Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

FSANZ Proposal P293 – Nutrition, Health & Related Claims Consultation Paper February 2012

Therapeutic Goods Administration Submission

The Therapeutic Goods Administration (TGA) is responsible for administering the provisions of the *Therapeutic Goods Act 1989* ('the TG Act'). The overall objective of the TG Act is to ensure the quality, safety, efficacy, and timely availability of therapeutic goods, including medicines and medical devices that are supplied in or exported from Australia.

The TGA appreciates the opportunity to provide a submission to Food Standards Australia New Zealand (FSANZ) on draft standard 1.2.7 - Nutrition, Health & Related Claims, arising from Proposal P293 - Nutrition, Health & Related Claims (P293).

The TGA is not in a position to comment on the matter regarding 'fat-free' and '% fat-free' nutrition content claims, or on the specific technical details within draft standard 1.2.7 and other proposed amendments to the Food Standards Code ('the Code').

The TGA can advise on any impact the proposed standard 1.2.7 may have on the regulation of therapeutic goods and the regulatory interface between therapeutic goods and food. In making comments on the consultation paper the TGA will draw significantly from the comments made in our submissions on P293 in May 2009 and March 2006 (at Attachment 1).

In the submissions of May 2009 and March 2006, the TGA raised the following two major concerns about P293, that relate to the key objective of maintaining the integrity of the food-medicine interface:

1. ensuring a rational and consistent risk-based approach to the regulation of food and medicine; and
2. having a regulatory framework for food health claims that delivers readily enforceable regulatory requirements; prompt and responsive complaints and problem resolution systems, suitable and accessible penalties and sanctions, and on-going monitoring, evaluation and review of the entire nutrition, health and related claims system.

In addressing these two issues the TGA has the following comments:

Draft Standard and Its Impact on Food Medicine Interface

The TGA understands that the purpose of the standard is to set out, among other things, the claims that can be made on the labels or in advertisements about the nutritional content of food and the claims that can be made about the relationship between a food, a property or properties of a food and a health effect (described as health claims), and the conditions under which such claims can be made.

Under the current TG Act, goods that are represented in any way to be, or that are, likely to be taken to be for therapeutic use are considered to be therapeutic goods, unless these goods are specifically excluded by the definition of therapeutic goods in subsection 3(1) of the TG Act. Paragraphs (e) and (f) of the definition specifically exclude certain goods for which there is a prescribed standard in the Code (paragraph (e)), and goods which have a tradition of use as foods in Australia and New Zealand in the form in which they are presented (paragraph (f)).

Therapeutic use is defined in subsection 3(1) of the TG Act as, relevantly, to mean use in or in connection with:

(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
(b) influencing, inhibiting or modifying a physiological process in persons; or
(c) ... .

Based on the definition of health effect/health claim included in the draft standard, and the definition of therapeutic use in the TG Act, it appears that health claims could also meet the definition of therapeutic use.

The TGA notes that Schedule 2 of the draft standard lists 'Conditions for Permitted Health Claims' for a number of specific food and/or food properties (ingredients). It is unclear whether, in doing so, the draft standard might provide sufficient basis to conclude that products consisting of, or containing, these ingredients (irrespective of whether the conditions set out in Schedule 2 are met or not) would be goods for which there is a prescribed standard for the purposes of paragraph (e) of the definition of 'therapeutic goods' in the TG Act, therefore excluding these goods from being therapeutic goods under the TG Act. If that were the case regulation of these goods would then be under the relevant food legislation.

A number of ingredients for which the draft standard would allow health claims to be made are permitted for use in complementary medicines. Many complementary medicines currently on the Australian Register of Therapeutic Goods (ARTG) contain these ingredients and make similar claims. These goods would not be eligible for inclusion on the ARTG should the draft standard 1.2.7 become a prescribed standard for these goods for the purpose of paragraph (e) of the definition of therapeutic good under section 3(1) of the TG Act. The TGA may be obliged to take action to remove these goods from the ARTG.

Where there is no prescribed standard in the Code for the purpose of paragraph (e) of the TG Act, determination of regulatory status of a good has typically been based on the overall presentation of the good, including route of administration (eg oral), dose instruction (medicinal or food serving suggestion), and whether a 'therapeutic claim' is made. As health claims permitted by the draft standard are also likely to be taken as 'therapeutic claims', addition of this standard to the Code may introduce further confusion at the food/medicine interface and pose an additional challenge in the enforcement of both foods and therapeutic goods legislation.

The TGA is therefore concerned that the draft standard may not provide clarity at the food medicine interface, and encourages FSANZ to provide further guidance to assist all relevant stakeholders in the interpretation and practical application of the draft standard.

Consistency in Regulating Therapeutic Goods and Food Making Health Claims

The TGA notes that in the Response to the Recommendations of *Labelling Logic: Review of Food Labelling Law and Policy (2011)*, the COAG Legislative and Governance Forum on Food Regulation ('the Forum') supports, in principle, recommendation 23, that a consistent, seamless regulatory approach for nutrition, health and related claims be adopted for food, complementary medicines and dietary supplements.

Under the current therapeutic goods legislation, unless specifically exempt, medicines supplied in Australia are either Registered or Listed on the ARTG. Registered medicines are higher risk medicines and are individually evaluated for quality, safety and efficacy. Listed medicines are low risk medicines. They may only contain low risk ingredients that are permitted for use in listed medicines and may carry indications only for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions. Generally all medicines must be manufactured by licensed or approved manufacturers in accordance with the principles of Good Manufacturing Practice. Advertisement for therapeutic goods is governed by the *Therapeutic Goods Advertising Code 2007* (the TGAC). Indications that refer to restricted representation, a representation in an advertisement about therapeutic goods that refers to a serious form of a disease, condition, ailment or defect identified in the TGAC may not be advertised to consumers unless approval is granted by the TGA. Some permitted health claims by the draft standard (eg reduced risk of coronary heart disease) would be restricted representation if they were used in an advertisement for therapeutic goods.

In light of recommendation 23 of the *Labelling Logic: Review of Food Labelling Law and Policy (2011)*, the TGA encourages FSANZ to ensure a consistent regulatory approach is applied to the regulation of therapeutic goods and food making health claims.

Other Comments

The heading of clause 7 of the draft standard states 'claims must not be therapeutic in nature'. As health claims are also likely to meet the definition of therapeutic use it is not clear how, in practice, this could be achieved. Further clarification of this clause may be required.

The TGA notes clause 7(a) of the draft standard states that a health claim 'must not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition'. According to clause 5 of the draft standard, if such a claim is expressly made by 'another standard' in the Code it does not need to comply with clause 7(a). 'Another standard' of the Code could be taken to mean a standard other than standard 1.2.7. The TGA notes a number of permitted health claims included in Schedule 2 of the draft standard 1.2.7 do refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. For example a claim regarding 'reduced risk of osteoporosis' could be made if the food contains not less than 290mg of calcium per serving. To avoid doubt it may be beneficial to state in clause 5(a) '....expressly permitted by a standard of the Code'.

Schedule 2 Part 1 (Minerals) of the draft stand includes biotin and folate. They should be moved to Part 2 (Vitamins) of this schedule.

Conclusion

The TGA appreciates the opportunity to provide a submission to FSANZ in response to the P293 consultation paper. We remain concerned that the draft standard may not provide clarity at the food medicine interface and may pose additional challenges in the enforcement of both foods and therapeutic goods legislations. We will continue to work with FSANZ, States/Territory jurisdictions and the Department of Health and Ageing to define and clarify the boundaries between therapeutic goods and food.

[redacted]

Office of Complementary Medicines
Therapeutic Goods Administration

2 April 2012

Submission

***To*: Food Standards Australia New Zealand**

***From*: Therapeutic Goods Administration**

***Re*: P293 Nutrition, Health and Related Claims Consultation Paper for First Review**

May 2009

The Therapeutic Goods Administration (TGA) is broadly supportive of Food Standards Australia New Zealand's (FSANZ's) consultation for first review of P293. In making comments on the review paper, we will draw significantly from the comments we made in our submission on P293 at Draft Assessment in March 2006 (Attachment 1 to this paper).

In that submission we said that the TGA has two major concerns about P293 that relate to the key objective of maintaining the integrity of the food-medicines interface, *viz*:

1. Ensuring a rational and consistent risk-based approach to the regulation of food and medicines; and
2. Having a regulatory framework for food health claims that delivers readily enforceable regulatory requirements; prompt and responsive complaints and problems resolution systems, suitable and accessible penalties and sanctions, and on-going monitoring, evaluation and review of the entire nutrition, health and related claims system.

The scope of the current FSANZ consultation paper is limited to changes to the approach to regulating general level health claims, and a revised text and structure for Standard 1.2.7 which will regulate food health claims.

In addressing these two issues, the TGA has the following comments.

Regulation of general level health claims

In our submission to FSANZ in 2006, the TGA strongly recommended that general level health claims be specifically regulated within the standard, saying that "The TGA recommends the substantiation requirements for general level claims should be included with the requirements for high level claims in the standard at the time of its introduction. Any other approach will almost certainly lead to a protracted period of varying degrees of industry compliance with the attendant probability of consumers being misled and imposing an unnecessary burden on enforcement agencies in the interim, or as in the TGA's experience, enforcement not being possible in the face of a manufacturer's challenge to the legal status of the guidelines."

To that end, the inclusion of a specific list of pre-approved general level health claims in the standard is an excellent change to the approach to regulating these claims.

There does, however, remain one serious concern about the prescribed wording of general level health claims and we continue to be concerned about foods being allowed therapeutic

claims in any but the most controlled circumstances. The basis for these concerns can be summarised from our 2006 submission, as follows.

The *Therapeutic Goods Act 1989* determines that any product that is represented to be, or likely to be taken to be for 'therapeutic use' is to be regulated under that Act. 'Therapeutic use' means use or in connection with:

a) Preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
b) Influencing, inhibiting or modifying a physiological process in persons or animals;
c) Etc.....

The Act excludes food from this definition.

This new draft Standard 1.2.7 specifies that products carrying claims as per provision (a) above may not be made without an express permission. It is essential that such permission would only be granted in extraordinary circumstances and in consultation with the TGA. However, the draft standard remains silent on products carrying claims as per provision (b).

The Policy Guideline states that claims that a food or component:

- "manages, influences, inhibits or modifies a physiological process;
- reduces the risk of a disease, condition, ailment, defect or injury;

may only be made in the context of the appropriate diet (that must be described)".

This requirement is central to ensuring that foods are not permitted to carry therapeutic claims. In turn, this distinction between the kinds of claims foods and medicines are permitted to carry is central to maintaining the integrity of the food-medicine interface.

Given the commonality of effect that both foods and medicines may be claimed to manage, influence, inhibit or modify a physiological process, the requirement in the Policy Guideline that for food, such a claim 'may only be made in the context of the appropriate diet (that must be described)' becomes paramount to differentiating between foods and medicines.

The new draft Standard 1.2.7 prescribes a clear dietary context for each high level health claim permitted, but most of the general level claims proposed to be permitted for foods lack a requirement for a dietary context to be given as part of the claim. As a minimum, each general level health claim should be required to be made in the context of some kind of statement about the importance of 'this food/nutrient/substance' in a 'varied diet' (as has been required for the folate health claim for many years now). Without a dietary context such as this, foods will be carrying claims relating to vitamins, minerals and other biologically active substances that are the same as the claims carried by complementary medicines. And the new draft standard reads as if this is what is intended.

Drafting of Standard 1.2.7

We will not make specific comment on the drafting proposed for Standard 1.2.7 (other than the policy issue outlined above), as it is the food regulators who will have to interpret and take action in accordance with it.

However, we remain concerned about the enforceability of the standard, as we outlined in our 2006 submission. The move to prescribe approved general level health claims will go some way towards improving the ability of the jurisdictions to be able to take action against non-compliant claims.

The matter of real concern here is that currently there is a prohibition on the use of health claims in food labels and advertising, which is a 'black and white' standard. Despite this, food labels are carrying health claims seemingly with impunity, and much food advertising not only carries food health claims but borders on therapeutic advertising. When the jurisdictions cannot enforce a black and white standard – a prohibition – serious concerns have to be raised about their capacity to enforce a standard which, under certain circumstances, allows such claims in labels and in advertising.

In reality it is doubtful that Standard 1.2.7 can ever be drafted strongly enough to give health claim labelling breaches precedence in the enforcement agencies' priorities, over food safety and other high risk matters. No matter how strong the intention of a jurisdiction to take strong action against a manufacturer who transgresses the provisions relating to health claims, jurisdictional law must allow for natural justice and this takes time, enforcement priorities are inevitably directed towards food safety problems rather than food labelling transgressions, and if a manufacturer is determined to keep an illegal health claim in the marketplace as long as possible, jurisdictions are seriously limited in their ability to take timely action by the time constraints and costs of the court system.

P293 does not explain very well the provisions that relate to health claims in food advertising, or the compliance measures that can be taken in this domain. As our 2006 submission explains, over the last decade the TGA has developed an effective co-regulatory scheme of advertising controls for therapeutic goods. This scheme relies on a co-regulatory governance system and approvals and complaints handling processes which are underpinned by legislative provisions, and industry self-regulatory initiatives are drawn into the scheme through contractual arrangements with peak industry bodies.

The strength of this scheme, which has been described to FSANZ officers and which is well-described on the TGACC website is the relationship between the key stakeholders – industry including the media, consumers, health professionals and the regulator – that is, those who advertise, those to whom advertising is directed and the regulator. Each of these key players is held accountable, ultimately to the Minister, through the governance system and/or contractual arrangements with the regulator.

Such a co-regulatory approach must be considered in relation to ensuring compliance of food health claims. Without such a scheme there can be no assurance of timeliness, consistency or ultimate effectiveness of enforcement by the jurisdictions of non-compliance with the standard. This situation then brings into question within the community the public health and safety of consumers, credibility of food labelling and more broadly, the food industry, and the capacity of enforcement agencies.

Such a scheme, assuming it were to be limited to food advertising, still calls into question the enforcement capacity of the jurisdictions for food labelling transgressions. However, it is advertising that tends to have the greater reach into the community and therefore deserves special regulatory attention in the interests of the broader community.

In summary

The TGA remains supportive of FSANZ's work on regulating food health claims. Our issue of greatest concern remains the potential for poor enforcement of non-compliance with the scheme. If the scheme is not well enforced, it puts at risk consistency at the food-medicine interface. And the risk is probably higher for advertising than it is for labelling, which creates a new level of complexity for a food standard.

We remain willing as always to discuss these matters agency-to-agency. We would be happy to comment on any drafting matters FSANZ would like us to consider, but unless requested, we continue to keep our comments at the regulatory policy level.

[redacted]
Senior Principal Research Scientist
Therapeutic Goods Administration

Submission

***To*: Food Standards Australia New Zealand**

***From*: Therapeutic Goods Administration**

***Re*: P293 Nutrition, Health and Related Claims Draft Assessment Report**

March 2006

In making this submission the Therapeutic Goods Administration (TGA) commends the Food Standards Australia New Zealand (FSANZ) P293 project team on the high calibre of the report its members have prepared. The report clearly describes the issues, considerations around them, and the reasons supporting the positions that have been put forward. It deals with a matter of much scientific, regulatory, legal and political complexity in a meaningful and thought provoking manner.

This submission from the TGA is confined to regulatory policy level comments. It has been prepared in consultation with, and with advice from, the Complementary Medicines Evaluation Committee (CMEC) and the Therapeutic Goods Advertising Code Council (TGACC).

Our comments relate mostly to the proposals relating to health claims (rather than related claims and nutrition claims), which is the area that has the potential to most directly affect the integrity of the food-medicine interface. The key objective for the TGA, and presumably FSANZ, is to ensure that any regulatory change on either side of the interface is given effect in such a way as to ensure that the food-medicine interface at least maintains its current standard of integrity, and where possible, increases in clarity and transparency.

Implementing a food health claims regime

By its nature, the P293 Draft Assessment Report (DAR) focuses very much on the regulatory framework for health claims. The focus is on the conceptual framework for claims, the claims classification framework, regulatory frameworks for high and general level claims, and proposals for substantiation requirements. Implementation, enforcement and monitoring are addressed, but given FSANZ's role as the standard-setter rather than the regulator, these issues are not addressed in significant detail.

The TGA has two major concerns about P293 that relate to the key objective of maintaining the integrity of the food-medicines interface, *viz*:

3. Ensuring a rational and consistent risk-based approach to the regulation of food and medicines; and
4. Having a regulatory framework for food health claims that delivers readily enforceable regulatory requirements; prompt and responsive complaints and problems resolution systems, suitable and accessible penalties and sanctions, and on-going monitoring, evaluation and review of the entire nutrition, health and related claims system.

1. An adequate and appropriate regulatory framework for food health claims

1.1 Avoiding confusion between foods and medicines - ensuring similar standards for substantiating claims

It is an agreed principle in Australia (if not spelled out in such simple words) that foods and medicines are regulated according to their relative risk. Foods are, in general, regulated as lower risk products than medicines. However, if health claims are to be permitted for foods, foods carrying health claims or 'promises' to consumers, inevitably carry a higher risk (to consumers) than foods which carry no claims at all. Such claims may result in dietary changes that are potentially detrimental to health.

Foods *per se* (excluding certain categories of foods such as unevaluated novel foods) are low risk products, unless they carry claims as to their efficacy. Similarly, many complementary medicines were they to be presented simply as a package of ingredients rather than as a product formulated for a defined and advertised purpose (i.e. with claims), are of low risk to consumers. It is therefore essential that in this context the claims permitted to be made by products on either side of the food-medicine interface have an equal regulatory footing in terms of promises being made to consumers.

P293 proposes substantiation requirements for high and general level claims for foods that appear to sit comfortably against the substantiation requirements for similar claims for medicines. Some modifications may need to be made after experience is gained in administering and enforcing the proposed food health claims substantiation requirements, however, with a good monitoring, evaluation and review process, this should occur by way of due process.

The TGA has experience from 1999 with allowing the guidelines for substantiating general level claims to be in 'guideline' form rather than underpinned by legislation. Apparent lack of compliance has led reviews from several groups, most importantly, the review conducted in 2003 by the Expert Committee on Complementary Medicine in the Health System, which have recommended that the substantiation guidelines for general (and medium) level, as well as high level, claims for complementary medicines be underpinned by legislation. The substantiation requirements for claims for Listed (low risk) medicines were introduced in 1999 as guidelines rather than legal requirements for reasons of educating the industry and a phased introduction. However, the transition phase of 4 years was too long in terms of encouraging industry compliance, leaving the guidelines unenforceable where non-compliant sponsors chose to challenge them.

The TGA recommends the substantiation requirements for general level claims should be included with the requirements for high level claims in the standard at the time of its introduction. Any other approach will almost certainly lead to a protracted period of varying degrees of industry compliance with the attendant probability of consumers being misled and imposing an unnecessary burden on enforcement agencies in the interim, or as in the TGA's experience, enforcement not being possible in the face of a manufacturer's challenge to the legal status of the guidelines.

1.2 Avoiding confusion between foods and medicines - differentiating between food and therapeutic claims

The *Therapeutic Goods Act 1989* determines that any product that is represented to be, or likely to be taken to be for 'therapeutic use' is to be regulated under that Act. The Treaty covering the establishment of the Australia New Zealand Therapeutic Products Authority (ANZTPA) has similar provisions (for humans, but excludes reference to animals). 'Therapeutic use' means use or in connection with:

d) Preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
e) Influencing, inhibiting or modifying a physiological process in persons or animals;
f) Etc.....

Both the Act and proposed ANZTPA definition seek to exclude food from this definition.

Draft standard 1.2.7 specifies that products carrying claims as per provision (a) above may not be made without an express permission under standard 2.6.2. It is essential that such permission would only be granted in extraordinary circumstances and in consultation with the TGA or its successor organisation. However, the draft standard remains silent on products carrying claims as per provision (b).

The Policy Guideline states that claims that a food or component:

- "manages, influences, inhibits or modifies a physiological process;
- reduces the risk of a disease, condition, ailment, defect or injury;

may only be made in the context of the appropriate diet (that must be described)".

This requirement is central to ensuring that foods are not permitted to carry therapeutic claims. In turn, this distinction between the kinds of claims foods and medicines are permitted to carry is central to maintaining the integrity of the food-medicine interface.

Given the commonality of effect that both foods and medicines may be claimed to manage, influence, inhibit or modify a physiological process, the requirement in the Policy Guideline that for food, such a claim 'may only be made in the context of the appropriate diet (that must be described)' becomes paramount to differentiating between foods and medicines.

Provision (2) (e) (iv) of clause 5 and (1) (c) (iv) of clause 6 of the draft standard spell out that food claims must be made in the total dietary context. However, in the table to clause 6, the provisions that will permit folic acid and neural tube defect claims to be made for foods do not have a requirement for the claims to be made within a dietary context. The claim relates simply to daily dietary folate intake with no reference to 'a healthy diet' 'or 'a variety of foods' as required for all other high level claims specified in the table. This could allow therapeutic type claims relating to folic acid and neural tube defects to be made in relation to foods and needs to be redressed. It is important that all food health claims are required to be made within the dietary context.

The folic acid neural tube defect claim could be placed in a dietary context with, as a minimum, an extra condition similar to what standard 1.1A2 currently requires – that there is a statement accompanying the claim that it is important to maintain a varied diet.

A further matter that arises in differentiating between food health claims and therapeutic claims is the definition of 'serious disease'. Draft standard 1.2.7 defines it to mean 'a disease, ailment, defect or condition that is not appropriate to diagnose, treat or manage without consultation with or supervision by a health care professional.....'.

The definition proposed to be applied for the ANZTPA scheme is 'a disease, disorder or condition is serious if the disease, disorder or condition (or any symptom of the disease, disorder or condition) is generally accepted as not suitable for at least one of the following:

- self-diagnosis;
- self-management.'

These two definitions appear to be reasonably consistent.

However, the draft ANZTPA definition specifically excludes reference to health care professionals, as their inclusion leads to debate as to which such professionals are deemed to be recognised for the purposes of the definition. Given there are so many health care professionals in Australia without a recognised accrediting body, this debate can become significant.

Additionally 'ailments' have not been included in the ANZTPA definition, on the basis that a serious ailment would manifest itself as a disorder or a condition. 'Injury' has not been included either because an injury is not a disease.

The drafting for standard 1.2.7 should probably also refer in more places than not to a 'condition' rather than to a 'disease'. The draft standard defines 'serious disease' to include a serious condition. However, it is not clear whether claims relating to non-serious conditions, as opposed to 'diseases' are accommodated within the standard. The word 'condition' has a much broader connotation than disease, which may be too limiting especially for general level claims. Condition includes such things as life stages eg pregnancy, menopause, which are generally non-serious but they are not diseases. It may be that the definitions for serious disease and general level claims work together to allow for non-serious conditions to be regulated as general level claims, however, that needs to be checked before drafting is completed.

1.3 *Avoiding confusion between foods and medicines – consistency in the regulation of biomarker claims*

P293 was preceded by a significant amount of policy level discussion and debate about the appropriate level of regulation for food biomarker claims. In fact, this was a specific topic on the agenda of the May 2004 meeting of the Australia and New Zealand Food Regulation Ministerial Council. Following their meeting, Ministers released Communique 28 which stated:

"The Ministerial Council determined that claims regarding the maintenance of a biomarker would be permitted on foods. They will be treated in the same way as enhancement claims. That is, manufacturers will be required to apply to FSANZ for approval of a biomarker maintenance claim, prior to releasing the product to market. This will ensure that claims are appropriately substantiated, and subject to public consultation, prior to their use."

The Ministers' Policy Guideline states that:

"High level claims are those claims which make reference to a serious disease, including:

- biomarker maintenance claims;
- biomarker enhancement claims; and
- biomarker claims that make reference to a serious disease."

This Ministerial guidance makes it clear that any biomarker claim relating to a serious disease/condition should be regulated as a high level claim, thus requiring, among other things, pre-market approval. However, it remains silent on the regulation of biomarker claims relating to non-serious conditions. For the moment, it is difficult to identify a biomarker for a non-serious condition. However, P293 is setting a framework for the regulation of health claims into the future and therefore all relevant contingencies need to be considered.

The TGA policy position on biomarker claims being made in relation to medicines is that all biomarker claims, with one specific exemption, must be regulated as high level claims thereby requiring Registration (with full pre-market evaluation). The specific exemption is for claims for Listed medicines that they ***may help maintain normal blood cholesterol levels in healthy individuals***. The TGA has received advice from two of its expert advisory committees, CMEC and the Medicines Evaluation Committee (MEC), that in the interest of avoiding consumer misunderstanding and the subsequent potential of untoward health effects, products carrying such cholesterol claims should include advice that such products are inappropriate for the treatment of high cholesterol levels and that blood cholesterol should be regularly checked. The risk-based approach for such products would require such statements to be also included on any foods which were permitted to carry such claims.

The TGA position that with the one exception, all biomarker claims should be regulated as high level claims,was revisited in the light of the deliberations that were occurring at the food Ministerial level on the regulation of biomarker claims, with the result that the Chairs of all TGA Expert Advisory Committees supported the position and urged the TGA to work strongly to ensure this overall policy of requiring pre-market evaluation for biomarker claims was applied to food biomarker claims also.

P293 does not refer to the Ministerial Policy Guideline or the Ministers' Communique 28 of May 2004 in the context of biomarker claims. It is not at all clear whether the Ministers' policy guidance has been taken into account within P293. Draft standard 1.2.7 defines high level claims to mean:

- "a health claim that directly or indirectly refers to a serious disease <u>or a biomarker</u>", thereby ensuring that all biomarker claims are to be regulated as high level claims.

A general level claim is defined to mean:

- "a health claim that does not, directly or indirectly, refer to a serious disease <u>or a biomarker</u>".

Biomarker is defined in the draft standard in relation to being predictive of a serious disease. This means that only biomarkers for serious diseases are to be regulated as high level claims. The draft standard remains silent on how biomarkers for non-serious diseases are to be regulated. In the text of P293, more often that not, it states that these claims should be regulated as general level claims. However, it is not immediately clear that the standard will provide for that.

At the time Ministers agreed on the parts of the Policy Guideline relating to biomarker claims, it is the TGA's understanding that only biomarkers for serious diseases were under consideration. In this context, Ministers agreed that all biomarker claims should be regulated as high level claims.

This would be consistent with the TGA position of a rational and consistent risk-based approach to the regulation of foods and medicines, and thereby support the integrity of the food-medicine interface.

1.4 *Avoiding confusion between foods and medicines – general level claims for biologically active substances*

The table to clause 11 in draft standard 1.2.7 allows for a food to carry a claim that it contains a biologically active substance, which could equally be an ingredient permitted in complementary medicines. Only the presence of the substance may be claimed for the food. If a recommended intake is made for the food or the substance the manufacturer must hold substantiating evidence for the claim. However, no effects of the substance may be claimed under this provision.

It is unclear whether clause 5 (2) (e) (iv) applies to the claims permitted in the table to clause 12 in draft standard. This table appears to allow content claims to be made for biologically active substances and their effect(s), outside of a dietary context. If this is the case, in effect it would allow general level claims for foods containing ingredients that may also be permitted in complementary medicines to make content claims and specify a health benefit. If this is the situation, how would these claims differ from a therapeutic claim, especially as the effective 'dose' is required to be specified as well?

As stated under section 1.2 above, the Policy Guideline states that claims that a food or component:

- "manages, influences, inhibits or modifies a physiological process;
- reduces the risk of a disease, condition, ailment, defect or injury;

may only be made in the context of the appropriate diet (that must be described)".

As discussed in section 1.2, given the commonality of effect that both foods and medicines may be claimed to manage, influence, inhibit or modify a physiological process, the requirement in the Policy Guideline that for food, such a claim 'may only be made in the context of the appropriate diet (that must be described)' becomes paramount to differentiating between foods and medicines.

A second question arises in relation to the provisions of the table to clause 12 and biologically active substance claims. The table states that a serve of the food must contain at least 10 percent of the amount of the substance that is required to be consumed each day to achieve the claimed health benefit. An amount as low as 10 percent seems to allow foods to carry claims in relation to biologically active substances when they have nowhere near the amount of the substance to deliver the claimed benefit, thereby arousing unrealistic consumer expectations.

If a consumer has to consume ten serves of one food each day to achieve their desired health benefit, inevitably their diet is going to be significantly skewed towards that food, with the

possible exclusion of other 'healthier' foods and with an increase in the magnitude of any risk the particular food carries within the overall dietary context.

2. Having an effective implementation system for food health claims

Of the 142 pages of the DAR for P293 (excluding its attachments) just two paragraphs are devoted to enforcement, and just over four pages in total to 'Implementation, Enforcement and Monitoring'.

Developing a food standard is about developing an appropriate and workable regulatory framework for the food matter at hand. This DAR has explored the appropriate regulatory requirements for nutrition, health and related claims in significant detail. However, no matter how stringent the pre-market requirements for health claims are, permitting such claims for foods without a surety of timely and effective enforcement with suitable penalties for breaches of the standard will:

- pose a serious risk of consumers being misled, at times with public health and safety ramifications;
- undermine the integrity of the food labelling message;
- create an inconsistent approach to management of risk between foods and medicines;
- compromise community confidence in the relevant enforcement agencies; and
- undermine industry credibility.

As stated earlier in this submission, P293 must deliver readily enforceable regulatory requirements; prompt and responsive complaints and problems resolution systems, suitable and accessible penalties and sanctions, and on-going monitoring, evaluation and review of the entire system.

Currently there is a prohibition on foods carrying health claims. The TGA has been advised by Government that high priority is being given by the States and Territories in Australia to ensuring that prohibition is enforced. The Ministers' Food Regulation Standing Committee's Implementation Sub Committee has established a Watchdog to help with appropriate and consistent enforcement measures for breaches of the existing prohibition and future non-compliance with the standard 1.2.7.

FSANZ has also advised that Coles and Woolworths supermarkets have indicated that they are not willing to sell foods which do not comply with regulatory provisions relating to health claims.

Despite all of these assurances within an environment of a prohibition on health claims any trip to the supermarket, including Coles and Woolworths outlets, reveals health claims being made for foods in Australia at the moment.

Where transgressions are identified by a consumer or other stakeholder, a complaint has to be made to the jurisdiction responsible for enforcement, and they must be in a position to take timely and effective action. Assuming resources allow attention to be devoted to a food labelling issue, the enforcement agency may ask the manufacturer responsible, among other things, to:

a) justify their food labelling claims; or
b) initiate relabelling of the product in question; or
c) undertake a recall of the product;

or take court action.

Should measures (a), (b) and (c) be ignored by the manufacturer, the jurisdiction must make a decision as to whether court action will be cost effective. Court action is extremely resource-intensive and ultimately may take a long period of time. Penalties that have been applied in two high profile cases in recent years, one in Australia and one in New Zealand, have been less than AUD$20,000 in each case. Such penalties are insignificant to large manufacturers.

In requesting actions such as (a), (b) and (c) significant amounts of time can elapse with the health claim remaining in the marketplace. P293 proposes that there should be a Register of Independent Experts to assist enforcement agencies with their expert opinions on potential breaches. This register is unlikely to be able to lead to significantly more timely enforcement action, but it should help with the veracity of the evidence acquired by the enforcement agency against the transgressor.

In summary, no matter how strong the intention of a jurisdiction to take strong action against a manufacturer who transgresses the provisions relating to health claims, jurisdictional law must allow for natural justice and this takes time, enforcement priorities are inevitably directed towards food safety problems rather than food labelling transgressions, and if a manufacturer is determined to keep an illegal health claim in the marketplace as long as possible, jurisdictions are seriously limited in their ability to take timely action by the time constraints and costs of the court system.

P293 does not explain very well the provisions that relate to health claims in food advertising, or the compliance measures that can be taken in this domain. Discussion with FSANZ staff elucidates that the health claims provisions that apply to food labelling apply to food advertising as well, and that the jurisdictions have enforcement powers over food advertising. However, no definition for advertising is proffered, and in the TGA's experience there is vigorous debate around this definition, most of which hinges around whether there has been any 'valuable consideration' for the communication in question. Where there has been, there is general agreement that the communication should be regulated as an advertisement. However, valuable consideration is not always easy to identify, even with a careful audit.

P293 describes self-regulatory initiatives in Australia and New Zealand for food advertising, *viz*, the Australian Advertising Standards Board and the New Zealand Advertising Standards Authority. The Australian Competition and Consumer Commission's role (though not the New Zealand's Commerce Commission's) in food labelling regulatory matters is also referred to.

Over the last decade the TGA has developed an effective co-regulatory scheme of advertising controls for therapeutic goods. This scheme relies on a co-regulatory governance system and approvals and complaints handling processes which are underpinned by legislative provisions, and industry self-regulatory initiatives are drawn into the scheme through contractual arrangements with peak industry bodies. The scheme addresses the problem of helping to ensure 'timeliness and teeth' for enforcement of non-compliance with advertising standards, whilst also requiring that industry bears appropriate levels of responsibility in maintaining advertising standards for therapeutic goods.

The strength of this scheme, which has been described to FSANZ officers and which is well-described on the TGACC website is the relationship between the key stakeholders – industry

including the media, consumers, health professionals and the regulator – that is, those who advertise, those to whom advertising is directed and the regulator. Each of these key players is held accountable, ultimately to the Minister, through the governance system and/or contractual arrangements with the regulator. The scheme is inclusive, open and transparent. There are proposals for further refinement to the scheme as part of the harmonisation process for the regulation of therapeutic products in Australia and New Zealand, but its fundamentals are sound.

The outcomes of the scheme mean that advertisements destined for 'mainstream' media and therefore broad community coverage are required to be pre-approved. Complaints about such advertising are resolved through a centralised, co-regulatory complaints resolution panel which has certain enforcement powers which are backed up by the TGA's regulatory enforcement powers. Advertisements in media with less community penetration (non-mainstream media) are not required to be pre-approved and complaints are dealt with through self-regulatory bodies, however, non-compliance is also subject to regulatory enforcement should self-regulation require further support. The TGACC oversees the working of this scheme and reports to the Minister on any aspects that require review, as well as making recommendations on the Therapeutic Goods Advertising Code, thereby helping to determine regulatory policy for advertising.

The result of this scheme is that the enforcement agency (which in this case is also the regulator) is the player of 'last resort' in the enforcement/compliance scheme, with most of the complaints about advertising of therapeutic goods being resolved through the co-regulatory processes.

Such a co-regulatory approach must be considered in relation to ensuring compliance of food health claims. Without such a scheme there can be no assurance of timeliness, consistency or ultimate effectiveness of enforcement by the jurisdictions of non-compliance with the standard. This situation then brings into question within the community the public health and safety of consumers, credibility of food labelling and more broadly, the food industry, and the capacity of enforcement agencies.

The TGA would willingly enter into discussion with FSANZ and its stakeholders as part of P293 as to whether it may be possible to extend the therapeutic goods co-regulatory scheme to accommodate food advertising as well as that of therapeutic goods, or whether the TGA could assist in establishing a separate but similar co-regulatory scheme for foods.

Such a scheme, assuming it were to be limited to food advertising, still calls into question the enforcement capacity of the jurisdictions for food labelling transgressions. However, it is advertising that tends to have the greater reach into the community and therefore deserves special regulatory attention in the interests of the broader community.

3. Sale versus supply

P293 and the draft standard appear to relate only to foods that are *sold*. The therapeutic goods legislation regulates, in general, the *supply* of products. There would appear to be a risk that draft standard 1.2.7 would allow unregulated health claims on foods that were supplied, but not for valuable consideration eg donations to people with special needs, who could easily be targeted and influenced by unregulated claims.

In this context, supply is taken to mean by way of sale, exchange, gift or by way of sample or advertisement.

In conclusion

As stated at the outset of this submission, most of our comments have been made at the regulatory policy level. The TGA remains most willing to continue discussions with FSANZ as to the finer levels of detail that may help in the final clarification of the regulation of nutrition, health and related claims and help ensure a clear, open and transparent food-medicine interface.

For further discussion please contact:

[redacted]
Joint Agency Establishment Group
Therapeutic Goods Administration

Telephone: 02 6232 8474