

**Proposal P293 Nutrition, Health and Related Claims  
Summary of submissions to the Draft Assessment Report**

**1. APPLICATION OF THE REGULATORY MODEL**

Submitter	Group	Comments
Winemakers' Federation of Australia	Industry - Australia	<ul style="list-style-type: none"> <li>• According to the definitions of labelling and advertising in the draft Standard, any form of additional information relating to the health and nutrition aspects of alcohol consumption would not be permissible, even if the information was generic to alcoholic beverages and not specific to a particular product, e.g., a beer, spirits or wine producer would not be able to include information on either the beneficial or harmful health and social effects of particular amounts and consumption patters on their website or even provide a link to websites such as those of the Department of Health and Aging (DoHA) and the National Health and Medical Research Council (NHMRC) or the Australian Wine Research Institute which was approved by DoHA.</li> <li>• Point of sale material such as brochures and drink coasters of the NHMRC's Australian Alcohol Guidelines – Alcohol and Your Health resources would not be permissible.</li> <li>• Such a restriction effectively prevents consumers from readily receiving balanced and appropriate additional information about alcohol and even from receiving reminders about how to consume alcohol responsibly.</li> <li>• Consumers should have access to generic health and nutrition information on alcohol and this information should be allowed to be provided by wine producers as long as it is not linked to the advertising or sales of a particular brand or category.</li> <li>• Are happy to provide further comments and information.</li> </ul>
Johnson & Johnson Pacific	Industry – Australia	<ul style="list-style-type: none"> <li>• Submission is concerned with finding a way of enabling manufacturers of food products to at least be able to provide technical information to health care professionals that might address requests for medical advice and answer common questions and concerns about health raised by consumers with their doctors/GPs.</li> <li>• The Model Food Act defines advertisement as; <i>'any words, whether written or spoken; or any pictorial representation or design; or any other representation by any means at all, used or apparently used to promote, directly or indirectly, the sale of food.'</i></li> <li>• This presents a technical difficulty with regard to providing health and safety information about particular foods and food additives (intense sweeteners in their case) to doctors and other health care professionals in response to common direct questions from consumers and special interest groups, particularly when an advertisement for food is not permitted..... <i>"to contain any word, statement, claim, express or implied, or design that directly or by implication could be interpreted as advice of a medical nature from any person."</i> [Standard 1.1A.2 Clause 3(c)]</li> </ul>

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Johnson & Johnson Pacific	Industry – Australia	<ul style="list-style-type: none"> <li>• Food manufacturers are often in the best position to access and provide technical information about health and safety required at a professional level, about their products.</li> <li>• With regard to intense sweeteners (or other food additives), it appears that it is not possible to prepare and distribute information to health care professionals (GPs, Dietitians) in a language they would understand, or advice they could pass on to their patients in answer to concerns and questions about the options available for special dietary requirements. Example questions - is the product suitable for my patients, Is the product safe, How is the product metabolised, does it effect blood insulin levels, does it interfere with blood glucose readings or urinary glucose tests, can the product be used by people with diabetes?</li> <li>• Therapeutic goods legislation recognises that consumers and health care professionals are separate and distinct groups of people (Therapeutic Foods Act 1989, Chapter 5, Part 5-1 Advertising and generic information, Section 42AA “This part does not apply to advertisements directed at health care professionals etc.”; Therapeutic Goods Regulations 1990, Part 2, Advertisements, “This Part applies to advertisements to which Part 5-1 of the Act applies.; Therapeutic Goods Advertising Code 2005, Section 3 Compliance with , and application of, the Code 1(b) “Advertisements for therapeutic goods directed exclusively to healthcare professionals are governed by industry codes of practice and are not subject to this Code”).</li> <li>• Health care professionals are well informed, capable of understanding complex information and have different needs than the patients they are responsible for. In consequence, the Therapeutic Goods Advertising Code applies only to advertising directed to consumers, and separate standards apply to advertising (including product information) prepared for distribution to health care professionals.</li> <li>• Given the objects of the Food Standards Code include the provision of safe and nutritious food and providing consumers with labelling and advertising that enables them to make informed and better choices about health and nutrition, it would seem to be remiss not to at least enable a process to make relevant medical information available to health care professionals by manufacturers rather than leaving them in isolation.</li> <li>• Health care professionals may be required to address consumer concerns about the misleading and confusing high level misinformation about food and health currently on the Internet.</li> <li>• Since therapeutic goods are excluded from food legislation and vice versa, provision of health and medical advice by manufacturers about food products to health care professionals cannot be made under therapeutic goods advertising rules and regulations.</li> <li>• It can only apparently only be done (if at all) under compliance with Australian and New Zealand food legislation, and the Food Standards Code. In this regard it would appear that health care professionals are likely to be better served with information about medicines than they are about food and health.</li> </ul>

Submitter	Group	Comments
Johnson & Johnson Pacific	Industry - Australia	<ul style="list-style-type: none"> <li>• A solution to this would be to revise Standard 1.2.7 to read; <ul style="list-style-type: none"> <li><b>“Purpose</b></li> <li><i>This Standard is designed to regulate nutrition content claims, health claims, endorsement and cause related marketing statements, whether appearing on food labels or in advertisements <b>directed to consumers</b>. It also consolidates a number ...”</i></li> </ul> </li> <li>• An additional clause might then be inserted in Standard 1.2.7 in the model of Section 42AA of the Therapeutic Goods Act* providing a scope of specific exempt professions and including; <ul style="list-style-type: none"> <li><i>“other types of activities, for example, government health promotional campaigns or public health materials published by community based organisations.”</i></li> </ul> referred to in paragraph two of Standard 1.2.7. <ul style="list-style-type: none"> <li>* <i>This Part does not apply to advertisements directed exclusively to</i> <ul style="list-style-type: none"> <li><i>a. medical practitioners, psychologists, dentists, veterinary surgeons, pharmacists, physiotherapists, Dietitians, scientists working in the medical laboratories or nurses; or</i></li> <li><i>b. persons who are:</i> <ul style="list-style-type: none"> <li><i>i. engaged in the business of wholesaling therapeutic goods; or</i></li> <li><i>ii. purchasing officers in hospitals; or</i></li> </ul> </li> <li><i>c. herbalists, homoeopathic practitioners, chiropractors, naturopaths, nutritionists, practitioners of traditional Chinese medicine, podiatrists or osteopaths registered under a law of a State or Territory.</i></li> </ul> </li> </ul> </li> <li>• They believe this would not adversely affect the objects in the Food Standards Code, would improve the level of knowledge currently available in the community and would not be out of step with accepted practices elsewhere in the world.</li> </ul>
Fonterra Co-Operative Group Limited supported by  Fonterra Brands Australia (P&B)	Industry – New Zealand  Industry - Australia	<ul style="list-style-type: none"> <li>• An exemption is required when providing scientific information and dietary information to health professionals. The food industry is an important source of information for health professionals on emerging nutrition related developments.</li> <li>• This is a time when poor dietary practice and resulting health problems are widespread so more people are looking to qualified experts for responsible and informed advice on ways to improve the nutritional profile of their diet. It is important that health professionals are educated on emerging science and trends, and that food companies are not limited from educating them.</li> </ul>
Queensland Health	Government – Australia	<ul style="list-style-type: none"> <li>• Advertising of foods is an important issue and efforts should be made to close any loopholes in distinguishing between implied claims and ‘puffery’. This is particularly important given the time required to enforce misleading advertising, which means an advertising campaign may be over by the time an advertisement is withdrawn.</li> </ul>

Submitter	Group	Comments
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>• There should be clarification in the user guide that these requirements are not intended to apply to information provided to health professionals or information that is provided to a manufacturer from a supplier, or in the context of providing information to the trade from a manufacturer.</li> <li>• It would be difficult for advertisements such as on television, to include all the information required for health claims in a meaningful and understandable way. It could be provided as a voice-over or superimposed but would have to be read quite quickly and therefore not as clearly understood.</li> </ul>
National Foods Ltd	Industry, Australia	<ul style="list-style-type: none"> <li>• Where is the evidence for regulatory market failure, and consumer misperception transcending to a negative impact on public health and dietary intake? Where is the evidence the proposed amendments by FSANZ will result in tangible outcomes whereby the benefits outweigh the costs?</li> </ul>
Therapeutic Goods Advertising Code Council	Therapeutic – Australia & Trans Tasman	<ul style="list-style-type: none"> <li>• Primary concerns relate to the promotion of health claims in advertising of food products, including: <ul style="list-style-type: none"> <li>– Maintenance of the integrity between foods and therapeutic goods regulations and enabling clear and accurate information to consumers about products on either side of the interface.</li> <li>– The regulatory framework for food health claims should be as robust as that applicable to similar claims made by medicines, to ensure an equitable market place.</li> </ul> </li> </ul>
Dietitians Association of Australia (DAA)	Public Health - Australia	<ul style="list-style-type: none"> <li>• Believes that certain health professional organisations that are recognised internationally for their expertise in food and nutrition should be included in the list of organisations to which the standard does not apply such as the Dietitians Association of Australia, the New Zealand Dietitians Association (NZDA) and the Nutrition Society of Australia.</li> <li>• Proposes the following amendment: <i>“It does not apply the requirements of the Code to other types of activities, for example, government health promotional campaigns or public health materials published by community based organisations or appropriate health professional associations that are recognised experts in food and nutrition.”</i></li> <li>• Seeking confirmation that; nutrition education materials and campaigns under DAA’s endorsement policy be exempt from the Standard; DAA’s nutrition communication for health professionals or consumers which are supported by branded products are not classified as advertising; and that DAA can provide health professionals with detailed nutrition education materials including product information.</li> <li>• Seeks clarification on the impact of the proposed Standard on information that food companies currently provide to health professionals.</li> </ul>
Lion Nathan LTD (LNL)	Industry- Australia	<ul style="list-style-type: none"> <li>• Supports provision of consumer information for alcohol products that may include a description of what is analytically present in the beverage, and, present in a non-branded context information on the scientifically accepted health effects of alcohol consumption in related booklets and websites.</li> <li>• Seeks clarity around the application of the Standard to company and industry websites which are designed to promote moderation and responsible consumption.</li> </ul>

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Lion Nathan LTD (LNL)	Industry-Australia	<ul style="list-style-type: none"> <li>• From one perspective, it seems that a ‘technical’ application of the Standard would allow for factual medical information to be included on an Industry website which aimed to achieve “moderation”. From another, the application of the Standard to such a website containing (for example) scientific papers discussing the health effects of alcoholic beverage consumption is making a prohibited ‘health claim about a category’ of food (alcoholic beverages are banned by the Standard from making health claims).</li> <li>• Submits that the Standard be clarified to ensure that non branded, editorial, booklets and websites can confidently continue to make factual comments around moderation and the “health” effects of alcohol consumption, either good or bad.</li> <li>• Category-specific health claims should be allowed to continue as they inform consumers about food choices.</li> <li>• Commends the submission from the Beer Wine &amp; Spirits Council of New Zealand on the need for FSANZ to acknowledge the strong evidence suggesting moderate alcohol consumption can result in some positive health effects. Under the proposed requirements these benefits cannot be communicated to consumers and it is questionable whether these arrangements maximise consumer awareness.</li> <li>• LNL have specifically launched BeDrinkAware.com.au and wishes to enhance this site in the future by providing linkages to further medical research.</li> </ul>
Meat and Livestock Australia	Industry - Australia	<ul style="list-style-type: none"> <li>• Advertising</li> <li>• Agrees that the recommendations made by FSANZ should apply to labelling as well as the advertising of foods.</li> </ul>
Therapeutic Goods Administration	Therapeutic – Australia & Trans Tasman	<ul style="list-style-type: none"> <li>• Proposal P293 and the draft Standard appear to relate only to foods that are sold. Therapeutic goods legislation regulates, in general, the supply of products. In this context, supply is taken to mean by way of sale, exchange, gift or by way of sample or advertisement.</li> <li>• There appears to be a risk that the Standard would allow unregulated health claims on foods that were supplied but not for valuable consideration e.g. donations to people with special needs who could easily be targeted and influenced by unregulated claims.</li> </ul>

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**2. INELIGIBLE FOODS (FOODS PROHIBITED FROM MAKING CLAIMS)**

<b>Submitter</b>	<b>Group</b>	<b>Comments</b>
Winemakers' Federation of Australia	Industry - Australia	<ul style="list-style-type: none"> <li>• Agree in principle that the label on the container of an alcoholic beverage is not an appropriate place to include high level claims and that nutrition content claims are restricted for alcoholic beverages, however at least nine countries mandate that health warning statements must appear on the label of an alcoholic beverage (US example "<i>Government warning:</i> (1) <i>According to the Surgeon-General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defect.</i> (2) <i>Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.</i>").</li> <li>• Although not advocating that health warning statements be adopted in Australia for alcoholic beverages, consider that the draft standard should contain a provision that statements that warn of potential health problems associated with certain patterns of alcohol consumption be permissible if considered appropriate by FSANZ and the alcoholic beverage industry.</li> <li>• Are happy to provide further comments and information – contact names and numbers provided in submission.</li> </ul>
John Birkbeck (Massey University)	Academic – New Zealand	<ul style="list-style-type: none"> <li>• Although not the place to debate 2.9.1, nutrient content claims should definitely be permitted where these are valid and show a differentiation from other similar products.</li> <li>• The idea that these would detract from breast feeding is fatuous.</li> <li>• As he has said before many times, better support of breast feeding women would do vastly more to enhance the rates of breast feeding than pettifogging regulations.</li> </ul>
New Zealand Food Safety Authority (NZFSA)	Government – New Zealand	<ul style="list-style-type: none"> <li>• Supports the proposal to exclude alcoholic beverages and infant formula products from making health claims.</li> <li>• Recommend that kava, as regulated under Standard 2.6.3 also be excluded from making health claims, as the rationale for excluding alcoholic beverages (social issues regarding abuse) is equally applicable to kava.</li> </ul>
Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<p><b>Introduction</b></p> <ul style="list-style-type: none"> <li>• Note the rationale that FSANZ states for health claims: “the current regulatory arrangements limit the opportunities for product development and placement while also limiting the benefits that might be achieved for consumers” (page 15 of the Draft Assessment Report).</li> <li>• Agree with this and support the use of appropriately substantiated nutrition and health claims that protect and promote consumer health as well as encourage fair trade.</li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>• Note that Standard 1.2.7 proposed to prohibit infant and follow-on formulas from making general level and high level health claims.</li> <li>• Promotion and protection of breastfeeding is of paramount importance, however most mothers (at least 80%) decide whether not to breastfeed either prior to or very early in pregnancy (Arora S et al. Major Factors influencing breastfeeding rates: Mother’s perception of father’s attitude and milk supply. Pediatrics 2000; 106:e67. Shaker I et al. Infant feeding attitudes of expectant parents: breastfeeding and formula feeding. J Advanced Nurs. 2004; 45:260-268.) This is long before reading labels on formulas.</li> <li>• For those who are unable to or choose not to breastfeed, formula feeding is the only suitable alternative.</li> <li>• In Australia more than 80% of infants are fed formula by 12 months of age (Australia Bureau of Statistics, National Health Survey, 2001), a figure that makes the inclusion of nutrition and health claims imperative and a prohibition of them inconsistent with the objectives of FSANZ and Standard 1.2.7.</li> </ul> <p><b>Recommendation</b></p> <ul style="list-style-type: none"> <li>• Request that infant formula and alcohol not be paired together in the Standard due to the implied negative health implication.</li> <li>• Believe that the inclusion of general level claims on both infant and follow-on formula will meet the objection of Standard 1.2.7 and FSANZ as well as the interests of consumers and industry, and requests that this be permitted.</li> <li>• At the very least, restrictions on nutrition and health claims should not apply to follow-on formula.</li> <li>• Claims would be restricted to non-mandatory ingredients that are permitted to be added to infant and follow-on formulas by the Food Standards Code, with the one exception of iron, which should be declared on follow-on formulas due to the prevalence of iron deficiency in Australian and New Zealand children.</li> <li>• The inclusion of an iron claim on follow-on formulas would also allow them to effectively compete with baby foods that are allowed to make similar claims.</li> <li>• The following outlines how the inclusion of nutrition and health claims on infant and follow-on formulas meets the objectives of Standard 1.2.7 and FSANZ, and how the proposal to ban these statements contravenes them.</li> </ul> <p><b>FSANZ objectives – objective 1 – protection of public health and safety</b></p> <ul style="list-style-type: none"> <li>• Claims promote appropriate selection and use of infant and follow-on formulas. <ul style="list-style-type: none"> <li>– claims are an important source of nutrition information and education;</li> <li>– providing factual, science-based nutrition information on labels maximises health of formula-fed infants by differentiating the composition of infant/follow-on formulas so that consumers can select the most appropriate formula;</li> <li>– manufacturers rely on labelling statements to communicate recent science based changes in formula composition;</li> <li>– the relationship between knowledge and ability to select appropriate foods is highlighted in a WHO/UNICEF position statement, which reads, “Inadequate knowledge about appropriate foods and feeding practices is often a greater determinant of malnutrition than lack of food.” (WHO, Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization, 2003.) (relevant to developed countries as well as developing).</li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<p><b>FSANZ objectives – objective 1 – protection of public health and safety</b></p> <ul style="list-style-type: none"> <li>• Claims promote appropriate selection and use of infant and follow-on formulas. <ul style="list-style-type: none"> <li>– claims are an important source of nutrition information and education;</li> <li>– providing factual, science-based nutrition information on labels maximises health of formula-fed infants by differentiating the composition of infant and follow-on formulas so that consumers can select the most appropriate formula;</li> <li>– manufacturers rely on labelling statements to communicate recent science based changes in formula composition.</li> <li>– the relationship between knowledge and ability to select appropriate foods is highlighted in a WHO/UNICEF position statement, which reads, “Inadequate knowledge about appropriate foods and feeding practices is often a greater determinant of malnutrition than lack of food.” (WHO, Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization, 2003.) (relevant to developed countries as well as developing).</li> </ul> </li> <li>• <b><i>Claims foster nutrition research that can benefit all infants – breast-fed and bottle-fed.</i></b> <ul style="list-style-type: none"> <li>– formula manufacturers invest heavily in research aimed at identifying individual components of breast milk and discovering their role in infant health and nutrition.</li> <li>– More than 2000 papers supported or conducted by infant formula manufacturers have been published in last 5 years.</li> <li>– Many lines of research have led to improvements in the health of infants (breast-fed and bottle-fed) and in some cases the broader population, e.g., <ul style="list-style-type: none"> <li>▪ studies of iron supplementation to neonates have revealed that iron deficiency in infancy can result in irreversible deficits in brain development;</li> <li>▪ two clinical trials have shown that nucleotide supplementation to infant formula enhances immunoglobulin titers in response to vaccine (Pickering LK, Granoff DM, Erickson JR et al, Modulation of the immune system by human milk and infant formula containing nucleotides. Pediatrics 1998; 101:242-249; Makrides M, Hawkes J, Robertson D et al, The effect of dietary nucleotides supplementation on growth and immune function in term infants: A randomized controlled trial. Abstr O0083 JPGN 2004; 39 Suppl 1:S39.);</li> <li>▪ preterm infants supplemented with long chain polyunsaturated fatty acids have improved visual acuity and maturation. (SanGiovanni, JP, Parra-Caberra, Colditz, GA, Berkey, CS, and Dwyer, JT. Meta-analysis of dietary essential fatty acids and long chain polyunsaturated fatty acids as they relate to visual resolution acuity in healthy preterm infants. Pediatrics 2000, 105:1292-1298.)</li> <li>▪ LCP supplementation improves cognitive performance in early life. (Birch EE, Garfield S, Hoffman DE et al, A randomized controlled trial of early dietary supply of long chain polyunsaturated fatty acids and mental development in term infants. Develop Med Child Neurol 2000; 42:174-181; Willatts P, Forsyth JS, DiModugno MK, et al, Effect of long-chain polyunsaturated fatty acids in infant formula on problem solving at 10 months of age. Lancet 1998;352:688-691.);</li> </ul> </li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>▪ Small feeding volumes reduce the incidence of necrotizing enterocolitis (Berseth, CL, Bisquera, JA, Paje, VU Prolonging small feeding volumes early in life decreases the incidence of necrotizing enterocolitis in very low birth weight infants. Pediatrics 2003, 111: 529-534.)</li> <li>– The proposed standard impedes promotion of public health and safety by denying formula manufacturers the right to communicate the nutritional content of their formulas in a language that is understood by consumers; and by acting as a disincentive for research.</li> <li>– The prohibition on messaging compromises optimal infant health because without adequate information, a consumer’s choice of formula may not be the best choice for their infant.</li> <li>– A ban on nutrition and health claims on infant and follow formulas translates into reduced return on investment. If unchanged, the proposed standard will stymie future research and innovation in infant nutrition.</li> <li>• Proposed standard treats infant formula and follow-on formula as one product, when in fact they are designed for two ages groups – 0 – 6 months (sole source of nutrition for bottle fed) and 6 – 24 months (nutritionally complete food consumed in combination with solid food) – this contributes to consumers’ lack of understanding of these products.</li> <li>• Coupling of infant formula with alcohol misrepresents the role of formulas which are the sole source of nutrition whereas alcohol is second only to tobacco as a cause of drug related deaths and hospitalization in Australia (reference given). Suggests that infant and follow-on formulas could/do pose a threat to infant health, reinforced by the statement “We have also identified foods ineligible to carry health claims (infant formula and alcohol) to guard against inappropriate consumption of the food” (FSANZ, A Guide to the Development of a food Standard for Australia and New Zealand, pg 10), whereas they are the only suitable alternatives to non-breast-fed infants. To indirectly imply that formulas may have a deleterious effect clearly contravenes FSANZ objective of protecting public health and safety and misleads consumers.</li> </ul> <p><b>ANZ objectives – objective 2 – provision of adequate information to enable informed choices</b></p> <ul style="list-style-type: none"> <li>• Nutrition and health claims are consistent with the WHO and World Health Assembly (WHA) position on provision of information <ul style="list-style-type: none"> <li>– quotes from the WHO Expert Consultation on recommendations for breast feeding and support for mothers who choose to bottle feed (WHO. The Optimal Duration of Exclusive Breastfeeding: Report of an Expert Consultation, 28-30 March 2001. Geneva: WHO,2002)</li> <li>– Article 7.2 of the WHO Code states that scientific and factual information should be provided. Article 4 of the Code recognises that information should be provided to both health care providers and families (WHO, International Code of Marketing of Breast-milk Substitutes. Geneva: World Health Organization, 1981). Nutrition and substantiated health claims will provide this information. If prohibited, the burden will fall back to government and health care providers to provide this information.</li> <li>– The Global Strategy for Infant and Young Feeding echoes the WHO Code Sentiment on provision of information (WHO. Global Strategy for Infant and Young Child Feeding. Geneva: World Health Organization, 2003.)</li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>– WHA resolution 54.2 asks that the WHO Code be taken into consideration in dealing with health claims, i.e. <b>it presumes they are permitted</b>. It calls on all sectors of society to “contribute to improved nutrition for infants and you children <u>by every possible means</u> at their disposal”. (World Health Assembly, Resolution 54.2. Infant and young child nutrition. WHA 54.2; 2001.), which must include description of nutritional components especially those shown to contribute to improved nutrition of infants.</li> <li>– Provision of information is also in keeping with the Australian Breastfeeding Association’s aim to “provide factual information for all women to make informed choices about feeding their babies and their parenting styles.” (Australian Breastfeeding Association. ABA Vision, Mission and Aims (Accessed 16 March 2006. <a href="http://www.breastfeeding.asn.au/aboutaba/purpose.html">http://www.breastfeeding.asn.au/aboutaba/purpose.html</a>).</li> <li>– Infant formula manufacturers are currently permitted to supply information to health care professionals. Expect that health care professionals would educate consumers about infant and follow-on formulas, yet consumers are still struggling to get the information they need to make an informed choice, e.g. New South Wales sales representatives have little access to early childhood nurses.</li> <li>– A June 2005 UK study concluded that “a process of cultural transmission seems to have turned provision of health information about the benefits of breastfeeding into hostility about formula use.” The findings report that more than half the women surveyed did not receive information about formula feeding and that they often had to work hard to find information about formula feeding, sometimes when in a state of anxiety because they had not intended to formula feed. The report’s main recommendation was that use of formula milk be depoliticized and treated objectively as a routine aspect of baby care, rather than as a moral issue. (School of Social Policy, Sociology and Social Research, University of Kent. Mothers’ experience of, and attitudes to, using infant formula in the early months. Key findings2005, 6.)</li> <li>– In her book, Adelia Ferguson provides a New Zealand perspective on the availability of information on formulas, with first-hand accounts from women who struggled to gain the support and information that the WHO Code and New Zealand Code of Practice on the Marketing of Infant Formulas mandate. (Ferguson A, Bottle Babies. A New Zealand Guide to Guilt-Free Bottle Feeding, 1998.)</li> <li>– Unintended consequence of the lack of consumer-friendly information is the common misconception that all formulas are the same. The complete absence of claims may have the unintended consequence of putting consumers in the position of choosing a formula based on marketing and pack design rather than nutritional content.</li> <li>• Nutrition and health claims bridge the information gap by providing nutrition education that enables consumers to make an informed choice. <ul style="list-style-type: none"> <li>– Statements about the role of nutrients in growth and development are useful.</li> <li>– Comparative claims provide valuable information about nutrients contained in formulas that are deficient in cow’s milk or other liquids, e.g. iron, of which children are not getting enough (reference provided).</li> <li>– Use of unmodified cow’s milk by the aboriginal community to feed infants less than 12 months of age remains an ongoing issue.</li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>– Follow-on formula is marketed as an alternative to cow’s milk in New Zealand rather than as a breast-milk substitute.</li> <li>– New Zealand Code of Practice on the Marketing of Infant Formulas differentiates between infant and follow-on formulas in that it expressly permits follow-on formulas to be advertised directly to consumers. FSANZ’s proposal to prohibit follow-on formulas from having the same substantiated nutrition and health claims on their labels that they are already allowed to make which is clearly at odds with New Zealand current practice.</li> <li>– Conflicting nature of the proposed standard is further complicated by Standard 1.1.1, where advertisements of foods are not permitted to claim anything that is not permitted to be on the label. This stipulation also puts the Food Standards Code at odds with New Zealand policy.</li> </ul> <p><b>FSANZ Objectives – objective 3 – The prevention of misleading and deceptive conduct</b></p> <ul style="list-style-type: none"> <li>• Appropriately substantiated claims provide consumers with accurate information to guide their food selection. <ul style="list-style-type: none"> <li>– By denying manufacturers the right to communicate the role of nutrients in growth and development, FSANZ may be inadvertently contributing to consumers making inappropriate choices, for example, a lactose-free formula is only intended for infants with lactose intolerance. While a lactose-free formula would still meet the nutritional needs of a child without lactose intolerance, it is a step further away from breast milk than a lactose-containing formula and therefore not an ideal choice.</li> <li>– Inclusion of validated nutrition and health claims on infant and follow-on formulas will help FSANZ meet the aim of removing the ambiguity that surrounds the current arrangement in relation to health claims and the objective of preventing misleading or deceptive conduct.</li> </ul> </li> </ul> <p><b>Additional considerations – the need for standards to be based on risk analysis using the best available scientific evidence</b></p> <ul style="list-style-type: none"> <li>• Nutrition and health claims do not interfere with a mother’s feeding decision <ul style="list-style-type: none"> <li>– FSANZ would need to consider what, if any, impact nutrition and health claims would have on breastfeeding rates.</li> <li>– There is no evidence to suggest that breastfeeding rates will be negatively impacted.</li> <li>– US experience supports the notion that nutrition and health claims do not dissuade women from breast feeding. With the beginning of direct-to-consumer promotion there was an increased initiation of breastfeeding, confirmed by the 2006 report from the US Government Accounting Office which states that despite an increase in direct-to-consumer promotion since 2001, breastfeeding rates have continued to increase (GAO. Breastfeeding: Some Strategies Used to Market Infant Formula May Discourage Breastfeeding; State Contracts Should Better Protect against Misuse of WIC Name, 2006).</li> <li>– There has been no specific research on the influence of nutrition and health claims on decision to breastfeed.</li> <li>– Study in Hong Kong reported that promotion of infant formulas had a limited impact on feeding choices; advice from health care workers and others was a more significant influencer (Kong SK, Lee DT. Factors influencing the decision to breastfeed. J Adv Nurs. 2004; 46:369-379.)</li> <li>– A study in the UK noted that advertisement of infant formula did not have an impact on feeding choice. (Hughes P and Rees C. Artificial feeding: choosing to bottle-feed Br J Midwifery. 1997; 5:135-142.)</li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>– To prohibit nutrition and health claims on the premise of them negatively affecting breastfeeding rates would be well intended but would have little effect.</li> <li>– Unreasonable to use that same argument to rationalise the prohibition of nutrient and health claims on follow-on formulas. After six months of breastfeeding there would be a myriad of factors that would contribute to a decision to stop (returning to work). To suggest that nutrition and health claims the culprit would be disingenuous. If anything, nutrition and health claims on follow-on formula would reassure mothers that their child is getting the next best alternative.</li> <li>– To prohibit claims on infant formula and follow-on product on the basis of ‘protecting and promoting breastfeeding’ would directly contradict the requirement for standards to be based on risk analysis using the best available scientific evidence.</li> </ul> <p><b>Additional considerations – the promotion of consistency between domestic and international food standards</b></p> <ul style="list-style-type: none"> <li>• Health claims on infant formula and follow-on formula are consistent with international policy: <ul style="list-style-type: none"> <li>– WHO International Code of Marketing of Breast Milk Substitutes, related resolutions, and the WHO/UNICEF Global Strategy for Infant and Young Child Feeding. Article 7.2 of the WHO Code (see above)</li> <li>– WHA resolution 54.2 presumes that they are permitted (see above)</li> </ul> </li> <li>• Many countries already allow or require claims on infant formula and follow-on formula products: <ul style="list-style-type: none"> <li>– United States, Europe, most Asian and Middle Eastern countries, to be consistent with the above objectives, Standard 1.2.7 should reflect these</li> <li>– EU Directive in Infant Formula specifically permits claims (Article 7.6 quoted, which allows nutrient content and disease reduction claims, e.g. reduction of risk to allergy to milk proteins)</li> <li>– In the US, claims are mostly regulated in the same way as for foods. Formulas that contain more than 1 mg/100 kcal of iron are to be labelled as ‘with iron’.</li> </ul> </li> </ul> <p><b>Additional considerations – The desirability of an efficient and internationally competitive food industry</b></p> <ul style="list-style-type: none"> <li>• Claims foster competitiveness within the food industry <ul style="list-style-type: none"> <li>– Support FSANZ view that to justify the costs of developing new food products, manufacturers need to be able to inform consumers about the benefits, and that an innovative food industry is in the best interests of Australia and New Zealand.</li> <li>– Believe infant and follow-on formulas should be afforded the same opportunity as other foods. Inclusion of nutrition and health claims enables manufacturers to differentiate their products from their competitors in a fair and truthful manner.</li> <li>– Claims provide industry with incentive to research, and the outcome of research is that all infants stand to benefit from an improved understanding of infant nutritional needs.</li> <li>– A prohibition on claims will restrict manufacturers’ ability to compete and act as a barrier to improvements in infant nutrition by deterring the type of research that has generated more than 2000 papers in the past five years and significant advances in our understanding of the components of breast milk and their specific role in infant nutrition and health.</li> </ul> </li> </ul>

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Wyeth Australia Pty Limited and Wyeth New Zealand Pty Limited	Industry – Trans Tasman	<p><b>Additional considerations – The promotion of fair trading in food</b></p> <ul style="list-style-type: none"> <li>• Claims promote fair trade practice across all industry <ul style="list-style-type: none"> <li>– Believe that as other food products on shelves will be able to make claims, the absence of any claim on infant and follow-on formulas will be an implied claim that they are all same, where in fact some of the optional ingredients contained in formulas are at the forefront of paediatric nutrition research. To indirectly imply that they are the same is misleading to consumers.</li> <li>– This is particularly relevant to follow-on formula (6-24 months of age). From six months, solids are gradually introduced meaning that many foods such as iron-fortified rice cereals become appropriate. In its current draft, Standard 1.2.7 would allow baby foods to claim iron fortified or good source of iron but follow-on formula would be prohibited from making such claims.</li> <li>– To disallow follow-on formula from carrying the same types of claims that other baby foods claim, puts follow-on formula manufacturers at a competitive disadvantage. It also has the potential to mislead consumers into thinking that a rusk biscuit, which claims to have added vitamins, is a nutritionally superior product to follow-on formula. This is particularly disconcerting given the fact that of all the foods designed for infants six months and older, follow-on formula is the <i>only</i> food designed to provide all the nutrients, including zinc and iodine, which are in short supply in the mixed diet of older infants.</li> <li>– In its current draft, Standard 1.2.7 applies its objectives inconsistently across industry and as a result impedes fair trading in food.</li> </ul> </li> </ul> <p><b>Conclusion</b></p> <ul style="list-style-type: none"> <li>– The proposed Standard contravenes FSANZ’s objectives and is at odds with current government sanctioned practice in New Zealand.</li> </ul>
Fonterra Co-Operative Group Limited supported by Fonterra Brands Australia (P&B)	Industry – New Zealand Industry - Australia	<ul style="list-style-type: none"> <li>• Supports the proposal that claims may be made on infant foods excluding infant formula. It is important that consumers are educated about nutrition for young children.</li> </ul>
Department of Human Services Victoria	Government – Australia	<ul style="list-style-type: none"> <li>• It is undesirable to permit a nutrition content claim in relation to alcohol other than ‘low alcohol’.</li> </ul>
NSW Food Authority	Government – Australia	<ul style="list-style-type: none"> <li>• Brewed soft drinks with 0.5 to 1.15% alcohol (contained in standard 2.7.1) should not be prevented from making general or high level claims. These products are sold alongside other soft drinks in shops and supermarkets.</li> </ul>
Queensland Health	Government – Australia	<ul style="list-style-type: none"> <li>• Infant foods should be ineligible to make claims as infant formula does not adequately cover the policy direction regarding prohibiting claims on ‘baby foods’.</li> </ul>

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Australian Consumers' Association	Consumers - Australia	<ul style="list-style-type: none"> <li>• Questions the FSANZ interpretation of the Policy Guideline in relation to the ineligibility of baby or infant foods. The Policy Guideline refers to 'infant foods' (page 2, 5th bullet point) and 'baby foods' (pages 4 and 6) yet FSANZ have adopted a very narrow definition of 'infant formula'. At no time does the policy guideline refer to 'infant formula', which is very different from 'baby foods' or 'infant foods'.</li> <li>• Believes baby foods should not be eligible to make nutrition or health claims, including canned and jarred meals and desserts on the market.</li> <li>• A CHOICE Magazine (July 2004) investigation of canned and tinned baby food found that some products contained very little of the characterising ingredients such as banana or beef and that in some cases these products contained significant amounts of water and thickener.</li> <li>• The World Health Organisation (<a href="http://www.who.int/inf-pr-2001/en/note2001-07.html">http://www.who.int/inf-pr-2001/en/note2001-07.html</a>) and the NHMRC encourage exclusive breastfeeding until six months of age. The use of health claims on baby foods may encourage consumers to use these products in place of breast milk at an earlier age and could encourage an over reliance on these products rather than on fresh fruits and vegetables, meats and cereal products which provide greater nourishment.</li> </ul>
Nestle Australia Limited and Nestle New Zealand Limited	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>• There is no evidence that a relaxation of the policy in Standard 2.9.1 to prohibit claims on infant formula will act against breast-feeding.</li> <li>• Support the Infant Formula Manufacturers Association of Australia in relation to this issue.</li> </ul>
New Zealand Food and Grocery Council (FGC)	Industry – New Zealand	<ul style="list-style-type: none"> <li>• Do not believe alcoholic beverages should be precluded from making general level claims.</li> <li>• Note the EU Parliament has recommended the provision that precludes nutritional claims on alcoholic beverages be removed.</li> <li>• By precluding such claims, FSANZ could be implying alcoholic products are unhealthy which is not the case; it is the excessive intake that is unhealthy. Any substance taken to excess is unhealthy. Thus is it inequitable to apply a different approach to alcoholic beverages.</li> <li>• There are strict labelling requirements on alcoholic beverages and providing the claim can be substantiated, general level claims should be permitted.</li> </ul>
Heinz Australia/Heinz Wattie's New Zealand	Industry – Trans Tasman	<ul style="list-style-type: none"> <li>• Recommends that the exclusion from the draft Standard in relation to products regulated by Standard 2.9.1 is deleted.</li> <li>• Infant formula is the sole source of nutrition for those infants who are not breast fed. It is life-giving and does not cause harm to the consumer and to place it with alcohol as being the only two foods that cannot make claims is illogical.</li> <li>• These products are not able to be marketed to consumers under the World Health Organization International Code of Marketing of Breast Milk Substitutes (the WHO Code). Under the WHO Code is an obligation to ensure "... The proper use of breast milk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution (Article 1). By not allowing claims on infant formula, Australia and New Zealand will be breaching their obligations under the WHO Code.</li> <li>• Parents/caregivers rely heavily on pack information to make an informed choice. Lack of information on important nutrient ingredients can exacerbate health and safety concerns.</li> </ul>

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New Zealand Nutrition Foundation	Public Health – New Zealand	<ul style="list-style-type: none"> <li>• Notes that alcohol used indiscriminately has high health and social risks but used in moderation and with food it has properties beneficial to health.</li> <li>• FSANZ should acknowledge existing guidelines for safe use and the circumstances under which it is an individual’s choice to use alcohol.</li> <li>• Regular alcohol, in doses of 10 to 20 grams daily in females and a little more in males, is beneficial in preventing coronary heart disease and type 2 diabetes in susceptible people, especially if taken with food.</li> <li>• Risks associated with alcohol use increase with higher doses, and especially if taken without food or in a fasting binge drinking situation.</li> </ul>
Nutrition Australia	Public Health - Australia	<ul style="list-style-type: none"> <li>• Support the exclusion of infant formula and alcoholic beverages from making any health claims.</li> </ul>
Nutricia Australia	Industry - Australia	<ul style="list-style-type: none"> <li>• Supports submission from Infant Formula Manufacturers Association of Australia (IFMAA), specifically that infant milk products are prohibited from all levels of nutrition, health and related claims.</li> <li>• This is inconsistent with promotion of health and safety as the primary objective of FSANZ and subsequent objectives for provision of information to allow an informed consumer decision and minimum effective legislation.</li> <li>• Not all women can breastfeed and there are other regulations and legislation that cover these products and ensure the mandatory promotion of breastfeeding as the best option.</li> <li>• New Zealand interpretation of the WHO Code permits the promotion of follow on formulas and this would be contradicted under the proposed prohibition in the Draft Assessment Report.</li> <li>• Proposed prohibition for follow on formulas places them at a distinct disadvantage when compared to other foods and/or beverages specifically marketed at this sector. E.g.: ‘a natural source of calcium’ found on a range of branded dairy products clearly declaring suitability ‘from 6 months’.</li> <li>• Lack of definition of advertisement in the Food Standards Code allows for State and New Zealand legislation to define it in their respective Acts. This means that in the NSW Model Food Act the definition of advertisement includes “any other representation by any means at all, used or apparently used to promote, directly or indirectly the sale of food.” This definition combines with the definitions and requirements in Standard 1.1.1 of the FSC for ‘Label’ and the application of labelling provisions to advertising.</li> <li>• This cumulative legislation with the proposed blanket prohibition for products covered under Standard 2.9.1 other than expressly prescribed, prevents effective communication with health care professionals and consumers.</li> <li>• Is essential that health care professionals are able to be fully informed of the nutritional properties for infant milk formulas and the rationale behind the addition/modification and the resulting balance of these nutrients.</li> <li>• Supports submission from the AFGC, specifically that food for special medical purposes be exempt from P293 provisions and claims be regulated within P242 when completed.</li> </ul>

Submitter	Group	Comments
Nutricia Australia	Industry - Australia	<ul style="list-style-type: none"> <li>• It is essential that Foods for Special Medical Purposes are available to, as well as safe and effective in meeting the needs of, the intended target population.</li> <li>• In relation to labelling of Foods for Special Medical Purposes (FSMP), FSANZ stated: “However the possible impacts of withdrawal of Foods for Special Medical Purposes, from domestic markets, due to highly prescriptive labelling requirements, as previously discussed, is likely to have a greater impact on public health and safety than withdrawing the application of generic labelling requirements.”</li> <li>• This approach applied above (in P242) would be consistent with an exemption of generic under P293 for foods for special medical purposes. Clause 8(5) of P242 for FSMP states: “Where food for special medical purposes have been specifically formulated for a condition, disease or disorder, the label on the package of the food must include a statement indicating the condition, disease or disorder, and any nutritional modifications for which the food has been specifically formulated.”</li> <li>• As many of these conditions, diseases and disorders for which Foods for Special Medical Purposes are formulated are serious and would therefore be regarded as high level health claims (due to disease reference).</li> <li>• Many of Nutricia’s products are only used by a very small number of consumers. Nutricia has 8 products for inborn errors of metabolism that are used by an average of 3 consumers per product in Australia. The time and cost involved in investigating high level claims for the 8 products would not be viable. Nutricia would have no option than to remove them from the market with resultant health and safety impacts for their consumers.</li> </ul>
Public Health Association of Australia	Public Health - Australia	<ul style="list-style-type: none"> <li>• Supports the exclusion of infant formula and alcoholic beverages from making health claims.</li> </ul>
Lion Nathan Limited (LNL)	Industry- Australia	<ul style="list-style-type: none"> <li>• FSANZ should acknowledge the strong evidence suggesting moderate alcohol consumption can result in some positive health effects.</li> <li>• Nutrient claims should be continued as there has been no known abuse of the current provisions by industry.</li> <li>• International practice on this matter is trending towards allowing nutrient claims. It would be regrettable if the current proposal resulted in an unintended barrier to trade.</li> </ul>
Rosemary Stanton	Public Health - Australia	<ul style="list-style-type: none"> <li>• Supports the exclusion of infant formula and alcoholic beverages from making health claims</li> </ul>
Beer Wine and Spirits Council of New Zealand (BWSC)	Industry – New Zealand	<ul style="list-style-type: none"> <li>• Under current Standards the alcoholic beverages industry is able to use nutrient claims and they are not aware of any ‘abuse’ as a result.</li> <li>• Nutrient claims should be allowed for alcoholic beverages rather than a piece meal approach to raise specific cases for alcohol descriptors and reduced energy, plus the addition of carbohydrate to this list.</li> <li>• European Union – the European Parliament recommended that prohibition of nutritional claims on alcoholic beverages should be removed from draft legislation (Draft Recommendation for second reading on the Council position for adopting a regulation on nutrition and health claims made on food. (9858/3/2005-C6-0018/2006-003/0165(COD))</li> </ul>

<b>Submitter</b>	<b>Group</b>	<b>Comments</b>
Beer Wine and Spirits Council of New Zealand (BWSC)	Industry – New Zealand	<ul style="list-style-type: none"> <li>• United States presently allow claims for carbohydrate, energy etc.</li> <li>• If this Standard continues then there is the risk incurred of being out of step with trading partners and will become a barrier to trade.</li> <li>• Have a good understanding of the political constraints and pressure from narrow interest groups in regards to the development of the health claims standard, which have in part led to the banning of any alcohol product from making claims with the exception of energy and alcohol strength. Submission includes detail on the scientific evidence regarding alcohol and the health effects of moderate alcohol consumption, including references.</li> <li>• The proposed Standard is contrary to the New Zealand Bill of Rights Act and infringes on the right of industry to inform the public of the significant health benefits of moderate alcohol consumption.</li> <li>• The proscription of nutrition and health claims for the alcohol category is outside “reasonable limits” and cannot be “demonstrably justified”, given that there is solid scientific evidence of the health benefits of moderate alcohol consumption.</li> <li>• Are unaware of any evidence that health claims in relation to alcohol has resulted in modifying drinking behaviour.</li> <li>• Under the New Zealand Bill of Rights, the onus is on the party attempting to impose the limitation, to show that the limitation is both reasonable and that it can be demonstrably justified. Therefore the BWSC requests that FSANZ presents the proposed Standard to the Auditor General prior to the final approval processes.</li> </ul>
The Cancer Council of Australia	Public Health – Australia	<ul style="list-style-type: none"> <li>• Supports that nutrition of health claims are not permitted on alcohol and infant formula, but support low alcohol claims and claims in relation to low calorie and reduced calorie alcohol.</li> </ul>
Coalition for a Healthy Australian Food Supply (CHAFS)	Public Health - Australia	<ul style="list-style-type: none"> <li>• Supports the exclusion of infant formula and alcoholic beverages from making health claims</li> </ul>
Food Products Association (FPA)	Industry- International	<ul style="list-style-type: none"> <li>• Believe it appropriate to permit general level health claims on infant formula if they can be substantiated</li> <li>• More appropriate to revise Clause 4 (1) (b) so that infant and subsequent formulas’ are included (nutrient content and general level health claims); believes it will meet FSANZ objectives of 1.2.7 and FSANZ and meet consumer and industry interests</li> <li>• Believe that the pairing of alcoholic beverages and infant formula is not appropriate</li> <li>• Infant formulas’ are often the sole source of food for bottle fed babies and truthful information must be available in language easily understood by consumers</li> <li>• Denying manufacturers’ the opportunity to communicate this information to differentiate various products’ is inconsistent with this proposal</li> <li>• The World Health Organization supports nutrition claims and lack of prohibition for health claims on infant formula</li> </ul>
Coles Myer Ltd	Industry, Australia	<ul style="list-style-type: none"> <li>• Clause 4(2) refers to the nutrition content claims in relation to alcohol and energy. Suggests that the information included in the explanatory notes to the Draft Report be included to clarify the meaning of this clause.</li> </ul>

Submitter	Group	Comments
<p>Australian Food and Grocery Council</p> <p>(Supported by Nestle Australia Ltd and Nestle NZ Ltd, Unilever Australasia, George Western Foods Limited/AB Food and Beverages, Simplot Australia Pty Ltd )</p>	<p>Industry, Australia</p>	<ul style="list-style-type: none"> <li>• Agrees with FSANZ approach to Alcoholic beverages and food containing alcohol</li> <li>• Rejects FSANZ approach to exclude infant formula from making health claims. The inclusion of general level health claims on infant and follow-on formula will meet the objectives of Standard 1.2.7 as well as being in the interested of informed choice by consumers.</li> <li>• Recommends that infant formula and follow-on formulas be permitted to carry scientifically substantiated nutrition and general level health claims.</li> </ul>
<p>NSW Food Authority</p>	<p>Government – Australia</p>	<ul style="list-style-type: none"> <li>• In relation to subclause 4(4) of Standard 1.2.8 there seems good reason for requiring a nutrition information panel on the label of alcoholic drinks rather than leaving it as voluntary e.g. a claim relating to a reduced alcohol content may lead to an expectation that the product as a whole may have a significant reduction in energy content. If consumers are to make informed decisions based on claims made as to the nutritional profile of a food, then they should be given the full picture and not just that part which is expedient for marketing purposes.</li> </ul>