

Sanitarium Health & Wellbeing

Application to amend the Australia New Zealand Food Standards Code

Inclusion of regulations specific to the addition of phytosterols to portion-controlled breakfast cereals in Schedule 25 – Permitted novel foods

22 June 2016

**EXECUTIVE SUMMARY**

[Section 3.1.1 A.2 of Application Handbook March 2016]

This Application seeks to amend Schedule 25 – Permitted novel foods specific to the addition of phytosterols to breakfast cereals. In particular, it seeks to add regulations specific to portion controlled breakfast cereals, where ‘portion controlled’ refers to either individually wrapped portions, or discreet portions that can be readily divided from a multi-serve container.

The specific proposed change includes an additional section 4. to the table S25-2 **Sale of novel foods**:

<i>Permitted novel food</i>	<i>Conditions of use</i>
*Phytosterols, phytostanols and their esters	<ol style="list-style-type: none"> <li>1. The food must comply with requirements in Standard 1.2.1 insofar as they relate to section 1.2.3—2.</li> <li>2. May only be added to edible oil spreads:               <ol style="list-style-type: none"> <li>(a) according to Standard 2.4.2; and</li> <li>(b) where the total *saturated and *trans fatty acids present in the food are no more than 28% of the total fatty acid content of the food; and</li> </ol> </li> <li>3. May only be added to breakfast cereals, not including breakfast cereal bars, if:               <ol style="list-style-type: none"> <li>(a) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve; and</li> <li>(b) the breakfast cereal contains no more than 30g/100g of total sugars; and</li> <li>(c) the *total plant sterol equivalents content is no less than 15 g/kg and no more than 19 g/kg.</li> </ol> </li> <li>4. May only be added to portion controlled^ breakfast cereals, if –               <ol style="list-style-type: none"> <li>(a) the total fibre content of the breakfast cereal is no less than 3 g/50 g serve;</li> <li>(b) the breakfast cereal contains no more than 30g/100g of total sugars; and</li> <li>(c) the total plant sterol equivalents content is no less than 0.8g and no more than 2g per serve.</li> </ol> <p>(^Definition of “portion controlled breakfast cereals” = Breakfast cereals that are either delivered in individually wrapped, single-serve portions, or in discreet portions that can be readily divided from a multi-serve container.)</p> </li> <li>5. Foods to which phytosterols, phytostanols or their esters have been added must not be used as ingredients in other foods.</li> <li>6. May only be added to milk in accordance with Standard 2.5.1.</li> <li>7. May only be added to yoghurt in accordance with Standard 2.5.3</li> </ol>

The primary purpose of the amendment is to improve public health & safety by increasing the accessibility of phytosterols through breakfast cereals, a food already approved for fortification with phytosterols.

The proposed change will also allow for a more convenient, cost effective and controlled delivery of the efficacious dose of phytosterols in an inherently healthy breakfast choice, contributing to grain or wholegrain and fibre intakes, and providing a choice for consumers who wish to avoid dairy and

margarines. A single-dose approach is supported by the FSANZ Phytosterols Expert Advisory Group who, in September 2005, stated it “would *consider any future applications for products that offer a suitable quantity of phytosterols in a single serve of food*” due to the benefits such products would confer to the consumer. Observations in EU Member States have shown that many consumers do not reach phytosterol intake levels required to gain a real benefit in terms of cholesterol reduction when using a mix of products, and that there is little over-consumption (EFSA, 2008).

Further, this amendment will increase consistency in regulation of the addition of phytosterol across the various food groups (edible oil spreads, cheese, milk, yoghurt, breakfast cereals). Current regulations create disadvantages *within* the breakfast cereal category as well as *between* the cereal and other food categories and consumers would benefit if this were rectified.

Firstly, as breakfast cereals can have highly variable serve sizes by weight as a result of diverse ingredients and processing methods used, regulations that permit fortification by weight of serving result in different fortification levels of comparable volumes of food. For example, a 30g flaked biscuit serve may only contain 0.57g phytosterol per serve, well below the minimum 0.8g phytosterol per serve level required to make a health claim “reduces blood cholesterol” that is easily achieved in the other food categories. By comparison, a loose breakfast cereal that claims a 45g serve could contain 0.855g phytosterols per serve.

Secondly, serve sizes of breakfast cereals are also dependent on manufacturer and consumer. A five-fold range between the minimum and maximum serving sizes declared on Nutrition Information Panels (NIP) has been observed (The George Institute, 2011). Surveys also show that actual serve sizes of loose cereals differ to on-pack recommendations. (Choice, 2014)

In contrast, there is no ambiguity as to what constitutes a serving with discretely portioned cereals such as flaked biscuits and individually wrapped serves, hence consumption of phytosterols can be highly controlled.

The current regulations also create disadvantages between breakfast cereals and other food categories when compared with levels of phytosterols permitted in the alternatives (edible oil spreads, milk, yoghurt and cheese). A serving of phytosterol enriched breakfast cereal would need to be a prohibitively large (for example, 105g cereal or seven flaked biscuits, or typically three or more serves) to deliver two gram of phytosterols, compared to one 25g tablespoon of margarine, two x 100g tubs yoghurt or a single 22g slice cheese.

The corresponding increased nutrient intakes of such large servings of cereal do not support public health efforts in reducing consumption of energy and sodium (approximately >1.5 times that of edible oil spread and about 3 times that of low-fat cheese eaten with a slice of wholemeal bread). The large servings are also impractical for the target group (45 years and over), discouraging product innovation. It is likely that this is a major contributing factor to no phytosterol-fortified breakfast cereals currently existing within the Australian and New Zealand market.

There are no cost/benefit impediments to the proposed change to allow fortification of up to two gram per portion controlled serve of breakfast cereals, other than the additional cost of the phytosterol itself, for which consumers would pay a premium for the benefits, albeit within a less-distorted competitive framework of various phytosterol enriched foods.

There are no new health and safety concerns associated with the proposed change. FSANZ has previously concluded that there are no public health and safety risks from consumption of approved plant sterol fortified products (FSANZ, 2010).

It is expected that approval of the proposed change to the Code will lead to a greater number of phytosterol-containing breakfast cereals on the market (currently none). This may increase consumption of such products by target and possibly non-target populations. However, survey data suggests that, any increased consumption in children and other non-target populations is likely to be low and with no evidence of any adverse health effect (FSANZ, 2010).

Portion controlled breakfast cereals (with sugar and fibre controlled) containing two grams per serve will carry mandatory advisory statements and other communication to target the intended consumer. Packaging will be distinctive to differentiate it from non-fortified counterparts and a price premium is also expected to be a purchase signal to non-target groups.

Finally, this amendment will also provide greater consistency with international regulations.