

Food Standards Australia New Zealand
Standards Management Officer
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Date: 14th September 2017

Re: Response to FSANZ consultation paper W1109 about beta-glucan and blood cholesterol health claims

Freedom Foods Group welcomes the opportunity to make a submission in response to Consultation Paper - W1109 Consultation about beta-glucan and blood cholesterol health claims.

Freedom Foods considers that because the systematic review is now more than 2 years old, it requires revision and cannot fully inform the current conclusion that amendment to the Food Standards Code is required. Furthermore, we suggest FSANZ has reached some erroneous conclusions of the evidence presented in the systematic review relating to the health effects of whole grain barley on LDL-cholesterol, resulting in the flawed conclusion that amendments to the Food Standards Code are required.

Therefore, Freedom Foods Group does not support the conclusion FSANZ has reached. Specifically, Freedom Foods considers that erroneous conclusions have been reached because FSANZ has not adhered to the criteria outlined in its Standard 1.2.7, which states that “*a reasonable conclusion*” is required when making a general level health claim of a notified relationship via systematic review. Further, Schedule 6 states that a conclusion reached on a causal relationship between the food/food property and health effect following a systematic review of the literature is based on “*the totality and weight of evidence*”.

The Systematic Review states:

- 1) “*The meta-analysis demonstrated that consumption of barley significantly changed total and LDL cholesterol concentrations by -0.32 and -0.25 mmol/L, respectively*”; and
- 2) “*The relationship between barley and blood total and LDL cholesterol concentrations was shown to be consistent, with plausible mechanisms to explain the observed effect. The magnitude of the noted reduction was significant regardless of the participant’s blood cholesterol status, that is, whether they had a normal concentration (< 5.5 mmol/L blood total cholesterol concentration) or were hypercholesterolaemic (≥ 5.5 mmol/L).*”

That is, nearly all studies assessed in the systematic review have shown an effect on LDL-cholesterol reduction with barley feeding in high quality research design studies. To dismiss all of these studies, as demonstrated in the conclusion with “*However, the GRADE was down-rated for serious imprecision due to the low number of participants*” is not applying the “*reasonable conclusion*” and “*totality of the evidence*” advice outlined in Standard 1.2.7 and Schedule 6. That is, it is implausible that all of the independently conducted studies suffered the same systematic errors to result in flawed research outcomes. Further, one of the benefits of a meta-analysis is that pooling of data may overcome the



limitations of small sample sizes. As the meta-analysis outcomes support the totality of the evidence of individual papers, we suggest that down rating the evidence is not warranted.

It is our position that it is a reasonable conclusion, based on the totality of the evidence assessed, that barley does reduce LDL-cholesterol. Whether this stems from the beta-glucan fraction of barley or whether this occurs via some mix of the various soluble and fermentable fibres in the barley whole grain is, in our opinion, largely irrelevant. That is, for the purposes of communicating an established barley health effect to consumers, whether the effect is purely attributable to one particular fibre component in the barley grain or other fractions of the barley grain does not undermine the take home health-effect conclusion that barley whole grain reduces blood cholesterol, especially in the target population of individuals with elevated blood LDL-cholesterol.

We suggest that the burden of proof be reversed in relation to the barley-reducing blood cholesterol health effect. That is, consumption of whole grain barley will do no harm at a population health level and on the basis of the totality of the evidence, should improve population health outcomes with increased consumption. Thus, it is our opinion that any systematic literature review that seeks to amend the barley / beta-glucan and blood cholesterol health claim should establish that there is no evidence of a beneficial effect.

In addition to the above, Freedom Foods suggests that any action FSANZ may pursue to amend the Food Standards Code relating to Barley, beta-glucan and blood cholesterol health claims will result in the following:

- 1) Seriously undermine and challenge the marketing practices undertaken by Freedom Foods Group, which involves interrogation of standard 1.2.7 to improve the health profile of its cereal and whole grain offerings, with a view to attract permissible health claims. This process involves extensive market research and investment and can take months and sometimes years to achieve a product to market.
- 2) Will generate serious commercial consequences. The recently launched Barely⁺ Muesli and Porridge range is an extremely healthy, whole grain barley rich breakfast offering that provides around 2.5 g beta-glucan per serving and as such, qualifies for a "Reduce blood cholesterol" claim. Removal of this claim from Barely⁺ will cause unnecessary consumer confusion and negatively impact on consumer understanding of one of the key benefits of barley and more particularly whole grains, which is a positive influence on cardiovascular risk factors, including that of "Blood cholesterol reduction".
- 3) Undermine the intention of Standard 1.2.7, which is to establish a framework that improves manufacturing innovation to produce healthier and better foods that attract permissible health claims, which subsequently lead to the promotion and facilitation of improved population health outcomes in Australia.
- 4) Create misalignment with the scientific consensus in other jurisdictions on the food-health relationship of barley and LDL-cholesterol lowering effects, including the USA Food and Drug Administration and the European Food Safety Authority.

On the basis of the above, we respectfully urge that FSANZ to refrain from taking action to revise the barley / beta-glucan and blood cholesterol health claim.



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Yours sincerely,

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