



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

**06/03**

**18 December 2002**

## **INITIAL 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:

**12 February 2003**

*(See “Invitation for Public Submissions” for details)*

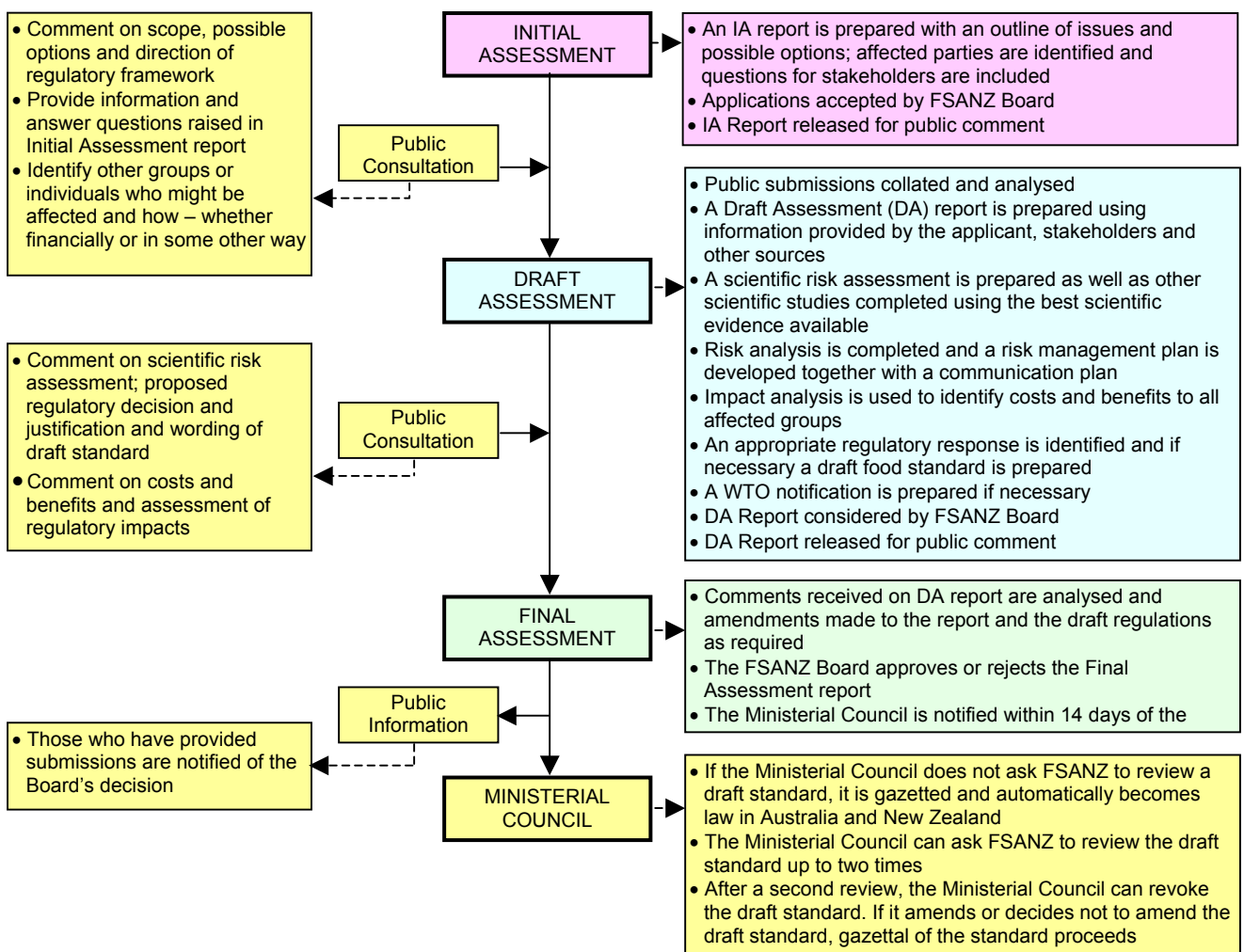
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Federal, State and Territory governments of Australia and the New Zealand Government. It is a statutory authority under Australian Commonwealth law and an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards for food available in Australia and New Zealand including primary production and processing standards and for a range of other functions including coordinating national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of conduct with industry.

The FSANZ Board approves new standards or variations to food standards, which are then accepted by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council accepts the changes made by FSANZ, the food standards are automatically adopted by reference under the food laws of Australian States and Territories and New Zealand.

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 an Initial Assessment Report of Proposal P264 – Review of Gluten Claims with Specific Reference to Oats and Malt, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the 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 FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the 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. 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](http://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](http://www.foodstandards.govt.nz)**

Submissions should be received by the Authority by **12 February 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Food Standards tab and then through Documents for Public Consideration. 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](mailto:info@foodstandards.gov.au) including other general enquiries and requests for information.

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](mailto:slo@foodstandards.gov.au).

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## EXECUTIVE SUMMARY

The purpose of this review is to determine the need to retain the specific prohibition of gluten claims on foods containing oats and/or malt in clause 16, Standard 1.2.8 and if so, to determine the need to extend the prohibition on oats and malt to include oats and malt ‘and their products’. FSANZ’s primary objective during this review is to protect the health and safety of individuals with Coeliac disease, by ensuring that the regulation of gluten claims adequately reflects current scientific evidence. In addition, this review seeks to ensure that consumers are provided with adequate information to make appropriate food choices for their level of gluten intolerance.

Coeliac disease is a life-long dietary intolerance to gluten resulting in damage to the lining of the small bowel (intestine) such that food is not absorbed properly. Based on membership data held by the Coeliac Societies of Australia and New Zealand, it is estimated that the prevalence of Coeliac disease in Australia and New Zealand is approximately 1 in 1600 of the population in both countries.

The conditions for making claims in relation to the gluten content of a food are set out in clause 16, Standard 1.2.8 – Nutrition Information Requirements of the *Food Standards Code* as at Attachment 1. 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’. The specific prohibition of gluten claims on foods containing oats or malt was introduced due to the unreliability of the methods of detection available to detect the gluten equivalent fractions in oats and malt that may be toxic to individuals with Coeliac disease.

The Initial Assessment Report is intended to raise a number of issues and questions in relation to the toxicity of oats and malt in individuals with Coeliac disease, together with the adequacy of current analytical methods to detect gluten in oats and malt. It also identifies regulatory options, the parties that are likely to be affected, and the potential impact on stakeholders of any of the options identified. The regulatory options identified include:

- Option 1: Maintain the status quo and retain the specific prohibition of gluten free and low gluten claims on foods containing oats and malt;
- 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; and
- 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.

The progress and direction of P264 will be guided by information received through the consultation process where advice will be sought from External Advisory Groups and through public consultation. Public submissions are now invited in response to this Initial Assessment Report.

## **1. Introduction**

P264 considers the need to amend Standard 1.2.8, clause 16 to ensure that current scientific evidence is reflected and that the needs of consumers with gluten intolerance are addressed.

Specifically, P264 seeks to:

- determine the need to retain the specific prohibition of gluten claims on foods containing oats and/or malt in Standard 1.2.8, clause 16 rather than regulating gluten claims on such foods as for any other gluten containing cereal; and if so,
- determine the need to extend the current specific prohibition on oats and malt to include oats and malt ‘and their products’.

## **2. Regulatory Problem**

### **2.1 Current Regulations**

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 100g of the food and no oats or malt.

Under clause 4, Standard 1.2.3, cereals containing gluten and their products, namely, wheat, rye, barley, oats and their hybridised strains must be declared on the label at all times when present in a food. This declaration is required in addition to any claims that may be made in relation to the gluten content of the food.

In relation to the current regulations there is confusion as to what is covered in paragraph (b) of Standard 1.2.8 subclauses 16(2) and 16 (3). Specifically, the question has been raised as to whether ‘oats and malt’ as listed in the paragraphs outlined above, should also include the ‘products of oats and malt’. If this is the case, then to what level of refinement should they be included?

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

### **2.2 Public Health Risk**

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 avoiding foods containing gluten. 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.

Coeliac disease has been associated with many other disorders such as neurological problems (Hadjivassiliou et al. 1996; Cooke & Smith, 1996), auto-immune diseases (Collin et al. 1994) and malignancy (Egan et al. 1995; Holmes et al. 1989).

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

*In addressing the risk and potential consequences of gluten consumption, should we regulate for the needs of the most sensitive people with Coeliac disease as opposed to the majority of people with Coeliac disease, bearing in mind that those people who are considered most 'sensitive' would have close interaction with a health care team?*

### **3. Objective**

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 *Food Standards Australia New Zealand Act 1991*. 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;
- 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**

Gluten can be defined as the rubbery mass that remains when wheat dough is washed to remove starch granules and other soluble constituents. (Wieser, 1995) Gluten is a combination of proteins that can be divided into those that are soluble in ethanol solution, termed prolamins and those that are not, the glutenins. (Buttriss, 2002) It is believed that prolamins are the toxic fractions of gluten responsible for gluten sensitivity and therefore injurious to people with Coeliac disease. The prolamins from wheat is gliadin, from rye is secalin, from barley, hordein and from oats, avenin.

Coeliac disease is a life-long dietary intolerance to gluten resulting in damage to the lining of the small bowel (intestine) such that food is not absorbed properly. Based on membership data held by the Coeliac Societies of Australia and New Zealand, it is estimated that the prevalence of Coeliac disease in Australia and New Zealand is approximately 1 in 1600 of the population in both countries.

### **4.2 The regulation of gluten claims**

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 *Food Standards Code*.

As a result of P176, claims in relation to the gluten content of a food are currently regulated in Standard 1.2.8 of Volume 2 of the *Food Standards 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, clause 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 100g of the food and no oats or malt. As part of P176, it was recognised that the level of 20mg/100g food was accepted internationally by the medical profession to be tolerated by the majority of people with Coeliac disease. This is also consistent with the proposed Codex standard. The current Codex standard does not specify an amount of gluten/kg food but alternatively specifies an amount of nitrogen. The current and proposed Codex standards are at Attachment 2.

As part of P176, a separate prohibition on oats and malt in relation to gluten claims was introduced at paragraph (b) of subclauses 16(2) and 16(3). 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 paragraph (a) of subclauses 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.



In August 2001, the 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 *Food Standards Code*.

In response to the P254 Draft Assessment Report 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.

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 abandoned and 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 specialised nature of the issues covered by this Proposal, FSANZ has established two External Advisory Groups (EAG) consisting of experts in the areas of analytical methodology for the detection of gluten and the dietary management of Coeliac disease. A teleconference has been held with each of the EAGs to address a range of key issues and the information obtained has been incorporated into the discussion of the issues below.

## **5. Public Health Risk**

### **5.1 The ability to detect gluten in oats and malt**

To manage the gluten content of the diet of people with Coeliac disease, most of the immunological methods employed, for example enzyme-linked immunosorbent assay (ELISA), are currently based on antibodies which recognize mainly wheat gliadins and rye secalins and to a much lesser extent, barley hordeins (including those in malt and malt ingredients), while they fail to detect 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 is 20 ppm (0.002%).

In addition to the detection of gluten in barley, a further issue relates to the ability to detect gluten in malt and malt ingredients as malt is usually derived from barley.

*Are you able to provide further information in relation to the reliability of current analytical methodology for the detection of gluten in oats and malt and their products?*

## 5.2 Toxicity of oats in individuals with Coeliac disease

A number of studies have reviewed the toxicity of oats in individuals with Coeliac disease. In the most recent of such studies, Picarelli (2001) concluded that oats can be safely included in the gluten free diet of people with Coeliac disease. In agreement, Janatuinen et al. (2002) indicated 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 recognised 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) recognises 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.

The Dietary Management EAG was divided on the issue of the toxicity of oats in individuals with Coeliac disease. Whilst 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 an issue, rarely with wheat, but 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%.

*Are you able to provide further information in relation to the toxicity of oats in individuals with Coeliac disease?*

## 5.3 Toxicity of malt in individuals with Coeliac disease

Malt is 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 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 in the fermentation 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 whilst 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 contains 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.

*Are you able to provide further information in relation to the toxicity of malt in individuals with Coeliac disease?*

## **6. Regulatory Options**

The following regulatory options have been identified:

### **6.1 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.

### **6.2 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.

*It has been suggested that a 'low gluten' diet (as opposed to a 'gluten free' diet) may be appropriate for less 'sensitive' Coeliac patients. Should a specific prohibition on oats be retained for:*

- *both 'gluten free' and 'low gluten' claims; or*
- *'gluten free' claims only; or*
- *neither 'gluten free' nor 'low gluten' claims?*

*Why?*

*Should a specific prohibition on malt be retained for:*

- *both 'gluten free' and 'low gluten' claims; or*
- *'gluten free' claims only; or*
- *neither 'gluten free' nor 'low gluten' claims?*

*Why?*

**6.3 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.

*If a specific prohibition on oats was retained in the regulations, should it be extended to include oats 'and its products'?*

*Why?*

*If a specific prohibition on malt was retained in the regulations, should it be extended to include malt 'and its products'?*

*Why?*

## **7. Impact Analysis**

Parties who are likely to be affected by the options listed above include:

- consumers with Coeliac disease and health professionals;
- manufacturers of 'gluten free' and 'low gluten' foods; and
- Government agencies responsible for enforcement of food standards.

To ensure that FSANZ is fully aware of the impact of each of the regulatory options on the different stakeholder groups, relevant issues and questions have been outlined below. Please provide any qualitative or quantitative data to support your responses to the questions below.

## **7.1 Option 1: Maintain the status quo and retain the specific prohibition of gluten free and low gluten claims on foods containing oats and malt.**

### *7.1.1 Consumers and public health professionals*

It has been suggested by some members of the Dietary Management EAG that the current regulations are confusing for consumers and are unduly restrictive for the majority of Coeliac patients. Other members of the EAG have indicated that the current regulations meet the requirements of the most sensitive Coeliac patients and that this is appropriate.

*What would be the impact, both positive and negative, on individuals with Coeliac disease and health professionals, of retaining the current regulations around 'gluten free' and 'low gluten' claims?*

*To what extent do you rely on current food labels in the dietary management of Coeliac disease?*

*To what extent, if any, have you experienced confusion in selecting suitable food products to effectively manage Coeliac disease?*

*If you have experienced confusion, to what extent have you narrowed your product choice?*

### *7.1.2 Industry*

*What would be the impact on industry, both positive and negative, of retaining the current regulations around 'gluten free' and 'low gluten' claims?*

*What is the range of food products on the market that are able to meet a 'gluten free' or 'low gluten' claim under the current regulations?*

*To what extent, if any, have you experienced confusion in interpreting the current regulations around 'gluten free' and 'low gluten' claims?*

*Are you aware of any differences in interpretation of the current standard and hence variations in products and their labelling?*

### *7.1.3 Government*

*What would be the impact, both positive and negative, on government and enforcement agencies of retaining the current regulations around 'gluten free' and 'low gluten' claims?*

*To what extent, if any, have you experienced difficulties in interpreting and/or enforcing the current regulations around 'gluten free' and 'low gluten' claims?*

## 7.2 Option 2: Amend Standard 1.2.8 to remove the prohibition on oats and/or malt in 'gluten free' and 'low gluten' claims

### 7.2.1 Consumers and public health professionals

*Do you believe that Option 2 would result in a significantly greater range of food choices for people with Coeliac disease?*

### 7.2.2 Oats

Advice from the Analytical Methodology EAG suggests that if the specific prohibition on oats was removed from the criteria for making gluten claims, there would only be an impact on a limited number of food products currently on the market (primarily oat cereals and muesli). However, it was also suggested by the Dietary Management EAG that it could result in the inclusion of oats into a larger range of possible gluten free and low gluten food products.

From a consumer perspective, the result of this would be that such products would be allowed to carry gluten claims (provided they met other criteria for 'gluten free' and 'low gluten' claims at paragraph (a) of subclauses 16(2) and 16(3)), and would therefore be more accessible for Coeliac patients. It would then be up to individuals to determine their ability to tolerate products containing oats.

*What would be the impact, both positive and negative on individuals with Coeliac disease, if the specific prohibition on oats was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

*What proportion of people with Coeliac disease would be affected?*

### 7.2.3 Malt

Advice from the Analytical Methodology EAG suggests that if the prohibition on malt was removed from the criteria for making gluten claims, the main products affected would be breakfast cereals derived from cereals that do not contain gluten, for example rice or corn, which have malt extract added (eg Corn Flakes).

From a consumer perspective, the result of this would be that such products would be allowed to carry gluten claims (provided they met other criteria for 'gluten free' and 'low gluten' claims at paragraph (a) of subclauses 16(2) and 16(3)) and would therefore be more accessible for people with Coeliac disease. It would then be up to individuals to determine their ability to tolerate products containing malt ingredients.

*What would be the impact, both positive and negative on individuals with Coeliac disease, if the specific prohibition on malt was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

*What proportion of people with Coeliac disease would be affected?*

#### *7.2.4 Industry*

*Would Option 2 significantly affect the labelling of existing product ranges? If so, please indicate the extent of this impact either by the predicted change to product lines or proportion of sales?*

*Would Option 2 affect future product development?*

*What would be the impact on industry if the prohibition on oats was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

*What would be the impact on industry if the prohibition on malt was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

*What food products currently on the market would be advantaged?*

#### *7.2.5 Government*

*What would be the impact, both positive and negative on government if the prohibition on oats was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

*What would be the impact, both positive and negative on government if the prohibition on malt was removed from the criteria for making 'gluten free' and 'low gluten' claims?*

**7.3 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.**

*7.3.1 Consumers and public health professionals*

It has been suggested by the Dietary Management EAG that an extension of the specific prohibition on oats to include oats ‘and its products’ would further restrict the range of food choices available to people with Coeliac disease, as very few foods would meet the criteria for ‘gluten free’ and ‘low gluten’ claims. Experts have also suggested that there is insufficient evidence to support such an amendment.

A similar argument has been presented by the Dietary Management EAG in relation to malt. It is suggested that an extension of the specific prohibition on malt to include malt ‘and its products’ would result in very few foods being able to meet the criteria for ‘gluten free’ and ‘low gluten’ claims. For example, advice provided to FSANZ is that some breakfast cereals (e.g. Rice Bubbles and Corn Flakes) are not based on gluten containing cereals but do contain small amounts of malt extract, which have been added to achieve a browning effect. Laboratory analysis of these products has revealed ‘nil detected’ gluten levels. If the prohibition on malt is extended to ‘malt products’, it would mean that these products cannot be classified as ‘gluten free’ or ‘low gluten’ despite having no detectable gluten.

*Option 3 provides additional regulation to Option 1. Would this level of regulation be necessary?*

*What are the impacts, both positive and negative on individuals with Coeliac disease, if the prohibition on oats was extended to oats ‘and its products’ in the criteria for making ‘gluten free’ and ‘low gluten’ claims?*

*What proportion of people with Coeliac disease would be affected? Are these from a particular sub-group of people with Coeliac disease?*

*What are the impacts, both positive and negative on individuals with Coeliac disease, if the prohibition on malt was extended to malt ‘and its products’ in the criteria for making ‘gluten free’ and ‘low gluten’ claims?*

*What proportion of people with Coeliac disease would be affected? Are these from a particular sub-group of people with Coeliac disease?*



### 7.3.2 Industry

*What would be the impact on industry if the prohibition on oats was extended to oats 'and its products' in the criteria for making 'gluten free' and 'low gluten' claims?*

*What food products currently on the market would be disadvantaged?*

*What would be the impact on industry if the prohibition on malt was extended to malt 'and its products' in the criteria for making 'gluten free' and 'low gluten' claims?*

*What food products currently on the market would be disadvantaged?*

### 7.3.3 Government

*What would be the impact on government if the prohibition on oats was extended to oats 'and its products' in the criteria for making 'gluten free' and 'low gluten' claims?*

*What would be the impact on government if the prohibition on malt was extended to oats 'and its products' in the criteria for making 'gluten free' and 'low gluten' claims?*

## 8. Consultation

FSANZ is committed to actively engaging stakeholders in the review and development of food standards. To achieve this, the following consultation processes have been or will be undertaken.

### 8.1 External Advisory Groups

The engagement of key stakeholders from both Australia and New Zealand at Initial Assessment, was considered essential for the examination of matters related to this review. As such, FSANZ established two External Advisory Groups (EAGs), the Dietary Management Group and the Analytical Methodology Group, consisting of medical specialists and representatives from government, industry and consumers, respectively, to provide expert advice when required. The membership of the EAGs and their terms of reference are at Attachment 3. To date, the EAGs have met by teleconference on one occasion.

### 8.2 Invitation for Public Submissions

This report has raised a number of questions in relation to oats and malt and gluten claims. These are intended to guide comment but should by no means be seen to pre-empt or restrict any views.

Submitters' comments will be taken into account in the development of any regulatory measures arising from this review. Furthermore, please note that comments on relevant subject matter not identified by this report are also welcome. Comments that would be useful could cover:

- scientific aspects of the Proposal, in particular, information about any recent research conducted on the relationship between gluten/oats/malt and Coeliac disease, or information in relation to the use of analytical methodology in assessing the presence of gluten in foods;
- parties that might be affected (either negatively or positively) by the proposed regulatory options;
- evidence in support of or opposition to the proposed regulatory options or any alternative options identified; and
- the potential impact of the proposed or any alternative regulatory options to consumers and public health professionals, industry and government.

The Initial Assessment Report will be made available for public access via the FSANZ website. In addition, a copy of the report will be sent to key stakeholders. All stakeholders that make a submission in relation to the Proposal will be included on a mailing list to receive further FSANZ documents in relation to the Proposal. Other interested parties, as they come to the attention of FSANZ, will also be added to the mailing list for public consultation.

### **8.3 International and World Trade Organization**

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by Coalition of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory.

Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

## **9. Conclusion and Recommendation**

This report discusses a range of issues relating to the regulation of gluten claims, specifically in relation to oats and malt. FSANZ seeks comment on these matters from all sectors of the community including consumers and health professionals, industry and governments. Submissions to this Initial Assessment will be used to further develop P264, including the preparation of draft regulatory measures, which will be circulated for public consideration within the context of the Draft Assessment Report for P264.

## 10. References

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## Attachments

1. Standard 1.2.8, Clause 16.
2. International Regulations Relating to Gluten Claims.
2. Membership of External Advisory Groups and their terms of reference.

**Standard 1.2.8, Clause 16**

**16 Claims in relation to gluten content of food**

(1) Claims in relation to the gluten content of food are prohibited unless expressly permitted by this Code.

**Editorial note:**

This subclause does not prohibit the declaration of the presence of gluten, for example, in an ingredient list on the label on a food.

(2) A claim to the effect that a food is gluten free must not be made in relation to a food unless the food contains no -

- (a) detectable gluten; and
- (b) oats or malt.

(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 –

- (a) more than 20 mg gluten per 100 g of the food; and
- (b) oats or malt.

**Editorial note:**

Subclauses (2) and (3) of this clause permit claims to the effect that a food is gluten free or has a low gluten content, providing certain specified conditions are met.

(4) A claim to the effect that a food contains gluten or is high in gluten may be made in relation to a food.

**Editorial note:**

Subclause 16(1) prohibits all claims about gluten unless expressly permitted. Subclauses 16(2), (3) and (4) provide those express permissions.

### 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 0.05g per 100g 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 than 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 100g 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 prolamins from wheat is gliadin, from rye is secalin, from barley hordein and from oats avenin. The prolamins 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.

### **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.

### External Advisory Groups and Terms of Reference

#### 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

#### Terms of Reference

Within the scope of Proposal PP264 – Review of Criteria for Gluten Claims, the terms of reference for the External Advisory Group are to:

1. Provide expert advice on the reliability of current methods of analysis to detect gluten and gluten equivalent fractions in foods, and specifically, in oats and malt.
2. Consider and provide feedback on information received as part of stakeholder consultations for PP264 and previous related matters, specifically in relation to current methods of analysis to detect gluten and gluten equivalent fractions in foods.

#### 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

#### Terms of Reference

Within the scope of Proposal PP264 – Review of Criteria for Gluten Claims, the terms of reference for the External Advisory Group are to:

1. Provide expert advice on the dietary management of coeliac disease, and specifically, in relation to the toxicity of oats and malt and their products for people suffering from coeliac disease.
2. Consider and provide feedback on information received as part of stakeholder consultations for PP264 and previous related matters, specifically in relation to the dietary management of coeliac disease.