Fonterra Submission

P293 Nutrition, Health and Related Claims

March 2012

Fonterra is a leading global dairy nutrition business, owned by 10,500 New Zealand farmer shareholders. Responsible for more than one-third of international dairy trade, Fonterra is the world's leading exporter of dairy products and is the preferred supplier of dairy ingredients to many of the world's leading food companies.

Fonterra is New Zealand's (NZ) largest company involved in large-scale milk procurement, processing and management, with a supply chain spanning more than 140 countries. The company has NZ$14.1 billion in total assets and revenues of NZ$16 billion, employing more than 16,000 people worldwide.

The company's Australian operations, which is based in Melbourne, has 10 manufacturing sites, employs around 1,500 people and collects 1.8 billion litres of milk annually from some 1,400 farmer suppliers. The majority of the milk Fonterra processes goes into manufacturing bulk dairy ingredients, such as milk powders, cheese and a range of dairy-based fats and proteins, which are sold to domestic and international customers.

Fonterra is also a market leader in the consumer dairy market, with a portfolio of iconic cheese, butter and yoghurt brands including Bega, Mainland, Perfect Italiano, Western Star and Nestle Ski. Fonterra also operates a dedicated sales channel for the foodservice industry which includes restaurants, cafes and hotels.

Dairy innovation is a key to every part of the Fonterra business. Through its state-of-the-art research facilities in Palmerston North, New Zealand and Melbourne, Australia, and its global network of research and development facilities, Fonterra is a leader in dairy science and innovation. Fonterra products are synonymous with innovation in bone health, maternal health, child nutrition and dairy goodness. Fonterra products and ingredients are found in many types of manufactured food products, pharmaceuticals, food service outlets including bakeries, restaurants and hotels, and homes across Australia, New Zealand and around the world.

Introduction

The Fonterra Cooperative Group Pty Ltd (Fonterra) welcomes the opportunity to provide comment on the draft nutrition, health and related claims Standard 1.2.7.

Fonterra understands that this FSANZ consultation will not revisit issues previously considered as part of P293 nor is it seeking any further comment on issues raised in the Review Request.

The consultation specifically seeks comments on the structure and regulatory clarity of the draft Standard 1.2.7 as provided which includes:

1) Pre-approval of food health relationships underpinning both general & high level claims and the ability to add claims through FSANZ periodically translating appropriate food & health relationships that are the basis for health claims permitted in the EU & via confidential applications

2) Removal of proposed provisions for the related claims relating to dietary information & cause related marketing as these can be addressed through consumer law

3) Proposed options for the management of fat free & %fat free nutrient content claims in the context of claims potentially misleading consumers, including inviting evidence that consumers are being mislead are also covered

Fonterra Comments

Submitter name: Fonterra	
1. Does the revised drafting accurately capture the regulatory intent as provided in Attachment B? Please consider the clarity of drafting, any enforceability issues and the level of 'user-friendliness'. If not, please provide specific details in the table below. Ensure that the relevant clause number, schedule number or consequential variation item number that you are commenting on is clearly identified in the left column. Lines may be added if necessary.	
Clause number	**Comment**
Part 2 – Claims framework and general principles 3 Nutrition content claims or health claims not to be made about certain foods (c) an infant formula products	Fonterra fully supports the promotion of strategies to increase the rate of breast feeding. However in recognition that there are circumstances when an infant is not or cannot be breastfed or is partially breastfed, where commercial infant formulas are used, consideration must be given to supporting ongoing innovation in the development of infant formula nutritional and functional profiles. To exclude the ability to state nutritional contents of infant formula will discourage innovation in these products and subsequently restrict the potential for improved health outcomes for infants where breast milk is not available or only partially available. Fonterra supports evidence based regulation. However in this instance there does not seem to be sufficient evidence to support the restriction of nutrition content claims on any product regulated under Standard 2.9 including infant formula. Products regulated under Standard 2.9 are developed to meet the specific needs of particular populations. The development process of these products involves significant research and innovation at a substantial expense to the company. If there is no ability to communicate outcomes of research and innovation benefits to the consumer the outcome of the research, ongoing innovation and research will be difficult to be justified on a cost benefit analysis basis. The result will be the restriction of improved health outcomes for the consumer. Although we understand that FSANZ cannot consider the ability to communicate product innovation to improve health/performance outcomes via nutrient related claims for products regulated under Standard 2.9.1 in relation to P293, there is an opportunity for FSANZ to consider this issue when they undertake the review of Standard 2.9.1.
2. Definition of endorsing body and endorsement.	Fonterra is of the opinion that further definitions relating to endorsing body and endorsement are required for clarity. While the definition of "endorsing body" may be understood, it's not clear what (in relation to clause 21) an endorsing body being "related to" a supplier or "free from influence" of a supplier means. Being "related to" an endorsing body includes having a "financial interest" in the endorser. What is a "financial interest"? Many not for profit organisations require businesses to enter into licensing arrangements where the business pays to use their trademarks on products (e.g. the Heart Foundation). Would these types of arrangements be considered to be "financial interest" in the endorser or would they fall outside it? Would having licensing or contractual arrangements in place with an "endorser" be seen as having "influence" on the endorser? There needs to be clarity around what is and isn't acceptable in relation to endorsers. We have to assume that organisations such as the Heart Foundation will continue to be able to license their trademarks to commercial organizations. Clarity is required around the meaning of "financial interest" and "having influence" in relation to an endorser.
16. New health claims deemed to be high level health claims	The intention of clause 16 is unclear and clarification is required as to whether the clause is intended to reflect the process under which new claims would be considered, or if it relates to the level of evidence industry is required to submit when FSANZ considers a new claim. We provide comments on both the issue of substantiation and process below:

LEVEL OF SUBSTANTIATION

Clause 16, as written, infers that consideration of new general level health claims may include the requirement to meet the level of substantiation required for a high level health claim. This issue requires further clarification as in the Ministerial Council policy principles it is our understanding that the level of substantiation is required is to align with the degree of promise.

We note that during the standards development process that high level health claims have had to meet a substantiation level of convincing before being accepted. Fonterra has concerns about this and the impacts that it would have on innovation and the advancement of the science in respect to human nutrition.
The policy principles endorsed by the Australian New Zealand Food Regulation Ministerial Council (ANZFRMC) for nutrition, health and related claims for food states that any intervention by government should "contain a process of substantiation which aligns levels of scientific evidence with the level of claims along the theoretical continuum of claims, and at minimum costs to the community"[1]. The requirement for new General Level Health Claims to meet a convincing level of substantiation would be contrary to these guidelines.

Fonterra is concerned about the effect that unreasonably high substantiation requirements will have on innovation and ultimately on the advancement of health via human nutrition. The ability to make a health and nutrition claim provides considerable incentive to industry to undertake research in the area of nutrition science. The requirement for a level of overly high levels of substantiation, beyond the degree of promise of the claim, will ultimately increase the risk of investing in research into nutrition and health relationships and eventually funding for new nutrition research may cease. The benefit that the general public currently gain from industry funded nutrition research will be compromised.

We are also concerned that the requirement may not, ultimately, be aligned with that of international requirements for consideration of nutrient/disease relationships or nutrient/physiological function relationships.

For several years the Codex Committee for Nutrition and Foods for Special Dietary Uses (CCNFSDU) has participated in a prolonged and difficult discussion on the use of probable versus convincing evidence in relation to nutrients and non- communicable disease risk. As yet there has been no consensus as to the appropriate level of evidence.

The Representative of the World Health Organisation at the 2010 meeting of CCNFSDU[2] stated that when comparing the categories of "convincing" and "probable", a major difference is that "probable" requires "evidence of biological plausibility" whereas "convincing" requires the presence of a "biological gradient" and "strong and plausible experimental evidence"; if "probable" evidence was excluded from the criteria, NRVs-NCD for sugars and dietary fibre could not be established because they had "probable", not "convincing" associations with non-communicable-diseases.

The difficulty in obtaining a level of convincing substantiation is illustrated by the concern voiced at CCNFSDU, and the fact that it would not be possible to establish NRVs-NCD for dietary fibre and sugars; despite considerable literature on the topics, significant enough to influence nutrition policy development globally.

Fonterra considers that advancement in nutrition knowledge, and potentially the innovation of new biologically active ingredients, will be obstructed by the proposed standard because of the unrealistic and unnecessary requirements related to communicating a health benefit. We are concerned the requirement of convincing evidence in order to make a new health claim (function or disease related) will ultimately be to the detriment of the advancement of health through food and nutrition.

PROCESS

Fonterra notes that a high level health claim variation is defined in the Food Standards Act. Although we do understand that the Act has provisions for confidentiality in order to

[1] http://www.health.gov.au/internet/main/publishing.nsf/Content/00E8A0712A1A5C3BCA2578A7007FBE77/$File/nutrition_guidelines.pdf

[2] CL2010/53 – NFSDU, November 2010

	ensure market advantage for paying applicants, it does not make it sufficiently clear as to what the process would be in relation to time, costs and who/how the claims would be considered. There is insufficient information available for industry to make a considered submission on the question of the process of new claims consideration. The requirement to make an application to have additional health claims approved under the new standard has the potential to impede and inhibit innovation and new product development. Often the product lifecycle can be short – the time cycle for development of new products, launch into the market and possible removal from market if unsuccessful, can be very short. Aside from the issues pertaining to levels of substantiation, manufacturers are less likely to undertake product innovation and fund research to meet the health demands of consumers if they cannot state the basic benefit to the consumer, without incurring considerable cost and delay to the product reaching the market. Fonterra notes that FSANZ are considering using the European Food Safety Authority (EFSA) process as an avenue for approving health claims. There are considerable issues and learning's from the EFSA consideration of health claims. Unless addressed, these learning's pose concerns for Fonterra in relation to the applicability of this system for the ANZ market. These are outlined in full in Appendix 1. In summary our concerns relate to: the confusion created by the lack of guidance to industry applicants before EFSA began assessing new claims; a shortage of resourcing which resulted in EFSA considering all claims, not just health claims as initially intended and ultimately requiring the same level of substantiation for both health and function claims; confusion over claims classification; and issues around consistency of enforcement relating the breath of the standard in marketing and education strategies. Export of foods provides considerable value to the domestic profits of both Australia and New Zealand. Although many importing countries have their own food standards, they look to Australia and New Zealand for information on best practice regulation. These importing countries may not look favourably on permitting a claim in their country that is not permitted in the exporting countries regulation. Overly tight regulation for new claims will have a significant impact on Fonterra's export business. **STOCK IN TRADE** Considering the lack of clarity in the requirements to apply for a claim that is not listed in the draft standard, Fonterra requests an extension of the stock in trade provision to allow for the application process for new claims to be refined and application for new claims to be made.
Schedule	Comments
Schedule 1. % Fat-free claims	Currently under the CoPoNC guidelines, fat-free claims are allowed for if the amount of the nutrient concerned is physiologically insignificant. We note that there is no consideration of this in the current draft standard. It may be technologically impossible to produce a product that is completely fat-free. However, it may be that the very small amounts of fat in the product are physiologically insignificant. These products provide a solution to public health demands and offer a virtually fat free alternative for those consumers who want it. Fonterra requests that FSANZ retain the ability to make fat free claims on products that contain physiologically insignificant amounts of fat.

Question 2	Comment
2. What evidence can you provide that shows consumers are purchasing foods of lower nutritional quality because they are being misled by fat-free or % fat-free claims?	Fonterra has no evidence to indicate consumers are purchasing foods of lower nutritional quality because they are misled by fat-free or % fat-free claims. Conversely we are concerned by antidotal evidence that suggests consumers are beginning to associate low fat claims with products that are high in sugar.
3. Do you support option 1 (status quo), option 2 (voluntary action through a code of practice), or option 3 (regulate with additional regulatory requirements for fat- free and % fat-free claims)? Please give your reasons.	Fonterra supports option 1 – The status quo – with the status quo defined as the current standards in CoPoNC in regards to % fat-free and fat-free claims. Fonterra supports the concept of truth in labeling and, despite the potential impact on the integrity of % fat- free and fat-free claims which are on many of our products, believe that industry are entitled make statements concerning their products so long as those statements are true.
4. Please comment on the possible options for additional regulatory requirements for fat-free and % fat-free claims (option 3) (refer section 8) as follows: a. Which option do you support and why? b. What is an appropriate sugar concentration threshold for options 3(b) and 3(d)? Where possible, provide information and evidence to support your suggested threshold value. c. Are there other suitable options for additional regulatory requirements for fat-free and % fat-free claims? Please describe.	Fonterra supports the status quo, that is, no further requirements for % fat-free and fat-free claims. A sugar restriction on a fat claim may have the unintended outcome of loss of low fat categories of foods resulting in the removal of the 'better for you' category. A sugar restriction could potentially result in consumers no longer having the choice of low fat yoghurts or low fat frozen dairy desserts (full fat being ice cream). This may result in lack of variety and choice of reduced fat and sugar offerings for consumers. For example, low fat, low sugar yoghurts may not be palatable and as a result will have lower consumer acceptance (without the use of artificial sweeteners). In addition, the sugar content of a food is shown on the NIP irrespective of a fat claim. Fonterra suggests that further efforts are made to educate consumers on how to interpret the NIP in order to ensure they are making an informed choice. FSANZ are investigating additional criteria based on the principle of informed choice by consumers and to ensure they are not being misled by fat-free claims. "FSANZ is primarily interested in the substitution of foods of higher nutritional quality with foods of lower nutritional quality which have fat-free claims. Substitution within a general food group (e.g. choosing a different confectionery product) is of lesser importance." In this context Fonterra take's the opportunity to point out that the need for consumers to have provisions to make informed choices is not limited to claims on the fat content of a food but that the same principle applied in relation to making the most appropriate infant formula choice. Fonterra's position is that food standards should be based on science and we challenge the evidence or proof of harm to infants from the inclusion of a content or substantiated health claim on pack. Further, Fonterra requests the consideration of commentary by Berthold Koletzko in the

	Annals of Nutrition and Metabolism where he discussed the issue of health claims and made the following comment "*Preventing communication of scientifically assured benefits of optimised products bears the risk that it may slow or even stop the significant quality improvements of foods for infants that has occurred over the last decades in numerous single steps, and which has led to large benefits for child health.*" Although Fonterra understands that FSANZ will not consider this issue in relation to P293, there is an opportunity for FSANZ to consider permissions for nutrition and health claims when they undertake the review of Standard 2.9.1. Trade impacts need to be considered if claims on infant formula products are prohibited when Standard 1.2.7 is gazetted. Stock in trade is one issue –there may be a difficulty in meeting the stock in trade provisions especially for low volume imported products. Marketers are required by the distributers and supermarkets to have 6 months of stock available. The lead-time required for the ordering and transit of these low volume specialty products is approximately 6 months. Industry would be appreciative if the stock in trade period was extended to 3 years.

Appendix 1

European Directive 1924/2006/EC

In December 2006 the European Directive 1924/2006/EC was published. This Directive which requires the positive approval of Food Health Claims (including a scientific assessment of supporting evidence by EFSA) has attracted much criticism from the European food industry. Many in the European Food industry believe that this Directive is limiting innovation. Major areas of dissatisfaction resulted from both the lack of guidance on the assessment criteria and review process of claim submissions. Fundamental issues such as the positive list of health claims and nutrient profiles are still unresolved 6 years after the regulation was published. It is our belief that the problems of and lessons to be learnt from the European experience are:

A. Variances in Interpretation and Enforcement

The EU Nutrition and Health Claims Regulation (NHCR) covers claims not only on product labels, but in all commercial communications (including publicity, advertising, websites etc) and it comes from the principle that all nutrition and health claims need pre-approval before they can be made. This scope, and whether or not it applies to communications to health care professionals, is being interpreted differently by each Member State causing confusion to business and eventually causing a barrier to the free movement of foods.

B. Lack of Clarity Prior to Adoption of the Directive

The principles included in the regulation are very complex and as a result, regulator deadlines have not been met leaving fundamental issues such as the positive list of health claims and nutrient profiles unresolved six years after the regulation was published. this situation has undermined the intent of the Directive. The process could have been much improved if satisfactory guidance material had been available prior to the adoption of the Directive

The EFSA, which is the EU's central scientific and risk assessment authority was asked to assess the scientific evidence supporting all claims. Essentially, the EFSA started reviewing dossiers before the guidance and interpretation was offered to industry. Every possible aspect from guidance on the format of dossiers, studies used to the actual scientific methodology that was used by EFSA were not communicated in advance to industry. EFSA's openness and willingness to communicate came about only after very strong criticism from the industry and media attention.

A good example for this is the probiotic claims; EFSA published guidance on requirements for characterisation after all of the submissions were submitted and subsequently rejected. The EFSA has given those claims a second opportunity for assessment and companies and MS which had submitted the claims were allowed to provide additional evidence for the characterisation. Also, the claims on botanicals have not been reviewed at all yet, for exactly the same reason. It is possible that other claims may also be given such a second chance but it is not clear at the moment.

C. EFSA were Under-Resourced to Deal with Submissions

Originally Article 13.5 and Art 14 health claims were to be assessed using different review criteria than Article 13.1 'general function' claims. The Commission was to assess Article 13.1, and EFSA the former claims. However The Commission asked EFSA for the review via the Terms of Reference and EFSA interpreted these requirements in a way as to bring them as close as possible to the process they had in mind for the article 13.5 and art 14 claims. As a result, all claims (however well-established) were reviewed the same way. EFSA should have had different substantiation requirements for different claim groups.

Above all the means of assessment should have been clearly thought out and published before the Directive was published.

D. Clarity around Scoping and Definitions

The Regulation lays down provisions for many different types of claims which are not all specifically defined (health claims vs. nutrition claim vs. function claim). Since each type of claim needs to be approved following a specific process, this lack of definitions is very confusing for the industry. A good illustration of this is the nutrition claim 'Contains[name of the nutrient or other substance]' when the nutrient of substance is expressed as 'probiotic' then the claim is no longer a nutrient claim but becomes a health claim, however such a claim is seen as factual information if the specific name of the microorganism is mentioned. This last element is still the subject of discussion amongst the EU Member States.