

6-04
4 August 2004

FIRST REVIEW REPORT

PROPOSAL P264

REVIEW OF GLUTEN CLAIMS WITH SPECIFIC REFERENCE TO OATS & MALT

1. Objectives of Review

The Australia and New Zealand Food Regulation Ministerial Council has requested a First Review of a draft variation to Standard 1.2.8 – Nutrition Information Requirements, of the *Australia New Zealand Food Standards Code* (the Code). FSANZ is required to review the decision by 17 August 2004.

Proposal P264 – Review of Gluten Claims with Specific Reference to Oats and Malt, seeks to clarify subclauses 16(2) and 16(3), Standard 1.2.8 in terms of whether to retain the prohibition of gluten claims on foods containing oats or malt and if so, whether to extend the prohibition to foods that contain products of oats or malt.

The objective of this Review is to reconsider the draft variations to Standard 1.2.8 in light of the Ministerial Council’s concerns as outlined in Section 2.

2. Review on grounds requested by the Ministerial Council

The review of Proposal P264 is requested on the grounds that ‘it does not promote consistency between domestic and international food standards where they are at variance’. Specifically, the following points were raised by the Ministerial Council:

- A. FSANZ has not provided adequate justification to extend the prohibition of *gluten free* claims on foods containing *products* of oats or malt;
- B. FSANZ has presented no evidence that the current situation is causing a problem for either the average person with Coeliac disease or the most sensitive persons with Coeliac disease. The most sensitive consumers are generally at such risk that they would be under the supervision of a medical professional. If there is any doubt about products of oat and/or malt, the ingredient list may be consulted;
- C. Opinion is divided amongst experts in terms of the extent to which oats and malt cause an adverse reaction in persons with Coeliac disease;
- D. The recommendation concerning extending the prohibition on oats and malt to products of oats and malt is not consistent internationally. The Codex standard for gluten free foods is currently being revised, and is being held at Step 7 pending the resolution of issues (the methods of determination of gluten and the threshold levels of gluten intolerance); and
- E. Under the current Standard, there is a requirement that *gluten free* foods contain no detectable gluten.

3. Background

The criteria and conditions for making gluten claims were considered under Proposal P176 – Review of Provisions for Gluten Free and Low Gluten Foods during the review of the Code. 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.

Under clause 16, Standard 1.2.8, a *gluten free* claim can be made if the food contains no detectable gluten and no oats or malt, whereas a *low gluten* claim can be made if the food contains no more than 20 mg/100 g gluten and no oats or malt. The separate prohibition on oats and malt in relation to gluten claims 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 individuals with Coeliac disease.

In addition to voluntary claims made in relation to the gluten content of a food in accordance with Standard 1.2.8, there are additional mandatory labelling requirements for cereals containing gluten and their products in Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. Clause 4 of Standard 1.2.3 requires that cereals containing gluten, namely, wheat, rye, barley, oats and spelt and their hybridised strains, including their products, 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.

Proposal P264 was prepared in response to a stakeholder enquiry which sought clarification about whether the prohibition on oats and malt in relation to gluten claims in Standard 1.2.8 of the Code, also included the ‘products of oats and malt’. Consistent with Standard 1.2.3, the term ‘products of oats and malt’ is considered to include those substances derived from oats or malt that may be added to foods. Some examples of malt products (in order of refinement) are: malted flours, malt extract, malt vinegar and maltose. These substances are obtained from gluten containing cereals via a malting process.

FSANZ’s primary objectives in relation to Proposal P264 are to protect the health and safety of individuals with Coeliac disease and to ensure that consumers are provided with adequate information from a regulatory perspective to make appropriate choices for their level of gluten intolerance. Specifically, Proposal P264 seeks to clarify subclauses 16(2) and 16(3), Standard 1.2.8 in terms of whether to retain the prohibition of gluten claims on foods containing oats or malt and if so, whether to extend the prohibition to foods that contain products of oats or malt.

The scope of Proposal P264 was limited to an assessment of the issues related to oats and malt in gluten claims. Additional criteria for making a *gluten free* claim, that is, that a food contains *no detectable gluten* were considered in earlier Proposals and therefore the issue of whether *no detectable gluten* is a suitable criterion for making a gluten free claim was outside the scope of this Proposal (**this comment relates to Item E in Section 2 above**).

4. Options

There are three options proposed for consideration under this Review:

1. reaffirm approval of the draft variations to Standard 1.2.8 of the Code as notified to the Council; or
2. reaffirm approval of the draft variations to Standard 1.2.8 of the Code subject to any amendments FSANZ considers necessary; or
3. withdraw approval of the draft variations to Standard 1.2.8 of the Code as notified to the Council.

5. Review of Proposal P264 on the grounds that it ‘does not promote consistency between domestic and international food standards where these are at variance’(including Item D of specific comments raised)

In terms of the regulation of gluten claims internationally, only Canada and Codex specifically regulate *gluten free* claims. Regulation B.24.018 of the Canadian Food and Drug Regulations states that *no person shall label, package, sell or advertise a food in a manner likely to create an impression it is a gluten-free food unless the food does not contain wheat, including spelt and kamut, or oats, barley, rye or triticale or any part thereof*. This approach is more restrictive than both Codex and the current requirements and proposed variation to Standard 1.2.8 of the Code in relation to *gluten free* claims.

Under the Codex Standard for ‘Gluten-Free’ Foods (Codex Stan 118-1981) (amended 1983), a gluten free claim can be made if the total nitrogen content of the gluten-containing cereal grains (wheat, triticale, rye, barley or oats) used in the product does not exceed 0.05 g per 100 g of these grains on a dry matter basis.

The Codex Standard for ‘Gluten-Free’ Foods is currently being revised. This review commenced in 1995. The Draft Revised Codex Standard is currently being held at Step 7 of the Codex procedure pending the resolution of issues on the method of determination of gluten and the threshold levels of gluten tolerance in individuals with Coeliac disease.

FSANZ is aware that research is being undertaken in Europe in relation to small dose gluten challenge and gluten analysis using the proposed new R5 method. This research will be discussed in association with the next Codex Committee meeting on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to be held in November 2004. However, it is unlikely that a consensus will be reached and that the Draft Revised Standard for Gluten-Free Claims will be progressed beyond Step 7 at the next Codex meeting.

FSANZ recognises that the amendments to the provisions for *gluten free* claims as proposed in P264 are inconsistent with the current Codex Standard for ‘Gluten-Free’ Foods and the Draft Revised Codex Standard (in its current form, and noting that this may change). However, whilst having regard to the promotion of consistency between domestic and international standards, FSANZ believes that its primary objectives of the protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices (as discussed further in Section 5) are best promoted by these draft amendments. Therefore, in FSANZ’s view, the draft variations to Standard 1.2.8 of the Code should be reaffirmed. FSANZ will re-evaluate its position in relation to *gluten free claims* following completion of the Codex review.

6. Other comments relevant to specific points raised by Ministerial Council

The following information relates to Items A to C as raised by the Ministerial Council (Section 2 of this Report):

FSANZ acknowledges that no direct evidence has been provided that the current situation is causing a problem for individuals with Coeliac disease. FSANZ also agrees that the most sensitive consumers would be under the supervision of a medical professional and that the ingredient list can be consulted to determine the presence of oats and/or malt (refer Background Section). However, as discussed under Section 3, the current standard is ambiguous and clearly has the potential to have a negative impact on industry and enforcement agencies due to difficulties in ensuring consistent interpretation and enforcement of the Standard.

As part of the assessment of proposal P264, FSANZ conducted a review of the scientific literature in relation to the toxicity of oats and malt in individuals with Coeliac disease, as well as a review of current analytical methods to detect gluten in oats and malt. In addition, FSANZ convened two Expert Advisory Groups (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 to the FSANZ Project Team when required. The EAGs met on two occasions and input from the meetings was incorporated in the Assessment Reports for P264.

A review of the scientific literature suggests that the majority of individuals with Coeliac disease can tolerate moderate amounts of uncontaminated oats in the diet without adverse effects. However, these studies were not conclusive, and in many cases uncontaminated oats were used (which are not generally available in the food supply in Australia and New Zealand). Consultations with the Dietary Management EAG and stakeholder comments revealed that opinion was divided in terms of the dietary management of individuals with Coeliac disease. Representative health professionals in New Zealand 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 ‘sensitive’ individuals with Coeliac disease who are unable to tolerate even the smallest amounts of oats and malt.

In addition to the issues associated with the dietary management of Coeliac disease, a review of the scientific literature and consultation with the Analytical Methodology EAG highlighted the limitations of commercial analytical methods in their ability to detect barley hordeins (and therefore malted barley products) and oat avenins, the gluten equivalent fractions that are toxic to individuals with Coeliac disease.

Given these issues, a range of regulatory options was considered by EAG members at their face-to-face meeting in May 2003, with members agreeing on a preferred approach. The approach agreed at this meeting formed the basis of the proposed variation to Standard 1.2.8 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 and malt.

Under this approach, those individuals with Coeliac disease who are ‘less sensitive’ are able to choose foods that are labelled as *low gluten*, while ‘sensitive’ individuals are able to choose foods labelled as *gluten free*.

This approach was presented as an additional regulatory option at Draft Assessment and, following a cost-benefit assessment of the regulatory options, was subsequently recommended as the preferred option at Final Assessment. The drafting was amended slightly at Final Assessment to clarify that the prohibition on malt and malt products in *gluten free* claims relates only to malt and malt products from **gluten containing cereals**. In other words, malted rice, sorghum and buckwheat, which are not derived from gluten containing cereals, would not prevent a *gluten free* claim providing the food does not contain detectable gluten. This is in fact less restrictive than the current requirements in Standard 1.2.8.

The recommendation to extend the prohibition on oats and malt to foods containing products of oats and malt clarifies the existing provisions for making *gluten free* claims in Standard 1.2.8 and will enable the Standard to be interpreted consistently by industry and enforcement agencies. Individuals with Coeliac disease can also be assured that foods labelled as *gluten free* will be safe to eat.

7. Impact analysis

The parties affected by this First Review are consumers with Coeliac disease, health professionals, manufacturers of *gluten free* and *low gluten* foods and governments. Option 3, to withdraw approval of the draft variations, would not deliver the specific objective of this First Review, as it would still be inconsistent with the current Codex Standard for ‘Gluten-Free’ Foods. To await the outcome of the Codex review process would be undesirable, in view of the ambiguity in Standard 1.2.8 and the potential for misinterpretation. Furthermore, Option 3 would not be consistent with FSANZ’s primary objectives of the protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices.

FSANZ does not consider it appropriate to make any amendments to the draft variations in accordance with Option 2, as a variation would not deliver the specific objective of this First Review. Option 1 is preferred over Options 2 and 3 as it addresses the Ministerial Council’s concerns and best promotes FSANZ’s objectives of protecting public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices.

The preferred option is therefore Option 1.

8. Conclusion and recommendation

The Board reaffirmed its approval of the draft variations to Standard 1.2.8 – Nutrition Information Requirements of the Code, for the following reasons:

8.2 Statement of Reasons

- The current Standard regarding claims in relation to the gluten content of a food provides that:
 - a ‘gluten free’ claim can be made if the food contains no detectable gluten, and no oats or malt;
 - a ‘low gluten’ claim can be made if the food contains no more than 20 mg gluten / 100 g food, and no oats or malt (clause 16, Standard 1.2.8)

- The variation as approved at Final Assessment would mean that:
 - a 'gluten free' claim can be made if the food contains no detectable gluten, and no oats or their products; or no cereals containing gluten that have been malted, or their products;
 - a 'low gluten' claim can be made if the food contains no more than 20 mg gluten / 100 g food.
- The separate prohibition on oats or malt in the current Standard was included due to a lack of reliable methods of analysis for detecting gluten equivalent fractions of oats and malt that may be toxic to individuals with Coeliac disease.
- The variation as approved at Final Assessment also clarified that the prohibition on malt and malt products in *gluten free* claims relates only to malt and malt products from *gluten containing cereals*, as opposed to malt and malt products from all cereals. This amendment would mean that the requirements in Standard 1.2.8 would be less restrictive than the current requirements.
- Commercial analytical methods continue to be limited in their capacity to detect barley hordeins (and therefore malted barley products) and oat avenins in food, the gluten equivalent fractions that are toxic to individuals with Coeliac disease.
- Inquiries received by FSANZ indicate that some stakeholders find the current Standard is ambiguous as to whether the prohibition on oats or malt extends to products of oats or malt. Such ambiguity has the clear potential to make it difficult for industry to interpret the Standard in order to comply with it, and to make it difficult for enforcement agencies to interpret the Standard and so to enforce it.
- A review of the scientific literature suggests that the majority of individuals with Coeliac disease can tolerate moderate amounts of uncontaminated oats in the diet without adverse effects. However, these studies are not conclusive. The food supply in Australia and New Zealand contains contaminated oats, which were not the subject of these studies.
- Health professionals' views differ as to whether individuals with Coeliac disease can tolerate small amounts of oats and malt. A significant proportion believes that sensitive individuals cannot tolerate even the smallest amounts of oats or malt, including oat or malt products.
- The current Codex Standard for 'Gluten Free Foods' provides that a gluten free claim can be made if the total nitrogen content of the gluten containing cereal grains used in the product do not exceed 0.05 g/100g of these grains on a dry matter basis. The review of this Standard commenced in 1995. The Draft Revised Codex Standard is not finalised, and is unlikely to progress beyond Step 7 at the next Codex meeting.
- FSANZ's primary objectives in relation to food standards are to protect public health and safety, to provide adequate information relating to food to enable consumers to make informed choices, and to prevent misleading or deceptive conduct. However, FSANZ must also have regard to other matters, including the promotion of consistency between domestic and international food standards.

- FSANZ considers that the health and safety of individuals with Coeliac disease is best protected by the variation as approved at Final Assessment. This variation allows ‘less sensitive’ individuals with Coeliac disease to choose low gluten foods, whilst ‘sensitive’ individuals are able to choose gluten free foods. Both groups are thus protected, and provided with adequate information to make informed choices. If the variation were not made, the Standard may continue to be interpreted inconsistently, resulting in inconsistent use of gluten claims by industry. This would appear likely to make it more difficult for individuals with Coeliac disease to choose appropriate foods, than would be the case if the ambiguity is resolved through the variation to clause 16 of Standard 1.2.8. It also gives rise to difficulties in ensuring consistent interpretation and enforcement of the Standard.
- FSANZ has had regard to the fact that this variation does not promote consistency between clause 16 of Standard 1.2.8, and the current and draft Codex standards in this area. However, the current Standard dates back to the early 1980’s and is presently under review. As such, it does not reflect the current scientific knowledge in this area. Clause 16 of Standard 1.2.8, even without the proposed variation, is not consistent with the current Codex standard. The draft revised Codex standard is not yet finalised, and is unlikely to progress beyond Step 7 at the next Codex meeting. FSANZ does not consider it prudent to seek to align with this draft revised Codex standard, which may be subject to further amendment. Nor does FSANZ consider it appropriate to refuse to resolve an ambiguity in clause 16 of Standard 1.2.8, which has real consequences in promoting compliance and enforcement, and in ensuring consistent labelling for use by individuals with Coeliac disease, for an indefinite period whilst the revised Codex standard is finalised. Following completion of the Codex review, FSANZ will re-evaluate its position in relation to *gluten free* claims.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.

DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE

To commence: on gazettal

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

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

(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 –

- (a) no detectable gluten; and
- (b) no –

- (i) oats or their products; or
- (ii) cereals containing gluten that have been malted, 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.