

# 12 November 2014 [24–14]

## Call for submissions - Proposal P1035

## Gluten Claims about Foods containing Alcohol

FSANZ has assessed a Proposal to permit nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume to continue to be made when Standard 1.2.7 – Nutrition, Health and Related Claims becomes mandatory. FSANZ has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 24 December 2014

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to <a href="mailto:standards.management@foodstandards.gov.au">standards.management@foodstandards.gov.au</a>.

Hard copy submissions may be sent to one of the following addresses:

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## **Executive summary**

Standard 1.2.7 – Nutrition, Health and Related Claims, which regulates nutrition content and health claims, was included in the *Australia New Zealand Food Standards Code* in January 2013. When that Standard becomes mandatory in January 2016, nutrition content claims about gluten content in relation to food containing more than 1.15% alcohol by volume (including beverages) will be prohibited. Until then, under the transitional arrangements for Standard 1.2.7, nutrition content claims about gluten content in relation to such foods are permitted, as long as the food meets specified conditions.

Consumers with coeliac disease must avoid consuming gluten to prevent ill-health. These consumers will no longer have access to *gluten free* or *low gluten* information within the range of foods containing more than 1.15% alcohol by volume when Standard 1.2.7, as it currently reads, becomes mandatory.

FSANZ has therefore prepared this Proposal to amend Standard 1.2.7 so that nutrition content claims about gluten content in relation to food containing more than 1.15% alcohol by volume continue to be permitted after January 2016. Under this Proposal, the conditions for gluten content claims, previously in Standard 1.2.8 – Nutrition Information Requirements and now in Standard 1.2.7, are unchanged and will continue to apply. The amendments proposed will allow gluten content claims to continue to be made about such food, under the same conditions that were in place before Standard 1.2.7 was gazetted.

This will enable consumers with coeliac disease to continue to make suitable choices appropriate for their condition, within the range of alcoholic beverages and other food containing alcohol.

FSANZ is calling for submissions to help the assessment of this Proposal.

## 1 Introduction

## 1.1 The Proposal

FSANZ has prepared this Proposal to continue to permit nutrition content claims about gluten content in relation to food containing more than 1.15% alcohol by volume (including beverages) to be made after 18 January 2016. The conditions for gluten content claims prescribed in the *Australia New Zealand Food Standards Code* (the Code) were developed because of the relevance of these claims to the health and safety of consumers with coeliac disease.

### 1.2 The current Standard

In the Code, clause 3 of Standard 1.2.7 – Nutrition, Health and Related Claims, prohibits nutrition content claims (including *gluten free* and *low gluten*) in relation to a food that contains more than 1.15% alcohol by volume (except for nutrition content claims about energy or carbohydrate content). Standard 1.2.7 was gazetted in January 2013 and has a three year transition period, until January 2016.

Schedule 1 of Standard 1.2.7 sets out conditions for making nutrition content claims about gluten (see Table 1 below). Subclause 11(7) states that a nutrition content claim for gluten may only state that –

- the food is gluten 'free' or 'low' in gluten (or words that mean the same thing); or
- the food contains gluten or is high in gluten.

Table 1: Conditions for nutrition content claims about gluten (Schedule 1 of Standard 1.2.7)

Claim	Conditions
Free	The food must not contain –
	<ul><li>(a) detectable gluten; or</li><li>(b) oats or their products; or</li></ul>
	(c) cereals containing gluten that have been malted, or their products.
Low	The food contains no more than 20 mg gluten per 100 g of the food.

Before Standard 1.2.7 was gazetted, these conditions were in Standard 1.2.8 – Nutrition Information Requirements, and nutrition content claims about gluten in relation to food containing alcohol were permitted. Suppliers can continue to rely on the provisions that were in the Code before Standard 1.2.7 was gazetted until the end of the transition period for Standard 1.2.7 in January 2016.

Beverages containing 0.5% alcohol by volume or more; and other alcoholic beverages standardised in Standards 2.7.2 to 2.7.5 (Beer; Fruit Wine and Vegetable Wine; Wine and Wine Product; Spirits) are exempt from the requirement for the label to include a nutrition information panel (clause 3 of Standard 1.2.8). However, if a nutrition content claim is made about such food, this exemption no longer applies and a nutrition information panel must be provided (clause 4 of Standard 1.2.8).

Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations, requires the presence of cereals containing gluten to be declared in food, however beer and spirits standardised in Standards 2.7.2 – Beer and 2.7.5 – Spirits respectively, are exempt from this requirement.

This exemption was provided when Standard 1.2.3 was developed in 2000, because FSANZ (then the Australia New Zealand Food Authority (ANZFA)) considered that coeliac societies and health professionals could provide targeted information to people with coeliac disease about the types of alcoholic beverages to avoid. The brewing and distilling industry in Australia and New Zealand were also encouraged to assist in educating people with coeliac disease about appropriate consumption of beer and spirits with respect to their condition.

### 1.3 Reasons for preparing the Proposal

When Standard 1.2.7 becomes mandatory in January 2016, nutrition content claims about gluten content in relation to food containing more than 1.15% alcohol by volume will be prohibited. Consumers with coeliac disease, who must avoid consuming gluten to prevent ill-health, will no longer have access to *gluten free or low gluten* information within the range of food containing more than 1.15% alcohol by volume, if nutrition content claims about gluten content in relation to these products continue to be prohibited.

Most beers and some other alcoholic beverages are produced from ingredients containing gluten, for example, barley, wheat, rye. Some beers however, are produced to be *gluten free* in both Australia and New Zealand, under the conditions in place before Standard 1.2.7 was gazetted. For beers and spirits, as there is no requirement to declare the presence of gluten and when Standard 1.2.7 becomes mandatory – with no permission to make gluten content claims, there will be no way of ensuring that consumers of such food receive information about the gluten content of the food. Most alcoholic beverages are also exempt from the requirement to have an ingredient list.

Manufacturers of *gluten free* beers in New Zealand and Coeliac New Zealand are concerned that *gluten free* beer will no longer be permitted to be labelled or advertised as such, when Standard 1.2.7 becomes mandatory. There are also some other foods that contain more than 1.15% alcohol by volume for which *gluten free* options may be appropriate or are currently available, e.g. soy sauce, marinades and essences.

### 1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

## 2 Summary of the assessment

### 2.1 Risk assessment

Coeliac disease is an autoimmune disease affecting around 1% of the Australian and New Zealand populations (Chin et al. 2009; Tanpowpong et al. 2012). In genetically predisposed individuals, coeliac disease is caused by ingestion of gluten protein that is usually present in wheat, rye, barley and oat-based food products. In these individuals, the immune system becomes sensitised to gluten. The sensitised immune system then cross-reacts with normal intestinal tissue, resulting in tissue damage which affects the absorption of nutrients from the gastrointestinal tract and increases the risk of osteoporosis and intestinal cancer. While the disease can be caused by a reaction to wheat proteins, it is not the same as wheat allergy.

No medication currently exists that prevents the sensitised immune system from causing gut damage when gluten is present in the diet. The only known effective treatment for coeliac disease is a lifelong diet without gluten, but in practice this can be difficult to achieve. Strict adherence to a diet which avoids gluten allows the intestines to recover, leading to resolution of symptoms in most cases, which in turn reduces the osteoporosis and cancer risks.

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.

The conditions for gluten content claims prescribed in Standard 1.2.7 (and in Standard 1.2.8 before the gazettal of Standard 1.2.7) were developed because of the relevance of these claims to the health and safety of consumers with coeliac disease. These conditions, including the conditions for *free* claims, are not being reviewed as part of this Proposal.

The conditions in Standard 1.2.7 would apply to gluten content claims in relation to food containing more than 1.15% alcohol by volume, if permitted. FSANZ therefore considers that an assessment of the risks to public health and safety associated with food carrying claims that meet those conditions is not necessary at this time.

## 2.2 Risk management

FSANZ is proposing to permit nutrition content claims about gluten for all food containing alcohol (including beverages). This approach would enable consumers with coeliac disease to continue to make suitable choices appropriate for their condition, within the range of alcoholic beverages and other food containing alcohol.

The conditions for gluten content claims previously in Standard 1.2.8 and now in Standard 1.2.7, would apply. This would allow gluten content claims to continue to be made about such food, under the same conditions that were in place before gazettal of Standard 1.2.7. Manufacturers of foods carrying gluten content claims are responsible for ensuring the food meets prescribed conditions.

The permission for nutrition content claims about gluten content would apply to all food containing alcohol, including those that do not naturally or inherently contain gluten, consistent with the approach in the Code for *free* claims. The potential for *free* claims to be misleading when made about food naturally or inherently free of the property that is the subject of the claim, was considered under Proposal P293 – Nutrition, Health & Related Claims. FSANZ determined that this risk could be managed by consumer law, which requires that representations are not misleading. Specific conditions to address this risk were therefore not included in Standard 1.2.7. This was also the approach for *gluten free* claims before gazettal of Standard 1.2.7.

A nutrition information panel would be required to be provided for food making nutrition content claims about gluten content, including alcohol beverages, in accordance with existing requirements in Standard 1.2.8. This requirement also applied before Standard 1.2.7 was gazetted.

### 2.3 Risk communication

#### 2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by this Proposal and the effects of regulatory options. Every submission is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

FSANZ develops communication plans to ensure stakeholders are aware of proposed changes to the Code. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received following this call for submissions. Anyone who is an interested party or who makes a submission will be notified at each stage of the assessment. Subscribers and interested parties are also notified by email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, stakeholders will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

### 2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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.

There are relevant international standards. Removing the prohibition on nutrition content claims about gluten content for food containing more than 1.15% alcohol by volume is unlikely to have a significant effect on international trade. This is because the proposed amendment allows these claims to continue to be made, under the same conditions that were in place before Standard 1.2.7 was gazetted. Therefore, notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## 2.4 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

### 2.4.1 Section 59

### 2.4.1.1 Cost benefit analysis

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Proposal are likely to outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

The Office of Best Practice Regulation (OBPR) has advised FSANZ that the Proposal is not likely to have a regulatory impact on business, community organisations or individuals and that a COAG Regulatory Impact Statement (RIS) is not required to be prepared (OBPR ID: 17751). This is because the changes are minor and machinery in nature and are also deregulatory. The changes will allow gluten content claims to continue to be made, under the same conditions that were in place before Standard 1.2.7 was gazetted.

Affected parties include the following:

**Consumers:** The draft variation will allow for consumers with coeliac disease to continue to make suitable choices appropriate for their condition, within the range of alcoholic beverages and other food containing alcohol. No costs to consumers have been identified as a result of continuing with permissions in place before Standard 1.2.7 was gazetted.

**Industry:** The draft variation will benefit manufacturers of food containing more than 1.15% alcohol by volume as they will continue to be permitted to produce and label *gluten free* or *low gluten* alternatives. There are not expected to be any additional costs resulting from this Proposal to manufacturers, as the conditions previously in Standard 1.2.8 applying to these voluntary gluten content claims will remain the same in Standard 1.2.7. This includes the requirement to provide a nutrition information panel if a nutrition content claim about gluten content is made.

**Government:** There are no additional costs to government as the draft variation maintains the position before the gazettal of Standard 1.2.7. The permission for gluten content claims will apply to all food containing alcohol and the associated conditions will be consistent with those in Standard 1.2.7, providing for ease of enforcement.

#### 2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more costeffective than a food regulatory measure developed or varied as a result of the Proposal.

FSANZ considered requiring cereals containing gluten to be declared on beer and spirits standardised in standards for beer and spirits (i.e. removing the exemption from declaring cereals containing gluten that currently applies to these beverages). The proposed draft variation however, maintains an approach that has been in place for a number of years. FSANZ is not aware of any problems arising from this regulatory approach and it is more cost-effective than amending the Code to require the presence of cereals containing gluten to be declared on all beers and spirits containing gluten.

### 2.4.1.3 Any relevant New Zealand standards

The draft variation amends a joint Australia New Zealand standard. There are no relevant New Zealand only standards.

### 2.4.1.4 Any other relevant matters

There are no other relevant matters.

### 2.4.2 **Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### 2.4.2.1 Protection of public health and safety

The gluten content claim conditions prescribed in Standard 1.2.7 were developed because of the relevance of these claims to the health and safety of consumers with coeliac disease. These claim conditions would continue to apply to all alcoholic beverages and other food containing alcohol, if permission for gluten content claims continues as proposed.

## 2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

If permission for gluten content claims continues as proposed, consumers with coeliac disease will continue to have access to information about gluten (e.g. *gluten free* or *low gluten*) in alcoholic beverages and other food containing alcohol, where manufacturers voluntarily make these claims.

### 2.4.2.3 The prevention of misleading or deceptive conduct

The current claim conditions will apply and these will assist in addressing issues of misleading or deceptive conduct. Legislation that prevents misleading and deceptive behaviour will also apply to these claims (i.e. the *Competition and Consumer Act 2010* in Australia; consumer protection laws in States and Territories; and the *Fair Trading Act 1986* in New Zealand).

### 2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

## • the need for standards to be based on risk analysis using the best available scientific evidence

The proposed amendment means that existing gluten content claims could continue to be made, under the same conditions that were in the Code before Standard 1.2.7 was gazetted. No scientific risk analysis has therefore been undertaken by FSANZ.

## the promotion of consistency between domestic and international food standards

The United States of America, Canada and the European Union permit *gluten free* claims about alcoholic beverages, as long as specified conditions are met. Although, the conditions for gluten content claims are not consistent internationally, this is the case for all foods across the food supply and is not unique to beverages and other food containing alcohol.

### the desirability of an efficient and internationally competitive food industry

It is possible that permitting nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume will make it easier for Australian and New Zealand food businesses to trade such food internationally.

### the promotion of fair trading in food

The proposed variation allows for fair trading in food, as all alcoholic beverages and food containing alcohol would be subject to the same claim conditions.

### any written policy guidelines formulated by the Ministerial Council<sup>1</sup>

In December 2003, the Ministerial Council released the *Policy Guideline on Nutrition, Health and Related Claims*<sup>2</sup>. The Policy Guideline sets out the policy principles underpinning the regulation of nutrition content claims (and health claims) and aims to permit claims and encourage industry to innovate, whilst ensuring consumers are not misled.

<sup>&</sup>lt;sup>1</sup> Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

<sup>&</sup>lt;sup>2</sup> The Policy Guideline is available at: <a href="http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx">http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx</a>

An overarching policy principle is that claims can be made providing the eligibility criteria, including qualifying and/or disqualifying criteria (and any excluded categories of foods, such as alcohol and infant foods), are complied with; and the claim is socially responsible and does not promote irresponsible food consumption patterns.

The prohibition of nutrition content claims about food containing more than 1.15% alcohol by volume was considered when Standard 1.2.7 was developed under P293. At that time, in accordance with the Policy Guideline and given social issues regarding the abuse of alcoholic beverages, FSANZ restricted the use of claims that attribute a health benefit on alcohol. Nutrition content claims about carbohydrate and energy were permitted to continue as they were established in the marketplace. Although already permitted, FSANZ was not aware that gluten content claims in relation to food containing alcohol were in the marketplace at that time and therefore nutrition content claims about gluten were inadvertently caught within the general prohibition of nutrition content claims and not specifically considered.

## 3 Draft variation

The draft variation is at Attachment A. The variation is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

## 3.1 Transitional arrangements

The transition arrangements already in place for Standard 1.2.7 will apply. The transition period for Standard 1.2.7 ends in January 2016.

FSANZ considers that no additional transitional arrangements are required for this Proposal on the basis that the draft variation will take effect before the transitional arrangements for Standard 1.2.7 end.

### 3.1.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – Code Revision, details of which are on the FSANZ website<sup>3</sup>. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A.

## 4 References

Chin MW, Mallon DF, Cullen DJ, Olynyk JK, Mollison LC, Pearce CB (2009) Screening for coeliac disease using anti-tissue transglutaminase antibody assays, and prevalence of the disease in an Australian community. Med J Aust. 190: 429-32.

<sup>&</sup>lt;sup>3</sup> http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

Tanpowpong P, Ingham TR, Lampshire PK, Kirchberg FF, Epton MJ, Crane J, Camargo CA Jr (2012) Coeliac disease and gluten avoidance in New Zealand children. Arch Dis Child. 97:12-6

## **Attachments**

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

# Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Proposal P1035 – Gluten Claims about Foods containing Alcohol) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

### Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

### 1 Name

This instrument is the Food Standards (Proposal P1035 – Gluten Claims about Foods containing Alcohol) Variation.

### 2 Variation to Standards in the Australia New Zealand Food Standards Code

The Schedule varies a Standard in the Australia New Zealand Food Standards Code.

### 3 Commencement

The Variation commences on the date of gazettal.

### **SCHEDULE**

[1] Standard 1.2.7 is varied by omitting from paragraph 3(b) "energy content or carbohydrate content", and substituting "energy content, carbohydrate content or gluten content"

### **Attachment B – Draft Explanatory Statement**

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1035 – Gluten Claims about Foods containing Alcohol to amend Standard 1.2.7 – Nutrition, Health and Related Claims to permit nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation of Standard 1.2.7.

### 2. Purpose

The Authority has approved a draft variation to Standard 1.2.7 to permit nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume.

### 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

### 4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1035 will include one round of public consultation following an assessment and the preparation of a draft variation of Standard 1.2.7and an associated report.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.2.7 is not likely to have a regulatory impact on businesses and individuals.

### 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

#### 6. Variation

Item [1] amends paragraph 3(b) of Standard 1.2.7 by inserting a reference to gluten content in the paragraph. The effect of the amendment is to permit nutrition content claims about gluten content to be made in relation to a food that contains more than 1.15% alcohol by volume.

Any nutrition content claim made about the gluten content of a food would have to be made in accordance with the conditions specified in clause 11 and Schedule 1 of Standard 1.2.7.