FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Supporting document 6

Regulation impact statement

P293 – Nutrition, Health & Related Claims

Contents

Executive Summary

- In Australia and New Zealand some nutrition claims on the labels of food products are permitted. However, health claims are generally not permitted. Removing these restrictions has merit because consumers may benefit from more information on food labelling regarding health and nutrition.

- Proposal P293 seeks to provide a regulatory arrangement to ensure that food labels (including advertisements) bearing nutrition, health and related claims provide adequate information to enable consumers to make informed choices, while preventing misleading or deceptive information. The Proposal also seeks to support industry innovation and provide certainty for industry and enforcement agencies.

- At final assessment in 2008, FSANZ approved draft Standard 1.2.7– Nutrition, Health and Related Claims which regulated nutrition content claims, general level health claims (GLHC) relating to non-serious disease, and high level health claims (HLHC) relating to serious disease.

- In 2008 Ministers requested a review of the draft Standard. The regulation of GLHC was a major element of the review request. This Review RIS has been undertaken in order to address the issue of the regulation of GLHC and therefore only considers alternative regulatory options for GLHC.

- The RIS considers three possible options with regard to the regulation of GLHC. Option 1 is industry self-substantiation as proposed in the Final Assessment Report (FAR). Under this option, food businesses making claims would self-substantiate GLHC by developing and holding the scientific evidence to substantiate a food-health relationship underpinning a GLHC, and make that information available on request to enforcement authorities.

- Option 2 was developed by FSANZ in response to Ministers' review request pertaining to GLHC. This was driven by concerns raised by jurisdictions, that there would be resource and cost burdens imposed on them in assessing the scientific evidence supporting GLHC. Option 2 therefore proposes that all food-health relationships underpinning GLHC will be pre-approved by FSANZ on the basis of the available scientific evidence.

- During the review process, some jurisdictions and industry groups raised concerns that FSANZ pre-approval would impose additional industry costs by limiting their ability to optimally time the introduction of a new GLHC into the market. Consequently, in June 2012, Ministers agreed to further consider the regulation of GLHC. Following consultation with a range of stakeholder groups, including jurisdictions, consumers, public health and industry parties, FSANZ was asked to consider, in addition to pre-approval, the inclusion of self-substantiation of food-health relationships underpinning GLHC. This constitutes option 3.

- While option 1 gives industry flexibility in marketing of health claims, all companies must substantiate food-health relationships underpinning all claims. This will result in some inefficiency as substantiation is duplicated. Option 1 is likely to impose costs and administrative burdens on jurisdictions. These cost burdens could be significantly reduced in both options 2 and 3.

- Option 2, while providing a significant number of pre-approved food-health relationships and in doing so reduces industry costs for these, does limit company returns from investment in research and development (R&D) as the first to market advantage is limited and flexibility to precisely time market launch is impaired. The benefit arising out of consumer confidence would appear to be maximised under option 2, because it provides a tighter regulatory framework and in doing so enables consumer certainty and confidence.

- Option 3, a hybrid option, incorporates elements of options 1 and 2. A range of pre-approved relationships for GLHC will be provided in the Standard, enabling many small and medium enterprises to make claims with a reduced scientific investment. Option 3 also allows companies wishing to invest in R&D to develop and self-substantiate new food-health relationships to maximise their returns through control of intellectual property and timing of marketing activities. Requirements for self-substantiation will be included in the Standard and companies using this method will be required to notify FSANZ prior to marketing products using claims based on self-substantiation.

- Making a quantitative assessment of the relative advantages of the three possible options is difficult because the proportion of GLHC that may be progressed through each option is unknown. An assessment based partly on qualitative arguments is however possible.

- While option 3 may not maximise the benefits to all individual stakeholders simultaneously, it endeavours to maximise the net benefit to the community without seriously disadvantaging any one stakeholder group. Option 3 is able to achieve this by providing more flexible arrangements for industry while not significantly adding costs to any stakeholder group concerned in so far as the regulation of GLHC is concerned.

- Option 3 safeguards the flexibility that industry, particularly large enterprises, requires to minimise business risk, and in doing so it promotes innovation. It can therefore be argued that while it is possible that there may be some reduction in consumer benefit arising from a perception of reduced certainty and confidence in GLHC derived from self-substantiated food-health relationships, consumers may also gain additional benefit arising from the higher incentive for industry to innovate. It is therefore the preferred option.

- The updated cost-benefit analysis (based on industry self-substantiation, as at final assessment) indicated that the overall net benefit of Standard 1.2.7 could be in the region of A$84 million in today's prices. We consider that with the addition of FSANZ pre-approved food-health relationships to Standard 1.2.7, thereby enabling industry to be able to derive GLHC from either self-substantiated or pre-approved food-health relationships, and the extension of the transition period to three years, the overall net benefit of Standard 1.2.7 is likely to be more favourable than that estimated for Standard 1.2.7 when food-health relationships could only be self-substantiated.

- In December 2011, Ministers requested FSANZ to also consider further the regulation of fat-free and % fat-free claims due to concerns that these types of claims may mislead consumers. FSANZ is recommending a deferral of considering further regulation of fat-free and % fat-free claims on the grounds that there is insufficient evidence that consumers are misled by such claims, and the possible costs involved in regulating such claims. Further, the confectionery industry has advised that they are taking voluntary action to remove fat-free claims. The deferral will allow industry time to implement this action, and for government to evaluate whether further regulatory action is warranted.

1 Background

This Review RIS has been undertaken in order to address the issue of the regulation of General Level Health Claims (GLHC). This issue was raised by Ministers in their request for review of the draft Standard in 2008.

This RIS therefore only considers alternative regulatory options for GLHC. However in order to meet the requirements of a stand-alone RIS, this background section summarises the issues, events and developments that preceded the review process so that it is clear how the standard development process arrived at this point and reasons for the amendments that are presently being proposed. It also provides both the background and the context for the Review RIS.

This background section summarises the rationale for P293, the problem that it sought to address and was addressed in the Final Assessment Report (FAR), the options considered, the RIS that was presented in the FAR and the subsequent review request.

1.1 Introduction

Following receipt of the Policy Guideline on Nutrition, Health and Related Claims from the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council), now the COAG Legislative and Governance Forum on Food Regulation (the Forum) in 2003, FSANZ began assessing Proposal P293 – Nutrition, Health and Related Claims.

The Proposal considered the regulation of the following types of claims:

Nutrition content claims describe or indicate the presence or absence of energy, a nutrient or biologically active substance in food. For example: *this food is high in calcium.*

General level health claims refer to the presence of a nutrient or substance in a food and its effect on a health function. General level health claims may not refer to a serious disease or to a biomarker of a serious disease. For example: *calcium is good for healthy bones and teeth.*

High level health claims refer to the presence of a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example: *Diets high in calcium may reduce the risk of osteoporosis.*

In Australia and New Zealand nutrition claims on the labels of food products are regulated under *Standard 1.2.8 – Nutrition Information Requirements* of the Code. Standard 1.2.8 regulates the use of nutrition content claims about fatty acids, lactose, gluten, salt, sodium, potassium and energy content. *Standard 1.3.2 – Vitamins and Minerals* regulates claims that can be made about the vitamin and mineral content of foods.

In Australia guidance for industry is also provided on the use of nutrition claims in the *Code of Practice on Nutrient Claims in Food Labels and in Advertisements* (CoPoNC). Some types of claims like nutrition function claims are not directly regulated, but nor are they explicitly prohibited. Like all food label claims they must however abide by fair trading legislation.

In both Australia and New Zealand, *Standard 1.1A.2 - Transitional Standard for Health Claims*, prohibits health claims both on labels and in advertising, with the exception of claims regarding maternal folate consumption and the reduced risk of foetal neural tube defects.

1.2 The problem at final assessment

The problems addressed at final assessment in Proposal P293 – Nutrition, Health and Related Claims were the:

- current limited explicit permissions for health claims
- restrictions on providing information to consumers about nutrition and health related aspects of foods at point of sale and in advertisements for food, and limiting consumer opportunity to make informed food choices
- potential for misleading or deceptive conduct relating to nutrition and health claims on food labels and in food advertising
- restrictions under the current regulatory arrangements that impede the ability of industry to innovate
- ambiguities and limitations under the current regulatory arrangements that diminish the effectiveness of enforcement actions by government enforcement agencies. The enforcement agencies advise that prosecution of infringements is difficult, hence they are reluctant to commit scarce resources towards such action.

Some nutrition content claims are currently made in Australia on packaged foods under a voluntary code of practice, the CoPoNC. A survey of 6662 foods undertaken in 2001 revealed that 15 per cent of nutrition content claims were non-compliant with the CoPoNC (Williams et al 2003). It was also estimated that approximately 10 per cent of '% fat-free claims' were used on foods containing more than 3 per cent fat. Because this is a voluntary code it cannot legally be enforced by the jurisdictions.

The objectives of P293 at final assessment were to provide regulatory arrangements that:

- ensure that food labels bearing nutrition, health or related claims provide adequate information to enable consumers to make informed choices
- prevent misleading or deceptive nutrition, health or related claims on food labels or in food advertising
- support industry innovation, giving consumers a broader range of healthy food choices
- have regard to Ministerial Council policy guidance.

P293 also seeks to address the ambiguities and limitations under the current regulatory arrangements that restrict industry innovation and lead to difficulties with enforcement.

1.3 Options at final assessment

The options considered at final assessment were as follows:

Option 1: Maintain the *Status Quo*

Under this option, Standard 1.1A.2 – Transitional Standard for Health Claims, would need to be amended to ensure that the status quo remained.

Currently. it is stated that Standard 1.1A.2 will operate as an alternative standard to Standard 1.2.7 for the two-year transition period after the commencement of Standard 1.2.7.

Option 2: Develop a New Standard and Guideline(s) for Nutrition, Health and Related Claims

FSANZ would develop a new standard that would allow food suppliers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated. Standard 1.1A.2 would be revoked on gazettal of a new standard. High level health claims would be fully regulated.

In relation to HLHC:

- a list of pre-approved claims including criteria and conditions regarding the application of the claim would be included in the standard
- additional user guidance would be developed to facilitate understanding of the requirements in the standard including the process for seeking pre-approval of high level health claims and review mechanisms.

General level health claims would be partially regulated with certain elements such as claims criteria (other than certain claims specified in the Code) being included in a guideline document.

The Guideline would operate under a co-regulatory management system, where:

- FSANZ would write the Guideline
- a management committee would monitor the use of nutrition content and general level health claims
- the management committee would consist of representation from food industry, jurisdictions, consumer groups, public health groups, and FSANZ
- the management committee could be integrated with the monitoring of claims by the Implementation Sub-Committee
- the management committee would have no enforcement power in a legal sense although it could implement other ‘quasi’ regulatory mechanisms such as various forms of moral suasion
- the management committee would evaluate the performance of the guideline annually and its report would be publicly available
- the management of a Guideline could be funded either wholly by Government or jointly by Government and industry
- regulatory agencies would likely be the first point of contact for many enquiries.

Option 3: Develop a New Standard for Nutrition, Health and Related Claims

FSANZ would develop a new standard that would allow food suppliers to make nutrition, health and related claims on food products providing they meet specific conditions and are fully substantiated. Food businesses would be able to self-substantiate claims according to a substantiation framework contained in the standard. Standard 1.1A.2 would be revoked on gazettal of a new standard.

In relation to HLHC:

- a list of pre-approved claims including criteria and conditions regarding the application of the claim would be included in the standard
- additional user guidance would be developed to facilitate understanding of the requirements in the standard including the process for seeking pre-approval of high level health claims and review mechanisms.

In relation to GLHC and nutrition content claims:

- prerequisite and wording conditions would be included in the standard, and thus legally enforceable
- the substantiation requirements would be in a schedule in the standard
- claims criteria would be included in the standard, and thus legally enforceable
- additional user guidance would be developed to facilitate understanding of the requirements in the standard, provide a list of claims and provide detail on how the Substantiation Framework should be applied.

1.4 The RIS at final assessment

The RIS at final assessment contained a multi-stage impact analysis. The first step was a study conducted in 2005 by The Allen Consulting Group (ACG) that compared the policy options under consideration. The consultant applied Multi-Criteria Analysis (MCA) for this study because this technique when applied, even where all impacts cannot be quantified, provides an outcome which ranks the options.

The ACG study identified five key criteria which were used to assess each of the options: industry costs, industry opportunities, claim credibility, consumer welfare and enforcement costs. From stakeholder consultation the ACG arrived at a system of weighting in order to equitably compare the impacts of the five criteria.

The ACG study reviewed the available data on possible impacts and costs arising out of each of the three policy options. After tabulating them under each of the five cost/benefit criteria, and subjecting them to weighting, they came to the conclusion that a new standard (option 2) with guidelines, was preferable, but only by a small margin, since the standard-only option (option 3) came a close second. What it did clearly indicate was that there was a strong case for a standard. FSANZ decided to proceed with option 3 with all claims regulated in a standard. This decision was taken after weighing up a range of factors including the ACG study, comments from submitters and the higher degree of certainty and confidence that would be achieved through all claims being regulated through a standard.

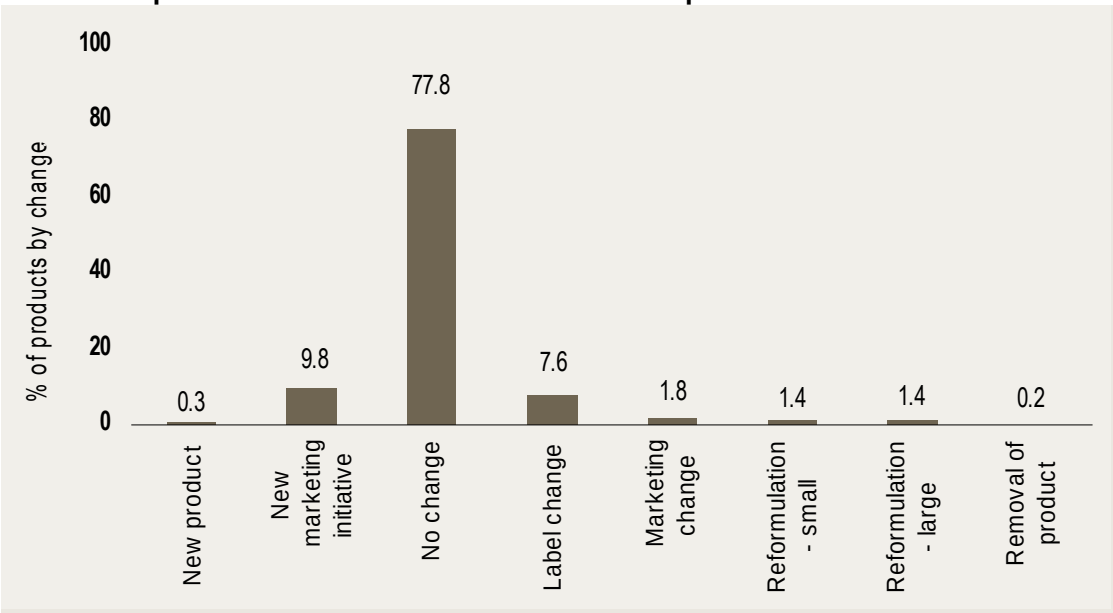
1.5 Cost benefit analysis at final assessment

FSANZ thereafter commissioned The Centre for International Economics (CIE) to undertake a cost benefit analysis (CBA) of the impact of the draft Standard for nutrition, health and related claims. CIE identified seven possible market outcomes (see Chart 1) as a consequence of the proposed health claims Standard.

They developed a financial/activity model to evaluate each possible outcome, and then assessed the likely result. CIE used market data on the introduction of new food products with a health attribute; and employing an economic model of consumer preferences they determined willingness-to-pay for a health attribute, as well as the consequent change in consumer expenditure as well as the impact on substitute products.

Consultation with food companies indicated that around 80% of products would be unaffected – mainly those not making claims and those making only nutrition content claims. About 10% would make new claims and would enjoy new marketing opportunities, while about 12% of products would suffer negative impacts.

Chart 1: Impact of health claims standard on seven possible market outcomes



NB: One outcome 'reformulation' is divided in this chart into small and large

Data source: CIE calculations. The proportion of different impacts in Chart 1 was calculated according to the survey responses conducted in 2008 and adjusted by respondents' production values.

The matrix that emerged from this exercise was then translated into monetary terms (see Chart 2). While food businesses in Australia would profit from new opportunities, they would incur losses on account of both lost opportunities and higher compliance costs. Consumers would gain from the supply of new products, but they may incur higher costs on other food products.

The present value benefits from claims promoting new products and marketing initiatives (outcomes 1 and 2) are A$280.7 million. This includes:

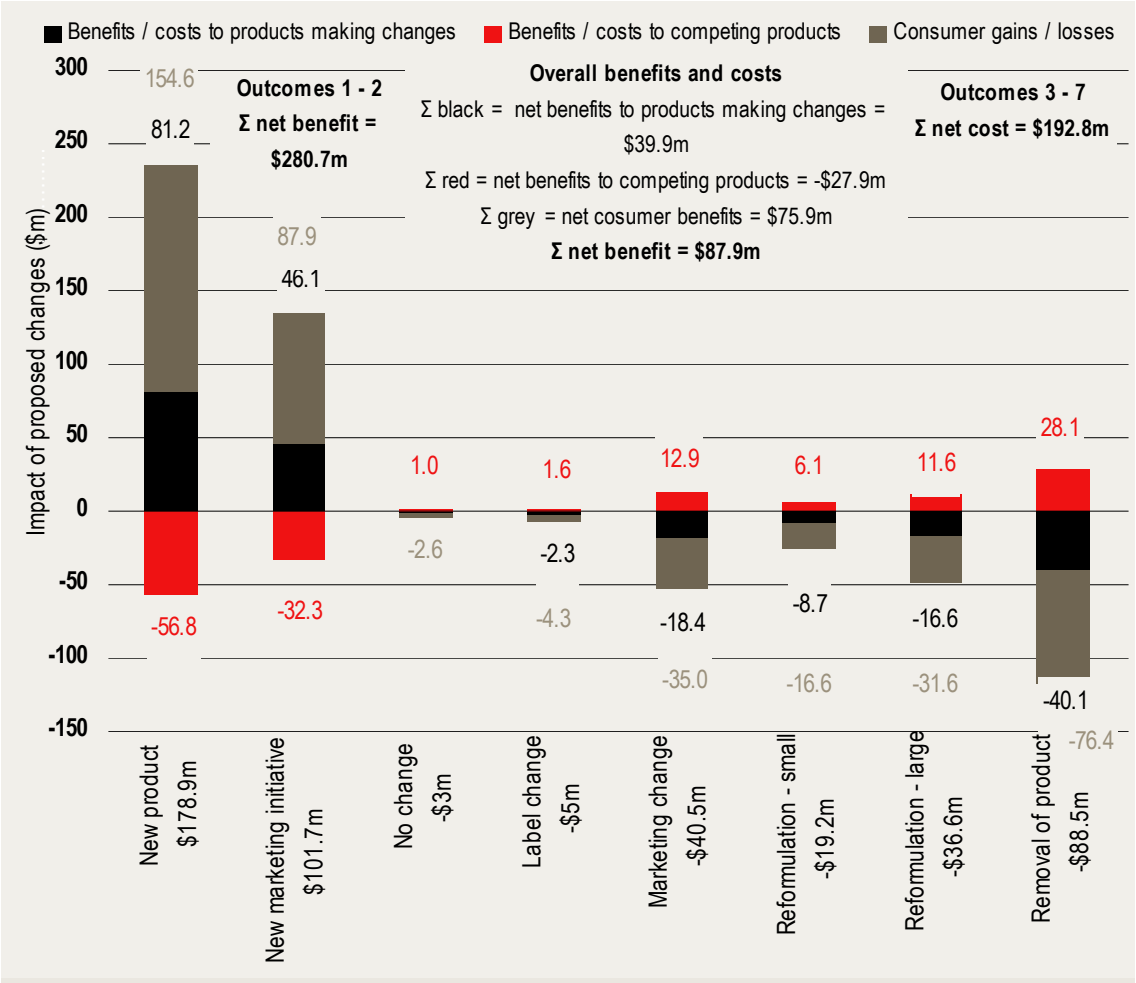
- direct benefits to consumers of A$242.5 million (154.6 + 87.9)
- direct benefits to food suppliers of A$127.3 million (81.2 + 46.1)
- indirect losses to competing food suppliers of A$89.1 million (-56.8 + -32.3).

For outcomes 3 to 7 the draft Standard will result in a net present value cost of A$192.8 million. Food suppliers that need to change products or marketing initiatives face costs of A$87.5 million. This has a flow-on impact to consumers of A$166.5 million, while competing food suppliers gain by A$61.2 million. For the 80 per cent of products not affected by the draft Standard, it still carries a A$3 million cost due to food businesses having to inspect all products to ensure compliance with changes.

Overall the draft Standard provided an Australian net present value benefit of A$ 87.9 million.

CIE derived their data from both Australian and trans-Tasman food companies, the latter accounting for 55 per cent of total food sales in Australia. New Zealand food consumption is equal to about 14.5 per cent of the Australian. It was estimated that net benefits for New Zealand were around NZ$14.1 million (A$12.8 million at the then prevailing rate of exchange).

Chart 2: Total net present value benefits by market outcome (A$ million)



Data source: CIE calculations. Costs and benefits were calculated by applying the CIE evaluation model to the 2006 Australian food data with the expenditure structure being derived from the ABS 2003-04 household expenditure survey (the latest available household survey data when the study was conducted).

FSANZ also sought cost estimates for the enforcement of Standard 1.2.7 from government enforcement agencies. These agencies estimated cost structures for enforcement strategies which they would develop. These costs included training, administration, auditing, inspection, analytic testing and documentation. It was estimated that in Australia these costs would amount to A$140,000 in the first year, and A$490,000 per annum thereafter. New Zealand would have proportionately lower enforcement costs, NZ$32,000 in the first year and thereafter, an annual ongoing cost of NZ$112,000.

Having considered all of these cost centres, and including New Zealand, the RIS at final assessment arrived at a net benefit to the Australian and New Zealand communities of A$95 million.

1.6 Health benefit analysis

In addition to CIE's CBA, a second approach was incorporated in the RIS, in the form of a health economics exercise. But unlike the economic approach which was predictive in nature, this was illustrative only. It sought to assess the potential health benefits to the community which would arise out of consumers moving towards healthier foods as a consequence of a new health claims regime.

In a study commissioned by FSANZ, the Centre for Health Economics Research and Evaluation (CHERE) in Sydney, sought to examine the impact of salt and saturated fat intake on the burden of disease.

Excessive salt intake is a risk factor for high blood pressure, one of the largest contributors to cardiovascular disease. Since 90 per cent of salt consumed by adults comes from processed and manufactured foods, reformulation of food products to reduce salt could have a significant effect on disease.

CHERE's modelling indicated that reformulation of processed foods, ten years after the introduction of the Standard, could enable a reduction in saturated fat intakes in both Australia and New Zealand of between 15 and 25 per cent. The study predicted that a reduction in salt intake after ten years could potentially reduce the burden of some cardiovascular diseases by 10 to 12 per cent.

Although the benefits modelled were hypothetical and not quantified, the presumption is that if the introduction of the Standard did lead to reduced salt or saturated fat in the food supply, then this in turn could lead to a reduction in disease and therefore reduced health care expenditure.

1.7 Preferred option at final assessment

Having considered the report of the Allen Consulting Group, CIE's CBA, the CHERE Report, independent consumer research, extensive stakeholder consultation, responses to the Initial and Draft Assessment Reports, international practice and national dietary guidelines and nutrition policies, at final assessment the standard-only option was recommended by FSANZ.

This decision was based on the findings that:

- there was widespread support from all stakeholders for a new clearly enforceable standard which provided the greatest level of support for consumers
- a standard, rather than a guideline, would assist small food companies improve the quality and accuracy of the nutrition information they provide
- it would be equitable towards all participants in the food industry as the most workable and easiest to regulate
- it would give consumers greater confidence in the food supply
- the CBA indicated that the regulation of nutrition content and health claims had greater long term benefits for all stakeholders than the current system.

At final assessment (2008), FSANZ approved draft Standard 1.2.7 – Nutrition, Health and Related Claims for regulating nutrition content claims, GLHC relating to non-serious disease, and HLHC relating to serious disease.

It was proposed that:

- the use of claims by industry would continue to be voluntary
- all claims would be substantiated
- wording conditions and qualifying criteria for nutrition content, GLHC and HLHC would be specified in the draft Standard (while not prescribing claim wording)
- food carrying GLHC and HLHC would have to meet the nutrient profiling scoring criterion (disqualifies foods of overall lower nutrition quality from carrying such claims)
- food-disease relationships underpinning HLHC would be pre-approved by FSANZ
- food businesses could choose one of four methods to self-substantiate food-health relationships underpinning GLHC and provide documentation to enforcement authorities on request.

In relation to the regulatory approach for GLHC, the four methods industry could use to self-substantiate such claims were as follows:

- use of the list of 25 nutrient function statements in the draft Standard
- use of the prescribed list of 9 pre-approved food-disease relationships for HLHC
- drawing food-health relationships from a list of authoritative sources
- a systematic review, supported by evidence prepared as specified in the Scientific Substantiation Framework.

The original RIS made the case for and established the validity of the regulatory option (Option 3: new standard, only). Therefore, this Review RIS which only addresses the regulatory approach for GLHC, does not consider a status quo, or non-regulatory option.

This decision was based on an evidence-based assessment which included cost benefit analysis, consumer research, label monitoring studies, consideration of international approaches to the regulation of nutrition and health claims and advice received via public submissions, targeted consultation of stakeholders and expert advisory groups.

In reaching this decision FSANZ sought to minimise the degree of regulation commensurate with the risk to consumers of not providing adequate information for informed choice and the risk of misleading claims. FSANZ concluded that the proposed approach provided overall benefits to the community, government and industry that outweigh the costs arising from the proposed regulation.

1.8 Review request

In June 2008 the Ministerial Council requested a review of draft Standard 1.2.7. The review request included a number of concerns that FSANZ has addressed; however the only concern of relevance to the RIS relates to the regulation of GLHC. Many jurisdictions were of the view that under industry self-substantiation they would bear a disproportionate share of the implementation burden, particularly in relation to resources and expertise required to assess the scientific evidence held by food business to substantiate their claims. To address this concern FSANZ proposed that a pre-approval approach be used instead for GLHC.

A pre-approval-only approach however drew concerns from some sections of industry and some jurisdictions. They were concerned that it would impose additional industry costs as a result of delaying industry's ability to take new products with GLHC immediately to market or for them to manage the strategic timing of their introduction into the market. Conversely, some jurisdictions, consumers groups and public health advocates were strongly in favour of this approach as it provided certainty that all claims would be underpinned by approved food-health relationships.

More recently, in response to stakeholder concerns with the pre-approval approach, Ministers agreed to further consider the regulation of GLHC. More specifically FSANZ was asked to consider an additional pathway to the proposed pre-approval of food health relationships for GLHC. Following consultation with a range of stakeholder groups, including jurisdictions, consumers, public health and industry parties, FSANZ was asked to again consider self-substantiation.

Therefore, this Review RIS addresses the issue of developing the most cost effective regulatory framework for GLHCs, one that achieves the high-level overall regulatory deficiencies that P293 is intended to address, as well as meeting stakeholder objectives.

The issue of the regulation of fat free (and %fat-free) claims was also raised at review. FSANZ is not recommending further regulatory change in this area at this point in time. This issue is discussed in section 9.

2 The problem

The problems that this Proposal is attempting to address are:

- current limited explicit permissions for health claims
- restrictions on providing information to consumers about nutrition and health related aspects of foods at point of sale and in advertisements for food, and limiting consumer opportunity to make informed food choices
- potential for misleading or deceptive conduct relating to nutrition and health claims on food labels and in food advertising
- restrictions under the current regulatory arrangements that impede the ability of industry to innovate
- ambiguities and limitations under the current regulatory arrangements that diminish the effectiveness of enforcement actions by government enforcement agencies. The enforcement agencies advise that prosecution of infringements is difficult, hence they are reluctant to commit scarce resources towards such action.

As stated above, this RIS is only considering these problems in the context of GLHC.

3 Objectives

The objectives of this Proposal are to provide regulatory arrangements that:

- ensure that food labels bearing nutrition, health or related claims provide adequate information to enable consumers to make informed choices
- prevent misleading or deceptive nutrition, health or related claims on food labels or in food advertising
- support industry innovation, giving consumers a broader range of healthy food choices
- have regard to Ministerial Council policy guidance
- address the ambiguities and limitations under the current regulatory arrangements that restrict industry innovation and lead to difficulties with enforcement.

As stated above, this RIS is only considering these objectives in the context of GLHC.

4 Options for regulating general level health claims

Given the deliberations and consultations that have transpired over the last four years, and given the outcomes of successive Forum meetings, this Review RIS will consider the following three regulatory options for GLHC (while HLHC and nutrition content claims remain unchanged) (see Table 1):

- **Option 1** Self-substantiation of food-health relationships as recommended at final assessment

- **Option 2** FSANZ pre-approval of food-health relationships

- **Option 3** FSANZ pre-approval of food-health relationships plus industry self-substantiation.

The status quo is not considered as an option as a clear benefit is likely to be achieved under all the regulatory options. This has been demonstrated in the original RIS undertaken for this Proposal.

At final assessment a cost benefit analysis was carried out by the CIE which enables the RIS to express the net benefit of option 1 in dollar terms. It is more difficult to express the net benefit for options 2 and 3 in such precise quantitative terms. This is because it is difficult to anticipate the number of industry-initiated claims that would arise, given the large and growing number of FSANZ pre-approvals that will be made available. It is possible however to make an assessment, based partly on available quantitative data, and partly on the basis of qualitative reasoning, what level of benefits options 2 and 3 are likely to deliver.

Table 1: Summary of Options

Option	Attributes
1 Industry self-substantiation (as at final assessment)	• **Industries** to hold documentation that indicate they have followed the GLHC substantiation framework described in the Standard. • In order to assess compliance, if and when necessary, **Jurisdictions** would ask industry to provide documentation that shows the substantiation framework described in the Standard was followed.
2 FSANZ pre-approval	• **Industries** wishing to make GLHC will have to base their claims on food-health relationships pre-approved by FSANZ and listed in Standard 1.2.7. • **FSANZ** to include more than 200 food-health relationships in the Standard for industry to use without having to prepare and hold substantiation documents. • **FSANZ** assessment of applications from industry seeking pre-approval of new food-health relationships underpinning GLHC via the 'high level health claims variation' procedure in the FSANZ Act. The 'high level health claims variation' procedure allows applications to be assessed without public consultation thereby enabling first to market advantage. Approved food-health relationships would be added to Standard 1.2.7, for industry to use to derive claims. • **FSANZ** would monitor approvals of GLHC overseas to assess whether they are appropriate for Australia and New Zealand and consider adopting the relevant food-health relationships in Standard 1.2.7. Public comment would be sought in this process. • **Jurisdiction**s will monitor compliance to ensure that GLHC on foods are based on FSANZ pre-approved food-health relationships, as well as meeting other requirements of the Standard.
3 FSANZ pre-approval plus industry self-substantiation	• **Industries** wishing to make GLHC will have the option of either basing their claims on: - food-health relationships pre-approved by **FSANZ** and listed in Standard 1.2.7 (**FSANZ** to include more than 200 food-health relationships in the Standard for industry to use without having to prepare substantiation documents) OR - new food-health relationships pre-approved by FSANZ via submitting an application to FSANZ OR - self-substantiated food-health relationships with notification of the established food-health relationship to FSANZ prior to launching the associated GLHC on the market. • **FSANZ** would monitor approvals of GLHC overseas, assess whether they are appropriate for Australia and New Zealand and consider adopting the relevant food-health relationships in Standard 1.2.7. Public comment would be sought in this process. • **Jurisdictions** will monitor compliance to ensure that GLHCs on foods are based on FSANZ pre-approved food-health relationships or industry self-substantiated food-health relationships.

5 Impact analysis

5.1 Cost and Benefits of draft Standard 1.2.7 - Nutrition, Health and Related Claims

At final assessment industry self-substantiation was the only option considered for GLHC. In the 2008 draft Standard it was proposed that all food companies making claims would be required to self-substantiate GLHCs and provide the documentation on request to jurisdictions. At the time the RIS was prepared in 2008, it was estimated that a draft Standard (which included self-substantiation for GLHCs, and also included nutrition content and high level health claims) would provide the community with a net benefit of A$94.7 million (see Table 2 below).

Table 2: Summary of Benefits and Costs[1] (A$ million)

Market Impacts	Benefits (A$ million)	Costs (A$ million)	Net Impact (A$ million)
Australia			
Consumers	242.5	166.5	76.0
Industry (direct)	127.3	87.5	39.8
Industry (indirect)	61.3	89.1	-27.8
Industry (Total)	188.6	176.6	12.0
Australia Total	431.1	343.1	88.0
New Zealand Total	62.5	49.7	12.8
Total market impact	493.6	392.8	100.8
Total enforcement costs			-6.0
Total impact for Australia and New Zealand			94.7

In preparing this Review RIS, FSANZ requested CIE to update the Cost Benefit Analysis that was prepared for nutrition and health claims in 2008. Their 2012 revision based on ABS data indicated that food consumption had increased by 27 per cent in aggregate value on account of inflation, population and income changes. In dollar terms this amounts to an increase from A$68 billion in 2008 to A$86 billion in 2012. However once inflation on account of costs and prices are discounted, food consumption in volume was estimated to have increased by only 8.5 per cent (Attachment 6.1 to SD6).

CIE also found that costs, prices and profit margins for the food industry have also changed during the period under review. These changes were adjusted for by using the Labour Price Index and Material Input Price Index. According to the ABS, labour rates have increased by 21 per cent and other material costs by 16 per cent. As a result, profit margins for the food industry have declined from 8.2 to 7.3 per cent.

[1] The costs and benefits were calculated by applying the CIE evaluation model to the 2006 Australian food data with the expenditure structure being derived from the ABS 2003-04 household expenditure survey (the latest available household survey data when the data was conducted).

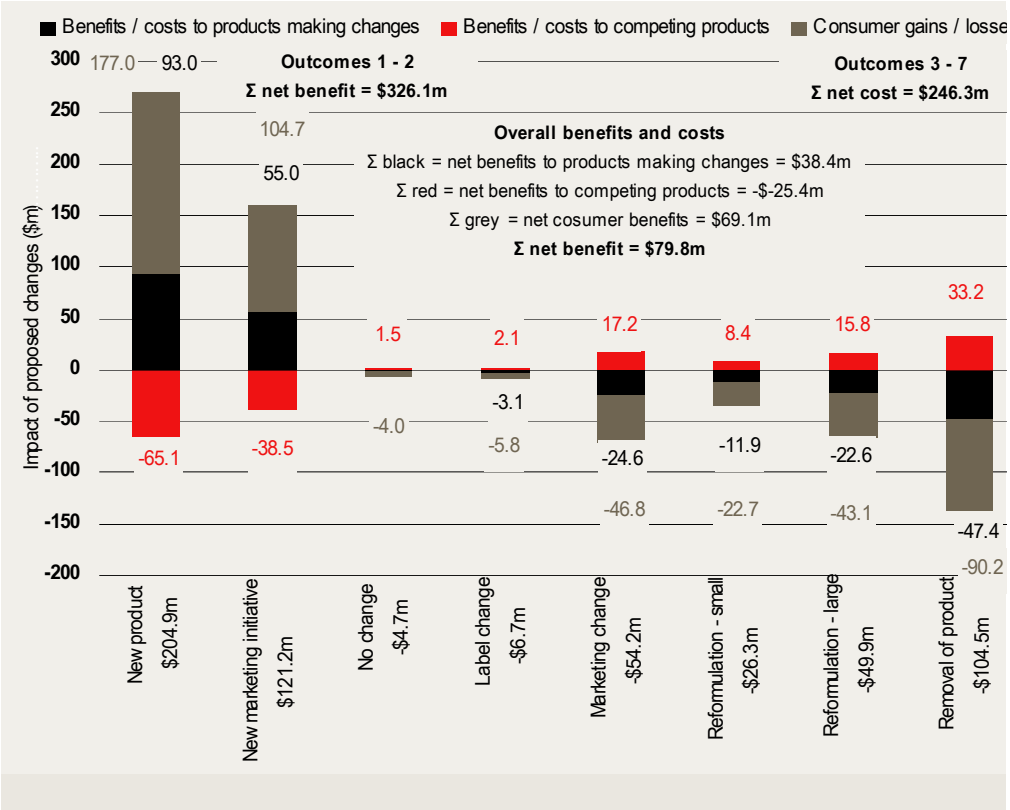
CIE applied the new data to their original seven possible market outcomes as a consequence of the health claims Standard. The outcome (see Chart 3 below) is that benefits to both producers and consumers have declined since the 2008 cost benefit analysis.

Overall benefits from new products and new marketing initiatives increased from A$280.7 million to A$326.1 million (outcomes 1 and 2 in Chart 3). On the other hand the costs of outcomes 3 to 7 (label changes, reformulations and removals) has increased from A$192.8 million to A$246.3 million (Chart 3).

CIE's findings are that with costs increasing at a greater rate than benefits, net benefits have declined in their model from A$87.9 million in 2008 to A$79.8 million in 2012. Including benefits arising in New Zealand and deducting enforcement costs, overall net benefits have declined from A$94.7 million in 2008 to A$83.8 million for 2012 at net present value. The updated 2012 CBA prepared by CIE is appended (Attachment 6.1 to SD6).

The net benefit of nutrition and health claims at current prices would be in the region of A$67 million for consumers and A$11 million for industries in Australia, A$9 million for consumers and A$2 million for industries in New Zealand and the cost impact on jurisdictions, in both Australia and New Zealand, would be around A$5 million. Note that this cost benefit analysis is based on draft Standard 1.2.7 at final assessment which included provisions for nutrition content claims, HLHC as well as GLHC.

Chart 3: Total net present value benefits by market outcome (2010/11)(A$ million)



Data source: CIE calculations. Costs and benefits were calculated in a similar way to those in Chart 2, with the following adjustments:

1) The model parameters (costs) were updated using the relevant price indices (Labour Price Index and Material Input Price Index) as stated on page 11 of Attachment 6.1 to SD6.
2) The food consumption was derived from the 2010-11 total household consumption data and the composition of consumption from the 2009-10 household expenditure survey data (the latest available household survey data).

As mentioned above, FSANZ sought cost estimates for the enforcement of Standard 1.2.7 from government enforcement agencies for the Final Assessment Report (option 1). These agencies estimated cost structures for enforcement strategies which they would develop. These costs included training, administration, auditing, inspection, testing and documentation (Table 3). It was estimated that in Australia these costs would amount to A$140,000 in the first year, and A$490,000 per annum thereafter. New Zealand would have proportionately lower enforcement costs, NZ$32,000 in the first year and thereafter, an annual ongoing cost of NZ$112,000. These costs were based on draft Standard 1.2.7 at final assessment which included provisions for nutrition content claims, HLHC as well as GLHC. Some submissions raised the concern that they had not had enough time to develop sufficiently accurate cost estimates.

Table 3: Up front and ongoing costs for Australian States and Territories 2008 (A$)

Costs	QLD	SA	TAS	ACT	NSW	WA	VIC	TOTAL
UPFRONT COSTS								
Training & Awareness	31,110	945	30,850	3,200	10,285	3,116	720	80,226
Communication	140		3,800		364	288		4,592
Administration	13,540	32,000	3,400	4,560	1,819	1,172		56,491
TOTAL UPFRONT COSTS								**141,309**
ONGOING ANNUAL COSTS								
Training & Awareness	7,490		7,420	3,360	5,097	2,016		25,383
Communication			2,250		4,096	2,920		9,266
Enforcement	89,430	21,250	12,700	2,880	301,091	10,774	20,000	458,125
TOTAL ONGOING ANNUAL COSTS								**492,774**

As part of the review process jurisdictions were asked to provide updated cost estimates based on the new draft Standard (March 2009), which included costing the alternative regulatory approach for GLHC of requiring all underpinning food-health relationships to be pre-approved. Jurisdictions provided initial support for this approach and agreed that the enforcement burden would be reduced as there would be no requirement for them to assess food-health relationships. Cost estimates received were extremely similar to those that had been previously supplied. The reason for the similarities in estimates is uncertain, as jurisdictions were provided with a four week consultation period to ensure they had sufficient time to provide accurate cost estimates.

FSANZ did not attempt to conduct a survey on the cost of implementing and enforcing option 3 given the previous surveys only predicted a small difference in costs between options 1 and 2. Option 3 should theoretically fall somewhere in between these two estimates. The uncertainty associated with the quality of the cost estimates provided may be symptomatic of problems characterising and estimating these types of costs. Jurisdictions often undertake implementation and enforcement from a set budget with the opportunity cost being forgone for implementation and enforcement in other areas. Jurisdictions have noted that assessing the validity of self-substantiated food-health relationships is likely to be costly and resource intensive. They are also of the view that it is difficult to make assessments of costs as the nature and scale of such activities is unable to be estimated with precision. However, jurisdictions are able to prioritise enforcement activity and manage their resource commitments.

Some jurisdictions' concerns were not limited to the costs of implementation and enforcement. Some of the jurisdictions with substantial food manufacturing industries and large individual producers that undertake research and development activities were concerned that option 2 may not provide sufficient incentive to innovate limiting the future growth of this sector, affecting the overall economic position of their jurisdiction. Therefore option 3 was preferred to option 2. Table 4 provides details of the food manufacturing industry in Australia.

Table 4: Employment and Sales and Service Income – Food Manufacture in Australia

	NSW	VIC	QLD	SA	WA	TAS	NT	TOTAL
Employment 2010-*11*[2]	61 000	70 500	49 750	21 750	16 050	7000	1000	227 750
Sales and Service Income (A$ m)[3]	111,442	104,568	70,257	28,586	52,220	6,931	-	381,165[4]

New Zealand also has a significant food manufacturing industry relative to its economy. However, easily comparable statistics were not readily available.

Given the range of possible approaches to compliance and enforcement open to jurisdictions it is not possible at this stage to determine the likely compliance and enforcement costs for each jurisdiction. The implementation and enforcement undertaken in a given year is often driven by specific problems and the historic compliance performance of industry in relation to specific regulation. As Queensland, New South Wales and Victoria are the home jurisdictions for between 70 - 80% of the food industry, it is likely that the bulk of any enforcement activity would fall to those jurisdictions.

More recently discussions have been held amongst jurisdictions under the aegis of the Implementation Sub Committee (ISC), which is a subordinate body of the Food Regulation Standing Committee. ISC is responsible for considering coordinated approaches to the implementation of food standards. These discussions are in their early stages so it is not possible to determine with any certainty whether a nationally coordinated approach for the implementation of the new Standard will be agreed or what the nature of any agreed approach might be. Based on past ISC decisions, a nationally coordinated approach could range from agreement to a common approach to compliance monitoring which is then implemented by individual jurisdictions in accordance with jurisdictional priorities and resource availability - to agreement to undertake national survey-based approaches to assessing compliance with national level discussion of the findings and any implications for enforcement. In this latter case, decisions about what, if any, enforcement action should be taken would remain the responsibility of the home jurisdiction. National surveys may be designed to be small sample, indicative surveys or larger scale more comprehensive surveys depending on the nature of the issue and views about priorities and resources. All jurisdictions may agree to participate in sample collection and analysis, or some jurisdictions may agree to undertake the work and share the results with others.

[2] Source: ABS, Labour Force, Australia, Detailed-Electronic Delivery, cat. N. 6291.0.55.001, Canberra; unpublished data ABS

[3] Department of Agriculture, Fisheries and Forestry, Australian Food Statistics pages 74- 81

[4] Total is for 2009-10 the jurisdictional figures relate to the 2006-07 financial year.

FSANZ is a member of ISC and often participates in nationally coordinated survey work. Had FSANZ been aware six or more months ago that detailed implementation costs by individual jurisdictions may have been required it may have been possible to have asked ISC to move forward its discussions on whether to adopt a national approach to implementation and determine what that would entail. However, given the timeframes imposed on this regulatory process this has not been possible.

5.2 Option 1: Self-substantiation

Option 1 is industry self-substantiation as proposed in the Final Assessment Report (FAR). Under this option, food businesses making claims would self-substantiate GLHC by developing and holding the scientific evidence to substantiate a food-health relationship underpinning a GLHC, and make that information available on request to enforcement authorities. The costs and benefits modelled above were developed on the basis that GLHC would be managed through a self-substantiation process.

An assessment is made below of the costs and benefits that option 1 can be expected to have on each stakeholder group.

5.2.1 Industry

This option provides industry with an opportunity to innovate and take advantage of incorporating health claims into their marketing strategies. CIE found, through its consultations with industry, a significant level of innovation would occur once the Standard came into effect. These incentives would also encourage industry to reformulate their products in the direction of healthier food.

5.2.2 Jurisdictions

In order to enforce the Standard, jurisdictions would potentially be called upon to assess the scientific evidence for food-health relationships. The same information could potentially be assessed by numerous jurisdictions. Not all jurisdictions have access to appropriately skilled staff who could conduct this assessment, requiring them to outsource the assessments. Subject to the complexity and details of the evidence this could become very expensive and inefficient if repeated in multiple jurisdictions. The jurisdictions may also benefit from savings as a result of improved health in the general community. CHERE found that the draft Standard could potentially facilitate reductions in the burden of disease in Australia and New Zealand

5.2.3 Consumers

Option 1 would provide benefits to consumers by making nutrition and health claims on food available to them, and they would therefore have the opportunity to make better informed purchasing decision. This will allow consumers to achieve better health outcomes and otherwise maximise their welfare.

However consumer groups have some concerns about industry self-substantiation leading to the potential for misleading or deceptive conduct relating to nutrition and health claims on food labels and in food advertising. The change in the potential for misleading and deceptive conduct from the status quo is uncertain. However, health claims are likely to be persuasive to consumers so clear incentives exist to make direct health claims. This risk also exists in the absence of regulation. One of the clear outcomes of P293 needs to be a regulatory system that removes ambiguities where possible which is cost effective to comply with and enforce.

5.2.4 FSANZ

FSANZ would not have a direct day-to-day role in the implementation and enforcement of provisions for GLHC in the Standard.

5.3 Option 2: FSANZ pre-approval

Self-substantiation and pre-approval do not represent alternatives of requirements in terms of type and quality of evidence required for substantiation, but alternatives in the process for the substantiation of food-health relationships underpinning health claims. Under this option, food-health relationships underpinning GLHC will be substantiated through pre-approval by FSANZ on the basis of the available scientific evidence and any other relevant information.

FSANZ is including more than 200 pre-approved food-health relationships pertaining to GLHC in the Standard at gazettal, for industry to draw on. This includes more than 100 food-health relationships from approved claims in the EU. FSANZ has considered each of the 241 EU approved health claims for potential inclusion in draft Standard 1.2.7. The majority have been added to Standard 1.2.7 or were already captured in the Standard.

The FSANZ pre-approved list has been developed from:

- UK Joint Health Claims Initiative (includes well established nutrient function statements)
- US Food and Drug Administration health claims
- Health Canada health claims
- some pre-approved HLHC
- approved claims in the EU as of August 2012.

Into the future FSANZ will continue to monitor the approval of health claims in the USA, Canada and the EU and consider adopting relevant food-health relationships in the Standard. If there needs to be any particular conditions around the use of the claim, these will be noted in the Standard. Public comment will be sought when changes to the Food Standards Code are proposed.

Once the new Standard comes into operation, it will also be possible for food businesses to submit applications to FSANZ for the approval of new food-health relationships, based on new science or new interpretations of existing science. Industry will be required, in support of their application, to provide the necessary scientific evidence regarding the new food-health relationship.

In February 2012, FSANZ proposed that food businesses would be able to have applications for the approval of new food-health relationships assessed without public notification, by virtue of the 'high level health claims variation' procedure in the FSANZ Act. The retention of this option was supported by stakeholders at workshops held in August 2012.

The 'high level health claims variation' procedure enables applicants to have an application seeking approval of a new food-health relationship assessed without the normal public notification process. This addresses, in part, the concerns expressed in submitter comments arising from the 2009 consultation and provides both the opportunity for first to market advantage and the certainty afforded by the pre-approval process. Food businesses will also have the options of paying application fees to fast-track FSANZ assessment processes according to current FSANZ procedures and allowing FSANZ to call for public submissions.

FSANZ will provide guidance on the information requirements in support of an application in the *Application Handbook*. The cost of assessing these applications will either be borne by FSANZ or by industry in accordance with the usual FSANZ application process.

The level of evidence required will not change from what was specified for industry self-substantiation at final assessment. Pre-approval has the benefit of being an equitable process with respect to substantiation by reducing the possibility of short-cuts and simplifying implementation and enforcement.

Since FSANZ will be making assessments of new food-health relationships, uncertainty around the validity of food-health relationships for certain food properties and health effects will be greatly reduced.

The costs and benefits are likely to be broadly similar to option 1. However, this option will have different impacts on the different stakeholders and have an effect on regulatory effectiveness and efficiency. An assessment is made below of the costs and benefits that option 2 can be expected to have on each stakeholder group.

5.3.1 Industry

The use of health claims is voluntary and therefore a business decision based on expected costs and benefits.

The pre-approval approach for GLHCs will, from the food business' perspective, include a number of benefits and advantages. For a start, because FSANZ makes these assessments that provide industry with a suite of pre-market approved food-health relationships, industry will enjoy a greater degree of certainty.

This will be a potential cost saving advantage to industry as food businesses will not be required to substantiate those food–health relationships already recognised. For industry, especially for small and medium enterprises (SME), this is a substantial benefit compared with the original industry self-substantiation approach (option 1) where each food business would have to provide substantiation for each food-health relationship used to underpin GLHCs on its products. Small and medium enterprises are therefore much more likely to make a claim under this option than under option 1, benefiting themselves and consumers, due to the lower cost of doing so.

As under option 1, industry may need to withdraw labels with GLHC that are not supported by an established food-health relationship. These costs have been accounted for in the original cost benefit analysis prepared by CIE in 2008, and would not be expected to change substantially if option 2 was adopted.

When a food business wants to make a voluntary claim not covered by a food-health relationship pre-approved by FSANZ, it will need to make an application seeking approval. Such applications will be processed by FSANZ free of charge unless FSANZ determines that an applicant has an exclusive capturable commercial benefit or the applicant chooses to pay for consideration of their application to be fast-tracked.

This option gives industry the opportunity to expedite approval where there is a commensurate financial gain. The applicant will also be able to have an application assessed without public notification, thereby enabling them to have a first-to-market advantage. The first-to-market advantage will enable companies that choose to innovate to extract economic rent from these activities.

An application to FSANZ for approval of a food-health relationship will incur some additional costs such as preparation and lodgement of a dossier and the opportunity cost arising from the time taken to consider the application. The opportunity cost may be reduced to some extent by early engagement with FSANZ and where possible, scheduling project activities in parallel.

Since FSANZ, into the future, will be seeking to increase the number of food-health relationships by drawing on developments in the EU and other international jurisdictions, this option will provide a high degree of certainty for Australian and New Zealand food businesses seeking to make health claims.

The cost disadvantage to industry of option 2 relative to option 1 is that industry participants may experience delays in introducing a new product to market or loose the capacity to optimally time the introduction of a new product. This may reduce the incentives for industry participants to innovate reducing their profits and denying consumer access to new and beneficial products.

5.3.2 Jurisdictions

There will be benefits for jurisdictions since, compared with their obligations under industry self-substantiation, they will not be called upon to assess the scientific evidence for food-health relationships, as this will be determined by FSANZ. Pre-approval will also avoid the duplication of effort across the jurisdictions under option 1 for the review of food-health substantiation dossiers.

Jurisdictions will also benefit from increased certainty arising from pre-approval of food-health relationships, providing a more robust regulatory framework for health claims. Increased certainty has the potential to result in improved enforcement outcomes.

As part of the review process, in 2009 when FSANZ was recommending pre-approval, jurisdictions were asked to provide updated cost estimates based on the draft Standard provided in the consultation paper. They reported that enforcement costs would remain largely unchanged, in the range of A$100,000 – A$140,000 in the first year (for Australia only). However, it is likely that their resources could be expended more optimally to achieve better regulatory outcomes.

5.3.3 Consumers

Consumers will benefit through additional information on nutrition and health claims on food, and consumers would therefore have the opportunity to make better informed purchasing decisions. Under this option more small and medium companies are likely to include claims about their products. However, fewer large companies may have sufficient incentives to innovate and create new beneficial products. It is unclear what the net result in terms of impact (additional health information) on consumers will be from these different trajectories in large versus small and medium sized businesses.

Consumers may benefit from a more robust regulatory framework and from increased certainty and confidence that health claims have valid underpinning food-health relationships.

The food-health relationships prepared by FSANZ will be available to all food industries operating in the market. This will create a level playing field and may serve to moderate price premiums on products.

5.3.4 FSANZ

FSANZ will raise proposals from time to time, for which it will bear the cost; but FSANZ will have the benefit of drawing on validated and approved claims from overseas. Where FSANZ is required to assess industry applications, it may bear this cost, as it does when normally assessing unpaid applications.

The assessment of individual applications could be in the range of forty to one hundred thousand dollars depending on their complexity. The actual number of applications is highly uncertain given the high number of pre-approved claims under this option. This increase in cost to FSANZ under Option 2 is likely to be partially or fully offset by the costs avoided by the jurisdictions that would have been incurred under option 1.

5.4 Option 3: FSANZ pre-approval plus industry self-substantiation

In July 2012, in response to stakeholder concerns with the pre-approval approach, Ministers agreed to further consider regulation of GLHC. More specifically FSANZ was asked to consider an additional pathway to the proposed pre-approval of food health relationships for GLHC. Following consultation with a range of stakeholder groups, including jurisdictions, consumers, public health and industry parties, FSANZ was asked to consider the inclusion of self-substantiation of food health relationships underpinning GLHC. In August 2012 at stakeholder workshops the key elements of this revised approach were also discussed.

Under this option, food businesses wishing to make GLHC will be able to base their claims on either:

- food-health relationships pre-approved by FSANZ and listed in Standard 1.2.7
- self-substantiated food-health relationships established in accordance with Standard 1.2.7.

It is proposed that Standard 1.2.7 will state that food businesses making a GLHC derived from a self-substantiated food-health relationship will be required to:

- notify the Chief Executive Officer of FSANZ of the relationship that has been established between a food or property of food and a health effect
- certify that the relationship that has been notified has been established by a process of systematic review as described in Standard 1.2.7
- provide records to a relevant authority, if requested, that demonstrate that the systematic review was conducted in accordance with the process for systematic review outlined in the Standard and that the notified relationship is a reasonable conclusion of the systematic review.

The costs and benefits are likely to be broadly similar to option 1 and 2. However, this option will have different impacts on the different stakeholders and have an effect on regulatory effectiveness and efficiency. An assessment is made below of the costs and benefits that option 3 can be expected to have on each stakeholder group.

5.4.1 Industry

Some jurisdictions and industry groups have concerns that option 2 (pre-approval) would impose additional industry costs because it would limit industry's ability to optimally time the introduction of a new GLHC into the market. It would also delay their ability to take a new product with a claim to market, and hence incur an opportunity cost as a result of a larger delay between expending research and development funds and entering the market.

Option 3 allows companies to move away from a pre-approval-only option, as by using the self-substantiation pathway they can exploit the marketing advantage arising from the strategic timing of launching new food products or minimise the opportunity costs of delaying the introduction of a product to the market. Option 3 is also protective of Intellectual Property (IP), as only the company or companies holding the evidence can utilise the food-health relationship and make the claim.

Because this option enables industry to make GLHC through both industry self-substantiation and FSANZ pre-approval, it would deliver a greater degree of flexibility such as that potentially enjoyed by industry in option 1. In addition SMEs would have a greater certainty in adopting health claims from pre-approved food-health relationships compared with option 1, similar to the level of certainty associated with option 2.

5.4.2 Jurisdictions

At final assessment enforcement costs were estimated at A$6 million (see Table 2 above) for the Standard as a whole, with industry self-substantiation applying to GLHC. Under option 3 jurisdictions will not be burdened with the costs of assessing science supporting the food-health relationships of those GLHC which are pre-approved by FSANZ. Hence the cost burden for jurisdictions will be reduced compared with option 1, while still being higher than that which would be incurred under option 2 due to costs incurred for enforcement activities associated with self-substantiated food-health relationships. These enforcement activities may include checking the notification list for the established food-health relationship, requesting records to determine if a systematic review of the relevant evidence was conducted in accordance with the Standard (both inexpensive), and an assessment of the evidence, if necessary. Jurisdictions may need to outsource the latter activity.

5.4.3 Consumers

Consumer groups have some concerns about industry self-substantiation. There is a perception that there is potential for claims to be underpinned by food-health relationships that have been based on inadequate evidence. This could translate into some loss of consumer confidence, compared with option 2. However, it is likely to provide greater consumer safeguards than option 1 for the following reasons:

- the same degree of certainty in the food-health relationship underpinning a GLHC will be required for both pre-approved and self-substantiated food-health relationships
- an authorised individual in the food business will need to certify to FSANZ that the self-substantiation process has been followed
- the food business will be required to notify FSANZ of the established food-health relationship before any product marketing activity
- FSANZ will provide more extensive guidance on self-substantiation requirements.

5.4.4 FSANZ

Compared with option 2, this option has the potential to reduce the administrative burden on FSANZ as a number of larger companies are likely to self-substantiate and therefore not submit applications to FSANZ for pre-approval of new food-health relationships.

5.5 Options compared

All three options considered will deliver a net benefit to the community compared to the status quo. Where quantitative data are lacking, the RIS has used qualitative means to compare the three options under consideration. Refer to Table 5 for a summary of the costs and benefits of the three options.

Option 1 provides a flexible approach to health claims for **industry** in general while option 2 would deliver cost advantages to SMEs. Under option 1, the flexibility and control of IP afforded by self-substantiation is advantageous, although there is likely to be replication of effort as each food business is required to substantiate its claims.

Under option 2 food businesses will have access to a range of pre-approved food-health relationships at little or no cost where previously they would have been required to compile and hold the evidence to substantiate each health claim voluntarily made. The FSANZ pre-approved list of food-health relationships which FSANZ will keep adding to will provide industry with a ready list of relationships from which to derive GLHC, and they can do this at little risk because of the certainty that FSANZ pre-approval provides. Where food businesses seek a new food-health relationship, they will have the choice of making applications for new food-health relationships on a paid or unpaid basis. Where favourable market conditions prevail and where innovative products are available, food businesses can maximise their revenue through fast-tracked paid applications and a confidential process.

Option 3 combines the features and benefits of options 1 and 2, including the benefits of access to a range of pre-approved food health relationships with an improved application process for new food-health relationships, as well as the flexibility and marketing advantage of self-substantiation. Overall option 3 is likely to deliver financial greater benefit to food businesses.

Option 1 is certain to impose costs and administrative burdens on **jurisdictions** and has the potential to create issues regarding their ability to deliver on the compliance role expected of them. These cost burdens could be significantly reduced in practice both by options 2 and 3, depending on the extent to which industry adopts self-substantiation. Both options provide jurisdictions with a high degree of certainty with regard to compliance-monitoring, because FSANZ pre-approvals provide a reference point with regard to GLHC and reduce the level of risk for jurisdictions or inconsistencies across jurisdictions. The adoption of a centralised list of self-substantiated food-health relationships will contribute towards this.

The direct benefit arising out of **consumer** confidence would appear to be maximised under option 2. Because it provides a more robust regulatory framework and gives consumers the certainty and confidence that health claims have valid underpinning food-health relationships.

For consumers option 3 (like option 1) presents a level of risk because there is the possibility that food businesses may not apply the same level of evidence as FSANZ does for pre-approval. However with a significant level of detail in the Standard on the substantiation process to be used, the need for food businesses to notify FSANZ of a self-substantiated food-health relationship and providing industry with extensive guidance on the requirements for self-substantiation, safe-guards have been built into this approach to minimise the level of risk, especially when compared with the expected benefits.

Moreover this can be achieved without compromising on compliance. Jurisdictions are expected to achieve this by carrying out co-ordinated surveys across states and territories, as well as by responding to complaints. Jurisdictions will benefit from improved regulatory certainty of pre-approved food health relationships included in the Standard, although enforcement resources will be required to evaluate a reduced number of self-substantiated claims.

The risk element for consumers in option 3 may be greater than option 2 but less than option1. Further, as option 3 is supportive of innovation, consumers may gain additional benefit from an increased number of food products with healthy attributes and health claim labels, and this may deliver additional consumer benefits.

FSANZ may incur some costs associated with assessing applications under both options 2 and 3 as well as by having to include food-health relationships based on overseas approvals.

Table 5: Summary of benefits and costs across the three options for GLHCs

Stakeholder group	Option 1 (self-substantiation)	Option 2 (pre-approval)	Option 3 (pre-approval plus self-substantiation)
Large Enterprises	Provides greater flexibility Can go to market at a time they determine	Possible delays in getting product to market.	Provides greater flexibility Can go to market at a time they determine avoiding possible delays
Small & Medium Enterprises	Lack of capacity to research and develop food-health relationships. Limited number of relationships/claims in the Standard to draw on	Benefit from increasing number of food-health relationships approved by FSANZ on which to draw cost-free.	Benefit from increasing number of food-health relationships approved by FSANZ on which to draw cost-free.
Consumers	Not have assurance that food-health relationships have been approved by a regulatory agency.	Greater certainty that GLHC have been approved by a regulatory agency.	Will not have the same level of certainty that all GLHC have been approved by FSANZ. However, greater certainty exists compared with option1.
Jurisdictions	Require technical staff with scientific expertise to review industry dossiers.	Will not incur costs of reviewing industry dossiers.	Will have costs around enforcement of GLHC based on self-substantiated food-health relationships. However, costs are likely to be lower than those for option 1.
FSANZ	Would not incur costs in having to pre-approve food-health relationships.	Would incur costs in having to pre-approve food-health relationships.	Would incur costs in having to pre-approve food-health relationships. However, costs are likely to be lower than those for option 2.

6 Consultation and communication

Throughout the review process, FSANZ has consulted with key stakeholder groups on the approach for the regulation of GLHC. FSANZ undertook targeted briefings of key stakeholder groups (Australia Food and Grocery Council, New Zealand Food and Grocery Council, public health and consumer peak bodies) in November 2011 to discuss the revised pre-approval approach for the regulation of GLHC.

In February 2012 FSANZ prepared a further paper on the proposed revised draft Standard for public consultation. Issues pertaining to the RIS that were raised by stakeholders in their submissions in response to this consultation paper are shown in the following Table 6.

Feedback from consultations indicated that consumer groups and enforcement agencies support the pre-approval option for GLHC. Industry submitters however expressed concern over the cost of the application process, the impact on existing claims in the market and a perception that in option 2 moving from self-substantiation to pre-approval would result in the substantiation bar being raised.

In response to these concerns, FSANZ requested that CIE undertake additional sensitivity analysis which has shown that only a very skewed or extreme set of factors, which are not the norm, will result in a net cost, even if option 2 were adopted (Attachment 6.2 to SD6).

Targeted industry consultation on the revised CBA was also carried out during April 2012, covering industry apex groups.

In August 2012, as option 3 was being developed, stakeholder forums were undertaken both in Australia and New Zealand. The feedback from these sessions was incorporated in the revised approach and appears in section 5.4 above. There was a general recognition that option 3 with self-substantiation, could meet the key concerns of stakeholder groups.

FSANZ will be providing guidance to industry on substantiation requirements and has clarified that these requirements are the same for both pre-approval and self-substantiation. FSANZ will consult further as guidance is being developed.

FSANZ will also adopt a process of assessing new food-health relationships which would benefit industry e.g. food-health relationships approved overseas.

Additionally FSANZ is proposing a lengthened transition period (three years) to provide further time for industry to comply with the new Standard which will likely result in reduced costs from labelling changes.

FSANZ will develop and implement communication strategies for the education of consumers and industry about the new Standard, including web material. This material will be updated should the Standard be amended. FSANZ also has a Code Enquiry Unit that will be ready to respond to enquiries from the public.

Table 6: Summary of stakeholder views relating to the RIS in response to the February 2012 consultation paper

Issues Raised	Response
Industry:	
• Innovation discouraged by pre-approval • Level of substantiation for GLHC inappropriate • Oppose pre-approval of GLHC • Support self-substantiation • Scientifically substantiated claims not permitted • Include self-substantiation as an option • Support pre-approval as being practical • Concerned about level of substantiation required • Meeting this level will impact on innovation	• In general most of these concerns have been addressed by considering option 3 which allows for both self-substantiation and pre-approval of GLHC
• Concerned about confidentiality of claims	• Applications can be considered confidentially using HLHC variation process
• Should make use of claims approved by the European Food Safety Authority • Approved claims from overseas not included.	• Claims adopted overseas to be considered and adopted, as appropriate.
• Process, timing and level of evidence unclear	• FSANZ will be providing guidance to industry on substantiation requirements.
• Code of practice for GLHC preferred	• Decision to regulate adopted at final assessment
Jurisdictions:	
• Support pre-approval • Support industry self-substantiation • Concerned that a one-size-fits all approach will be applied to substantiation	• Both self-substantiation and pre-approval of GLHC included in option 3
• Include EU approved claims	• Claims adopted overseas to be considered and adopted.
Public health/consumers:	
• Strongly opposes health claims on food labels • Supports substantiation of claims	• Decision to regulate adopted at final assessment

7 Conclusion

While a net benefit in dollar terms can be established for option 1, it is not possible to express in dollar terms the net benefit provided by options 2 and 3.

We can however make an assessment, based partly on available quantitative data, and partly on the basis of qualitative reasoning, what magnitude of benefits each of the different options are likely to deliver.

The empirical evidence establishes that a regulatory system for GLHC is preferable to the prevailing status quo. The debate about choosing between an industry self-substantiation approach (option 1) and a FSANZ pre-approval approach (option 2), arises out of attempting to maximise the performance of the regulatory regime using different criteria based on stakeholder needs.

Option 1, self-substantiation, whilst representing a flexible approach to many in industry was seen as deficient because of concerns about enforceability, whether it provided sufficient assurances to consumers and resources required by jurisdictions for implementation. In order to address these issues FSANZ pre-approval (option 2) was offered as a means for GLHC substantiation. However, this approach was seen to be not providing flexibility and sufficient incentive for industry to innovate.

Therefore it has become necessary to move towards seeking an approach that enables all stakeholders to forego minor benefits to secure major benefits.

Option 3, through a combination of pre-approval and self-substantiation, seeks to retain as far as possible the benefits of both options 1 and 2. Option 3 delivers flexibility to industry players that have the capacity to undertake the science needed to self-substantiate, and provides the certainty of pre-approved food-health relationships that benefits jurisdictions, consumers and smaller enterprises. While there is some potential detriment resulting from lesser certainty of self-substantiated food health relationships, this will be mitigated through including self-substantiation requirements in the Standard, requiring pre-market notification of a self-substantiated food-health relationship and providing extensive guidance on the requirements for self-substantiation. Option 3 endeavours to maximise the total benefit to the community without seriously disadvantaging any one stakeholder group.

Because option 3 safeguards the flexibility that industry, particularly large enterprises, requires to minimise business risks, it promotes innovation. It can therefore be argued that while it is possible consumers may lose some benefits in relation to confidence they have in GLHC, they may gain some benefit from the increased incentive industry may have to innovate.

Option 3 therefore maximises the community's net benefit because in addition to delivering a high degree of flexibility it also ensures an adequate element of certainty that translates into trust for both consumers and jurisdictions. The latter contributes to ease of enforcement, while imposing some costs on jurisdictions.

Overall option 3 minimises costs to the community and maximises net benefits. It achieves this by being the option that delivers an aggregate high on flexibility, certainty, cost reduction and ease of enforcement. Hence option 3 is the preferred option.

Because of the time lag between the completion of the Final Assessment Report in 2008, and the finalisation of the review report, a re-examination of the cost-benefit outcomes and a revision of the RIS have been deemed necessary. Industry consultation has occurred throughout the review and submissions have been taken into account by both CIE and FSANZ.

The updated cost-benefit analysis (based on industry self-substantiation, as at final assessment) indicated that the overall net benefit of Standard 1.2.7 could be in the region of A$84 million in today's prices. We consider that with the addition of FSANZ pre-approved food-health relationships to Standard 1.2.7, thereby enabling industry to be able to derive general level health claims from either self-substantiated or pre-approved food-health relationships, and the extension of the transition period to three years, the overall net benefit of Standard 1.2.7 is likely to be more favourable than that estimated for Standard 1.2.7 when food-health relationships could only be self-substantiated.

8 Implementation and review

The Implementation Sub Committee is developing guidance documents to support the implementation of the new Standard and expects to have these documents available upon or soon after gazettal of Standard 1.2.7. FSANZ is preparing an Explanatory Memorandum as well as providing guidance regarding substantiation for those adopting self-substantiation. This will assist industry, enforcement agencies and other stakeholders with the implementation of this Standard.

The ministerial policy guidance foreshadows a review of the nutrition, health and related claims system within two years of implementation of Standard 1.2.7. In response to submitter comments, the proposed transition period has been increased from two to three years. This three year transition period for Standard 1.2.7 (with no additional stock-in-trade period) will provide an extended period of time for industry to align themselves and their processes, to the health and nutrition labelling regime.

9 Fat-free claims

At its meeting in December 2011, the Forum asked FSANZ to consider the regulation of fat-free and % fat-free claims due to concerns about the potential for consumers to be misled by these types of claims. There was a view that certain products carrying such claims were otherwise high in sugar and energy but that consumers might be misled into thinking fat free or % fat free claims were indicative of low energy foods or healthier food choices.

In response to this request, FSANZ released a consultation paper in February 2012 seeking comments on three options:

- status quo (regulation of % fat-free claims as proposed in the FAR)
- voluntary action through a code of practice
- additional regulation (approaches presented included prohibition of fat-free and % fat-free claims via the application of the nutrition profiling scoring criteria, a sugar concentration threshold or definition of specific food categories, or the use of a disclaimer on foods above a sugar concentration threshold).

Of the 62 submitters who commented on the fat-free issue, 30 supported the status quo (industry and some jurisdictions), 24 submitters supported additional regulation for the claims (public health, consumers and some jurisdictions) and eight submitters supported voluntary action through a code of practice (industry, therapeutic agencies, private and media stakeholders).

The key reasons given by submitters for supporting the status quo included the lack of evidence of a problem, possible inconsistency with considering fat-free and % fat-free claims and not other fat-related claims such as 'low-fat', voluntary action by confectionery manufacturers to remove fat-free claims from over 80% of the confectionery market, and that front-of-pack labelling currently under development may affect industry use and consumer understanding of the claims.

In contrast, key reasons provided by submitters for supporting additional regulation included reference to evidence that suggests 'fat-free' claims on 'less healthy' foods are misleading and a general desire for additional regulation of all foods carrying nutrition content claims.

FSANZ commissioned a literature review on consumer use and understanding of fat-free claims on foods of 'lower nutritional quality'. This review of the peer-reviewed literature identified very few studies directly relevant to any of the research questions.

While the review indicates that % fat-free claims are capable of influencing some consumers perceptions of the healthiness or energy content of foods, there is very little evidence of consumers being misled by fat-free claims on foods of 'lower nutritional quality'. There are no reported studies investigating the impact of fat-free claims on consumer purchase behaviour in relation to high sugar foods or on whether fat-free claims cause substitution behaviour whereby consumers may purchase foods of lower nutritional quality in place of foods of higher nutritional quality.

9.1 Cost-benefit analysis

FSANZ also commissioned a CIE report on the impact of possible additional regulation of fat-free claims on the CBA prepared in 2008 at final assessment (Attachment 6.3 to SD6). It was found that the impact is dependent on the approach taken. If a 30 per cent sugar concentration threshold was applied to either prohibit claims or require a disclosure statement, it was estimated that the net benefit of Standard 1.2.7 would decline by A$5 million, with the possibility of industry costs rising to around A$52 million should industry make more than label changes if claims were prohibited above the sugar concentration threshold. If foods not meeting the nutrient profiling scoring criterion were prohibited from carrying the fat-free claims, it was estimated that costs to industry would be around A$126 million, resulting in a net cost for the nutrition and health claims Proposal.

9.2 Conclusion

Following the evaluation of all available information and submissions received, FSANZ is recommending deferral of the consideration of further regulation of 'fat-free' and '% fat-free' claims on the following grounds:

- lack of evidence that consumers are misled as few studies about the impact of fat-free claims on consumer purchase decisions have been reported
- consideration of additional regulation for only selected fat related nutrition content claims could result in an inconsistent approach to regulation
- all proposed regulatory approaches present technical implementation difficulties and potentially undesirable consequences
- an evaluation of the impact of additional regulation on the CBA prepared in 2008 indicates that the regulatory approach most favoured by public health, consumer and some government submitters — the application of the nutrient profiling scoring criterion — would result in significant costs for industry that would lead to an overall net loss to the community upon implementation of Standard 1.2.7

- a front-of-pack labelling scheme is currently being considered as part of the government's response to *Labelling Logic*. If a decision is made to proceed with such a scheme it may have an impact on industry use and also consumer understanding of claims, and address the concern that has been raised
- the confectionery industry peak body submission advised that this industry is taking voluntary action to remove fat-free claims and indicates that it will apply to approximately 80% of the confectionery market. A delay in considering further regulation will allow industry time to implement and for government to evaluate whether further regulatory action is warranted.

The ministerial policy guidance foreshadows a review of the nutrition, health and related claims system within two years of implementation of Standard 1.2.7. Therefore, FSANZ proposes that consideration of the regulation of fat-free claims be deferred until this review. This will enable any impact of industry voluntary action, front-of-pack labelling and implementation of Standard 1.2.7 as a whole, on fat-free claims to be considered.