

# 29 June 2015 [13–15]

# Approval Report – Proposal P1035

# Gluten Claims about Foods containing Alcohol

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared 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.

On 12 November 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 53 submissions.

FSANZ approved the draft variation on 1u June 2015. The Australia and New Zealand Ministerial Forum on Food Regulation<sup>1</sup> (Forum) was notified of FSANZ's decision on 26 June 2015.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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<sup>&</sup>lt;sup>1</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

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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* on 18 January 2013. When that Standard becomes mandatory on 18 January 2016, nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume (including beverages) will be prohibited. However 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 currently drafted, becomes mandatory.

FSANZ released a call for submissions on a proposed draft variation to the Code in November 2014 to permit nutrition content claims about gluten content in relation to food containing more than 1.15% alcohol by volume to continue to be made after January 2016. All submitters supported the proposed variation.

FSANZ has finalised its consideration of this Proposal, having considered all relevant matters, and has decided to amend Standard 1.2.7 so that nutrition content claims about gluten in relation to food containing more than 1.15% alcohol by volume continue to be permitted after January 2016.

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 amendment will allow gluten nutrition content claims to continue to be made about food containing more than 1.15% alcohol by volume, under the same conditions that were in place before Standard 1.2.7 was gazetted.

The amendment 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, for example, soy sauce.

Some submitters requested that gluten claims on food containing alcohol should not trigger the requirement to label with a nutrition information panel (NIP). FSANZ therefore undertook targeted stakeholder consultation to assist consideration of an exemption from the requirement to label with a NIP if a *gluten free* claim is made in relation to an alcoholic beverage. The majority of stakeholders consulted were supportive of this approach.

FSANZ has subsequently decided to amend Standard 1.2.8 to provide an exemption from the requirement to label with a NIP if a *gluten free* (but not *low gluten*) claim is made in relation to a beverage that is currently exempt from the requirement to be labelled with an NIP<sup>2</sup>. FSANZ considers that for these beverages, the requirement triggered by a *gluten free* claim to provide a NIP is not justified as the NIP does not provide any useful information to support consumer understanding of gluten content, or to compare the gluten content of alcoholic beverages.

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<sup>&</sup>lt;sup>2</sup> Alcoholic beverages standardised in Standards 2.7.2 to 2.7.5 (Beer; Fruit Wine and Vegetable Wine; Wine and Wine Product; Spirits respectively) and beverages containing no less than 0.5% alcohol by volume (clause 3 of Standard 1.2.8 of the current Code).

### Revised Code

A revision of the Code via Proposal P1025 – Code Revision, will replace the existing Code on 1 March 2016. FSANZ has therefore also approved draft amendments to both the current and the revised Code, to implement the changes outlined above.

# 1 Introduction

## 1.1 The Proposal

FSANZ prepared this Proposal to continue to permit nutrition content claims about gluten 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

### 1.2.1 Gluten claims

In the Code<sup>3</sup>, 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) of Standard 1.2.7 provides 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> <li>(c) cereals containing gluten that have been malted, or their products.</li> </ul>	
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 more than 1.15% alcohol by volume 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 on 18 January 2016.

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.

<sup>3</sup> The Code references in this report reflect the current Code. A revision of the Code through Proposal P1025 – Code Revision will replace the existing Code on 1 March 2016.

The exemption for beers and spirits 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 industries 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.

The above Standards and requirements are replicated in the revised Code.

### 1.2.2 Nutrition information panel requirements

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; and Spirits respectively) are exempt from the requirement for the label to include a nutrition information panel (NIP) (clause 3 of Standard 1.2.8 of the current Code). However, if a nutrition content claim is made about such food, this exemption no longer applies and a NIP must be provided (clause 4 of Standard 1.2.8). Therefore, a nutrition content claim about gluten on an alcoholic beverage will trigger the requirement for that beverage to be labelled with a NIP. Other foods containing alcohol, e.g. soy sauce, must be labelled with a NIP even if a claim is not made. These requirements applied before Standard 1.2.7 was gazetted.

The above requirements are also replicated in the revised Code.

# 1.3 Reasons for preparing Proposal

When Standard 1.2.7 becomes mandatory on 18 January 2016, nutrition content claims in general, 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. In Australia and New Zealand however, some beers are produced to be gluten free, under the claim conditions in place in the Code before Standard 1.2.7 was gazetted. For beer and spirits, as there is no requirement to declare the presence of gluten and, when Standard 1.2.7 becomes mandatory, no permission to make gluten content claims, there will be no way on the label to ensure that consumers 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 were 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 was assessed under the General Procedure.

### 1.5 Decision

The draft variation, as proposed following assessment, was approved with amendments. The variation takes effect on the date of gazettal. The approved draft variation, as varied after consideration of submissions, and related explanatory statement are at Attachment A.

Given that a revision of the existing Code will take effect on 1 March 2016, a draft variation to the revised Code was also approved. The approved draft variation and related explanatory statement are at Attachment B. The variation is intended to take effect on 1 March 2016.

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

The draft variation on which submissions were sought is at Attachment C.

# 2 Summary of the findings

# 2.1 Summary of issues raised in submissions

FSANZ received 53 submissions in total. All submitters supported the draft variation proposed.

The main issues raised in submissions were:

- NIPs should not be required when gluten claims are made about food containing alcohol, or alternatively, consider mandatory declaration of cereals containing gluten on alcohol beverages (remove existing exemption)
- there should be consideration of whether claims on alcoholic beverages imply a health benefit
- inadequate governance of food testing of *gluten free* food in Australia
- clarification is required of whether voluntary declaration of gluten ('contains' statements) are claims
- salt and sodium claims should be permitted on food containing alcohol (soy sauce was specifically of concern).

Further detail about these issues and the FSANZ responses are provided in Table 2 below.

A late comment was received from Rebellion Brewing Pty Ltd after the closing date for receipt of submissions. Whilst FSANZ is not required to have regard to late comments, we note they supported the proposed draft variation.

Coeliac New Zealand also wrote to FSANZ after the closing date, expressing support for the proposed variations.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
Exemption from NIP Suggestion that NIPs should not be required when gluten claims are made on food containing alcohol (if subject to exemption from the general requirement to label with a NIP).	Brewers Guild of New Zealand New Zealand Winegrowers New Zealand Food and Grocery Council Ministry for Primary Industries	Following targeted consultation, FSANZ decided to amend Standard 1.2.8 to provide an exemption from the requirement to label with a NIP if a gluten free (but not low gluten) claim is made in relation to an alcoholic beverage. Refer to section 2.3.2 for further information.
Alternative option to NIP exemption  - remove exemption for beer and spirits from labelling presence of cereals containing gluten.  This declaration would not generate the requirement for a NIP.  Advantage would be consistency of labelling of all gluten free foods.  Some consumers (with coeliac disease) indicated a preference for the labelling of the presence of gluten as well as gluten free claims.	Ministry for Primary Industries Consumers	A requirement to declare the presence of cereals containing gluten in beer and spirits is out of scope of this proposal, which is limited to maintaining permissions for claims about gluten content.  All stakeholders consulted supported the suggested option of a NIP exemption.  Therefore, FSANZ has not investigated removing the exemption for beer and spirits from labelling the presence of cereals containing gluten any further.
Need to ensure that the use of content claims on alcohol do not confer an implied health benefit, given the health risks associated with excessive alcohol consumption.  Suggest FSANZ conducts consumer research to determine whether the existing content claims, including energy, carbohydrate and gluten free, and the explicit usage of the word free, confer an implied health benefit to the consumption of alcohol.	Victorian Departments of Health, Business & Innovation and Environment & Primary Industries	The decision to permit claims about energy and carbohydrate was made during the development of Standard 1.2.7 and is not under consideration as part of this Proposal.  FSANZ recommends that gluten claims about alcoholic beverages continue to be permitted as they provide useful information to those with Coeliac disease.  FSANZ is not planning to conduct consumer research as suggested.

Issue	Raised by	FSANZ response
Would like FSANZ to facilitate a system of improved governance over testing of imported foods labelled gluten free.  Particularly problematic for imported food manufactured in countries which have established a gluten threshold of 20ppm or have no gluten standard.  Acknowledge that the 'ISFR subcommittee of FSANZ' has some responsibility in this area and the matter has been brought to the attention of two subcommittee members.	Dr Geoff Forbes and Frances Phillips, Royal Perth Hospital	Enforcement of the requirements of the Code, including for gluten claims, is the role of jurisdictions in the states and territories in Australia and the Ministry for Primary Industries in New Zealand.  The Implementation Subcommittee for Food Regulation (ISFR) is made up of representatives from these government agencies (it is not a subcommittee of FSANZ).  The ISFR Nutrition and Health Claims Implementation Working Group is monitoring the implementation of Standard 1.2.7 via a number of activities and intends to conduct a survey of nutrition, health and related claims in 2016.
Is declaration of 'gluten' a claim?  Some manufacturers declare 'contains gluten' or 'may contain (traces of) gluten' sometimes after an allergen statement. Technically, this is a nutrition content claim and must meet Standards 1.2.7 and 1.2.8, unless it is intended that gluten is captured by 'products' in Standard 1.2.3.  If a 'contains gluten' statement is meeting the requirements of Standard 1.2.3, suggest amending Standard 1.2.3 by including 'Gluten or' before 'Cereals containing' or clarifying that gluten is captured by the words 'products'.	Ministry for Primary Industries	This issue is outside the scope of this proposal as it could impact on a broader range of foods. FSANZ intends to consider this issue under a more appropriate project.
Salt and sodium claims should be permitted on foods containing alcohol Alternative suggestion to confine the prohibition of claims to either:  1. alcoholic beverages only 2. beverage, essence or confectionary product.  3.	Australian Food and Grocery Council Kikkoman Food and Beverage Importers Association	Permission for salt and sodium claims on foods containing alcohol will be considered as part of Proposal P1038 – Vitamin & Mineral Claims & Sodium Claims about Food containing Alcohol.

### 2.1.1 Requirement for nutrition information panels when gluten claims are made

As indicated above, some submitters requested an exemption from the requirement for alcoholic beverages to be labelled with a NIP when a gluten claim is made. FSANZ carried out targeted consultation with relevant stakeholders from the jurisdictions, the food and alcoholic beverage industry and consumer and public health agencies to assist with consideration of this request.

These stakeholders were specifically asked whether they supported an exemption from the requirement to label with a NIP if a *gluten free* (but not *low gluten*) claim is made in relation to an alcoholic beverage. This approach was proposed on the basis that for *gluten free* claims, the presence of a NIP does not provide any useful information to assist consumer understanding of gluten content, or to compare the gluten content between alcoholic beverages. However, for *low gluten* claims, it may be useful to provide the amount of gluten present for consumers with coeliac disease in the standardised NIP format.

The majority of stakeholders consulted were supportive of this approach, as follows:

- McCashin's Brewery
- Brand Evolution
- Rebellion Brewing
- Wine Federation of Australia
- DB Breweries
- Carlton & United Breweries
- Coeliac NZ, Brewers Guild of NZ
- NZ Winegrowers
- Dietitians Association of Australia (DAA)
- Lion
- Brewers Association of Australia and New Zealand
- Ministry for Primary Industries (MPI)
- Victorian Department of Health and Human Services
- NZ Food and Grocery Council (NZFGC)
- Australian Food and Grocery Council (AFGC)
- Coeliac Australia
- CHOICE
- some members of the Technical Sub Committee of the Food Technology Association of Australia (FTAA)).

### Reasons provided for support were:

- The NIP does not provide any relevant information required for consumers with coeliac disease.
- Consumers of the *gluten free* alcoholic beverage will not gain any useful information from a NIP with regard to the presence or absence of gluten.
- The NIP would not assist consumers to compare the gluten content of alcoholic beverages.
- Requirement for a NIP puts gluten free alcoholic beverage manufacturers at a
  disadvantage to all other alcoholic beverage manufacturers and is likely to prevent
  alcoholic beverage manufacturers from making gluten free claims.
- View gluten statements as an allergen warning and not a health statement or nutrition content claim.
- This approach is consistent with the current exemptions for alcoholic beverages regarding the provision of NIPs in Standard 1.2.8.
- It would be less confusing for consumers to not include gluten in a NIP when a *free* claim is made.

The majority of committee members from Technical Subcommittee of the FTAA did not support the exemption and instead indicated a preference for NIPs and ingredient labelling on all alcoholic beverages (irrespective of whether claims are made or not). Additional comments provided during this targeted consultation and the FSANZ responses are provided in Table 3.

Table 3: Summary of comments from targeted consultation on NIP exemption

Issue	Raised by	FSANZ response
The majority of the Technical Sub Committee of the FTAA members did not support the exemption. Indicated a preference for NIPs and ingredient labelling on all alcoholic beverages (irrespective of whether claims are made or not).	Food Technology Association of Australia (FTAA)	Comments about requiring NIPs and ingredient labelling on alcoholic beverages are noted, but are out of scope of this proposal.  Refer to section 2.3.2 for discussion about NIP exemption.
For low gluten, agree that it may be useful to provide the amount of gluten present but are not convinced that a standardised full NIP format is the necessary approach.  Suggest amount of gluten is declared in conjunction with a low gluten claim.	Brewers Guild  Vic Health	If the standardised NIP format was not required, requirements for how to declare the gluten content (e.g. per 100 mL or other basis, where on the label) would need to be considered and further consultation may be required. This may also have implications for the labelling of alcoholic beverages with nutrition information more generally, e.g. when claims about energy or carbohydrate content are made.  Consideration of an exemption from the
		standardised NIP format is therefore outside the scope of this Proposal, but could be considered if nutrition labelling of alcoholic beverages more generally was reviewed in the future.
Exemption from NIP should also apply to foods carrying low gluten claims.  Consumers who are conscious of gluten content will understand the meaning of a low gluten claim.  A requirement to include a NIP for low gluten claims could even be counterproductive to consumer disclosure as it may deter alcohol suppliers from making gluten claims.	Carlton & United Breweries (CUB)	Although consumers who are gluten conscious may be aware of the maximum amount of gluten permitted in a food with a <i>low gluten</i> claim, that food could contain any amount of gluten up to the limit of 20mg per 100g of the beverage. The declaration of the actual amount of gluten present may therefore provide useful information for those consumers. The information may also be of value to enforcement agencies.
Support if the <i>gluten free</i> label is used predominantly for allergen purposes.  If the <i>gluten free</i> claim is used in conjunction with <i>low carb</i> , highly recommend that the product carries a NIP.	Choice	If a claim about carbohydrate or energy content is made in relation to an alcoholic beverage that also makes a gluten free claim, a NIP will be required but it will not be required to include the gluten content.
Further information to the industry around how much gluten is <i>low gluten</i> would be useful.	McCashin's Brewery Brewers Guild	The conditions for <i>low gluten</i> claims are prescribed in Schedule 1 of Standard 1.2.7.
Testing precision adds some uncertainty to the use of a NIP for low gluten but it does provide consumer information to allow a decision.	Lion	Noted
Considers alcoholic beverages tend to include gluten or not, and <i>low gluten</i> products would be rare.	DB Breweries	Noted

Issue	Raised by	FSANZ response
Need to justify why the presence of gluten is not required to be declared on beers and spirits	QLD Health	The exemption was considered at the time the labelling requirements for the presence of cereals containing gluten in foods were developed. At that time, it was considered that coeliac societies and health professionals could provide targeted information to people with coeliac disease about the types of alcoholic beverages to avoid. FSANZ has not been advised that this is no longer the case.  Further consideration of this exemption is out of scope of this Proposal, which is limited to maintaining permissions for claims about gluten content.
Questions the rationale that for gluten free claims, the presence of a NIP does not provide any useful information to assist consumers with regards to gluten content, or to compare the gluten content between alcoholic beverages. If this is the case then it would apply equally to all products required to declare gluten in the NIP.  In the future, should the definition of gluten free change, for example to align with CODEX, then the NIP may well provide useful information to assist consumers with regards to gluten content.	AFGC	The rationale provided was in support of a proposed exemption from a NIP when a <i>gluten free</i> claim is made for alcoholic beverages not normally required to be labelled with a NIP, rather than exemption of the declaration of gluten content per se. Although the rationale could apply to other foods in terms of the requirement to declare gluten content, other foods are not within the scope of this Proposal.

### 2.2 Risk assessment

### 2.2.1 Coeliac disease

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 *gluten 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 such claims are permitted via this Proposal). 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.

# 2.3 Risk management

### 2.3.1 Gluten claims

FSANZ has determined that nutrition content claims about gluten for all food containing more than 1.15% alcohol by volume (including beverages) should continue to be permitted. 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.

The conditions for gluten content claims previously in Standard 1.2.8 and now in Standard 1.2.7, will apply. This will 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 will apply to all food containing more than 1.15% alcohol by volume, 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.

### 2.3.2 Nutrition information panels

to label with a NIP if a *gluten free* (but not *low gluten*) claim is made in relation to a beverage that is currently exempt from the requirement to be labelled with an NIP<sup>4</sup>. FSANZ considers that for these beverages, the additional requirement triggered by the *gluten free* claim to provide a NIP is not justified as the NIP does not provide any useful information to support consumer understanding of gluten content, or to compare the gluten content of alcoholic beverages, when the gluten content is not detectable. Costs to industry of providing a NIP and a submitter comment about providing a disincentive to provide useful gluten claims also provide support to the approach taken by FSANZ. NIPs can voluntarily be provided about alcohol (refer subclause 19(4) of Standard 1.2.8) and therefore would not be required to be removed if currently on labels in response to *gluten free* claims.

FSANZ has decided to amend Standard 1.2.8 to provide an exemption from the requirement

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<sup>&</sup>lt;sup>4</sup> Alcoholic beverages standardised in Standards 2.7.2 to 2.7.5 (Beer; Fruit Wine and Vegetable Wine; Wine and Wine Product; Spirits respectively) and beverages containing no less than 0.5% alcohol by volume (clause 3 of Standard 1.2.8).

For beverages containing alcohol with *low gluten* claims however, it is recommended that the requirement to provide a NIP is retained, as this will provide useful information to consumers and enforcement agencies about the actual content of gluten in the food. Declaration in the standardised NIP format provides consistency with the provision of nutrition information about other foods and for alcoholic beverages with energy or carbohydrate claims.

### 2.4 Risk communication

### 2.4.1 Public consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent.

Public submissions were sought to obtain the views on the proposed variation to the Code. The call for submissions period was from 14 November 2014 to 24 December 2014. Submissions were invited via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified via email.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal.

A total of 53 submissions were received. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. A summary of the submissions and the responses to these are provided in Table 2 above.

### 2.4.2 Targeted consultation

In response to the request from submitters that food containing alcohol is exempt from the requirement to declare a NIP when a gluten claim is made, FSANZ carried out consultation with relevant stakeholders to assist consideration of this request. A summary of the comments received and the responses to these are provided in Table 3 above.

## 2.5 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:

### 2.5.1 Section 59

### 2.5.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR) advised FSANZ that the Proposal was not likely to have a regulatory impact on business, community organisations or individuals and that a COAG Regulation Impact Statement was not required to be prepared (OBPR ID: 17751). This was 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 additional 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 suppliers of food containing more than 1.15% alcohol by volume as they will continue to be permitted to 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. The exemption from the requirement to provide a NIP if a nutrition content claim about gluten content is made will reduce costs for the suppliers of food containing more than 1.15% alcohol by volume.

**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 more than 1.15% alcohol by volume and the associated conditions will be consistent with those in Standard 1.2.7, providing for ease of enforcement.

#### 2.5.1.2 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.

### 2.5.1.3 Any relevant New Zealand standards

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

### 2.5.1.4 Any other relevant matters

There are no other relevant matters.

### 2.5.2. Subsection 18(1)

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

### 2.5.2.1 Protection of public health and safety

FSANZ 's position is that nutrition content claims about gluten for all food containing more than 1.15% alcohol by volume (including beverages) should continue to be permitted to 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 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 will continue to apply to all alcoholic beverages and other food containing more than 1.15% alcohol by volume.

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

As a result of continuing permission for gluten content claims, 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.

The exemption for beverages containing alcohol from the requirement to declare a NIP when a *gluten free* claim is made is not considered to impact on the provision of adequate information to consumers to enable informed choice. This is because the presence of a NIP does not provide any additional information to assist consumers understanding of gluten content.

### 2.5.2.3 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 with regards to gluten content. 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).

### 2.5.3 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 recommended amendment means that existing gluten content claims can continue to be made, under the same conditions that were in the Code before Standard 1.2.7 was gazetted. No further scientific risk analysis was therefore undertaken by FSANZ.

# the promotion of consistency between domestic and international food standards

The United States of America (USA), 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.

With regard to the requirement for a NIP when a *gluten free* claim is made, the recommended exemption is consistent with the approach in the European Union and the USA.

In the European Union, provisions for mandatory nutrition declarations will apply to foods, excluding alcoholic beverages of more than 1.2% alcohol by volume, from 13 December 2016. A gluten claim on alcoholic beverages of more than 1.2% alcohol by volume will not trigger a requirement for nutrition labelling of the alcoholic beverage.

In the USA, most alcoholic beverages do not require labelling with a nutrition panel and a gluten claim about an alcoholic beverage does not trigger a requirement for nutrition labelling of that beverage.

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

### • any written policy guidelines formulated by the Ministerial Council<sup>5</sup>

In December 2003, the Ministerial Council released the *Policy Guideline on Nutrition, Health and Related Claims*<sup>6</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.

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 more than 1.15% alcohol by volume were in the marketplace at that time and therefore nutrition content claims about gluten were inadvertently caught within the prohibition of nutrition content claims and not specifically considered.

# 3 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 Transitional arrangements for Code Revision

FSANZ has completed a review of the Code undertaken under Proposal P1025<sup>7</sup> in order to improve its clarity and legal efficacy. Following approval of the revision and Ministerial consideration, the new Code will commence on 1 March 2016 (following gazettal 10 April 2015 and registration on the Federal Register of Legislative Instruments). The current Code will also be repealed on this date. The approved variation at Attachment B varies the revised Code on 1 March 2016 to ensure that the revised Code is consistent with the current Code as amended by the variation at Attachment A.

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<sup>&</sup>lt;sup>5</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>6</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>
<sup>7</sup> http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

# 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.

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. Approved draft variation to the *Australia New Zealand Food Standards Code* and related Explanatory Statement
- B. Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016) and related Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

# Attachment A – Approved 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 Standards 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"
- [2] Standard 1.2.8 is varied by
- [2.1] inserting in subclause 1(1) in alphabetical order

"prescribed beverage means -

- (a) an alcoholic beverage standardised in Standards 2.7.2 to 2.7.5; or
- (b) a beverage containing no less than 0.5% alcohol by volume."

"prescribed beverage gluten free claim means a nutrition content claim in relation to gluten content of a prescribed beverage that uses the descriptor 'free' in conjunction with gluten, or a synonym of such a descriptor."

- [2.2] insert after paragraph 4(1)(c)
  - "(ca) a prescribed beverage gluten free claim, or"

## **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.

The Authority 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 Standards 1.2.7 and 1.2.8.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation<sup>8</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act* 2003.

### 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.

The Authority has also approved a draft variation to Standard 1.2.8 to provide an exemption from the requirement to provide nutrition information if a nutrition content claim about gluten content, using the descriptor 'free' or a similar descriptor, is made in relation to an alcoholic beverage standardised in Standards 2.7.2 to 2.7.5 or a beverage containing no less than 0.5% 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 14 November 2014 for a six-week consultation period.

<sup>&</sup>lt;sup>8</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

Targeted consultation was also carried out with key stakeholders regarding an exemption from the requirement to declare a nutrition information panel if a gluten claim is made about a beverage containing alcohol.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.2.7 and 1.2.8 are likely to have a minor impact on business 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.

Item [2] amends Standard 1.2.8.

Item [2.1] amends subclause 1(1) to add definitions of the terms 'prescribed beverage' and 'prescribed beverage gluten free claim'.

A 'prescribed beverage' is an alcoholic beverage standardised in Standards 2.7.2 to 2.7.5 or a beverage containing no less than 0.5% alcohol by volume. A 'prescribed beverage gluten free claim' is a nutrition content claim in relation to the gluten content of a prescribed beverage that uses the descriptor 'free' or a synonym of such a descriptor.

Item [2.2] amends paragraph 4(1)(c) to provide that a prescribed beverage gluten free claim is not a claim requiring nutrition information. The effect of the amendment is to exempt prescribed beverages from the requirements for nutrition information when a prescribed beverage gluten free claim is made.

# Attachment B – Approved draft variation to the revised *Australia New Zealand Food Standards Code* (commencing 1 March 2016)



Australia New Zealand Food Standards Code – Transitional Variation 2015 (Proposal P1035 – Gluten Claims about Foods containing Alcohol)

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 2 of the 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.

#### 1 Name of instrument

This instrument is the Australia New Zealand Food Standards Code – Transitional Variation 2015 (Proposal P1035 – Gluten Claims about Foods containing Alcohol).

### 2 Commencement

This instrument commences on 1 March 2016 immediately after the commencement of Standard 5.1.1 – Revocation and transitional provisions — 2014 Revision.

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

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

#### **SCHEDULE**

- [1] Standard 1.1.2 is varied by
- [1.1] omitting subparagraph (b)(ii) of the definition of **claim requiring nutrition information** in subsection 1.1.2—2(3) and substituting
  - "(ii) an endorsement; or
  - (iii) a \*prescribed beverage gluten free claim."
- [1.2] inserting in subsection 1.1.2—2(3) in the appropriate alphabetical position

### "prescribed beverage means:

- (a) a \*standardised alcoholic beverage; or
- (b) a beverage containing no less than 0.5% alcohol by volume."

"prescribed beverage gluten free claim means a nutrition content claim in relation to the gluten content of a \*prescribed beverage that uses the descriptor 'free' in conjunction with gluten, or a synonym of that descriptor."

- **Standard 1.2.7** is varied by omitting from section 1.2.7—4 "energy content or carbohydrate content", and substituting "energy content, carbohydrate content or gluten content"
- [3] Standard 1.2.8 is varied by omitting the definition of *claim requiring nutrition information* from the first Note to section 1.2.8—4 and substituting

#### "claim requiring nutrition information:

- a) means:
  - (i) a nutrition content claim; or
  - (ii) a health claim; and
- (b) does not include:
  - (i) a declaration that is required by an application Act; or
  - (ii) an endorsement; or
  - (iii) a \*prescribed beverage gluten free claim."

## **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.

The Authority 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 Standards 1.2.7 and 1.2.8.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation<sup>9</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act* 2003.

### 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.

The Authority has also approved a draft variation to Standards 1.1.2, and 1.2.8 to provide an exemption from the requirement to provide nutrition information if a nutrition content claim about gluten content, using the descriptor 'free' or a similar descriptor, is made in relation to an alcoholic beverage standardised in Standards 2.7.2 to 2.7.5 or a beverage containing no less than 0.5% 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 14 November 2014 for a six-week consultation period.

<sup>&</sup>lt;sup>9</sup> convening as the Australia and New Zealand Food Regulation Ministerial Council

Targeted consultation was also carried out with key stakeholders regarding an exemption from the requirement to declare a nutrition information panel if a gluten claim is made about a beverage containing alcohol.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.1.2, 1.2.7 and 1.2.8 are likely to have a minor impact on business 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 Standard 1.1.2.

Item [1.1] amends the definition of 'claim requiring nutrition information' in subsection 1.1.2—2(3) to provide that a prescribed beverage gluten free claim is not a claim requiring nutrition information. The effect of the amendment is to exempt prescribed beverages from the requirements for nutrition information when a prescribed beverage gluten free claim is made.

Item [1.2] adds definitions of the terms 'prescribed beverage' and 'prescribed beverage gluten free claim' to subsection 1.1.2—2(3).

A prescribed beverage is a standardised alcoholic beverage (beer, brandy, cider, fruit wine, fruit wine product, liqueur, mead, perry, spirit, vegetable wine, vegetable wine product, wine or wine product) or a beverage containing no less than 0.5% alcohol by volume.

A prescribed beverage gluten free claim is a nutrition content claim in relation to the gluten content of a prescribed beverage that uses the descriptor 'free' or a synonym of such a descriptor.

Item [2] amends section 1.2.7—4 of Standard 1.2.7 by inserting a reference to gluten content in the section. 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 section 1.2.7—12 and Schedule S4–3.

Item [3] omits the definition of claim requiring nutrition information from the first Note to section 1.2.8—4 and replaces it with a new definition, as a consequence of the amendments made to this definition by item [1.1].

# Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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"