



## Department of Health

### Sports Supplements Roundtable: Report on Discussions and Next Steps

August 2018

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## **Sports Supplements Roundtable – Report on Discussions and Next Steps**

In July 2018, Deloitte was commissioned to facilitate a Roundtable on the Regulation of Sport Supplements.

The roundtable was convened by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee after a request from the Australian Government Minister for Health, the Hon Greg Hunt MP.

The Minister requested a roundtable discussion to consider whether there are opportunities at the Australian Government and/or state and territory levels to enhance the safety of consumers who choose to use sports supplements.

The attached document reports on the proceedings of the Roundtable, the key issues raised and recommends further work on some options for improving safety for consumers of such products.



**Gary Rake**

**Partner**  
**Deloitte Consulting Pty Ltd**

# Background

The roundtable was convened by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee (FRSC) after the Australian Government Minister for Health wrote to the Acting Chair of FRSC in relation to the death of a young woman in Western Australia. The young woman's death was attributed to 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).

The Minister asked FRSC to convene a roundtable to investigate whether there are opportunities at the commonwealth and/or state and territory levels to enhance the safety of consumers who choose to use sports supplements.

## Attendees

The roundtable was attended by representatives from Australian Government agencies, state and territory governments, public health organisations and from industry.

Name	Organisation
Gary Rake	Facilitator, Deloitte
Lyndall Soper Christel Leemhuis Holly Jones Belinda Turk Andrew Godkin Dr Lucas de Toca Dr Lisa Studdert (afternoon only)	Australian Government Department of Health
Mark Phythian	Department of Agriculture and Water Resources
Sarah Gifford	Department of Industry, Innovation and Science
Dr David Cusack Ian Beer	NSW Department of Primary Industries
Sophie Dwyer	Queensland Health
Stan Goodchild	Health WA
Conrad Barr	ACT Health
Janelle Kwon	Department of Health and Human Services Victoria
Dr Fay Jenkins	SA Health
Karen Lau	New Zealand Ministry for Primary Industries
Dr Eva Bennet	Implementation Subcommittee for Food Regulation Chair
Mark Booth Janine Lewis Peter May	Food Standards Australia New Zealand
Dr Adam Cook Cheryl McRae	Therapeutic Goods Administration
Louise Healy	Metabolic Dietary Disorders Association
Dr Kaustuv Bhattacharya	Representing the Australasian Society of Inborn of Metabolism
Professor Louise Bourke	Australian Institute of Sport
Chloe McLeod	Sports Dietitians Association
Amelia Webster	Nutrition Australia (Qld)
Dr Adam Castricum	Australian College of Sport and Exercise Physicians
Dr Jon Wardle	Representing Public Health Association of Australia)
Matt Rees	Australian Sports Nutrition
Stephen Eddy	ATP Science
Harriet Walker	BodyScience
Jess Crowley Ben Crowley	Bioflex Nutrition (Bulk Nutrients)

# Presentations

The roundtable commenced with presentations from key organisations to help participants understand the current regulatory environment and some of the emerging issues.

## **Lyndall Soper, First Assistant Secretary, Population Health and Sport Division, Australian Government Department of Health**

- Ms Soper welcomed the attendees on behalf of Dr Studdert who would be arriving later in the day.
- Ms Soper noted the diverse range of attendees and the valuable opportunity to draw on the expertise in the room.
- The aim of the meeting is to have a robust discussion, taking into account all points of view and to gain insight into how the regulatory system is operating and identify opportunities to improve the safety of sports supplements.
- An Action Plan will be developed from discussions and a report provided to the Minister, through the appropriate channels.

## **Mark Booth, Chief Executive Officer and Janine Lewis, Principal Nutritionist, Food Standards Australia New Zealand (FSANZ)**

- Food safety is a priority for the food regulatory system. Food standards are developed for the general population and are not designed to fully protect all consumers at all times. They cannot seek to manage rare adverse effects in the population and focus on risk management, not risk elimination.
- Food for sale must be safe and suitable. Food is considered to be 'unsafe' if it contains a biological or chemical agent likely to cause physical harm including if it was consumed by the person according to its reasonable intended use. Food is not considered unsafe because its inherent nutrition or chemical properties cause adverse reactions only in persons with allergies or sensitivities. Urea Cycle Disorders are considered to be similar to allergies or sensitivities in this instance.
- Standard 2.9.4 – Formulated Supplementary Sports Foods (FSSF) of the Australia New Zealand Food Standards Code (the Code) was established in 1998 and has not been substantially changed since. It reflected the market at the time and did not anticipate such common use of FSSF in the general population.
- When Australia and New Zealand created a joint food system Standard 2.9.4 was the only Standard that was not reviewed.
- Definitions under the Standard state that a formulated supplementary sports food means a product that is specifically formulated to assist sports people in achieving specific nutrition or performance goals. The definition includes sports drinks, but excludes electrolyte drinks.
- Definitions under the Standard may be outdated and some newer products do not fit neatly into these. This exacerbates the grey area between foods and medicines, known as the Food-Medicine Interface.
- Under Standard 2.9.4, a warning statement is required on FSSF: Not suitable for children under 15 years of age or pregnant women: Should only be used under medical or dietetic supervision. However, this sometimes can be misinterpreted and could be made clearer.
- The Standard allows for several label statements about usefulness and appropriate use in 3 categories of sports foods.

- Planning for a review of the Standard began in 2010 and consumer research undertaken in 2010 and 2012, but work has been deferred awaiting further development of P1024 – Nutritive substances and novel foods. The current priority for this review is under consideration.

### Dr Adam Cook – A/g Director, Listing Compliance Section, Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Act 1989 defines what products are and are not therapeutic goods. Goods that are foods according to the definition in the Act are not therapeutic goods, and are therefore not regulated by the TGA.
- The Food-Medicine Interface Guidance Tool assists in determining whether a product is a food or a medicine when there is uncertainty about its regulatory status.
- If a sports supplement were considered a therapeutic good, it would generally fall under the Listed Medicine category of the Australian Register of Therapeutic Goods (ARTG). This is a class considered to have a low level of risk.
- The safety of sports supplements that are therapeutic goods is assured by pre-market eligibility criteria, post-market monitoring and enforcement and detection and enforcement action for therapeutic goods that are not on the ARTG.

### Dr David Cusack, Manager, Food Standards and Programs, NSW Department of Primary Industries Food Authority

- Part 2.9 of the Code: Special Purpose Foods has its own policy guidance recognising the specific role of these foods:
  - food standards that prescribe specific requirements for foods processed or manufactured for use by physiologically vulnerable individuals and population sub-groups. Requirements within food standards in Part 2.9 are prescribed relative to the particular intended dietary use of the food.
- This is further explained as physiological vulnerability and risk of dietary inadequacy from;
  - physical and physiological needs that relate to stage of life (e.g. infancy),
  - physical disease or disorder,
  - conditions that require altered energy intake (such as elite sport).
- Sports supplements have more prescription on composition, labels and claims than general foods.
  - standard 2.9.4 has not been reviewed since it was written (1990's) and the market has changed significantly since that time. Internet sales more prevalent, imports are important source of product and 'pre-workout' products have emerged as an important sector in the market. These products are now far more easily available to a broader range of consumers than was the case when the standard was first developed.
- Previous sports foods compliance action undertaken in NSW.
  - Several consumer complaints were received in 2011, which led to a large compliance operation in 2012-13.
  - In 2012, DMAA was added to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).
  - The compliance action focussed on:

- composition, use of prohibited or restricted materials
- Use of synthetic derivatives of prohibited substances
- Non-compliance with labelling requirements
- Exceeding defined limits in the Code for permitted substances.
- Key findings:
  - Pre-workout supplements were found to be more likely to contain stimulants, mood enhancing ingredients and harmful substances.
  - Seizures of products containing prohibited ingredients – e.g. DMAA, NADB.
  - Seizure of products exceeding permitted limits in the Code – e.g. amino acids.
  - Listing non-approved novel foods and nutritive substances as ingredients.
  - Non-compliance with allergen and Nutrition Information Panel labelling.
  - Very high levels of caffeine.
  - An education sheet was developed and an increase in compliance was found during re-visits.
- Products containing DMAA were seized as its use has been associated with various adverse health effects such as high blood pressure, headaches, vomiting and cerebral haemorrhage and stroke.
- Products containing NADB were seized as it has very similar structural chemistry to methamphetamine.
- The market has significant quantities of imported products, with online sales making a large percentage of the market. Challenges in compliance in relation to FSSF come largely through online sales. Some supply of product is also through the NZ supplemented food standard.
- The FSSF market is a demand driven market, with some consumers actively motivated to seek an edge or advantage. Consumers within this market are considered unlikely to respond to traditional risk messaging of 'buyer beware'.
- Cooperation between Commonwealth agencies, addressing risk products at the border and gathering intelligence may be able to help compliance and enforcement issues into the future.
- The recent TGA ban on DMHA and DMBA and any similar analogues has led to some products manufactured overseas including synthetic caffeine derivatives e.g. teacrine and dynamine. There is a lack of safety assessment information about these compounds.
- the amount of caffeine in these products should be reviewed. Some products contain 400mg of caffeine per serve. This is the daily limit suggested by EFSA in its 2015 scientific opinion on caffeine to not give rise to safety concerns.

### Mark Phythian, Director, Imported Food Section, Department of Agriculture and Water Resources (DAWR)

- DAWR administers the Imported Food Control Act 1992 in relation to FSSF and conducts inspections of imported food at the border. Other agencies such as Australian Border Force may also screen foods for other purposes.

- Products sent through mail (including small parcels), or that are in consignments of under 10kg are considered for private use and are not subject to the above Act.
- The Trans-Tasman Mutual Recognition Arrangement (TTMRA) is an agreement between the Australian and New Zealand governments. This agreement recognises that if food produced or imported into one country meets that country's food standards, it may be legally sold in the other country. The Imported Food Control Act exempts food imported from New Zealand where the food is covered by the terms of the TTMRA, so there is no border inspection. This applies to FSSF and dietary supplements imported from New Zealand
- Testing at the border is undertaken through a risk based approach. FSANZ provides food safety assessments that identify the level of risk that food products pose, with the department then classifying foods in accordance with the risk advice which determines the frequency of inspection and testing.
- Note that FSANZ risk assessments are based on the inherent properties of the food (e.g. potential for toxins or microbiological risk), not the potential for non-compliance.
- FSSF are considered to be a surveillance food in the imported food inspection scheme with around 5% of surveillance foods assessed at the border. Therefore, most FSSF are not subject to inspection by DAWR.
- If food enforcement authorities or individual businesses become aware of non-compliant imported products in the domestic market, they are encouraged to notify DAWR.
- Failed food reports are listed on the DAWR website each month..

**Dr Lucas de Toca, Principal Adviser, Office of Health Protection,  
Australian Government Department of Health**

- The definition of 'sports supplements' is viewed differently by consumers, regulators and the media. This makes it hard to generalise risks on such a diverse range of products. Focus for this presentation is products taken orally, by the general population and without medical supervision. Not focussing on elite athletes.
- These products are taken by otherwise healthy people and have the potential to interact with drugs being taken concurrently. The products being consumed are regularly changing, which makes it difficult to get a full history from consumers where there have been adverse effects.
- The sports supplement industry has grown dramatically in recent years, with 14% growth each year from 2009-2014.
- The FSANZ Sports Food Consumption Survey 2013 found that 10% of survey respondents consumed a sports supplement in the four weeks preceding the survey. Of this group, 6% reported having experienced side effects. However, the exact product and severity of the side effect was not recorded.
- There is anecdotal evidence that supplement use is starting at a young age, especially in the adolescent male population.
- Protein powders are by far the most commonly used product.
- The common perception that 'natural' and 'organic' means a product is automatically safe and good can be misguided.
- The effectiveness of a number of products is still largely unknown. Ingredients such as Branched-Chain Amino Acids (BCAA) have strong evidence to show they



work well when produced by the body, but evidence is not clear on the effectiveness of the external intake of these.

- Potential contributors to adverse effects include:
  - Underlying conditions such as metabolic dietary disorders.
  - High amount of nutrients or unknown effects of 'natural' and 'herbal' products.
  - Steroids and stimulants in products.
  - Supplement 'stacking' (i.e. taking multiple supplements together) or drug interactions
  - Use of prohibited substances, which may also come about through mislabelling, adulteration or contamination.
- The Australian Institute of Sport (AIS) Sports Supplements Framework groups supplements into four categories (A, B, C or D) based on the strength of the evidence base for safety and effectiveness. This advice is, however, intended to guide elite athletes in controlled environments, not the general public.
- The Australasian College of Sport and Exercise Physicians (ACSEP) position statement on supplements takes a 'food first' approach and states that consumers should not assume that a sports supplement available for purchase in Australia or New Zealand is safe for use and free of ingredients with harmful health effects.

# Register of Issues Raised

This register is a summary of key concerns and points of interest raised by attendees throughout the roundtable.

## Regulations

- There are a number of Standards under Part 2.9 of the Code. It may be worth considering whether these can be consolidated when reviewing Standard 2.9.4 to simplify compliance. However, it was noted that including more Standards into the potential review of Standard 2.9.4 would increase the workload and slow the process. Furthermore, most components of these Standards would need to be retained.
- Any review of the Standard should aim to be future-proofed. The review process should include anticipation of the style of products that may be released into the future. This concept is challenging as keeping the standard broad to allow for future product innovations means that a large number of products will fall under the Standard and it is unclear whether these products are foods or medicines.
- It was noted that manufacturers are able to put the statement 'Formulated supplementary sports food' on labels, when these products are not necessarily a food. Consideration needs to be given to how broad definitions will be and what groups of products will potentially be captured under these.
- Consideration could be given to whether DAWR could increase the inspection rate of FSSF and what evidence or advice would be required from FSANZ to facilitate this. It was noted that the FSANZ risk assessment, which is used by DAWR to determine if a food is a 'risk' or 'surveillance' food, is based on the extent to which a product is a risk to human health.

## Metabolic Dietary Disorders

- People with these disorders are not only affected by protein (or other nutrient) intake, exertion placed on the body also has an impact. There are a range of disorders including metabolising other nutrients.
- Urea Cycle Disorders were added to newborn screening in 1998, but have since been removed. The presence of the condition does not necessarily mean a person will be symptomatic and therefore the testing was not particularly helpful.
- Any extreme variants in diet and lifestyle can have consequences for people with a range of disorders.

## Pre-trainers and weight loss supplements- Caffeine

- A number of products have been presenting with up to 400mg of caffeine in one serving.
- FSANZ advice (considered potentially outdated) states that increased anxiety levels occur in adults with an intake of 210mg per day. However, current advice from the European Food Safety Authority in its 2015 scientific opinion on caffeine suggests that consumption of up to 400mg does not give rise to safety concern.
- It is considered that general consumers are unsure of what the safe maximum daily intake is.
- Concerns were raised over the addition of caffeine derivatives, such as theacrine (TeaCrine®) and Dynamine. Some products contain large amounts of caffeine and these derivatives. This could increase the inherent risk in those products.
- It was noted that sports dietitians have the knowledge to advise consumers of a safe level for their needs, but qualified personnel are rarely available when consumers are purchasing these products.

## Composition and interactions with other products

- Some sports supplements provide a very large serving of a single ingredient that under the Code is considered 'safe', but when this ingredient is consumed at high levels it may have the potential to become toxic.
- Consumers assume that if a product is on the shelf then it is safe to consume at the dose they should be taking it.
- Research shows consumers are frequently taking more than one product at the same time. The interaction between these products and other medications is important to know. St John's Wort is an example of this.
- Natural or organic does not mean that these products are safe. Unsafe ingredients can be sourced naturally.

## Reporting of adverse effects

- It was noted that there is a lack of data available on the incidence of adverse effects to consumers when taking sports supplements. Work could be done to improve this data gap.
- The FSANZ telephone survey from 2010 is available, but no further questions were asked on the types/severity of adverse event or the specific products that were taken. Further research into this area would be valuable.
- Furthermore, consideration was given to including doping violations as adverse effects of taking these products. Australia's obligations under international anti-doping codes should be considered.

## Reporting of sales data

- The option to obtain sales data from industry would allow for further insight into what products are being purchased and why.

## Capacity of compliance and enforcement officers

- It is widely accepted that there are a number of non-compliant products that are available to Australian and New Zealand consumers. From previous compliance activities, this is considered to be largely from overseas products that are privately purchased on the internet.
- It was also noted that consumer education is important, but when products contain undeclared ingredients, then education can only go so far.
- This is now a global industry. It was acknowledged that the Australian sports supplements industry should be protected when considering potential action. Any scrutiny should be equally applied to both domestic and international companies.

# Options to Improve Consumer Safety

After an extended group discussion, participants worked in small groups to consider options for improving the safety of consumers who use sports supplements.

Each small group presented a summary of their ideas and options to the broader group roundtable participants – allowing discussion, questions and counter-issues to be raised. This part of the roundtable was particularly productive and conducted with goodwill.

Participants were advised, and acknowledged, that evidence-based, best practice regulatory evaluation would need occur before any options could be formally recommended to government.

There was a clear and unanimous view within the roundtable that all parties were willing to work together to improve product safety and would be willing to continue further engagement to develop options.

The following ideas and options were raised during the roundtable and attracted broad support within roundtable participants. No significant objections were raised by any roundtable participant in response to any of the following options.

## Full review of Standard 2.9.4 – Formulated Supplementary Sports Foods

- This may include a review of the definition of a sports supplement. A new definition may pull more products under the Code to minimise the number of products that fall into the FMI.
- The maximum permitted levels of caffeine and its derivatives to be a consideration in this review. Potential maximum levels of other permitted ingredients would also be considered. This could also relate to product risk tiers.
- Consideration of including a warning statement on products to the effect of – Medical or dietetic advice should be sought prior to consuming this product.

***This option had the strongest level of support.***

## Compliance and Enforcement

- Increase the enforcement capacity for regulators and increase the ability for enforcement officers to efficiently remove non-compliant products from the market.
- Give consideration to closing import loopholes.

***This option had strong support, with all parties expressing a desire to see dangerous products and unethical businesses removed from the market.***

## Data collection and better understanding of the problem

- Consider better and more consistent reporting is needed to understand the nature of the problem and adverse events. This could include reporting to the TGA or to health departments.
- Data from industry would also be helpful.
- Undertake more work to understand the issue and what regulatory options are available to address the issue.

***This option had strong support – with industry participants indicating they could also share information on emerging trends (positive and negative) based on their interactions with consumers.***

### Education campaigns targeted at:

- Critical care professionals – to support health care professionals to maintain their knowledge and skills in identifying and managing a patient with a metabolic condition.
- Health professionals – to encourage general health professionals to enquire whether sports supplements have been consumed when determining the cause of a reaction.
- Consumers and agents who sell/recommend products – to educate all consumers, manufacturers and suppliers (online and retail) of the potential risks of consuming sports supplements. This includes targeting users and the specific industry. The need for carefully planned communication messages was recognised, as warning consumers not to take supplements is unlikely to be engaging, consumers that are seeking a competitive advantage may be more likely to take risks to achieve their desired outcome.
- Gym owners and personal training educators - to educate personal trainers that they should be providing only basic health eating information, not specific advice on taking sports supplements. Advice should be sought from a qualified health professional prior to recommending sports supplements.

***This option had the strong support but noting the risk of alienating consumers if the message was poorly pitched.***

### Risk tiers

- This would see products classed into specific groups aligned with an agreed risk level. For example, higher risk products (such as those with very high caffeine levels) may be placed behind the counter and require advice prior to purchase.
- Concerns were raised on this matter as to the equality between a retail business versus an internet business.
- Further concerns were raised that if domestic products are placed behind a counter, consumers will purchase products online which may be less likely to be compliant.

***This option had support in-principle, noting that further policy work would be required to consider the effectiveness of such an option and means of implementing it without undue regulatory burden.***

# Next Steps

Based on the proceedings of the roundtable, including the presentations and subsequent discussions and ideation, we recommend the Australian Department of Health:

1. Consider the options raised by the roundtable and provide a brief evaluation report to the FRSC and the Australia and New Zealand Ministerial Forum on Food Regulation including a recommended Action Plan for consideration by the Australian Government Minister for Health.
2. Develop a stakeholder engagement plan to ensure that industry, consumers, public health organisations and regulators have reasonable opportunity to continue contributing to the development of options to improve consumer safety.
3. Consider convening a further roundtable/s at a later date to discuss how to progress the potential actions.



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