a sports supplement food and that are presented in a form associated with a medicine are appropriately regulated as medicines.

The Noetic Report (Appendix 1) states that industry mostly indicated a preference to avoid entering the therapeutic goods regulatory framework and so are more likely to change their product to avoid being declared a therapeutic good or withdraw their product from the Australian market.

The regulatory impact on industry based on the potential pathways they choose for their product are analysed below.

Change the claims of the product to be regulated as a food

Manufacturers may choose to change the claims for the product so that the product is not "*used, advertised or presented for supply to improve or maintain physical or mental performance in sport, exercise or other recreational activity*" and therefore not fall in scope of the proposed declaration.

However, in their analysis of the sports supplement industry, the Noetic Report (Appendix 1) states that industry consider that a product's claims are fundamental to the marketing appeal of the product and therefore changing the product's claims is not an attractive option. Therefore, the impact of this pathway has not been assessed, as it is unlikely any manufacturers will choose to change their product's marketing claims.

Changing the product formulation (remove ingredients in scope) to be regulated as a food

Manufacturers of in-scope products can choose to remove ingredients from the products that are in the scope of the proposal (i.e. substances in the Poisons Standard, WADC Prohibited Substance List or Relevant substance list). Appendix 2 provides examples of ingredients included in sports supplements and some of those that would be impacted by this proposal.

In the case of food products containing substances in the Poisons Standard, it should be noted that while removing these ingredients may be seen as a regulatory impost to industry, the majority of these products are likely to be considered as either unapproved therapeutic goods or non-compliant foods under current legislation. Access restrictions on products containing scheduled substances should already be in place and it is therefore not considered an increased burden if such products are clarified in law to fall under the therapeutic goods regulatory framework.

Reformulation of the product to avoid being affected under Option 2A will be product dependent. It is likely that 'pre-workout supplements' and 'weight loss products' are the product range most likely to be affected, as these products have often been identified as products containing ingredients of concern (2; 5; 57). Industry advised Noetic (Appendix 1) that, in relation to products presented as powders, it is most likely that pre-workout powder products contain ingredients of concern.

Industry also advised Noetic that non-premium products, that generally have low profit margins and are presented as powders or other traditional food presentations, would most likely be reformulated to remove the ingredients in question. The key driver of this response was the additional costs that would arise from GMP manufacturing relative to the high price elasticity of demand and existing low profit margins, meaning increases in the Costs of Good Sold (COGS) would need to be passed onto consumers.

In products with presentation other than tablets, capsules and pills, Noetic estimate 20% of pre-workout products, 10% of fat burner and 5% of post-workout supplements are likely to reformulate to remove ingredients in scope of the proposal and be regulated as foods (see Table 15). These figures correlate with the 2016 LGC study (2) reporting 20% of supplements have

ingredients of concern and that pre-workout supplements and weight loss products are the products most likely to be affected (2; 5; 57). It is assumed, that that the remainder of these products do not contain ingredients of concern and will not be affected by the proposal and can appropriately be regulated as foods.

Table 15: Products likely reformulate (ingredients) to be regulated as foods* under Option 2A

Presentation	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders , liquids and novel foods #	225 (10%) = 23	160 (5%) = 8	271 (20%) = 54	85

*extrapolated from table 6 of the Noetic Report (Appendix 1) – note that the basis for these calculations is provided on page 22 of the Noetic Report.
#liquids, novel foods represent only 7% of product total

The Noetic Report (Appendix 1) states that industry stakeholders estimate that the total time to complete a simple reformulation with one ingredient is 16 hours, while a complex reformulation with multiple ingredients may take 36 hours to complete, per product. Based on an hourly rate of $84.84, the cost of a complex formulation could be $3, 054.24 per product. This should be a once only cost for the product manufacturer to enable the product to be regulated as a food.

Changing the presentation from tablets, capsules and pills to a more traditional food presentation to be regulated as a food

The Noetic Report (Appendix 1) suggests that the 'fat burner' product category represents the largest proportion of products presented as tablets, capsules or pills (34% of 'fat burner' products are presented as tablets, capsules and pills, compared to 3% of pre-workouts and 5% of post-workout products). Therefore, it is likely that the 'fat burner' product range will be the most affected by the requirement to change their product dosage form to be regulated as foods. Industry stakeholders have advised that it is unlikely that manufacturers/sponsors will opt to change their presentation, as tablet/capsule/pill presentation was a differentiator in the market. Therefore if product owners do not enter their products in the ARTG as therapeutic goods, it is likely that a significant number of fat burner products presented as tablets, capsules or pills will be withdrawn from the market.

Noetic estimate that the percentage of reformulation of dosage form for all tablet, capsule or pill products would be low (5%). Table 16 provides the number of these products that are estimated to change their dosage from to be regulated as food.

Table 16: Product likely to reformulate (presentation) to be regulated as foods* under Option 2A

Presentation	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Tablet, capsule, pill	114 (5%) =6	9 (5%) =1	9 (5%)= 1	8

*extrapolated from table 6 of the Noetic report (Appendix 1) – note that the basis for these calculations is provided on page 22 of the Noetic Report.

The cost of reformulating the dosage from is estimated to cost the same as reformulating ingredients (i.e. 36 hours to complete, per product, based on an hourly rate of $84.84, the cost of a reformulation could be $3, 054.24 per product). This should be a once only cost for the product manufacturer to enable the product to be regulated as a food.

List or register their product in the ARTG and be regulated as therapeutic goods

If Option 2A is implemented, another pathway for manufacturers of affected products is to enter their product in the ARTG and for it to be regulated as a therapeutic good.

The Noetic Report (Appendix 1) notes that there are already several sports supplement products that are listed as therapeutic goods. This includes products such as creatine powders, branched chain amino acid supplements, weight loss ('fat burner') and pre-workout products. Feedback from targeted stakeholder consultation was that several manufacturers either already have, or are in the process of, transitioning part or all of their range into the listed medicine space, in particular, for the incentive that listed medicines can make higher-level claims than permitted under the Code. For such products, there will be no increase in regulatory burden arising from the proposal.

The Noetic Report (Appendix 1) state that only a small percentage of powder products would be likely to proceed down an ARTG listing pathway, with most powder products that have ingredients of concern likely to be either reformulated or withdrawn from the market. It is more likely that tablet /capsule/pill products would proceed down the ARTG route, as reformulation is not an option likely to be pursued by industry for these products. Further, a small percentage of products in this category (i.e. tablets, capsules, pills,) are already listed in the ARTG (and therefore no action is required in relation to the proposed regulatory clarification). See Table 17 for an estimation of the number of products likely to pursue the therapeutic goods pathway.

Table 17: Products likely to be included in the ARTG and regulated as therapeutic goods* under Option 2A

Presentation	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders, liquids and novel foods#	225 (5%) =11	160 (5%) = 8	271 (5%) = 14	33
Tablet/capsule/pill	114 (40%) = 46	9 (40%) = 4	9 (40%) = 4	54
Total products				87

*extracted from Table 4 of the Noetic report (Appendix 1) - note that the basis for these calculations is provided on page 22 of the Noetic Report.
#liquids and novel foods represent only 7% of product total

Transitioning to the therapeutic goods regulatory framework would require that the product be entered in the ARTG and comply with all applicable therapeutic goods regulatory requirements (refer to Different regulatory requirements for food and medicines) in relation to:

- manufacturing
- ingredients
- indications
- labels

- advertising
- evidence to support the safety, quality and efficacy of the product

Noetic (Appendix 1, Table 8) estimate that the cost of all regulatory activities associated with listing a product in the ARTG to be $5,952.94, with ongoing maintenance costs of $339.36. In addition to these figures, there is an initial application fee of $ 840 and ongoing annual fee of $1,140 to maintain the ARTG entry.

In addition to the costs associated with entering a medicine in the ARTG, there also costs associated with meeting the regulatory requirements for therapeutic goods, the most significant of which is manufacturing the product in accordance with the principles of GMP. The vitamin and supplement manufacturing industry is characterised by a small number of manufacturers producing vitamins and supplements, many of which are contract manufacturers operating in the wider pharmaceutical product manufacturing industry (58). Advice to the TGA from DISER is that sports supplements appear to be most commonly produced by pharmaceutical-producing organisations, rather than food manufacturers. As a result, there may not be a significant impact to food manufacturers from the change in the way these products are regulated. This advice is reiterated in the Noetic Report (Appendix 1) who state that no evidence was provided to Noetic of existing food manufacturers who, because of this specific regulatory clarification, would seek to obtain a TGA manufacturing licence. Rather, some businesses already have a TGA manufacturing licence or are utilising a contract manufacturer who holds a current TGA manufacturing licence/GMP certification for the production of their supplements.

The costs of listing a medicine, as provided above, assume that the product's ingredients are all permitted for use in listed medicines. If a manufacturer wishes to list a product that does not have permitted ingredients, the substances will need to be assessed for inclusion in the list of Permitted Ingredients. The application and evaluation fees for a new substance evaluation ranges from $15,690 to $22, 680. In addition, the applicant will incur the cost of compiling a dossier. The Noetic Report (Appendix 1) states that, given the complexity of the submission process and evidentiary requirements, former food manufacturers would likely outsource the preparation of the submission to a regulatory affairs consultant (with estimated fees to be

$30,000). In consultation feedback, industry have advised they are unlikely to pursue applications for new ingredients, as they consider that the costs are prohibitive.

For those products with substances in the Poisons Standard or the WADC Prohibited List, these high-risk substances will not be appropriate for inclusion in low risk listed medicines, so if manufacturers of these products wish to maintain the formulation they will have to apply for these goods to be registered medicines. The cost of registering a medicine is significantly higher than listing a medicine. The application and evaluation fees for a registered complementary medicine range from $3,630 to $39,780. In addition, a sponsor will incur the costs of compiling a dossier, which has significantly higher requirements than for a lower risk listed medicine, given that a dossier for a registered medicine needs to establish the quality, safety and efficacy of the product. In consultation feedback, industry have advised they are unlikely to pursue the registration pathway.

In conclusion, it is unlikely manufacturers of products affected by the proposal will pursue the registration pathway or submit applications for new ingredients. If manufacturers of products pursue the regulatory pathway, it is most likely to be the listed pathway and, the most likely products will be those presented as tablets, capsules and pills (estimated to be 54 products compared to 33 products with other presentations- refer to Table 17).

Noetic Group's regulatory costings (refer to Appendix 1) estimate $0.22m average annual regulatory burden cost over 10 years for Option 2A.

Withdraw the product from the market

It is likely there will be some products that will exit the market under any option other than the status quo. Noetic (Appendix 1) states that products might be withdrawn from the market because:

- the projected profit from sales does not justify the expense of going down an ARTG pathway
- the product may contain active ingredients that are unlikely to be approved for sale by the TGA outside a pharmacy (or might require a prescription) and are therefore unable to be sold through sports supplements retail or online store
- it is possible that some overseas manufacturers will reformulate their products but it is likely that this will not be done for the unique Australian market
- it is likely that a number of capsule products will be withdrawn rather than proceeding down an ARTG pathway

It is difficult to estimate how many products will be withdrawn from the market by manufacturers. Table 18 (products presented as powders, liquids, novel foods) and Table 19 (products presented as tablets, capsules and pills) provides estimates of the number of products that may not require modification, may be required to be reformulated or may be required to be entered in the ARTG, with the remaining products potentially removed from the market. The figures in Tables 18 and 19 relating to reformulation and entry in the ARTG are based on Noetic calculations (Appendix 1). The estimated number of products not requiring action or requiring removal from the market have been calculated based on the LGC 2016 survey (2) results that identified approximately 20% of sports supplements products sold in Australia contained ingredients banned in sport (and therefore estimated that 80% of products may not contain ingredients impacted under Option 2A). The limitations of the LGC 2016 survey are such that the results may represent an over-estimation of the number of products containing ingredients banned in sport and therefore provide a similar over-estimation of number of products that may be withdrawn from the market if Option 2A is implemented.

Based on the Noetic report and other findings such as those in the LGC 2016 study, pre-workout powders have been noted to be more likely than other product categories to include ingredients that would be affected under Option 2A. In acknowledgement of this, it has been estimated that an additional 10% (making a total of 30%) of products in this category may be affected under Option 2A due to the ingredients they contain

Table 18: Estimated number of products (powders, liquids, novel foods) in pathway options under Option 2A

Powders , liquids and novel foods #	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
No action required	225 (80%*) = 180	160 (80%*) = 128	271 (70%#) = 190	498
Reformulate	225 (10%) = 23	160 (5%) = 8	271 (20%) = 54	85
ARTG entry	225 (5%) =11	160 (5%) = 8	271 (5%) = 14	33

Powders , liquids and novel foods #	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Removed from market	225-(180+23+11) = 11	160- (128+8+8) = 16	271-(190+54+14) = 13	40

*The 2016 LGC study (2) reported that approximately 20% of sports supplements tested were found to contain ingredients affected under Option 2A. Based on this, it is estimated that 80% of products will not have ingredients affected under Option 2A.
#The 2016 LGC study reported that approximately 20% of sports supplements were found to contain ingredients that meet the criteria for inclusion under Option 2A. For other product categories, it is estimated that 80% of products do not have these ingredients. However, consultation with industry has suggested pre-workout products may be more likely to contain to contain ingredients of concern, and so it has been estimated that only 70% of these products will not be impacted under Option 2A.

Table 19: Estimated number of products (tablets, capsules, pills) in pathway options under Option 2A

Tablets, capsules, pills	Fat burner products	Post-workout products	Pre-workout products	Total products
No action required*	~20*	~2*	~2*	~24*
Reformulate	114 (5%) = 6	9 (5%) = 1	9 (5%) = 1	8
ARTG entry	114 (40%) = 46	9 (40%) = 4	9 (40%) = 4	54
Removed from market	114 –(20+6+46) = 42	9 –(2+1+4) = 2	9 –(2+1+4) = 2	46

*Estimated number of products already in the ARTG, based on product presentation and indications referring to performance in sports.

Using the above figures, approximately 86 products (~46 tablets, capsules, pills and ~40 powders) may need to be removed from the market.

It should be noted that the products affected under the proposal are considered to pose an inappropriate level of potential risk to consumers for a food and may already be unlawful/non-compliant products under existing legislation. While the removal of products from the market may reduce the choice available to consumers, the products that remain on the market will be regulated commensurate with the safety profile of food or medicines.

The impact on the industry in relation to potential revenue and job losses from withdrawal of products from the market is not known. While industry feedback has indicated a preference to either reformulate or exit the market to avoid regulation as a therapeutic good, this remains speculative (and has been provided within the context of manufacturers being opposed to the proposal). The medium to long-term view may see a market opportunity being capitalised upon by existing manufacturers with GMP certified facilities in order to replace products withdrawn from the market (Noetic-Appendix 1).

It is difficult to comment on the viability of existing retailers following any product withdrawals. The 2019 Euromonitor report states that sports protein products account for 70% of 2019 sports nutrition product sales in Australia and that 50% of these protein products are in the

presentation of powders (21). These products are unlikely to be impacted by the proposal as they are less likely to be presented as tablets, capsules or pills and reportedly less likely to contain high-risk ingredients. The remaining approximately 30% of sports nutrition sales (representing non-protein products) may include a proportion of products impacted by Option 2A, which may result in a loss of a retailer's product range and sales. However, a proportion of those impacted products may be reformulated or included in the ARTG (as outlined in the Noetic Report and in Table 19) and remain on the market.

A potential impact on sales was considered when recommending a 3-year transition period, in order to allow businesses a reasonable transition time to manage their product range, stock levels and develop alternative product lines.

Benefits and negative impacts of Option 2A

Benefits of Option 2A for industry

Option 2A will provide long-sought clarity for manufacturers and retailers of sports supplements and reduce their risk of accidental non-compliance.

The improvement in enforcement efficiency and the legal standing of products will see products that are harmful and/or unlawfully supplied removed from the market more effectively, providing support and incentive to those manufacturers who are diligent in ensuring they are fulfilling their regulatory obligations. Several members of industry noted they felt that the lack of enforcement put them at a disadvantage compared to manufacturers willing to include dangerous or prohibited substances in their products. Option 2A would go towards resolving this concern. It will also assist in lifting the reputation of Australian sports supplements in terms of safety and quality, which may boost consumer confidence both within Australia and in international markets.

Providing clarity about which imported sports supplements meet compliance standards will enable the Department of Agriculture, Water and the Environment and the Australian Border Force to more readily detect products entering the country unlawfully. This will enable prompt regulatory action for imported sports supplements not compliant with the Australian regulatory framework, including those imported under the Personal importation Scheme. This may provide a marketing advantage for Australian sponsors and manufacturers of sports supplements who are 'doing the right thing' and are compliant with Australian legislation.

Industry asserts that restrictions on the product claims, ingredients and presentations permitted for use in sports supplements will reduce Australia's competitiveness in the global market.

However, there is also a potential for increased competitiveness in the overseas market, due to the strong reputation of Australian listed medicines and regulation by the TGA.

Negative impact of Option 2A for industry

The product manufacturer/owner of products in scope may incur increased regulatory costs, depending on which pathway they choose for their product - see Potential action for manufacturers of products in scope.

The increased regulatory costs for these sports supplements (for example: associated with reformulation or being entered in the ARTG as therapeutic goods) could result in increased prices for consumers and potentially a decline in sales. It is recognised that cost is a significant factor determining consumer purchasing choices. However, the consumers who purchase these products appear willing to pay a premium price for sports supplements promoted to increase their performance and paying extra for a safe product may not be deterrent for all consumers.

Some industry stakeholders claim that, as a result of expected reduction in product lines arising from the regulatory clarification, there is likely to be a shift in consumer purchasing behavior, with consumers increasing the number of goods purchased from overseas online retailers.

Sports supplements products are often sold in a 'bundle'. For example, a pre-workout, fat burner and a recovery product. Consumers may buy, not only the in-scope products such as the pre-workout, but the other non-affected products (secondary sales), such as general health products, from overseas online retailers. However, this trend in consumer purchasing already occurs and is also likely affected by other factors such as exchange rates, irrespective of the proposed regulatory clarification.

Benefits of Option 2A for consumers

The benefits to consumers achieved under Option 2A include an improvement in the safety and confidence with which they will be able to purchase and consume sports supplements in Australia.

Implementation of option 2 is anticipated to reduce the number of serious adverse events experienced by otherwise healthy individuals who consume sports supplement products, as well as reducing the risk to athletes of inadvertent doping due to contaminated/adulterated products.

The legal clarity provided by Option 2A will provide for prompt action being able to be taken against products found to pose a safety risk to consumers, such as those that contain scheduled ingredients.

Negative impact of Option 2A for consumers

Consumers may face a reduction in product choice because of the implementation of Option 2A. Owners of some affected products may withdraw the product from the market rather than choose to transition to therapeutic goods regulation, which will decrease the consumer choice available in the short-term. It is difficult to estimate future populations, noting that the industry is growing in Australia and internationally, however, it is reasonable to expect that some of the products withdrawn will be replaced in time by other companies willing to progress down the therapeutic goods pathway.

Products that transition to the therapeutic goods regulatory framework are anticipated to incur additional costs, much of which may be passed on to the consumer, increasing product costs.

While there may be some consumers willing to pay a premium in order to gain additional assurances of safety and quality, increased cost may be a disincentive for purchases by other consumers.

The potential for a greater portion of consumers to purchase products online under the Personal Importation Scheme may expose consumers to additional risks. The safety of imported products is not known as these products are not regulated by the TGA. There is also a risk for consumers that if an import of therapeutic goods is made that does not comply with the rules of the Personal Importation Scheme (such as including Schedule 4 or 8 substances without relevant approval), the importer may be charged with an offence under the TG Act.

Table 20 summarises the impacts on stakeholders of the implementation of 2A.

Table 20: Summary of impacts on stakeholders from implementation of Option 2A

Stakeholder	Benefits	Negatives
Australian manufacturers	• Clarity of legislation will reduce inadvertent non-compliance. • Increased consumer confidence in safety of Australian products. • Improved enforcement against non-compliant businesses will support others that work to understand and comply with their regulatory obligations.	• Affected products will require reformulation (~ 93 products), entry in the ARTG (~ 87 products) or withdrawal from market (~ 86 products)[11]. • Potential loss of revenue. • Increased regulatory burden if transitioning from food to therapeutic good GMP.
Overseas manufacturers	• Clarity of legislation will reduce inadvertent non-compliance.	• Products determined to be therapeutic goods may be seized at the Australian border. • Loss of revenue.
Consumers	• Reduced exposure to actual and potential risks from sports supplements marketed as foods. • Increased consumer confidence in the food and medicine regulators. • Reduced risk of consuming adulterated products due to improved enforcement. • Reduced risk to athletes of inadvertent doping due to contaminated/adulterated products.	• Change in the availability, cost, formulation or presentation of the products available to consumers. • Increased risk to consumers who choose to import unregulated products for their personal use.
Retailers	• Legal clarity if a product they are selling is a therapeutic good. • Reduced risk of inadvertently retailing adulterated products due to improved enforcement.	• Change in the availability, cost, formulation or presentation of the products available for retail sale. • Loss of revenue.

[11] Product total from Tables 18 and 19

Stakeholder	Benefits	Negatives
Australian Government	• Reduced waste of Government resources and taxpayer's money in pursuing legal proceedings against owners of high-risk products. • Reduced actual and potential risks to the Australian public from certain sports food supplements. • Reduced society and government costs arising from adverse events.	• Potential detrimental effect to the Australian economy arising from potential job losses from potential decreased retailer and manufacturer revenue.

Option 2B. Declare that sports supplements including substances (in the Poisons Standard or Relevant substance list) and/or presented as medicines are therapeutic goods

Option 2B would declare under the existing authority of section 7 of the TG Act that certain sports supplements are therapeutic goods with the effect that they are not foods. A declaration would complement the FSANZ pending update to Food Standard 2.9.4.

The Option 2B proposed declaration is the same as the Option 2A declaration, with the exception of including substances included in the WADC Prohibited List.

Option 2B proposed declaration: Declare that following sports supplements are therapeutic goods

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

AND

- 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 **Relevant substance** (as declared by the Secretary)
- and/or are presented in **a form associated with medicines** rather than foods (i.e. a tablet, capsule or pill)

Elements of Option 2B

Products will only fall within the scope of the declaration if they carry indications relating to the improvement or maintenance of performance in physical or mental activity in sports, exercise or any other recreational activity. If there is no sports performance related therapeutic claim, whether explicit or implied, they will not be affected by the proposed declaration and will remain food. For example, artificial sweeteners and pectin tablets.

Ingredients in scope of Option 2B

As per Option 2A, the ingredients in scope of Option 2B include substances included in the Poisons Standard and/or Relevant substance list. However, unlike Option 2A, this option does not provide for the WADC Prohibited List to be expressly referred to in the declaration.

It is important to note that it is not intended that Option 2B would preclude products containing WADC prohibited substances from being clarified as being therapeutic goods. This is because the majority of these substances are already included in a schedule to the Poisons Standard either explicitly or under scheduled drug classes (as outlined in Table 2) and therefore are already in scope of the declaration. What it does mean is that, if Option 2B is implemented, the TGA will need to analyse the substances on the WADC Prohibited List (that are not already expressly included in the Poisons Standard) and, on the basis of consumer safety, either develop a scheduling application for those substances for inclusion in the Poisons Standard; or include them in the 'Relevant substance' list at the discretion of the delegate of the Secretary. Both approaches will be subject to industry and public consultation, and may lead to some substances being scheduled but others not.

Medicine presentation in scope of Option 2B

As per Option 2A- sports supplements products in the medicinal dosage form of, tablets, capsules or pills are in scope for Option 2B.

Implementation of Option 2B

As for Option 2A, Implementation of Option 2B will mean that the manufacturer/owner of products in scope would need to undertake action for their product to either comply with regulations as a therapeutic good or modify their product in order for it to be regulated as a food- see Impacts on manufacturers of products in scope of Option 2A.

If Option 2B is implemented, sports supplements that are in scope of the proposed declaration and being supplied in Australia prior to the commencement date would, in general, have the benefit of 3-year transition period to comply with the legislative requirements for foods or medicines, as applicable. This transition period is anticipated to afford suppliers sufficient time for their stock in trade to be used up, thereby helping to minimise the disruption of the proposal on business.

Products in scope of the declaration that contain substances of significant safety concerns to consumers (for example, prescription medicine ingredients) will be affected from the date that the Section 7 declaration is made, enabling swift enforcement action by the regulator in the interest of protecting public safety.

How Option 2B will mitigate the risk associated with certain sports supplements

Effect of Option 2B on ensuring appropriate regulatory controls are applied reduce risks to public health

The products in scope of the proposed regulatory clarification contain higher risk ingredients that are not appropriate for food and/or are being presented as medicines rather than food. Clarifying that these products are medicines in law will ensure an appropriate level of regulatory oversight commensurate with their risk to public safety.

Industry stakeholder response to the TGA consultation process provided no objection to products containing a substance in a schedule to the Poisons Standard being in scope of the declaration. Implementation of Option 2B will mean that timely and appropriate enforcement

activity (such as removal of products from the market) can be undertaken by the TGA against these products where they are identified.

Implementation of Option 2B will mean that sports supplements presented in medicinal dosage forms, such as tablets, capsules and pills will be regulated as therapeutic goods. The rationale for including this criterion is provided in the section in this RIS entitled Presentations of concern in sports supplements. Medicinal dosage forms are generally used to deliver concentrated amounts of 'active' ingredients which, combined with therapeutic indications, aligns with being regulated under the therapeutic goods framework to ensure their quality, safety and efficacy.

Implementation of Option 2B will mean that these goods will be require to be made under the principles of good manufacturing process, ensuring their batch to batch consistency.

Effect of Option 2B on reducing the risk of athletes/consumers from WADC Prohibited substances

Implementation of Option 2B could see a potential continued consumer exposure to WADC prohibited substances that are not expressly included in the Poisons Standard or the Relevant substance list.

During the consultation process for Alternative approach 2, some industry stakeholders raised objection to the WADC Prohibited List being included as a criterion in the proposed declaration, which is why Option 2B is explored in this RIS. Industry argument against the inclusion of the WADC list was that substances identified with a safety concern should be included in a schedule to the Poisons Standard, rather than the Australian legislation relying on a list maintained by a third party. In addition, industry contended that the requirement for product owners to be aware of all the entries in the WADC Prohibited list would be an additional regulatory burden. Further, there would also be increased uncertainty for industry, given that the WADC Prohibited List is subject to change. The benefit for industry of Option 2B is that the list of substances will be contained in therapeutic goods legislation, rather than relying on a list from a third party.

The section in this RIS, Substances in the WADC Prohibited List outlines the reasons for including these substances in a proposed declaration. In addition to WADC prohibited substances posing health risks for athletes, the presence of a WADC prohibited substance in a supplement may result in an anti-doping rule violation for an athlete, whether its use was intentional or unintentional. In addition, a number of professions in Australia, such as the Australian Defence Force, have strict anti- doping policies, the violation of which can be grounds for dismissal.

Given the safety concerns associated with substances included in the WADC prohibited List, if Option 2B is implemented, the TGA will need to analyse the substances on the WADC Prohibited List (that are not already expressly included in the Poisons Standard) and, on the basis of consumer safety, either develop a scheduling application (for those substances for inclusion in the Poisons Standard); or include them in the 'Relevant substance' list (at the discretion of the delegate of the Secretary). Either route will require significant time and Government resources, which may enable products with such substances to remain on the market for some time, resulting in a continued risk of exposure to consumers to potentially hazardous substances. This will not achieve the objective of regulatory intervention, which is to protect the Australian public from the actual and potential safety risks associated with the use of certain sports supplements.

In addition, as a State Party to the UNESCO Convention Against Doping in Sport, the Australian Government has international obligations to adopt appropriate measures at the national and international levels to prevent doping in sport, consistent with the principles of the WAD Code, which includes the WADC Prohibited List. Including the WADC Prohibited List as a criterion in the proposed declaration will enable the Australian Government to meet our international obligations as a State Party to the Convention.

Limitations of Option 2B

As for Option 2A, some manufacturers may choose to continue marketing their product with substances of concern (declared, or undeclared, on the label) and/or in medicinal dosage forms. This is a known issue with products from this category and there is a risk that businesses could continue this practice. However, the legal clarity provided by Option 2B, will mean that timely and appropriate enforcement activity can be undertaken by the TGA against these products (with the exception of those products containing substances on the WADC Prohibited List that are not already expressly included in the Poisons Standard or in the Relevant substance list) .

The TGA already has testing protocols in place for sports supplements, which will be increased if Option 2B is implemented. While undeclared ingredients in supplements may continue to be a risk under any option discussed in this RIS, the clarified enforcement pathway and compliance actions under Option 2B will assist in providing a disincentive for such practices by manufacturers of products in Australia and encourage the development of a compliant industry in the long-term.

It is possible that consumers may purchase products no longer available in Australia online (under the Personal Importation Scheme) and thereby continue to be exposed to products with potential risks, as the safety of unregulated imported products is not known (refer to Importation of food and medicines into Australia for information on this scheme). Further, products with Schedule 4 or 8 substances require a prescription from an Australian registered medical practitioner in order for lawful import under the Personal Importation Scheme. If an import of therapeutic goods is made that does not comply with legislative requirements, the importation can be seized and destroyed and the importer may be charged.

Impacts of Option 2B

Implementation of Option 2B will mean that the product manufacturers/owners of products in scope would need to undertake action for their product to either comply with regulations as a therapeutic good or modify their product in order for it to be regulated as a food. The options available to sponsors are the same as those outlined in Option 2: Potential action for manufacturers/owner of products in scope.

The number of products pursuing the available pathway options is expected to be essentially the same as per Option 2A (as detailed in Tables 18 and 19). However, there may be slightly more products not requiring any action, where these products contain WADC prohibited substances that are not expressly included in the Poisons Standard (or in the Relevant substance list).

Option 2B may pose a lower level of regulatory burden when compared to Option 2A due to industry not having to refer separately to the WADC Prohibited List of substances. However, regulatory costings undertaken by Noetic (Appendix 1) predict no material difference in regulatory costing between Options 2A and 2B due to the high correlation between the substances listed on the Poisons Standard and the WADC Prohibited list. Noetic Group's regulatory costings estimate that the regulatory burden cost for option 2B is $0.22m average annual regulatory burden cost over 10 years.

Benefits and negative impacts of Option 2B

Benefits of Option 2B for industry

Option 2B will provide long-sought clarity for manufacturers and retailers of sports supplements and reduce their risk of accidental non-compliance.

The improvement in enforcement efficiency and the legal standing of products will see products that are harmful and/or unlawfully supplied removed from the market more effectively, providing support and incentive to those manufacturers who are diligent in ensuring they are fulfilling their regulatory obligations. Several members of industry noted they felt that the lack of

enforcement put them at a disadvantage compared to manufacturers willing to include dangerous or prohibited substances in their products. Option 2B would go towards resolving this concern. It will also assist in lifting the reputation of Australian sports supplements in terms of safety and quality, which may boost consumer confidence both within Australia and in international markets.

A benefit for industry of substances in the WADC prohibited list not being included as a criterion for the declaration may be less regulatory burden and uncertainty. This would be due to the list of substances (deeming a sports supplement to be a therapeutic good) being contained only in therapeutic goods legislation, without additionally relying on a list from a third party.

Providing clarity about which imported sports supplements meet compliance standards will enable the Department of Agriculture, Water and the Environment and the Australian Border Force to more readily detect products entering the country unlawfully. This will enable prompt regulatory action for imported sports supplements not compliant with the Australian regulatory framework, including those imported under the Personal importation Scheme. This may provide a marketing advantage for Australian sponsors and manufacturers of sports supplements who are 'doing the right thing' and are compliant with Australian legislation.

Industry asserts that restrictions on the product claims, ingredients and presentations permitted for use in sports supplements will reduce Australia's competitiveness in the global market.

However, there is also a potential for increased competitiveness in the overseas market, due to the strong reputation of Australian listed medicines and regulation by the TGA.

Negative impact of Option 2B for industry

The product manufacturer/owner of products in scope may incur increased regulatory costs, depending on which action they choose for their product - see Potential action for manufacturers of products in scope.

The increased regulatory costs for these sports supplements (for example: associated with reformulation or being entered in the ARTG as therapeutic goods) could result in increased prices for consumers and potentially a decline in sales. It is recognised that cost is a significant factor determining consumer purchasing choices. However, the consumers who purchase these products appear willing to pay a premium price for sports supplements promoted to increase their performance and paying extra for a safe product may not be deterrent for all consumers.

Some industry stakeholders claim that, as a result of expected reduction in product lines arising from the regulatory clarification, there is likely to be a shift in consumer purchasing behavior, with consumers increasing the number of goods purchased from overseas online retailers.

Sports supplements products are often sold in a 'bundle'. For example, a pre-workout, fat burner and a recovery product. Consumers may buy, not only the in-scope products such as the pre-workout, but other non-affected products (secondary sales) such as general health products, from overseas online retailers. However, this trend in consumer purchasing already occurs and is likely to be affected by other factors such as exchange rates irrespective of the proposed regulatory clarification.

Benefits of Option 2B for consumers

The benefits to consumers achieved under Option 2B include an improvement in the safety and confidence with which they will be able to purchase and consume sports supplements in Australia.

Implementation of Option 2B is anticipated to reduce the number of serious adverse events experienced by otherwise healthy individuals who consume sports supplement products, as well as reducing the risk to athletes of inadvertent doping due to contaminated/adulterated products.

The legal clarity provided by Option 2B will provide for prompt action being able to be taken against products found to pose a safety risk to consumers (with the exception of products that contain WADC prohibited substances not expressly included in the Poisons Standard or in the Relevant substance list).

Negative impact of Option 2B for consumers

Consumers may face a reduction in product choice because of the implementation of Option 2B. Owners of some affected products may withdraw the product from the market rather than choose to transition to therapeutic goods regulation, which will decrease the consumer choice available in the short-term. It is difficult to estimate future populations, noting that the industry is growing in Australia and internationally, however, it is reasonable to expect that some of the products withdrawn will be replaced in time by other companies willing to progress down the therapeutic goods pathway.

Products that transition to the therapeutic goods regulatory framework are anticipated to incur additional costs, much of which may be passed on to the consumer, increasing product costs.

While there may be some consumers willing to pay a premium in order to gain additional assurances of safety and quality, increased cost may be a disincentive for purchase by other consumers.

Under Option 2B there remains a potential continued risk of athlete and other consumer exposure to food products that contain WADC prohibited substances (not expressly included in the Poisons Standard or in the Relevant substance list).

The potential for a greater portion of consumers to purchase products online under the Personal Importation Scheme may expose consumers to additional risks. The safety of imported products is not known as these products are not regulated by the TGA. There is also a risk for consumers that if an import of therapeutic goods is made that does not comply with the rules of the Personal Importation Scheme (such as including Schedule 4 or 8 substances without relevant approval), the importer may be charged with an offence under the TG Act.

Table 21 summarises the impacts on stakeholders of the implementation of 2B.

Table 21: Summary of impacts on stakeholders from implementation of Option 2B

Stakeholder	Benefits	Negatives
Australian manufacturers	• Clarity of legislation will reduce inadvertent non-compliance. • Increased consumer confidence in safety of Australian products. • Improved enforcement against non-compliant businesses will support others that work to understand and comply with their regulatory obligations. • Less regulatory burden and uncertainty for industry because the list of substances (deeming a	• Affected products will require reformulation (~ 93 products), entry in the ARTG (~ 87 products) or withdrawal from market (~ 86 products)[12]. • Potential loss of revenue. • Increased regulatory burden if transitioning from food to therapeutic good GMP.

[12] Product total from Tables 18 and 19. These figures may be slightly reduced under Option 2B as some products containing WADC prohibited substances not expressly included in the Poisons Standard or in the Relevant substance list may not be affected

Stakeholder	Benefits	Negatives
	sports supplement to be a therapeutic good) will be contained in therapeutic goods legislation, rather than relying on a list from a third party	
Overseas manufacturers	• Clarity of legislation will reduce inadvertent non-compliance.	• Products determined to be therapeutic goods may be seized at the Australian border. • Loss of revenue.
Consumers	• Reduced exposure to actual and potential risks from sports supplements marketed as foods. • Increased consumer confidence in the food and medicine regulators to effectively regulate goods that pose a potential risk to the safety of consumers. • Reduced risk of consuming adulterated products due to improved enforcement. • Reduced risk to athletes of inadvertent doping due to contaminated/adulterated products.	• Change in the availability, cost, formulation or presentation of the products available to consumers. • Increased risk to consumers who choose to import unregulated products for their personal use. • Potential continued exposure to WADC prohibited substances that are not expressly included in the Poisons Standard or the Relevant substance list.
Retailers	• Legal clarity if a product they are selling is a therapeutic good. • Reduced risk of inadvertently retailing adulterated products due to improved enforcement.	• Change in the availability, cost, formulation or presentation of the products available for retail sale. • Loss of revenue.

Stakeholder	Benefits	Negatives
Australian Government	• Reduced waste of Government resources and taxpayer's money in pursuing legal proceedings against high-risk products. • Reduced actual and potential risks to the Australian public from certain sports food supplements. • Reduced society and government costs arising from adverse events.	• Potential detrimental effect to the Australian economy arising from potential job losses from decreased retailer and manufacturer revenue. • Potential continued public exposure to WADC prohibited substances that are not expressly included in the Poisons Standard or the Relevant substance list. • Risk of not meeting our international obligations as a State Party to the UNESCO Convention Against Doping in Sport Convention.

Option 3: Declare that sports supplements including substances (in the Poisons Standard, WADC or Relevant substance lists) are therapeutic goods

Option 3 would declare under the existing authority of section 7 of the TG Act that certain sports supplements are therapeutic goods with the effect that they are not foods. A declaration would complement the FSANZ pending update to Food Standard 2.9.4.

The Option 3 proposed declaration is the same as the Option 2A proposed declaration, except that the criterion that products presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill) has not been included.

Option 3 proposed declaration: Declare that following sports supplements are therapeutic goods

Products for oral administration that are used, advertised or presented for supply to improve or maintain physical or mental performance in sport, exercise or other recreational activity **AND** 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 included in the **WADC Prohibited List**
- a **Relevant substance** (as declared by the Secretary)

Elements of Option 3

Products will only fall within the scope of the declaration if they carry indications relating to the improvement or maintenance of performance in physical or mental activity in sports, exercise or any other recreational activity. If there is no sports performance related therapeutic claim,

whether explicit or implied, they will not be affected by the proposed declaration and will remain food.

Ingredients in scope of Option 3

As per Option 2A, Option 3 would declare that sports supplements are therapeutic goods if they contain: a substance above the restrictions provided in a schedule to the **Poisons Standard**; substances in the **WADC Prohibited List**; or substances in the '**Relevant substance**' list.

Medicine presentation in scope of Option 3

The presentation of a product in the medicinal dosage form of tablets, capsules or pills is not in scope of Option 3.

Implementation of Option 3

As for Option 2A, implementation of Option 23 will mean that the manufacturer/owner of products in scope would need to undertake action for their product to either comply with regulations as a therapeutic good or modify their product in order for it to be regulated as a food- see Impacts on manufacturers of products in scope of Option 2A.

If Option 3 is implemented, sports supplements that are in scope of the proposed declaration and being supplied in Australia prior to the commencement date would, in general, have the benefit of 3-year transition period to comply with the legislative requirements for foods or medicines, as applicable. This transition period is anticipated to afford suppliers sufficient time for their stock in trade to be used up, thereby helping to minimise the disruption of the proposal on business.

Products in scope of the declaration that contain substances of significant safety concerns to consumers (for example, prescription medicine ingredients) will be affected from the date that the Section 7 declaration is made, enabling swift enforcement action by the regulator in the interest of protecting public safety.

How Option 3 will mitigate the risk associated with certain sports supplements

Effect of option 3 on ensuring appropriate regulatory controls are applied reduce risks to public health

The products in scope of the proposed regulatory clarification contain higher risk ingredients that are not appropriate for food. Clarifying that these products are medicines in law will ensure an appropriate level of regulatory oversight commensurate with their risk to public safety.

Implementation of Option 3 will mean that timely and appropriate enforcement activity (such as removal of products from the market) can be undertaken by the TGA against these products where they are identified.

During the consultation process for Alternative approach 2, some industry stakeholders raised objection to the product presentation in the medicinal form of tablets, capsules or pills being included in the scope of the proposed declaration, which is why Option 3 is being explored in this RIS. Conversely, other submissions from health professional groups, including dieticians and exercise physiologists, considered that the product presentation in scope for the proposed declaration should include additional presentations such as wafers and oral gels.

Effect of Option 3 on mitigating risks to consumers from food sports supplements presented in medicinal form

The omission of medicinal dosage forms in the proposed declaration will represent a decreased regulatory burden for industry, which is discussed at Impacts of Option 3. However,

implementation of Option 3 will not fully achieve the primary objective of regulatory intervention, which is to protect the Australian public from the actual and potential safety risks associated with the use of certain sports supplements.

The rationale for including tablet, capsule or pill dosage forms as a criterion in a proposed declaration is provided at Presentation of concern for sports supplements. Industry's argument against the inclusion of medicinal dosage forms being in scope of the declaration was that presentation in these dosage forms was appropriate for food, because these dosage forms:

- are used where the flavour of the substance may be unpalatable
- are convenient for athletes to carry with them when they exercise
- provide a portion controlled delivery form for an active ingredient thereby reducing the risk to consumer health
- pose less chance of cross-contamination due not needing to introduce other substances, such as a liquid, when consuming the product as opposed to powders
- encourage product innovation to accommodate consumer preferences for convenient dosage forms

In relation to industry's argument that dosage forms of tablets, capsules and pills are appropriate in instances where a product is encapsulated purely for taste considerations (for example spirulina, apple cider vinegar), these products would only fall within scope of the Options 2A and 2B proposals if they carry health claims related to sport or exercise. Goods that do not carry sports-related claims are not within scope of any of the proposed declarations.

An analysis of the presentation of sports supplement products by the Noetic (Appendix 1) shows that the product category known as 'fat burners' represents the largest portion of products being presented as tablets, capsules and pills in Australia (51% of fat burner products are in the presentation of tablets, capsules or pills, compared to 6% post-workout products and 3% of pre-workout products). The product category of 'fat burners' has been linked to serious adverse events and deaths in Australia and in 2018 the NSW Ministry of Health urged the public to avoid any product from an unverified source being promoted as a weight-loss agent such as 'fat burners' or 'shredders' (24). That is, the majority of products affected by this criterion are demonstrably higher risk and thus the use of the criterion is aligned to the high-level objectives of the proposed clarification.

It is usual for the consumption of a food to be promoted as a recommended daily intake or a recommended portion size for their nutritional health benefits. A product that is promoted with health claims/indications and contains an active ingredient that poses such a risk to consumer health that it is necessary to be dosage controlled (in the form of a tablet, capsule or pill) fits the profile of a therapeutic good and should be regulated as such. There have been small-scale studies of different food supplements that have found concerning rates of variability in batch consistency, particularly with the higher-risk ingredients such as caffeine and other stimulants (41; 48; 47). Products manufactured as medicines have higher manufacturing requirement than foods in order to ensure their quality and batch consistency, reducing the risk of overdosing.

Limitations of Option 3

As for Option 2A, some manufacturers may choose to continue marketing their product with substances of concern (declared, or undeclared, on the label). This is a known issue with products from this category and there is a risk that businesses could continue this practice. However, the legal clarity provided by Option 3, will mean that timely and appropriate enforcement activity can be undertaken by the TGA against these products (with the exception of those products containing substances on the WADC Prohibited List that are not already expressly included in the Poisons Standard or in the Relevant substance list) . The TGA already has testing protocols in place for sports supplements, which will be increased if Option 3 is

implemented. While undeclared ingredients in supplements may continue to be a risk under any option discussed in this RIS, the clarified enforcement pathway and compliance actions under Option 3 will assist in providing a disincentive for such practices by manufacturers of products in Australia and encourage the development of a compliant industry in the long-term.

It is possible that consumers may purchase products no longer available in Australia online (under the Personal Importation Scheme) and thereby continue to be exposed to products with potential risks, as the safety of unregulated imported products is not known (refer to Importation of food and medicines into Australia for information on this scheme). Further, products with Schedule 4 or 8 substances require a prescription from an Australian registered medical practitioner in order for lawful import under the Personal Importation Scheme. If an import of therapeutic goods is made that does not comply with legislative requirements, the importation can be seized and destroyed and the importer may be charged.

Impacts of Option 3

In relation to ingredients, the implementation and impacts of Option 3 are the same as Option 2A. However, the impact of not including the dosage form of tablets, capsules and pills will represent a reduced regulatory burden for industry compared to Options 2A and 2B.

Noetic Group's regulatory costings (refer to Appendix 1) estimate $0.12m average annual regulatory burden cost over 10 years for Option 3, compared to $0.22m average annual regulatory burden cost for Options 2A or 2B over 10 years.

Potential action for manufacturers/owner of products in scope

If Option 3 is implemented, manufacturers/owners of affected products can choose from the following pathways to establish that their product would be regulated as a food or a therapeutic good, as applicable:

- modify their product, as required, to be regulated as a food:
  - by changing the product claims to not refer to performance in sport, exercise or other recreational activity
  - by changing the product formulation to remove ingredients in scope
- list or register their product in the ARTG and comply with all relevant regulatory requirements for therapeutic goods
- withdraw their product from the market

Not including the medical dosage form as a criterion will mean that a large number of sports supplement foods presented in tablet, capsule or pill dosage forms will not be affected by the implementation of Option 3, unless they contain ingredients in scope of the proposed declaration. The 2016 LGC study (2) reported that approximately 20% of sports supplements were found to contain ingredients of concern, so it is therefore estimated that approximately 80% of products may not have ingredients of concern.

Noetic's assessment(Appendix 1) is that only a low percentage of capsule products (5% of total) will continue down the ARTG pathway under Option 3 on the basis of the ingredients they contain. Based on stakeholder commentary, Noetic also found that no tablet/capsule/pill products that would be captured under Option 3 (based on ingredients) would be reformulate by the manufacturers.

As fewer products will fall in scope of Option 3, it is also anticipated that there will be fewer products withdrawn from the market.

Table 22 estimates the number of sports supplement products presented as tablets, capsules and pills that will proceed down the various pathway actions if Option 3 is implemented.

Table 23 estimates the total number of products (i.e. powders and tablets, capsules and pills) that may pursue the various pathway actions if Option 3A is implemented. These figures are based on data previously provided in Tables 14 and 19.

Table 22: Number of sports supplements products presented as tablets, capsules and pills that may proceed down the various pathway actions if Option 3 is implemented compared to Options 2A and 2B

Pathway action	Number of products (tablets, capsules, pills)	Total products under Option 3	Total products under Options 2A and 2B
No action required	32 (80%) = 106	106	24
Reformulate	0	0	8
ARTG entry	132 (5%) = 7	7	54
Removed from market	132- (106+7) = 25	19	46

From the data provided in Table 22, if Option 3A is implemented, the majority of sport supplement products (106 of 132 products) presented as tablets, capsules and pills will not be affected by the proposal.

Table 23 Estimated number of all products (powders, liquids, novel foods plus tablets, capsules, pills) in pathway options

Pathway action	Total products under Options 2A and 2B	Total products under Option 3
No action required	498(P) + 24(T) = **522**	498(P) + 106(T) = **604**
Reformulate	85(P) + 8(T) = **93**	85(T) + 0(T) = **85**
ARTG entry	33(P) + 54(T)=**87**	33(P) + 7(T) = **40**
Removed from market	40(P) + 46(T)=**86**	40(P) + 19(T) = **59**

P=Powders, liquids, novel foods
T= Tablets, capsules, pills,

Benefits and negative impacts of Option 3

Benefits of Option 3 for industry

The benefits for industry of Option 3 will be the same as for Option 2A, in addition, Option 3 will present a lower level overall regulatory burden for industry when compared to Options 2A and 2B due to products presented as tablets, capsules or pills no longer being included in the declaration. Manufacturers and retailers will be able to continue marketing sports supplements food in medicinal dosage forms.

Negative impact of Option 3 for industry

The negative impacts on industry will be the same as for Option 2A, except that manufacturers of products presented as tablets, capsules and pills will be less affected by the proposal. However, while the proposed section 7 may not apply to these products, many products presented as tablets, capsules or pills carrying therapeutic claims may be deemed to be therapeutic goods on an individual basis through the existing Food-Medicine Interface assessments pathway and so there would remain ambiguity for sponsors and the risk for them to be inadvertently non-compliant with these product types.

Benefits of Option 3 for consumers

Similar to Option 2A, Option 3 will present a considerable improvement for consumers in terms of risk posed by the consumption of sports supplements. Ensuring that scheduled and WADC Prohibited substances are appropriately regulated as therapeutic goods will make consumers more aware of the risks of these substances and be more likely to seek appropriate medical advice both before and after use. Other benefits will be similar to those discussed in Option 2A, with the exclusion of any relating to the inclusion of the dosage form criteria.

Option 3 would see less products withdrawn from the market with a lower impact on consumer choice.

Negative impact of Option 3 for consumers

The negative impacts for consumers will be the same as for Option 2A with an increase in risk exposure of foods presented in medicinal forms containing active ingredients that are not subject to the appropriate manufacturing controls to ensure batch consistency. The risks include batch-to-batch variation, for which the food regulatory framework does not have sample testing requirements, meaning products can be under or over-dosed.

Table 24 summarises the impacts on stakeholders of the implementation of Option 3.

Table 24: Summary of impacts on stakeholders from implementation of Option 3

Stakeholder	Benefits	Negatives
Australian manufacturers	• Clarity of legislation will reduce inadvertent non-compliance. • Increased consumer confidence in safety of Australian products. • Improved enforcement against non-compliant businesses will support others that work to	• Affected products will require reformulation (~85 products), entry in the ARTG (~40 products) or withdrawal from market (~54 products)[13]. • Potential loss of revenue.

[13] Product total from Tables 18 and 19

Stakeholder	Benefits	Negatives
	understand and comply with their regulatory obligations. • Will be able to continue marketing sports supplement foods in medicinal dosage forms.	• Increased regulatory burden if transitioning from food to therapeutic good GMP.
Overseas manufacturers	• Clarity of legislation will reduce inadvertent non-compliance. • Will be able to continue marketing sports supplements food in medicinal dosage forms	• Products determined to be therapeutic goods may be seized at the Australian border. • Loss of revenue.
Consumers	• Reduced exposure to actual and potential risks from sports supplements marketed as foods. • Increased consumer confidence in the food and medicine regulators to effectively regulate goods that pose a potential risk to the safety of consumers. • Reduced risk of consuming adulterated products due to improved enforcement. • Reduced risk to athletes of inadvertent doping due to contaminated/adulterated products. • Still able to purchase food sports supplements products presented in medicinal dosage forms.	• Change in the availability, cost, formulation or presentation of the products available to consumers. • Continued potential risks to consumers from food sports supplements presented in medicinal dosage forms.
Retailers	• Legal clarity if a product they are selling is a therapeutic good. • Reduced risk of inadvertently retailing adulterated products due to improved enforcement. • Will be able to continue selling sports supplements food in medicinal dosage forms	• Change in the availability, cost, formulation or presentation of the products available for retail sale. • Loss of revenue.
Australian Government	• Reduced waste of Government resources and taxpayer's money in pursuing legal proceedings against high-risk products.	• Potential detrimental effect to the Australian economy arising from potential job losses from decreased

Stakeholder	Benefits	Negatives
	• Reduced actual and potential risks to the Australian public from certain sports food supplements. • Reduced society and government costs arising from adverse events.	retailer and manufacturer revenue. • Consumer dissatisfaction that products are no longer available • Continued potential risks to consumers from food sports supplements presented in medicinal dosage forms.

Alternative approaches considered

In addition to the four options listed above, the following alternative approaches were also considered.

Alternative approach 1: Non-regulatory intervention

Alternative approach 1 considered a non-regulatory invention of conducting educational campaigns for product manufacturers to inform them of the appropriate regulatory pathway for their product under existing legislative frameworks, as well as educational campaigns targeted to consumers advising of the potential and actual risks associated with sports supplement use.

Issues arising from the lack of legal clarity for sports supplements at the FMI have been around for some time. In response to these issues, the TGA published an online Food-Medicine Interface Guidance Tool in collaboration with state/territory food authorities in 2014. The tool was designed to take manufacturers and importers through the relevant definitions in the TG Act to determine whether particular products are likely to be therapeutic goods or not. However, since that time, sports supplements that meet the criteria for therapeutic goods (due to their claims, ingredients or presentation) have continued to be marketed as foods, continuing to pose actual and potential risks to public health and it is apparent that the guidance tool did not have the desired effect of increasing regulatory compliance for these goods.

While many manufacturers produce safe sports supplement products that are appropriately marketed as foods or medicines in Australia, it must be recognised that some companies knowingly market supplements as food products, rather than therapeutic goods, to avoid appropriate regulatory scrutiny, even though they contain ingredients that may cause harm. A driver for this behaviour is likely the product revenue to be gained from increased consumer demand for products with a reputation for providing the desired performance enhancement. It is unlikely that a non-regulatory approach will have any effect on this behaviour; timely and effective enforcement action must be enabled in order to compel a segment of industry to adhere to the law.

Attempts at further education campaigns for product owners and stronger enforcement actions will be unable to have the desired outcome without an unambiguous legal clarification of which sports supplements are considered to be food or medicines in law. Until such time, regulatory enforcement options are limited by the ambiguous regulation that applies and those cases that do proceed to legal proceedings are lengthy and costly due to the lack of legal clarity on the status of these products.

In relation to consumer education campaigns, for many years the AIS and ASADA have conducted continual education campaigns targeted at athletes to inform them of the potential

risks of inadvertent doping and health risks associated with sport supplement use. These campaigns are targeted at a narrow range of consumers, with a very high level of self-interest in avoiding inadvertent doping. In spite of these targeted consumer education campaigns, adverse analytical findings resulting from spots supplement use continue to occur at a rate of approximately one athlete per month. Extrapolating such education campaigns to the broader consumer base is considered unlikely to achieve any significant benefit, especially where this is accompanied by the potential for undeclared substances and a hampered enforcement process for non-compliant goods.

This approach was excluded from further exploration, as it was considered it would not address the threat to consumer safety, particularly where it is evident that previous education campaigns have not had success in addressing the problem.

Alternative approach 2: Declare that sports supplements with a broad range of ingredients or presented as medicines are therapeutic goods

Section 7 of the TG Act provides the Secretary the power to declare that goods are or are not therapeutic goods generally, or when used, advertised or presented for supply in a particular manner. Alternative approach 2 proposed making a declaration under the existing authority of section 7 of the TG Act that products meeting the criteria in the text box below would be therapeutic goods.

Alternative approach 2 proposed declaration: Declare that following sports supplements are therapeutic goods

Oral 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/OR

- 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 included in the **WADC Prohibited List**
  - a substance identified in the **Imported Food Notices**
  - a **Relevant** substance (as declared by the Secretary)
  - an ingredient in an amount that exceeds any limit for the ingredient specified in the **Permissible Ingredients Determination**
  - 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**
  - a substance in an amount that exceeds any limit for the substance specified in section **S29—19 of the Food Standards Schedule 29**
- are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill)

The TGA held a public consultation and two workshops on this approach in November to December 2019 and February 2020 respectively. Feedback was received from consumers, retailers, manufacturers, industry representative bodies, medical professionals, sporting bodies and other government agencies.

Stakeholders considered that the scope of ingredients included in the proposed declaration was too broad and raised the following concerns:

- Some legitimate foods may be captured by the criteria, for example:
  - protein bars with high amino acid content (due to exceeding the limits provided in Schedule 29-18 and 29-19 of the Code)
  - products only containing whey protein and glucose (due to containing ingredients that exceed the limits specified in the Permissible Ingredients Determination)
- The WADC Prohibited List:
  - may be subject to change, creating uncertainty
  - bans some substances that are naturally present in food ingredients in sports supplements (for example, IGF-1 in whey protein products)

In consideration of this stakeholder feedback, this approach was excluded due to its likelihood to inadvertently declare some legitimate food products to be therapeutic goods.

Options 2A, 2B and 3 are refined versions of this approach and give consideration to the concerns raised by industry.

Recommended option

In determining the preferred option, greater emphasis has been placed on the degree by which the options would likely address the identified actual and potential safety risks associated with the use of the following sports supplements:

- products which are either non-compliant or illegal (in relation to the ingredients they contain, namely substance included in a Schedule to the Poisons Standard) but are not being sufficiently regulated (due to lack of clarity on their legal status as a food or medicine in current legislation)
- other products which may not be illegal under current legislation, but present a level of risk to consumers (in relation to their ingredients, namely those included in the WADC Prohibited List, or presentation in medicinal form such as tablets, capsules or pills,) such that it is appropriate to mitigate these risks through regulation

Option 1 (status quo) would fail to address the safety concerns and regulatory ambiguity that currently exists. It would fail to resolve the issues relating to product classification (i.e. as either a food or therapeutic good) that make regulatory enforcement actions inefficient and result in prolonged legal proceedings. As the status quo will not address the problem, it is not considered a viable option and has not been considered further.

Table 25 compares the benefits of Options 2A, 2B and 3 and provides the regulatory cost of each option under the proposal as an average annual cost over a ten-year period. These costings have been prepared by Noetic, whose full report is available as Appendix 1. The major regulatory costs associated with the proposed Options 2A, 2B and 3 fall under the activities required to reformulate and list a product in the ARTG and applications that may be required to include an ingredient in the Permissible Ingredients Determination.

Table 25: Comparison of Options 2A, 2B and 3

	Option 2A Products with ingredients of concern or presented as tablets, capsules or pills.	Option 2B Products with ingredients of concern (excluding the WADC Prohibited List) or presented as, tablets, capsules or pills.	Option 3 Products with ingredients of concern (excludes products presented as tablets, capsules or pills).
Risk to consumers from food sports supplements containing **WADC Prohibited substances**	Reduced risk to consumers of inadvertent doping due to inclusion of WADC prohibited substances.	Less reduced risk to consumers of inadvertent doping due to the potential for products to include WADC Prohibited substances not expressly included in the Poisons Standard or in the Relevant substance list	Reduced risk to consumers of inadvertent doping due to inclusion of WADC prohibited substances
Risk to consumers from food sports supplements containing **scheduled substances**	Reduced risk to consumers due to increased ability of regulators to take compliance action against food products containing scheduled substances.	Reduced risk to consumers due to increased ability of regulators to take compliance action against food products containing scheduled substances.	Reduced risk to consumers due to increased ability of regulators to take compliance action against food products containing scheduled substances.
Risk to consumers from food sports supplements presented in **medicinal forms**	Reduced risk to sports supplements presented in medicinal forms, as these will be subject to appropriate manufacturing, testing and labelling requirements.	Reduced risk to sports supplements presented in medicinal forms, as these will be subject to appropriate manufacturing, testing and labelling requirements.	Continued exposure to potential risks from food sports supplements presented in medicinal forms as these will not be subject to appropriate manufacturing, testing and labelling requirements
Provision of **clarity** in legislation	Improved enforcement against non-compliant businesses will support others that work to understand and comply with their regulatory obligations.	Improved enforcement against non-compliant businesses will support others that work to understand and comply with their regulatory obligations.	Regulatory ambiguity remains for sports supplements marketed as foods but presented in medicinal dosage forms. These good will continue to present at the FMI and require evaluation of a product's status on a case by case basis

	Option 2A Products with ingredients of concern or presented as tablets, capsules or pills.	Option 2B Products with ingredients of concern (excluding the WADC Prohibited List) or presented as, tablets, capsules or pills.	Option 3 Products with ingredients of concern (excludes products presented as tablets, capsules or pills).
Effect on Government **resources**	Reduced waste of Government resources in pursuing legal proceedings against high-risk products.	Reduced waste of Government resources in pursuing legal proceedings against high-risk products. Requires significantly greater resources to implement than Option 2A or Option 3.	While there may be a reduction in the waste of Government resources in pursuing legal proceedings against high-risk products, such proceedings may still occur in relation to sports food products in medicinal dosage forms presenting at the FMI
Effect on manufacturer **compliance**	Reduced inadvertent non-compliance.	Reduced inadvertent non-compliance.	There may still be inadvertent sponsor noncompliance due to the ambiguity for food sports supplements presented in medicinal dosage forms.
Effect on products in scope of proposed declaration	Reformulation ~ 93 products Entry in the ARTG ~ 87 products Withdrawal from market ~ 86 products	Reformulation ~ 93 products Entry in the ARTG ~ 87 products Withdrawal from market ~ 86 products These figures may be slightly less as some products may include WADC Prohibited substances that are not yet scheduled or included in the Relevant substance list.	Reformulation ~85 products Entry in the ARTG ~40 products Withdrawal from market ~40 products
Average annual regulatory costs /10 years (Noetic Appendix 1)	$0.22m	$0.22m	$0.12m

Option 2B may provide less regulatory uncertainty for industry but appears to represent the same level of regulatory burden, particularly as the substances from the WADC Prohibited List that are not expressly scheduled may be included in the list of Relevant substance or subject to a scheduling application. Given Australia is a state party to the UNESCO Convention Against Doping in Sport, Australia has a commitment to limit the availability of prohibited substances in in sport that Option 2B may be seen as failing to meet.

Healthcare professionals, government bodies, regulatory bodies, athletes and sports associations strongly favoured the inclusion of products containing WADC prohibited substances in scope of the declaration. However, other consumers, retailers and manufacturer contested that it is a consumer's right to be able to consume such substances, based on their own personal risk/benefit assessment.

Without inclusion of the WADC Prohibited List, implementation of the reform would require considerable Government resources to achieve the same effect, causing Option 2B to be a much less efficient mechanism for achieving the proposal's intent without any considerable increase in benefits to industry or consumers. Rather, there is an increased risk to consumers of unknowing exposure to WADC Prohibited substances until these substances are evaluated by the TGA for inclusion in the Relevant substance list or the Poisons Standard.

Option 3 is not preferred as it is considered that products making therapeutic indications and presented in medicinal forms more closely align with their being regulated under the therapeutic goods framework. These dosage forms are generally used to deliver concentrated amounts of 'active' ingredients and there is a potential for batch variation and accidental overdose if not manufactured safely. Without legal clarity on the jurisdictional responsibility for these products, there will continue to be regulatory uncertainty requiring complex technical FMI assessments thereby delaying action to protect public health when safety concern arises.

Implementation of all the elements of Option 2A will clarify that sports supplements containing certain ingredients (i.e. substances in the Poisons Standard, WADC Prohibited list or Relevant substance list) and/or presented in the form of a tablet, capsule or pill are therapeutic goods in law. Option 2A represents a considered regulatory approach, which has been fully consulted on, that would address many of the safety concerns surrounding the use of sports supplements, while imposing the minimum necessary regulatory burden.

Providing greater clarity for manufacturers and producers of sports supplements will assist them in meeting their obligations, as well as setting a clear standard for Australian supplements that may boost their existing reputation as high-quality products and therefore their desirability in the international market. It also will complement the FSANZ review of the Food Standard and align the approaches of FSANZ and the TGA to the regulation of these products.

The proposal has received broad support from all areas involved in the regulation of food, including the state and territory food regulation authorities, FSANZ and the Department of Agriculture Imported Food Section. It also has the support of health professionals and sporting bodies, including ASADA, as it will provide a safeguard for consumers.

Stakeholder consultation on this proposal identified that there are some legitimate food products that exist in tablet, capsule or pill form for various reasons, such as products with food ingredients encapsulated due to taste (for example spirulina, apple cider vinegar, fermented soy). Many of these examples may not meet the 'therapeutic use in sport' criteria and so would not be affected under the proposal.

Consideration has been given to products (such as glucose tablets) not intended to be included under Option 2A but which may be affected inadvertently. During the consultation process, industry was asked to identify any other relevant examples for consideration, but as no additional products were provided it is assumed there are only a small number of food products that may inadvertently be declared therapeutic goods under the proposal. These products are

considered the exception, rather than the rule, for this product class and dosage form and so are recommended to be managed by exclusion, particularly in light of the safety risks outlined.

Specific efforts will be given to avoiding such products' inclusion under the declaration should the preferred option be implemented.

Taking relevant considerations into account it is considered that Option 2A provides the highest net benefit as it best mitigates the actual and potential safety risks posed by two categories of sports supplements, currently being marketed as foods in Australia, while imposing the minimal necessary regulatory burden.

Implementation and evaluation

Implementation

When designing the implementation and considering the transition approach, the TGA took the following considerations into account:

- The need to implement the changes as quickly as reasonable, while keeping in mind any additional regulatory burden the changes will impose.
- Allowing reasonable time for those manufacturers that are required to obtain compliance for their products, as either foods or medicines.

The consultation period for this work, which commenced in 2019, has already resulted in increased understanding of affected stakeholders.

If a decision is made by the Government to implement Option 2A, the implementation process will include:

Development of the Section 7 declaration instrument

A Section 7 declaration will be drafted and subject to internal and external targeted consultation, the delegate of the Secretary of the Department of Health will make the declaration, which will be a disallowable instrument. The expected publication on the Federal Register of Legislative Instruments and effective date is anticipated to be around August 2020.

Transition

In general, sports supplements that are being supplied in Australia prior to this commencement date, and that would be affected by the proposed reforms, would have the benefit of 3-year transition period to comply with the legislative requirements for foods or medicines, as applicable. The transition period is expected to allow suppliers to use up their stock in trade and help to minimise the disruption of the revised requirements.

For products containing substances of significant safety concerns to consumers (for example, prescription medicine ingredients) the legislation will be applicable from the effective date of the Section 7 declaration, which will enable swift enforcement action by the regulator in the interest of protecting public safety.

Education

The implementation of the proposed reforms would require an education effort from the TGA in collaboration with FSANZ. The TGA will publish guidance material on the TGA website and hold stakeholder workshops/webinars.

The TGA will also work collaboratively with Sport Integrity Australia[14] in providing education to athletes.

An education program will be put in place and resources provided to the ABF to allow for faster decision making on products, which will enable a greater number of products to be assessed and improve compliance in this area.

TGA surveillance program

The TGA will develop an enhanced post market testing laboratory program for sports supplements to identify ingredients of concern and take regulatory action as required.

Evaluation

The purpose of the evaluation will be to assess the impact of the regulatory changes, whether the benefits have been realised, the impact on key stakeholders, and patient safety.

Evaluation will begin from the commencement of the instrument and conclude 1 year after the transition period ends.

Methods

Methods used for data gathering are likely to include:

- formal and informal engagement with stakeholders through consultation and bi-lateral discussions
- analysis of data held in the ARTG and adverse reporting database
- analysis of calls to the TGA Information Line

Stakeholders

Stakeholders that will be consulted as part of the evaluation will include:

- industry associations and peak bodies
- industry—manufacturers and sponsors
- consumers
- health practitioners
- governments, the Department of Health, states and territories

Potential questions

Questions that the evaluation may consider or address include:

- Did the clarification in regulatory scope encompass all of the products of concern?
- Which stakeholders and stakeholder groups did the TGA expect to be impacted by the changes, and did this align with the actual results? For example, did the organisations that now are regulated conform to the regulatory requirements?

[14] On 1 July 2020, Sport Integrity Australia will commence. Sport Integrity Australia will bring together the Australian Sports Anti-Doping Authority (ASADA) the National Integrity of Sports Unit (NISU) and national integrity programs of Sport Australia into one entity

- How effective were the communication and education methods that were employed prior to, and during the implementation?
- How many sports supplement products are now included in the ARTG because of the changes?
- What was the number of adverse events or recalls involving sports supplements post implementation
- How many products were entered the ARTG?
- How many products were removed from the market?
- How many products were reformulated?
- Were there any unintended consequences for manufacturers, sponsors, retailers or consumers?
- Did the regulatory burden align with the estimates? If not, where did they differ?
- Was there a perceived change in consumer confidence in the safety and performance of sports supplements because of the changes?
- How many market samples did the TGA carry out? What were the overall results of these?
- What have the impacts been on the broader community – for example has this promoted the growth of Australian manufacturers and innovation in this area?

Table 26: Estimated timeframe

Activity	Estimated date
Government decision	~ August 2020
Drafting of section 7 declaration	~ August 2020
Publication of declaration	~ September 2020
Declaration comes in to effect	~ September 2020
Legislation applicable to products containing substances of concern (included in the Poisons Standard or in the WADC prohibited list)	From effective date of instrument ~ September 2020
3 year transition commences for products (other than those with ingredients of concern)	From effective date of instrument ~September 2020
Enhanced post market testing of sports supplements– regulatory action taken a required	From effective date of instrument ~September 2020- ongoing

Activity	Estimated date
Education campaign in collaboration with FSANZ and Sport Integrity Australia[15]: • Education material and notices on TGA website • Sponsor workshops/webinars	~September 2020- ongoing
Transition period ends	~September 2023
Evaluation	~September 2020 – ~September 2024

[15] On 1 July 2020, Sport Integrity Australia will commence. Sport Integrity Australia will bring together the Australian Sports Anti-Doping Authority (ASADA) the National Integrity of Sports Unit (NISU) and national integrity programs of Sport Australia into one entity

Appendix 1 Regulatory Burden costings

30 June 2020

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BACKGROUND

In Australia there is currently confusion for both manufacturers/brand owners and consumers as to how sports supplements are regulated, as different regulatory frameworks may apply (either the Australian New Zealand Food Standards Code or the) to a single good at any given time. As such, the Therapeutic Goods Administration (TGA) has proposed a regulatory clarification to provide greater clarity around the categorisation of sports supplements and the related regulation framework, specifically for those products that should be regulated as a therapeutic good rather than as a food.

PURPOSE OF THIS REPORT

The purpose of this report is to provide a quantification of the regulatory impact of the proposed clarification to the regulation of sports supplements to inform the Regulation Impact Statement (RIS) prepared by the Department of Health.

APPROACH

The modelling detailed in this report was conducted in accordance with the Office of Best Practice Regulation's (OBPR) guidance for the calculation of regulatory costs. Noetic Group (Noetic) engaged directly with a range of industry representatives (retailers, manufactures, sponsors etc.), relied on advice provided by the Department and other Government agencies and their own professional judgement to determine the time taken to undertake the activities associated with the implementation of the proposed regulatory clarification.

CONCLUSION

As per OBPR guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost. The following table provides the average estimated regulatory compliance costs arising from the proposed regulatory clarification.

Table ES1. Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) ($million)				
Change in costs	Business $	Community Organisation $	Individual $	Total change in costs
Option 1				
Status quo: Current food and therapeutic goods regulatory frameworks are appropriate - no clarification is required				
Option 2A				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (includes WADC Prohibited List)	$0.22m			$0.22m
Option 2B				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (excludes WADC Prohibited List)	$0.22m			$0.22m
Option 3				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (excludes presentation of sports supplements as pills, tablets and capsules)	$0.12m			$0.12m

GENERAL

BACKGROUND

Sports supplements may be regulated as either a food or a medicine depending on the applicability of criteria and definitions outlined in the Australian New Zealand Food Standards Code and the (TG Act) The TG Act defines therapeutic goods as those that are likely to be taken to influence, inhibit or modify a physiological process in persons, unless, in the absence of a relevant declaration under section 7 of the TG Act, there is an existing food standard for these goods. This exception materialises in the form of Food Standard 2.9.4, which states that a product that is 'specifically formulated to assist sports people in achieving specific nutrition or performance goals'[2] can also be classified as a food; convoluting the appropriate regulatory pathway for products that sit within the food-medicine interface (FMI).

Whether a product is classified as a food or medicine in law can depend on ingredients, claims and overall presentation (powder, pill, capsule etc.); however, a product cannot be classified as both a food and medicine simultaneously. 'Sports supplements' encompass a broad range of products that often blur the lines between food and medicine classification. Some of these products claim to provide therapeutic benefits (and thus are likely to be marketed and consumed for therapeutic use) yet may still be considered food under law.

The TGA's proposed regulatory clarification aims to establish greater clarity around the categorisation and regulation of sports supplements. In October 2019, the TGA released a public consultation paper outlining the proposed regulatory clarification. This clarification entailed pre-market quality and safety assessments (largely via self-assessment by the sponsor), stricter evidentiary requirements for therapeutic claims, revised advertising and labelling, appropriate use of ingredients (in relation to substance and quality) and ongoing regulatory oversight by the TGA. The proposed clarification generated a fair amount of concern in the sports supplements sector, resulting in considerable media attention and public response. One such response was the formation of a grass roots campaign 'Save Aussie Supplements', which pushed for more consultation around the proposed clarification (the campaign had collected 14,000 signatures in support by mid-December 2019). The campaign made claims linking the clarification to the withdrawal from sale of a large number of products from the Australian market and the potential loss of tens of thousands of jobs across the country.[3]

After consideration of submissions to the public consultation paper and feedback from two stakeholder workshops held in Sydney and Melbourne in February 2020, the proposal was refined to clarify the intent of the reform and avoid unintentionally capturing food products (such as whey protein, sugar substitutes and meal replacement shakes). Specifically, the following changes were made to the proposed draft declaration:

- Exclude from the scope of the declaration products containing substances in excess of the limits provided in Schedule 29-18 and 29-19 of the Food Standards Code.
- Exclude from the scope of the declaration products containing ingredients exceeding the limits specified in the Permissible Ingredients Determination.

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[1] https://www.legislation.gov.au/Details/C2020C00028>.

[2] 'Australia New Zealand Food Standards Code – Standard 2.9.4 – Formulated supplementary sports foods', see <https://www.legislation.gov.au/Details/F2017C00336>.

[3] See <https://www.saveaussiesupplements.com.au/faqs/>.

Clarify that substances included in the World Anti-Doping Code (WADC) Prohibited List, the Poisons Standard, or the relevant substances list, are in-scope of the declaration only if the substances are added as ingredients to the formulation of the products (to avoid capturing products which contain these substances only because they are naturally present in other ingredients in the product).[4]

These changes addressed some of the key stakeholder concerns.

Summary of proposed regulatory clarification

The proposed regulatory clarification (Option 2A) sets out the following criteria for products in-scope of the proposed draft declaration:

Products for oral administration that claim to improve or maintain physical or mental performance in sport, exercise or other recreational activity (e.g. gaming)

AND either

A. contain ingredients that are not appropriate for food:

a substance included in a schedule to the Poisons Standard

a substance that is prohibited from sport under the World Anti-Doping Code

a substance that the Secretary or their delegate includes in the list of relevant substances.

OR

B. are presented in a form associated with medicines rather than foods (i.e. a pill, capsule or tablet).[5]

Transition period

While a formal transition period has not been announced[6], for the purpose of preparing the regulatory costing, Noetic has assumed a three-year transition period[7] from 1 July 2020 to 30 June 2023.

PURPOSE OF THIS REPORT

The purpose of this report is to provide a quantification of the regulatory impact of the proposed clarification to the regulation of sports supplements to inform the Regulation Impact Statement (RIS) prepared by the Department of Health.

[4] For example, Insulin Like Growth Factor-1 (IGF-1) is found in cow's milk and thus included in many whey proteins products.

[5] TGA, 'Update on proposed clarification that certain sports supplements are therapeutic goods', viewed 2 April 2020, < https://www.tga.gov.au/update-proposed-clarification-certain-sports-supplements-are-therapeutic-goods>.

[6] TGA has publicly stated that, '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', TGA, presentation delivered by Adjunct Professor John Skerrit to the February 2020 stakeholder workshops titled 'Regulation of sports supplements – proposal and consultation', see < https://www.tga.gov.au/sites/default/files/tga-presentation-regulation-sports-supplements-proposal-consultation.pdf>.

[7] The proposed transition period of up to three years (the duration of which will be decided by the Minister) will not apply to products that contain ingredients that are present on the Standard for the Uniform Scheduling of Medicine and Poisons (SUSMP), commonly known as the 'Poisons Standard', as such ingredients represent the greatest risk to consumer safety.

APPROACH

The modelling detailed in this report was conducted in accordance with the Office of Best Practice Regulation's (OBPR) guidance for the calculation of regulatory costs[8] and the approach was briefed and agreed in principle by the OBPR.

The below activities were undertaken to inform the development of the Regulatory Costing:

- undertook desktop research to understand the baseline regulatory activity (noting a large portion of sport supplement products are currently regulated as foods)
- identified changes to the regulatory baseline (on an activity basis), focusing on administrative and substantive compliance costs
- identified regulatory touch-points for the proposed change to regulation (including second-order touch-points necessary to achieve the sought outcomes of the proposed regulatory clarification)
- determined the respective populations impacted by identified touch-points (i.e. Sponsors, Manufacturers etc.) and mapped pathways and requirements (i.e. leave market, change product etc.)
- utilised existing and developed new datasets (via desktop review of online product catalogues) to determine current and future (growth) population numbers and to quantify frequency and time required for each activity
- determined the impact of the proposed transition period and assessed how this aligns to normal business product refresh cycles (e.g. how often product labels are redesigned/printed)
- determined appropriate labour costs using the Australian New Zealand Standard Industrial Classification (ANZSIC) groupings.

The above activities were supported by various consultation activities with both industry and government representatives. These activities were undertaken to gain further information, identify likely business response pathways and to test and validate some of Noetic's assumptions. Key stakeholder engagement activities included:

- In October 2019, the Department released a public consultation paper outlining the proposed regulatory clarification and Noetic reviewed key submissions provided to Noetic by the Department.
- Noetic facilitated (with the Department attending) two ½ day stakeholder workshops in Sydney and Melbourne in February 2020.
- Noetic conducted a series of stakeholder interviews with manufacturers, retailers and industry associations in March 2020 (see Annex C) with a focus on understanding the likely response by industry to the proposed regulatory clarification and the potential in-scope population of products.
- Regular engagement occurred with Departmental staff in the Complementary & Over the Counter Medicines Branch to discuss and obtain feedback on progress; seek advice or direction regarding assumptions, qualifications and inputs; and communicate and resolve challenges.
- Noetic also engaged with representatives from the Department of Health's National Integrity of Sport Unit, the Australian Sports Anti-Doping Authority (ASADA) and Food Standards Australia New Zealand (FSANZ) via a series of meetings (and attendance at the stakeholder workshops).
- One teleconference with the OBPR (attended by both Noetic and the Department) in March 2020 to confirm the proposed approach and seek advice or direction regarding assumptions, qualifications, and inputs, which was followed by a further teleconference with OBPR to discuss a preliminary draft report in May 2020.

[8] Department of the Prime Minister and Cabinet, 'Regulatory burden measurement framework guidance note', 30 March 2020, see <https://www.pmc.gov.au/resource-centre/regulation/regulatory-burden-measurement-framework-guidance-note>.

Noetic relied on advice provided by the Department and previous regulatory costings for the quantification of existing regulatory activities (albeit applied to a new population of sponsors and manufacturers), such as the regulatory burden arising from listing a product in the Australian Register of Therapeutic Goods (ARTG).

Specifically, Noetic has considered the following options in the preparation of these regulatory costings:

Option 1 (Status quo option): No clarification of the therapeutic goods regulatory framework is required; the current food and therapeutic goods regulatory frameworks are appropriate.

Option 2A (Includes Word Anti-Doping Code (WADC) Prohibited List): Declare that sports supplements are therapeutic goods if they:

contain ingredients that are not appropriate for a sports supplement food:

a substance above the restrictions provided in the Poisons Standard

a substance that is included in the WADC Prohibited List

a relevant substance as declared by the Secretary of the Department of Health (the Secretary);

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

Option 2B (Excludes Word Anti-Doping Code (WADC) Prohibited List): Declare that sports supplements are therapeutic goods if they:

contain ingredients that are not appropriate for a sports supplement food:

a substance above the restrictions provided in the Poisons Standard

a relevant substance as declared by the Secretary;

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

Option 3 (Excludes the presentation of sports supplements as tablets, capsules or pills): Declare that sports supplements are therapeutic goods if they:

contain ingredients that are not appropriate for a sports supplement food:

a substance above the restrictions provided in the Poisons Standard

a substance that is included in the WADC Prohibited List

a relevant substance as declared by the Secretary.

From a regulatory costing perspective, there was not considered to be any material change to the arising regulatory burden between options 2A and 2B due to the high correlation between the substances listed on the Poison Standard[9] and the WADC Prohibited List, which is unsurprising given the consumer safety focus of both documents.[10] [11] While there is no material change to the regulatory burden between options 2A and 2B, this option has been put forward to address

[9] The current Poisons Standard is SUMSP No.27, February 2020.

[10] The WADC Prohibited List may include any substance and methods that satisfy any two of the following three criteria: 1) It has the potential to enhance or enhances sport performance; 2) It represents an actual or potential health risk to the Athlete; 3) It violates the spirit of sport (this definition is outlined in the Code). WADC, 'Prohibited List Q&A', viewed 2 April 2010, < https://www.wada-ama.org/en/questions-answers/prohibited-list-qa>.

[11] It is noted that there are some substances present on the WADC Prohibited List that are not currently included in the Poisons Standard, as no application has been made to have them considered for scheduling. An example is Higenamine (a prohibited Beta-2 Agonist) - an ingredient in some pre-workout products. This results in a slightly increased regulatory burden for Option 2A, when compared to Option 2B, as manufacturers/brand owners would need to be aware of the ingredients listed in both the WADC Prohibited List as well as the Poisons Standard. However, noting that the Poisons Standard is approximately 700 pages in length, it is assumed that manufacturers/brand owners (or advising regulatory consultants) will be using key word searches for both documents to check their ingredients name (as well as any synonyms). As detailed in the RIS proper, the key determinant for the inclusion of Option 3 was not related to a change in the regulatory burden but rather in response to stakeholder concerns about the incorporation of the WADC Prohibited List into the TGA's regulatory framework.

stakeholder concerns about the legitimacy of the WADC Prohibited list and its incorporation (as a list developed by an international body that is subject to change) in the Australian regulatory framework.

Changes to the regulatory burden between options 2A (and 2B) and Option 3 were largely incurred due to the difference in product and sponsor populations.

THE REGULATORY COSTING

COSTING MODEL

The development of the regulatory costing model was undertaken in accordance with the OBPR Guidance Note: 'Regulatory Burden Measurement Framework'[12], dated March 2020. Costs were estimated for the compliance burden arising from the proposed regulatory clarification.

The labour cost formula was used to determine the compliance costs (administrative and substantive):

> price x quantity (or in its more expanded version: (Time required × Labour cost) × (Times performed × Number of businesses or community organisations × Number of staff)).

As detailed earlier in this report, various engagement activities have been undertaken to identify the first- and second-order touchpoints for stakeholder groups to allow the arising regulatory burden to be quantified.

Labour Cost

The Australian Bureau of Statistics (ABS) publishes 'Average Weekly Earnings' semi-annually. As at 3 April 2020, the latest dataset is November 2019.[13] Given that sponsors or manufacturers could be based in any state/territory, the national dataset was used. The relevant table is Table 10H ('Average Weekly Earnings, Industry, Australia (Dollars) - Original - Persons, Full Time Adult Total Earnings' (includes overtime)). Two Australian and New Zealand Standard Industrial Classification (ANZSIC) divisions were considered by Noetic as being relevant to the particular activities being costed:

1. Professional, Scientific and Technical Services (ANZSIC Division M).

   Industry subdivisions are: Professional, Scientific and Technical Services (Except Computer System Design and Related Services), and Computer System Design and Related Services.

   For November 2019, the figure for weekly earning is $1910.00.

2. Health Care and Social Assistance (ANZSIC Division Q).

   Industry subdivisions are: Hospitals, Medical and Other Health Care Services, Residential Care Services, and Social Assistance Services.

   For November 2019, the figure for weekly earning is $1645.80.

It was assessed by Noetic that the Professional, Scientific and Technical Services was the more appropriate industry division because it is the division most likely to include the regulatory staff employed by the businesses who would undertake the sponsor/manufacturer activities required by the TGA.

For November 2019, the figure for weekly earnings is therefore $1910. To determine the average hourly cost, this figure is divided by the average number of total hours worked (includes overtime) for full-time non-managerial employees (the 'All Industries' category has been used) (39.40

[12] Department of the Prime Minister and Cabinet, 'Regulatory burden measurement framework guidance note', 30 March 2020, see <https://www.pmc.gov.au/resource-centre/regulation/regulatory-burden-measurement-framework-guidance-note>.

Australian Bureau of Statistics, 6302.0 - Average Weekly Earnings, Australia, November 2019, viewed 2 April 2020, <https://www.abs.gov.au/ausstats/abs@.nsf/0/7F76D15354BB25D5CA2575BC001D5866?Opendocument >.

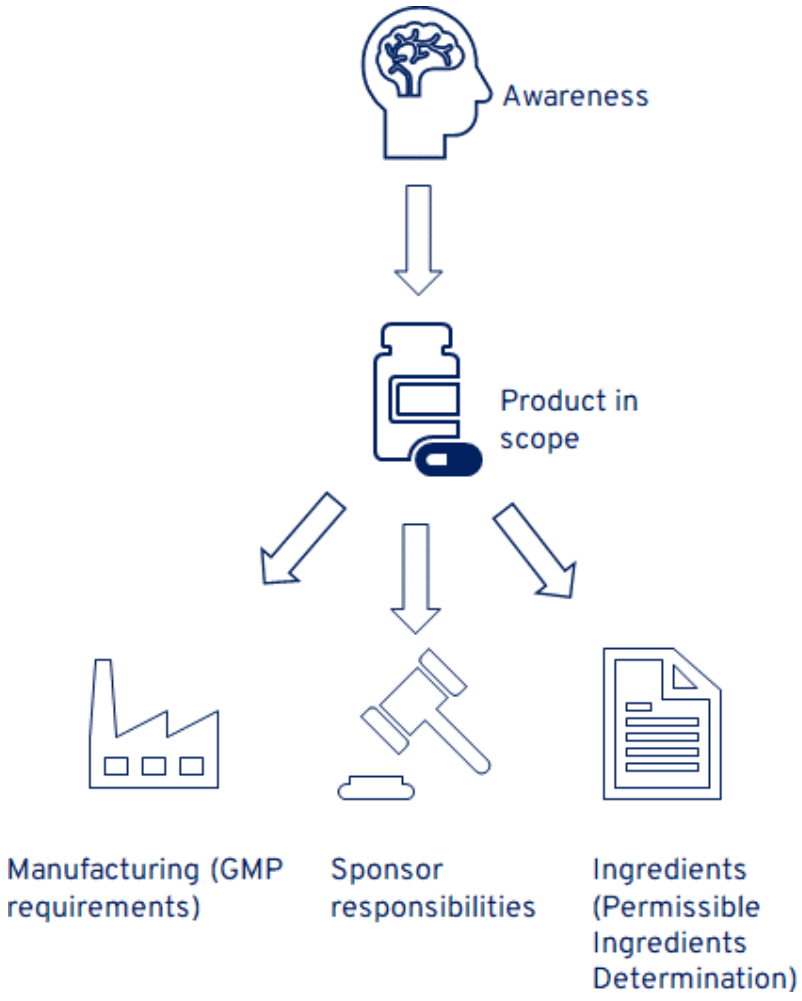
hours).[14] In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the non-wage labour on-costs and overhead costs. The arising calculation is shown below.

($1910/39.40)*1.75 = $84.84[15]

Regulatory impact

The figure below details the key element considered in the regulatory impact analysis.

Figure 1. Overview of regulatory impact analysis



Australian Bureau of Statistics, 6306.0 - Employee Earnings and Hours, Australia, May 2018, <https://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/6306.0May%202018?OpenDocument >.

[15] By way of comparison, the suggested hourly labour rate by OBPR is $73.05 as compared to a value of $84.84 as calculated above.

All sports supplements manufacturers and retailers in Australia[16] will need to be aware of the proposed regulatory clarification. This awareness will include a general awareness that is not product specific, noting that an analysis, perhaps requiring advice from a regulatory affairs consultant,[17] will be required for each potentially in-scope product to determine the applicability of the proposed regulatory clarification.

The potential change in the regulation of certain sports supplements may also impact upon the decisions made by sports dietitians (and similar health professionals, including sport and exercise physicians) to recommend/prescribe certain substances to their clients/patients. Likewise, the potential reclassification of certain sports supplements from a food to a therapeutic good may also influence the purchasing decisions by consumers. However, it was considered that these parties would already have been considering the appropriateness of product use based on the individual's need and risk profile. Therefore, it is considered that the proposed regulatory clarification will not have a material impact upon the regulatory burden of these parties from an awareness perspective.

In Australia, food manufacturers and retailers are responsible for complying with the food safety standards (of which standards 3.1.1. (Interpretation and Application), 3.2.2 (Food Safety Practices and General Requirements) and 3.2.3 (Food Premises and Equipment) are mandatory for all food businesses). These standards are detailed in the 'Safe Food Australia' guide, which is aimed primarily at the state and local government agencies responsible for enforcing the standards. This is because the food standards that comprise the (the Code) are applied in Australia by state and territory food laws – noting that it is these laws that make the failure to comply with the Code requirements an offence.[18]

Food manufacturers may also seek to be certified under the Hazard Analysis Critical Control Point (HACCP) food safety program or ISO 22000, which sets out the requirements for a food safety management system. Additionally, those food manufacturers exporting products to the United States of America will need to be audited against the Food and Drug Administration (FDA) Current Good Manufacturing Practice (CGMP) regulation for food.[19] [20]

Within Australia, manufacturers of medicines (including complementary, over-the-counter and prescription) and biologicals must hold a TGA manufacturing licence. To obtain this licence the manufacturer must demonstrate compliance with the relevant GMP requirements, while overseas

[16] Impact on overseas entities not operating or seeking to operate in Australia are excluded from a regulatory costing. See Regulatory Burden Measurement Guidance Note, p.5.

[17] While it is acknowledged that regulatory affairs consultants for both the food and therapeutic goods sectors will need to be aware of the proposed regulatory clarification, their key value proposition is their currency with the respective regulatory frameworks which are frequently changed, and hence it is expected that they would be regularly reviewing changes (and proposed changes) to the regulatory frameworks. Therefore, it is considered a non-material increase in regulatory burden from an awareness perspective for regulatory affairs consultants.

[18] At the Commonwealth Level, the Commonwealth Department of Agriculture, Water and the Environment administers the , which applies the food standards to imported food.

[19] Code of Federal Regulation (CFR) Title 21 – Food and Drugs, Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food.

[20] The FDA has three distinct CGMP systems – food (CFR Title 21 Part 110), dietary supplements (CFR Title 21 Part 111), and pharmaceuticals (CFR Title 21 Part 211).

manufacturers of medicines supplied in Australia are also required to meet an acceptable standard of GMP. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme (jointly known as PIC/S) have developed international standards between countries and pharmaceutical inspection authorities to provide a harmonised approach to GMP. [21] The sections of the PIC/S guide that apply will be determined by the nature of manufacturing operations and the types of products and dosage forms manufactured.[22] Australian sponsors may also import products from overseas manufacturers who meet the TGA's GMP requirements via either the Mutual Recognition Agreement (MRA) GMP clearance pathway or the Compliance Verification (CV) GMP clearance pathway.[23]

While there is a relatively high correlation between the elements of the Food Safety Standards and the PIC/S, the PIC/S are more prescriptive in relation to quality systems and associated staff training, as well as fit-out aspects. These fit-out aspects include maintaining positive air pressure to avoid contamination and cross-contamination and hence require a higher capacity heating, ventilation and air-conditioning system (HVAC) than for food manufacturing. As such, additional capital expenses and ongoing expenses are required to obtain and maintain a TGA manufacturing licence than to meet the Food Safety Requirements or obtain FDA CGMP for food production.

In relation to GMP manufacturing, the options (as determined by stakeholder comments and possible pathway analysis) for potential sponsors[24] [25]are detailed in the figure below.

Figure 2. Manufacturing options for potential sponsors

In relation to industry intentions, some businesses will already have a TGA manufacturing licence or are utilising a contract manufacturer who holds a current TGA manufacturing licence/GMP certification. Industry has advised Noetic that some manufacturers operate separate production lines for therapeutic goods and food (perhaps even within the same facility), while other manufacturers will produce food products under TGA pharmaceutical grade GMP standards. In the first instance, there may be additional capacity for former food products to be produced using the therapeutic goods production facility.[26] In the second instance, there may be some additional operating expenses incurred, such as additional batch testing and a more rigorous equipment cleaning regime required when switching between batches when manufacturing therapeutic goods as opposed to food. Additionally, some manufacturers may already have been proceeding down obtaining a TGA manufacturing licence pathway prior to the announcement of

[21] The extant PIC/S guide is 'Guide to Good Manufacturing for Medicinal Products', PE 009-13 dated 1 January 2017 except for annexes 4 (Manufacture of veterinary medicinal products other than immunologicals), 5 (Manufacture of immunological veterinary medical products) and 14 (Manufacture of medicinal products derived from human blood or plasma), which have not been adopted by Australia.

[22] Manufacturers of finished dosage forms follow the principles of Part 1 and relevant annexes, while manufacturers of active pharmaceutical ingredients follow the principles of Part II and relevant annexes. For example, Annex 7 relates to the Manufacture of Herbal Medicinal Products.

[23] The MRA GMP clearance pathway is open only to Canada, EU members states, New Zealand, Singapore and Switzerland, while evidence from the US FDA for GMP clearance applications will be accepted only for the CV pathway.

[24] As at 30 June 2019, there were 254 Australian companies holding manufacturing licences covering 396 sites. Refer to TGA, Annual Performance Statistics Report: July 2018 to June 2019, p.58.

[25] As at 30 June 2019, there were 141 overseas manufacturers covering 164 manufacturing sites that were subject to TGA inspection (CV GMP clearance pathway) and approximately 2,600 overseas manufacturing sites that relied on evidence from recognised regulators (MRA GMP clearance pathway). Refer to TGA, Annual Performance Statistics Report: July 2018 to June 2019, p.58.

[26] Industry has advised Noetic that many if not most Australian GMP facilities are already operating at capacity as well as having minimal order quantities that might be cost prohibitive for smaller retailers due to the switch-over costs (such as cleaning) required for pharmaceutical manufacture.

the regulatory clarification.[27] Stakeholders detailed several factors for why they were already proceeding (or planning to proceed) down the TGA manufacturing licence pathway, such as ability to produce a wider range of products (food and therapeutic goods), broader contracting/commercial opportunities, and consumer demand for higher quality (ingredients and production) products. It was noted that some of these pathways may result in additional capital investment in new equipment. This would, however, be a business decision to do so (arising from a number of factors (some identified above)) and cannot be attributed solely to the regulatory clarification. Therefore, obtaining a new TGA manufacturing licence has been excluded from the regulatory burden costing for the following population groups:

- those manufacturers/sponsors who already hold a TGA manufacturing licence/GMP certification will not incur any additional regulatory costs in relation to obtaining a TGA manufacturing licence/GMP certification
- those manufacturers who were already proceeding down the pathway to obtain a TGA manufacturing licence/GMP certification will most likely continue to do so and this action, while likely influenced by the proposed regulatory clarification, would also likely have occurred in its absence – so no direct regulatory costs arise
- no evidence was provided to Noetic of existing food manufacturers who, because of this specific regulatory clarification, would now seek to obtain a TGA manufacturing licence.

The identified pathways (and related regulatory burdens) were tested with a range of businesses, across a broad continuum of manufacturing status (already TGA licenced facility, transitioning to TGA licenced facility or not currently TGA licenced facility). Stakeholders validated that the most likely reaction to the proposed regulatory clarification by sponsors who wish for their sport supplements products to be listed in the ARTG is to use an existing TGA licenced manufacturing facility/GMP certified manufacturing facility (capacity issues notwithstanding). It was concluded that no business was forced to transition to a TGA licenced manufacturing facility based purely on the regulatory changes, but that if they were to go down that pathway it would be a business decision to do so. It is possible that additional demand for TGA licenced manufacturing facilities may create favourable business conditions/opportunities for new entrants, but to proceed down this pathway would also be a business decision. Such a decision is not directly related to this regulatory clarification, as a TGA licenced contract manufacturer would most likely be able to produce a wider range of products, including existing complementary medicines (such as vitamin, mineral, herbal, aromatherapy and homeopathic products), and not purely sport supplements products.

It has been assessed that the factors detailed above (that is, no new TGA manufacturer licences sought that directly arise from the proposed regulatory clarification) are constant over the default ten-year period for the regulatory costing. Likewise, it is assessed that no new GMP facilities will likely be added as a direct result of the proposed regulatory clarification, regulatory costs arising from TGA inspections of existing and future GMP facilities are also excluded from the regulatory costing.

Nil additional regulatory costs incurred in relation to the requirements for therapeutic products to be manufactured in a TGA licenced manufacturing facility arise from the proposed regulatory clarification.

[27] Noetic notes from site visits to supplement retailers and pharmacies (as well as a review of listed medicines on the ARTG) that some sports supplements are already AUST L. Noetic's understanding is that these products have been listed on the ARTG due to the nature of the therapeutic claims that can be made, which are more precise in their therapeutic nature than the nutrition and health claims that can be made under Australia New Zealand Food Standards Code – Standard 1.2.7 – Nutrition, health and related claims. Noetic further notes that under this standard there are 13 pre-approved food-health relationships that underpin high level health claims detailed in Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims (e.g. beta-glucan products can claim a specific health effect of 'reduced blood cholesterol' and folic acid (but not folate) can claim a specific health effect for women of child-bearing age of 'reduces risk of foetal neural tube defects').

It is noted that although the costings outlined in this section are common across options 2A and 2B only, the majority of the impacts outlined (timings and requirements) are also common for Option 3.

Noetic notes that there are currently a number of sport supplements that are already listed in the ARTG[28], though these tend to be more in the 'fat burner' rather than 'pre/post-workout' product categories. For such products there will be no increase in regulatory burden arising from the proposed regulatory clarification. For other products, they will be impacted by the proposed regulatory clarification if they make a therapeutic claim relating to improving or maintaining physical or mental performance in sport, exercise or other recreational activity AND contain substances that are not appropriate for foods[29] OR are presented in a form associated with medicines rather than foods (i.e. a tablet, capsule or pill).

Manufacturers/retailers of sports supplements captured by the proposed regulatory clarification are presented with three broad response options (see the figure below).

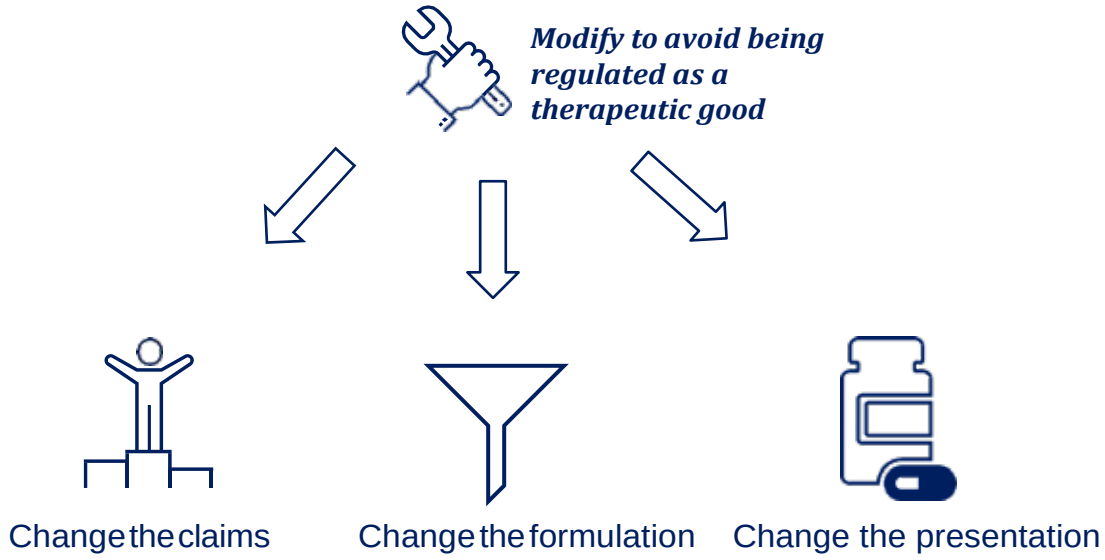
Figure 3. Broad responses to regulatory clarification

In relation to modifying the product to avoid being regulated as a therapeutic good, industry also has three broad options (see figure below).

[28] For example, ARTG ID 321750 is for Hydroxycut Hardcore (a listed medicine), with the sponsor of Iovate Health Sciences Australia Pty Ltd with permitted indications of 'enhance/promote energy levels' and 'helps enhance/promote calorie burning'; and ARTG ID 227714 is for FatBlaster Max (a listed medicine), with the sponsor of Cat Media Pty Ltd and permitted indications (among others) of help improve/promote body metabolism/metabolic rate and enhance/improve/promote/increase mental endurance/stamina.

[29] That is, a substance above the restrictions provided in a schedule to the Poisons Standard, ingredient that is banned by the WADC (Option 2A and 3 only) or a substance listed on the Relevant substance list (as declared by the Secretary)

Figure 4. Broad options for modifying the product to avoid regulatory capture



Industry stakeholders have commented to Noetic that they are unlikely to seek to modify the product claims[30], as these are integral to the product's positioning in the marketplace. That is, the product category is clearly identified as 'pre-workout' or 'fat burner' (for example) and to claim otherwise would confuse consumers as to the product's purpose. Therefore, if they seek for the product to remain regulated as a food, they either need to remove the ingredient(s) that 'trip the therapeutic goods wire' or change how the product is presented.

Industry advice to Noetic is that the approach to be taken very much depends on where the product sits along a continuum of product substitution. That is, non-premium products that generally have low profit margins and that are powders or other traditional food presentations (such as bars) would most likely seek to reformulate to remove the ingredients in question. The key driver of this response was the additional costs that would arise from GMP manufacturing relative to the high price elasticity of demand and existing low profit margins, meaning increases in the Costs of Good Sold (COGS) would need to be passed onto consumers.

There were some indications from industry that high profit, premium products may go down the ARTG listing pathway. It was commented that there is a high degree of uncertainty as to the extent of the need to add ingredients to the Permissible Ingredients Determination. Industry noted that there are a number of relatively common ingredients used in the manufacturing of sports supplements that are not present on the Permissible Ingredients Determination – as this list largely relates to the ingredients used in existing complementary medicine products, such as vitamins.

Additionally, some ingredients may be of a risk profile that is not suitable for inclusion on the Determination and rather would be present in Schedules 3/4 of the Poisons Standard and therefore can be sold only in pharmacies (Schedule 3) or require a prescription (Schedule 4) and not by sports supplement retailers. Noetic's sense is that a minority of products will proceed down the ARTG listing pathway, with the likely industry reaction, if not feasible from a production or marketing perspective to reformulate, to no longer offer the product for sale in Australia.

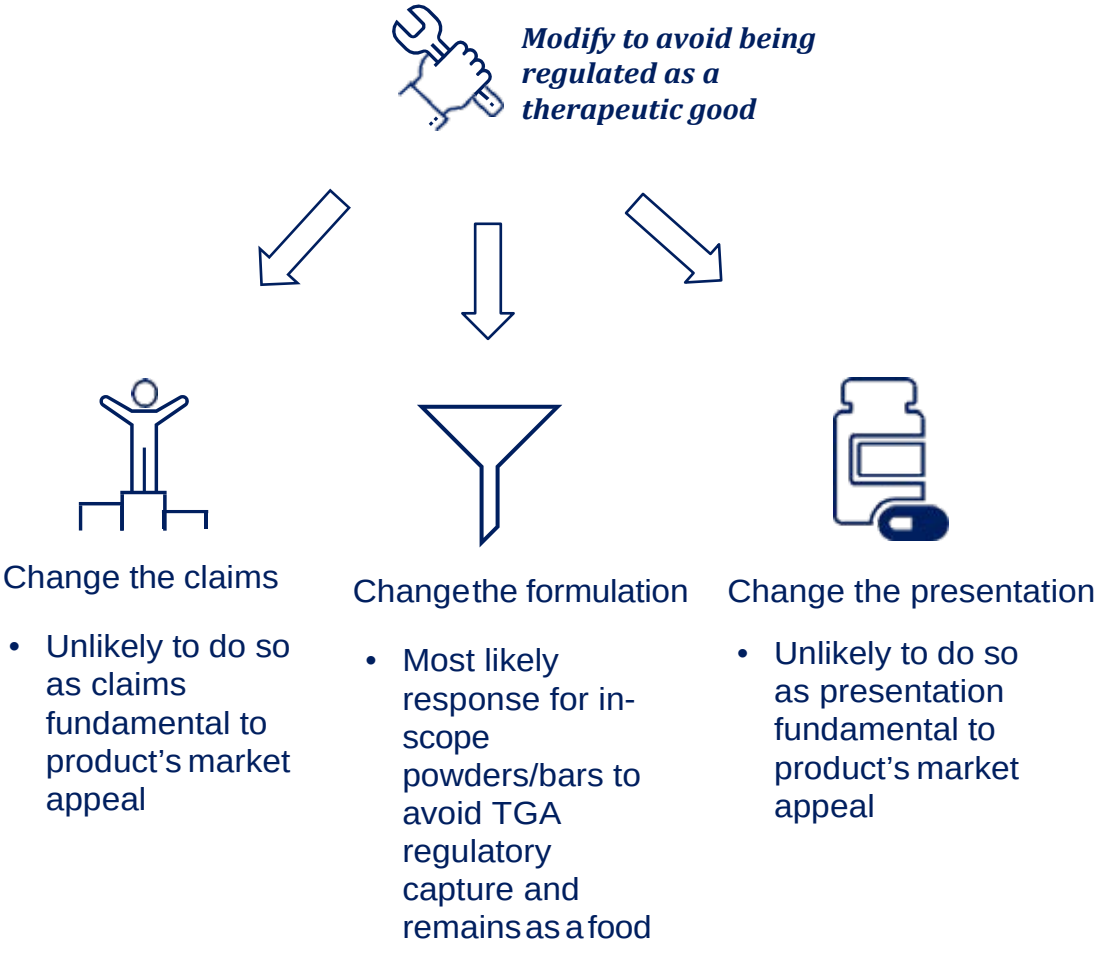
For those products that are currently presented in a form such as a capsule, while it is possible for these products to be reformulated and presented as a powder or another traditional food form, industry advice is that they are unlikely to go down that pathway. This is principally because the product is sold as a pill/capsule due to consumer demand related to convenience of consumption (i.e. they do not need to mix the product with liquid for consumption – as is the case with a powder)

[30] Noting that if the claims do not accord with Australia New Zealand Food Standards Code – Schedule 4 – Nutrition, health and related claims then it would be considered a non-compliant food rather than specifically a therapeutic good.

or because of the precise portion control, which provides the consumer with more certainty as to dosage, or perhaps due to the taste (noting that powders generally need to taste better than capsules). It is possible that some novel presentations, such as a gel, strips, vials, could be adopted but there exists uncertainty as to whether this would be considered more closely aligned to a traditional food presentation as opposed to a therapeutic use presentation.

Again, industry advice to Noetic is that due to the cost of obtaining and maintaining an ARTG listing a number of products will no longer be made available for sale in Australia, though it is likely that a higher proportion of in-scope products presented as pills/capsules rather than powders/bars will proceed down the ARTG pathway. This is principally due to the need to change the fundamental nature of the product, rather than reformulating to remove ingredients of concern, as is the case for powders/bars. The likely industry responses, from a product perspective, to the proposed regulatory clarification are detailed in the figure below.

Figure 5. Likely industry responses



As sports supplements to date have largely been regulated in the food space (under FSANZ Standards and regulated by individual States and Territories), the current population of products is mostly not listed and/or registered with the TGA (in the ARTG) nor is there an equivalent data set for FSANZ/State and Territory food products. Noetic therefore needed to create a product dataset.

Noetic consulted several industry reports[31] which detailed that the dominant market player for sales from both physical stores and online was Grubie Pty Ltd (trading as Nutrition Warehouse(NW)). A meeting with Nutrition Warehouse senior executives revealed that their key competitors were Elite Supplements (ES) and Australian Sports Nutrition (ASN)[32] and that the product categories most likely to be impacted by the proposed regulatory clarification were 'pre-workout', 'fat burner' and 'post-workout'/'recovery' products. In order to develop an inclusive data set, Noetic visited each retailer's website and collected details for all products listed under these categories. As of 25 March 2020, ASN had the largest product range (n=362), followed by NW (n=346) and ES (n=213). The breakdown of product across categories is detailed in the table below.

Table 1. Product analysis

Retailer	Number of Products
ASN	362
Fat Burner	107
Post-Workout	119
Pre-Workout	136
NW	346
Fat Burner	155
Post-Workout	29
Pre-Workout	162
Elite Supps	213
Fat Burner	107
Post-Workout	15
Pre-Workout	91
Total	921

As some products were repeated across product categories internal to a retailer, as well as being sold across multiple retailer websites, an adjustment was made to the data to show distinct products only, as detailed in the table below.

Table 2. Distinct products by presentation

Product Category	No. of products	Percentage of product category
Capsule		
Cookie		
Cream		
Liquid		

[31] Industry reports consulted were Arna Richardson, IBISWorld, 'Vitamin and Supplement Manufacturing in Australia', Industry Report OD5417, October 2019, Arna Richardson, IBISWorld, 'Vitamin and Supplement Stores in Australia', Industry Report OD5364, June 2019, Arna Richardson, IBISWorld, 'Online Vitamin and Supplement Stores in Australia', Industry Report OD4091, February 2019, and Euromonitor International, 'Passport: Consumer Health in Australia', October 2019. Both IBISWorld reports (OD5364 and OD4091) identified Grubie Pty Ltd (trading as Nutrition Warehouse) as the dominant market player.

[32] All three retailers have physical stores across the country in addition to their online sales platforms. NW has the largest number of retail stores (75, with the 76th scheduled to open in May). ASN is the next largest with 38 stores closely followed by ES with 35 stores (as at 30 March 2020).

Product Category	No. of products	Percentage of product category
Powder		
Spread		
Tablet		
Capsule		
Liquid		
Powder		
Candy		
Capsule		
Gel		
Liquid		
Powder		

Of the potentially in-scope products, the dominant method of presentation is powder (93% of post-workout, 87% of pre-workout and 60% of fat burner products), followed by capsules/tablets (34% of fat burners, 3% of pre-workouts and 5% of post workouts). Liquids and other forms of presentation, including novel foods, make up 10% of pre-workouts, 7% of fat burners and 2% of post-workouts). This represents 7% of the total product population.

Table 3. Aggregated product populations

	Fat Burner Products	Post-Workout Products	Pre-Workout Products
Powders +[33]	180	128	217
Capsule/tablet	91	7	7

Follow-up conversations were undertaken with major retailers to determine the likely national proportion of sports supplement products in the three identified product categories represented by their combined product listing: this was estimated to be approximately 80%. The table below details the revised product populations extrapolated across all Australian retailers.[34]

Table 4. Product dataset extrapolated across all Australia retailers[35]

	Fat Burner Products	Post-Workout Products	Pre-Workout Products
Powders +[36]	225	160	271
Capsule/tablet	114	9	9

[33] Population includes powders, liquids and novel foods.

[34] It is acknowledged that Australian consumers, under the Personal Importation Scheme, may purchase additional products not represented in this dataset direct from overseas manufacturers.

[35] Figures have been rounded to the nearest integer.

[36] Population includes powders, liquids and novel foods.

Country of manufacture

In some cases, it was possible to identify the country of origin of the manufacturer/brand owner by the product information provided on the retailer's website. Where the country of origin could not be established (n=32) these manufacturers/brand owners were assumed to be Australian[37], as were manufacturers were there was evidence of both domestic and international manufacturing. It is acknowledged that this approach has likely resulted in an overestimation of the number of Australian manufacturers/brand owners, given that a high proportion of sports supplements products are produced overseas but a conservative approach has been applied to this specific factor of the calculation of the regulatory cost. The breakdown of the country of manufacture for the identified distinct products is shown in the table below.

Table 5. Country of manufacture

Country of Manufacture	Count	Percentage
Not determined	32	
AUS	224	
AUS/UK	1	
AUS/US	9	
sub-total	266	42%
CAD	5	
Int'l	1	
NZ	1	
UK	12	
US	345	
sub-total	364	58%
Total	630	

Product pathways (including population)

As detailed above, products have three distinct pathway options. The sponsor/manufacturer can either modify their product (to remain a food and avoid being regulated as a therapeutic good), list/register their product (in the ARTG) or withdraw the product from the market. However, stakeholder interviews revealed that the percentage of products likely to be impacted by the proposed regulatory classification differ across product categories and presentations. Key insights derived from the stakeholder interviews were that:

- pre-workout powder products are much more likely to contain ingredients of concern than post-workout powder products (which mainly consisted of protein)
- powder products in the fat burner category have less ingredients of concern than powder products in the pre-workout category
- most powder products that have ingredients of concern are likely to be either reformulated or withdrawn from the market[38] – only a small percentage of powder products would proceed down an ARTG listing pathway
- capsule/tablet products are not likely to have their presentation changed to a powder (or liquid/novel presentation)

[37] This number of products where the country of origin could not be determined, represents approximately 5% of the total number of distinct products. Noetic considers that imported products were more likely to be identified as such and therefore has assumed that the majority of these products were produced domestically, noting that some may indeed be imported. However, for all product categories, less than 50%, and in some cases less than 5% of products, are taken forward into the calculation of regulatory costs. Any overestimation of the number of domestically-produced products is considered not material to the regulatory costing.

[38] Products might be withdrawn from the market because projected profit from sales did not justify the expense (and effort) of going down an ARTG pathway or the product may contain active ingredients that are unlikely to be approved for sale by the TGA outside a pharmacy (or might require a prescription) and are therefore unable to be sold through sports supplements retail or online stores.

capsule/tablet products are more likely to proceed down an ARTG pathway than powder products (as reformulation is not an option likely to be pursued by industry)

it is likely that a number of capsule products will be withdrawn rather than proceeding down an ARTG pathway

a small percentage of products in the calculated populations are already listed in the ARTG (and therefore no action is required in relation to the proposed regulatory clarification)

capsule products are more likely to be already listed in the ARTG than powder products.

Table 6. Reformulation pathway[39]

	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders +[40]	225 (10%[41]) = 23	160 (5%[42]) = 8	271 (20%[43]) = 54	85
Capsule/tablet	114 (5%[44]) =6	9 (5%) =1	9 (5%)= 1	8
			Total	93

Table 7. ARTG pathway

	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders +[45]	225 (5%[46]) =11	160 (5%) = 8	271 (5%) = 14	33
Capsule/tablet	114 (40%[47]) = 46	9 (40%) = 4	9 (40%) = 4	54
			Total	87[48]

Industry stakeholders estimated that a relatively simple reformulation (one-for-one ingredient swap) would involve two stages. The initial stage would involve sample development, sample testing, a re-costing activity and some additional paperwork. It was estimated this would take roughly half a

[39] It is possible that some overseas manufacturers will reformulate their products but they are considered less likely to do so than domestic manufacturers, as the Australian market may comprise only a small portion of the overall market and it may not be economically justified to reformulate. However, while the actual percentage of products reformulated may indeed be higher than the percentages applied, for the purpose of the regulatory costing only the regulatory impact of reformulation on domestic manufacturers is included (therefore 42% of distinct products).

[40] Population includes powders, liquids and novel foods.

[41] The number of products likely to reformulate is assessed to be low (10%) as stakeholders identified some ingredients of concern, but less than those in the Pre-Workout category.

[42] Given that Post-Workout products are likely to contain more protein based ingredients (such as whey powder) only a small portion of the population are likely to not be affected by the proposed regulatory clarification, thus the percent of reformulation (out of total population) is assessed to be low (5%) .

[43] As stakeholders indicated that Pre-Workout products contain the most ingredients of concern (out of the three product categories), the population is likely to have a higher rate of reformulation (20%) than the other product populations.

[44] The percentage of reformulation of all capsule/tablet products was assed to be low (5%), as reformulating to a different presentation is not a preferred option for stakeholders (as capsule/pill presentation was a differentiator in the market). To remain in the food space some products would need to undergo presentation and ingredient reformulation; this decreases the likelihood of reformulation as it would fundamentally change the product.

[45] Population includes powders, liquids and novel foods.

[46] The number of powder products (all categories) likely to go down the ARTG pathway was assessed to be low (5%) as stakeholders noted several challenges (including expense) in listing these products on the ARTG. Further details provided in footnote 25.

[47] Stakeholders noted that capsule/pill supplements make up a significant portion of their revenue (around 40%). This is because the consumer is prepared to pay for products which provide higher quality, convenience, dosage control and increased shelf life. Thus, it was assessed that 40% of the product population would likely be listed on the ARTG as they would not want to lose the significant portion of company revenue, nor reformulate to move away from consumer preference.

[48] In 2017/18 there were 1792 new listed medicines on the ARTG, with 1893 new listed medicines in 2018/19 (therefore a two-year average of 1842.5). The projected increase of 87 new application therefore represents an uplift of approximately 5%.

day's[49] (240 minutes) effort to complete. The second part of this reformulation process would involve label design and review and updates to a range of sales documentation (sell and technical sheets, websites, brochures, price lists and a notification to distributers and retailers of the changes made). It was estimated that the effort required for the second stage was approximately 1.5 days (720 minutes). Total time to complete a simple reformulation is therefore 960 minutes.

For a more complex reformulation (multiple ingredient changes), this may take up to 7 days (3,360 minutes). The increased time is directed towards additional research, product and sample development, testing, and development of marketing collateral. As the proportion of simple and complex reformations needed is unknown, the average reformulation time will be used for the regulatory costing. Therefore, simple reformulation time (960) + complex reformulation time (3,360)/2 = 2,160 minutes per product.

The below table provides a summary of all regulatory activities associated with listing a product in the ARTG.[50] It is assumed that all potentially in-scope products will be listed rather than registered in the ARTG due to the nature of the product ingredients and the additional expenses entailed with the registration of a product.

Table 8. Regulatory activities (and associated time) for listing a product in the ARTG

[49] Working days (8 hours) used consistently throughout the document.

[50] The format of this table was based on an assessment of the activities (and associated time) required to list a medical device on the ARTG previously agreed by OBPR (and TGA) and modified in accordance with the Australian Regulatory Guidelines for Complementary Medicines (ARGCM). This table has been reviewed by the TGA and modified in accordance with the advice given.

[51] See <https://www.tga.gov.au/form/listed-medicines-evidence-package-checklists>.

[52] This checklist could contain the results of clinical trials if conducted; however, due to the expected level of indications, clinical trials are not likely to be conducted.

[53] Likely label changes include the addition of an AUST L number, the removal of nutritional information, additions to ingredients list etc. Internal staff involved include marketing team, senior general managers (GMs), graphics team, regulatory and scientific teams, QA team and legal sign-off.

[54] See following paragraph regarding likelihood of selection for post-market compliance review.

[55] Assumed that 'Additional Conditions of Listing' have not been applied as low risk products.

Listed medicines may be selected for a post-market compliance review to determine whether these medicines comply with the relevant regulatory requirements. In 2018-19, 139 compliance review were undertaken for a population of over 10,000 ARTG listings (therefore slightly more than a 1% probability of any single listing being selected for review).[56] It has been assessed that less than 100 additional ARTG listings (a less than 1% increase of the current population) will arise from the proposed regulatory clarification. It is therefore considered unlikely that there will be any material increase in the regulatory burden directly related to post-market compliance reviews of the arising additional ARTG listings.

The regulatory costing has a default duration of ten years, which incorporates the proposed transition period of up to three years. Industry stakeholders commented that the sports supplements market is dynamic with a relatively high changeover of products due to consumers seeking out new products (usually on the expectation of improved physiological effects). Due to the point-in-time method for establishing the product population, Noetic has been unable to determine longitudinal changes in the overall product population.[57] However, industry reports[58] note that this is a growing retail sector driven by rising health consciousness among consumers and associated wellness trends.

In relation to the impact of the proposed regulatory clarification on future products the following assumptions have been made:

- no new Australian manufactured sports supplement products will be required to be reformulated as the existing ambiguity in relation to the FMI will have been removed
- to the extent that overseas regulations (in particular the United States) differ to Australia, some imported products will be required to be reformulated (which would not have occurred in the absence of the proposed regulatory clarification) – however, as this reformulation occurs external to Australia it is excluded from the regulatory costing (noting that the reformulation cost is likely to be passed onto Australian retailers via higher unit prices)
- there is assessed to be a 10% year-on-year growth in the number of additional products listed in the ARTG arising from the proposed regulatory clarification.

The current population is assessed to transition over a three-year period, with the projected growth in products listed on the ARTG shown in the table below.

Table 9. Projected growth in the number of products listed on the ARTG

Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Total Growth from Base
20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	30/31	
87			96	106	117	129	142	156	172	85
Increase per year			9	10	11	12	13	14	16	85

[56] TGA, Annual Performance Statistics Report: July 2018 to June 2019, p.30.

[57] Industry reports focus on changes in the value of sales rather than the volume of products.

[58] See footnote 19 for the list of reviewed industry reports.

Labelling design and re-print is included in the regulatory costing as sport supplement product labels are refreshed every 5-10 years[59] and this period is longer than the anticipated transition period (expected to be up to three years).

All potentially in-scope products will be included in the ARTG as listed medicines rather than registered medicines.

Withdrawing a product from the market incurs no additional regulatory burden[60] and has therefore been excluded from the regulatory costing.

New listings in the ARTG for affected sports supplements are likely to occur in the latter part of the expected transition period (i.e. Years 2-3).

The ongoing requirements to maintain an ARTG listing (see Table 8) apply from the year of listing (less the 'fees (ongoing)' for the initial year of listing).

Number of products likely to be reformulated = 93 (85 powders + 8 capsules/tablets products)

Number of products likely to be listed on the ARTG = 87 (33 powders + 54 capsules/tablets products)

Number of products likely to be listed on the ARTG = 85

Time required to reformulate (per product) = 2,160 minutes

Time required to list a product on the ARTG = 4,210 Minutes

Time required (ongoing annual) to maintain listing on the ARTG = 240 minutes

Time excluded for first year of listing in relation to 'fees (ongoing)' = 30 minutes

Time required (ongoing annual) to maintain listing on the ARTG – 30 minutes for 'Fees (ongoing)' = 210 minutes

Number of ARTG entries x years of listing (Years 4 to 10) = 309

Number of ARTG entries (less year of listing) for Years 4 to 10 = 224

. Calculate total time in minutes to fulfil regulatory requirement:

Reformulation: 93 x 2,160 = 200,880 minutes

List on the ARTG: 87 x 4,210 = 366,270 minutes

Time to reformulate and list on the ARTG = 200,880 + 366,270 = 567,150 minutes

Calculate total time in hours to fulfil regulatory requirement:

567,150/60 = 9,453 hours

. Apply the hourly rate to determine overall regulatory compliance cost:

9,453 x $84.84= $801,950

[59] Multiple industry stakeholders noted that the only exceptions to the 5-10-year label refresh period would be in the case of reformulation (ingredients) or a regulatory change requiring changes to labelling information.

[60] It is noted that while withdrawing a product from the market does not incur increased regulatory costs (assuming that this will be done over the transition period and that stock refresh cycles are such that no product recall will be required), significant economic costs in relation to lost sales (with business likely flowing to overseas online retailers via the Personal Importation Scheme rather than substitution products retailed in Australia) would be incurred by industry. This cost is included in the broader Regulatory Impact Statement (RIS).

. Calculate total time in minutes to fulfil regulatory requirement:

Current population fulfill ongoing requirements (years 4 to 10) = 87 x 240 x 8 = 167,040 minutes

Future population list on the ARTG = 85 x 4,210 = 357,850 minutes

Future population fulfill all ongoing requirements (years 4 to 10) less 'Fees (Ongoing)' = 309 x 210 = 64,890 minutes

Future population fulfill 'Fees (Ongoing)' less year of listing: 224 x 30 = 6,720 minutes

Carry forward time for future population to fulfil ongoing requirements = 64,890 + 6,720 = 71,610 minutes

Time for future population to list in the ARTG and for both current and future populations to fulfil ARTG ongoing requirements = 167,040 (current population ongoing requirements) + 357,850 (future population ARTG listing) + 71,610 (future population ongoing requirements) = 596,500

Calculate total time in hours to fulfil regulatory requirement:

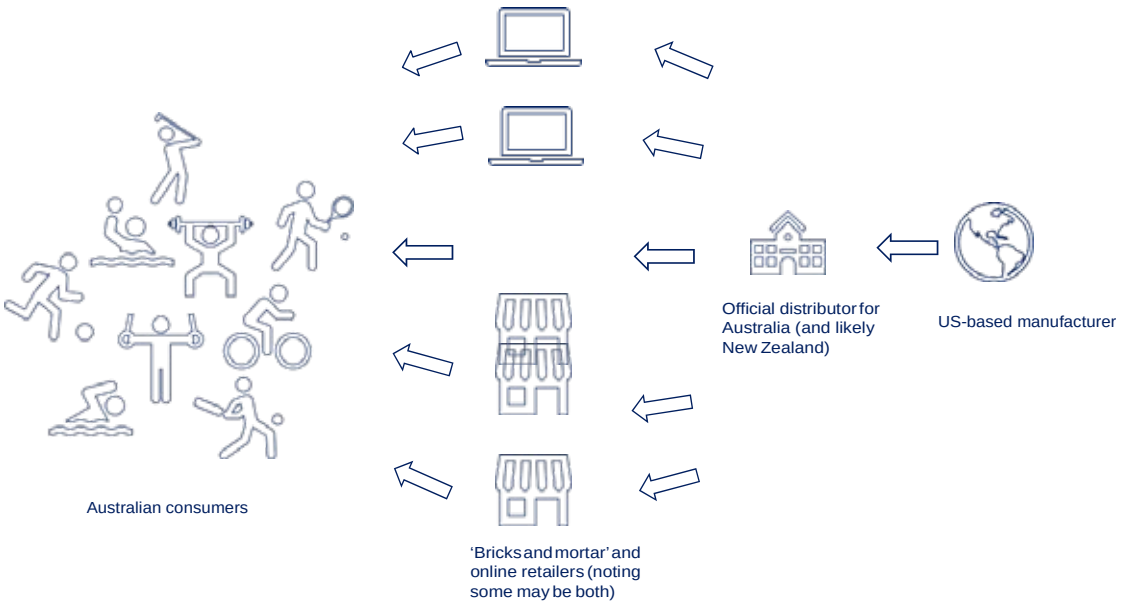
596,500/60 = 9,942 hours

. Apply the hourly rate to determine overall regulatory compliance cost:

9,942 x $84.84 = $843,451

A number of manufacturers/retailers of sports supplements are existing sponsors on the ARTG, likely due to their product range encompassing existing complementary medicines. Such businesses are already aware of their responsibilities under the TG Act and likely already have a regulatory affairs team. Others, such as domestic producers of sports supplements, or distributors with exclusive rights to distribute foreign (mainly US) produced products within Australia, may choose to become sponsors. It is considered unlikely that retailers will seek to become sponsors other than for their own brand products, most likely relying on the distributor to do so, due to the dynamics of the supply chain, in particular due to the distributor's central role (one-to-many relationship), as detailed in the figure below.

Figure 6. Simplified supply chain for sports supplement products



It is likely that potential new sponsors who have not previously had any exposure to the TGA will need to obtain the service of regulatory affairs consultants[61] to advise them of their responsibilities under the TG Act. Noetic considers it unlikely that existing sponsors will wish to take on sports supplement manufacturers/retailers as clients due to the legal risks involved.

The TGA supplied Noetic with a complete dataset of all listed medicines on the ARTG as at 20 March 2020. After data cleansing was completed there were 10,595 distinct entries and 1016 sponsors.

Separately, Noetic produced a second dataset through desktop research on various Australian sports supplement companies (including manufacturers (but excluding contract manufacturers), distributers and retailers), supplemented by cross-referencing against the TGA's known stakeholder list (i.e. invited/attended workshops) and companies mentioned in industry reports on the sports supplements and vitamins sector. The purpose of this dataset was to identify companies within the sports supplement industry that are or could be potential sponsors. This population largely consisted of manufacturers/brand owners who sell products through online websites; either their own or via a major retailer (such as Nutrition Warehouse). This data was cross-checked and supplemented by the listing of domestic manufacturers/brand owners[62] determined via the product analysis. The key purpose of this dataset was to compile a listing of existing manufacturers/brand owners in the sports supplements retail sector. The comparison between the two datasets resulted in a population of 112 potential sponsors of which 19[63] (17%) were current sponsors of products on the ARTG.

In relation to awareness, for potential future sponsors the proposed regulatory clarification will form but part of the complex regulatory considerations involved with registering a new complementary medicine on the ARTG and therefore is considered to represent a non-material increase in the

[61] See https://www.tga.gov.au/regulatory-affairs-consultants.

[62] Manufacturers/brand owners who could be clearly identified as being based offshore where excluded from the dataset as it was considered that they were unlikely to seek to be sponsor themselves but would rather seek to engage the services of an existing or new sponsor (likely a distributor). Where the country of residence could not be determined they were included in the dataset. It is acknowledged that this likely results in an overestimation of the population as many sports supplements are produced overseas.

[63] The identified current sponsors were: Amway of Australia, ATP Science; Biomedica Nutraceuticals; Blackmores; Body Science International; Bronx Import & Manufacture; Herbalife Australasia; Herbs of Gold; Metagenics (Aust); Iovate Health Sciences Australia, Musashi; PremaLife t/a Natural Vitality Australia; Pharmacare Laboratories; Rapid Nutrition; Swisse Wellness; Top Nutrition; Vitaco Health Australia; Vitaminhaus and Vitex Pharmaceuticals.

overall regulatory burden. Likewise, the proposed regulatory clarification will form but part of the complex regulatory framework that new food manufacturers/brand owners will need to be aware of and therefore is considered to represent a non-material increase in the overall regulatory burden.

Noetic considered that current sponsors would be aware of the TGA's regulatory framework and would require less time than companies completely new to the TGA's regulatory framework to understand this framework. It is considered that at a minimum the existing sponsors would likely have read the TGA's consultation paper in October 2019 as well as the two stakeholder presentations added to the TGA's website in early March 2020 and associated material on the TGA website.[64] The carry-forward population of 93 (112 potential sponsors minus 19 existing sponsors) would likely have also read the consultation paper but would need to have undertaken additional research or engaged a regulatory affairs consultant (considered at least 25% would have – so n=23) to provide advice as to the potential impact on their business of the proposed regulatory clarification. Of the 93, given that stakeholder interviews with industry indicated that the majority of the impacted retailers, distributors and manufacturers would actively seek to have their products continue to be regulated as food, less than 10% (therefore 9) would actually seek to be sponsors (which represents an uplift of just under 50% of the existing sponsors for these kind of products). [65]

All potentially affected companies will seek to become aware of the extent to which the proposed regulatory clarification impacts upon their company.

Most businesses that would have sought to gain a marketing advantage of being able to make higher-level therapeutic claims than permissible under the Foods Standards would have already proceeded down the sponsor pathway.

Number of existing sponsors =19

Number of potential new sponsors = 93

Number of potential new sponsors who do not engage with a regulatory affairs consultant to understand the potential impact on their business of the proposed regulatory clarification = 70

Number of potential new sponsors who do engage with a regulatory affairs consultant to understand the potential impact on their business of the proposed regulatory clarification = 23

Number of potential new sponsors proceeding to sponsor application = 9

Time required to read s.7 declaration and explanatory material (approximately 10 pages in total)[66] = 30 minutes per person and considered that a minimum of two persons per company would read the material, so a total of 1 hour (60 minutes).

Time required for potential new sponsors to equate themselves with the TGA's regulatory framework without the advice of a regulatory affair consultant = 1 day (so 480 minutes).

Time required to consult with a regulatory affairs consultant = 3 hours (so 180 minutes)

[64] Choosing to submit a response to the public consultation paper and/or attend a TGA sponsored stakeholder workshop is considered a business decision and not necessarily the action of the a 'normal efficient business', and therefore is excluded from the regulatory costing.

[65] This equates to a projected new sponsor population of 28 for sports supplements. Therefore the projected increase of 87 new ARTG listings equates to an average of three new listings per sponsor.

[66] It is noted that a range of explanatory material has already been produced by the TGA (including a consultation paper and the Powerpoint presentations from the stakeholder workshops) and while this would likely have been read by current sports supplements manufacturers and brand owners, technically, as this effort was incurred prior to the Ministerial decision, it has been excluded from the regulatory costing.

Approximate cost of the awareness advice provided by a regulatory affairs consultant = $300[67] per hour x 16 hours (2 days) = $4,800 x 23 business = $110,400

Time taken to become aware of responsibilities of being a sponsor = 4 hours (so 240 minutes)

Time required to complete 'Organisation Details' form (3 pages), have it checked and submit to obtain a Client ID and then create eBS account = 30 minutes

. Calculate total time in minutes to fulfil regulatory requirement:

Existing sponsors review regulatory clarification: 19 x 60= 1,140 minutes

Potential new sponsors equate themselves without use of regulatory consultant with TGA regulatory framework: 70 x 480 = 33,600 minutes

Potential new sponsors equate themselves with use of regulatory consultant with TGA regulatory framework: 23 x 180 = 4,140 minutes

New sponsors become aware of responsibilities of being a sponsor: 9 x 240 = 2,160 minutes

New sponsors complete 'Organisation Details' form and register on eBS: 9 x 30 = 270 minutes

Time required for awareness activities: 1,140 (existing sponsors review documents) + 33,600 (new sponsors without regulatory consultant support review documents) + 4,140 (new sponsors with regulatory consultant support review documents) + 2,160 (new sponsors become aware of sponsor responsibilities) + 270 (new sponsors get onto eBS) = 41,310 minutes.

Calculate total time in hours to fulfil regulatory requirement: 41,310/60 = 689 hours

.

Apply the hourly rate to determine overall regulatory compliance cost: 689 x $84.84= $58,412

Add the regulatory consultant charges: $58,412 + $110,400 = $168,812

The extant Permissible Ingredients Determination[68] lists 5250 ingredients (across 6 volumes) and their permitted uses when contained in a medicine. Listed complementary medicines must contain only ingredients included in this determination. Additions to the list are made via the 'Substance Evaluation' form on the TGA Electronic Business Services TGA Business Services (eBS) electronic platform. An application can be submitted for:

a new complementary medicine substance not currently listed in the determination

a proposed new role or change to the existing requirements for use of a current permitted ingredient, such as:

for an ingredient permitted for use as an excipient to be used as an active ingredient[69]

to change the permitted level of use

to change the permitted route(s) of administration.

The evaluation of the substance will consider whether it is of appropriate quality and safety to be permitted for use in listed complementary medicines. Key considerations are that the substance is not a prohibited import, and for substances of herbal origin, the substance or its constituent(s)

[67] As advised by industry stakeholders.

[68] The current determination is 'Therapeutic Goods (Permissible Ingredients) Determination (No.2) 2020', which commenced on 27 May 2020.

[69] The TGA Regulations 1990 define an active ingredient for a medicine as the 'therapeutically active component of the medicine's final formulation that is responsible for its physiological or pharmacological action'. An excipient ingredient is not therapeutically active and does not contribute to the physiological or pharmacological action within the medicine's final formulation. Types of excipient ingredients include: a fragrance, flavour, preservative, printing ink, antioxidant, coating, binding agent, filler or an anticaking agent. Refer to https://www.tga.gov.au/types-ingredients-listed-and-registered-complementary-medicines.

is/are not subject to the conditions of a Schedule (or applicable Appendix) to the Poisons Standard. Once determined to be safe and listed in the Determination, the substance may be used in any listed complementary medicine provided any requirements for use are complied with.

Industry stakeholders have raised concerns with Noetic that many common ingredients in sports supplements are not listed on the determination. Noetic checked common ingredients used in products in the pre-workout[70] and fat burner[71] categories against the Permissible Ingredients Determination and that some ingredients are not currently included in the Determination.

Following an evaluation of a substance, subsection s.26BB(2A) of the Act allows the Minister to permit the successful applicant to have exclusive use of that ingredient (the protected ingredient) for a period of two years. During this period, the use of a protected ingredient in a listed medicine will be restricted to:

- the applicant who requested evaluation of the substance (who may or may not be a medicine sponsor)
- other persons nominated by the applicant.[72]

At the end of the exclusivity period, any sponsor can include the ingredient in a medicine and list that medicine in the ARTG. Use of a protected ingredient within the exclusivity period without an approval from the ingredient applicant would contravene the requirement relating to the use of the ingredient and is grounds to cancel the medicine from the ARTG under s.30 of the TG Act.

Exclusivity will only be permitted for a new complementary medicine ingredient (active or excipient) that is not currently included in the Determination provided that:

- it has not previously been evaluated by the TGA for use in listed or registered medicines
- it is not used in, or available for use in, registered medicines.

Exclusivity will not apply to applications submitted for a new role or a change to any existing requirements for use of a permitted ingredient.

As noted previously, one of the defining characteristics of the sports supplement sector is continual product development driven by customers seeking the 'next new thing'. Therefore, it is likely that new ingredients will be continually sourced, evaluated and used in sports supplements. Further complications are that there is no comprehensive listing of ingredients used in sports supplements and that the use of synonyms for ingredients is common practice.[73] Noetic was therefore unable to undertake a data matching exercise of ingredients in sports supplements against the ingredients listed in the Permissible Ingredients Determination.

There is likely a correlation between the number of ARTG applications for sports supplements to become listed medicines and applications for new listed medicine ingredients. Industry has advised that for powders the default position will likely be to reformulate to avoid the product being regulated as a therapeutic good. Applications for new listed medicine ingredients are therefore more likely to be linked to applications for capsulated sports supplements to become listed

[70] Common ingredients contained in pre-workout products that were checked against the Permissible Ingredients Determination were l-citrulline, amino acids (the most commonly used branched-chain amino acids are leucine, isoleucine and valine), beta-alanine, and caffeine.

[71] Common ingredients contained in fat burner products that were checked against the Permissible Ingredients Determination were Green Tea Extract, Conjugated linoleic acid, Caffeine, Forskolin, 5-HTP (5-Hydroxytryptophan), L carnitine, L-Tyrosine, L-Theanine, protein powders (such as Whey), and soluble fibres (such as Glucomannan and Psyllium husk).

[72] An option available to manufacturers/brand owners is to register (rather than list) the product on the ARTG, in which case the exclusivity provisions would not apply. However, registering the product entails additional regulatory costs as the product is required to undergo a full pre-market assessment of the evidence supporting its safety, quality, and efficacy.

[73] For example, the Australian Sports Anti-Doping Authority notes the following synonyms for Higenamine (a prohibited Beta 2 Agonist): Demethylcoclaurine, Norcoclaurine, Tinospora crispa, Nandina domestica, Nelumbo Nucifera, Argemone Mexicana, Magnolia salicifolia, Aconite Root, Coptis japonica, Aconitum japonicum, Gnetum Parvifolium, Asarum hetertropoides, Aconitum carmichaelii, Galium divaricatum and Annona squamosa. See < https://www.asada.gov.au/substances/supplements-sport>.

medicines. It should be noted that each new ARTG application may not drive any applications for new listed medicines or may drive multiple applications and that most ingredients would be present in multiple sports supplements products. Furthermore, it should be noted that there a number of sport supplement products already listed in the ARTG.[74]

Over the period 2014/15 to 2018/19, there was on average 18 applications per year for new listed medicine ingredients.[75] Over the corresponding period there was an average of 1758 new listed medicines in the ARTG.[76] Therefore, there is an average of 1 application for new listed ingredients per 100 new listed medicines. If we assume this represents the lower end of the range, noting that the complementary medicines segment is relatively mature (complementary medicines being listed in the ARTG for a number of years), then it would seem reasonable to assume that the upper band would be no greater than 10 times the lower band (therefore 10 applications for new listed ingredients per 100 new listed medicines) – that is, an application for a sports supplement to be a listed medicine is 10 times more likely to contain an ingredient not listed in the Permissible Ingredients Determination than an application for another form of listed medicine. Noting that we are projecting an additional 87 ARTG applications, this will produce 9 new listed medicines ingredient applications[77] (which equates to a 50% uplift on the previous five-year average).

Given the degree of product turnover in the sports supplement sector, as previously stated, there is assessed to be a 10% year-on-year growth in the number of additional products listed in the ARTG arising from the proposed regulatory clarification (therefore 85 additional listings over the period 2023/24 to 2030/31). Assuming the relationship between new products listed and new ingredients is consistent with historical averages for listed medicines, this equates to an additional 1 new listed medicines ingredient applications.

For an ingredient to be added to the Permissible Ingredient Determination, sponsors are required to complete the 'Application for evaluation of a substance for use in listed complementary medicines' form. There are four application categories (IN1 to IN4), of which IN4 (full independent evaluation of safety and quality by the TGA)[78] is assessed to be the most likely due to it being considered unlikely that there will be pre-evaluated information from an acceptable comparable overseas regulator (COR), as sports supplements are not widely regulated as therapeutic goods by COR. Conversely, where testing has been undertaken by commercial laboratories on a specific ingredient, the results are the property of the business that commissioned the testing and may not be made available to an Australian sponsor.

It is considered likely that sponsors will need to prepare for and have a pre-submission meeting with the TGA prior to lodging the application and that multiple requests for information[79] will be made from the TGA to the sponsor during the evaluation phase. There will also be up to three letters sent from the TGA to the sponsor (acknowledgement of lodgement, notification of application accepted/not accepted for evaluation, and notification of delegate decision (substance considered

[74] For example, ARTG ID 321173 is for 'Weight Loss Max', a capsule product produced by Bella Figura Wellness Pty Ltd and ARTG ID 157099 is for 'Bronx Wild Bull Thermogenic', produced by Bronx Import and Manufacture, another capsulated product.

[75] The number of new ingredient applications for FY 2016/17 (n=80) has been excluded from the calculation of the average applications per year as it was considered an outlier due to a new legislative instrument being introduced under s.26BB of the TG Act. This legislative instrument simplified the range of instruments detailing ingredients permitted for use in listed medicines and required a number of ingredients in existed listed medicines to be added to the Permissible Ingredients Determination.

[76] Information drawn from TGA Annual Performance Statistics Reports.

[77] Noting that not all ingredients will be suitable for listing on the Permissible Ingredients Determination. For example, due to the risk they pose to consumers, some may need to be scheduled on the Poisons Standard. However, due to the low number of applications for new ingredients forecast, and industry advice that due to the additional cost they were unlikely to seek to register sports supplements in the ARTG, the regulatory cost of registering a new product on the ARTG has been excluded from the costing.

[78] It is noted that while the screening timeframe for all application categories is the same (40 days), the evaluation time for IN4 (180 days) is considerably greater than the other categories (IN1 – 70 days, IN2 – 120 days and IN3 – 150 days).

[79] TGA has advised that, on average, there are two requests for information per application.

suitable/not suitable for use as an ingredient in listed medicines). It is considered that in total the time taken by the sponsor to undertake these activities (exclusive of any time taken to prepare the application form and accompanying evidence) will 2 days (so 960 minutes).

The following information is required to be provided on the application form:

- administrative information (includes covering letter, details of any pre-submission meeting etc.)
- general substance information (details required for inclusion in the determination include ingredient name (and any synonyms), role (active/excipient), route of administration, dosage form and target populations)
- information required to demonstrate the quality of the substance (includes definition, chemical identity/structure, general properties, manufacturing details, characterisation, control of substance, reference standard, container closure system, and stability information)
- information required to demonstrate the safety of the substance (includes literature search and material produced by sponsor relating to history and patterns of human use, biological activity, toxicological data, clinical trials, adverse reactions and risks relating to transmissible spongiform encephalopathy (such as Creutzfeldt-Jakob ('Mad Cow') disease)).

Information is expected to be provided in an electronic dossier format similar to the European Medicines Agency Common Technical Document (CTD). Given the complexity of the submission process and evidentiary requirements, Noetic has assumed that the work will be commonly outsourced to a regulatory affairs consultant. It was estimated that the effort required to consult with the regulatory affairs consultant over the 6 to 12 months it takes to get the evidence together was 1/2 day (240 minutes) per month (for an average of 9 months) – therefore 2160 minutes (this includes time taken to engage with a regulatory affairs consultant arising from any requests for information from the TGA).

Applications are likely to be under the IN4 category (full independent evaluation of safety and quality by the TGA) due to it being considered unlikely that there will be pre-evaluated information from an acceptable COR.

Once the current population of in-scope sports supplement products transitions onto the ARTG (or conversely is withdrawn from sale or reformulated), the relationship between new products listed and new ingredients will be consistent with the historical average for complementary medicines.

Given the complexity of the submission process and evidentiary requirements, the preparation of the submission will be outsourced to a regulatory affairs consultant.

Number of new ingredient applications ( ) = 15

Number of new ingredient applications ( ) =2

Time taken to engage with TGA for complete process = 960 minutes

Approximate cost of a regulatory affairs consultant to prepare an 'Application for evaluation of a substance for use in listed complementary medicines' = $300[80] per hour x 100 hours =

$30,000[81] x 9 applications (current population) = $270,000 and for 1 application (future population) = $30,000

Time taken to engage with a regulatory affairs consultant = 2160 minutes

[80] As advised by industry stakeholders.

[81] As advised by a regulatory affairs consultant.

. Calculate total time in minutes to fulfil regulatory requirement:

Prepare and submit application for a new ingredient to be added to the Permissible Ingredients Determination: 9 x 960 (engage with TGA) + 9 x 2160 (engage with regulatory affairs consultant)

= 9 x 3,120 = 28,080 minutes

Calculate total time in hours to fulfil regulatory requirement: 28,080/60 = 468 hours

.

Apply the hourly rate to determine overall regulatory compliance cost): 468 x $84.84= $39,705

Add the regulatory consultant charges: $39,705+ $270,000 = $309,705

. Calculate total time in minutes to fulfil regulatory requirement:

Prepare and submit application for a new ingredient to be added to the Permissible Ingredients Determination: 1 x 960 (engage with TGA) + 1 x 2160 (engage with regulatory affairs consultant)

= 1 x 3,120 = 3,120 minutes

Calculate total time in hours to fulfil regulatory requirement: 3,120/60 = 52 hours

.

Apply the hourly rate to determine overall regulatory compliance cost): 52 x $84.84= $4,412

Add the regulatory consultant charges: $4,412 + $30,000 = $34,412

Option 3 excludes sports supplement products which are presented as either a pill, tablet or capsule. Option 3 includes a reduced scope for products affected by the regulatory clarification rather than a reduced or modified requirement (regulatory activity). Therefore, much of the regulatory impacts (timings and costs) are the same as those outlined for options 2A & 2B. Therefore, the key differences in regulatory burden for Option 3 are driven by the reduced product population and the flow-on impact in the number of potential new sponsors and new ingredient applications.

Table 10 (below) represents an extrapolation of the data collected by Noetic via desktop research. As this table reveals, of the products most likely to be affected by the clarification (Fat Burner, Post-Workout and Pre-Workout), 20% are presented as a capsule/tablet.

Table 10. Product dataset extrapolated across all Australia retailers[82]

	Fat Burner Products	Post-Workout Products	Pre-Workout Products
Powders +[83]	225	160	271
Capsule/tablet	114	9	9

Although Option 3 does not include products based solely on their presentation (e.g. as a capsule/tablet), these may still be affected by the proposed regulatory clarification based on their ingredients. As such, it is assessed that only a low percentage of capsule products (5% of total) will continue down the ARTG pathway for this option. Drawing on stakeholder commentary, it is

[82] Figures have been rounded to the nearest integer.

[83] Population includes powders, liquids and novel foods.

assessed that no capsule/pill products captured (based on ingredients) will reformulate. Thus, only 7 capsule/tablet products will be included in the regulatory costing.

Table 11. Calculation of capsule/tablet products proceeding down ARTG pathway

Total capsule/tablet products in-scope	% of capsule/tablet products proceeding down ARTG pathway	Total capsule/tablet products carried forward
132	5%	7

The pathway for the remaining powder+ product population is as detailed for options 2A and 2B. A revised population calculation is provided below.

Table 12. Reformulation pathway

	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders +[84]	225 (10%) = 23	160 (5%) = 8	271 (20%) = 54	85
Capsule/tablet	0	0	0	0
			Total	85

Table 13. ARTG pathway

	Fat Burner Products	Post-Workout Products	Pre-Workout Products	Total
Powders +[85]	225 (5%) =11	160 (5%) = 8	271 (5%) = 14	33
Capsule/tablet				7
			Total	40

As this option requires no changes to the regulatory impacts (timings) outlined for options 2A and 2B, the previous figures will be carried through to this costing.

In relation to the impact of the proposed regulatory clarification on future products, the assumptions outlined for options 2A and 2B remain applicable. Therefore, a 10% year-on-year growth has been used in the number of additional products listed in the ARTG arising from the proposed regulatory clarification. The current population is assessed to transition over a three-year period, with the projected growth in products listed on the ARTG shown in the table below.

Table 14. Projected growth in the number of products listed on the ARTG

Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	Total Growth from Base
20/21	21/22	22/23	23/24	24/25	25/26	26/27	27/28	28/29	30/31	
40			44	48	53	58	64	70	77	37
Increase per year			4	4	5	5	6	6	7	37

[84] Population includes powders, liquids and novel foods.

[85] Population includes powders, liquids and novel foods.

All key assumptions highlighted in the product regulatory costing for options 2A and 2B are applicable.

Number of products likely to be reformulated = 85

Number of products likely to be listed on the ARTG = 40

Number of products likely to be listed on the ARTG = 37

Cumulative count (less year of listing) of number of products likely to be listed on the ARTG for ongoing requirements = 97

Number of ARTG entries x years of listing (Years 4 to 10) = 134

. Calculate total time in minutes to fulfil regulatory requirement:

Reformulation: Number of products likely to be reformulated (85) x Time required to reformulate per product (2,160) = 183,600 minutes

List on the ARTG: Number of products likely to be listed on the ARTG (40) x Time required to list a product on the ARTG (4,210) = 168,400 minutes

Time to reformulate and list on the ARTG = 183,600 + 168,400 = 352,000 minutes

Calculate total time in hours to fulfil regulatory requirement:

352,000/60 = 5,867 hours

. Apply the hourly rate to determine overall regulatory compliance cost:

5,867 x $84.84= $497,728

. Calculate total time in minutes to fulfil regulatory requirement:

Current population fulfill ongoing requirements (years 4 to 10) = current population (40) x time required (ongoing annual) to maintain listing on the ARTG (240) x years (8) = 76,800 minutes

Future population list on the ARTG = Future ARTG population (37) x time required to list a product on the ARTG (4,210) = 155,770 minutes

Future population fulfill all ongoing requirements (years 4 to 10) less 'Fees (Ongoing)' = 134 x 210 = 28,140 minutes

Future population fulfill 'Fees (Ongoing)' less year of listing: 97 x 30 = 2,910 minutes

Carry forward time for future population to fulfil ongoing requirements = 28,140 + 2,910 = 31,050 minutes

Time for future population to list in the ARTG and for both current and future populations to fulfil ARTG ongoing requirements = 76,800 (current population ongoing requirements) + 155,770 (future population ARTG listing) + 31,050 (future population ongoing requirements) = 263,620

Calculate total time in hours to fulfil regulatory requirement:

263,620/60 = 4,394 hours

. Apply the hourly rate to determine overall regulatory compliance cost:

4,394 x $84.84= $372,759

As highlighted in the products section, Option 3 represents a 46% decrease in predicted additional ARTG listings for the current population (87 products (Options 2A & 2B) and 40 products (Option 3)). However, it has been assumed that all in-scope brand owners/manufacturers have more than one product. It has also been assumed that many brand owners/manufacturers produce both powder and capsule/tablet products. Furthermore, it is considered likely that all capsule/tablet manufacturers have the ability to produce powders but not vice versa, due to the technological uplift required to shift from powder production to capsule/tablet production. The removal of the presentation aspect from the proposed regulatory clarification is not likely to exclude many brand owners/manufacturers as they will still need to be aware of the potential impact across their range of products.

As a key element of the sponsor regulatory costing equates to awareness of the regulatory changes, it is considered that there will not be a material reduction in the number of potentially impacted sponsors (which was calculated based on existing brand owners/manufacturers with products in the in-scope sports supplements product categories). For options 2A and 2B an estimate of 10% was used for the number of potential new sponsors who will proceed down the pathway of becoming a sponsor. This has been reduced by 40% (n=6) to account for the reduction in brand owners/manufacturers needing to become a sponsor purely because of the presentation of their product (that is, they will become a sponsor purely on the basis on their product ingredients).

As outlined in options 2A & 2B, the future population for sponsors is considered to represent a non-material increase in the overall regulatory burden. Likewise, the proposed regulatory clarification will form but part of the complex regulatory framework that new food manufacturers/brand owners will need to be aware of and therefore is considered to represent a non-material increase in the overall regulatory burden.

As there is no difference between the timings and requirements for proceeding down the sponsor pathway across options 2A, 2B and 3, the previously listed timings have been used.

Assumptions are consistent with those identified for options 2A and 2B

Number of existing sponsors =19

Number of potential new sponsors = 93

Number of potential new sponsors who do not engage with a regulatory affairs consultant to understand the potential impact on their business of the proposed regulatory clarification = 70

Number of potential new sponsors who do engage with a regulatory affairs consultant to understand the potential impact on their business of the proposed regulatory clarification = 23

Number of potential new sponsors proceeding to sponsor application = 6

. Calculate total time in minutes to fulfil regulatory requirement:

Existing sponsors review regulatory clarification: number of existing sponsors (19) x time required to read explanatory material (60 minutes) = 1,140 minutes

Potential new sponsors equate themselves without use of regulatory consultant with TGA regulatory framework: number of potential sponsors who do not engage (70) x time required for potential sponsor to equate themselves with regulatory framework without consultant (480 minutes) = 33,600 minutes

Potential new sponsors equate themselves with use of regulatory consultant with TGA regulatory framework: number of potential sponsors who do engage (23) x time required to consult with a regulatory affairs consultant (180 minutes) = 4,140 minutes

New sponsors become aware of responsibilities of being a sponsor: number of new sponsors (6) x time taken to become aware of responsibilities of being a sponsor (240 minutes) = 1,440 minutes

New sponsors complete 'Organisation Details' form and register on eBS: number of new sponsors proceeding to sponsor application (6) x time required to complete 'Organisation Details' form (30 minutes) = 180 minutes

Time required for awareness activities: 1,140 (existing sponsors review documents) + 33,600 (new sponsors without regulatory consultant support review documents) + 4,140 (new sponsors with regulatory consultant support review documents) + 1,440 (new sponsors become aware of sponsor responsibilities) + 180 (new sponsors get onto eBS) = 40,500 minutes.

Calculate total time in hours to fulfil regulatory requirement: 40,500/60 = 675 hours

.

Apply the hourly rate to determine overall regulatory compliance cost: 675 x $84.84= $57,267

Add the regulatory consultant charges: $57,267 + $110,400 = $167,667

As noted previously, applications for new listed medicine ingredients are more likely to be linked to ARTG listings for capsulated fat burner sports supplements than powder products. As outlined earlier, a conservative factor was applied (10 applications for new listed ingredients per 100 new listed medicines) to estimate the number of applications for new listed medicine ingredients in relation to estimated new ARTG listings. Under Option 3 the estimated number of new ARTG listings (for the current population) is 40, which will produce 4 new listed medicine ingredient applications.[86] This equates to a 22% uplift on the previous five-year average (n=18) and is a 55% decrease for that identified for options 2A and 2B (n=9).

Given the degree of product turnover in the sports supplements sector, as previously stated, there is assessed to be a 10% year-on-year growth in the number of additional products listed in the ARTG arising from the proposed regulatory clarification (therefore 37 additional listings over the period 2023/24 to 2030/31). Assuming the relationship between new products listed and new ingredients is consistent with historical averages for listed medicines, this equates to an additional 1 new listed medicines ingredient applications.

As no timings and/or requirements for completing new listed medicines ingredient applications differ across options 2A, 2B and 3, please refer to the information previously provided.

[86] Noting that not all ingredients will be suitable for listing on the Permissible Ingredients Determination. For example, due to the risk they pose to consumers, some may need to be scheduled on the Poisons Standard. However, due to the low number of applications for new ingredients forecast, and industry advice that due to the additional cost they were unlikely to seek to register sports supplements in the ARTG, the regulatory cost of registering a new product on the ARTG has been excluded from the costing.

Assumptions are consistent with those identified for options 2A and 2B

Number of new ingredient applications ( ) = 4

Number of new ingredient applications ( ) =1[87]

Approximate cost of a regulatory affairs consultant to prepare an 'Application for evaluation of a substance for use in listed complementary medicines' = $300[88] per hour x 100 hours = $30,000[89] x 4 applications (current population) = $120,000 and for 1 application (future population) = $30,000

. Calculate total time in minutes to fulfil regulatory requirement:

Prepare and submit application for a new ingredient to be added to the Permissible Ingredients Determination: 4 x 960 (time taken to engage with TGA) + 4 x 2160 (time taken to engage with regulatory affairs consultant) = 4 x 3,120 = 12,480 minutes

Calculate total time in hours to fulfil regulatory requirement: 12,480/60 = 208 hours

.

Apply the hourly rate to determine overall regulatory compliance cost): 208 x $84.84= $17,647

Add the regulatory consultant charges: $17,647 + $120,000 = $137,647

. Calculate total time in minutes to fulfil regulatory requirement:

Prepare and submit application for a new ingredient to be added to the Permissible Ingredients Determination: 1 x 960 (time taken to engage with TGA) + 1 x 2160 (time taken to engage with regulatory affairs consultant) = 1 x 3,120 = 3,120 minutes

Calculate total time in hours to fulfil regulatory requirement: 3,120/60 = 52 hours

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Apply the hourly rate to determine overall regulatory compliance cost): 52 x $84.84= $4,412

Add the regulatory consultant charges: $4,412 + $30,000 = $34,412

[87] Noting that this number has been rounded up to the closest whole number.

[88] As advised by industry stakeholders.

[89] As advised by a regulatory affairs consultant.

CONCLUSION

The tables below consolidate the estimated regulatory costing for each of the specific regulatory changes. As per OBPR guidance, regulatory costs are projected over a 10-year period and then averaged to arrive at an average annual regulatory cost.

Table 15. Summary of regulatory costing for options 2A and 2B

Summary Sheet	Cost for Current Population	Cost for Future Population	Average cost over 10-year period
Products	$801,950	$843,451	$164,540
Good Manufacturing Practice	No additional regulatory burden		
Sponsors	$168,812	No additional regulatory burden	$16,881
Ingredients	$309,705	$34,412	$34,412
	$1,280,467	$877,863	$215,833
			$0.22m

Table 16. Summary of regulatory costing for Option 3

Summary Sheet	Cost for Current Population	Cost for Future Population	Average cost over 10-year period
Products	$497,728	$372,759	$87,049
Good Manufacturing Practice	No additional regulatory burden		
Sponsors	$167,667	No additional regulatory burden	$16,767
Ingredients	$137,647	$34,412	$17,206
	$803,042	$407,171	$121,022
			$0.12m

The table below provides the average (over the default ten-year period) estimated regulatory compliance costs.

Table 17: Summary of estimated regulatory compliance costs

Average annual regulatory costs (from business as usual) ($million)				
Change in costs	Business $	Community Organisation $	Individual $	Total change in costs
Option 1				
Status quo: Current food and therapeutic goods regulatory frameworks are appropriate - no clarification is required				
Option 2A				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (includes WADC Prohibited List)	$0.22m			$0.22m
Option 2B				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (excludes WADC Prohibited List)	$0.22m			$0.22m
Option 3				
Clarify the therapeutic goods regulatory framework to make clear that certain sports supplements are therapeutic goods (excludes presentation of sports supplements as pills, tablets and capsules)	$0.12m			$0.12m

ANNEX A – ACRONYMS AND ABBREVIATIONS

Acronym/ Abbreviation	Meaning
ABS	Australian Bureau of Statistics
ANZSIC	Australian New Zealand Standard Industrial Classification
ARTG	Australian Register of Therapeutic Goods
ASADA	Australian Sports Anti-Doping Authority
ASN	Australian Sports Nutrition
CGMP	Current Good Manufacturing Practice
COGS	Cost of Goods Sold
COR	Comparable Overseas Regulator
CTD	Common Technical Document
CV	Compliance Verification
eBS	TGA Electronic Business Services
ES	Elite Supplements
FDA	Food and Drug Administration
FMI	Food-Medicine Interface
FSANZ	Food Standards Australia and New Zealand
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HVAC	Heating, Ventilation and Air Conditioning
MRA	Mutual Recognition Agreement
NW	Nutrition Warehouse
OBPR	Office of Best Practice Regulation
PIC/S	The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-Operation Scheme
RIS	Regulation Impact Statement
TG Act	Therapeutic Goods Act 1989
TGA	Therapeutic Goods Administration
WADA	World Anti-Doping Agency
WADC	World Anti-Doping Code

ANNEX B – BIBLIOGRAPHY

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ANNEX C – STAKEHOLDER CONSULTATION

Industry Stakeholder Consultation

Stakeholder Company Name	Industry Group	Consultation Type
ATP Science	Manufacturer/Sponsor	Face-to-face
Australian Sports Nutrition (ASN)	Retailer/Manufacturer	Telephone
Consumer Healthcare Products Australia (CHP Australia)	Industry Body	Telephone
Dieticians Association Australia	Industry Body Note: Interviewee was also an independent Food Regulation Consultant	Face-to-face
Metagenics	Manufacturer/Sponsor	Face-to-face
Morlife	Manufacturer	Face-face
Natural Vitality Australia	Manufacturer/Sponsor	Telephone
Nutrition Warehouse	Retailer/Brand Owner	Face-to-face
Pharmacare	Manufacturer/Sponsor	Face-to-face
Purvis Regulatory Consulting	Regulatory Consultant	Face-to-face/email correspondence

Government Stakeholder Consultation

Stakeholder Organisation	Consultation Type
Australian Sports Anti-Doping Authority (ASADA)	Face-to-face
Department of Health National Integrity of Sport Unit	Face-to-face
Food Standards Australia and New Zealand (FSANZ)	Face-to-face

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Appendix 2: Examples of ingredients in sports supplements

The following list of ingredients were drawn from several sources (reference list provided below) and provide examples of some of the different kinds of ingredients that have been found, or could be contained, in sports supplements overseas and in Australia.

Ingredient name (alternative names)	Class	Poisons Standard	WADC Prohibited	Notes
Beta-alanine(1,2)	Amino acid	No	No	
Oxedrine (Bitter orange extract/synephrine) (2)	Stimulant	Poisons Standard - Schedule 4 - Oxedrine for human internal use except in preparations labelled with a recommended daily dose of 30 mg or less of oxedrine.	No	Not scheduled when labelled with a recommended daily dose of 30mg or less of oxedrine.
Caffeine(1,2)	Stimulant	As of 1 June 2020, Schedule 4 and Schedule 6 (See notes)	No	An final decision has been made to schedule caffeine as follows (date of effect is 1 June 2020): Schedule 4: Caffeine for internal human therapeutic use except: – in divided preparations when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or – in undivided preparations with a concentration of less than 5 per cent of caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine. Schedule 6: Caffeine except: – when included in Schedule 4; or – in divided preparations for internal human therapeutic use when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or – in undivided preparations for internal human therapeutic use with a concentration of less than 5 per cent of total caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or – in preparations for external use; or – in other preparations with a concentration of less than 5 per cent of caffeine
Carnitine/L-Carnitine(1,2)	Amino acid	No	No	
Citrulline(1,2)	Amino acid	No	No	
Creatine(1,2,3)	Organic compound	No	No	

Ingredient name (alternative names)	Class	Poisons Standard	WADC Prohibited	Notes
Glutamate/L-Glutamate(1)	Amino acid	No	No	
Green Tea Extract(2)	Herbal extract	No	No	**Caffeine is a component of this ingredient and may result in the product being scheduled if the amount of caffeine meets the scheduling criteria (see Caffeine in this table)
Higenamine(2,5)	Beta-2 agonist	No	Yes	
Hydroxyephedrine (Oxilofrine) (6)	Stimulant	Poisons Standard - Schedule 4	Yes	
Ligandrol(5)	Selective Androgen Receptor Modulator (SARM)	Poisons Standard - Schedule 4	Yes	
N-acetyl cysteine(5)	Antioxidant	Poisons Standard – Schedule 2 in preparations for oral use except when labelled with a recommended daily dose of 1 g or less of acetylcysteine. Schedule 4 except: a) when included in Schedule 2; or b) in preparations for oral use when labelled with a recommended daily dose of 1 g or less of acetylcysteine.	Yes	Unscheduled when labelled with a recommended daily dose of 1g or less
Panax ginseng root(1)	Herb	No	No	
Quercetin(4,5)	Antioxidant	No	No	
Sibutramine(5)	Stimulant	Poisons Standard - Schedule 4	Yes	

Ingredient name (alternative names)	Class	Poisons Standard	WADC Prohibited	Notes
Taurine(1)	Amino acid	No	No	
Tribulus terrestris(4,5)	Herb	No	No	Not WADC Prohibited List but at high risk of being contaminated (AIS)
Tryptophan (1)	Amino acid	Schedule 4: for human therapeutic use except in preparations labelled with a recommended daily dose of 100 mg or less of tryptophan	No	Unscheduled when labelled with a recommended dose of 100mg or less of tryptophan.
Tyrosine/L-Tyrosine(1)	Amino acid	No	No	
Whey protein concentrate(1,2)	Protein	No	No	
Yohimbine alkaloids(2,4)	Herbal component	Poisons Standard - Schedule 4	No	

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