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

12/03
8 October 2003

DRAFT ASSESSMENT REPORT

PROPOSAL P264

REVIEW OF GLUTEN CLAIMS WITH SPECIFIC REFERENCE TO OATS AND MALT

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
19 November 2003
(See 'Invitation for Public Submissions' for details)

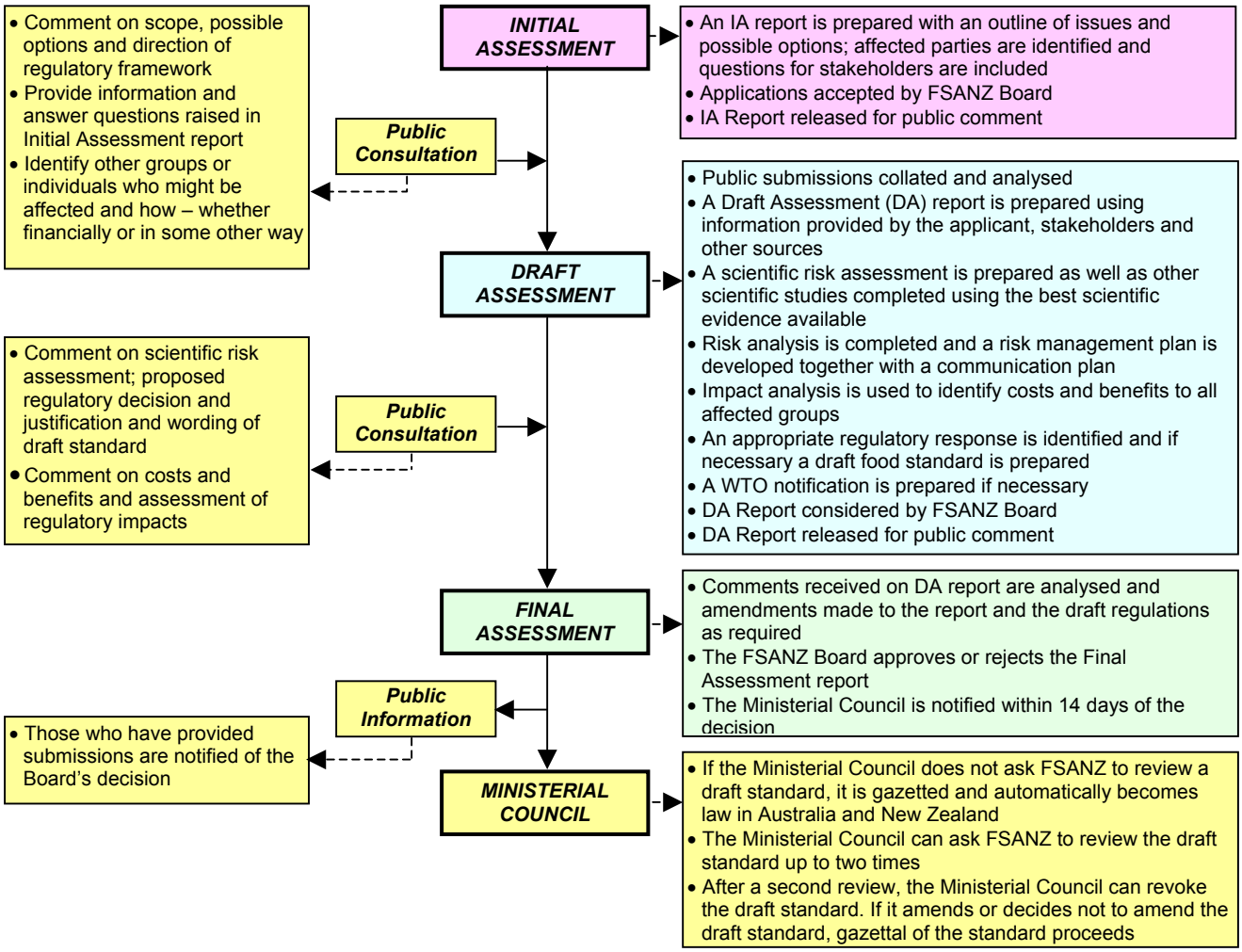
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has prepared a Draft Assessment Report of Proposal P264 and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

The Authority invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the *Australia New Zealand Food Standards Code* for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this proposal. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards Code* from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by the Authority **by 19 November 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

Further Information

Further information on this Application / Proposal and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

Food Standards Australia New Zealand
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CONTENTS

Executive Summary and Statement of Reasons

Current Regulations

Gluten claims are currently regulated in clause 16, Standard 1.2.8 – Nutrition Information Requirements in the *Australia New Zealand Food Standards Code* (the Code). Under the current regulations, a food containing oats and/or malt is unable to carry a claim in relation to the gluten content of the food, even if it meets the general criteria for *gluten free* or *low gluten*. In addition, clause 4, Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations requires that cereals containing gluten and their products, namely wheat, rye, barley, oats and spelt and their hybridised strains must be declared on the label if present in a food. The specific prohibition of gluten claims on foods containing oats or malt was introduced due to the unreliability of the methods of analysis available to detect the gluten equivalent fractions in oats and malt that may be toxic to individuals with Coeliac disease.

Regulatory Problem

The current regulations in Standard 1.2.8 in relation to gluten claims are unclear. Specifically, the question has arisen as to whether the prohibition of gluten claims on foods containing 'oats or malt', as listed in paragraphs 16(2)(b) and 16(3)(b) of Standard 1.2.8, also includes the 'products of oats or malt'. If this is the case, then to what level of refinement should they be included?

Ingestion of gluten in foods by a person with Coeliac disease may result in weight loss, chronic diarrhoea, chronic anaemia, tiredness, vomiting, abdominal distension, mouth ulceration, constipation and other symptoms. Treatment of Coeliac disease is undertaken by a lifelong elimination diet in which foods containing gluten are avoided. The consequences of not adhering to a gluten free or low gluten diet (depending on the individual's sensitivity) are potentially life threatening in the long term. However this can vary, with the majority of people with Coeliac disease having some level of intervention to assist in the management of the condition.

Objective of P264

The objective of this review is to determine whether to retain the prohibition of gluten claims on foods containing oats or malt and if so, to determine whether to extend the prohibition to foods that contain oats or malt 'and their respective products'.

The specific objectives for this Proposal are:

- the protection of public health and safety by ensuring that the regulation of gluten claims accurately reflects current scientific evidence regarding the relationship between oats, malt and Coeliac disease; and
- the provision of adequate information in order for consumers to make appropriate food choices for their level of gluten intolerance.

Consultation / Key Issues for Consideration

To date, consultation on P264 has included public consultation on the Initial Assessment Report (IAR) as well as consultation with the External Advisory Groups (EAGs). A total of 19 submissions were received in response to the IAR. Key issues that have been considered during consultation to date are further considered in this Draft Assessment Report (DAR) and include: the ability to detect gluten in oats and malt; the toxicity of oats in individuals with Coeliac disease; and the toxicity of malt in individuals with Coeliac disease. In relation to these issues, the consultation process indicates that:

- Current analytical testing methods, enzyme-linked immunosorbent assay (ELISA) tests, are able to detect wheat gliadins and rye secalins, however they have limited reactivity to barley hordeins and fail to detect oat avenins.
- The detection of gluten in malt is unreliable as barley hordeins are not well detected and the concentration of prolamins present in malt and malt ingredients is likely to be very low.
- Other methods are available to detect the presence oat avenins, however, these methods may not be as readily accessible to food manufacturers as an ELISA test.
- While scientific evidence suggests that the majority of Coeliacs can safely consume a moderate amount of oats as part of a gluten free diet, Australian and New Zealand health professionals are clearly divided on this issue.
- Similarly, opinion is divided amongst experts in terms of the extent to which malt causes an adverse reaction in individuals with Coeliac disease.

Regulatory Options

Three regulatory options are proposed as follows:
Option 1: Maintain the status quo and retain the specific prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt.
Option 2: For *gluten free* claims – extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and for *low gluten* claims – remove the prohibition of *low gluten* claims on foods containing oats or malt.
Option 3: For *gluten free* claims – extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and for *low gluten* claims – remove the prohibition of *low gluten* claims on foods containing oats or malt but require an advisory statement to the effect that the product contains oats or malt and may not be suitable for the most sensitive Coeliacs.

Preferred Option

The impact analysis indicates that Option 2 is the preferred option for the regulation of gluten claims. This option provides a high level of protection of public health and safety for the most sensitive Coeliacs when purchasing *gluten free* foods. At the same time, the removal of the prohibition of oats and malt on *low gluten* claims allows an appropriate level of protection of public health and safety for less sensitive Coeliacs who are able to tolerate small amounts of gluten in the diet, including gluten from oats or malt.

Statement of Reasons

- It is recommended that the most appropriate regulatory option with which to proceed is that Clause 16, Standard 1.2.8 – Nutrition Information Requirements be amended as follows: 1) extend the prohibition of *gluten free* claims to foods such that the criteria for making a *gluten free* claim will include no detectable gluten; and no oats or malt; and no products of oats or malt; and 2) remove the prohibition of *low gluten* claims on foods containing oats or malt such that the maximum level of 20 mg gluten per 100 g is the sole criterion for making a *low gluten* claim.

- Current ELISA tests for gluten have limited reactivity to barley hordeins and are unable to detect oat avenins. The detection of gluten in malt is unreliable as barley hordeins are not well detected and the concentration of prolamins present in malt and malt ingredients is likely to be very low. Other methods are available to detect the presence of oat avenins, however, these methods may not be as readily accessible to food manufacturers as an ELISA test. The proposed amendment takes into consideration current testing methods to detect gluten in oats and malt.

- Australian and New Zealand health professionals are divided on the issue of the toxicity of oats and malt in individuals with Coeliac disease. New Zealand health professionals consider that small amounts of oats and malt can be consumed by people with Coeliac disease. Conversely, Australian health professionals believe that there are some people with Coeliac disease that are unable to tolerate even the smallest amounts of oats and malt. The proposed amendment takes into consideration the opposing views of Australian and New Zealand health professionals in terms of the toxicity of oats and malt and the dietary management of Coeliac disease.

- By making the current prohibition on *gluten free* claims on oats or malt more stringent by extending the prohibition to include products of oats or malt, this option promotes increased protection of public health and safety for the most sensitive Coeliacs when purchasing foods carrying a *gluten free* claim.

- Standard 1.2.3 requires the mandatory declaration of cereals containing gluten and their products in addition to any gluten claims. Given this, it is considered that the removal of the prohibition of *low gluten* claims on oats or malt allows for appropriate protection of public health and safety for less sensitive Coeliacs who are able to tolerate small amounts of gluten in the diet, including that from oats and malt but also provides a greater choice of suitable foods for this group of people. Option 2 allows the majority of people with Coeliac disease a broader diet and therefore provides significant increased net benefits to consumers.

- FSANZ considers that the proposed amendment is the most appropriate approach to the regulation of gluten claims. It meets the objectives to protect the public health and safety of individuals with Coeliac disease and to provide adequate information so that consumers can make appropriate food choices for their level of gluten intolerance. On balance, this approach also meets the needs of stakeholders in both Australia and New Zealand.

1. Introduction

P264 considers the need to amend Standard 1.2.8, clause 16 to clarify the intent of the Standard, as at present it is ambiguous; and to ensure that in providing protection for consumers with gluten intolerance, that scientific evidence is reflected both in terms of both the toxicity of specific cereals and current analytical methodology for detecting gluten in foods.

Specifically, P264 seeks to:

- determine whether to retain the prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt in Standard 1.2.8, clause 16; and if so,
- to determine whether to extend the current prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt to foods that contain oats and malt 'and their products'.

In this proposal, it is not intended to reassess the regulation of *gluten free* and *low gluten* claims broadly. This issue, in particular the need for two levels of gluten claims was considered in detail as part of Proposal P176 - Review of Provisions for Gluten Free and Low Gluten Foods, during the review of the Code.

2. Regulatory Problem

The current regulations in Standard 1.2.8 in relation to gluten claims are unclear. Specifically, the question has arisen as to whether the prohibition of gluten claims on foods containing 'oats or malt', as listed in paragraphs 16(2)(b) and 16(3)(b) of Standard 1.2.8, also includes the 'products of oats or malt'. If this is the case, then to what level of refinement should they be included?

2.1 Current labelling regulations relevant to P264

2.1.1 Standard 1.2.8

Clause 16 of Standard 1.2.8 sets out the conditions for making claims in relation to the gluten content of a food. Under subclause 16(2) a *gluten free* claim can be made if the food contains no detectable gluten and no oats or malt. Under subclause 16(3), a *low gluten* claim can be made if the food contains no more than 20 mg gluten per 100 g of the food and no oats or malt. Where a claim is made in relation to the gluten content of a food, the nutrition information panel must include the average quantity of gluten per serving of the food and in the unit quantity of the food (ie per 100 g or 100 mL). Any claims in relation to the gluten content of food are voluntary.

International regulations relevant to this Proposal are provided at Attachment 2.

2.1.2 Standard 1.2.3

Clause 4, Standard 1.2.3 requires that cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains must be declared on the label at all times when present in a food as an ingredient, an ingredient of a compound ingredient, a food additive or a processing aid. The term 'and their products' includes all products

derived from the gluten containing cereals, regardless of whether they contain allergenic protein. This declaration is required in addition to any claims that may be made in relation to the gluten content of the food.

The implication of Standard 1.2.3 for consumers is that they do not need to rely solely on the use of *gluten free* or *low gluten* claims on the label in order to make a decision about the suitability of a particular product. Both the ingredient list and the claim can be used to inform purchasing choices.

2.1.3 Therapeutic Goods Order No 69

Under Therapeutic Goods Order No 69, the term *gluten free* may be used on labels of medicines if the product contains no detectable gluten and no oats or malt. This is consistent with the requirements of subclause 16(2), Standard 1.2.8.

2.2 Risk to individuals with Coeliac disease

Ingestion of gluten in foods by a person with Coeliac disease[1] may result in weight loss, chronic diarrhoea, chronic anaemia, tiredness, vomiting, abdominal distension, mouth ulceration, constipation and other symptoms. Treatment of Coeliac disease is undertaken by a lifelong elimination diet in which foods containing gluten are avoided. The consequences of not adhering to a 'gluten free' or 'low gluten' diet (depending on the individual's sensitivity) are potentially life threatening in the long term. However this can vary, with the majority of people with Coeliac disease having some level of intervention to assist in the management of the condition.

3. Objective

This is the second phase of the review of Gluten Claims with Specific Reference to Oats and Malt. The DAR has been prepared to discuss potential solutions to the issues raised in the IAR and the comments made by submitters. The DAR aims to encourage and facilitate further public comment on the regulatory framework proposed in this report as a workable option for gluten claims that meets FSANZ's objectives.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

[1] Where the term Coeliac disease is used in this paper, it also refers to Dermatitis Herpetiformis unless otherwise stated.

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objectives for this Proposal are:

- the protection of public health and safety by ensuring that the regulation of gluten claims accurately reflects current scientific evidence regarding the relationship between oats, malt and Coeliac disease; and
- the provision of adequate information in order for consumers to make appropriate food choices for their level of gluten intolerance.

In determining if a public health and safety risk exists, FSANZ will give due regard to the need for standards to be based on risk analysis using the best available scientific evidence.

4. Background

4.1 Gluten and Coeliac disease

The strict chemical definition of gluten is the rubbery mass that remains when wheat dough is washed to remove starch granules and other soluble constituents (Wieser, 1995). The term 'gluten' has now been extended to include all those proteins that are deleterious to individuals with Coeliac disease and other gluten sensitive disorders (Buttriss, 2002). The latter use of the term is consistent with the definition of gluten in clause 1, Standard 1.2.8 of the Code, which defines gluten as "the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions, Coeliac disease and dermatitis herpetiformis". Buttriss (2002) also describes gluten as a combination of proteins that are soluble in dilute ethanol solution: the prolamins, with those that are insoluble: the glutelins.

As discussed by Picarelli et.al (2001), cereals are divided into four major groups, one of which is the Pooideae group. The Pooideae group comprises 2 subgroups: Triticum (wheat, rye, barley) and Avena (oats). The constituents of wheat (gliadin), rye (secalin), barley (hordein) and oats (avenin) that are injurious to Coeliac disease patients are the alcohol-soluble protein fractions known as prolamins (Picarelli, 2001). As discussed by Janatuinen et al (1995), the prolamins in wheat, rye, and barley constitute 40-50%, 30-50%, and 35-45% of total proteins respectively, but in oats, they constitute only 10-15%. Given that wheat, rye and barley are members of the Triticum subgroup and oat is a member of the Avena subgroup, avenin is genetically less like gliadins than are secalin and hordein. Despite this greater difference, sequence homologies (and weak immunological cross reactivity) have been found between avenin and the prolamins from barley, wheat and rye (Schmitz, 1997).

Many cereals contain small amounts of peptides suspected to be toxic to the small-intestinal mucosa of patients with Coeliac disease (Shewry, 1992). These possible toxic constituents of cereal prolamins consist of the amino acid sequence proline-serine-glutamine-glutamine or glutamine-glutamine-glutamine-proline, according to in vitro studies of biopsy specimens of jejunal mucosa (Shewry, 1992). One molecule of wheat prolamin (gliadin) contains 5 sets of these sequences; one molecule of barley (hordein) and oats (avenin) contains 2 sets; and one molecule of maize (zein), none (de Ritis, 1988).

When consumed, the amino acid sequences trigger histologic changes to the small intestinal

mucosa that can lead to the malabsorption of nutrients. Other conditions that are associated with Coeliac disease have been addressed in Section 5.4.

4.2 The regulation of gluten claims

4.2.1 Proposal P176 – Review of Provisions for Gluten Free and Low Gluten Foods

The provisions for *gluten free* and *low gluten* claims were considered in 1999 under Proposal P176 - Review of Provisions for Gluten Free and Low Gluten Foods, during the review of the Code.

Prior to P176, the criteria for making *gluten free* and *low gluten* claims in the Australian Code were similar to the current regulations in Standard 1.2.8, although there was no prohibition on malt. However, under the *New Zealand Food Regulations* 1984, where a food contained ingredients derived from a gluten-containing cereal, a *gluten free* claim was permitted, providing the nitrogen content of these ingredients did not exceed 0.05%. There was no specific prohibition on oats or malt in making a *gluten free* claim.

As a result of P176, provisions regarding the regulation of claims in relation to the gluten content of a food were included in Standard 1.2.8 of the Code. Clause 1, Standard 1.2.8 defines gluten as 'the main protein in wheat, rye, oats, barley, triticale and spelt relevant to the medical conditions, Coeliac disease and dermatitis herpetiformis'. Under clause 16 of Standard 1.2.8 a *gluten free* claim can be made if the food contains no detectable gluten and no oats or malt. Under food law and fair trading laws claims should not be false, misleading or deceptive. Therefore, to permit a food to be called *gluten free* when the food contains detectable gluten was not considered appropriate, as such a claim would be false.

In accordance with Standard 1.2.8, subclause 16(3), claims that a food has a *low gluten* content should not be made unless the food contains no more than 20 mg gluten per 100 g and no oats or malt. As part of P176, it was recognised that the level of 20 mg/100 g food was accepted internationally by the medical profession to be tolerated by the majority of people with Coeliac disease.

As part of P176, a separate prohibition on oats and malt in relation to gluten claims was introduced at paragraphs 16(2) and 16(3) of Standard 1.2.8. This prohibition means that even if foods containing oats or malt are eligible to carry a *gluten free* or *low gluten* claim by meeting the criteria at paragraphs 16(2) or 16(3), they would remain ineligible to make such a claim. The prohibition on oats and malt was introduced as the methods of analysis that were available to detect gluten at that time, were not considered to be reliable for regulatory purposes when it came to detecting the gluten equivalent fractions of oats and malt that may be toxic to people with Coeliac disease.

4.2.2 Proposal P254 – Minor Omnibus Amendments to Volume 2 of the Code

In August 2001, the former Australia New Zealand Food Authority (ANZFA) (now FSANZ) was asked to clarify whether the prohibition of oats and malt in relation to gluten claims also applied to oats and malt products. Based on the unreliability of analytical methods, ANZFA considered that oats and malt products should also be included in the prohibition. A proposed amendment to clause 16, Standard 1.2.8 to that effect was included in Proposal P254, Minor Omnibus Amendments to Volume 2 of the Code.

In response to the P254 DAR eight submissions were received. Six submissions were from New Zealand medical and health professionals and government organisations, and all expressed strong opposition to the proposed amendment. Two submissions were from Australian analytical laboratories and provided comment on the analytical methods.

4.2.3 Proposal P264 – Review of Criteria for Gluten Claims with Specific Reference to Oats and Malt

Given the feedback received in response to P254, FSANZ considered it important to extensively review aspects of clause 16, Standard 1.2.8 to ensure that the regulation of gluten claims was in line with the most up to date scientific evidence with regard to gluten intolerance and the analytical methodology for the detection of gluten. Therefore, the proposed changes to clause 16, Standard 1.2.8 were removed from P254 and a new Proposal, P264 - Review of Criteria for Gluten Claims with Specific Reference to Oats and Malt was raised.

In recognition of the specialized nature of the issues covered by this Proposal, FSANZ has established two External Advisory Groups (EAGs). The first of these, the Analytical Methodology EAG, consists of experts in the areas of analytical testing for the detection of gluten, while the second group, the Dietary Management EAG, consists of experts in the dietary management of Coeliac disease. A list of members of the EAGs is at Attachment 3. A teleconference and a face-to-face meeting have been held with the EAGs to address a range of key issues and the information obtained has been incorporated into the discussion of the issues below.

5. Relevant Issues

5.1 The detection of gluten in cereals

To manage the gluten content of the diet of people with Coeliac disease, most of the immunological methods employed, for example ELISA tests, are currently based on antibodies which recognize mainly wheat gliadins and rye secalins. These tests recognize barley hordeins (including those in malt and malt ingredients) to a much lesser extent, whereas they fail to detect oat avenins (Camafeita 1998).

The predominant ELISA test used in Australia and New Zealand is the Tepnel BioSystems Gluten Assay. It is designed for the detection of bread wheat gluten, but also has good reactivity to durum wheat, triticale and rye. It has a much lower reactivity to barley and no reactivity to oats. The Analytical Methodology EAG advised that the ELISA tests look for a specific sequence of amino acids rather than protein per se and that the Tepnel Biosystems Gluten Assay Kit's lowest limit of detection for gluten is 20 ppm (0.002%).

Several submitters commented that the Tepnel BioSystems Gluten Assay is most commonly used to measure gluten in foods, however, it was noted that this test has limited or no reactivity to oat avenins or barley hordeins. Two submitters commented that modern immuno-chemical methods for identifying wheat protein (and perhaps other cereal protein) in foods are inadequate and that satisfactory analytical methods based on the sensitising peptides are not yet available. It was also acknowledged by an international submitter that the Codex review of gluten standards has been held at step 7 for this reason.

5.1.1 The detection of gluten in oats

Oats come from a different taxononomic family to wheat, barley and rye and their main storage proteins are avenins. Although ELISA tests can detect wheat gliadins, rye secalins, and to a lesser extent barley hordeins, they do not detect oat avenins. Avenins have some of the same amino acid sequences (which contribute to the whole protein) as gliadins, as discussed in Section 4.1, and it is thought that these sequences may induce a response experienced by someone with Coeliac disease who has consumed oats. As it is not conclusive as to which part of the oat protein (if any) triggers a reaction in Coeliac patients, there is still no simple, low cost test that measures the amino acid sequences or peptides from oats that may be deleterious to individuals with Coeliac disease.

Although ELISA tests do not measure oat avenins, HPLC is one technique that will measure oat avenins when present. HPLC involves a two-stage process to detect oat avenins: an initial extraction of protein; and then subsequent quantitation of avenins if they are present. The method that is used by the New Zealand Institute for Crop and Food Research is Reverse Phase High Performance Liquid Chromatography (RP-HPLC) (Lookhart & Peterson, 1994). Unlike ELISA tests which react to a specific amino acid sequence, HPLC separates out each avenin and measures the actual amount of each avenin present, the physical quantity, which may be expressed as a percentage or a weight ratio (eg ug/g). As different HPLC techniques vary in sensitivity, an estimate of the level of detection of avenins using HPLC is 50 ppm (5 mg/100 g) (Simmons, personal communication). Given that HPLC is a more complex process that relies on the use of specific analytical equipment rather than a testing kit that can be purchased, it may be more expensive and not as readily accessible to food manufacturers as commercially available test kits such as the ELISA test.

5.1.2 The detection of gluten in malt

There are two issues relating to the ability to detect gluten in malt derived from barley. Firstly, the prolamin in barley, hordein is not well detected by ELISA tests, and secondly, the concentration of prolamins present in malt and malt ingredients is likely to be very low. Given this, the detection of gluten in malt is considered to be unreliable.

5.2 Toxicity of oats in individuals with Coeliac disease

5.2.1 Scientific Literature

A number of studies have reviewed the toxicity of oats in individuals with Coeliac disease. In a recent review of studies published since 1995, Thompson (2003) concludes that the body of research on oats supports the conclusion that most adults with Coeliac disease can consume moderate amounts of uncontaminated oats without causing damage to the intestinal mucosa. However, it is not known whether this is due to oats lacking in harmful amino acid sequences or due to those sequences occurring in small enough quantities so as to not cause a problem.

Thompson (2003) also notes some concerns with the methodologic limitations of some of these studies. One issue that was noted relates to the differences in the protein composition of oats versus that of wheat, rye and barley. Wheat, rye and barley prolamins account for 30% to 50% of total protein, whereas oat prolamins account for only 10% to 15% of total

protein. Therefore, it has been suggested that a far greater quantity of oats would have to be consumed to cause the same adverse effects as wheat, rye or barley.

In one of the most recent of such studies, Picarelli (2001) aimed to define the role of oats in Coeliac disease to determine whether oats can be safely included in a gluten free diet. The study design involved an in vitro model to test whether oats induced antiendomysial antibodies production in supernatant fluid from cultured duodenal mucosa specimens collected from 13 treated Coeliac disease patients. Antiendomysial antibodies are produced by intestinal mucosa and are highly sensitive and specific for Coeliac disease. The biopsy specimens were cultured with and without peptic-tryptic (PT) digest of gliadin and avenin (from oats) and in medium alone. Samples from 5 of the 13 patients were cultured with the C fraction of PT-avenin. Antiendomysial antibodies were detected in specimens from all 13 patients after the challenge with gliadin but not after culture with medium alone. By contrast, no antiendomysial antibodies were detected in any of the specimens cultured with PT-avenin and its C fraction. Given this, it was concluded that oats can be safely included in the gluten free diet of people with Coeliac disease.

In agreement, Janatuinen et al. (2002) aimed to assess the safety of long term ingestion of oats in the diet of Coeliac patients. In an initial study, the effects of a gluten free diet and a gluten free diet including oats were compared in a randomised trial involving 92 adult patients with Coeliac disease, with 45 in the oats group and 47 in the normal group. After 6-12 months, patients in the oats group were able to eat oats freely with an otherwise gluten free diet. After 5 years, 35 patients in the original oats group (23 still on an oats diet) and 28 in the control group on a conventional gluten free diet were examined (Janatuinen, 2002). Clinical and nutritional assessments were undertaken, duodenal biopsies for conventional histopathology and histomorphometry were examined and a number of antibodies were measured. The study found that there was no significant differences between the control group and those people consuming oats with respect to duodenal villous architecture, inflammatory cell infiltration of the duodenal mucosa, or antibody titres after five years of follow up. In both groups histological and histomorphometric indexes improved over time. It was concluded that both adults and children with Coeliac disease can use oats as part of an otherwise gluten free diet and that even long term use of moderate amounts of oats included in a gluten free diet in adult patients with Coeliac disease is safe.

Janatuinen (2002) suggests that the reason why individuals with Coeliac disease can tolerate oats is based on structural differences of proteins among oats, wheat, barley and rye. It is recognized that the injurious agent in wheat is the gliadins and it is possible that the absence of certain amino acid sequences from oat avenin that are found in wheat gliadin, make oats tolerable to people with Coeliac disease.

In addition, Janatuinen et al. (2002) recognizes that recent guidelines from the Finnish and the UK Coeliac Societies conclude that moderate amounts of oats can be consumed by most individuals with Coeliac disease without risk. The guidelines also suggest that removal of oats from the list of forbidden cereals in the diet for people with Coeliac disease could increase compliance with a gluten free diet by giving more choices and reducing the cost of gluten free foods.

5.2.2 Views of the External Advisory Groups

Consultations with the Dietary Management EAG on the issue of the toxicity of oats in

individuals with Coeliac disease revealed that opinion was divided. Although it was acknowledged that a number of studies have been published indicating that oats can be tolerated by many people with Coeliac disease, there was no overall agreement amongst members that this information is conclusive. Representative health professionals in New Zealand were of the view that the majority of Coeliac patients can tolerate some oats in the diet. However, representative Australian health professionals indicated that not all Coeliacs can tolerate oats, therefore the prohibition on oats in *gluten free* claims should be retained.

A further issue to be considered is the potential contamination of oats with protein from other sources such as wheat or barley. It has been suggested by the Analytical Methodology EAG, that contamination is rarely an issue with wheat, but is more likely with barley, with an estimated contamination level of 0.04 - 0.05%. Given this and assuming that there is 10% protein in the contaminant, the Analytical Methodology EAG, suggested that the gluten level in oats would be around 0.004-0.005%.

5.2.3 Submissions

Views were mixed amongst submitters to the P264 IAR in relation to the toxicity of oats, particularly in relation to whether there should be a specific prohibition of *gluten free* and *low gluten* claims on foods containing oats. Many submitters referred to recent studies indicating that the majority of people with Coeliac disease can tolerate oats, and that therefore there should not be a specific prohibition of gluten claims on foods containing oats in the Code. Others however, felt that while evidence is not absolutely conclusive, caution should be applied within the regulatory setting. The rationale provided for this approach included the following points:

- although studies found that the majority of people could tolerate oats, it was noted that the studies have limitations and that more work is required to resolve the issue;
- it was suggested that approximately 15% of Coeliac sufferers who ate oats reacted symptomatically and if the prevalence of Coeliac disease is 1:250-300, this represents a significant number of people who may react symptomatically to the presence of oats in foods labelled as *gluten free*; and
- the potential contamination of oats with barley or wheat presents a problem for people with Coeliac disease. Although studies have shown a certain degree of tolerance to oats amongst people with Coeliac disease, in many cases uncontaminated oats were used which do not necessarily represent the food supply where uncontaminated oats are less freely available.

In relation to the issue of contamination, the question was raised as to whether the risk of contamination with protein from other sources is an appropriate basis for excluding a significant cereal source from carrying a gluten claim? Further to this, one submitter made the point that there are no other provisions in the Code that regulate for cross-contamination during processing. It was stated that a consistent approach should be adopted throughout the Code and therefore it would seem unreasonable to continue to include a prohibition regulating for cross contamination or a 'may contain' type position.

5.3 Toxicity of malt in individuals with Coeliac disease

Malt is a dried, germinated grain, primarily derived from barley, although it may also be processed from other gluten containing cereals such as wheat. The malting process increases the soluble sugar content and gives a sweeter taste to the grain. The 'malt ingredients' primarily

used in food products (in order of refinement) are: malted flours; malt extract; malt vinegar and maltose.

Maltodextrin is not strictly a malt ingredient and is produced from wheat or maize starch by enzymatic processes that are different from a malting process. Malt is used as an ingredient in the production of beer, while malt extract is commonly used as a flavouring and toasting agent, for example, in breakfast cereals and beverages.

There is currently an issue around the toxicity of malt in people with Coeliac disease. Opinion is divided amongst experts in terms of the extent to which malt causes an adverse reaction in people with Coeliac disease. Some experts suggest that malt has a minimal effect while others report a detrimental effect, particularly those people with Coeliac disease who are more 'sensitive'.

A further issue is whether or not protein remaining from the malting process is present in the malt ingredient. According to the Analytical Methodology EAG, malt and malt extract generally contain some protein, however, if malt is used as an ingredient, it would be present in the food at a maximum level of 5%. It is not known whether malt vinegar contains protein, as it has not been detected when analysed using current testing methods.

There was some difference of opinion from submitters to the P264 IAR in relation to both the gluten content of malt as well as the toxicity of malt in individuals with Coeliac disease. Some submitters commented that malt extract will certainly contain hordeins (albeit at very low levels), while another submitter stated that if gluten in malt cannot be detected by currently accepted methods, then it most certainly would not contain gluten. However, as indicated previously, analytical experts agree that current ELISA tests have limited or no reactivity to barley hordeins.

In terms of the toxicity of malt and its products, two submitters commented that the consumption of gluten in malt and malt extract can cause symptoms in individuals with Coeliac disease, although these would generally be considered the more 'sensitive' cases as the amount of gluten present would be very small. Malt vinegar and maltose, which are more refined are less likely to contain the offending peptides.

It was also noted that the use of the term 'malt' needed to be clarified. Malt products can be obtained from a variety of cereals including wheat and rice, although barley is most common. Given that rice does not contain gluten, and gluten in malted wheat should be detectable by current testing methods, 'malt' in this context refers only to malted barley.

5.4 Risk to individuals with Coeliac disease

Coeliac disease is associated with a number of medical conditions such as neurological problems (Hadjivassiliou et al. 1996; Cooke & Smith, 1996), malignancies (Egan et al. 1995; Holmes et al. 1989) and a range of autoimmune diseases (Collin et al. 1994). Buttriss (2002) suggests that the most worrying disease association with Coeliac disease is malignancy; once gluten sensitivity is diagnosed, a strict gluten-free diet is the best insurance against malignancy.

Dermatitis Herpetiformis is a chronic skin disease characterised by small blisters, which are intensely itchy. It may be seen in association with Coeliac disease. A gluten-free diet often alleviates the symptoms, but medication may also be required.

In terms of the prevalence of Coeliac disease, based on information received from members of the P264 Expert Advisory Groups, it is estimated that the prevalence of Coeliac disease in Australia and New Zealand is approximately 1 in 250-300.

In terms of the level of public health risk within the group of the affected population with Coeliac disease, there appears to be a wide spectrum of sensitivity to gluten amongst individuals. Studies have indicated that there are some individuals who are unable to tolerate small, residual amounts of gluten present in some foods and strict adherence to a gluten free diet alleviates symptoms. However, for many other Coeliac patients, the inclusion of small amounts of gluten in the diet produces no adverse effects.

The exact proportion of the more 'sensitive' Coeliacs in Australia and New Zealand is unknown, however, based on a review of oat studies (Faulkner-Hogg, 2002) from the last decade, around 15% of individuals reported symptomatic reactions following the consumption of 50g uncontaminated oats per day. Additionally, a survey conducted by the NSW Coeliac Society with 965 respondents in 1995 found that 18.2% of individuals had some time previously made changes to their diet to exclude ingredients such as wheat starch and malt (ie a strict gluten free diet).

In terms of public health risk associated with individual behaviour, it has been noted by members of the EAGs and by submitters to the P264 IAR, that by either removing the prohibition of claims on oats and malt, or by making the prohibition on oats and malt more stringent by prohibiting claims on oats, malt and their products, an individual's purchasing patterns may be altered. It has been suggested that if the regulations are made more stringent by extending the prohibition to oats and malt and their products, that consumers will find their choice of foods so restrictive that they will become frustrated and choose foods outside the recommended range, which may cause adverse effects. Alternatively, many feel that by making the regulations less restrictive, it may result in greater compliance. As stated previously, the UK Coeliac Society guidelines suggest that removal of oats from the list of forbidden cereals in the diet for people with Coeliac disease could increase compliance with a gluten free diet by giving more choices and reducing the cost of *gluten free* foods.

6. Regulatory Options

6.1 Options provided in the Initial Assessment Report

The following regulatory options were identified in the Initial Assessment Report, however, these options have been refined after consideration of stakeholder views and are presented in Section 6.2:

Option 1. **Maintain the status quo and retain the specific prohibition of gluten free and low gluten claims on foods containing oats and malt.**
Under this option, if the food contains oats and/or malt, a 'gluten free' or 'low gluten' claim cannot be made even if the food contains no detectable gluten or no more than 20 mg gluten /100 g food, respectively.

Option 2. **Amend Standard 1.2.8 to remove the specific prohibition of gluten free and low gluten claims on foods containing oats and/or malt.**
Under this option, if the food contains no detectable gluten or no more than 20 mg gluten /100 g food, then claims of 'gluten free' and 'low gluten', respectively, can be made.

Option 3. Amend Standard 1.2.8 to retain the specific prohibition of gluten free and low gluten claims on foods containing oats and malt and extend it to include the products of oats and malt.
Under this option, if the food contains oats and/or malt, including derivatives of oats and/or malt, a 'gluten free' or 'low gluten' claim cannot be made even if the food contains no detectable gluten or no more than 20 mg gluten /100 g food, respectively.

The following section summarises comments from submitters in response to the three regulatory options proposed in the IAR.

6.1.1 Option 1 – Maintain the status quo and retain the specific prohibition of gluten free *and* low gluten *claims on foods containing oats or malt.*

One submitter favoured option 1, although considered that the situation should be reviewed if oats are demonstrated as suitable for Coeliac patients. They felt that no change should be considered for malt and malted products.

Another submitter recommended that Option 1 be retained with modifications so that foods containing no gluten but containing oats or malt could be labelled with 'may contain gluten'. In this way, consumers would be advised that the product may be suitable for those individuals who can tolerate small amounts.

6.1.2 Option 2 – Amend Standard 1.2.8 to remove the specific prohibition of gluten free *and* low gluten *claims on foods containing oats or malt.*

The majority of submitters favoured Option 2 for the following reasons:

- the level of detectable gluten should be the only acceptable criteria;
- recent information on the toxicity of oats suggests that they can be included safely in the diet of Coeliac patients;
- if cross contamination is a concern, then it is not appropriate to regulate for cross contamination as to do so, would set a precedent in the Code; and
- Option 2 is most consistent with the proposed Codex standard.

Two submitters opposed Option 2 on the basis that permitting oats or malt in gluten claims would compromise the health and well being of some Coeliac patients. Additionally, in view of the unreliability of testing methods, to label such products as *gluten free* would be false and misleading.

6.1.3 Variations on Option 2

Submitters suggested the following variations on option 2:

Removal of the specific prohibition on oats only

Two submitters favoured this option based on recent evidence indicating that people with Coeliac disease do not experience adverse immunological, clinical or histological effects from the long-term ingestion of oats. However, specific evidence on the toxicity of barley hordein is not available.

Removal of the specific prohibition on oats for low gluten claims only

One submitter favoured this option, expressing concern about unnecessarily strict requirements for low-gluten claims that could limit the range of foods that has commonly been available to people with Coeliac disease.

Removal of the specific prohibition on oats and malt for low gluten claims only

One submitter supported this option on the basis that:

- oats is not yet fully proven and accepted by all researchers as truly gluten free; and
- the quantity of prolamin in malt that causes mucosal damage is not well detected by current analytical methods and there is a lack of consensus on whether malt can be consumed as part of a gluten free diet.

Require the declaration of oats and barley in conjunction with a gluten free claim

One submitter in favour of Option 2 presented an alternative view, namely, that the presence of oats or barley in a *gluten free* food could be made more prominent by requiring a statement such as '*gluten free* (contains oat and barley products)'.

6.1.4 Option 3 – Amend Standard 1.2.8 to retain the specific prohibition of gluten free *and* low gluten *claims on foods containing oats and malt and extend it to include the products of oats or malt.*

One submitter supported this option, while another submitter favoured Option 3, but only in relation to *gluten free* claims. This view is based on continuing controversy surrounding the suitability of oats and oat products, and the lack of an acceptable test to conclusively show that barley derived malt and its products contain no detectable gluten.

Five submitters opposed Option 3 based on a lack of research data to support such a change and that this would further limit the diet of Coeliac patients.

One industry submitter stated that the current regulations were already being interpreted to include oats and malt 'and their products', and as such, there are no *gluten free* or *low gluten* claims on foods containing derivatives of oats and malt. It was suggested that an alternative could be 'oats/malt and their protein containing products'.

6.2 Revised Options

Given the comments on the options proposed in the IAR and subsequent discussions with the EAGs, it was decided that the options proposed would not meet the needs of all stakeholders. In a meeting that was held with the EAGs, it became evident that *gluten free* and *low gluten* claims needed to be treated separately with respect to oats and malt, whereas in the options proposed, the prohibition of gluten claims on oats and malt were either included in both or removed from the criteria for making both *gluten free* and *low gluten* claims. Given this, the following regulatory options are now proposed:

Option 1

Maintain the status quo and retain the prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt.

Option 2

For *gluten free* claims - extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and

For *low gluten* claims - remove the prohibition of *low gluten* claims on foods containing oats and malt.

Option 3

For *gluten free* claims - extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and

For *low gluten* claims - remove the prohibition of *low gluten* claims on foods containing oats or malt but require an advisory statement to the effect that the *product contains oats or malt and may not be suitable for the most sensitive Coeliacs.*

7. Impact Analysis

7.1 Affected parties

The parties affected by this Proposal are:

- Consumers with Coeliac disease and health professionals;
- Manufacturers of *gluten free* and *low gluten* foods; and
- Government agencies responsible for enforcement of food standards.

7.2 Cost-benefit assessment of regulatory options

7.2.1 Option 1

Maintain the status quo and retain the specific prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt.

7.2.1.1 Consumers and health professionals

In Australia, the approach towards the dietary management of Coeliac disease, recommended by the Coeliac Society of Australia and supported by health professionals is a gluten free diet. Therefore, the current regulations in Standard 1.2.8 for *gluten free* claims provide a suitably high level of protection of public health and safety for individuals with Coeliac disease. Neither a *gluten free* nor *low gluten* claim can be made if the food contains oats or malt, although such claims are permitted if the food contains derivatives of oats or malt. If the food contains products of oats or malt, a *gluten free* claim can still be made if no gluten is detectable, however the consumer wishing to avoid a food containing products of oats or malt still needs to consult the ingredient list to determine whether to purchase the food or not.

Advice provided by industry is that *low gluten* claims are not used by Australian food manufacturers. As health professionals in Australia recommend a gluten free diet, Option 1 has no impact on consumers and health professionals in Australia. It is unclear whether any imported products carry a *low gluten* claim.

In New Zealand, the approach towards the dietary management of Coeliac disease recommended by the Coeliac Society of New Zealand and health professionals allows small amounts of gluten in the diet, including gluten from oats and malt. On this basis, the current regulations for *gluten free* severely limit the choice of foods available to individuals with Coeliac disease. While the level of gluten permitted in *low gluten* claims is considered appropriate, the prohibition of *low gluten* claims on products containing oats and malt also limits the choice of foods available to people with Coeliac disease, which increases the risk of non-compliance and therefore is a cost to people with Coeliac disease.

7.2.1.2 Industry

There are not likely to be any impacts on Australian manufacturers of retaining the prohibition of *gluten free* and *low gluten* claims on foods containing oats or malt. Currently, only a limited number of products carry a *gluten free* claim and there are no products carrying a *low gluten* claim.

The impact on New Zealand industry of retaining the current regulations is neutral.

7.2.1.3 Government

There are not likely to be any direct impacts on government of retaining the current regulations.

Key Question
Are you able to identify any additional costs and benefits to consumers, public health professionals, industry and government of proceeding with Option 1?

7.2.2 Option 2

For *gluten free* claims - extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and

For *low gluten* claims - remove the prohibition of *low gluten* claims on foods containing oats or malt.

7.2.2.1 Consumers and health professionals

The extension of the prohibition of *gluten free* claims to foods containing products of oats or malt would provide a very high level of protection for individuals with Coeliac disease, including those that are highly sensitive. Consumers will be able to rely solely on a *gluten free* claim to determine the suitability of a particular food, rather than also referring to the ingredients list to ascertain whether the food contains oat or malt products. *Gluten free* claims made under this arrangement would be more protective for people with Coeliac disease than *gluten free* claims made under the current regulations.

Based on information received to date, the view of health professionals in Australia is that the level of gluten permitted under the current *low gluten* criteria does not provide a sufficient level of protection of public health and safety for individuals with Coeliac disease. However, if Option 2 was accepted and foods that contained less than 20 mg gluten/100 g food could contain oats or malt, there could be greater potential for people in Australia to broaden their diet, as some people may be able to tolerate such a diet. The extent to which this potential benefit can be realised depends on the views and advice provided by health professionals and the Coeliac Society of Australia.

The extension of the prohibition of *gluten free* claims to foods containing products of oats or malt means that fewer products would be able to carry *gluten free* claims. However, based on information received to date, consumers will be encouraged to look for *low gluten* claims as *gluten free* claims are considered too restrictive. For this reason, there may be minimal impacts of Option 2 on New Zealand consumers.

New Zealand health professionals generally recommend that the inclusion of oats and malt is suitable in a gluten free diet. Therefore, for New Zealand consumers there would be a larger number of products that would be eligible to carry a *low gluten* claim and therefore a greater choice of foods available.

7.2.2.2 Industry

In Australia, there appears to be limited supply of *low gluten* products, associated with advice from the Coeliac Society of Australia and health professionals. However, to the extent that consumer perceptions are changed, there is potential for the food industry in Australia to supply these products in the future.

The extension of the prohibition of *gluten free* claims to foods containing products of oats or malt is unlikely to impact on Australian industry as the prohibition on oats and malt is currently being interpreted to also include products of oats and malt. Therefore, there should be no fewer products eligible to make a *gluten free* claim.

The extension of the prohibition of *gluten free* claims to foods containing products of oats or malt is unlikely to impact on New Zealand industry, given that health professionals believe that a gluten free diet is unnecessarily restrictive and will therefore be encouraging consumers to consume a low gluten diet.

The permission for oats or malt in *low gluten* claims is likely to result in a greater number of products that would be eligible to make a *low gluten* claim. Given the demand by consumers for a greater choice of foods, there is likely to be an increase in the production and sale of *low gluten* foods.

Key Questions

Are analytical methods such as HPLC that test for oat avenins available to you?

If so, would you use such methods to measure the gluten content of oat containing products?

7.2.2.3 Government

There is unlikely to be any significant impact on Australian or New Zealand government agencies if Option 2 is adopted because the regulations under Option 2 will give greater clarity for the purposes of enforcement and will not have significant resource implications.

Key Question

Are you able to identify any additional costs and benefits to consumers, public health professionals, industry and government of proceeding with Option 2?

7.2.3 Option 3

For *gluten free* claims - extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and

For *low gluten* claims - remove the prohibition of *low gluten* claims on foods containing oats or malt but require an advisory statement to the effect that *the product contains oats or malt and may not be suitable for the most sensitive Coeliacs.*

7.2.3.1 Consumers and health professionals

The impact on Australian and New Zealand consumers is likely to be similar to that of retaining the status quo. An advisory statement could in fact alarm consumers and discourage them from purchasing the product as they may inaccurately classify themselves as a 'sensitive Coeliac'.

7.2.3.2 Industry

The impact of Option 3 could be similar to that of retaining the status quo because demand for an expanded range of products may not develop as consumers and public professionals may avoid products with an advisory statement.

Conversely, the permission to allow *low gluten* claims on foods containing oats and malt may result in an increase in the production and sale of *low gluten* foods.

7.2.3.3 Government

There is unlikely to be any significant impact on Australian or New Zealand government agencies if Option 3 is adopted because regulations under Option 3 will give greater clarity for the purposes of enforcement and will not have significant resource implications.

Key Question

Are you able to identify any additional costs and benefits to consumers, public health professionals, industry and government of proceeding with Option 3?

7.3 Recommended option

The recommended option is Option 2 as follows:

For *gluten free* claims - extend the prohibition of *gluten free* claims to foods containing products of oats or malt; and

For *low gluten* claims - remove the prohibition of *low gluten* claims on foods containing oats or malt.

Option 2 is favoured over Option 1 as it offers clear benefits to consumers, health professionals and the food industry in both Australia and New Zealand. Consultation with the EAGs for this Proposal also indicates that Option 2 offers an appropriate solution to the regulation of gluten claims, and takes into consideration the different approaches to the dietary management of gluten claims in Australia and New Zealand. Australian health professionals consider that a strict gluten free diet should be followed by individuals with Coeliac disease, therefore the extension of the prohibition of *gluten free* claims to foods containing products of oats and malt provides a sufficiently high level of protection for these individuals. Conversely, New Zealand health professionals consider that small amounts of oats and malt in the diet can be safely consumed by individuals with Coeliac disease. Therefore, the removal of the prohibition of *low gluten* claims on foods containing oats and malt means that an increased range of foods can be labelled as *low gluten*, resulting in an

increased choice of foods for individuals with Coeliac disease. Option 2 may also have benefits for the food industry arising out of increased consumer demand and sale of *low gluten* foods.

Option 1 is ambiguous in terms of whether the prohibition of gluten claims on foods containing oats and malt also includes the products of oats and malt. Clarification of clause 16, Standard 1.2.8 is therefore required.

Option 3 is considered to have lower net benefits to consumers and industry than Option 2. While this option was not explored at Initial Assessment, the inclusion of an advisory statement may be unnecessary and could inappropriately alarm some consumers. Additionally, as individuals with Coeliac disease would generally be aware of whether they are able to consume oats or malt, the use of an advisory statement in this instance is not consistent with FSANZ's principles for the use of advisory statements. These principles state that advisory statements should be provided '…where the general population or a sub group of the population are largely unaware of a potential, but non life threatening, risk to public health and safety and need advice about that risk'.

The proposed drafting amendments to Standard 1.2.8 are at Attachment 1.

8. Consultation

8.1 External Advisory Groups

Given diverse opinions on the role of oats and malt in the dietary management of Coeliac disease, the engagement of key stakeholders from both Australia and New Zealand was considered essential for the examination of matters related to this review. As such, FSANZ established two EAGs, the Dietary Management EAG and the Analytical Methodology EAG, consisting of medical specialists and representatives from government, industry and consumers, respectively, to provide expert advice when required (Attachment 3).

An initial teleconference of the EAGs was held in September 2002 prior to the release of the IAR. Subsequently, a face-to-face meeting of the EAGs was held in Auckland in May 2003 to discuss a number of key issues and the range of regulatory options put forward by submitters in response to the IAR.

FSANZ intends to engage the EAGs again following receipt of comments from the DAR and prior to the development of the Final Assessment Report to assist in the analysis of issues arising from the DAR and possibly refine the regulatory framework proposed in this report.

8.2 Submissions received in response to the Initial Assessment Report

In response to the IAR, a total of 19 submissions were received from a variety of stakeholders which included industry, health professionals, consumer groups and government. Of those, 7 were from New Zealand, 11 were from Australia and 1 was from an international organisation.

The IAR sought comment on a number of issues related to this Proposal which are outlined in Section 5 of this report. A full summary of submissions is at Attachment 4.

8.3 Australian Competition and Consumer Commission (ACCC) / New Zealand Commerce Commission (NZCC)

In the context of ensuring consistency between the *Food Standards Code* and the *Trade Practices Act 1974,* FSANZ requested the ACCC and the NZCC to provide advice on the suitability of allowing a *gluten free* claim based on the criteria of 'no detectable gluten'.

The ACCC has advised FSANZ that:

"*It is the Commission's view that failing to disclose material conditions about a food that contains gluten is likely to contravene section 52, 53(a), or 55 of the (TP) Act.";*

"*….the Commission has formed a position on 'free' claims and has widely promoted that position to be: a 'free' claim means no presence of. Whether this is the same as saying no detectable presence of, as is proposed with the 'gluten free' claim, would rely on whether the claim can in fact be substantiated.";*

"Whether claims such as 'gluten free' potentially breach the Trade Practices Act 1974 will ultimately depend on the circumstances of each case."; and

"... the Commission does not propose to take enforcement action against the use of the descriptor 'free' on products where the level of the nutrient in the product is nutritionally insignificant."

The capacity to determine 'the presence of gluten', is based on the ability to detect gluten, therefore it is considered that the criteria of 'no detectable gluten' is consistent with the requirements of the *Trade Practices Act 1974*. The food industry is expected to use the most sensitive analytical methodology available.

FSANZ is also in the process of consulting with the NZCC, although a response has not been received at the time of preparing this report.

8.4 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The WTO will be advised of this matter as a TBT notification because the proposed amendments to the Code relating to the regulation of gluten claims differ from the current regulations, and although more liberal in relation to low gluten claims, could potentially remain as a barrier to trade.

9. Conclusion and Recommendation

It is recommended that the most appropriate regulatory option with which to proceed is Option 2 such that clause 16, Standard 1.2.8 – Nutrition Information Requirements is amended as follows: 1) the prohibition of *gluten free* claims to foods is extended such that the criteria for making a *gluten free* claim includes no detectable gluten; and no oats or malt; and no products of oats or malt; and 2) the prohibition of *low gluten* claims on foods containing oats or malt is removed such that the level of 20 mg gluten per 100 g of the food is the sole criterion for making a *low gluten* claim.

Current ELISA tests for gluten have limited reactivity to barley hordeins and are unable to detect oat avenins. The detection of gluten in malt is unreliable as barley hordeins are not well detected and the concentration of prolamins present in malt and malt ingredients is likely to be very low. Other methods are available to detect the presence oat avenins, however, these methods may not be as readily accessible to food manufacturers as an ELISA test. The proposed amendment takes into consideration current testing methods to detect gluten in oats and malt.

Australian and New Zealand health professionals are divided on the issue of the toxicity of oats and malt in individuals with Coeliac disease. New Zealand health professionals consider that small amounts of oats and malt can be consumed by people with Coeliac disease. Conversely, Australian health professionals believe that there are some people with Coeliac disease that are unable to tolerate even the smallest amounts of oats and malt. The proposed amendment takes into consideration the opposing views of Australian and New Zealand health professionals in terms of the toxicity of oats and malt and the dietary management of Coeliac disease.

By making the current prohibition on *gluten free* claims on oats or malt more stringent by extending the prohibition to include products of oats or malt, this option promotes increased protection of public health and safety for the most sensitive Coeliacs when purchasing *gluten free* foods.

Standard 1.2.3 requires the mandatory declaration of cereals containing gluten and their products in addition to any gluten claims. Given this, it is considered that the removal of the prohibition of *low gluten* claims on oats or malt allows for appropriate protection of public health and safety for less sensitive Coeliacs who are able to tolerate small amounts of gluten in the diet, including that from oats and malt but also provides a greater choice of suitable foods for this group of people. Option 2 allows the majority of people with Coeliac disease a broader diet and therefore provides significant increased net benefits to consumers.

FSANZ considers that the proposed amendment is the most appropriate approach to the regulation of gluten claims. It meets the objectives to protect the public health and safety of individuals with Coeliac disease and to provide adequate information so that consumers can make appropriate food choices for their level of gluten intolerance. On balance, this approach also meets the needs of stakeholders in both Australia and New Zealand.

10. Implementation and review

Following the consultation period for this document, the Final Assessment of this Proposal will be completed. The Final Assessment Report is expected to be considered by the FSANZ Board in March 2004, following which, a notification will be made to the Ministerial Council. It is expected that this will be completed by mid 2004.

The variation to clause 16, Standard 1.2.8 will take effect from the date of gazettal. The default 12 month transition period provided under subclause 1(2) of Standard 1.1.1 will apply.

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Attachments

1. Draft variation to clause 16, Standard 1.2.8
2. International Regulations Relating to Gluten Claims
3. Membership of the EAGs
4. Summary of submissions

ATTACHMENT 1

DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

[1] *Standard 1.2.8 of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting paragraph 16(2)(b), substituting –*

(b) oats or malt (other than malt derived from rice) or their products.

[1.2] *omitting subclause 16(3), substituting –*

(3) A claim to the effect that a food has a low gluten content must not be made in relation to a food unless the food contains no more than 20 mg gluten per 100 g of the food.

ATTACHMENT 2

International Regulations Relating to Gluten Claims

Codex Alimentarius

Current Requirement

The Current Codex Standard for Gluten-free Foods applies to those processed foods that have been specially prepared to meet the dietary needs of persons intolerant to gluten. It does not apply to foods that in their normal form do not contain gluten.

Codex defines a gluten-free food as:

- consisting of or containing as ingredients such cereals as wheat, triticale, rye, barley or oats or their constituents which have been rendered "gluten free"; or

- a food in which any ingredients normally present containing "gluten' have been substituted by other ingredients not containing "gluten".

Codex states that for the purpose of the standard gluten-free means that the total nitrogen content of the gluten-containing cereal grains used in the product do not exceed 0.05 g per 100 g of these grains on a dry matter basis.

Codex stipulates that gluten-free foods substituting important basic foods like flour or bread, must supply approximately the same amount of vitamins and minerals as the original foods they replace.

Codex states that the following provisions for the labelling of gluten-free foods applies:

- the term gluten-free shall be given in the immediate proximity to the name of the food;

- a complete list of ingredients shall be declared on the label, vitamins and minerals need not be listed in descending order of proportion;

- the nature and source of the starch or starches shall be declared on the label. In the case of starch prepared from gluten- containing cereal grains, the declaration of this starch shall be accompanied by a statement "containing not more then 0.3% protein in the dry matter";

- in terms of claims, a food meeting the requirements of this standard may be called a "gluten-free" food.

- a food which naturally has no gluten may not be called "gluten-free"; however a cereal or a food product containing a cereal which naturally has no gluten, may be labelled to show that it is naturally free of gluten and is suitable for use in gluten-free diets.

Codex states that the following nutrition information shall be declared:

- the amount of energy, expressed in Calories or kilojoules and the number of grams of protein, carbohydrate, and fat per 100 g of the food and, where appropriate, per specified quantity (e.g. one biscuit) of the food as suggested for consumption;

- in addition to any other nutritional information required the total quantity in the final product of those vitamins and minerals which have been added shall be declared per 100 g as well as according to the serving size of the food suggested for consumption.

Proposed Revised Standard

The Codex standard for gluten free foods is currently being revised. The Revised Standard is currently being held at Step 7 of the Codex procedure until such time as the scientific basis for the establishment of a level and the method of determination are clarified. The main differences between the current standard for gluten free foods and the new proposed draft standard for gluten free foods are as follows. The new proposed standard:

- Describes gluten-free as:

  (a) consisting of or made only from ingredients which do not contain any prolamins from wheat or all Triticum species such as spelt, kamut or durum wheat, rye, barley, [oats] or their cross bred varieties with a gluten level of not exceeding [20 ppm].

  (b) consisting of ingredients from wheat, rye , barley, oats, spelt or their crossbred varieties which have been rendered 'gluten-free'; with a gluten level not exceeding [200 ppm]; or

  (c) any mixture of the two ingredients as in (a) and (b) with a gluten level not exceeding [200 ppm].

- Defines prolamins, it is believed that these fractions of gluten are responsible for gluten sensitivity. These are the fraction from gluten that can be extracted by 40-70% ethanol. The prolamin from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin. The prolamin content of gluten is generally taken as 50%.

- States that the product shall be prepared with special care under Good Manufacturing Practice (GMP) to avoid contamination with prolamins.

- States that any foodstuff that meets the requirements set out in the standard may be labelled "gluten-free'.

- States that to enforce the compliance to the limits for gluten-free products an analytical method is needed which has a high level of accuracy. Up until now it has not been possible to design such a method in detail, as several factors impair its performance. It is proposed that a more comprehensive investigation to address these questions has to be carried out. The proposed standard gives a general outline of the method of analysis and sampling as a framework for such investigation. This method is based on an immunologic method.

Explains the extraction of prolamins from food.

- Describes the determination of gliadin.

- States that the total daily intake of prolamin for coeliacs should not exceed 10 mg per day.

Canada

The Canadian Food and Drug Regulations prohibit the labelling, packaging, sale or advertising of a food as gluten free unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof.

United Kingdom

There are no specific provisions in the Food Labelling Regulations 1996, as amended, in relation to claims about the gluten content of foods. However, under the general provisions in the Food Safety Act 1990, it is an offence to label or advertise a food in a way that falsely describes the food or is likely to mislead as to the nature, substance or quality of the food.

In the absence of specific criteria, manufacturers are advised to contact Coeliac UK (the UK's charity supporting people with gluten intolerance), who provides advice to manufacturers wishing to market products as suitable for Coeliacs.

European Union

Under the European Council Directive on food stuffs intended for particular nutritional uses (Council Directive 89/398/EEC, as amended), rules on the use of terms about the absence of gluten in food labelling are to be established but have yet to be developed.

ATTACHMENT 3

Membership of the External Advisory Groups

Analytical Methodology Group

Mr Lyall Simmons	New Zealand Institute for Crop and Food Research
Mr Frank Lee	Goodman Fielder
Dr Clarence Ng	Arnott's Biscuits Ltd

Dietary Management Group

Mr Graham Price	Coeliac Society of Australia
Ms Raywin Head	Coeliac Society of New Zealand
Ms Kim Faulkner-Hogg	Dietitians' Association of Australia
Ms Vicki Robinson	New Zealand Dietetic Association
Dr Mark Lane	New Zealand Society of Gastroenterology
Dr Grace Chapman	Gastroenterological Society of Australia
Ms Lyn Gillanders	New Zealand Manufactured Food Database
Ms Jenny Reid	New Zealand Food Safety Authority

ATTACHMENT 4

Summary of Submissions

SECTION 2.2 PUBLIC HEALTH RISK

Arnott's	• supports the need to regulate for the most sensitive people with Coeliac disease.
Coeliac Society of NZ	• recommends that regulations should apply to the majority of Coeliacs. • does not agree that some Coeliacs have ongoing close contact with professionals – need to correct paper in this respect.
Coeliac Society of Australia	• states that there are a number of people with Coeliac disease who choose to remove all foods derived from gluten containing grains because of their concern regarding more serious consequences of Coeliac disease such as malignancies, osteoporosis etc. • states that they have a range of members who are very sensitive and suffer symptoms following consumption of products which include maltodextrin, malt extract, oats etc and have improvement when those products are removed. If the gluten free standard is removed or diluted, 'sensitive Coeliacs' would have no food choices in relation to grains/complex carbohydrates (a paper by Kim Faulkner-Hogg is included). • has had recent conversations with UK Coeliac Society who have members experiencing symptoms after eating foods labelled gluten free according to Codex standard (equivalent to low gluten in Australia) containing malt extract and wheat starch. • points out that there can be damage to the small bowel (with the increased risk of cancer) and can occur with no apparent symptoms.
Goodman Fielder	• regulation should be aimed at the majority of people with Coeliac disease and not the minority. • agrees that the most sensitive individuals are involved with groups such as the Coeliac Society and other health care professionals who offer support and guidance in the management of the disease. Therefore, this group of people are normally very aware/educated about foods they can/can't consume. • states that it is in the interest of sensitive Coeliac patients to obtain as much information as possible to control the disease.
Kim Faulkner-Hogg	• feels that the food regulations should be for the most sensitive and not the majority. • questions the statement that those who are more sensitive have a closer interaction with their health care team and the relevance of this statement to labelling. Little or lots of interaction with a health care team still means that the person is required to make appropriate food selections.
Manildra Group	• states that Coeliac disease is an auto-immune disease. It is a genetically determined predisposition which results in sensitivity to some cereal based components.
Mark Lane	• states that the 'sensitive' Coeliac is a special case and their health care needs are best addressed by close interaction with their healthcare provider and cannot be met under the broad umbrella of this legislation. • states that they have a variety of causes for their symptoms, many of which are not gluten related.
Manufactured Food Database	• states that last sentence, paragraph 1 is unclear, as the only effective intervention for managing Coeliac disease is a lifelong gluten-free diet.

	• considers that regulations should apply to the majority of Coeliacs. • agrees that those with ongoing problems are to continue to seek advice from a healthcare team.
NZ Dietetic Association	• states that regulations should apply to the majority of Coeliacs and not minority groups. There is evidence that so called 'sensitive Coeliacs' may have other issues as well as gluten intolerance. • feels that by restricting the diet further will lead to less choice, therefore possibly less compliance and not necessarily a significant clinical benefit. Persistent villous atrophy does exist in some people but the reasons for this are unclear and it could be more multifactorial than simple gluten intake.
Queensland Health	• states that the regulations should cater for the needs of the majority of Coeliacs. • recent evidence suggests that people with Coeliac disease experience no adverse immunological, clinical or histological effects from the long-term ingestion of oats. • there may be individuals that do experience adverse effects of oats and require specific advice to manage this. This may be due to co-morbid sensitivity such as allergy. • states that contamination of oats with other gluten-containing grains would be detected by current analytical methods.

SECTION 4.1 GLUTEN AND COELIAC DISEASE

Kim Faulkner-Hogg	• considers that the membership of the Coeliac Societies of Australia and New Zealand does not accurately represent the number of people with Coeliac disease or dermatitis herpetiformis in these countries. • a recent serological screening test in Western Australia has revealed a prevalence of approximately 1:250. A worldwide average is estimated to be 1:266.
Manildra Group	• states that the term 'gluten' alone should not be used in food literature or food labelling as it is imprecise and confusing and leads to 'misleading or deceptive conduct'. Proposal P264 should be redrafted so as to identify the source of food ingredients/components. • states that section 4.1, paragraph 1 is incorrect and should read '<u>wheat gluten</u> is the rubbery mass that remains when <u>wheat dough</u> is washed to remove starch granules…'. Barley, rye or oat gluten does not really exist under this definition as none of them form a rubbery dough. Barley, rye and oat proteins (prolamins) exist which are nonetheless quite similar to those of wheat and may elicit a Coeliac reaction. By contrast, corn or maize contains protein that behaves like wheat gluten in that it forms a rubbery mass, but is chemically quite distinct and does not trigger a Coeliac response. The term 'gluten' can be confusing to the average person who does not know the difference between corn gluten and wheat gluten. • comments that the information in the IAR with respect to Coeliac disease and its aetiology is inadequately presented, the information presented being half correct and out-of-date with respect to current knowledge. • states that sentence 2, Section 4.1 is incorrect. The majority of wheat protein is contained in the wheat gluten; a small portion of the wheat protein is soluble in water and termed the globulin fraction. The wheat gluten is mixture of wheat prolamins; the gliadins are more soluble than the glutenins but they are all prolamins. The gliadins and glutenins are quite similar to each other with small differences in amino acid composition. Coeliac sensitising peptides have been identified in the gliadins but are also likely to

	be identified in the glutenin fraction. • states that the incidence figure quoted of 1 in 1600 is probably a considerable underestimate; incidences of about 1 in 300 are quoted in most European literature and perhaps as high as 1 in 100. This also indicates that >99% of the population is not sensitive. • states that the aetiology of Coeliac disease is quite well established. The mechanism is that of a genetically determined enzyme anomaly in the intestinal lining that recognises at least two specific amino sequences in wheat gliadin, effects a biochemical modification at a point in the sequence which triggers the autoimmune response.

SECTION 4.2 THE REGULATION OF GLUTEN CLAIMS

European cereal starch industry (AAC)	• queries whether there is a precise definition for 'no detectable gluten' and whether this notion of non-detectability is linked to a given analytical method? • queries the basis according to which the differentiation between 'no detectable gluten' and max. 20 ppm gluten has been established.
Kim Faulkner-Hogg	• states that the Australian and New Zealand standard for gluten free foods has only been compared with the Codex requirements. • the Canadian food standard does not permit a food to be labelled, packaged, sold or advertised as gluten free if it contains wheat, including spelt and kamut, oats, barley rye, triticale or part thereof. This is stricter than the Australian/New Zealand standard.
Manildra Group	• states that FSANZ's comments that the definitions for 'gluten free' and 'low gluten' are 'consistent with the proposed Codex Standard' are incorrect. The Codex proposal specifies 'gluten free' as not derived from gluten containing cereals and containing max. 20 ppm gluten, and 'rendered gluten free' as containing max. 200 ppm gluten, which is a substantially different approach. • states that the Codex proposal is halted at Step 7 to enable validation of analytical methods. • states that there are difficulties with the adequacy and reliability of analytical methods in relation to cereal products and FSANZ should heed the position taken by Codex.

SECTION 5.1 THE ABILITY TO DETECT GLUTEN IN OATS AND MALT

AAC	• acknowledges that the Codex review of gluten standards has been held at Step 7 due to the lack of reliable method of determination of gluten content in food. So to their understanding there is no reliable analytical method available so far in this respect and this is also confirmed with their own experience with the detection kits currently available on the market.
Arnott's	• states that the current test kits (for Arnott's Rice Cookies) were developed for wheat gluten and may not be appropriate for oats (that may be contaminated with barley) and malt. This may be due to the low levels of protein fragments detected by the assay or the interference from the sample matrix. • comments that malt is not solely derived from barley or wheat and rice malt is also available. Therefore, if the Standard includes malt, it should define the type eg barley malt.

CSIRO (David Topping)	• states that he is unable to find information to link the detection of gluten in foods and clinical findings in humans. • raises the question of whether the level of gluten measured by the kit relates in any way to the development of symptoms in susceptible individuals.
Goodman Fielder	• states that ELISA or antibody tests are used to measure gluten and look for a specific sequence of amino acids. • the Tepnel Biosys systems kit's lowest level of detection is 20ppm (0.002%). • most labs in Australia and NZ use the Tepnel kit that is manufactured in the UK and has a shelf life of around 6 months. • available information suggests that most Coeliac patients do not have a problem at this level of detection although the most sensitive Coeliacs may still have an issue. • ELISA are about to release a gluten test kit, however it does not detect the avenins in oats or malt products, which would require separate assays.
Manildra Group	• states that modern immuno-chemical methods presently available for identifying wheat protein or perhaps other cereal protein in foods are inadequate and unreliable as the basis for any international standard. • comments that the only satisfactory analytical method to determine whether a food is suitable for a person with Coeliac disease will have to be based on the specific biochemistry of the sensitising peptides and that this is not yet available.
Mark Lane	• states that the report does not clearly address the issue of the reduced sensitivity of the ELISA to barley gluten and would value more detail on this issue.
NZ Crop and Food	• states that the most commonly used test for the measurement of gluten in foods is the Tepnel BioSystems Gluten Assay. This is an ELISA test which works well for wheat proteins has but no reactivity to oats. • notes a number of other ELISA kits are available as well as other methods. • states that there is a high interest in improving the methods for gluten analysis so commercially acceptable detection methods should improve.

SECTION 5.2 TOXICITY OF OATS IN INDIVIDUALS WITH COELIAC DISEASE

Arnott's	• states that the medical advice appears to support that oats do not pose a risk to Coeliacs. Previous studies indicated that toxicity could have been due to oats that had been contaminated with barley or wheat. • recommends that '2(b) oats or malt' and '3(b) oats or malt' be removed from clause 16, Standard 1.2.8 as '2(a) no detectable gluten' protects the consumer.
Coeliac Society of WA	• states that the study on oats toxicity conducted by Freighery et al. used a specific type of oats from Germany which were tested for evidence of gluten contamination and found to be gluten free. This study concluded that oats can be consumed safely as part of a gluten free diet. • indicates that there remains serious doubt about the inclusion of oats in the gluten free diet possibly due to contamination during growing, milling etc.
Coeliac Soc. of NZ	• expresses concern about estimations of contamination provided by Analytical External Advisory Group.
Goodman Fielder	• advises that information sourced to date indicates that oats are not a problem for Coeliacs, but oats are frequently contaminated with small quantities of foreign grains eg barley and sometimes wheat. GF has a dedicated plant for oats and contamination levels are low (0.04-0.05%). Assuming 10% protein in the contaminant, gluten levels in oats would be around 0.004-0.005%.

Kim Faulkner-Hogg	• states that both the Finnish and United Kingdom Coeliac Societies recommend the consumption of uncontaminated oats. • studies suggest that ~15% of people who ate oats reacted symptomatically. If the prevalence of Coeliac disease is 1:250-300, this represents a lot of people who may react symptomatically to the presence of oats in gluten free foods. • states that although oats appear to be well tolerated in many people, they have not yet been shown conclusively to be gluten free.
Mark Lane	• states that scientific evidence demonstrates that oats in moderate amounts can be consumed safely by Coeliacs in well controlled trials and this view is supported by experts in the field. • indicates that unless there is evidence to the contrary, FSANZ should not exclude oats as this would be contrary to the FSANZ Act 1991, as quoted in Section 3.0 of the IAR.
Manufactured Food Database	• agrees that from research oats appears to be safe. • feels that the risk of contamination with protein from other sources is not a good basis for excluding a significant cereal source. • acknowledges that the Analytical EAG indicates that even if contamination occurs the levels of gluten would be minimal.
NZ Crop and Food	• notes that recent work suggests that oats could be included in a gluten free diet, however all the studies have some limitations. More clinical work is required to resolve these issues.
Nutrinova	• states that a study conducted by Dr Steve Taylor submitted to the FDA in January 1998 suggests that there is 'no risk associated with the ingestion of any OPTA Oat Fibre products…relative to the provocation of celiac disease'.
NZ Dietetic Association	• agrees that from research oats appears to be safe. • feels that the risk of contamination with protein from other sources is not a good basis for excluding a significant cereal source. • acknowledges that the Analytical EAG indicates that even if contamination occurs the levels of gluten would be minimal.
Coeliac Society of Australia	• states that the gluten free standard with 'zero' gluten has given people with Coeliac disease a level of awareness of ingredients unknown elsewhere in the world. Given how successful our gluten regulations are, why would we introduce ingredients into gluten free or low gluten for which the true gluten level can not be measured. • has no objection to these ingredients being included once the testing methods have been developed to give an accurate measure of residual gluten. But to allow these ingredients into food which have a firm and predetermined gluten level weakens these standards. • if oats/malt are allowed in the food, queries what would be listed in the NIP if there is not certainty about the amount in the food. • includes a paper by Kim Faulkner-Hogg re oats/gluten free diet.
Queensland Health	• quotes a study by Kilmartin et al (2003) that suggests that the immunogenic sequences in gliadin are not present in avenin (oat protein). • in vivo studies report that oats are safe for consumption by Coeliac patients.

SECTION 5.3 TOXICITY OF MALT IN INDIVIDUALS WITH COELIAC DISEASE

Arnott's	• recommends that '2(b) oats or malt' and '3(b) oats or malt' be removed from clause 16, Standard 1.2.8 as '2(a) no detectable gluten' protects the consumer.
Coeliac Society of WA	• quotes a study which concluded that foodstuffs containing malt extract should be considered to contain gluten. • provides a number of case studies indicating that, in the long term, the consumption of small amounts of gluten as contained in malt and malt extract has consequential effects on those with Coeliac disease and dermatitis herpetiformis.
Coeliac Society of NZ	• expresses that if malt is not detected by currently accepted methods, then it would certainly not contain gluten.
Goodman Fielder	• states that the extent to which malt and malt products causes adverse reactions in Coeliac patients is probably minimal, although there may be more of an effect on the more sensitive Coeliac. • the malted grains that are widely used in Australia and NZ are predominantly barley and wheat. The malt products used throughout the processed food industry are mainly malt extract, malt vinegar and maltose. These products would be present in a food at a maximum of 5% and probably contain very low levels of hordein (the barley prolamin). • states that the more refined or processed an ingredient is, the less likely it is to cause any issues for Coeliacs.
Kim Faulkner-Hogg	• states that the weight of evidence from clinical experience as well as research conducted at the RPA Allergy Unit indicates that [wheat starch] and malt can cause symptoms in a subgroup of 'sensitive' patients with Coeliac disease.
Mark Lane	• states that to exclude malt in a blanket manner without reference to its detectable gluten content is scientifically invalid. • states that he is unaware of any evidence that there are "undetectable gluten equivalent fractions that may be toxic to individuals with coeliac disease" in malt. • indicates that other foods that may potentially be contaminated with barley can qualify for a gluten free/low gluten claim providing they meet the appropriate standard for detectable gluten. Therefore it is not rational to exclude a product of barley (malt) on a different basis. • states that as malt is added in small quantities to foods, any gluten will be significantly diluted.
Manufactured Food Database	• considers that malt is not a problem as an ingredient especially in something such as malt vinegar where if it cannot be detected, it almost certainly does not contain gluten. Exclusion of malt vinegar denies many people with Coeliac disease the choice of many sauces and pickles.
NZ Crop and Food	• states that malted flours and malt extract will certainly contain gliadins or hordeins (prolamins of barley). Malt vinegar is far less likely to contain such proteins or peptides and maltose not at all.
NZ Dietetic Association	• considers that malt is not a problem as an ingredient especially in something such as malt vinegar where if it cannot be detected, it almost certainly does not contain gluten. Exclusion of malt vinegar denies many people with Coeliac disease the choice of many sauces and pickles.
Coeliac Society of Australia	• states that the gluten free standard with 'zero' gluten has given people with Coeliac disease a level of awareness of ingredients unknown elsewhere in the world. Given how successful our gluten regulations are, why would we

	introduce ingredients into gluten free or low gluten for which the true gluten level cannot be measured. • has no objection to these ingredients being included once the testing methods have been developed to give an accurate measure of residual gluten. However, to allow these ingredients into food which have a firm and predetermined gluten level weakens these standards. • queries what would be listed in the NIP if there is not certainty about the amount in the food, if oats/malt are allowed in the food.

SECTION 6 REGULATORY OPTIONS

6.1 Option 1 – in favour	
Crown Public Health	• recommends that Option 1 be retained with modifications ie foods containing no gluten but contain oats or malt could be labelled with 'may contain gluten'. • this would warn consumers that the product may contain gluten but is suitable for those individuals who can tolerate small amounts. • would increase food choice and enhance the quality of the diet for people with less severe forms of the disease. • may increase the sales of products previously considered contain gluten.
NZ Crop and Food	• states that Option 1 is the best option for the present and that this is based on the continuing work on the suitability of oats as part of the gluten diet. The situation should be reviewed if oats are demonstrated as suitable for Coeliac patients. • states that malt and malted products will never be considered to be suitable and therefore no change should be considered for these. • feels that the 'low gluten claim' is non-specific and confusing. A food either has gluten present in it or it does not, and Coeliac patients need to know this.
6.2 Option 2 – in favour	
Arnott's	• states that Option 2 is preferred, namely, that the specific prohibition on oats or malt (from barley or wheat) should not be retained for either 'gluten free' or 'low gluten' claims. • the adoption of Option 2 would allow products such as rolled oats and breakfast cereal (containing malt) to be labelled 'gluten free' provided there is no detectable gluten.
Coeliac Society of NZ	• states that the level of detectable gluten should and must be the only acceptable criteria.
FTA (Victoria)	• problems arise in the apparent detection and presence of gluten in oats/and or malt due to cross contamination with wheat. • 'gluten free' and 'low gluten' claims cannot be made unless they are true and can be proven by testing. • the presence or absence of gluten is testable. • the Trade Practices Act is enforceable re the truth or otherwise of any claim.
Goodman Fielder	• states that recent information on the toxicity of oats suggests that they can be included safely in the diet of Coeliac patients. • considers that if the main area of concern is cross contamination then it is not appropriate to regulate for cross contamination as there are no other examples of this in the Food Standards Code and a consistent approach should be a key objective.
Kim Faulkner-Hogg	• states that her preference is continue to prohibit both oats and malt for foods in the 'gluten free' category only. • oats is not yet fully proven and accepted by all researchers to be truly gluten

	free. • malt is less well studied than oats. The quantity of prolamin that causes musosal damage is not well detected by the monitoring assay and there is a lack of consensus on whether malt can be consumed as part of a gluten free diet. • would like to see the 'gluten free' category kept as free of controversial ingredients as possible so that these foods can be purchased by the whole population of people with Coeliac disease and not just a proportion. • the prohibition on oats and malt should not include foods in the 'low gluten' category.
Manufactured Food Database	• does not wish to have 'gluten free' or 'low gluten' claims. • believes that all Coeliac disease patients should have full choice of foods as they doubt that 'so called sensitive patients' respond to more stringent restriction. • believes that the only criteria should be the level of gluten.
Mark Lane	• supports Option 2 to amend Standard 1.2.8 to remove the specific prohibition of 'gluten free' and 'low gluten' food claims on foods containing oats and malt. • states that Option 2 is most consistent with the proposed Codex standard and that FSANZ must also have "regard to the promotion of consistency between domestic and international food standards".
Nutrinova	• believes that FSANZ should remove the prohibition on oats and oat derivatives in gluten claims.
NZ Dietetic Association	• does not wish to have 'gluten free' or 'low gluten' claims. • believes that all Coeliac disease patients should have full choice of foods as they doubt that 'so called sensitive patients' respond to more stringent restriction. • believes that the only criteria should be the level of gluten.
NZ Food Safety Authority	• supports the removal of oats from the restrictions for 'low gluten' claims based on information to date. • expresses concern about unnecessarily strict requirements for 'low gluten' claims that could limit the range of food that has commonly been available to people with Coeliac disease. • indicates that in many cases 'low gluten' levels may have little adverse effect on people with Coeliac disease.
Queensland Health	• feels that the specific prohibition on oats should not be retained on either 'gluten free' or 'low gluten' claims as recent evidence indicates that people with Coeliac disease experience no adverse immunological, clinical or histological effects from the long-term ingestion of oats. • states that the situation is less clear for barley as specific evidence of the toxicity or otherwise of hordein is not available. Suggests contacting experts in the field to determine if studies will be available in the near future.
Sanitarium	• supports Option 2 to remove the prohibition on oats and/or malt in 'gluten free' and 'low gluten' claims provided there is agreement between medical experts as to the safety of these foods and ingredients for people with Coeliac disease. • also recommends an alternative view, that the presence of oats or barley in a gluten free food could be made more prominent by requiring a statement such as 'gluten free (contains oat and barley products)'. • recommends that the regulations need to define 'malt' as 'malt derived from a gluten containing grain' (as opposed to rice malt which is gluten free). The Code also needs to differentiate maltodextrin and malt. Wheat based

	maltodextrin containing no detectable gluten is permitted but the same product made using enzymes derived from malt may fall outside of the current regulations.
Not in favour	
Crown Public Health	• states that an amendment to Standard 1.2.8 to include 'gluten free' and 'low gluten' claims containing oats and/or malt would compromise the health and well being of some patients. • states that to date, there is no test that has confirmed that these products are 100% gluten free so to label with this would be false and misleading. • states that industry could use this claim to their advantage by replacing standard gluten free staples with oat and malt type ingredients and still label it as gluten free.
NZ Crop and Food	• states that it would be unwise to remove the restrictions on oats with regard to gluten free claims.
6.3 Option 3	
In favour (only for 'gluten free' claims)	
Kim Faulkner-Hogg	• states that her preference is to extend the prohibition on oats and malt and their products for 'gluten free' claims only. • at this stage, there is still enough controversy surrounding oats to keep oats and its products out of the gluten free diet. • there is no acceptable test to conclusively show that barley derived malt and its products contain no detectable gluten, therefore it should not be acceptable in a gluten free diet. • the extension of the prohibition on oats and malt should not include foods in the 'low gluten' category.
Not in favour	
Coeliac Society of NZ	• believes there is not the research/data to support such a change.
Crown Public Health	• states that this would further constrict an already limited diet and could compromise the health status of the patient due to possible nutrient deficiencies.
Manufactured food Database	• believes that this would be very inappropriate.
NZ Dietetic Association	• believes that this would be very inappropriate.
Queensland Health	• states that if the specific prohibitions on oats or barley were retained, they should not be extended to 'products of oats' or 'products of barley'.
General comments	
Goodman Fielder	• has assumed that the current criteria also apply to oats and oat products and malt and malt products. • there are no 'gluten free' or 'low gluten' claims on any GF products containing products of oats or malt. • if the prohibition were retained then a possible alternative to 'oats and its products' would be 'oats/malt and their protein containing products'.

SECTION 7 IMPACT ANALYSIS

Option 1	
7.1.1 Consumers and public health professionals - positives	
Arnott's	• states that the current regulations reduce the choice of 'gluten free' products to the consumer as these products cannot be labelled 'gluten free' even though they would contain no detectable gluten. • states that many consumers have contacted Arnott's on the removal of the 'gluten free' statement on Rice Cookies, indicating that the consumer is looking for this information in the selection of suitable products.
Kim Faulkner-Hogg	• the individual will have enough information from their healthcare team to confidently read food labels and choose appropriate foods. • the individual can make instant decisions on whether to purchase the food or not as information on the source of gluten ingredients are required on food labels. • the level of the gluten free standard lets ALL people diagnosed have access to the commercial foods. • individuals who can tolerate malt or wheat starch can be counselled individually to include them. • oats are not recommended due to the problem of contamination.
Coeliac Society of Australia	• feels that the impact of introducing the new gluten free standard (in the review) has been that the range of gluten free foods has improved dramatically with an increasing number of foods conforming to the strict standard.
7.1.1 Consumers and public health professionals - negatives	
Coeliac Society of NZ	• a further diminishing of food choice for Coeliacs.
Kim Faulkner-Hogg	• it takes time to become confident with respect to purchasing suitable foods. • some confusion arises when products such as glucose syrup and caramel colour and some maltodextrins are declared to be from wheat. This requires re-education.
Manufactured Food Database	• believes that this option has 2 possible outcomes: • that the advice given by health professionals will disregard the FSANZ standard or • food choices will be curtailed. • at the time of P176, MFD estimated the impact of the new ANZFA 'gluten free' standard compared with the old NZ Regulations and the current Codex Standard (both of which allowed trace amounts of gluten). It was estimated that as a result of the new standard over 5% of the products listed in the MFD database would be eliminated. This represents the most recent estimate of consumer impact.
New Zealand Dietetic Association	• believes that this option has 2 possible outcomes: • that the advice given by health professionals will disregard the FSANZ standard or • food choices will be curtailed.
Reliance on food labels	
Kim Faulkner-Hogg	• as an educator, relies on food labelled 'gluten free' and those not labelled 'gluten free' for all the food consumed by her clients.
Confusion	
Kim Faulkner-Hogg	• most products labelled gluten free under the FSANZ standard are not confusing.

	• the pre-2003 standard for gluten free did not require that ingredients derived from wheat be declared. The new standard therefore causes less stress for people who wish to know the source of eg glucose syrup. • the pre-2003 standard caused the most problems for foods not labelled gluten free as the source of eg cornflour was not required to be declared.
Manufactured Food Database	• states that all stakeholders are very confused and seek MFD's clarification on a weekly basis.
New Zealand Dietetic Association	• states that there is increased confusion amongst health professionals and people with Coeliac disease and that conflicting views and advice are regularly encountered.
Narrowing of product choice	
Kim Faulkner-Hogg	• indicates that some clients would purchase the product, knowing that they can consume wheat starch and malt, whilst others would not purchase the product or would make a decision after researching the ingredient makeup of the product.
Manufactured Food Database	• considers that retention of the current regulations may severely curtail food choices.
New Zealand Dietetic Association	• considers that retention of the current regulations will continue to severely restrict food choices for people with Coeliac disease.
7.1.2 Industry	
Arnott's	• states that although Arnott's do not market gluten free products that also contain oats or malt, the current standard restricts the ability to inform the consumer of the suitability of the product. • has not seen any need for 'low gluten' claims as, following discussions with the Coeliac Society of NSW, the limit of 20 mg/100g is too high for most sufferers.
Goodman Fielder	• states that there would be no immediate labelling impact on Goodman Fielder products if the current restrictions on oats and malt are retained for both 'gluten free' and 'low gluten' claims. • there are no GF products in Australia and NZ that carry a 'low gluten' claim and only a limited number of products that carry 'gluten free' claims ie cornflours, rice chips. cornflakes, commercial custard powders, pavlova mixes and some Asian and Indian sauces. • the main confusion with the current regulations is with the use of the word malt with respect to the gluten claim criteria. Malt is a process and should be better defined if the prohibition is to be retained eg 'malt and its protein containing products'. • the regulation as it currently exists could be interpreted with the restriction being specifically for just 'oats' and 'malt' or 'oats and oat products' and 'malt and malt products'. This could cause issues if the restrictions are retained without amendment or further clarification. Suggests that the criteria be more specifically defined.
Manufactured Food Database	• considers that the impact on industry of retaining the current regulations would be the blanket exclusion of foods. MFD currently has contact with 124 companies and there are only a few foods that make specific gluten free claims for cereal products.
New Zealand Dietetic Association	• considers that the impact on industry of retaining the current regulations would be the blanket exclusion of foods.
7.1.3 Government	
Option 2	

7.2.1 Consumers and public health professionals	
Coeliac Society of New Zealand	• greater choice for consumers • lower cost to Coeliac consumer • both of these costs would be greater for the NZ consumer as their choice is significantly less in comparison with Australia plus gluten free/low gluten food costs approximately 3 times that of the products in Australia. Approximately 80% of products are imported from Australia. Cost comparison are provided.
Goodman Fielder	• states that if the restrictions on oats or malt were removed then more products may meet the criteria for gluten claims, which would open up available choices for Coeliac patients. However, the change would not initially be significant as large numbers of products containing oats also contain other gluten containing cereals. • states that the more sensitive Coeliac patient would look for oats and malt in the ingredient list despite the fact that the product may carry a gluten claim.
Kim Faulkner-Hogg	• states that option 2 would result in a greater range of breakfast cereal for people who do not have sensitive disease, as some of the breakfast cereals that have malt extract will fulfil the category. • there are currently more than 20 gluten free breakfast cereals available that do not contain components of malt or oats, therefore considers it unnecessary to alter the standard so that a few more cereals can be purchased. • how manufacturers may change their existing range to include malt and oat ingredients is unpredictable and may result in fewer foods being available to the sensitive individual. • given the advertised health benefits of oats, gluten free manufacturers may utilise more oat flour and oat bran in the whole range of cakes, breads, biscuits, pastas etc. This will reduce the range of foods for those that are sensitive.
Manufactured Food Database	• would result in a greater range of food choices.
New Zealand Dietetic Association	• states that option 2 would result in a greater range of food choices which could result in greater compliance with diets through less rigid restrictions.
Coeliac Society of Australia	• if health professionals/Coeliac Societies recommend to members that low gluten or gluten free foods containing oats/malt not be consumed, the gluten free and low gluten standards will become meaningless.
Queensland Health	• removal of the prohibition on foods containing oats and/or malt and subsequent labelling would enable consumers to confidently choose a wider range of foods.
7.2.2 Impact of the Removal of the Prohibition on Oats	
Positives	
Coeliac Society of New Zealand	<u>Consumers</u> • an increased choice of manufactured food at lower cost. • allow choice based on informed decision rather than product prohibition. <u>Food manufacturers</u> • oats would be included in many products currently made and ranges would be expanded. • product development in New Zealand that would be cheaper and more accessible that would comply with gluten free and low gluten criteria. <u>Health professionals</u> • increased dietary options for Coeliacs. • it would clarify an issue that has long been an area of confusion and doubt.

	• it would allow decision making for the patient based on individual tolerances and choice.
Kim Faulkner-Hogg	• the inclusion of oats would provide Coeliac patients with a good fibre source. • those with IDD would have a low glycaemic index source of carbohydrate. • may have benefits in preventing heart disease if eaten in a quantity that is greater than the recommended 30-60g/day. • another grain could be incorporated into gluten free cooking.
Manufactured Food Database	• a range of manufactured baked goods using oats would be possible if manufacturers were willing to produce them.
NZ Crop and Food	<u>Consumers</u> • considerable benefit would be derived from the introduction of oats to the gluten free diet. • oats would provide a welcome variation in flavour and texture of gluten free foods. • oats are a valuable source of soluble fibre which is difficult to obtain in the gluten fee diet. • soluble fibre helps to reduce blood cholesterol and aids in blood sugar control in patients with diabetes. • because malted products contain gliadins or hordeins, there is no reason to suggest Coeliac patients will benefit from adding malted products to their diet.
New Zealand Dietetic Association	• would provide a significant increase in food choice for people with Coeliac disease as there would be a positive increase in the range of foods available.
Negatives	
Kim Faulkner-Hogg	• there is no consensus that oats are gluten free, therefore those with sensitive disease will be disadvantaged as they will be unable to buy foods labelled as gluten free. • oats should not be eaten until there is an uncontaminated source of oats. • people who cannot tolerate oats will have to scrutinise gluten free food labels. • if the oats are uncontaminated: gluten free food manufacturers are likely to utilise more oat flour and oat bran, which will lead to a diminished range of foods for those that are sensitive. • a rough estimate of Coeliacs affected may be 15%.
7.2.3 Impact of the Removal of the Prohibition on Malt	
Positives	
Coeliac Society of New Zealand	• states that the impacts of removing the prohibition on malt is the same as for 7.2.2 above. • for both 7.2.2 and 7.2.3, the proportion of people affected by lifting the prohibition on both oats and malt would be significant in New Zealand. The full effect could only be determined after existing Coeliacs were re-educated and health practitioners became aware of the new inclusions.
Kim Faulkner-Hogg	• some mainstream breakfast cereals, hot chocolate drinks and chocolates can be labelled 'gluten free'. However, people who can tolerate malt can be taught to read the food labels without necessarily having them labelled as gluten free.
Manufactured Food Database	• MFD listings would be able to include a range of rice and corn cereal products and sauces and pickles.
New Zealand Dietetic Association	• people with Coeliac disease will be able to include a range of rice and corn cereal products and sauces and pickles in their diet.

Negatives	
Kim Faulkner-Hogg	• a proportion of the target group will have symptoms if they eat malt (and presumably its products). • sensitive Coeliacs can no longer trust the gluten free labels to mean gluten free and will have to read all labels. • those not wanting to consume ingredients derived from a gluten grain will have more products labelled gluten free that they cannot eat. • approximately 18.2% may be affected.
7.2.4 Industry	
Goodman Fielder	• the products that would be opened up to Coeliacs would be traditional style oats, instant oats and mueslis (natural and toasted) and some snack products. In terms of malt, the products affected would be Worcestershire and mint sauces, mayonnaises and some Indian and Asian cooking sauces. • in relation to oats, a risk assessment would need to be conducted to establish the risk level of contamination with gluten containing grains before a claim could be considered. • believes that there would be minimal impact on future product development unless a company was specifically targeting a product or range of products to carry a gluten claim. However, this can already be achieved using the wide selection of ingredients currently available to product developers and manufacturers.
Sanitarium	• believes that for existing products, it would be desirable to promote specific products as 'gluten free' as long as analytical testing was adequate to substantiate the claims. • this would enable certain products (eg Corn Flakes and Ricies) to be made available to Coeliacs and others requiring avoidance of gluten. • Option 2 could have significant impact on availability of foods suitable for Coeliacs. In the long term, the removal of the prohibition of oats and malt in low gluten and gluten free foods could result in significant opportunities for companies to develop and market gluten free foods, providing more variety and choice for consumers.
7.2.5 Government	
Option 3	
7.3.1 Consumers and public health professionals	
Coeliac Society of New Zealand	• states that there is no evidence for additional regulations.
Goodman Fielder	• suggests that further clarification is required if the prohibition on oats and malt is retained. A preferred suggestion is to use the term 'malt/oats and its protein containing ingredients'.
Kim Faulkner-Hogg	• states that she is unaware of any food labelled gluten free (in Australia) that contains a product derived from either oats or malt, despite the fact that this specific language is not stated on the food standard. • on this basis, there would be no further restriction of the range of food choice available as they currently are not labelled gluten free. • disputes the statement that 'restricting oats and malt would result in very few foods being able to meet the criteria for gluten free claims' as there are at least 20 gluten free cereals that do not contain malt, oats or any derivatives of these grains. • considers it unnecessary to change the gluten free category as Australia has a wide choice of acceptable breakfast cereals and other gluten free foods. • states that the current test for malt is gliadin based (and not hordein based), therefore the testing method is not reliable enough for the gluten free

	category. As malt extract may be well tolerated by many Coeliacs, it should be allowed in the low gluten category and not the gluten free. • agrees that the low gluten category can contain oats, malt and their products as long as the end product contains <0.02% gluten by current testing methods. • states that the impacts on Coeliacs for the products of oats will be the same as for oats (refer section 7.2.2). Those with sensitive disease may be affected ie approximately 15-18% of the population (refer section 7.2.2). • states that until better testing methods are found it is difficult to compare the gluten amounts in malt to that in malt extract and then compare these to better known standards such as wheat starch and glucose syrup (refer section 7.2.2).
Manufactured Food Database	• unnecessary and no evidence from clinical studies on those with Coeliac disease or analytical data to support it.
New Zealand Dietetic Association	• states exactly the same as MFD.
Coeliac Society of Australia	• supports this option.
7.3.2 Industry	
Goodman Fielder	• states that there would be no products disadvantaged by the extension of the criteria to oats/malt 'and their products' as there are no 'gluten free' or 'low gluten' claims made on any GF products containing products of oats or malt.
7.3.3 Government	
General Comments	
Arnott's	• recommends that the term 'Coeliac safe' is a more desirable and informative label to assist persons with Coeliac disease than 'gluten free', which implies that the food is better, more nutritious or safer. FSANZ should take initial steps to introduce this term.
Manildra Group	• states that the term 'Coeliac safe' is a more desirable and informative label to assist persons with Coeliac disease than 'gluten free', which implies that the food is better, more nutritious or safer. FSANZ should take initial steps to introduce this term.