

Sanitarium Health Food Company

Application to amend the Australia New Zealand Food Standards Code

Extension of use to permit 2 grams per serve of plant sterols in plant-based milk alternatives in Schedule 25 – Permitted novel foods

21 December 2021

Executive Summary

Plant sterol enriched foods have a long history of use in the Australian and New Zealand, being available to consumers for the past two decades via enriched edible oil spreads, and permitted in other foods including reduced fat milks, reduced fat cheese, yoghurt and breakfast cereals.

This Application seeks to amend Schedule 25 (Permitted novel foods) to extend the use of phytosterols, phytostanols and their esters to plant-based milk alternatives which are products recommended by Australian Dietary Guidelines as well as Eating Guidelines for New Zealand Adults. Specifically, the proposed change will permit the addition of phytosterols, phytostanols and their esters so that plant-based milk alternatives can contain 2g of total plant sterol equivalents per 250ml serve.

The primary purpose of the requested amendment is to safely improve public health by increasing the accessibility of efficacious and recommended amounts of plant sterols for consumers seeking to lower their cholesterol – a modifiable risk factor for cardiovascular disease.

The Australian National Heart Foundation recommends 2–3 g of plant sterol equivalents per day from products enriched with phytosterols within a healthy balanced diet for people to benefit from the cholesterol-lowering effects. The LDL-cholesterol (LDL-C) lowering effect of plant sterols/stanols has been demonstrated in several systematic reviews and meta-analyses of randomized controlled trials in humans and shows a dose-response relationship with intakes of up to 3 g/day lowering LDL cholesterol. Plant sterols lower cholesterol when delivered across a wide range of food and liquid formats/ matrices and occasions, and studies have demonstrated their cholesterol lowering effects when delivered via plant sterol enriched plant-based milk alternatives.

Sales of plant-based milk alternatives as a category, and each major segment of soy, almond and oat, has been growing steadily over the past decade in Australia and New Zealand driven by an increase in users of these products. The proposed change will, for the first time provide Australian and New Zealand consumers who are interested in lowering their cholesterol the choice of accessing effective amounts of plant sterols via one serve of plant sterol enriched plant-based milk alternative as part of their diet.

The proposed extension of use, to allow the addition of 2 grams of plant sterol equivalents in a single serve of plant-based milk alternatives is consistent with the outcomes from the two most recent plant sterol related applications (A1019 plant sterols addition to reduced fat cheese, and A1134 plant sterol addition to breakfast cereals). The benefits to the consumer of single serve products with 2 grams of plant sterols was also recognised by the FSANZ Phytosterols Expert Advisory Group in September 2005 when it stated *“Some phytosterol-enriched products available in Europe contain the target amounts required for a cholesterol-lowering benefit in a single serve of food. For example, a single-shot of drinking yoghurt can contain two grams of plant sterols. Such products diversify the phytosterol-enriched foods market in general and, for some consumers, undoubtedly offer a simpler choice for obtaining the target amount of plant sterols in one meal event. FSANZ would consider any future applications for products that offer a suitable quantity of plant sterols in a single serve of food.”*

Plant sterol enriched plant-based milk alternatives will carry mandatory advisory statements and other communication to target the intended consumer and packaging will be distinctive to differentiate it from non-fortified counterparts. A price premium is also expected to be a purchase signal to non-target groups. There are no cost/benefit impediments to the proposed change, other

than the additional cost of the plant sterol itself, which will be passed to the consumer via a price premium for the product.

There are no new health and safety concerns associated with the proposed change, which is consistent with FSANZ's previous assessment that there are no public health and safety risks from consumption of approved plant sterol fortified products.

In addition to widening consumer choice, the proposed regulatory change is consistent with other categories where 2 grams plant sterols are permitted in one serve of other foods and internationally where the use of plant sterols in plant-based milk alternatives is currently permitted.

To align with dietary guidelines we propose eligible products are plant-based milk alternatives with at least 100mg of added calcium per 100ml and low in saturated fat. The below drafting is provided as an example of proposed changes that would achieve the outcome being sought:

S25—2 Sale of novel foods

<i>Permitted novel food</i>	<i>Conditions of use</i>
<i>food</i> *Phytosterols, phytosterols and their esters	7. May only be added to plant-based milk alternative (beverages derived from legumes, cereals, nuts, seeds, or a combination of those ingredients); and, if: (a) the beverage has at least 100mg of added calcium per 100ml; and (b) the beverage has no more than 0.75g of saturated fat per 100ml; and (c) the *total plant sterol equivalents content is the prescribed amount. 7A. For the purposes of condition 7(c) above: (a) the prescribed amount during the exclusive use period is: (i) for beverages sold under a brand from Sanitarium Health Food Company – an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml; and (ii) for all other plant-based milk alternative – no phytosterols, phytosterols and their esters are to be added. (b) the prescribed amount after the end of the exclusive use period is an amount that is no less than 0.8 g per 250ml and no more than 2.2 g per 250ml.