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15 September 2017

## **Submission prepared on behalf of Kellogg Australia**

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

Kellogg Australia has prepared the following responses to the documented questions in the Consultation paper for W1109.

**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.**

It is our view that the interpretation of the systematic review be re-evaluated before making changes to the Code as there are potential implications across the board for Health Claim Substantiation.

In the case of beta glucan, the current proposal makes the establishment of food-health relationships on nutritive substances within a food matrix difficult, particularly if 100% pure extracts are required in randomised controlled trials. Pure extracts of food constituents (not only related to beta-glucan) are not always feasible; as is consideration of feasibility of human testing. Randomised controlled trials using a low/no exposure control food matched with a higher exposure intervention in controlled conditions should be sufficient to deduce that the difference in exposure resulted in the effect. The approach from FSANZ favours supplemental therapy rather than food therapy.

We are also of the view that there is evidence of a cholesterol lowering effect in both oats and in barley based on the review and FSANZ has not adequately explained why the latter does not meet the burden of proof. We are also of the view that the systematic literature review has not substantiated the decision to not assign a “High Degree of Certainty” to the ‘barley and cholesterol reduction’ relationship given the significance of the effect in people with a broad range of characteristics. No study within the barley review favoured the control. If, as indicated, this is based on sample size, a calculation of appropriate sample size for a “high degree of certainty” should be provided in the review for stakeholders to evaluate as this will effect claim substantiation works moving forward.

FSANZ will need to make very clear to industry just what parameters are acceptable to move forward with a positive food health relationship. The assessment of the evidence proposed in this review will not be representative of many pre-approved and/or self-substantiated health claims currently in market.

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

Based on the criteria used to assess the effectiveness or otherwise of the change, it is likely to confuse consumers. There is no current case that comes to mind where this disparity occurs, but

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there is potential for consumers to confuse the difference between HLHC and a GLHC where a biomarker is mentioned as proof of the effect in a GLHC e.g. reduces cholesterol reabsorption, but not permitted as a HLHC.

There is also potential to confuse when the claims were allowed in Australia and are allowed in other countries, but no longer allowed in Australia.

### **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?**

Wholegrain foods are a cornerstone of the Dietary Guidelines and have a high level of evidence in being linked to a lower risk of type 2 diabetes, overweight and obesity, cancer and cardiovascular disease.<sup>1</sup> Amendments to the code that discourage the promotion of key foods within the dietary guidelines 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 based primarily on the evidence not attaining a subjective level of certainty when the evidence is directional and significant will not be consistent with past recommendations.

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

The proposed amendment has significant impacts on the food industry for the playing field they operate in in making use of good quality science to inform consumer health messages. Repealing a previously approved health claim based on a conclusion from a systematic literature review that otherwise showed a consistent effect of barley on blood cholesterol the same as oats, but was mostly questioned based on the number of trials; provides inconsistent guidance for industry when making health claims on just what is an acceptable level of evidence.

The conclusion from the systematic literature review specifically stated in regards to barley that: *“All studies showed a decrease in total cholesterol and the majority showed a decrease in LDL cholesterol concentration after consumption of barley, although not all results were statistically significant.”* Very few systematic reviews have all studies showing statistical significance, but the key was the overall effect was significant and of a similar magnitude to oats. This was not a case where the benefit was null or of very questionable clinical significance. No studies favoured the control.

The greater issue for food industry then becomes at just what level of attained evidence can an industry generated schedule 6 systematic literature review be used to inform a health claim? What level of evidence is required to achieve a “high degree of certainty” as is the case FSANZ has applied to the latest review on beta-glucan and cholesterol. How will applicants know when enough of a population has been tested? In the guide for informing schedule 6 systematic literature review, the following guidance is given:

*“It is not possible to predict the number of studies that would be needed to allow a causal relationship to be established following the finding of a consistent association and consideration of the other criteria. This is due to the variation in the magnitude of the association, study quality, sample size and control for confounding across the wide range of food-health relationships that might underpin health claims. One way of thinking about causality might be to consider whether it is*

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*likely or not that another large, well-conducted study would have such different results from the available studies that the conclusion from the systematic review would be altered importantly.”*

Without providing a firm benchmark and clear expectations on what is an acceptable level of evidence, FSANZ is opening up food industry to considerable risk in pursuing beneficial health claims. The repealing of a health claim for barley serves to provide a greater uncertain operating environment for food companies. The concern is that the reversal was not based on opposing or contrary evidence which could be argued as being a valid reason, only that the original evidence is now deemed to be insufficient whereas in the past it was deemed sufficient. 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.

On the issue of the nutritive substance beta-glucan, including and excluding food compounds, based on purity, has an implication on the burden of proof. Having to show that a compound is able to be effective as a pure substance as well as in a food matrix is going to add significant cost to any product development. An investment that is likely to be unsustainable by Australian based industry.

In addition, there is an economic cost to industry whereby other markets with permission to make these claims are at an advantage which will not be offered to Australian food businesses.

Multinationals will need to then consider how innovation is conducted across regions and where to invest their dollars, putting the Australian and New Zealand market at a disadvantage.

## **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:**

Kellogg currently do not make this claim on pack on any of our brands or variants. Our interest in this review of the evidence is related to the review methodology itself rather than impact on our current portfolio.

In saying that, there has always been an interest in using barley and barley products in our foods as we do in Guardian, and therefore the brands that have a heart health platform will no longer consider barley, which could discourage the use of this grain in innovation. That would be inconsistent with current advice to eat whole grains as part of the dietary guidelines and encourage industry to use more whole grain, especially a wide variety.

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<sup>1</sup> Fardet, A. and Boirie, Y. (2014), Associations between food and beverage groups and major diet-related chronic diseases: an exhaustive review of pooled/meta-analyses and systematic reviews. *Nutr Rev*, 72: 741–762. doi:10.1111/nure.12153