

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

Due date of submission – 24 January 2017

The Victorian Departments of Economic Development, Jobs, Transport and Resources, and Health and Human Services (the departments) welcome the opportunity to provide comments on Application A1134 Increased concentration of plant sterols in breakfast cereals.

Application A1134 seeks approval for the exclusive use for 15 months of an increased concentration of plant sterols to be added to breakfast cereals under the novel food provisions.

From the FSANZ assessment report it is understood that:

- Schedule 25 of the Australia New Zealand Food Standards Code (the Code) contains permissions for the addition of total plant sterol equivalents to breakfast cereals (not including breakfast cereal bars).
- Dose-response models have demonstrated that plant sterols are efficacious at a dose of 2g/day, reducing low density lipoprotein (LDL) blood cholesterol concentrations by 9% without adversely affecting high density lipoprotein (HDL) cholesterol levels. The proposed increased concentration permissions for plant sterols therefore agrees with the Specific Order Policy Principle; *the substance is added in a quantity and a form which is consistent with delivering the stated purpose*¹.
- The proposed increase in the permitted concentration of plant sterols includes an allowance for overages to enable compliance with the declared average quantity of the novel food (Standard 1.2.4) and the health claims standards (Standard 1.2.7). In addition, the draft variation facilitates greater alignment with permissions for the addition of plant sterols to foods in Europe and the USA.
- Plant sterols added to different food matrices appear to be stable to heating (SD1). The departments recognise there is no robust evidence to suggest that the oxidation products of dietary plant sterols pose a risk to consumers or that any such risk outweighs the cholesterol-lowering benefits of dietary plant sterol intake (SD1). The departments refer FSANZ to a recent additional reference examining the stability of different plant sterols and the formation of their oxidation products: Gonzalez-Larena M. *et al.* (2011) *Stability of plant sterols in ingredients used in functional foods*. Journal of Agricultural and Food Chemistry, 59; 3624-3631.
- The increased permissions for the addition of plant sterols up to 2.2 g per serving to breakfast cereals does not pose a safety risk to Australian and New Zealand populations, as explained in the dietary exposure assessment (SD1).

The departments note the application seeks to increase the concentration of plant sterols permitted to be added to portion-controlled breakfast cereals only. However existing permissions in the Code allow plant sterol addition to both portion controlled and, non-portion controlled breakfast cereals that meet the nutrient criteria. The departments support consistency in the Code and FSANZ's proposal to allow permissions for both portion controlled and non-portion controlled breakfast cereals to add efficacious amounts of plant sterols on a per serve basis.

¹ Ministerial Policy Guideline - Addition to Food of Substances other than Vitamins and Minerals

The departments support FSANZ's recommendation to permit all breakfast cereals (excluding breakfast cereal bars) to fortify with plant sterols to the proposed higher concentration (minimum 0.5g plant sterols per serving; maximum of 2.2g per serving) provided these breakfast cereals meet the existing nutrient criteria.

The departments note within the application a request that the permission apply exclusively to selected products within the applicant's product range on the basis that the applicant has invested significant financial resources in research, technical and regulatory arenas. However, the application is an extension of use of an already approved novel food in an already approved food format, requiring limited investment in research and development by the applicant. The departments consider that investment in ingredient costs or manufacturing technology and assets are typical of a commercial food business and would be incorporated in the new product development process of the food business. The departments consider that this application has not demonstrated significant investment in the development of the novel food.

In addition, the departments refer to the the Higher Order Policy Principle on Novel Foods, *to provide a regulatory environment that is timely, cost effective, transparent and consistent with minimum effective regulation, and which encourages fair trade, industry growth, innovation and international trade*. To enable fair trade, industry growth and innovation, the departments recommend that the increased permissions for plant sterols be applied non-exclusively.

The departments agree with FSANZ's observation that it is debateable whether plant sterols should still be considered novel. This point further supports non-exclusive application of increased permissions for plant sterols. The departments suggest that FSANZ should give consideration to how foods and substances can be transitioned from being of novel to non-novel status in the Code, which may be addressed through the Novel Food Standards Development Advisory Group.

Subject to these recommendations, the departments support the progression of Application A1134.