



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

14 September 2017

Food Standards Australia New Zealand

Submitted via the FSANZ website

Submission: Consultation Paper – W1109 – Consultation about beta-glucan and blood cholesterol health claims [20-17]

Gateway Brands (Gateway) welcomes this opportunity to respond to the Food Standards Australia New Zealand (FSANZ) *Consultation Paper – W1109 – Consultation about beta-glucan and blood cholesterol health claims*.

Gateway is an importer and distributor specialising in the healthcare channel. Gateway markets and distributes a product in Australia called Betaglucare - an oat based food made from made high quality Scandinavian oats, rich in beta-glucan. Betaglucare is available for purchase through pharmacies and online through the Betaglucare website (<https://betaglucare.com.au/>).

Gateway has reviewed the consultation paper provided by FSANZ and wishes to provide comment in relation to the FSANZ Systematic Review (SD1) and the questions for submitters. Our responses are provided in the attachment to this letter.

Overall, we do not support FSANZ progressing a proposal based on the review which is the subject of this consultation paper.

Please do not hesitate to contact me if you have any questions in relation to our response or require further information.

Yours sincerely

Greg Butts

Gateway Brands Pty Ltd

E:

W: www.betaglucare.com.au



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

Background

Gateway have marketed Betaglucare in Australia for 4.5 years and utilised the claim in our communications about the product. The product is based on oats but it is the beta-glucan which is specifically called out in relation to the claim and communication about the amount required for the health effect.

The business focus for the past 2 years has been on driving recommendation through healthcare professionals based on the clinical evidence and approved high level health claim relating to beta-glucan and reduction in blood cholesterol.

General Comments

Systematic Review (SR) of the Evidence for a Relationship between Oats, Barley and their derived β -glucans on Blood Cholesterol Concentration [SD1]

1. Age of the Systematic Review (SR)

We note that the report is dated August 2015 and is therefore two years old – we consider the SR needs to be updated before any action to change Schedule 4 is considered.

2. Criteria established for a SR supporting health claims

Schedule 6 criteria require:

(g) A conclusion based on the results of the studies that includes:

(i) whether a causal relationship has been established between the food or property of food and the health effect based on the totality and weight of evidence; and

Standard 1.2.7 established for a general level health claim a requirement that the “*notified relationship is a reasonable conclusion of the systematic review*”.

FSANZ has not followed the criteria in the Food Standards Code (the Code) in its own reviews but has applied a higher standard of proof to the current Systematic Reviews. In respect of the intake of both oats or barley and reductions in blood cholesterol concentration, FSANZ concludes that the meta-analysis results support a causal link.

3. Comments on the specific systematic reviews

In both cases it may be argued that the relationship is a reasonable conclusion of the systematic review.



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

In the case of barley, there is a very high level of consistency between all of the studies, regardless of whether the subjects were hypercholesterolaemic or had normal cholesterol levels. The fact that the majority of subjects were hypercholesterolaemic is not a relevant disqualifying criterion as they are clearly a part of the target population. The claim is relevant to individuals who wish to prevent lifestyle induced rises in LDL or lower their LDL. There is no benefit in the claim for individuals with normal & stable LDL. Furthermore, the benefit in terms of lowered LDL, without an effect on HDL, would appear to be highly beneficial in terms of public health outcomes.

Neither the Oat or Barley SR address Schedule 6 (g)(ii)(b) *whether the amount of the food or property of food to achieve the health effect is likely to be consumed in the diet of the Australian and New Zealand populations or by the target population group, where relevant*. Oats and barley contain 2 to 8% of beta-glucans on a dry weight basis, consequently a consumer would need to consume up to 150g of grains per day to achieve an intake of 3g beta-glucans. We consider this would have a significant impact on diversification into other foods and the ability of consumers to access the amounts required to achieve a health effect.

In the case of beta-glucans, the Whitehead meta-analysis indicates a high level of consistency between the intake of beta-glucan rich fractions derived from both oats and barley and lowering of blood cholesterol. However, the FSANZ analysis suggests that this could be due to *“other fibres or other components in oats or barley”*. However, there is no attempt to identify or establish a causal relationship for any other fibres or components. In Schedule 4 the beta-glucan claim must be associated with bran or whole grain. Beta-glucan concentration is used as a means of standardising whole grain or bran fractions. This does not preclude that possibility that cholesterol lowering effects may also be achieved from other components of the grains or bran that contains the beta-glucans. The FSANZ reviewer appears to be under the impression that manufacturers should add highly purified beta-glucan products to achieve the claim – this would seem to show a lack of understanding of the food industry. For a claim to be allowed the food must contain at least 1 g per serving of beta-glucan from one or more of the following oat or barley foods:

- (i) oat bran; or
- (ii) wholegrain oats; or
- (iii) wholegrain barley.

Logic would dictate that if the claim is to be reviewed, the scope could be broadened to recognise the other components of bran and whole grains which, in addition to beta-glucans, may also contribute to lowered blood cholesterol.

4. Burden of proof

The claim in relation to beta-glucan and blood cholesterol has been in the Code since the gazettal of Standard 1.2.7. The inclusion was as a result of an assessment undertaken as a part of P293, and presumably met the criteria considered acceptable at that time. On the basis of this food manufacturers have modified existing products and developed new products to meet the requirements of the claim based on beta-glucan content. Indeed, the product that our business markets is based on communication around beta-glucan rather than oats specifically.

The current approved claim is consistent with current nutrition/public health consensus/advice and there is a plausible mechanism for the food-health effect relationship.



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

FSANZ has presented no evidence of adverse public health outcomes associated with the claim – the fact that the SR was concluded in 2015 with no further action until 2 years later would support the this.

In the circumstances, the burden of proof which should properly be applied regarding removing or limiting a claim currently in Schedule 4 should be reversed. It should be a requirement that a SR has established, that there is **no evidence of a causal relationship** between the food or the property of the food and the health effect.

Questions for Submitters

1. **What do you consider to be the best approach for managing this food-health relationship in the Code, given the outcomes of the systematic review for the food-health relationship for a HLHC about beta-glucan (see Section 7.1)? Please give reasons for your response.**

Gateway consider that the current status of the high-level health claim for beta-glucan and blood cholesterol should be maintained. We **do not support** the suggested amendments to Schedule 4:

- the property of food from *beta-glucan* to *wholegrain oats and oat bran*
- the specific health effect from *reduces blood cholesterol* to *reduces blood total and LDL cholesterol concentrations*
- the context claim statements to remove reference to diets containing 3 g of beta-glucan per day
- the conditions to remove reference to barley and to refer to appropriate oat foods and foods containing oats.

The reasons for our response are set out under our comments on the SR – there should be no changes to the Code.

2. **What do you consider to be the impacts of amending the Code for consumer understanding of beta-glucan, oats and barley and blood cholesterol?**

The amendments proposed by FSANZ will create confusion for consumers – the communication message will have to be changed from a focus on beta-glucan to oats and the amount of the food required to provide the health effect will need to be determined and subsequently communicated.

3. **Do you consider that such amendments to the Code would be consistent with dietary guidelines and other relevant public health messages? Why/why not?**

Our business has had consistent and regular communication with Healthcare Professionals on the clinical evidence of 3g of beta-glucan consumed daily will reduce LDL cholesterol.

4. **What do you consider to be the impacts on the food industry of such an amendment?**

The proposed changes to the Code will have a significant effect on our business as there will be a cost to change packaging and advertising materials and to re-educate health professionals.



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

As an example - we do this by attend Dietitian, Diabetic Educator and GP conferences around the nation and along with the cost of attending these shows as well as the expense we have invested in excess of \$100K in education and marketing. We also have developed a healthcare professional database and send out regular newsletters. We consider that a similar investment would be required if the changes go ahead – this would place a considerable burden on the business.

5. **What foods do you sell that currently carry health claims (GLHC or HLHC) about beta-glucan? Please provide the following information for these foods:**

Betaglucare currently makes two health claims as follows:

High level Health Claim

Name of the food	Betaglucare
Wording of the health claim	Reduces cholesterol - each sachet contains 3 grams of beta-glucan, the amount proven to reduce cholesterol when eaten daily combined with a diet low in saturated fat.
Total number of foods and SKUs currently carrying the health claims about beta-glucan	2 products – a crisp heart version and a powder version

Self-substantiated general level health claim

Name of the food	Betaglucare
Wording of the health claim	Betaglucare reduces blood glucose levels after meals when 4 grams of beta-glucan is eaten along with 30-80 grams of carbohydrates.
Property of the food	Beta-glucans from oats
Total number of foods and SKUs currently carrying the health claims about beta-glucan	2 products – a crisp heart version and a powder version

The food-health relationship has been established in accordance with the requirements set out in Schedule 6 (Required elements of a systematic review) of the Australia New Zealand Food Standards Code (the Code) and with reference to the *Guidance on establishing food-health relationships for general level health claims* (FSANZ, September 2013).

The **property of the food** is beta-glucan from oats and the **health effect** is 4g of beta-glucan from oats, when consumed in conjunction with 30–80g available carbohydrate, reduces blood glucose rise after a meal.

The potential wording of a general level health claim supported by the systematic review is:

4g of beta-glucan from oats, when consumed in conjunction with 30–80g available carbohydrate as part of a healthy diet made up of a variety of foods, can reduce blood glucose rise after a meal.



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

OR

The dietary inclusion of 4g/day of beta-glucan from oats together with 30–80g available carbohydrate can reduce blood glucose rise after a meal in a generally healthy population representative of the Australian and New Zealand populations.

The claim was notified to FSANZ in January 2016.



Gateway Brands Pty Ltd
PO Box 561
Round Corner NSW 2058
Tel. 02 9651 1643
info@gatewaybrands.com.au
www.betaglucare.com.au
ABN 80 485 371 781

Attachment 1 - Betaglucare Product Information

Betaglucare is an oat based food made from made high quality Scandinavian oats, rich in beta-glucan

There are two formats - Crispy oat hearts and Oat Powder. Both retail packs contain 28 daily sachets and each sachet contains 3g of beta-glucan.

Hearts ingredients: beta-glucan from Scandinavian oats Oatbran (100%)

Oat Powder ingredients: Oatbran (100%) from Scandinavian oats

Hearts Nutritional Information

(servings per pack: 28)	Quantity (per 25 g serving)	Quantity (per 100 g serving)	%DI* (per 25 gm serving)
Energy kJ	366.75	1467	4.2
Protein g	5.1	20.4	10.2
Total Carbohydrate g	11.55	46.0	3.7
- Sugars g	0.4	1.5	0.4
Total Fat	1.0	4.1	1.4
- Saturated Fat g	0.2	0.7	0.8
- Unsaturated Fat g	0.9	3.4	-
Dietary Fibre g	5.9	23.5	19.7
- beta-glucan g	3	12	-
Sodium	0	0	0

Powder Nutritional Information

(servings per pack: 28)	Quantity (per 14 g serving)	Quantity (per 100 g serving)	%DI* (per 14 gm serving)
Energy kJ	176	1259	2.0
Protein g	2.8	20.0	5.6
Total Fat g	0.7	5.0	1.0
- Saturated g	0.1	0.9	0.4
Total Carbohydrate g	3.1	22.0	1.0
- Sugars g	0	0	0
Dietary Fibre g	6.2	44.0	19.4
- Beta-glucan g	3.0	22.0	-
Sodium	0	0	0