The challenge for the dairy industry arising from the new Health Claims Standard: an impetus for innovation

Introduction

In December 2003, the Australia New Zealand Food Regulation Ministerial Council issued policy guidelines for Food Standards Australia New Zealand (FSANZ) to develop a health claims standard. The principles in these policy guidelines included a requirement that the new Standard “enable the responsible use of scientifically valid nutrient, health and related claims” and “support government, community and industry initiatives that promote healthy food choices by the population” (Australia New Zealand Food Regulation Ministerial Council 2003).


This paper looks at the likely impact of this standard specifically in relation to dairy products being sold in Australia.

The current position on ‘health claims’

A study in August and September 2003 of the prevalence of nutrition and health claims on Australian food products found that 8.1% of products surveyed carried “some type of health or related claim” (Williams et al. 2006). In this study, “health or related claim” was defined as “a claim other than a therapeutic claim, that describes or indicates the relationship between the consumption of a food, a category of food or one of its constituents and health” which is a slightly broader definition than that proposed under the Preliminary Final Assessment Report (PFAR) of Proposal P293 and is narrower than, but more closely resembles, the prohibitions currently set out in Transitional Standard 1.1A.2.

In the case of the 353 yogurt products surveyed, 29.7% carried health-related claims, with a total of 286 claims or an average of 2.7 claims per product. Of these 286 health claims, 124 promoted yoghurt for general health maintenance and 118 made ‘specific health function’ claims; six other types of health-oriented claims were also recorded in lesser numbers. While a total of 65 general or specific health claims were made (Williams et al. 2006).

Before gazettal of a final version of the new Health Claims Standard, the Australian legal position in relation to health claims has been that food labels or advertisements must not contain:

i) a claim or statement that the food is a slimming food or has intrinsic weight-reducing properties of a food; 
ii) a claim relating to ‘therapeutic or prophylactic action’ of a food ‘or a claim described by words of similar import’;

iii) the word “health” or any word or words of similar import as a part of or in conjunction with the name of the food; 
iv) any “word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature”; or 
v) the name of or a reference to any disease or physiological condition. (FSANZ, Standard 1.1A.2 April 2007)

The 8.1% of food products currently carrying health claims could be said to have been making these claims illegally. In fact, the vendors of some such products have been prosecuted, e.g. A2 Dairy Marketers was fined $15,000 in that case. Under the April 2007 draft of the new Standard, a ‘health claim’ is defined as:

- a claim that directly or indirectly refers to a relationship between:
  - (a) food; or 
  - (b) a property of the food; and 
  - a health effect, but does not include an endorsement, dietary information or a cause-related marketing statement.

The publication of a Preliminary Final Assessment Report on 4 April 2007 heralded another step towards the introduction of a new Health Claims Standard to be inserted into the Australia New Zealand Food Standards Code. This Health Claims Standard, once approved by the Board of Food Standards Australia New Zealand and by the Australia New Zealand Food Regulation Ministerial Council, will permit the making of certain substantiated health claims. Prior to the introduction of the new Standard, health claims have not been permitted on food labels, with the exception of claims in relation to maternal folate consumption and its positive effect in reducing the risk of foetal neural tube defects. The new Health Claims Standard as outlined in the Preliminary Final Assessment Report is likely to have a significant impact on the dairy industry. This paper seeks to analyse that impact, including threats, opportunities and challenges that the Standard poses to the dairy industry and other food suppliers.
where ‘health effect’ means –
(a) a measure of the impact of a substance on the healthy functioning of the human body; or
(b) a measure of the impact on the health or performance of a specific population, where the impact is associated with a particular dietary intake;
and for the purposes of this definition, ‘impact’ includes maintenance (Food Standards Australia New Zealand 2007).

The separate exclusions expressed by this definition for endorsements, dietary information and cause-related marketing statements present avenues for some alternative marketing opportunities that would be available for dairy marketers, as mentioned later in this paper.

The April 2007 draft of the new Standard sets new requirements for the making of a ‘general level health claim’ and a ‘high level health claim’ (FSANZ 2007).

A ‘general level health claim’ is defined as ‘a health claim that does not, directly or indirectly, refer to a serious disease or a biomarker’. An example of a ‘general level health claim’ may be the claim that B group vitamins are important for energy production. Other requirements for the making of general level health claims will be discussed later in this paper.

A ‘high level health claim’ is defined as ‘a health claim that directly or indirectly refers to a serious disease or a biomarker’. An example of a ‘high level health claim’ is a claim on a high calcium food that calcium and vitamin D reduces the risk of osteoporosis and enhances bone density.

How health claims can be made under the proposal

Eligibility criteria for high level health claims

The April 2007 draft of the new Standard explicitly recognises a number of positive or negative diet-disease relationships which may be the subject of high-level health claims:
• calcium, vitamin D and osteoporosis;
• calcium and enhanced bone density;
• folic acid and neural tube defect;
• saturated fatty acids and LDL cholesterol;
• saturated and trans fatty acids and LDL cholesterol;
• sodium and blood pressure; and
• vegetables and fruit and coronary heart disease.

Potentially, some of these high-level health claims could relate to dairy products, and various dairy products such as soft cheeses might be excluded by the eligibility criteria for the making of a positive health claim as explained below.

In order to make such high level health claims, the food product must contain a sufficient amount of the claimed property and also meet the scoring criteria as outlined below.

Eligibility criteria for general level health claims

General level health claims can be made as long as a nutrition content claim can be made in relation to the property of the food being claimed under the health claim (FSANZ 2007), the supplier has records that substantiate the claim and the requirements of the scoring criteria formula are met. FSANZ released, as Attachment 8 to the Draft Assessment Report for Proposal P293, a document outlining the substantiation requirements for nutrition, health and related claims. The document provides an indication of the level of substantiation that will be required by FSANZ once any health claims Standard is passed.

It is also worth noting that unlike health claims, the eligibility criteria for nutrition content claims are generally threshold requirements that can be met if a sufficient quantity of the claimed nutrient is present. Foods do not need to satisfy the new scoring criteria in order to be eligible to make a nutrition content claim.

The April 2007 draft of the new Standard does not attempt to circumscribe limits on the subject of a general level health claim except that the claim must not relate to a ‘serious disease or a biomarker’ as indicated within the actual definition of a ‘general level health claim’.

The scoring criteria

As mentioned above, the scoring criteria are included in the April 2007 draft of the new Standard and present a core of threshold requirements for the making of health claims.

Under the scoring criteria formula, foods are given ‘baseline points’ based on the amount of energy, saturated fat, sugar and sodium in the product.

For all foods other than cheese and processed cheese, butter, edible oils, edible oil spreads and margarine, points are then taken off for fruit, vegetable, nut and legume content, protein content and fibre content. The reference among these foods to some dairy product types will present the dairy industry with a challenge to convey the ‘good health’ message for these food product types. Several alternative solutions are posited later in this paper.

A health claim is allowed to be made if the final score remains below a certain threshold score. Three different threshold scores are used for different types of foods.

While a Standard that permits the making of health claims may help the food industry promote a good health message for many products, the threshold requirement of the scoring criteria needs to be overcome in order for health claims to be made in relation to some dairy products.

Likely impact of the proposal on dairy

Opportunities

As mentioned above, numerous high level claims can be made in relation to dairy products. As long as the dairy product can meet the threshold requirements under the scoring criteria, then a health claim can be made.

The commercial benefits of including a health claim on a label have been illustrated by overseas studies into the impact of health claims and found that solid positive scientific evidence about a product can result in significant sales growth (Marquart 2001). Examples given from the United States include the 37% sales growth in a single year following the purported health claim by Kellogg that fibre in its All-Bran product ‘may reduce your risk of some kinds of cancers’ (Marquart 2001) and the 5% sales growth for Cheerios breakfast cereal after publicised findings of a clinical study suggested that three ounces of the wholegrain cereal reduced total cholesterol by 3.8% and LDL cholesterol by 4.2% (Marquart 2001). In the Kellogg example, the US Food and Drug Administration acted to force Kellogg to withdraw the products from sale.

On the other hand, a study commissioned by FSANZ evaluating the outcomes of the folate-neural tube defects health claims trial suggested that the folate health claims had made no significant impact in Australia on sales of products carrying the claims...
Health and Medical Research Council’s Panel Calculator April 2007), most cheeses cannot carry a health claim as outlined.

However, a significant point of difference between the folate claims in Australia and the wholegrain or fibre claims used in the United States would have been the fact that the potential health benefits of folate would have related only to a small proportion of the population, namely pregnant women, whereas the perceived health benefits claimed for wholegrain or fibre would have been more generic and thus likely to have had influence on a broader cross-section of the wider population. Furthermore, a study by Kellogg on the impact of its folate claim in Australia found that while sales of products carrying folate claims fell by 4.6% in one year, “the total volume of all Kellogg cereals sales increased 1.9%” (Williams et al. 2001). The study notes “it is possible that the campaign [with the positive health claim for folate in some of its products] had a positive effect overall in maintaining continued growth of Kellogg’s market share”.

There is sufficient evidence to suggest that health claims can have a positive effect on the sales of a product and the April 2007 draft of the new Standard under Proposal P293 does justify the dairy industry, and other sectors of the Australian food industry, exploring the opportunities for promoting food products by reference the claim of a good health outcome from which consumers can derive benefit.

**Challenges**

While the introduction of laws to permit health claims as proposed under Proposal P293 presents opportunities for the dairy industry, it may also create challenges for the marketing of certain dairy products for which such claims may not be permitted as outlined.

Studies around the world, in Canada, Scandinavia, the United Kingdom and the United States, have found that about 50% of consumers rate health claims as useful and that only 10% of consumers see ‘little or no value for health claims’ (Williams 2006). This suggests that at least 50% of consumers would believe that a product carrying a health claim is healthier than one that does not carry a health claim. Given the consistency of the results of such studies in four different areas around the world, it is likely that a similar proportion of consumers in Australia would also appreciate the value of health claims. This presents a challenge to dairy companies whose products would not meet the eligibility requirements for making a health claim.

Some dairy products such as cheese and butter are naturally high in nutrients which would increase the baseline points in the scoring criteria to the level of disqualifying the product from being eligible for a health claim to be made. For example, using the values for energy, saturated fat, sugar and sodium provided by the FSANZ Nutrition Panel Calculator (FSANZ Nutrition Panel Calculator April 2007), most cheeses cannot carry a health claim because of their inherently high energy, high saturated fat and high sodium content. This is despite the fact that the National Health and Medical Research Council’s Dietary Guidelines for Australian Adults recommend that adult diets “include milks, yoghurts, cheeses” (NHMRC 2003).

For such dairy products to be eligible legally to carry a health claim, aspects of the nutrient profile of the product may need to be modified. If this course is to be taken, one effect of the new Health Claims Standard could be a resultant increase in innovation and marketing towards producing a healthier product to the point that it needs in order to qualify for eligibility for the making of a health claim.

**Promoting innovation**

As mentioned above, the challenge will be to make some dairy products eligible for the making of health claims by overcoming the inherently high energy, saturated fat and salt content which precludes such products having health claims under the proposed scoring criteria, irrespective of the existence of valuable nutrients such as calcium and vitamins.

The April 2007 draft of the new Standard clearly encourages low energy, low saturated fat and low sodium products. For dairy products other than cheese and butter, it also promotes the addition of fibre and protein because points are given towards enhancing the eligibility for a potential health claim if the fibre and/or protein content of the product can be increased.

An example of the direction of future innovations that could benefit under the new Health Claims eligibility regime is the recent introduction by Parmalat of its REV Healthplus+ Fibre product (Parmalat Products and Recipes cited April 2007). While the REV product without the added fibre may already have satisfied the scoring criteria for making health claims, the concept of adding fibre to improve health claims eligibility could be adopted for a wider range of other dairy products, such as ice cream, which might not ordinarily meet the scoring criteria.

**Overcoming legal limitations on innovation**

**Compositional issues**

While the April 2007 draft of the new Health Claims Standard encourages innovation and alteration of natural properties of food to improve the health benefits of the food, there would be several compositional limitations on how far innovation might currently go.

For the time being, under the Australia New Zealand Food Standards Code (ANZFSC), there are prescriptive compositional requirements for milk (Standard 2.5.1), cream (Standard 2.5.2), fermented milk products (such as yogurt) (Standard 2.5.3), cheese (Standard 2.5.4) butter (Standard 2.5.5), ice-cream (Standard 2.5.6) and dried milks, evaporated milks and condensed milks (Standard 2.5.7).

Although there is currently a compositional requirement that ice-cream contain no less than 100 g/kg of milk fat (Standard 2.5.6), it is clear that there are ice-cream products on the market that claim to be ‘98% fat free’ which means that the ‘ice-cream’ products have a fat content of less than 10% fat. Clearly, a review of some or all of the prescriptive definitions for dairy products ought to be undertaken by FSANZ to consider a revision of the prescribed compositional requirements set by these definitions in the Code. This would necessitate variation of the Code (Commonwealth Government of Australia 1991). In its assessments of proposed variations to the Code, FSANZ regularly expresses its preference for less prescriptive food standards (Food Standards Australia New Zealand 2007).

New procedures accompanying the introduction of the Food Standards Australia New Zealand Bill 2007 may assist the process by which Food Standards can be varied either on the application of the dairy industry as a whole or by an individual company acting with the support of the industry. The new processes aim to streamline the process of varying food standards by relying on a system of self-assessment by the applicant and speeding up the process by reducing the number of required public consultation rounds (Lederman and Gao 2007).

**Mixed foods**

Another innovative approach might involve the development of new mixed food products that can meet the eligibility criteria for the carrying of a health claim, even if such products do not necessarily meet the definition of the food type they more resemble. It is unlikely that any such products would be considered as a non-traditional ‘novel food’ (FSANZ, Standard 1.5.1). However, the addition of synthetic processing aids or additives not expressly permitted under the Food Standards Code in relation to the particular product would still require FSANZ approval (Standard 1.3.1).

**The dangers of comparative advertising**

One of the legal dangers inherent in promoting one’s product as being superior over a comparable product is the risk that the claim may be misleading. The seller of any product for which an exclusive health benefit is being claimed runs the legal risk of potential civil action by a competitor if the health benefit is in fact generic to the food product type or category rather than being as exclusive as claimed. For example, a health claim for a particular new form of milk product might be considered denigrating, in a misleadingly unfair or deceptive way, of a comparable product that does not carry the claim but has the same qualities.

The Australian Competition and Consumer Commission (ACCC) is empowered by the Federal Government to enforce the provisions of the Trade Practices Act 1974 including sections 52 and 53 dealing with ‘misleading and deceptive conduct’ and ‘false and misleading representation’. In August 2006, the ACCC issued guidelines for comparative advertising between competing products and the precautions that one might need to take to avoid legal action under these sections (ACCC 2006). In some such situations, a solution to consider might involve an appropriate usage of a new brand name or product descriptor or an innovative name to describe a new product type in order to avoid comparison with more conventional but comparable products.

Also bear in mind that Clause 4(b) of Standard 1.3.2 of the Australian Food Standards Code prohibits making claims and including a comparison of the vitamin or mineral content of a food with that of any other food unless the comparison has been expressly permitted elsewhere in the Food Standards Code (FSANZ Standard 1.3.2).

**Alternative means to convey a ‘good health’ message**

As mentioned earlier, the definition of ‘health claim’ expressly excludes endorsements, dietary information and cause-related marketing statements. These exclusions have the potential to weaken the impact of the new Health Claims Standard as each offers a separate marketing opportunity that would circumvent the need to make a health claim in one’s marketing and yet potentially have the same effect.

Another avenue to achieve the same objective might involve use of a trade mark that conveys a positive health message without actually making a health claim. Section 109 of the Australian Constitution states that: “When a law of a State is inconsistent with a law of the Commonwealth, the latter shall prevail, and the former shall, to the extent of the inconsistency, be invalid.” Because the law giving rights to use a registered trade mark is Commonwealth law (Commonwealth Government 1995) while the laws enforcing the Australia New Zealand Food Standards Code are State and Territory laws, the Code cannot invalidate the use of a registered trade mark.

A search of the Australian Trade Mark register using the Australian Trade Marks Online Search System (‘ATMOSS’) reveals that at present, there are 284 Trade Marks already registered in Australia in the Food and Beverages classes that contain the words ‘health’ or ‘healthy’ or ‘healthier’. Search was conducted using ‘health’ as a ‘part word’ in class 29 which covers ‘Meat, fish, poultry and game; meat extracts; preserved, dried and cooked fruits and vegetables; jellies, jams, fruit sauces; eggs, milk and milk products; edible oils and fats’.

Apart from these 284 trade marks, there are many other words which also may carry a health or nutrition claim or implication and which might also have succeeded to become registered as trade marks.

**‘Medicinalising’ dairy products**

Dairy companies need to remain alert to the existence of some remaining legal risk associated even with an approved health claim. For example, if a substance added to a product has health benefits but also potential side-effects for a small section of the population, then while a health claim may be made, it may also need to be accompanied by an advisory statement, which can mitigate any legal risk. The Australia New Zealand Food Standards Code sometimes recognises this aspect of legal risk by mandating an advisory statement. For example, Standard 1.2.3 requires mandatory advisory statements including one for food containing phytosterol that states that the product may not be suitable for children under five and pregnant or lactating women. This is notwithstanding that phytosterols can be added

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2. See e.g. Food Standards Australia New Zealand, *Preliminary Final Assessment Report, Proposal P293 – Nutrition, Health and Related Claims*, Canberra, April 2007, pp. 51, 58, and 83. On these pages in the report, options which were described as ‘less prescriptive’ were preferred over ‘more prescriptive’ options.

3. A mixed food is a combination of more than one type of food in the one food product. Although the Australia New Zealand Food Standards Code does not offer a definition of a ‘mixed food’, it refers to ‘mixed food’ in the context of permitted food additives, where a mixed food may contain the additives which are permitted for use in the component foods. The former shall, to the extent of the inconsistency, be invalid.”

4. Under the April 2007 draft of the new Standard, nutrition content claims that relate to a property that is naturally present or absent in similar foods, must relate to the food and not the brand of food. Food Standards Australia New Zealand, *Preliminary Final Assessment Report, Proposal P293 – Nutrition, Health and Related Claims*, Canberra, April 2007, Appendix 1 – Standard 1.2.7, clause 5(d).
to low-fat milks and low-fat yogurts (ANZFSC Standard 2.5.1) as they have a positive health benefit.

**Biotechnology and health claims**

Biotechnology creates opportunities for the development of functional foods as well as food additives and processing aids. There might be a dangerous temptation for some food producers to justify their new technological developments with reference to perceived health benefits. For example, the Australian Government’s Biotechnology Online website claims that GM technology can help modify the nutritional values of certain foods. It then gives the example of genetically modifying soy to contain ‘longer-chain unsaturated fatty acids’ to ‘lower the levels of low-density lipoproteins (LDL) and cholesterol in the blood, thereby reducing the risk of heart disease’ (Biotechnology Australia cited April 2007).

Although such particular claims might be permissible under the new Health Claims Standard, there may be a temptation for food companies to make similar claims in relation to technology-derived benefits that might not be permitted under the new Health Claims Standard. It might therefore be legally safer for food marketers who wish to demonstrate the benefits of such biotechnological developments to promote the improvements in the characteristics of the product (such as taste, texture, mouth-feel, thermal stability, longer shelf-life), rather than over-promoting the health effects of the product.

**Conclusion**

The April 2007 draft of the new Standard for Health Claims presents opportunities for those in the dairy industry to promote the health benefit of their products. Studies around the world have shown that health claims have a positive effect in promoting the sales of food products.

Some dairy products may face challenges in making health claims due to inherent nutritional properties of some dairy products being high in energy, saturated fat and sodium. It is likely that the new Standard will encourage innovation and the development of new products and ingredients to make products healthier in order to meet the scoring criteria under the new Health Claims Standard. There are ways by which the legal barriers might be shifted to make health claims permissible even if this involves seeking further variation to the Food Standards Code. In any case, care must be taken to ensure that any claim will not give cause for a legal action for misleading or deceptive practices by which dairy product businesses can convey a ‘good health’ related message even in the absence of a Health Claim as defined under the new Standard.

**References**

- National Health and Medical Research Council (2003), Dietary Guidelines for Australian Adults. Canberra, p xii.