Synergistic Nutritional Solutions

POSITION STATEMENT
November 2019
Sports Supplements Consultation

In respect of the Australian Government public consultation by the Therapeutic Goods Administration, closing 3 December 2019: '*Proposed clarification that certain sports supplements are therapeutic goods'*.

14 Pages including signing page.

To:
Sports Supplements Consultation
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
Department of Health
PO Box 100 WODEN ACT AUSTRALIA
TGA.sports.supplements.consultation@health.gov.au.

Dear Sir / Madam,

I am writing to you to express my views on the proposed Section 7 Declaration to declare that certain sports supplements including all capsule, tablet or pill form are therapeutic and submit the following communication for your consideration.

Firstly, let me introduce myself... My name is [redacted]. Syn-Tec manufactures, distributes and retails Sports Supplements specifically formulated for use by sports people in the New Zealand and Australian domestic marketplace. Syn-Tec is a multimillion-dollar business and has been in operation since 1995 and carries on its business in both Australia and New Zealand. As such, [redacted] and have gained a very informed insight into the wants and needs of consumers, regulators and industry alike and have also gained a wealth of knowledge in regards to the operation of a business that operates within different regulatory frame works within different countries and the application there of, either jointly or singularly as the case may be.

Let's start by reflecting on a very important single visionary mandate that has been expressed by governments over recent years. That direction is given to policy makers that the development of new or revised policies should be carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to **remove** unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community, which can be encapsulated in the phrase **'minimum effective regulation'.** This minimum effective regulation principal is also required to be adopted by the TGA.

In my submission I will cover many issues that I feel need to be addressed and considered by policy makers at the TGA and at a parliamentary level before a decision is made to affect this proposed section 7 declaration under consideration. Furthermore, communication between policy makers and a wide spectrum of industry stakeholders and other regulatory agencies must transpire to effectively affect a very informed decision that considers all current issues, views and legal parameters facing both policy makers and industry stakeholders alike.

Issues that need to be addressed regarding this proposal are very real and cover topics such as:

1 What really is the true definition of therapeutic good versus a food in the eyes of consumers? Considering the perceived difference between a Sports Food Supplement and or Supplemented Food versus a Complementary Medicine and or Therapeutic Good and the classification there of.

2 The legal definition of a Therapeutic Good as described by a justice of the Supreme Court and International court rulings of the same.

3 Past precedence's that have been set by the TGA in regard to assessments of food items versus Therapeutic Goods and determinations made there of.

4 Current food standards and regulations with reference to FSANZ joint food standards and the New Zealand Supplemented Food Standard and their impact on the classification of what is a food versus a Therapeutic Good.

5 Free trade agreements and treaties covering food items between Australia and New Zealand with specific mention of the Trans Tasman Mutual Recognition Act 1997 and the legal right for New Zealand manufacturers of food items to be freely traded with Australia and vice versa.

6 Health and Safety Issues.

7 Impact on consumers if supplies of Sports Supplements are restricted through policy changes.

8 The impact on the food manufacturing industry if faced with complying with GMP manufacturing standards that are designed for Complementary Medicines and Therapeutic goods.

1... What is the true definition of a therapeutic good versus a food in the eyes of consumers and industry alike, considering the perceived difference between a Food Type Dietary Supplement FTDS verses a Therapeutic Good and the classification there of?

There are very many different types of presentations for both food and therapeutic goods. All forms of presentations such as liquid drinks, oral powders and capsules, tablets or pills are used in the consumption of both food and therapeutic goods so the form of presentation alone should **not** determine a products classification as either being food or therapeutic. We must look at the active ingredients that are being presented for consumption, their history of use within a recognised consumer group and their defined purpose for use as described in their labelling and advertising.

A therapeutic good is regarded by consumers as being medicinal and is consumed to help, treat, cure or prevent diseases. The definition of the word therapy as detailed in the Australian Macquarie dictionary is:

Noun **(*plural*** therapies**) 1. The treatments of disease, disorder, defect, etc., as by some remedial or curative process:**
2. a curative power or quality. [New Latin *therapīa*, from Greek *therapeia* healing]

This definition is an accurate representation for what an average Australian consumer would regard a therapeutic good to be and does not in any way represent what an average Australian would regard food to be. Food in all of its forms of presentations and preparations including FTDS is regarded by consumers as being consumed for its nutritional value and is consumed by consumers to supply their daily needs of the very many and differing types of vitamins, minerals and proteins that are needed for nourishment of one's body. Food is not consumed by the average Australian with the mindset that it has a therapeutic effect but is consumed with a mindset that food supports one's general health by supplying the bodies' nutritional needs to **maintain natural and normal physiological processes**. The term **physiological** cannot be taken to mean providing a therapeutic effect where the body's physiological function is supported by the consumption of food "being natural or supplemented and is a natural part of the human body's response to food. 2/14

The definition of the word physiological as detailed in the Australian Macquarie dictionary is:

Adjective 1. **Of or relating to physiology.**
noun 1. **the science dealing with the functioning of living organisms or their parts.**
2. the processes and functions of a particular organism or part of an organism. [Latin *physiologia*, from Greek]
3. consistent with the normal functioning of an organism.

I do not agree with the TGA view for example, that a protein supplement or amino acid / botanical formula presented as a sports food is a therapeutic good because its perceived to help grow muscle and help recovery after training or has ingredients in its presentation that are a larger serving size than currently allowed under FSANZ Formulated Supplementary Sports Food Standard 2.9.4. These types of foods are also captured and are legal to sell in Australia under the New Zealand Supplemented Food Standard for which consideration must be given as these Supplemented Foods from New Zealand are freely traded with Australia and form a large proportion of Sports Food Supplements sold in Australia. I will comment on this when covering free trade issues.

The consumption of protein and extra amino acids promotes a natural physiological process that triggers growth that we all understand from being children. Who among us, hasn't had our parents instil in us to eat protein to grow healthy strong bodies? There are 1000's of general food products with packaging images of healthy, active strong and / or slim individuals implying "eat or drink this product and you'll look like this" many food labels that are not directed to be sports supplements have written statements saying "contains protein for strong bodies or to nourish growing muscles etc"; it's actually endless when you go through the many types of general food products such as drink mixes, cereals, bars, fortified foods etc which are available these days and offer a health benefit. These foods aren't therapeutic goods in the eyes of consumers, and many have a tradition of being a food due to their well-established time in the marketplace. In some cases, well over half a century with no ill effect on consumers.

To touch on Caffeine… Caffeine is an ingredient found in many lifestyle foods and drinks etc and has been used in recent times by sports people in pre workout sport supplement formulas to help boost focus and energy. There is even a FSANZ food standard "formulated caffeinated beverage' which cover drinks like [redacted] etc. There are Billions of people worldwide who have a caffeine boost for energy and focus when they drink their coffee presentations in the morning or even several times a day, so why should a sports supplement which contains caffeine be classed as therapeutic when these other presentations are not?

In reference to sport food ingredients presented in a capsule or tablet. The consumer has a choice; powdered food to be eaten with a spoon or mixed in a drink base, or have the same powdered ingredient presented in a capsule form as a convenient no fuss way of supporting their nutritional needs where a prepared and precise measured serving size is desired. The capsule presentation method is used in regard to **"out in the field nutrition"** so to speak, where it is impractical to have a spoon-fed application and prepared serves in a convenient capsule are so much more practical.

For example, Creatine Monohydrate (Creatine) is a nutritional supplement used by many sports persons. It is also used in the baking industry and it is endorsed by the Australian Institute of Sport as a category A sports food supplement and is highly recommended for use by many athletes as a nutritional supplement. Under the FSANZ food code, a manufacturer can have a 3.0g daily serve in formulated supplementary sports food products. If the serve is over 3.0gms, in New Zealand, it will be classed as a Supplemented Food and regulated under the New Zealand Supplemented Food Standard 2016, which falls under the watchful eye of the New Zealand Ministry for Primary Industries MPI.

Creatine can be presented in many forms such as in oral protein amino acid formulas, drink bases, in a gel base chewable form or in capsules and tablets. How can the TGA determine that the capsule and tablet form or even a powder serving size of over 3.0gm is therapeutic, when all other forms and presentations are not? The serving size of a Creatine capsule is usually only 500mg ... 1/6th of the allowable serving size as detailed in the formulated supplementary sports food standard 2.9.4 and is the same active ingredient "Creatine" that is used in all of its forms of presentation and is designed to deliver the same nutritional support. In the eyes of sports people who consume these types of products, they see no difference or determination between all these different types of presentations and the capsule or tablet form in this instance cannot be taken as being therapeutic. This reasoning can be applied to thousands of sports food supplements that are found to have the same food ingredients presented in many different forms and are regulated under existing food regulations.

2... The legal definition of a therapeutic good as described by a justice of the Supreme Court.

In a court case "NSW Food Authority versus Nutricia Australia PTY Ltd', the NSW Supreme Court made reference to the Australian Macquarie dictionary as to the meaning of the term "Therapeutic" and recorded "**Therapeutic, *adj*" Pertaining to the treating or curing of disease; curative"**

This has helped to set a further precedent regarding what the term therapeutic can be taken to mean in the context of accessing a food item that is presented as a food within the regulatory framework of the many food standards regarding its overall form of presentation which may also include general nutritional based health claims in Australia and New Zealand.

There are also international court rulings in world markets who have determined that food ingredients that are presented in a capsule or tablet are not therapeutic. Take for example a case in Germany where German regulators claimed that red rice powder which is a food item in its powdered form was declared therapeutic when it was presented in a capsule and imported into Germany. The manufacturer filed a complaint with the European Court of Justice which ruled that this product was not therapeutic in its capsule form. As Australia is a member of the World Trade Organisation (WTO), the TGA should be mindful of the views and precedents set by international regulators on similar matters.

3... Past precedence's that have been set by the TGA in regard to assessments of ingredients presented in a capsule form in regard to food items verses therapeutic goods and determinations made thereof.

TGA evaluations have been carried out on many Syn-Tec products as the same has been carried out on other brands of products over the past years and determinations have been made by the TGA that Syn-Tec products are food and not therapeutic. These evaluations included assessments on ingredients presented in capsules and made in reference to Section 7 of the Therapeutic Goods Act 1989 (the Act) which covers issues within the food and medicines industries and regulators in determining whether a product is a food or a therapeutic good.

It should be known that Syn-Tec products are manufactured in New Zealand and marketed as sports foods which are clearly defined as being a Supplemented Food and or a Formulated Supplementary Sports Food. They are not therapeutic supplements or complementary medicines and are not marketed to diagnose, treat, cure or prevent any disease. They are formulated to assist and support the nutritional supplementation requirements of sports persons. They are extensively used by sports people to provide and support specific nutritional requirements in respect to their desired nutritional and performance goals. They are not a sole source of nutrition and are consumed in conjunction with a nutritious diet and appropriate fluid intake. Sports people as an informed healthy consumer group recognize these facts and in no way think that sports Syn-Tec sports supplements are therapeutic.

Here is an exact extract from a TGA communication I had covering this matter...

"Something that is presented in capsule form and has a dosage is likely to be taken to be therapeutic. However there are exceptions and that is why we also have to look at parts c, d, e and f of the above definition. ***If a good has a food standard, it can never be a therapeutic good, no matter how it is presented.*** *The Food Standards of Australia and New Zealand is the guide to be used in recognising what good has a food standard. Regarding your type of products we have to look at Standard R10 Division 1 which is "Formulated Supplementary Sports Foods Generally" The interpretation states; "formulated supplementary sports food is a food mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals". If your product, by its ingredients, label information and claims, fits this category then it complies with the standard and can never be a therapeutic good. If however it is not directed at being a supplement to sports foods, and it does not have a food standard then it could, under AUSTRALIAN law, be a therapeutic good, depending upon what claims it makes."*

I have all the official documents on file to support this communication and other events. I do not wish my business to be impacted by the TGA adopting a broad approach to all industry stakeholders when the TGA's mandate is actually a vehicle to target excessive claims or rogue internationally based manufacturers and distributors or maybe even a mechanism to raise revenue for the TGA through added ARTG listing fees.
I have acted in good faith and abided by all the requirements that the TGA has previously communicated to me as being conclusive to determining Syn-Tec products as being food. I am not a new entrant to the sports nutrition industry and have vast responsibilities to distributors and retailers whose lively hoods depend on the success of the Syn-Tec business so it is prudent that all of the Syn-Tec stakeholders are represented in a very thorough submission to the TGA.

4… Current food standards and regulations with reference to FSANZ joint food standards and the New Zealand Supplemented Food Standard and their impact on the classification of what is a food verses a therapeutic good.

The TGA needs to be mindful of other existing regulations and food standards that already regulate Sports food supplements and other food supplements in general. As FSANZ and New Zealand Ministry of Primary Industries MPI already have regulatory frame works in place that capture sports food supplements and all other types of food supplements, then it should be these agencies who are responsible for overseeing the regulating of policies regarding this issue… **Not the TGA.**

There are many different descriptions of what is deemed to be a **Food Type Dietary Supplement FTDS** in the context to a product that is taken to supplement the intake of substances normally derived from food sources. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulares, and metabolites.

Here are some descriptions of the same in reference to the appropriate regulatory frameworks as defined within **Australia, New Zealand and the USA** which cover sports supplements along with other types of FTDS. Note that there are no references to therapeutic goods in these definitions and reference to food and nutritional properties are the norm.

The FSANZ Formulated Supplementary Sports Food Standard 2.9.4 defines a sports food as:

A food or mixture of foods specifically formulated to assist sports people in achieving specific nutritional or performance goals. This Standard defines and regulates the composition and labelling of foods specially formulated to assist sports people in achieving specific nutritional or performance goals. Such foods are intended as supplements to a diet rather than for use as the sole or principal source of nutrition. Due to the particular physiological demands of sports people, this standard provides for the addition to formulated supplementary sports foods of certain micronutrients and other ingredients which are not permitted to be added to other foods. This means that such products are not suitable for consumption by children. 5/14

The New Zealand Supplemented Food Standard 2016

(1) A **supplemented food** is a product that is represented as a food that has a substance or substances added to it, or that has been modified in some way, to perform a physiological role beyond the provision of a simple nutritive requirement.
(2) The following products are not supplemented foods:
a) a dietary supplement (as defined in the Dietary Supplements Regulations 1985):
b) a medicine (as defined in the Medicines Act 1981):
c) a controlled drug or restricted substance (as defined in the Misuse of Drugs Act 1975):
d) a formulated meal replacement or a formulated supplementary food (as defined in standard 1.1.2–2 of the Code):
e) a formulated caffeinated beverage (as defined in standard 1.1.2–6 of the Code).
(3) To avoid doubt, subclause (2) does not contain an exhaustive list of products that are not supplemented foods.

This means that, basically any sports supplements or other food formulations that have been fortified with or are a mixture of legal to use ingredients which result in higher amounts of ingredients in them that is currently allowed under an existing FSANZ standard, can be legally be sold as a **Supplemented Food.**

The USA Dietary Supplement Health and Education Act (DSHEA) 1994:

"A dietary supplement is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulares, and metabolites. Dietary supplements can also be extracts or concentrates and may be found in many forms such as tablets, capsules, soft gels, gel caps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods", not drugs, and requires that every supplement be labelled a dietary supplement."

The manufacturer in the USA is responsible for ensuring that a dietary supplement is safe before it is marketed. The US Food and Drug Administration (FDA) are responsible for acting against any unsafe dietary supplement product after it reaches the market. There are no regulations that limit a serving size or the amount of a nutrient in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval.

Capsules, Tablets and Pill Presentation:

It should be noted that a capsulation aid used in the presentation of a food is not a declared therapeutic good in its own right or a prohibited good or a scheduled drug in either Australia, New Zealand or the USA and Australian consumers are free to engage in personal imports of all types of FTDS that are presented in capsules, tablets or pills which may be purchased direct from New Zealand and USA retailers alike. So why is the TGA proposing to declare an **Australian only standard** that all capsules, tablets and pills are to be classed as therapeutic goods, that is contrary to its global trading partners of New Zealand and the USA? This action will further restrict Australian sports food manufacturers from being able to compete on a global trading platform and support and compete in Australia for imported products of the same.

Taking the above mentioned into consideration, a full review of any regulatory framework or policy in Australia should expressly include specific mention of the legal right to use a tabletting aid in the manufacture of sports foods. The same should also be declared in the TGA section 7 Declarations that manufactured sports FTDS presented in capsules, tablets or pills are exempt from being classed as therapeutic goods if presented and labelled in a manner that identifies them as being formulated to assist sports people in achieving specific nutritional or performance goals. This statement alone would clarify these goods as to their intended purpose and send a clear message that they are NOT therapeutic or formulated for general use by all consumers.

The high standards required in Australia and New Zealand for the manufacture of food products should not come into question and should be respected by other Australian regulators such as the TGA. The NZ Ministry of Primary Industries MPI which has a has a de facto relationship with FSANZ and as such both regulators have very stringent regulating powers. In many cases New Zealand food standards are of a higher regulated standard than is required in Australia with certification requirements for many dairy based manufacturers of protein powders and milk products being global best practise.

There is a very safe history of use for sport food products in Australia and New Zealand and Risk Management Programme (RMP) standards used in the manufacture of many foods in New Zealand do not pose an unacceptable health risk, so for the TGA to use the health and safety issue as a way of circumnavigating the food regulations to apply TGA policies to food products is not valid as there is clearly no evidence of an unacceptable risk to Australian consumer's health while using any Australian or New Zealand manufactured sports food products or any other food product for that matter. It is the drugs and medicines that pose higher health risks and not FTDS and this why Australia has two separate regulators, the TGA "Therapeutic Goods Administration" for complementary medicines, drugs and therapeutic goods and FSANZ "Food Standards Australia and New Zealand" for food products. Two separate regulators for two very different classes of goods.

5… Free trade agreements covering food items between Australia and other global trading partners with specific mention of the Trans Tasman Mutual Recognition Act 1997 and the legal right for New Zealand manufacturers of food items (including food presented in capsules or tablets as is the case with many sports supplements) to be freely traded with Australia and vice versa.

The TGA also needs to be mindful of free trade agreements between other countries and mutual recognition agreements between the same when drafting its policies. The absence of supervision and contribution by parliamentary drafting staff and appropriate qualified legal council may see the TGA embark on a policy change that it legally will be unable to enforce and could have a very detrimental impact on Australian manufactures only. **Extreme care needs to be taken when embarking on an Australian only policy change which cannot be enforced within the sovereignty of other countries.** Let's take for example the **Trans Tasman Mutual Recognition Agreement**.

The Trans-Tasman Mutual Recognition Act 1997 (TTMRA).

Here is a brief summary of the Trans-Tasman Mutual Recognition Act 1997 (TTMRA) and how it relates to the importation of FTDS into Australia from New Zealand and vice versa. These brief outlines a legal interpretation of the TTMRA in its relation to food products.

The TTMRA applies to food products and under the Joint Food Standards System Treaty which is administered by Food Standards Australia and New Zealand (FSANZ) there has been harmonisation in many areas of food standards. However, variations in standards may occur in three ways: where an **'Australian only'** standard affects the content or labelling of food; where New Zealand has exercised its powers under Annex D of the treaty to **'opt out'**; and in relation to **Supplemented Foods** which are assessed under the New Zealand Food Act and regulated by NZ Ministry of Primary Industries MPI, where agreement is not reached with Australia, **the food item in New Zealand will be subject to mutual recognition as food is not exempted from the TTMRA.**

TTMRA applies to regulations affecting the sale of goods which include Food Type Dietary Supplements FTDS by allowing producers to meet only one set of standards, rather than two or more, which reduces barriers and costs to movement across jurisdictions. If goods meet the regulatory requirements of their home jurisdiction, they can lawfully be sold in all participating jurisdictions.

In Reference to TTMRA Part 2 Sections 10. Entitlement to sell goods:

The TTMRA principle is that, subject to this part, goods produced in or imported into New Zealand, that may lawfully be sold in New Zealand, either generally or in particular circumstances, may, by virtue of this Act, be sold in an Australian jurisdiction either generally or in particular circumstances, (as the case may be). **Without** the necessity for compliance with **further** requirements imposed by or under the law of that jurisdiction as described in part section 11.

Section 11. Requirements that DO NOT need to be complied with…

The further requirements referred to in section 10 are any one or more of the following requirements relating to sale that are imposed by or under the law of the Australian jurisdictions concerned:

(a) a requirement that the goods satisfy standards of the jurisdiction relating to the good themselves, including for example requirements relating to their production, composition, quality or performance;
(b) a requirement that the goods satisfy standards of the jurisdiction relating to the way the goods are presented, including for example requirements relating to their packaging, labelling, date stamping or age;
(c) the requirement that the goods be inspected passed or similarly dealt with in or for the purposes of the jurisdiction.

FSANZ Implications on the TTMRA:

It was clear that when the FSANZ treaty was negotiated, the Australian and New Zealand Governments agreed that the sovereignty of each country to opt out of a joint standard should be respected but that such a decision should have minimal impact on Trans Tasman trade. It would contradict the intention of the TTMRA if exemptions were called upon to regulate and or aid competitive issues where non harmonized standards were not in force. Exempting Supplemented Foods from the TTMRA would constitute a radical departure from the parties' original intention. Moreover, the New Zealand Government disputed the fact that current conditions have acted as a disincentive to harmonisation, asserting that New Zealand officials have been acutely aware of the need to resolve issues from a TTMRA perspective. It Argues that most of the issues are transitional as both countries seek to harmonise their separate systems and in doing so, that these separate systems and the goods that they regulate, if not expressively exempt from the TTMRA, continue to have non restrictive access to the Australian and New Zealand domestic markets.

TTMRA and its impact on TGA policy making:

There is also a concern by some consumers and industry stake holders that sports supplements captured under the New Zealand Supplemented Food Standard will be classed as being therapeutic goods by the TGA if the proposed new TGA declaration 7 "Certain Sports Supplements are Therapeutic goods" is adopted. Some officers at the TGA think that this would then cease the free trade between Australia and New Zealand of these types of products due to the exemption of Therapeutic Goods from the Trans Tasman Mutual Recognition Act 1997 (TTMRA). Their views however, have been formed with haste and without an involved legal discovery process being undertaken in regards to the legal standing of the TTMRA which includes not only trade with Australia as a federal entity, but also the mutual recognition of the many differing standards of each individual State and Territory of Australia and New Zealand and the right for an **individua**l to freely trade goods with New Zealand and within each State or Territory outside of any federal jurisdiction process.

Under the TTMRA rules, when an Australian standard differs from a New Zealand standard and a joint agreement between the two countries cannot be reached, then the goods which are assessed under the differing standards of either country will have mutual recognition and have free access to each other's countries domestic market place. TTMRA applies to regulations affecting the sale of goods which include Supplemented Food and as food is not exempt from the TTMRA, this allows manufacturers to meet only one set of standards, rather than two or more, which reduces barriers and costs to movement across jurisdictions. If goods meet the regulatory requirements of their home jurisdiction, they can lawfully be sold in all participating jurisdictions.

During a discovery process, it will be found to be true that all goods that are declared as being food under the law of New Zealand, will be declared as being food under the TTMRA rules and mutual recognition will apply to these goods in all jurisdictions that are trade partners under the terms of the TTMRA. This is regardless as to any differing standards, regulations or policies that may be imposed by a single jurisdiction in regard to a particular good.

For a good to be classed as a therapeutic good as reasonably defined in regards to medicines and medical devices for which the exemption of said goods from the TTMRA was enacted, then these said goods will also have to be classed as being therapeutic goods in New Zealand under New Zealand law for the TTMRA exemption to apply. When a good is legally classed as a food in New Zealand, then this same good cannot be classed as being therapeutic when it crosses into another jurisdiction that may have a different standard or policy in regard to this same food item.

The principal of the TTMRA is designed to encourage the free trade of all goods. **One country cannot amend their own standards or policies in an attempt to introduce a mechanism to appease a single regulatory authorities' own agenda or to create a barrier to trade**. This is prohibited under the trade rules and if agreement is not met as in this instance, a push for a joint harmonised standard is the logical step to take. In the interim, mutual recognition will apply as this is the implied intention of the TTMRA and the true spirit of free trade and what all mutual recognition agreements are based on.

6… Health and Safety Issues:

The high standards required in Australia and New Zealand for the manufacture of food products should not come into question and should be respected by other Australian regulators such as the TGA. The NZ Ministry of Primary Industries MPI has a de facto relationship with FSANZ and as such both regulators have very stringent regulating powers covering the manufacture, presentation and labelling of foods. In some cases, New Zealand food standards are recognised as being of a higher regulated standard than is required in Australia with certification requirements for many dairy based manufacturers of protein powders and milk products being global best practise. **Labelling information on Australian and New Zealand sports food supplements are second to none and offer full disclosure of what ingredients are in a formula. Amounts per serve, per 100g and even RDI's are included in NZ Supplemented Foods labelling.**

There is a very safe history of use for sport food supplements which are manufactured in Australia and New Zealand and Risk Management Programme (RMP) standards used in the manufacture of many foods in both countries go a long way in preventing a health risk to consumers. So for the TGA to use the health and safety issue as a way of circumnavigating the food regulations and apply TGA regulations to food products is not valid as there is clearly no evidence of an unacceptable risk to Australian consumer's health while using any Australian or New Zealand manufactured sports food product or any food product for that matter. It is the drugs and medicines that pose higher health risks and not FTDS and this why Australia has two separate regulators, the TGA "Therapeutic Goods Administration" for complementary medicines, drugs and therapeutic goods and FSANZ "Food Standards Australia and New Zealand" for food products. Two separate regulators for two very different classes of goods.

The TGA has communicated its view that sports food products may pose an unacceptable health risk to consumers if these types of products are not registered on the Australian Register of Therapeutic Goods (ARTG) and comply with the TGA's manufacturing requirements and standards. I also feel that the TGA may have specifically mentioned this reference to health and safety to throw light on a provision in the TTMRA which may exempt a good from the free trade protection allowed under the TTMRA regulations, as goods that are proven to have unacceptable health and safety issues can be exempt from free trade. But the health and safety issue must be substantial and be proven and this provision must not be used as a mechanism to act as a barrier to trade - I am well aware of this provision in the TTMRA and respond with the following mention…

Many Australian and New Zealand manufactured food formulas including those presented in capsules, tablets or pills are manufactured at premises with health and safety Risk Management Programmes (RMP) in place and are strictly regulated by FSANZ and MPI in New Zealand. Many quality food manufacturing premises are audited by regulatory authorities and in over 24 years of doing business in the sports nutrition industry, I have not once had a health and safety issue arise with a product that has been released to market. I haven't heard of a local Australian or New Zealand manufactured sports supplement posing a health risk and or being withdrawn from market. My brand Syn-Tec Nutriceuticals includes a very wide range of products incorporating a very diverse ingredient base and not once has a health or safety issue arisen with any product that has been released to market. Checks and balances taken in the manufacturing procedures of legitimate local manufacturers go a long way in helping to prevent health and safety issues from arising.

The TGA has communicated that it was reported that some sports supplements contained substances banned by the World Anti Doping Agency WADA. I feel that statement could create an ill-informed perception within policy makers and some consumers that this is inferring to the use of "illicit and illegal substances". I think it should be noted that WADA banned ingredients are banned for use by world and national level competitive athletes in sporting disciplines and associations overseen by WADA testing and in many cases these 'WADA banned ingredients or levels thereof" are not prohibited for use by general consumers who are not drug tested or competing in sporting disciplines overseen by WADA testing.

This needs to be made clear as this blanket statement that some sports supplements contain banned substances could be construed as being in reference to "illegal illicit substances" and the sports supplement Industry can't be trusted. Not all WADA banned substances maybe prohibited under the laws of different countries and many fall under different regulatory frameworks. Scheduled and regulated substances such as anabolic and androgenic steroids, hormones etc are therapeutic; they always have been and are regulated S4 or S8 prescription drugs in Australia. These ingredients will not be found in legitimate sports supplements manufactured by legitimate food manufacturers. A thorough policing of labels so they are compliant to food standards should be applied by FSANZ to underpin consumer awareness at point of sale. We do not require the TGA to come in and dismantle our sports food supplement industry just to affect a regulatory authority sweep on a few rouge international sport supplement brands that may working outside legal parameters.

I would put forward for consideration, that the sports supplements which have been found to contain WADA banned substances or other illegal ingredients did not have an accurate ingredient listing or comply with the FSANZ or the NZ Supplemented Food Standard and were most likely internationally sourced proprietary blends whose ingredients were understated or omitted from reference on product labels, making them very hard to identify for drug tested athletes. These types of products should never have been allowed access to the Australian marketplace in that form, regardless of who's jurisdiction they fell under. Once again, I stress that labelling information on Australian and New Zealand sports food supplements are second to none and offer full disclosure of what ingredients are in a formula. Amounts per serve, per 100g and even RDI's are included in NZ Supplemented Foods labelling.

It should also be noted that there will always be a black market for the "banned and illicit" substances which legitimate industry stakeholders and regulators will never be able to completely police effectively. We must deal with counterfeiters and criminal organisations who are set to work outside legitimate regulatory frameworks set by FSANZ or the TGA, and who will find ways to disguise any product and get it to market under stealth and misdirection. These cases are for criminal law enforcement authorities to resolve!

If the TGA or FSANZ have issues with any particular sports supplement product, manufacturer or importer that have been identified to use illegal substances in their formulations, then the TGA, FSANZ or local law enforcement should take steps to investigate or target these products and those importers on a case by case basis and not throw a blanket over the whole sports supplement industry and tarnish reputable long standing businesses in an attempt to affect a policy change that is really directed at a few rogue industry players.. "Throwing the baby out with the bath water" as they say, is not the answer. 10/14

7… Impact on Australian Business and Consumers:

As a New Zealand citizen, living in Australia and operating a jointly Australian and New Zealand based business; I am privy to the local Australian view on sports supplements. Believe me, the Australian consumers are just as concerned as the New Zealand consumers are with the current outdated FSANZ Formulated Supplementary Sports Food Standards which restrict local Australian consumers from purchasing Australian manufactured products containing ingredients and in serving sizes commonly used in sports' supplements all around the world. "Thank god for New Zealand", many Australian' consumers say, regarding the Supplemented Food Standard and the TTMRA. At least New Zealand's food regulations regarding sports nutrition currently support an aggressive and adaptive environment which enables New Zealand manufacturers to formulate and bring to the Australian market, products containing the latest sports food ingredients. So the question beckons; why doesn't Australia harmonise with New Zealand on this standard?

Sports food ingredients that are being pioneered around the world can be embraced under the NZ Supplemented Food Standard and brought to market in a timely manner, often giving New Zealand and Australian consumers a better understanding of the nutritional dietary supplements currently being used in the international sporting arena. This enables access to the most up to date sports nutrition formulas right here at home, which puts our sportsmen and women on an even playing field, nutritionally speaking.

Many sports Supplements are formulated using evidence and results of many years of research and development carried out on sports people from many sporting codes taking in consideration to what we know about the benefits of protein, amino acids, carbohydrates, vitamins and minerals etc. The manufacturers and retailers of specialized sports nutrition products are often operated by sports people themselves, who have firsthand experience in using these types of food products and can communicate the benefits of nutritional supplementation in a meaningful way to consumers.

This knowledge and the availability to consumers to be serviced by specialty retailers is at threat if specialty retail stores in Australia are forced to close due to a lack of a diverse range of competitive sports supplements being available for sale.

Regulators must keep in mind that the general public are not the target market for sports supplement retailers and as such should not be viewed upon or compared to by regulators when assessing and setting the regulatory framework appropriate for sports food supplement use. Sports people are a very informed consumer group and are a select market for specialised food manufacturers and retailers. The sports food standards need to be adaptive (not restrictive) to the ever-changing ingredients used in sports nutrition formulas around the world. All ingredients used in sports supplements should be allowed unless specifically prohibited. Not prohibited unless they are on an allowable list of ingredients as is the current mind set of Australian regulators such as the TGA.

Many ingredients used in sports supplements are not on the allowable list of TGA approved therapeutic ingredients because they never have been required to be. These ingredients have been used in formulations that are manufactured to food standards. Many of them are not used in therapeutic formulations as they have always been captured and defined as foods. There will be a lengthy and costly process involved to register ingredients and products to be TGA compliant, which will just be to exhausting for many small food manufacturers in Australia. Business will close and this will limit the consumers choice for locally manufactured sports supplements, encouraging many to take their business and access for advice offshore through international internet online sales platforms... More lost jobs and revenue for Australia!

Australia and New Zealand are proud sporting nations and pride themself on their sporting successes regarding small population-based countries. We are democratic countries and need to embrace the freedom of choice for Australian and New Zealand consumers regarding having access to locally produced sports food products and novel alternative formulas where nutritional supplementation is concerned. Let the risks of the actual food ingredients used in sports nutrition formulations dictate the level of regulations required for this market. If a product, by its ingredients, label information and claims, fits within the FSANZ Formulated Supplemented Food Standards or the New Zealand Supplemented Food Standard then it will be seen to comply and can never be a therapeutic good.

8… The impact on the food manufacturing industry if faced with complying with GMP manufacturing standards that are designed for Complementary Medicines and Therapeutic goods.

The TGA needs be mindful of the hundreds of specialized food manufactures in both Australia and New Zealand that manufacture sports food supplements. These manufacturers are set up to manufacture food and as such will not be able to comply with the TGA's GMP standards that have been developed for the manufacture of high-tech complementary medicines, drugs and therapeutic goods.

Yes, I think all industry players agree, that when the manufacturing of drugs and medicines etc is in question, that strict guidelines be in place to protect the health and safety of consumers. Chemical ingredients and the like that are used in the manufacture of medicines and contribute to a real risk of harm to consumers if manufactured or administered incorrectly should be tightly controlled and all of these types of ingredients that are presented in any form should be classed as being therapeutic. If excessive therapeutic claims are made in connection with the presentation and sale of any product regardless of their form of presentation, then those claims need to be justified and backed up through a more controlled regulatory system. This is a common-sense approach that is practiced by all modern countries including the USA and New Zealand.

However, food ingredients such as those used in sports supplements such as protein formulas, vitamins, minerals, amino acids, botanicals etc which can be found naturally and be extracted from within the foods we consume and in many cases have been used for hundreds of years by humans in diverse cultures, have no need to be manufactured to GMP standards and as such they are not required to be. The TGA cannot reasonably expect to make a declaration that food ingredients are therapeutic just because they are presented in a capsule, tablet or pill form or are directed as being therapeutic because it is a fortified protein drink or bar supplement which contains protein sources or amino acids which help build muscle.

We live in the 21st century which is known as the "information revolution" and consumers have free access to information about all topics including ingredients used in sports supplements around the world at a click of a button. The TGA and FSANZ cannot limit the access to this information so there is a real need for Australian consumers to be able to access all of their sports supplements from local suppliers and not rely on personal imports from global suppliers because their access to locally produced goods have been limited due to over regulation by policy makers which places burdens on industry and limits the manufacturing of different forms of food products.

If the TGA was successful in declaring that all products presented in a capsule, tablet or pill form and other presentations that contain a serving size of ingredients which are higher than the current FSANZ Formulated Supplementary Sports Food Standard allows, then all general food manufacturers including those using Risk Management Programmes RMP standards will not be certified to manufacture these TGA approved GMP therapeutic products and therefore would have to cease to manufacture these types of products for the Australian market. All the RMP Australian contract manufacturers would lose the manufacturing of these types of sports supplements from their business as brand owners would have to seek GMP manufacturers to manufacture these types of products for the Australian marketplace. This would be a huge detriment to the Australian manufacturing businesses which would cost many jobs and business closures.

The cost to sport supplement brand owners to procure GMP manufacturers would be a costly exercise and would result in a large increase in retail prices of goods. For a RMP food manufacturer to become GMP, it would entail a cost of many hundreds of thousands of dollars to set up and comply with the different manufacturing standards developed for the manufacture of therapeutic drugs and medicines. It would not be viable or cost effective for many small food manufacturers to meet these obligations due to the impact of the cost to meet all the TGA's bureaucratic requirements and pay the TGA registration and licence fees etc just to get started. Then there are the ongoing TGA annual registration fees etc for each product formula and annual audit fees which would impact on the profitability of a business going forward. Remember we are talking about many small food manufacturers here and not large drug companies with deep pockets.12/14

Any regulatory changes introduced should be done to help strengthen the local sports supplement industry and not inhibit it. Government and industry alike should embrace the growth and demand for sports supplements and model regulatory developments on meeting the international growth opportunities for businesses in this sector. The free trade agreement between China and New Zealand has opened the way for huge potential growth in the FTDS industry as the Chinese people become more westernised and adopt our way of living and desire our branded products. As Australia has a free trade agreement with the USA and New Zealand, then let's start exporting Australian manufactured sports supplements back to the USA and New Zealand. This can only be done if the Australian standards are such that allow Australian food manufacturers to manufacture products that are formulated with ingredients that can compete with the USA and New Zealand food products currently in the marketplace.

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by COAG requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, **FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO**. In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. **Notification is required in the case of any new or changed standards which may have a significant trade effect, and which depart from the relevant international standard (or where no international standard exists).**

The WTO could be brought in to restore the legal rights of all businesses to carry on their business as had been their normal course for many years prior to the time this declaration is gazetted. New Zealand manufacturers in particular would have a legally justified claim in regard to the application of the TTMRA if Australian authorities did not recognise the TTMRA as an internationally binding agreement. The loss of revenue to many businesses will be of significant value as New Zealand manufacturers of FTDS rely on the Australian market as a major source of sales revenue.

When considering policy changes, the development of sports food standards should be carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition and an assessment of proposed regulation on all affected sectors of the community and can be encapsulated in the phrase 'minimum effective regulation'.

In closing, I wish to express my good will to officers at the TGA as I have had many past dealings with many investigating officers, and I do understand their mindset and the culture in which they operate in. There is a need to identify and stop rogue distributors of imported dietary supplements from international manufacturers and distributors who blatantly show disregard for the FSANZ food standards and the presentation requirements of food labels etc. Yes, there have been cases where over lays have been placed over imported product labels to hide therapeutic claims and the identification of prohibited ingredients in Australia, and this cannot be tolerated. However, there are mechanisms available to identify these rogue distributors and act against them without branding the whole sports food industry with the same iron so to speak.

As the records held by the TGA regarding Syn-Tec Nutriceuticals will show, I have always been fair but forthright in my communications over many years now. Full assessments of Syn-Tec products involving TGA, FSANZ and AQIS select committees have transpired and assessments by individual TGA officers in the field have been carried out. The conclusion of all these assessments has always been the same "that Syn-Tec Nutriceuticals products are in fact food items and not therapeutic goods". I have always acted in a professional manner and offered unrestricted access to me personally for all communication purposes regarding matters pertaining to the Syn-Tec business and all its independent distributors. I just hope that the TGA in its capacity as a responsible regulator gives the appropriate due diligence and unbiased debate that this matter justifiably deserves.

Yours Faithfully,

[redacted]

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