



**FSANZ Submission**

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**Consultation Paper – W1109 – Consultation about beta-glucan and blood cholesterol health claims.**

**Background**

This submission is from the Healthy Grain Pty Limited (THG), which is a supplier of BARLEYmax(TM) food ingredients to the Australian and Japanese food industry. BARLEYmax(TM) wholegrain is a nutritionally superior non-GMO wholegrain barley with increased levels of resistant starch and insoluble fibre as well as increased levels of beta glucans and other soluble fibres compared to both standard barley wholegrains and oats.

In addition, the company is working to develop a grain export business to other Asian countries and is also working to develop a licensing business for BARLEYmax™ wholegrain in Europe and North America. Products containing BARLEYmax have recently become available through 1,600 health food stores in the USA and there are over 20 different BARLEYmax products currently being sold in Japan.

The company and its owners have made significant R&D investments in Australia to develop this nutritionally superior wholegrain. Equity in the company is owned by CSIRO, by Australian Capital Ventures Limited and Teijin Ltd.

This submission has been authorised and is signed by a Director of The Healthy Grain Pty Limited, Mr Stephen Hardy.



**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.**

THG considers that a cautious approach to changes to the Code is warranted. Any changes made to the Code have the potential to cause confusion in the minds of the Australian and New Zealand public and potentially result in a reduction in the consumption of oats and barley wholegrains/ingredients, which could in turn have a negative health impact for many Australian and New Zealand consumers.

Currently a percentage of the Australian population probably 'knows and understands' that oat and barley beta glucan lowers blood cholesterol (based on the number of URLs in a google search). We strongly feel that if changes to the Code are introduced to reflect the outcomes from the systematic review (SR), then the public will likely see only the headlines and will not appreciate the subtleties of the SR outcomes. Most importantly they will not understand that any changes to the Code are not due to new negative findings but due to a re-evaluation of the evidence as now being insufficient to support the HLHC.

In addition, there are a number of products containing oats and barley that market these health benefits, and we believe these benefits are sought out by consumers when making a purchase decision. If the proposed changes to the code are introduced, barley-containing products that currently use the existing HLHC will no longer be able to promote the HLHC beta glucan benefits to consumers. This could have a double negative effect:

- 1) Loss of business for barley-containing products
- 2) Consumers may choose a less healthy product if they don't believe they are receiving the heart health benefit from the barley product (if no health claim is allowed)

Changes to the Code may also impact on innovation. Companies such as THG that have invested in R&D to develop oats and or barley with higher levels of beta glucans, believing these to be of benefit to consumers, may not be able to recoup their investment if the Code is changed. The absence of this return may impact future decisions on whether to invest in R&D in Australia or New Zealand.

Another factor that supports taking a cautious approach is the continuing publication of additional trials in this field. The SR study only covered to 2013. As examples of later papers, please see Ho et al 2016 or Wang et al. 2015. The Ho paper reviewed the results of 14 studies (N=615) of subjects consuming a barley beta glucan enriched diet and concluded that the diet resulted in a lowering of LDL-cholesterol and non-HDL-cholesterol levels and may be a strategy for cardiovascular risk reduction. The results of such later meta-analysis reporting a link between barley beta glucan consumption and blood cholesterol fractions help strengthen the previous moderate certainty about the appropriateness of the HLHC. Also, additional publications relating to oats or barley beta glucan consumption in which the beta glucan is better defined, and if positive and if taken with the existing evidence (using less well defined beta glucan fractions) might further sway the decision in favour of retaining the HLHC. For this reason, we consider that the most appropriate approach is to wait until additional papers are published and a firm conclusion can be drawn as to the effect of oat/barley beta glucan /barley consumption and blood cholesterol.





One way of implementing this cautious approach would be for FSANZ to provide public information on both the SR and later trials by way of its website, so that interested members of the public can read the SR and more recent trials and be fully informed of the evidence in this matter. Once further clinical trials become available, this additional clinical trial evidence can be included in an update process.

The following three questions are in the context of amending the Code to align the pre-approved food-health relationship for a HLHC about beta-glucan and blood cholesterol with the outcomes of the systematic review, i.e. the food-health relationship between wholegrain oats or oat bran and the reduction of blood total and LDL cholesterol concentrations is substantiated.

## **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?**

A significant proportion of the public considers that they know about the beneficial effect of beta glucan and amending the code may cause confusion and thence to reduction in consumption of oats/barley wholegrains. This confusion would be especially likely if an amendment is made in the absence of any studies that demonstrate that the HLHC for barley beta glucan is not correct.

Consumers who read the SR will understand that the papers concerning oat/barley beta glucan could not be fully assessed as there were nutritional components beyond just the beta glucan. However they may well question whether or not some form of holistic approach (accepting that the beta glucan fractions used were not sufficiently concentrated beta glucan but that there was a consistent trend for an effect on blood cholesterol from these 'beta glucan' fractions) could not be adopted, particularly when this evidence had been deemed acceptable in the past and remains acceptable in major overseas jurisdictions.

## **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?**

Key dietary guidelines and public health messages are to consume wholegrains and to try and maintain a 'healthy' blood cholesterol. Removing the HLHC for barley beta glucan and blood cholesterol may lead the public to conclude that consumption of barley/barley beta glucan does not reduce blood cholesterol, rather than the conclusions of the SR (moderate degree of certainty/ effects of beta glucans could not be sufficiently disentangled from the effects of other nutritional components to assess their individual effect).

Consumers currently do not eat enough whole grains (comparison of ABS data with Grains and Legumes National Council recommendation (ABS.gov.au and GLNC.org.au ). The proposed amendment to the code could worsen the current intakes of wholegrains, as consumers may choose a non-wholegrain alternative to barley if they do not believe they are receiving the beta glucan health benefit, as currently allowed within the HLHC.

Amendments to the code that discouraged the promotion of key foods such as wholegrains of all varieties is at odds with the key messages of peak health bodies in advising of the benefits of such foods. Removing a health claim related to one particular wholegrain food of barley and blood cholesterol based on the evidence not attaining a subjective level of certainty is against the overall health benefits of consuming such foods for a host of disease and health parameters.





The removal of an existing health claim, particularly the removal of a claim without any contrary evidence, will only generate uncertainty in the public. Consumers generally seek clear guidelines and such a move, or even the public discussion of a proposed move will certainly generate uncertainty. It could even lead to consumers becoming increasingly sceptical about health claims in general.

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

Various food companies have made significant investments promoting the oats/barley beta glucan and cholesterol lowering link. THG itself recently raised \$8 million in foreign investment largely on the basis of the health benefits of BARLEYmax, with the health claim related to cholesterol lowering being a significant component. This investment may be partially nullified by changes to the Code.

We and, very likely, other companies would be very disappointed if the basis on which investments have been made are reversed. This disappointment would be magnified in a situation where such reversal was based not on evidence to the contrary but on the view that the original evidence is now deemed to be insufficient, whereas in the past it was deemed sufficient. Without providing a firm benchmark and clear expectations on what is an acceptable level of evidence in establishing a health claim, FSANZ is opening up the food industry to considerable risk in pursuing beneficial health claims. Any repealing of the health claims for barley serves to provide a more uncertain operating environment for food companies. With the moving of goal posts, it provides little assurance to food industry that any investment in research to inform health claims would be of value either today or in the future.

Changes to the wording relating to barley beta glucan consumption and blood cholesterol will mean that the ANZ legislation will differ from that in other jurisdictions such as the EU and the USA.

THG is an ingredient supplier to both the Australian food industry and to the international food industry. It is beneficial to the company to have legislation in Australia that is consistent with the rest of the world. We develop support programs for our products in Australia that can be used in other markets in the world. Success in the Australian market is often a prerequisite for take up abroad and this amendment might undermine the export potential of our premium Australian grain.

As mentioned changes to the Code may also impact on innovation in Australia. Companies that have invested in R&D to develop oats and or barley with higher levels of beta glucans, believing these to be of benefit to consumers, will not be able to recoup their investment. Investment decisions on such beta glucan research would be negated even though there remains evidence of a positive effect for barley beta glucan. Such evidence has continued to mount beyond the 2013 time-scale of the SR so that it would not be unreasonable to argue that the SR is in effect an interim assessment, and to question therefore whether it is reasonable for an interim assessment to potentially have such a large negative impact on the health and well-being of Australians and New Zealanders and on the prospects of local premium grain innovation.

Would companies wish to invest in R&D in Australia to develop new foods to benefit Australian public health, in relation to a HLHC or a GLHC, knowing that down the track FSANZ might re-evaluate the original evidence and decide that the original GLHC or HLHC decision was incorrect?



THG is a current investor in Australian food R&D and also commercialises this R&D. THG has a second nutritionally superior barley (from Australian R&D) that is scheduled for commercial launch in 2018/9. Our investment decisions are to an extent based on the current Code. There would be a clear disincentive to invest in research if there is possibility that this basis for the investment decision might possibly be reversed in the future.

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

- the name of the food
- the wording of the health claim
- the total number of foods and SKUs currently carrying health claims about beta-glucan.

THG supplies ingredients to two Australian food companies that use its BARLEYmax(TM) ingredients to assist in making beta glucan related claims. These products are:

#### **Freedom Foods**

<https://store.freedomfoods.com.au/products/heart-cereal?variant=25878492547>

Heart Breakfast Cereal

"Heart breakfast cereal contains beta-glucans, a type of soluble fibre which has been found to be beneficial in lowering cholesterol levels and enhancing the immune system.

The combination of wholegrain BARLEYmax™ and wholegrain oats in Goodness Superfoods Heart cereal provides high levels of beta glucan. ""

#### **Alpine Breads**

<http://alpinebreads.com.au/products/heart-wholemeal/>

Helps to lower cholesterol reabsorption\*

Made with BARLEYmax™ – 100% natural whole grain

More than 6g of fibre in every serve

Contains a unique combination of essential fibres, including b-glucan

1 serve contains 1g of beta glucan\*

<http://alpinebreads.com.au/products/heart-fibre/>

Helps to lower cholesterol reabsorption\*

More than 7g of fibre in every serve

Contains a unique combination of essential fibres, including b-glucan

1 serve contains 1.2g of beta glucan\*

Made with BARLEYmax™, a 100% natural whole grain that contains 70% more beta-glucan than oats





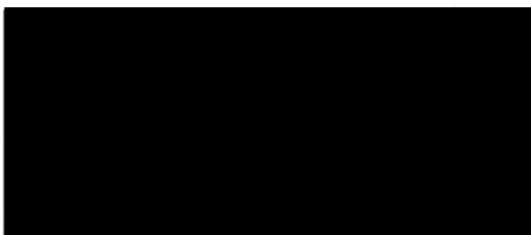
Both companies have expended significant resources in building the awareness of the health benefits of consuming these products. Freedom Foods has recently commenced sales of their products in the USA, after validating market acceptance in Australia, while Teijin has developed the Japanese market for over 20 products, but these are beyond the scope of FSANZ.

#### References

H.V.T. Ho et al, A systematic review and meta analysis of randomised controlled trials of the effect of barley beta glucan on LDL-C, non HDL-C and apoB for cardiovascular risk reduction. European Journal of Clinical Nutrition, 2016; DOI:10.1038/ejcn. 2016.89

Y. Wang et al. Mechanisms of cholesterol lowering effects of barley beta glucan. 2015; PhD thesis – University of Manitoba from Google Scholar.

Yours faithfully



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Director: The Healthy Grain