# Submission: Consultation: Sports supplements Proposed clarification that certain sports supplements are therapeutic goods Version 1.0, October 2019

[redacted]

2nd December 2019

I, [redacted] appreciate the opportunity to respond to the consultation paper that proposes clarification that certain sports supplements are therapeutic goods.

Whilst I do not have direct vested interest as an avid consumer, manufacturer or retailer of formulated sports supplements (FSS), professionally; as a former registered pharmacist, medicinal chemist, research scientist and personally; as a fitness enthusiast, I believe that the provision of critical appraisal in commentary of this consultation paper should hold valid consideration for subsequent deliberations

The objective of the proposed reforms describes an approach to resolve some of the uncertainty around the regulatory status of sports supplements, to ensure they are regulated appropriately to safeguard public health and safety. A collateral objective describes that some sports supplements carry explicit or implied claims relating to sport, fitness or recreational performance that mean they are likely to be consumed for therapeutic use and that those that are taken to be for therapeutic use should be subject to the same national system of controls that are established for other therapeutic goods.

- I do not support the proposed evidence that Australian manufactured FSS, upholding compliancy with the Australia New Zealand Food Standards Code- Standard 2.9.4- Formulated supplementary sports foods, pose a prominent or emerging risk to public health and safety. I do not believe that the cited materials within the consultation paper accurately substantiate a necessity to collectively reclassify many common food ingredients that are currently permissibly used in FSS on the basis of allegedly containing *'high risk ingredients not suitable for food'* that would predispose adverse or deleterious health effect (AE) and would require '*swift regulatory action by appropriating the TGA as the relevant regulator.'*

- I do not support the proposed interventions sort to be facilitated through a broad-stroking reform via the proposed order, under subsection 7(1) of the Therapeutic Goods Act- and believe this to be an extreme and largely indolent, yet futile measure control a very small subsection of product for which, the little evidence available suggests; have been interloped through importation from countries that have vastly different regulation of therapeutic goods and sports supplements. I believe that the consultation paper has overlooked some important and reliable sources of indirect TGA reported evidence regarding the safety of Australian manufactured FSS. I believe that the history of prior surveillance and reactionary legislative changes administered by the TGA have been largely successful and this model intervention by an external regulatory body, for the ascertaining and maintaining public health and safety, has had this success built on a case to case basis.

- I do support prior identified issues identified in the ongoing FSANZ Administration assessment report- Proposal P1010 that pertains to importation of products from overseas manufacturers that do not conform with the Food Standards Code: Standard 2.9.4 and agree with prior and ongoing analysis performed by FSANZ that the low level evidence demonstrating any incidence of reported adverse effects or potential public health risk more accurately reflects this facet of 'shoehorned' FSS, and are therefore not a reflection of the success or failure of the current dictating legislation. I also support the continuation and completion of FSANZ Administrative assessment report- Proposal P1010 to review Standard 2.9.4- Formulated Supplementary Sports Foods and be and believe this TGA mediated intervention serves only to disrupt this yet to be complete process.

My detailed response to the consultation is included below.

1. **The evidence cited as means of indicating potential risks or actual incidence of adverse effects for formulated supplementary sports foods manufactured and sold within Australia is insufficient, unreliable and in some cases irrelevant to provide impetus for the acutely devised and imminently proposed regulatory interventions/legislative reform.**

Given recent reliable data indicates increased prevalence of use of FSS to broader demographics[1-6] with FSS product categories amassing greater scope of intended purposes[7,8] and the expansion of the FSS industry in mainstream retail and online permitting the ease of accessibility, it would be suspected that the incidence of AE's should have a paralleling or trending increase. Subjectively, it could be assumed that if there was such predisposing risk of FSS supply and use under the current regulation and jurisdiction, AE's would reach frequent and widespread reportable proportions inside Australia. According to the limited explicit and directly assessed data sources and inferring from indirect sources, this would seemingly not be the case, and certainly not to the critical level of proclivity expressed in the TGA FSS consultation paper.

The Consultation document cites two forms of evidence[9,19] to highlight the importance of intervening regulatory action, and states:

*'Medicines are subject to a national system of controls established under the TG Act to assure quality, safety and efficacy according to the risk those medicines pose to consumers. The nature of and therapeutic claims associated with many sports supplements, which are **OFTEN(?)** also found to contain higher risk ingredients not suitable for food, demands that those products are, where appropriate, regulated as medicines.'*

***TWO(?)** recent **STUDIES(?)** on sports supplements available in Australia highlight the importance of ensuring appropriate sports supplement regulation:*

*• In 2016, life science company LGC analysed 67 leading brand sports supplements available in Australia. One in five products contained one or more substances banned in sport. Two products were found to contains such high levels of unlabelled stimulants that were considered to pose a significant health risk to athletes along with a significant risk of failing a drug test.*


1. O'Brien, S., Malacova, E., Sherriff, J., & Black, L. (2017). The prevalence and predictors of dietary supplement use in the Australian population. Nutrients, 9(10), 1154.
2. Shaw, G., Slater, G., & Burke, L. M. (2016). Supplement use of elite Australian swimmers. International journal of sport nutrition and exercise metabolism, 26(3), 249-258.
3. Waller, M. C., Kerr, D. A., Binnie, M. J., Eaton, E., Wood, C., Stenvers, T., ... & Ducker, K. J. (2019). Supplement Use and Behaviors of Athletes Affiliated With an Australian State-Based Sports Institute. International journal of sport nutrition and exercise metabolism, (00), 1-8.
4. Baker, B., Probert, B., Pomeroy, D., Carins, J., & Tooley, K. (2019). Prevalence and Predictors of Dietary and Nutritional Supplement Use in the Australian Army: A Cross-Sectional Survey. Nutrients, 11(7), 1462.
5. Whitehouse, G., & Lawlis, T. (2017). Protein supplements and adolescent athletes: a pilot study investigating the risk knowledge, motivations and prevalence of use. Nutrition & dietetics, 74(5), 509-515.
6. Barnes, K., Ball, L., Desbrow, B., Alsharairi, N., & Ahmed, F. (2016). Consumption and reasons for use of dietary supplements in an Australian university population. Nutrition, 32(5), 524-530.
7. Burke, L., Cort, M., Cox, G. R. E. G., Crawford, R., Desbrow, B., Farthing, L., & Warnes, O. (2006). Supplements and sports foods. Clinical Sports Nutrition. Sydney, Australia: McGraw-Hill, 485-579.
8. Kerksick, C. M., Wilborn, C. D., Roberts, M. D., Smith-Ryan, A., Kleiner, S. M., Jäger, R., ... & Greenwood, M. (2018). ISSN exercise & sports nutrition review update: research & recommendations. Journal of the International Society of Sports Nutrition, 15(1), 38.
9. LGC. Australia Supplement Survey Summary. 2016. https://www.informedsport.com/sites/default/files/LGC_Australian%20Supplement%20Survey_0.pdf
10. Cooper, E. R., McGrath, K. C., Li, X., & Heather, A. K. (2018). Androgen bioassay for the detection of nonlabeled androgenic compounds in nutritional supplements. International journal of sport nutrition and exercise metabolism, 28(1), 10-18.

• *In 2017, researchers from the University of Otago and the University of Technology Sydney screened 116 sports supplements available in Australia, including protein powders, preworkout formulations, fat metabolisers, vitamins and herbal extracts. More than 1 in 20 supplements contained* ***ANABOLIC STEROIDS(?)*** *that were not declared on the product labels. The research concluded there is a real health risk and doping violation risk for athletes consuming sports supplements.*

Furthermore, Deputy Secretary, Health Products Regulation Group of the TGA John Skerritt commented on ABC Illawarra radio on the 22 November 2019:

*'There is evidence that supplements that have been sold in Australia as having been tainted. There is one… [?research study?]'*

*It is those that are really being promoted as medicines- for example: affecting your heart (or whatever) or contain these undeclared (ahh) ingredients- that are actually already medicines but the grey area.'*

The first cited reference is in fact not a study as stipulated in the consultation documents, but rather results of an informal survey that also seemingly encompassed desperately incomplete disclosure of experimental procedures. The company whom conducted this; LGC UK, formerly known as HFL Sport Science primarily operate out of the United Kingdom, have used very little detail to indicate that survey was conducted for means of undisclosed 'anti-doping purposes on products that did not claim to undergo regular banned substance testing and had an aim to assess the risk to athletes and the general consumer'. Further research in to the company reveals that LGC are the facilitator of 'The Informed Sport (2008) certification programme' which is an independent and voluntary program for FSS companies who wish to register products. These FSS companies can purchase the services and product of Informed Sport. As such, given this company does indeed provide a direct service, the purpose for the self-funding of this survey evidently serves to provide information for which can substantiate the sale of this service and product. This is an undisclosed conflict of interest that limits the usability of the data produced and mitigates the scientific merit of the results. Additionally, the survey results were not peer-reviewed nor published or have been cited in any form of reputable scientific source and the explicit purpose of the survey, or the intended audience of the data produced is not made public in any associated media source that permits acquisition. In fact, the survey publication accessible only from the Informed-Sport website, the precise company for which offers the services facilitated by LGC. To further cloud any reliability of this survey results, the data is severely underpowered and incomplete to elucidate any form of usability for the purposes attempted within the TGA consultation document. There is no raw data provided, insufficient methodology and statistical analyses described and finally, admitted limitations to the precise measure of adverse effects for which should form the only usable information that would support the citation in the TGA consultation document.

As evidence for importance of the need to intervene with current governing legislation of FSS, the second reference; a research paper by Cooper et. al (2018) is also not reliable and, when the data produced from the study is critically assessed, does not appear to bear relevance nor the scientific rigour for the extrapolated reference of FSS safety in Australia. This published paper is in fact an extract of a student thesis that was subsequently published in a peer review journal, and much the same as the results of the LGC survey, was not actually produced through means that would be exclusively used for the purposes of providing information that could be used for reforming government legislation. Whilst this does not mitigate the credibility of the final published paper, the

fact this this is indeed the solitary peer-reviewed evidence used to support this position not only demonstrates a distinct lack of comprehensive direct data in this area but potentially; aberrant and speculative extrapolation of the findings, especially considering other means of comprehensive analysis have (seemingly) not yet been explored. Additionally, this paper does not have an appropriate qualitative methodology to discern the specific presence of 'anabolic steroids' in the samples assessed- as asserted in the consultation document; '*many sports supplements, which are **OFTEN(?)** also found to contain higher risk ingredients not suitable for food*' therefore does not appear reflect the actual evidence attained in this paper or that cited in the consultation document.

Dissecting the actual application of the information generated by this thesis extract (Cooper et. al 2018); the complete series of experiments assesses an in vitro method for detecting androgens using a yeast bioassay. This yeast bioassay is a method that has been used in different research studies in the past for many different preliminary applications[11-13] . It is very unlikely that it has been formally used by any government agency in the context of detecting anabolic steroid contaminants or adulterated food products . The thesis experiment primarily assessed the usability of the bioassay for the preliminary screening in a sequence by first testing frank designer anabolic steroids as modified androgens and then precursory androgens, both of which are not sold legally with inside Australia, let alone permissible as FSS components. This was performed by Cooper et. al to ascertain usability of this method and then later; to examine the presence of potentially unlabelled androgens in sport supplements purchased inside Australia. The latter experiment became the published paper in the International Journal of Sports Nutrition and Exercise Metabolism.

For the purposes of ascertaining the presence of both scheduled and unscheduled androgen receptor activating agents, which not only includes steroidal androgens but also non-steroidal ligands, the yeast bioassay methodology used in the experiment is in fact rather crude and non-discriminative.[11] In the context of specifically assessing for steroidal androgens it could be considered a preliminary and indirect qualitative method.[11-14] By using beta-galactosidase enzyme activity to determine androgen activation it is not possible to determine the actual ligand that is responsible for the activity[11-14]. Whilst the results indicating positive androgen receptor activation are not in any doubt- this needs to be considered in the greater context as to what these results have determined and the little discrimination they provide. There exists many identified unscheduled androgen receptor activating ligands, some of which are common as substances found in packaged foods.[14-17] Mertl et. al (2014) found that food contact substances consisting of many non-intentionally added substances, such as side products from complex polymerization reactions or breakdown products from antioxidants and food packaging might form a source of detected hormone activity using this same yeast model method of hormone assay. Svobodová et al (2009) and Coleman et. al (2009) found Triclosan, polychloro phenoxy phenol antimicrobial agent that is ubiquitous in plastics manufacture[18], can produce positive androgen activation using a similar yeast/beta-galactosidase assay.[16-17] This large limitation of the cited paper does indeed cast a doubt on the applicability to rationalize the importance of legislative reform. Without appropriate identification of the contaminants it can only be assumed that the source has come from a previously recognized illegal or scheduled medicines or poisons. This papers weight in the rationalization of the legislative reform should be there considered in this context only, until such a time that appropriate examination and analysis is performed.

I note that the TGA do acquire independent technical and scientific services from the National Measurement Institute (NMI), a faculty of the Australian Government Department of Industry, Innovation and Science. The NMI are the Government division whom hold leading expertise in sport

drug testing therefore it would seem most suitable and most reliable that any official materials identifying and referencing specific contamination or adulteration of FSS with anabolic steroids or steroid metabolites (and also stimulants) that are available to the Australian public, would have been produced using this ready-existing relationship between the NMI and the TGA.

Casting further doubt onto the actual pertinence of the Cooper et. al (2018) results to the Australian FSS market, as would pertain to Australian supplement manufacturers, is the fact that the results of the study indicate that United States of American based supplements imported into Australia accounted for nearly all of the 'contaminated' supplements tested (5 of 6 from 4 different companies). Not one of the 11 Australian manufactured supplements produce a positive. 3 of the positive results were from the same US based company (see below).

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11. Lee, H. J., Lee, Y. S., Kwon, H. B., & Lee, K. (2003). Novel yeast bioassay system for detection of androgenic and antiandrogenic compounds. Toxicology in vitro, 17(2), 237-244.
12. Bovee, T. F., Helsdingen, R. J., Hamers, A. R., van Duursen, M. B., Nielen, M. W., & Hoogenboom, R. L. (2007). A new highly specific and robust yeast androgen bioassay for the detection of agonists and antagonists. Analytical and bioanalytical chemistry, 389(5), 1549-1558.
13. Chatterjee, S., Majumder, C. B., & Roy, P. (2007). Development of a yeast-based assay to determine the (anti) androgenic contaminants from pulp and paper mill effluents in India. Environmental toxicology and pharmacology, 24(2), 114-121.
14. Bagchi Bhattacharjee, G., & Paul Khurana, S. M. (2014). In vitro reporter assays for screening of chemicals that disrupt androgen signaling. Journal of toxicology, 2014.
15. Mertl, J., Kirchnawy, C., Osorio, V., Grininger, A., Richter, A., Bergmair, J., ... & Tacker, M. (2014). Characterization of estrogen and androgen activity of food contact materials by different in vitro bioassays (YES, YAS, ERα and AR CALUX) and chromatographic analysis (GC-MS, HPLC-MS). PLoS One, 9(7), e100952.
16. Svobodová, K., Plačková, M., Novotná, V., & Cajthaml, T. (2009). Estrogenic and androgenic activity of PCBs, their chlorinated metabolites and other endocrine disruptors estimated with two in vitro yeast assays. Science of the total environment, 407(22), 5921-5925.
17. Coleman, H. M., Troester, M., Khan, S. J., McDonald, J. A., Watkins, G., & Stuetz, R. M. (2009). Assessment of trace organic chemical removal by a membrane bioreactor using gas chromatography/mass spectrometry and a yeast screen bioassay. Environmental toxicology and chemistry, 28(12), 2537-2545.
18. Glaser, A. (2004). The ubiquitous triclosan. A common antibacterial agent exposed. Pesticides and You, 24, 12-17.


Existing TGA operated pharmacovigilance monitoring and reporting requirements such as the 'Blue card' system is serviced and contributed to by healthcare professionals and are used a reliable means in which to gather AE data reported to or assessed by the same professionals. The blue card guidelines dictate:

*"Adverse drug reaction reports should be submitted for prescription medicines, vaccines, over-the-counter medicines (medicines purchased without a prescription), and* ***complementary medicines (herbal medicines, naturopathic and/or homoeopathic medicines, and nutritional supplements such as vitamins and minerals).***

*The TGA particularly requests reports of:*

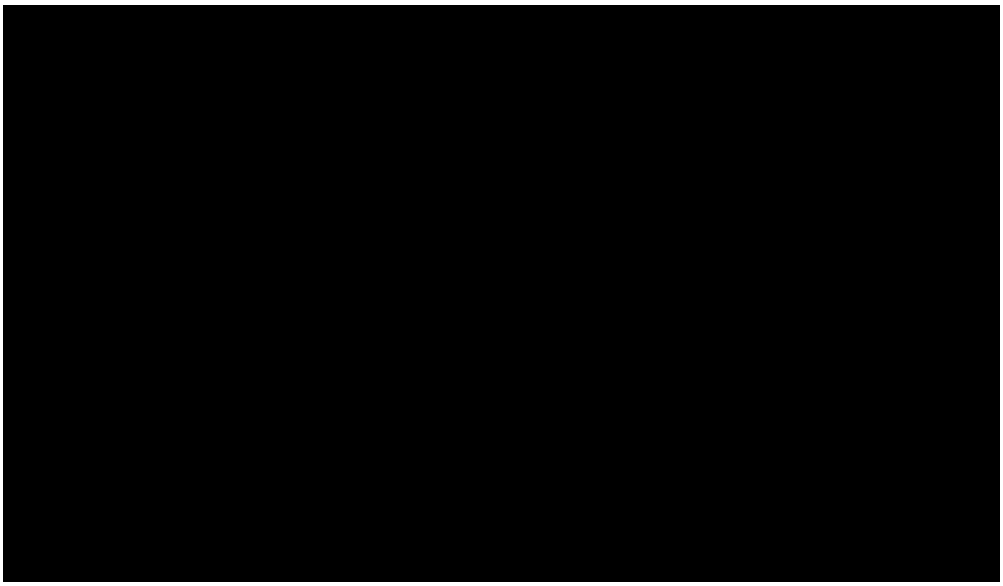
- *All suspected reactions to new medicines and vaccines*
- *All suspected drug interactions*
- *Unexpected reactions, that is not consistent with product information or labelling*
- *Serious reactions which are suspected of significantly affecting a patient's management, including reactions suspected of causing death, danger to life, admission to hospital, prolongation of hospitalisation, absence from productive activity, increased investigational or treatment costs, and birth defects."*

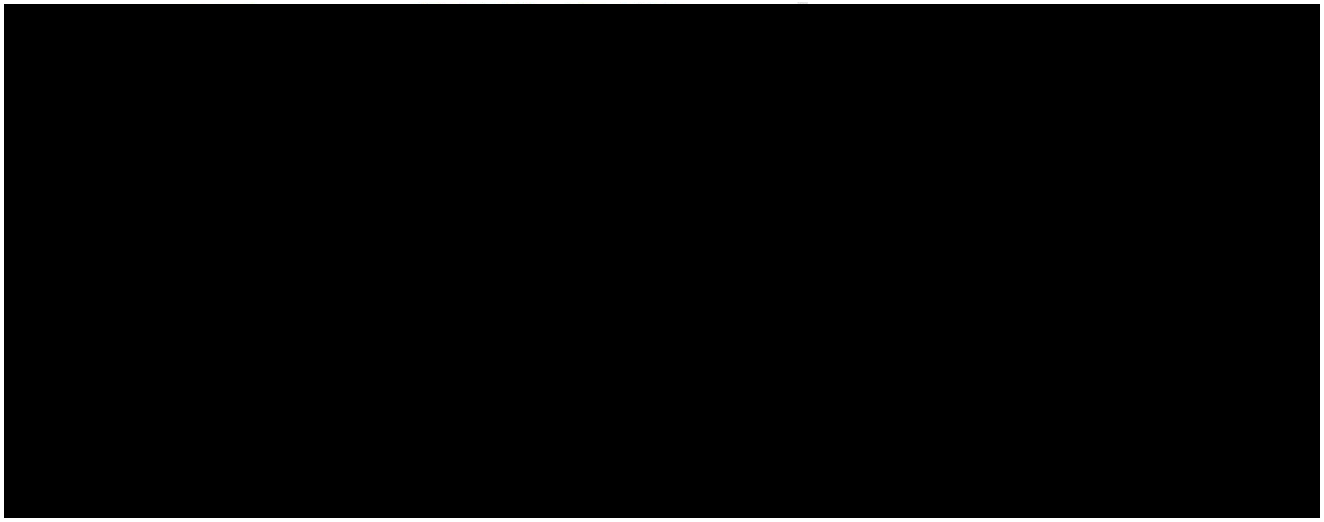
As the primary purveyors of the quality use of medicines, pharmacists hold very important role in the monitoring and reporting of AE identified or encountered their clinical practice. In fact, Australian research and statistics suggests that pharmacists are most likely to exercise pharmacovigilance and report AE's using these systems than other healthcare professionals or

stakeholders within the pharmaceutical industry.[19,20] Consistent with this; consumers are more likely to report AE's to pharmacists, more specifically, community pharmacists[19,20] whom, in effect, often do practice in premises where FSS are sold. Given the expansion of retail in pharmacies and the recent high-level of competition now in this area of pharmacy business,[21-22] community pharmacists can be directly or indirectly involved in the sale of FSS and/or interaction with FSS users. Research by Braun et. al (2010)[23] investigated the perceptions, use and attitudes of Australian pharmacy customers to herbal medicines, nutritional and dietary supplements and explored expectations of pharmacy practice. This research concluded that; most pharmacy customers have used or are using herbal medicines, nutritional and dietary supplements and expect the pharmacist to provide advice about these products as part of pharmacy practice[23]. Additionally, Culverhouse & Wohlmuth (2012)[24] describe results of their study indicating the intimate involvement of the sale and advice of these products by Australian pharmacists[24]. Therefore, should the pharmacist have any direct or indirect involvement in consumers of FSS, it could be reasonably assumed that any AE reported should be reflected by the data generated in such reporting tools as the 'blue card' system.

19. Kelly, M., Kaye, K. I., Davis, S. R., & Shenfield, G. M. (2004). Factors influencing adverse drug reaction reporting in New South Wales teaching hospitals. Journal of Pharmacy Practice and Research, 34(1), 32-35.
20. Nita, Y., Batty, K. T., & Plumridge, R. J. (2005). Adverse drug reaction reporting: attitudes of Australian hospital pharmacists and doctors. Journal of Pharmacy Practice and Research, 35(1), 9-14.Australian Bureau of Statistics 8501.0 (November 2017), Retail Trade, Australia, available at: http://www.abs.gov.au/AUSSTATS/abs@.nsf/ DetailsPage/8501
21. Richardson, A. Online Pharmaceutical Sales in Australia, IBISWorld, August 2017
22. Richardson, A. Pharmacies in Australia, IBISWorld, March 2017
23. Braun, L. A., Tiralongo, E., Wilkinson, J. M., Spitzer, O., Bailey, M., Poole, S., & Dooley, M. (2010). Perceptions, use and attitudes of pharmacy customers on complementary medicines and pharmacy practice. BMC Complementary and Alternative Medicine, 10(1), 38.
24. Culverhouse, S. E., & Wohlmuth, H. (2012). Factors affecting pharmacists' recommendation of complementary medicines–a qualitative pilot study of Australian pharmacists. BMC complementary and alternative medicine, 12(1), 183.

Very brief reconnaissance of popular pharmacy chain demonstrates examples of the exclusive supply of a brand manufacturing numerous FSS subject of this consultation (see pictures below). This product is indeed in breach the proposed legislative changes outlined in 'Column 3 use, advertising, or presentation' of the draft assigned by the TGA. This product shopfront retail supply is only provided via two pharmacy chains. It would collaterally fall within the sphere of pharmacist serviced pharmacovigilance.





Examining the total AE data published in the TGA's 'Adverse Drug Reaction Bulletin' for the periods of February 1995 through to December 2009, the 'Advisory Committee on the Safety of Medicines Meeting Statements' from March 2013 through to November 2016 and the 'Medicine Safety Update' from February 2010 through to August 2019 there is no indication of FSS product AE for which encompasses the aforementioned mandatory reporting. Whilst this is obviously not a perfect representation of a reliable means in which to survey the safety of these products, being in that it is a potential means in which the TGA have the exclusive capacity to derive usable safety data, and one in which there is only involvement of this regulatory body, the weight of evidence it bears should be of consideration to this consultation if current Food Standard Code 2.9.4 compliant FSS are to be considered as bearing the same or greater propensity of risk as therapeutic goods for which AE's are frequently reporting using these systems.

The lacking specific TGA administered and initiated pharmacovigilance systems for registered therapeutic goods would likely be underpowered to account for the proposed therapeutic good registration of FSS. As per the TGA Pharmacovigilance Inspection Pilot Program presentation materials delivered at the ARCS Scientific Congress Sydney, 11-12 May 2016[25] it would appear that a comprehensive exclusive pharmacovigilance system for manufactures that would encompass the therapeutic goods scheduling for which is proposed for many FSS is only development stages; being the prior conductance of the pilot trial.

25. Mina, M. The TGA Pharmacovigilance Inspection Pilot Program 2015-2016. Presented at ARCS Congress 11-12 May 2016. Signal Investigation Unit, Pharmacovigilance and Special Access Branch, Therapeutic Goods Adminstration. https://www.tga.gov.au/sites/default/files/presentation-tga-pharmacovigilance-inspection-pilot-program-2015-2016.pdf

**Legislative reform of FSANZ standard 2.9.4 compliant FSS to become controlled as therapeutic goods is unnecessary with the functioning system, let alone an untested, issue-fraught and ill-founded preventative system that is undoubtedly the beginning of an overwhelming, ongoing and compounding administrative sequelae. With the evidence produced regarding the most prominent issues, highlighted by both this public consultation and also the ongoing administrative forums and discussions held by the current regulatory body FSANZ, it is most apparent that government authority focus should be placed on improving the current system at the helm of this current body. At the admission of those involved with FSS regulation under FSANZ standard 2.9.4, this has not been performed at any large-scale capacity for over two decades. Whilst there appears to be no direct evidence of a dire need of improvement to the degree proposed by the TGA in this consultation, where Australian manufacturers of FSS continue their compliance with FSANZ**

**standards; there should be, at the very least, concerted movements made by FSANZ for any type of legislative changes or enforcement before such a drastic reform involves any other government regulatory bodies completely seizing control.**

Using the peer reviewed evidence brought forth by the TGA, the Cooper et. al (2018) research identified that none of the 11 Australian manufactured FSS produced any sign of contamination with suspected androgenic compounds, whilst of the meagre 5.6% positive test results, all but one product was manufactured in the United States and imported into Australia. If the results of this research were to be taken as sensitive enough to establish that the compounds were indeed 'anabolic steroids' it would seem most logical for the focus of risk assessment for the Australian public being directed at the level of importation. This in fact a topic that was broached in discussion during a 2018 forum "Sports Supplements Roundtable- Report on Discussions and Next Steps" administrated by Deloitte and 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[26]. This roundtable forum produced material that noted issues that highlighted the scope and options to improve consumer safety through ascertaining importation compliance and enforcement:

*'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.'*

Although 'wide acceptance' is not an objective measure, this information is more insightful and is in fact more congruent with that brought forth in the rationale of the TGA document: Consultation: Sports supplements Proposed clarification that certain sports supplements are therapeutic goods.

Further; [redacted] Food Standards and Programs, NSW Department of Primary Industries Food Authority, notes: *'The market has significant quantities of imported products, with online sales making a large percentage of the market. Challenges in compliance in relation to FSS come largely through online sales. Some supply of product is also through the NZ supplemented food standard.'*

[redacted] Imported Food Section, Department of Agriculture and Water Resources (DAWR) indicates: *'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. '*

Disregarding this commentary in the TGA consultation is not acting the best interests of public safety. It could be argued that the focus on Australian manufactured FSS is in fact a distraction from a very clear and substantiated issue that is; imported product that is sold under the guise of FSS within Australia. There is quite a number of published research papers indicating the presence of undeclared substances in FSS from other countries, predominantly the United States of America and also some European countries[27-31]. As previously mentioned, this level of evidence is in stark contrast to that associated with Australian manufactured FSS. This distinction needs to be made and considered, as has been performed by the FSANZ facilitated administrative activities surrounding Food Standard Code 2.9.4.

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26. Deloitte, Department of Health Sports Supplements Roundtable: Report on Discussions and Next Steps (August 2018).
27. Maughan, R. J. (2005). Contamination of dietary supplements and positive drug tests in sport. Journal of sports sciences, 23(9), 883-889.
28. Geyer, H., Parr, M. K., Koehler, K., Mareck, U., Schänzer, W., & Thevis, M. (2008). Nutritional supplements cross-contaminated and faked with doping substances. Journal of mass spectrometry, 43(7), 892-902.
29. Van Thuyne, W., Van Eenoo, P., & Delbeke, F. T. (2006). Nutritional supplements: prevalence of use and contamination with doping agents. Nutrition research reviews, 19(1), 147-158.
30. Baume, N., Mahler, N., Kamber, M., Mangin, P., & Saugy, M. (2006). Research of stimulants and anabolic steroids in dietary supplements. Scandinavian journal of medicine & science in sports, 16(1), 41-48.
31. Judkins, C. M., Teale, P., & Hall, D. J. (2010). The role of banned substance residue analysis in the control of dietary supplement contamination. Drug testing and analysis, 2(9), 417-420.


**Citing of the solitary case of the WA women whom tragically passed due to alleged hyperammonemia associated with a rare genetic urea cycle disorder aberrantly reflects any relevance to stipulated risks associated with the current regulation of FSS within Australia. This citation within the consultation document attempts to rationalize a position that, in effect, seems to draw from misleading media influence and anecdote. In doing so, it actually detracts the major overlying issues whereby 'pigeon-holed' FSS seem to form a 'straw man' in mainstream media that is largely driven by ill-founded stigma.**

Concerningly, citing this case seem to suggest that unreliable sources of information, such as speculative and emotionally provocative mainstream media news releases, actually do form an integral role in the surveillance and subsequent actions taken by the TGA. Further, this not only seems to be a trend in the area of scheduled medicines as therapeutic goods but also in the area of FSS for which have never fallen under direct legislation upheld by the TGA. Whilst these sources may provide some utility in preliminary reconnaissance or mediating public safety and perception, opinion or concern, any reliance on, or reference of such media releases as factual materials for means in which to formulate large-scale legislative reform, such as that used in the consultation document, is fraught with unreliability and in many cases can be misleading and deceptive. Referencing these materials for such application can exude a level of unprofessionalism through a lacking capacity to provide valid rationalization.

Given the case of the tragic death that involved a Western Australian women was cited in the consultation document, it can be plausibly assumed that it was heavily influential in the decisions to form this proposed reform. Upholding respect and sensitivity of the deceased and her loved ones, using reliance on the pathological findings reported, that appear to have been sourced via coroner investigations, her tragic death does in no way highlight any concern for the use of FSS, specifically a protein powder supplement for which was said to be the cause of her fatal hyperammonemia. It would be a plausible assumption that this woman was diagnosed post-mortem, or at the very least at a very advanced stage of an acute manifestation resultant of a potential late/adult onset urea cycle disorder, such as ornithine transcarbamylase deficiency. As such, it would seem apparent that her case most accurately illustrates a dire limitation of emergency and intensive care therapeutics to identify acute pathology of the assumed adult/late-onset urea cycle disorder and instigate appropriate treatment in a timely manner. The 'blame' directed at the use of protein supplements does seem to be misdirected and considering the pathogenesis of the acute condition resultant of the genetic disorder and the trends in prognoses outlined in published case studies[32-37], the gap in the investigative/diagnostic criterion used in the late subjects emergency diagnosis work-up and the lack of timeliness in the treatment really could have been the greatest travesty associated with the case. It is recognized that symptomatology of the late onset forms is not marked or characteristically defined however recognition of the differentials that would prompt blood ammonia testing is imperative for early diagnosis for which is the most important point in improving prognostic outcome[32-36]. Given the vast array of potential sources urea-precursor(s), the fact that it was assumed to be exclusively a protein powder is likely redundant to that fact that an appropriate treatment might not have been instituted in a period associated with positive prognosis.

Whilst the consultation paper does attempt to demonstrate the implications of this case to the broad scale population, late-onset urea cycle disorders are extremely rare[36.37]. According to thorough epidemiological research, the prevalence of other disorders related to innocuous and ubiquitous food products are greater than that of late-onset urea cycle disorders, whilst bearing similar prognosis and risk. Phenylketonuria is similar metabolic disorder of inborn error that is characterised by mutations of the phenylalanine hydroxylase (PAH) gene. Through loss of PAH enzyme activity dietary phenylalanine increases in concentration in the blood and toxic concentrations in the brain in a similar manner to which ammonia can in urea cycle disorders. The incidence is said to be 1 in 10000, as per Australian statistics, approximately 3 times greater than that associated with late-onset urea cycle disorders[37,38].

Using mainstream media as a source of information for impetus of investigation or action does not appear a foreign concept. Prior TGA publication have made explicit statement indicating that there was indeed an influence on Government by 'reports in the media' that instigated action of review and subsequent risk mitigation taken on a schedule 4 medication that has been legislated under the therapeutic goods act for two decades. This gives further insight into the weight given to this unreliable reporting source being actioned preceding appropriate independent review. This case involved the leukotriene antagonist medication, Montelukast and the previously identified, very rare serious neuropsychiatric AE's. Despite these AE's and the incidence being recognized and documented in pre-approval data over 22 years ago, as well as revisited, reviewed and reaffirmed in literature published in 2013, the risk mitigation activities appear to have be prioritized to garner further evidence. Should this be on the back of the 'reports in the media' this potentially speaks to the level of influence that this source of information holds with the TGA and the lacking capacity to adequately survey and draw information from existing data pools. Being in that historically FSS do not fall within the legislation upheld by the TGA, citing 'reports in media' as means to substantiate

safety concerns highlights this level of disconnection and separation existing between food standards and poisons and medicines.


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