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Australian Institute Of Physiological Sciences

'not just good research, great research'

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Australian Institute of Physiological Sciences response to proposal P236

Introduction

While areas of non-compliance with regards to imported foodstuffs are seen, many of the proposed changes to the R10 component are just the enforcement of the current code. These proposed changes will not aid local manufacturers and suppliers of sports supplements (SS) within Australia. More importantly it will not aid the consumer to gauge what is safe, real or efficacious.

Many products are disallowed for use within the current code and have been given Aust L(AL)/ Aust R (AR) numbers without having to prove any claims. It can be said that there are many sponsors selling AL products with no stability or clinical data on file with misleading or incorrect claims on the pack. With the ease of obtaining AL, particularly those that were grandfathered in the early 90's, it would seem that for approximately $1200 it is easier to obtain AL than comply with the current food code.

Some of the herbs, which have been forced outside the food code to AL, however, are still for sale under misleading claims, including:

St Johns Wort sold as a stress reliever when it is a MAO Inhibitor and is more likely to cause stress
Passion Flower also sold as a stress reliever when it is a MAO Inhibitor and is more likely to cause stress
HMB which failed as a growth inducer for steers, then failed in AIDS patients and now is sold to the most vulnerable market and those who will try anything for a gain, the SS market.
These are just a few of the many examples.

Many of the USA imports have been provided with a provisional AL. In some cases these imports could be considered dangerous and the addition of AL has done nothing for consumer safety. Just because a food has been forced into the AL category (whilst retaining the original formula) does not suddenly make it safe to take. Is an AL capsule recommending the intake of 600mg of caffeine per day (within the Guarana content) in the best interest of the consumer who automatically assumes it to be acceptable and safe since the government has *obviously* approved the product.

With the introduction of the Electronic Lodgement Form (ELF), it has been observed that most sponsors do not read the requirements of having an AL. As ANZFA squeezes out more chemicals (and reduces the allowed amounts) in the push towards AL consumers are put at risk. Take the situation where a manufacturer adhering to the food code can only add 3g/serve (1 serve per day) of creatine to a product. Under AL they are seemingly unlimited in the amount of creatine they can add. If a manufacturer was forced into the AL system, why would they only add 3g of creatine to their product when everyone else is adding 10g? This is the very situation that the food code is supposed to prevent. Another example would be the situation where an energy beverage could obtain AL with 10% 10:1 Guarana Extract, standardised to 14% caffeine giving the consumer 4.62 grams of caffeine in a 330 ml serve. There is

no consumer safety in this example and by the time the TGA Surveillance unit does the math someone could be seriously hurt.

Another body needs to be implemented, or all of the bodies incorporated.
The current government bodies include:

TGA
ANZFA
ACCC
PMAA
HCS

The TGA work with ANZFA the PMAA and HCS. ANZFA work with the TGA and HCS (with respect to prohibited substances) but the ACCC work alone, when they should be integral in policing the claims.
Ten Aust L weight loss products, some of which have been on the market for 10 years were found by the ACCC not to work, but without clinical data how did these products make it onto the shelves. If evidence was such that these products had no efficacy how were they allowed through the system. These products were not allowed within the food code due to their dose form and label claim, however, were listed without the sponsors having credible evidence of the mechanisms of action.
A TGA spokesperson stated publicly that all AL products were required to have their evidence on file and the TGA will not be responsible for misleaqding information.
If the current system, with or without the changes (including the incorporation of the New Zealand Code), was to remain, a body to view clinical data, an 'evidence division' needs to be implemented allowing a company to know whether its product meets ACCC regulations, and compliance to TGA, ANZFA and HCS have also been met. This division could supply a company with a submission number prior to the release of a good. This division could be the Functional Food and Cosmetic Authority and should be semi private with governmental ties (similar to NRA procedures).

High cholesterol and heart disease are the biggest killers in western society and many claims with reference to cholesterol reducing margarines have evolved, with marketing campaigns stating "my cholesterol went from 6 to 4.5 (or similar numbers) in 3 weeks". While the theory has credibility and b-Sitosterol has clinical data proving its worth, the possibility of over reduction of cholesterol exists, leading to conditions as bad as high levels. Self prescription with a Bach Flower Remedy (non-efficacious) and extra consumption of dietary margarine could be deadly. This especially could be dangerous if an individual's lipid lowering prescription medicine is deleted from their regime.

If a pharmaceutical company wished to release a pharmacy only antihypolipoproteinemic it could cost in excess of $100 000 for the TGA to begin reading the submitted toxicology and efficacy data. In the mean while, a full range of cholesterol reducing food products made it onto supermarket shelves with insufficient toxicology data. These products were later removed, however will no doubt be found safe to consume and will be re-released, without the required clinical data on file. If cholesterol reducing margarine is consumed on cholesterol reducing toast accompanied with cholesterol reducing milk poured onto cholesterol reducing cornflakes followed at morning tea with a cholesterol reducing donut, at lunch a

cholesterol reducing ham sandwich and for dinner cholesterol reducing alfredo pasta and for desert cholesterol reducing ice cream, this is a deadly combination. Refusal to regulate such an example and passing it over to the TGA will not help save consumers under the current system. Each sponsor or producer of a food should have to obtain and have read, a report on the possible implications of their product. Misinformed manufacturers assemble ingredients that are antagonistic, synergistic and can be detrimental to the consumer or simply don't work. There is no current hard and fast solution for this, however, something needs to change other than the current proposal.

Question 1

Are these policy principles appropriate to underpin the development of joint regulation? Why or why not?

1. This statement is true. If Australian athletes are to remain at the top of the world's rankings, accessible supplements at affordable prices and non-misleading label information needs to be provided. Assuming ingredient levels remain within the parameters offered in R10 acquiring AL should not be mandatory. Draw backs for foods and supplements obtaining AL are as follows:
   - Formulation adjustments cannot be made without re-listing leaving products antiquated in a quickly moving market place.
   - Stability trials, preservative efficacy and holding clinical trials (which most products fail to carry) add around $10 000 per product to launching product costs, inhibiting small businesses from having products for sale. Being a small business does not decrease the quality of a good.

2. Supplements are required to increase specific systemic activity using the lack of stimulation of other systems as synergistic amplifiers. Activity such as the use of potassium rich nutrients to increase fluid retention within muscle cells while reduction of sodium allows less fluid retention under the skin. A relatively non-toxic way to look 'buff' compared to the use of prescription anorexics. (B2 agonists such as duromine, clenbuterol)

3. The revision to the food code cannot ignore its responsibility by simply setting a substance outside the code. As described above obtaining an AL does not increase consumer safety. Secondarily with the increased rate at which information and new substances are available, it would leave Australian Food Technologists, AFT, in a position of vulnerability within the global market place, to use a fixed code of practice without annual modifications. As will be presented in the conclusion, R10 is already antiquated and leaves a large market for imported supplements from the USA. An example of the current food code's failure to meet international standards would be the Standard A9 maximum allowable level of Folic Acid, current evidence is that segments of the market, especially pregnant women need as much as 400mcg, twice the RDI. If these numbers are to be adhered to, at least the RDI needs to actually meet the levels required under current research, not that of 1965.

4. Claims need to be validated by the ACCC under advisement from a board of consultants within the industry. A company should also be able to demonstrate areas of possible interaction, such as under HACCP, and have adequate evidence that possible risk to consumer safety does not exist such as the example citing cholesterol. This evidence should be submitted for holding to a relevant authority.

5. Warnings should be mandatory.

6. What is a prescribed name? Authorities should be able to locate the manufacturer and persons responsible for consumer safety with relative ease. A sponsor database should be kept.

The principles listed in question 1 do not protect the public any more than the current system. It is not a bad system if the degree to which claims are made are reduced.

Question 2-4

Which is our preferred option for regulating sports foods and why?

Option 1 cannot remain. Simple economics say that Australian manufacturers cannot be hobbled by their own government any more. Grounds for a class action against the government for unequal trade practices with regard to manufacturing could see anarchy within the local market.

Option 2 Homogeneity is a must for fair trade. Stricter procedures for NZ are not our concern. This option is adequate.

Option 3 Self-regulation does not work. Large producers with high income will have their way over the smaller harder working companies. As with the CHC, unbalanced representation will cause hardship from those with less representation.

Option 4 would also leave regulating bodies at risk of having to provide compensation if customs were to allow imported products to enter the company. Large fines would have to be in place to discourage resellers to supply demand, and a huge black market would be created.

What are the costs to us?

As a consulting body, no costs would be incurred directly.

To what extent would the industry be prepared to be responsible for enforcement and monitoring of, for example, a code of practice?

A constant eye is kept on what is coming in and what is for sale. Lists are kept and constant complaints are heard from local producers but there is no consulting body to pass these onto. The ACCC are not chemists and do not have the ability to validate claims. The food authority currently only governs locally produced products and the

TGA are handing out permission to over stick AL to imported non-compliant products. It would seem that the market does not want to take any responsibility.

What level of resourcing of enforcement and reporting arrangements could the industry sustain?

If everyone had to work under the same rules, even those imported, the industry could sustain any level of control required. An even playing field is more important than the costs in providing one.

What level of resourcing of monitoring and reporting arrangements could the industry sustain?

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Questions 7 – 11 (page 13)

Is the purpose of a Sports Food standard appropriately encompassed by the opening paragraphs in Standard 2.9.4?

The basis of a sports food is well defined by paragraph 2.9.4.

Should sports foods be formulated for reasons beyond physiological demands? If so, what other needs or wants should be considered?

Food acts upon all biological systems. Sports foods do more than just aid physiological performance. Manipulation of psychological stance as a physiological change could be considered, ie chemical manipulation, it needs to be made available as a recognised action of food. Sugar manipulates adrenaline levels and in turn excites a subject. This could be considered a psychological response rather than a physical response. The application of psychological manipulation aids attitude, motivation and energy (sugar is an example and by no way indicates the extent to which a psychological response may be achieved). For this reason the code should be flexible to allow novel inventions to be employed within the industry.

Should a sports food standard focus solely on the needs of sports people or consider possible consumption by other groups (for example; children, people wanting convenient products in a form ready for consumption)? If so, which groups and why?

It must be assumed that people other than sports persons will consume products that are designed for active people. Convenience is one aspect that should be discouraged due to over supplementation for non-active individuals and the increasing level of obesity within society. Having a healthy person on the label does not necessarily make the product good for you. Another group that should be wary is those that want to get in shape but do no exercise. They will consume so-called healthy protein shakes (for example) in the belief that they will build muscle, not realising they will put on weight if not exercising in conjunction with taking the product.

There is also the question of what defines a sports food? Is a muesli bar with a claim of energy for 'get up and go' a sports food. If so how do you stop children consuming the product. If it is a general food, why should companies be restricted from selling the same bar with an athletic angle. Maybe a market should be defined as opposed to a product. All in all, sports foods will be consumed by the general market place also and the standards must be designed in accordance with this.

What other key features may need to be addressed?

One of the biggest issues we can see is the hypocrisy existing between general foods and sports foods. Take the example of a certain breakfast cereal fortified with folic acid and calcium, and aimed directly at pregnant women. Claims on the pack and the marketing strategies used push the product more towards the therapeutic category than a general food, yet somehow they get away with it.

Look at the contrasting situation of putting folic acid in a sports food. According to the current standard R10 in the required labelling statement section, item no.6 'Prohibition on Representation', "...a formulated supplementary sports food must not...include an express or implied representation that relates...proposed use of the food to...beneficial physiological effects". In other words, no claim relating to the benefits of folic acid and calcium may be made. These double standards need to be eliminated to create an even playing field.

Should a sports food standard control the representation of sports foods that might inappropriately make them appeal to children? How could this be achieved?

As previously stated, a market could be defined by the level of images and claims on a pack. A product for general sale should comply to a standard of whole nutrition while anything falling outside the description could be defined as a Formulated Sports Food (FSF).

Question 12 (page 14)

What is the most appropriate definition of a sports food?

At the moment there are too many options to specifically describe a sports food. It may be easier for the industry to look at the definition of a food and decide whether or not it meets that criteria. Maybe the group should not be defined as sports foods but functional foods. This would incorporate the issues of convenience and safety to children across the board. Ingestion of eucalyptus oil for children may be as harmful, if not more, than high protein snack foods.

Question 13 (page 15)

If the definition of "nutritive substance" is applied to this standard, is it necessary for a definition of sports food to exclude single-ingredient foods? If so, why?

This question assumes too many conclusions to be useful. It could be said that sugar (sucrose, dextrose or fructose) or linseed oil and gelatine, are all single ingredient foods, for which claims could be applied however could not be regulated for their importance if the consumers wish to produce their own formulated foods at home. Where will the line be drawn, without making all single ingredient producers AL bulk packers.

Questions 14 – 19 (page 16)

Should the definition of nutritive substances be clarified to extend beyond a potentially narrow definition of nutritional purpose of permitting added substances to sports foods? If so, how should that purpose be described?

A broad definition needs to be clarified, however not to the point of prohibiting the addition of all single ingredients. This definition and the laws surrounding their addition should denote a standard of practice, not force the AL of all FSF. The costs would reduce the number of players and reduce the brands to the larger companies, stifling development.

Should more nutritive (and other) substances be permitted additions to sports foods? If so, what criteria should be considered (for example safety, efficacy?)

As research continues more and more substances will be found to have nutritive benefits. As such it will be an on-going process to determine whether these substances should be permitted additions to sports foods. Safety and efficacy would obviously be the two most important criteria to consider when determining this.

In the past, certain substances have been permitted additions to sports foods, but it would seem that the aforementioned criteria were perhaps not examined closely enough. Following are a couple of examples of safety vs ridiculous claims. Bovine Colostrum is a high protein (peptide) substance, which is claimed to be extremely anabolic due to its Insulin Like Growth Factor and Lactalbumin content. Whilst the viability of these compounds is valid if administered via an intramuscular injection, the possibility of a protein passing through the stomach, especially a protein 130 amino acids long, is a medical impossibility. This is however accepted as an allowable claim to be made. On the other hand Chromium Picolinate (CP) is a permitted form of chromium addition when the FDA have issued a warning that toxicology trials have shown CP to be both carcinogenic and mutagenic. HMB is an example of over regulation. There is but one organization with sketchy evidence at best of its activity, however mandatory AL enforces the application of an anabolic label claim and a higher degree of public respect is given to a possibly non-efficacious substance. It could be considered to be endorsed as a therapeutic in the public's eyes.

Is there a need to reappraise ANZFA's approach to risk assessment, particularly in the absence of evidence?

Yes. There is however, no requirement for guessing the degree of toxicology with regard to a food. It is possible to produce a study using toxicology from the pharmaceutical industry. Relative alkaloids can be compared, historical use noted and

trial study participants canvassed. Without this data a warning denoting the lack of toxicology data should be displayed.

Are there particular botanicals used in sports foods which are not prohibited or restricted under Standard 1.4.4, but which should be specifically regulated under Standard 2.9.4?

The use of botanicals in our society is historically important. Whilst I, as an anglo-saxon descendant, have little botanical history, our multi-cultural status and varied population requires access to forms of treatment other than Western Medicine. With a lot of herbs not being available now, requirement to AL could close out availability even further. It is fair that toxic substances such as strychnine and datura be restricted from use, the current code adequately prohibits a range of toxic herbs. Once again provision for regular review should be made available.

Are there particular botanicals or other ingredients, which are currently added to sports foods, but are prohibited under Volume 2 of the FSC (for example Standard 1.4.4) that should be readdressed? If so, what evidence can be given to support this?

Comment with regard to this will be made within the conclusion. (to follow)

Is caffeine an appropriate ingredient in sports foods? If so, why, from what sources?

Caffeine is a powerful ergogenic agent and therefore is a valuable tool in sports supplementation. If caffeine is permitted in general foods (such as coffee) and added to beverages, with claims, provision needs to be made for the addition to sports foods. If this is not the case then we would have another example of hypocrisy on our hands.

Loopholes currently do not prohibit the addition of Camelia sinensis (tea), Coffee, Guarana and Kola. Consider the current Guarana extracts available, all standardised to caffeine at levels ranging from 6% to 25%. With this in mind, the production of Guarana extract 100:1 means a caffeine level of 90% is possible. Calling a spade a spade, caffeine is the substance being added not the various proteins and celluloses so what should be governed is the final available caffeine levels. Safe levels per day could easily be as high as 500mg, as the average daily intake of coffee is 7 cups per person (per capita). At a mean content of 90mg per cup, the average daily intake is already 630mg. LD50 levels orally are around 42mg per kg bodyweight for a sensitive individual and as high as 100mg for coffee drinkers.

Questions 20 – 28 (page 18)

Is the labelling of products with general advisory statements that warn against consumption by vulnerable groups an appropriate risk management strategy for sport foods? Should other strategies also be adopted? If so, what other strategies are needed and why?

General advisory statements are needed and seem to be appropriate. Further action would require controls such as those for tobacco and alcohol. This seems a little dire for food products where a general food could be sold with advisory statements, whilst a sports food would be sold with strict regulations and controls, even though the

difference between the two may be as small as the wording or pictures on a muesli bar.

Are the current advisory statements that warn against consumption by children less than 15 years and pregnant and lactating women, and which apply to all sports foods, appropriate in managing risk? Are there any other sub-groups of the population that should be generally warned against consumption of sports foods?

What is politically correct? Black and Indigenous American populations should not indulge in fat, salt or sugar due to diabetes, people who are already obese cost governmental health care billions per year and should not eat sports food, elderly people do not require higher calorie diets, those with blood pressure disorders and on and on. All subgroup denotation would be a mine-field for product liability insurers.

Maybe the ACCC should police incorrect or aggressive marketing campaigns aimed at vulnerable groups such as bodybuilders.

Should such statements, if continued, be more tailored to particular compositional criteria? If so why?

Yes. Some sports supplements are required by pregnant women partaking in exercise. They don't however require caffeine. Caffeine sensitive persons do not require caffeine, however may require iron. Tailoring can only go to educating the public.

Are there other substances, specific to sports foods, for which advisory or warning statements may be required? If so, what are the substances, and why are such statements necessary?

Weight loss and Mono Amine Oxidase Inhibitors (MAOI) warnings. An area not looked at by the TGA has been the introduction of the weight loss compound Citrus Aurantium, and its alkaloid synephrine. Concurrent use of St Johns Wort, Passion Flower and Synephrine, let alone real MAOI such as Deprenyl, has not been warned against. Simply passing these chemicals to the complementary medicines section of the TGA has done nothing for consumer safety. In fact it has allowed for some outrageous claims and encouragement of self-medication. If these substances were prohibited from having a claim and were left to consumers to source out what they wanted, the education gained during the search would go to consumer safety. Alternatively, if the claim were to remain advisory or warning statements should be mandatory.

What labelling statements are considered important for consumers to enable informed choice?

Labelling statements such as those seen on FCCC products in the USA would allow consumers to gauge the efficacy of the products they are purchasing. The following is an example "the statements contained within this label are not endorsed and have not been read by the FDA". A perfect example is that of Cellasene – a so-called cellulite controlling product containing sweet clover (schedule 4). Rather than being removed

from the market place for non-compliance, the product was "upgraded" with a provisional AL number. This was subsequently milked by the Cellasene marketers with outrageous claims through the media that Cellasene was now approved by the Australian Therapeutic Goods Administration. This was much to the detriment of the TGA's reputation and to those sponsors who try to do (or are forced to do) the right thing. Since neither ANZFA, the TGA or the ACCC read the clinical data, the public should be made aware of this.

Should sports foods be exempt from Standard 1.2.7 (if adopted) that proposes to regulate performance-enhancing claims, and therefore require prior submission of scientific substantiation before being used? If so, why?

The sports industry is the major victim of misinformation and scandalous behaviour. Words like Mega, Massive, Explosive Huge and the like are the triggers for endorphin surges which for some are addictive. The advertising wins over real science. Proof of claims is mandatory.

Should sports foods be exempt from the nutrition information requirements of Standard 1.2.8? If so, why?

No. If claims of the addition of an active substance are used, the consumer has the right to know the amount.

Is there a need for permitted labelling statements to be underpinned by compositional criteria for particular types of sports foods such as high protein, high carbohydrate, and energy supplements? Can these products be encompassed by general permission within the standard or more broadly in Volume 2 FSC?

All statements need to be proven.

Are there any other general labelling issues that need to be considered for sports foods?

We have covered these issues.

Conclusion

The system that needs to be adopted may not come from the choices offered as the role food plays in life is substantial. It is not as simple as a therapeutic acts upon a system and a food does not. In fact, many of the medicines we use today take the actions of a food and amplify them. What needs to be regulated is the degree to which a company may use a food's action in marketing.

Looking at the following list, it is hard to draw a line between what is a marketing slogan and what could be misconstrued as a claim. Is the fact that these products fail to offer a dosing regime and instead suggest a serving size allowing the manufacturing company to make claims which would not necessarily pass scrutiny by biochemical definition? The claims made by these companies could be made about any food.

Kraft Singles	Helps build stronger and healthier bones
Milk Rev	Prevents osteoporosis
Oil Of Olay	Reverses the visible signs of aging (cosmetic)
Provital	"I lowered my cholesterol from 6 to 3.5 in 3 weeks"
Logicol	The logical choice in lowering your cholesterol
Sunny Crust	Fibre for your body and DHA for your head
Soy Milk	Phyto-hormones for symptoms of menopause
Trim Milk	For weight loss
Airwaves	Vapour releasing gum to really clear your nose
Vegemite	Building healthy kids
Fisherman's Friend	Extra Strong Mint Lozenges
Burn Energy Drink	Energy for longer
Black Stallion	Ride all night (caffeine actually reduces the ability to 'perform')
Power Aid	Official energy drink of the AFL

Offered for your response is an overview of what we consider to be limited examples within the code and document studies including references, not to sports medicine trials but biochemical data, and theorem. This document will follow upon completion.

Cofounder AIPS

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