28th March 2012

COELIAC AUSTRALIA SUBMISSION TO FSANZ PROPOSAL P293
NUTRITION, HEALTH & RELATED CLAIMS

On behalf of Coeliac Australia, I make the following submission in response to selected clauses within the FSANZ P293 proposal.

Coeliac Australia (hereafter referred to as CA) is a member based not-for-profit association with the objectives of supporting those with coeliac disease through promotion, education and creating awareness of coeliac disease, dermatitis herpetiformis and the gluten free diet. In addition, it provides services and support to members using current medical advice and evidence based research to make suitable recommendations.

CA therefore makes this submission in reference to 6 aspects (gluten, definition of gluten free, nutritional claims in relation to gluten, endorsements, name or reference to a disease or physiological condition and cause related marketing) of proposal P293 in the interests of supporting and protecting its members. Although CA applauds the introduction and inclusion of endorsements and endorsing bodies to the foods standard, it is concerned that the definition for gluten free has remained unchanged and remains in stark contrast to international standards. CA strongly urges FSANZ to revisit the gluten free definition as the current standard unnecessarily limits the gluten free diet posing nutritional, financial and medical risks due to the lack of nutritionally complete, affordable and available food choices for a population group already at nutritional risk.

Included with this submission are two attachments:

Attachment 1: Letter to Coeliac Australia from Dr Jason Tye-Din – 27 March 2012
Attachment 2: Letter from ACCC to Mr Paul Fletcher MP – 30 August 2010

BACKGROUND

Coeliac disease is a serious medical condition in which the immune system reacts to the presence of gluten causing small intestinal and systemic inflammation. Typical symptoms of untreated coeliac disease can include gastrointestinal symptoms and malabsorption with potential serious long-term consequences including anaemia, lethargy, malnutrition, infertility (both male and female), stunted growth in children, osteoporosis, dental decay and cancer.

To date, the only known treatment for coeliac disease is a lifelong gluten free diet, where gluten is the main protein found in wheat, rye, barley and oats (and derivatives). Accordingly people with coeliac disease rely on suitable labelling of products in order to make appropriate gluten free food choices.

NATIONAL OFFICE
PO Box 271
Wahroonga NSW 2076
Suite 1, 41-45 Pacific Hwy
Wahroonga NSW 2077
T 02 9487 5088
F 02 9487 5177
E info@coeliac.org.au
W www.coeliac.org.au

The Coeliac Society of Australia Inc trading as Coeliac Australia ABN 60 103 887 670

COELIAC AUSTRALIA COMMENTARY

The following response to FSANZ Proposal P293, is provided by Coeliac Australia:

PART 1 – CLAUSE 2: INTERPRETATION

- **Endorsement**

  * CA supports the proposed interpretation of an endorsement.

  * CA recognises that an endorsement needs to have a related nutritional or health claim which is controlled by an independent third party, preventing manufacturers or for-profit organisations from setting up their own endorsement programs, that are not subject to independent scrutiny, for the purpose of increasing profits.

- **Endorsing body**

  * CA generally supports the proposed interpretation of an endorsing body, however it is recommended that the following (in bold below) be added to the statement to read:

    endorsing body is a not-for-profit entity which has a nutrition- or health-related purpose or function that permits a supplier to make an endorsement ***in relation to specified products only***.

  * The addition of the wording '*in relation to specified products only*' provides clarification to prevent the misconception that an endorsing body may endorse an establishment, premises of manufacture, a manufacturer or an entire product range. The definition is otherwise too broad and provides an opening for misleading marketing practices and inaccurate consumer perceptions.

  * CA supports the position that an endorsing body must be not-for-profit, thus preventing the possibility of random companies forming to take financial advantage of nutritional claims.

- **Gluten**

  * CA generally supports the proposed interpretation of gluten as it is not confused by complicated scientific or chemical references, keeping the definition simple.

  * The addition of examples of wheat hybrids (spelt and triticale) can tend to make the interpretation unnecessarily long and complicated. Mentioning these examples of hybrid grains may necessitate the mention of other specific gluten containing hybrids such as dinkel, emmer, freekeh and khorasan. CA believes manufacturers should have

a clear knowledge of synonyms and hybrids of gluten containing grains and therefore recommends the following change to the current interpretation:

> *Gluten means the main protein in wheat, rye, barley and oats* ~~***triticale and spelt,***~~ ***and their variants, and any hybrids*** *relevant to the medical conditions coeliac disease and dermatitis herpetiformis.*

* The addition of the words '*their variants and any hybrids*' is recommended to avoid extensive listing of hybrid product names. The listing of only the specified hybrids, triticale and spelt, provides the potential for use and mismanagement of the lesser known gluten containing grains or variants.

PART 3 – NUTRIENT CONTENT CLAIMS

- **Clause 11(7) - Content claim in relation to gluten**

  * CA supports the addition of a cross contact warning that gluten may be present in a product, using methods such as VITAL to determine potential contamination from ingredients or manufacturing equipment. Including cross contact statements in the standard would prevent the misuse of such statements.

  * The use of the word 'contains' in relation to gluten is valid in reference to ingredients. It provides further helpful information to ensure an informed choice in relation to the source of ingredients.

  * The words 'low' and 'high' in relation to gluten have no benefit. A product either contains gluten above or below the safe level of ingestion and the amount of gluten content above the safe level is irrelevant as it is not considered valid in a gluten free diet. There is no medical substantiation for either a moderate or high gluten diet. As such, there should be no requirement that products carry corresponding claims.

  * CA recommends that the only valid nutrient content claims that need to be made in relation to gluten are 'free' and 'contains'.

  * Some manufacturers have used words such as 'reduced' and 'no added' in relation gluten. Again, these descriptions have no benefit and more often than not confuse consumers.

- **Clause 21 - Endorsements**

  * CA supports the proposed definition (with suggested additions) of an endorsing body, which it currently follows. It is vital for an endorsing body to remain independent from the manufacturer or supplier of a product to ensure an unbiased seal of approval that meets defined criteria and standards expected by consumers.

* The endorsement program at CA is based on, and has further evolved from, protocols established by Coeliac UK, which has successfully implemented the program in the UK for 40 years in support of its members.

* The CA endorsement program has been in operation in Australia for approximately 12 years with the sole purpose of supporting its members and other coeliac consumers in making safe and informed food choices.

- **Clause 22 - Criteria for endorsements**

* CA supports the proposed criteria for endorsements. The CA endorsement program fits with these criteria and CA would welcome the ability to incorporate the endorsing body name with the endorsement design. The National Heart Foundation is currently permitted to incorporate its name within its 'Tick' endorsement design.

- **Clause 23 - Record keeping for endorsements**

* CA supports the proposal of record keeping. In the CA endorsement program this process is currently in operation. Manufacturers are issued with a letter of approval, a signed agreement with the terms and conditions of endorsement, an endorsement certificate and a letter of confirmation that the required endorsement administration is complete. This procedure has served to inform the manufacturer of the various endorsement stages achieved and reinforce the importance of a rigorous process.

SCHEDULE 1 – CONDITIONS FOR NUTRIENT CONTENT CLAIMS

- **Gluten free**

* CA strongly opposes the definition for gluten free as 'not detectable', yet agrees the inclusion of oats and malted gluten grains is vital. The inclusion of oats and malt need to remain in the definition as current analytical methods are not sensitive or specific enough to detect the gluten present within these two components.

* The issue of 'not detectable' has not been reassessed and is not aligned with international standards. The definition has simply been lifted from the existing standard 1.2.8 and placed into the proposed standard 1.2.7 without consideration for the validity of unnecessarily restricting gluten content.

* The definition of the term 'gluten free' in Australia is in stark contrast to that used internationally. The Codex standard for 'gluten free' has recently been revised from 200ppm to <20ppm. The EU and Canada have subsequently aligned their gluten free standard at <20ppm. The USA currently has no defined level for gluten free but the proposed standard also reflects the international position of <20ppm.

* This level of <20ppm has been endorsed as a safe level of gluten consumption by leading gastroenterologist and researcher, Dr Jason Tye-Din (see Attachment 1). CA supports the position of <20ppm gluten as safe for coeliac consumers and will endorse products at this level.

* The ACCC has provided advice (see Attachment 2: Letter to Mr Paul Fletcher MP 30 August 2012) that it generally considers the word 'free' to mean 'no presence of'. However this advice goes on to say that 'unless qualified is likely to produce error'. Also in the same paragraph the letter indicates that the word free is rich and diverse in meaning and the magnetism of the word 'free' ought to be appropriately qualified.

* Rich and diverse in meaning could imply that gluten free could mean other than "no presence of", and the terms "unless qualified" and "appropriately qualified" could mean that gluten free could be qualified to mean <20mg/kg without conflicting with ACCC policy. Recent FDA moves, as well as the fact that Codex & EU adopted a gluten free definition of <20ppm, may guide FSANZ in determining what an appropriate qualification for 'gluten free' could be. It is worth also noting that in the USA, the FDA also allows the claims 'fat free' and 'sugar free' to be subject to limits.

* The ACCC states that it promotes compliance and enforces the *Trade Practices Act 1974* (the Act), where the objective is to enhance the welfare of Australians, protect consumers and prohibit products from misleading and deceiving. The definition of 'gluten free' as 'not detectable' severely restricts food choices for those who need to follow a gluten free diet adversely impacting availability and variety. This population segment is already at nutritional risk and the current 'gluten free' definition is increasing their nutritional risk and dietary inadequacy. CA believes this does not meet the ACCC's objectives of enhancing the welfare of Australians and protecting consumers.

* The argument put forward by the ACCC, that the word 'free' is rich and diverse, does not necessarily translate to mean the 'absence of'. The same can be said of fat free which would follow the same principle. The educated few know that 97% fat free equates to a product that is still appropriate for those who need to control their fat intake for whatever health reason. Similarly, defining 'gluten free' at an evidenced based level would simplify labelling, avoid misleading claims and allow for a simple message to be communicated to consumers.

* CA maintains that the retention of the previous standard for gluten free does not address the grounds given by the Forum for the review request in that it does not protect public health and safety.

- **Low Gluten**

  * CA believes that having a definition of low gluten is without foundation or substantiation. It has no value in protecting public health and safety and, if anything, is counterproductive and potentially hazardous. The inclusion of permission for a low gluten claim in the draft standard is strongly opposed by CA.

PARAGRAPH 4.3 – CHANGES TO THE DRAFT STANDARD

- **4.3.1 - Name or reference to disease or physiological condition**

  * The current standard for health claims prohibits the name or reference to any disease or physiological condition (Standard 1.1A.2) except as expressly permitted. The draft standard seems to have dropped that prohibition. CA proposes the retention of that prohibition.

  * The draft standard appears to regulate reference to a disease only by establishing conditions to make a health claim. A health claim means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect, which includes an effect on a disease, disorder or condition.

  * Accordingly it appears that a label or advertisement under the proposed draft standard could include a reference to a disease such as coeliac disease as long as the reference is not caught by the definition of a "health claim". Some sections of the food industry may regard this as carte blanche to make reference to a disease, such as coeliac disease, overtly outside the scope of the definition of health claims, but from which consumers might mistakenly construe as claiming a therapeutic effect. This makes the standard particularly difficult to enforce, as the relevant authority would have to prove beyond reasonable doubt that the reference to the disease was in the context of a health claim in order to take action.

  * CA notes paragraph 4.3.1 states that "Dietary information type statements referring to a health effect will be considered to be and regulated as a health claim". This will not help State and Territory Authorities prove their case where the reference to a disease is ambiguous.

  * It also creates a potential health hazard for those suffering from a disease, disorder or condition, for example, coeliac disease.

  * CA maintains that the removal of this prohibition does not address the grounds given by the Forum for the review request in that it did not protect public health and safety, was difficult to enforce or comply with in both practical or resource terms, and placed an unreasonable cost burden on industry and/or consumers.

- **4.3.2 - Cause related marketing statements**

  * The previous draft standard had a clause dealing with cause-related marketing statements, which has now been removed, as per the explanation at section 4.3.2.

  * CA notes that cause-related marketing statements would not be prohibited by the draft standard, because of the removal of the current prohibition on the name of or reference to a disease, and reiterates its comments above on that point. In the context of coeliac disease, CA would support cause-related marketing statements only where the product is endorsed by CA as suitable for those with coeliac disease.

  * CA opposes deletion of the cause-related marketing provision on the basis that it creates unreasonable uncertainty for the industry and for organisations such as CA. To suggest that misleading aspects could potentially be addressed by Australian and New Zealand consumer law would seem to require action by ACCC or State Consumer Affairs which may have neither the resources nor competence to deal with such matters.

  * The removal of this provision does not address the grounds given by the Forum for the review request in that it is now difficult to enforce or comply with in both practical or resource terms, and placed an unreasonable cost burden on industry and/or consumers.

I make this submission on behalf of Coeliac Australia and its 25,000 members, in the interests of the 60,000 Australians medically diagnosed with coeliac disease and in the further interest of the 200,000 people still living with coeliac disease who are yet to be diagnosed.

David Sullivan
National Business Development Manager
COELIAC AUSTRALIA

Contact details regarding submission:
david.sullivan@coeliac.org.au
Phone: 02 9487 5088

FIAT LUX
Walter+Eliza Hall
Institute of Medical Research

27 March, 2012

Mr David Sullivan
National Business Development Manager
Coeliac Australia
PO Box 271
Wahroonga NSW 2076

Dear David

Re: Gluten Free Standard in Australia

I am writing in support of a fixed level of gluten to be defined as gluten free. The support is based on current medical data attesting to a safe threshold level of gluten consumption in patients with coeliac disease, the group most at-risk of medical ilness from gluten consumption. The support also acknowledges the need for suitable food choice for coeliac disease consumers who need to maintain a strict, lifelong exclusion diet.

At present, the Australian and New Zealand Food Standard defines gluten free as "No Detectable Gluten". However the limits of what are "detectable" are falling, as testing methods continue to be refined. The present sensitivity of the test is 3 parts per million (ppm) having fallen from 30 ppm a decade ago. This represents a detection level of 3 mg in 1 kg of food. The reality of crop harvesting and food manufacturing processes makes it is increasingly difficult for manufacturers to ensure foods remain below this falling "standard". There is the very real possibility that no food will be able to comply with a detection level of, say 1 ppm. This will have the effect of limiting suitable food choices for patients with coeliac disease and compromising their treatment.

I confirm my support of the level of 20 ppm gluten being defined as gluten free for two reasons.

1. **Medical safety data.**
   Several studies have been undertaken to establish a medically safe level of gluten intake in coeliac disease. Collectively, there is no evidence that 20 ppm of gluten intake causes any problem for people with coeliac disease. To the contrary, a study has shown that 10 mg of gluten daily for three months is safely consumed (*Catassi C et al. A prospective, double-blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. Am J Clin Nutr. 2007;85:160-6*).

In practical terms, it would require 500 g of a food containing 20 ppm of gluten to be consumed each day to even reach 10 mg (which has been shown to be safe even

The Walter and Eliza Hall Institute of Medical Research
ABN 12 004 251 423
1G Royal Parade Parkville Victoria 3052 Australia
T +61 3 9345 2555 F +61 3 9347 0852
www.wehi.edu.au

after 3 months daily ingestion).

2. **A level of 20 ppm is in line with international standards.** This will give a level of international uniformity with established European CODEX (2008) and the proposed North American standard set out by the FDA.

It is important that we have a definition of gluten free that is primarily safe for patients most at-risk of medical illness from gluten exposure (ie. people with coeliac disease) and also achievable in commercial food manufacturing processes. A level of 20 ppm will achieve both these goals. It is also essential that the term "gluten free" be retained as it is used internationally in the medical profession as the treatment for coeliac disease.

I am happy to be contacted if any further information is required.

Yours sincerely,

Chair, Medical Advisory Committee, Coeliac Australia
Head of Coeliac Disease Research Group, The Walter and Eliza Hall Institute
Gastroenterologist, Coeliac Clinic, The Royal Melbourne and Box Hill Hospitals
Consultant, ImmusanT Inc.

EXECUTIVE OFFICE

Australian Competition & Consumer Commission

GPO Box 3131
Canberra ACT 2601

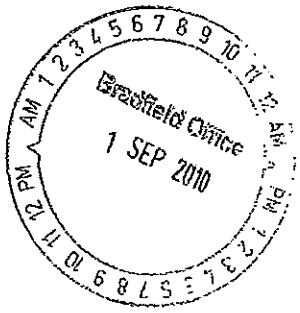
23 Marcus Clarke Street
Canberra ACT 2601

tel: (02) 6243 1111
fax: (02) 6243 1199

www.accc.gov.au

Our Ref: 37468
Contact Officer: Ebony McNally
Contact Phone: 02 6243 1373

30 August 2010



Mr Paul Fletcher, MP
Federal Member for Bradfield
Suite 8, 12 Tryon Road
LINDFIELD NSW 2070

Dear Mr Fletcher

Thank you for your letter of 26 July 2010 seeking the view of the Australian Competition and Consumer Commission (ACCC) on the establishment of a clinical advisory group to make recommendations about the level of gluten allowed in products which make a gluten free claim on labels. I note that you also attached a letter from the Coeliac Society of Australia in which concerns are raised that international best practice for gluten-labelling is not being adopted in Australia. I understand that these concerns have also been raised with the Australia and New Zealand Food Regulation Ministerial Council and the Council of Australian Governments (COAG) independent committee Review of Food Labelling Law and Policy.

The ACCC is responsible for promoting compliance with and enforcing the *Trade Practices Act 1974* (the Act). The object of the Act is to enhance the welfare of Australians through the promotion of competition and fair trading and the provision for consumer protection. In particular, the Act prohibits corporations from engaging in conduct which is misleading or deceptive or likely to mislead or deceive and also contains a number of specific prohibitions against the making of false representations.

Labelling and advertising must comply with the Act, and the Act does not prescribe the use or definition of particular terms.

The ACCC considers that generally 'free' claims mean 'no presence of' and that courts have held that the word 'free' has particularly strong attraction and unless qualified, is likely to produce error. For example in *Nationwide News Pty Ltd v ACCC* (1996) 71 FCR 215 the court stated that the word 'free' is 'rich and diverse in meaning' and: 'the magnetism of the word free' ought to be appropriately qualified.

The Australian New Zealand *Food Standards Code* (the Code) is administered by Food Standards Australia New Zealand (FSANZ). The Code prescribes a number of labelling requirements for food products sold in Australia, including mandatory disclosure of certain information. FSANZ may be an appropriate body to also assist with the proposed clinical

advisory group. FSANZ may be contacted on the following details:

www.foodstandards.gov.au

PO Box 7186
Canberra BC ACT 2610
Australia

Ph: 02 6271 2222

Having said this, the ACCC would be interested in the progress of the establishment of any clinical advisory group on the issue and could potentially assist that group, once formed, by providing information on the application of the Act to food labels.

I trust this information is of some assistance. Please contact Ebony McNally on (02) 6243 1373 for further information.

Yours sincerely

Chief Executive Officer