Comments from the Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources

Due date of submission – 14 September 2017

The Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to provide comments on Consultation W1109 – Consultation about beta-glucan and blood cholesterol health claims (the Consultation).

The Consultation concerns two existing pre-approved food-health relationships in Schedule 4 – Nutrition, Health and Related Claims of the Australia New Zealand Food Standards Code (the Code). FSANZ is seeking information from stakeholders to inform the next steps for both the high level health claim (HLHC) and general level health claim (GLHC), in light of the findings from the FSANZ systematic review of evidence for a relationship between oats, barley and beta-glucan derived from these foods and blood cholesterol concentration.

From the FSANZ systematic review it is understood that:

- The relationship between dietary intake of beta-glucan from oats or barley and the reduction of blood cholesterol concentration is not able to be established due to the lack of studies which tested pure beta-glucan.
- The assessment to determine a relationship between dietary intake of wholegrain barley to reduce blood total and Low-Density Lipoprotein (LDL) cholesterol concentrations demonstrated a **significant effect** on blood total and LDL cholesterol. However, due to the quality of evidence which demonstrates only a **'moderate' degree of certainty**, FSANZ considers the relationship is **not substantiated**.
- The assessment to determine a relationship between dietary intake of wholegrain oats or oat bran to reduce blood total and LDL cholesterol concentrations demonstrated a **significant effect** on blood total and LDL cholesterol. This evidence demonstrates a **'high' degree of certainty** that the relationship exists.
- The systematic review did not assess the relationship for the pre-approved food-health relationship for the GLHC about beta-glucan and reduced dietary and biliary cholesterol absorption.
- The results from the FSANZ systematic review are not consistent with the existing pre-approved HLHC.

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?**

The departments note that FSANZ claims to be reviewing the scientific currency of the pre-approved relationships for making health claims. However, the findings indicate that the initial approval of the beta-glucan HLHC was not based on a high degree of certainty to support the food health relationship. Given the findings of the systematic review and the requirement in the *FSANZ Application Handbook* that pre-approved food-health relationships must demonstrate a food-health relationship with a high degree of certainty, the departments accept that FSANZ should follow the process to raise a proposal for variation of the Nutrition, Health and Related Claims Standard. The departments accept the findings of the systematic review and their implications on the existing pre-approved HLHC. However, as the existing pre-approved food-health relationship for the GLHC about beta-glucan was not assessed, it is suggested this work is completed for potential inclusion in a proposal for variation of the Nutrition, Health and Related Claims Standard. This may allow time for any current research on barley, specifically studies with higher number of participants, to be submitted.

The departments note that the existing pre-approved food-health relationships for the GLHC about beta-glucan was not assessed as part of the systematic review. It is suggested this work is completed prior to a decision being made regarding its potential inclusion in a proposal for variation of the Nutrition, Health and Related Claims Standard.

The departments note FSANZ's intent to review existing HLHCs in Schedule 4 to ensure scientific currency. However, we note the uncertainty this creates for the food industry, particularly if the reviews are undertaken in an ad-hoc manner. Before this work is progressed further, it is suggested that FSANZ prepares, for public consultation, a work plan for the review of all pre-approved food-health relationships (including GLHCs).

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?

The departments have considered the proposed changes raised in Section 7.2 of the Consultation and agree that the scientific evidence supports the property of food changing from 'beta-glucan' to 'wholegrain oats and oat bran'. These changes support efforts to communicate with consumers of poor health literacy, and align with the Australian Dietary Guidelines' approach to recommendations based only on whole foods, rather than recommendations related to specific food components and individual nutrients. Changes to the statement of the specific health effect from 'reduces blood cholesterol' to 'reduces blood total and LDL cholesterol concentrations' is not supported. There is precedence within Schedule 4 to use simplified terminology such as that used for the saturated fatty acids HLHC, that is 'reduces total blood cholesterol or blood LDL cholesterol'.

The systematic review noted no apparent dose-response effect across intake ranges for wholegrain oats (45g-109g per day) and oat bran (20g-150g per day). However, if the context claim statement and beta-glucan conditions are removed, this would permit foods which contain either wholegrain oats or oat bran to make a HLHC (without a minimum quantity of these ingredients). Without a minimum quantity of the food (in this case wholegrain oats and oat bran) specified there is potential for abuse of the HLHC, for example instances where a food product may contain insignificant quantities of wholegrain oats or oat bran yet is able to make a HLHC marketing the health effects of these ingredients in the final product. Inclusion of a minimum quantity of the food is supported by the departments in accordance with the Policy Guideline on Nutrition, Health and Related Claims (the Policy Guideline) which requires health claims to comply with the overarching principles including:

- that there is enough of the specified component to achieve the claimed benefit when consumed as directed; and
- the claim is socially responsible and does not promote irresponsible food consumption patterns.

Additionally, the Policy Guideline states that a claimed benefit must be achievable when the food is consumed in quantities which can reasonably be expected to be consumed daily as part of an appropriate total diet.

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?

Changes to the property as discussed in question two are supported. However, it should be noted that the Australian Dietary Guidelines include both barley and oats as examples of grain foods. It is possible that by removing the ability for wholegrain barley products to make HLHCs this may undermine the credibility of the Australian Dietary Guidelines for some consumers.

Products containing wholegrain barley may already be making HLHC claims based on their beta-glucan content. To remove these claims from the market place may create confusion for some consumers.

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

It is noted by the departments that considerable research and innovation has been undertaken to commercialise the grain, BARLEYmax™ which claims to contain twice the dietary fibre and four times the resistant starch of a regular grain. It is understood that BARLEYmax™ is used as an ingredient in food products which may enable the use of GLHC or HLHC under the existing pre-approved food-health relationship with beta-glucan. Changes to the Code may have an impact on these products or the desire of industry to undertake future innovation. If a proposal is raised to remove these claims from the Standard, the departments suggest that FSANZ should undertake a full cost-benefit analysis to ensure that the costs to industry for product development and marketing are taken into account.

Public consultation on FSANZ's processes and workplan for review of activities would provide industry and regulators with transparency around the process and may reduce impacts on the food industry in the future.