



## FSANZ WW1109 Consultation about beta-glucan and blood cholesterol health claims – September 2017

### About Lion Dairy & Drinks

Lion Dairy & Drinks forms part of the Lion Group, a leading beverage and food company with a portfolio that includes many of our region's favourite brands, including Dairy Farmers, Pura, King Island Dairy, Dare iced coffee, Farmers Union, Yoplait and Berri.

The Lion group employs around 6,700 people, with 2,300 of them working in our Lion Dairy & Drinks business.

Lion is a company focused on long-term, sustainable growth. We have a clear 10 year strategy to transform our dairy and juice businesses and champion the nutritional credentials of our portfolio; reinvigorate our beer markets and contribute to vibrant and responsible drinking cultures; and, build our presence in high-value categories in targeted Asian markets. To achieve this we invest in our core strategic assets – our people, brands, production facilities and supply chain.

The core activities of Lion Dairy & Drinks in Australia are the manufacture and wholesale of white milk, flavoured milks, fresh dairy foods, speciality cheeses, and fruit juices. We also have a joint venture with Vitasoy International Holdings, of which Vitasoy Australia locally manufactures more than 30 plant-milk products under the Vitasoy brand and approximately 45 million litres every year. The Australian made Vitasoy products are distributed across Australia, New Zealand, Hong Kong, Mauritius and Singapore, and they employ around 75 people.

This submission is provided on behalf of Lion Dairy & Drinks, and includes an example relevant to the Vitasoy business.

### Executive Summary

In August 2015, Food Standards Australia New Zealand (FSANZ) undertook a systematic review to evaluate the current scientific evidence for food-health relationships between oats, barley and beta-glucan and blood cholesterol reduction. These pre-approved high level health claims (HLHC) were included as part of the Australian New Zealand Food Standard Code (the Code), Standard 1.2.7 – Nutrition, Health and Related claims in January 2013, on the basis of being approved for use in Europe, the United States and Canada.

The outcomes of this new systematic review were that a relationship between oats, but not barley or beta-glucan generically and blood cholesterol could be substantiated and as a result FSANZ are proposing to remove the HLHC for both barley and beta-glucan and cholesterol reduction from Standard 1.2.7.

Such changes to the Code will impact a number of products carrying these claim such as cereals and plant-based milks – with cost, resource and trust implications resulting for food and beverage manufacturers, as well as consumers. As an example, *Vitasoy Oat Milk Unsweetened carries the HLHC for beta-glucan and lowering cholesterol; 1.3g beta-glucan per serving – a fibre that helps lower cholesterol.*

To note, function-health claims and risk-reduction claims for barley and oat beta-glucan and cholesterol reduction remain approved for use in Europe and similar claims for oat and barley exist in the United States

(authorised health claim) and Canada (disease risk reduction claim) [quantified by the amount of eligible soluble fibre (such as beta-glucan) contained in the product].

The implications on the general level health claim (GLHC) for beta glucan from barley or oats and reducing cholesterol *absorption* in Standard 1.2.7 are also being considered as part of this Consultation Paper.

Lion Dairy & Drinks does not support the position that FSANZ has proposed in this Consultation Paper in relation to changing the claims for beta-glucan (from oats or barley) in the Code, based on the following:

- a lack of rationale for what prompted FSANZ to review this particular food-health relationship – to the best of our knowledge there have been no examples in Australia or New Zealand where it has been found that consumers are being misled, or any impact on public health safety;
- we believe that the systematic review conducted by FSANZ examining the evidence for beta-glucan (from oats or barley) and cholesterol reduction is flawed based on the fact that no evidence for beta-glucan was considered, and the evidence for barley and cholesterol reduction has been down-graded to 'moderate' based on a collective smaller study sample size (as opposed to the totality of quality evidence);
- the changes proposed by FSANZ are inconsistent with their equivalent international regulatory authorities (i.e. Europe – European Union; United States – Food and Drug Administration; and Canada – Health Canada) – whereby these health claims, or similar, are currently permitted;
- the proposed changes to these health claims within Australia and New Zealand have the potential to significantly impact food industry innovation and trade, and consumer understanding of beta-glucan (from barley or oats) containing food or beverage products; and
- a lack of clarity from FSANZ around the rationale for HLHCs & GLHCs needing to be based on scientific evidence that has a 'high-degree of certainty' rather than the 'weight' and 'consistency' of evidence (the latter of which is consistent with international regulatory authorities).

Therefore, Lion Dairy & Drinks recommends FSANZ:

- re-assess the scientific evidence, for the HLHC for both beta-glucan and barley on lowering cholesterol – beyond randomised controlled trials (RCTs), in line with Proposal P293 Review Report 2012, Supporting document 8 – The substantiation process for food-health relationships<sup>1</sup>;
- undertake a review of the *level* of evidence required to substantiate food-health relationships – both GLHC and HLHC;
- have a greater appreciation and regard for the food-health relationships assessed and approved by their equivalent international food regulatory authorities; and
- stay true to the Policy Principles for the Nutrition, Health and Related Claims Standard of supporting innovation and international trade<sup>2</sup>.

Lion Dairy & Drinks welcomes the opportunity to present this submission in response to the Consultation Paper *W1109 – Consultation about beta-glucan and blood cholesterol health claims*.

In preparing this submission, Lion Dairy & Drinks has taken also into consideration the position of the Australian Food and Grocery Council, which we are supportive of.

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<sup>1</sup> [http://www.foodstandards.gov.au/code/proposals/documents/P293\\_SD8.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD8.pdf)

<sup>2</sup> [http://www.foodstandards.gov.au/code/proposals/documents/Full\\_report\\_IARandattachments.pdf](http://www.foodstandards.gov.au/code/proposals/documents/Full_report_IARandattachments.pdf)

Lion Dairy & Drinks provides general comments to the FSANZ Consultation Paper W1109 – *Consultation about beta-glucan and blood cholesterol health claims*. These comments are set out below:

# 1. Scientific evidence for oat, barley and beta-glucan and cholesterol reduction:

The pre-approved food-health relationship for the HLHC about beta-glucan (from oats or barley) and reduced blood cholesterol was approved as part of the development of the new Nutrition, Health & Related Claims Standard 1.2.7, in January 2013.

This was based on a similar function-health claim and multiple risk-reduction claims that were authorised in the European Union at that time, as well as the authorised-health claims in the United States and disease-risk reduction claims in Canada.

In 2015, FSANZ conducted a systematic review of the evidence for beta-glucan from oats or barley and cholesterol reduction and concluded that:

- i. a relationship between *beta-glucan (from oats or barley)* and *reduction in blood cholesterol concentration* was **rated as non-assessable (and therefore not permitted) – change to current permissions in the Code which permit HLHC for beta-glucan (from oats or barley) and cholesterol reduction**
- ii. a relationship between *wholegrain oats and oat bran* and *blood cholesterol reduction (total and LDL)* is **substantiated to a high degree of certainty – new (a HLHC would remain for oats and cholesterol reduction in the Code, but any reference to beta-glucan would be removed)**
- iii. a relationship between *barley* and *blood cholesterol reduction (total and LDL)* is **substantiated to a moderate degree of certainty – change to current permissions in the Code (the HLHC for barley and blood cholesterol would be removed, leaving only a GLHC claim).**

These conclusions do not appear to reflect the findings of the FSANZ systematic review that demonstrated both barley and oats can have significant effects on lowering blood cholesterol, as shown in Table 1 below. In fact, barley consumption was found to result in a greater decrease in both LDL and total cholesterol than oats, and the degree of certainty that the results were indeed due to the barley or oat consumption is extremely high for both

**Table 1: Effect of oats and barley on LDL and total cholesterol (2015 FSANZ systematic review)**

Ingredient	Total Cholesterol (mmol/L, p value, 95%CI)	LDL – Cholesterol (mmol/L, p value, 95%CI)
Oats	-0.22 (p<0.00001) -0.27, -0.17	-0.21 (p<0.00001) -0.24, -0.17
Barley	-0.32 (p<0.00001) -0.42, -0.21	-0.25 (p<0.00001) -0.32, -0.18

Despite this, the food-health relationship between barley and blood cholesterol reduction (total and LDL) was downgraded to ‘moderate’ on the basis of a collective smaller study sample size as a result of fewer included studies (as opposed to the totality of quality evidence). Lion Dairy & Drinks believes this needs to be reviewed, having regard for the both the strength, consistency and power of the scientific evidence for barley and lowering cholesterol.

Similarly, FSANZ has rated the relationship between beta-glucan and cholesterol reduction as “unable to be assessed” due to the lack of RCTs utilising 100% pure beta-glucan. This seems unreasonable given their equivalent international regulatory authorities have deemed the relationship to be not only assessable, but substantiated with the specific function-health claim: “beta-glucan contributing to the maintenance of normal blood cholesterol”, for use on foods with a minimum of 1g of beta-glucan per serving (from oats or barley).

As per Proposal P293 Review Report 2012, Supporting document 8 – The substantiation process for food-health relationships<sup>3</sup>, the *weight, totality and consistency* of evidence needs to be considered when establishing a food-health relationship: “The dossier of scientific evidence for the food-health relationship must include a list of identified studies and all relevant human studies, and should include any supporting evidence from animal and in vitro studies”.

In light of the above, and as the GLHC for beta glucan (from barley or oats) and reduction in cholesterol *absorption* is also under consideration as part of this Consultation Paper, Lion Dairy & Drinks encourages FSANZ to re-assess the evidence-base for a HLHC for beta-glucan and barley and cholesterol reduction, and retain the GLHC around beta glucan (from barley or oats) and reduction in cholesterol *absorption* – recall, this food-health relationship was previously assessed and scientifically substantiated as part of the introduction of Standard 1.2.7.

Lion Dairy & Drinks therefore recommends FSANZ re-assess their evidence base, beyond RCTs for HLHC for both beta-glucan and barley on lowering cholesterol in line with Proposal P293 Review Report 2012, Supporting document 8 – The substantiation process for food-health relationships<sup>4</sup>, whilst retaining the current permissions for the GLHC.

## **2. The *level* of evidence required to substantiate food-health relationships – both GLHC and HLHC;**

The FSANZ Application Handbook<sup>4</sup> specifies that, when submitting an application to add a new food-health relationship to the Code, for the purposes of making either a HLHC or GLHC, the application must include a scientific assessment about how the studies reviewed demonstrate, with a *high degree of certainty*, that a causal relationship exists between the food or property of food and the health effect.

This is a change from the requirements for substantiating a food-health relationship that were outlined in Proposal P293 Review Report 2012, Supporting document 8 – The substantiation process for food-health relationships<sup>5</sup>, which stated that the substantiation process used to determine whether a causal relationship between a food or property of a food and the health effect can be established, needed to involve *critical appraisal* and *quality assessment* of the evidence considering the *weight* and *totality of the evidence* – all leading to a ‘*degree of certainty*’.

Similarly, the 2009 Consultation Paper for Proposal P293<sup>6</sup> stated that “if a manufacturer wishes to make a high level claim that has not already been approved, an application will need to be made to FSANZ. Manufacturers will need to submit supporting evidence with their applications. This may include ‘consistently agreed’ evidence, ‘weight of evidence’, or emerging evidence”.

These requirements outlined in Proposal P293 are consistent with the requirements of equivalent international food regulatory authorities for substantiating food health relationships, as evidenced by Table 2 below from the 2012 Review Report, Supporting Document 8 of Proposal P293<sup>7</sup>.

As a result, Lion Dairy and Drinks believes that FSANZs’ proposal is subjecting industry to a heightened level of scrutiny, above and beyond what is required by their equivalent international food regulatory authorities by enforcing the requirement for food-health relationships to be proven to a *high level* of certainty. This has the potential to severely restrict international trade opportunities, as well as local innovation.

<sup>3</sup> [http://www.foodstandards.gov.au/code/proposals/documents/P293\\_SD8.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD8.pdf)

<sup>4</sup> <http://www.foodstandards.gov.au/code/changes/Documents/Application%20Handbook%20as%20at%201%20March%202016.pdf>

<sup>5</sup> [http://www.foodstandards.gov.au/code/proposals/documents/P293\\_SD8.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD8.pdf)

<sup>6</sup> <http://www.foodstandards.gov.au/code/proposals/documents/P293%20Health%20Claims%20Cons%20Paper%20FINAL.pdf>

<sup>7</sup> [http://www.foodstandards.gov.au/code/proposals/documents/P293\\_SD8.pdf](http://www.foodstandards.gov.au/code/proposals/documents/P293_SD8.pdf)

**Table 2: Comparison of the substantiation processes used to establish food health-relationships among four international jurisdictions**

	ANZ	EU	Canada	USA
Characterisation of food		yes		
Systematic collation of evidence	yes	yes	yes	Not specifically stated – only publicly available evidence is considered
Documented process for collation of evidence	yes	yes	yes	
Comprehensive collation	yes	yes	yes	
Human studies required	yes	yes	yes	yes
Quality assessment	yes	Study design	yes	yes
Consistency across studies	yes	yes	yes	yes
Causality	yes	yes	yes	yes
Biological relevance	yes	yes	yes	
Feasibility of consuming effective amount	yes	yes	yes	If no, reflected in claim wording
Animal studies only used to establish mode of action	yes	yes	yes	yes

Lion Dairy & Drinks therefore recommend FSANZ review the *level* of evidence required to substantiate food-health relationships, for both GLHC and HLHC

### 3. Regard for food-health relationships assessed and approved by equivalent international food regulatory authorities

The Consultation Paper notes that there is a lack of consistency internationally with regards to health claims for beta-glucan, oats or barley and impact on blood cholesterol concentrations – that is, which health claims are approved for use by the various countries.

Lion Dairy & Drinks does not believe this is accurate, as although approved claims in the United States, Canada and the EU may not all specifically refer to beta-glucan in the approved wording of the health claim, **they are all based on the foods eligible to make the claim providing a minimum quantity of soluble fibre from oats, barley or other grains, of which 3g beta-glucan is listed as an example.**

These international food regulatory authorities only recently re-assessed the evidence base supporting beta-glucans: the EU reviewed their barley beta-glucans and cholesterol risk reduction claim in 2011; Health Canada reviewed their barley products and cholesterol lowering disease risk reduction claim in 2012; and the United States FDA reviewed their soluble fibre and coronary heart disease authorised health claim in 2008.

Lion Dairy & Drinks recommends that FSANZ should have greater appreciation and regard for the scientific rigour and substantiation process that our equivalent international food regulatory authorities undertake when developing their health claims, and should look to be consistent with and complement these international food-health claims wherever possible to facilitate fair trading, industry growth and international trade and innovation, while being responsive to future trends and developments

Lion Dairy & Drinks therefore recommends FSANZ have greater appreciation and regard for the food-health relationships assessed and approved by their equivalent international food regulatory authorities, for use in Australia and New Zealand

#### **4. The Policy Principles for the Nutrition, Health and Related Claims Standard**

The Policy Principles that underpin Standard 1.2.7 as outlined in the Initial Assessment Report for P293 (2004),<sup>8</sup> state that the aim of this Standard is:

- to ensure that the health and safety of the public is protected, while allowing for food industry innovation and trade. It does this by incorporating a number of elements designed to ensure claims made on food or in advertising are true, scientifically substantiated and not misleading.

Lion Dairy & Drinks is concerned that removing the currently permitted HLHC for beta-glucans, and specifically for barley, will contradict the Policy Principles underpinning Standard 1.2.7 in a multitude of ways, including:

- limiting the incentive for the food industry to innovate in the area of beta-glucans, and specifically barley;
- international trade may be limited, as international companies would need to either amend packaging and/ or ingredients to ensure compliance with the Australian or New Zealand market. Both of these options would incur considerable expense and may result in companies choosing not to export to Australia and New Zealand.

Lion Dairy & Drinks therefore recommends FSNAZ stay true to the Policy Principles of the Nutrition, Health and Related Claims Standard of supporting innovation and international trade.

Lion Dairy & Drinks would appreciate the opportunity for further engagement with FSANZ in working through the health claims for beta-glucan (from oat or barley) and cholesterol reduction.

For further information please contact:

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<sup>8</sup> [http://www.foodstandards.gov.au/code/proposals/documents/Full\\_report\\_IARandattachments.pdf](http://www.foodstandards.gov.au/code/proposals/documents/Full_report_IARandattachments.pdf)