

24 January 2017

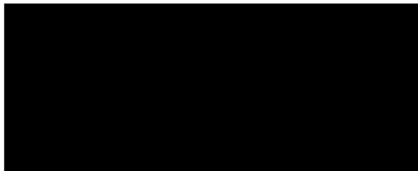
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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Call for Submissions – Application A1134: Increased Concentration of Plant Sterols in Breakfast Cereals.***

Yours sincerely



Katherine Rich
Chief Executive



***Call for Submissions – Application A1134:
Increased Concentration of Plant Sterols in
Breakfast Cereals***

Submission by the New Zealand Food & Grocery Council

24 January 2017

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council (“NZFGC”) welcomes the opportunity to comment on the ***Call for Submissions – Application A1124: Alternative DHA-rich Algal Oil for Infant Formula Products***.
2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over \$34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over \$31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

OVERARCHING COMMENTS

3. NZFGC supports the approval of an increased concentration of plant sterols in breakfast cereals in general.
4. FSANZ’s risk assessment covering technology, hazard, nutrition and dietary exposure assessments did not identify any issues of concern. NZFGC therefore concurs with the FSANZ conclusion that there is no safety issue with increased levels of plant sterols and their esters in cereals whether portion controlled or not. Overseas assessments of plant sterols in a range of food sources have similarly concluded there are no safety issues.
5. NZFGC considers that an increased concentration of plant sterols in breakfast cereals will benefit of consumers and notes that there may be a consumer preference for portion-controlled serves so that consumers might better manage their total daily consumption. Labelling requirements will inform consumers as to the products containing plant sterols, both portion controlled and non-portion controlled.
6. NZFGC supports the exclusivity period for the ‘Sanitarium Health and Wellbeing’ and the ‘Weet-Bix’ brands only, for an exclusive use period of 15 months commencing on the date of gazettal of the variation.
7. NZFGC suggests the amendment to Schedule 25 of the Australia New Zealand Food Standards Code, replace clauses 3 to 6 in the entry for ‘*Phytosterols, phytostanols and their esters’ with new and renumbered clauses 3 to 8 for readability.

SPECIFIC COMMENTS

Previous Assessments of Plant Sterols

8. FSANZ has assessed several applications relating to plant sterols over the past 15 years. Approval to use phytosterol esters derived from vegetable oils first came into effect in Australia and New Zealand in mid-2001 but limited to edible oil spreads. Plant sterols were subsequently permitted to be added to certain edible oil spreads, and certain breakfast cereals, milk and yoghurt (after two reviews requested by Ministers) in 2006.
9. Clarity of the plant sterol permissions was achieved in Standard 1.5.2 in 2008 with a single generic permission for phytosterols, phytostanols and their esters, for the four food vehicles to which specified plant sterols could then be added. Tall oil phytosterol esters were subsequently added for cheese and processed cheese (subject to conditions on fat content) in 2010.

The Application

10. The application made by Sanitarium Health and Wellbeing Australia is for an increased concentration of plant sterols to levels between 0.8g and 2g per serving in portion-controlled breakfast cereals only. 'Portion-controlled' is intended to mean servings that are either individually wrapped or easily divided. The application is also for an exclusive period of use of the increased level for 15 months (the maximum period) from gazettal as permitted under the provisions for novel foods in the Food Standards Code.

Risk Assessment

11. FSANZ undertook a comprehensive risk assessment of the proposed increase in the addition of plant sterols to breakfast cereal covering a food technology assessment, a hazard assessment a nutrition assessment and a dietary exposure assessment. None of these assessments identified issues of concern for the increased levels being sought.

Technology Assessment

12. From a food technology perspective, FSANZ concluded that as breakfast cereals are not generally exposed to very high processing temperatures and oxidising conditions that very few losses of plant sterols in breakfast cereals are made. The process of adding plant sterols to breakfast cereals is also aided by the properties of plant sterols to coat cereal ingredients with the appropriate amount of the sterol in a controlled manner.

Hazard Assessment

13. The science as to consumption of high levels of plant sterol-enriched food is inconclusive with some studies suggesting there are potential risks associated with chronic consumption of such foods and others finding the reverse. Consumption by the general population therefore presents no particular concerns. Occasional consumption of plant sterol-enriched breakfast cereal by young children or pregnant or lactating women is also not considered by FSANZ to be of toxicological concern.

Nutrition Assessment

14. FSANZ repeated a nutrition assessment of plant sterols in breakfast cereals and confirmed that the reduction in serum carotenoid concentration in the blood caused by consuming plant sterols does not pose a health risk to the adult population.

Dietary Exposure Assessment

15. No health based guidance value has been established for plant sterols. As a result, the dietary exposure assessment, which was conducted at a baseline consumption rate and at a 'worst-case scenario' rate (maximum permitted level), supported the conclusion that the addition of plant sterols at 2.2g/serve to breakfast cereals would not pose a safety risk to the Australian and New Zealand populations.

Portion- control vs non-portion controlled breakfast cereals

16. The application sought an increased concentration of plant sterols in portion-controlled breakfast cereals only. This was on the basis that manufacturer accuracy and consumer confidence in amount added/consumed would be maximised. FSANZ proposes that the increase be permitted in non-portion controlled cereals as well on the basis that consumers are not at risk of unsafe dietary exposures to plant sterols. Consumers wanting certainty of level of consumption can still opt for portion controlled products.

Labelling

17. Added plant sterols must be declared in the statement of ingredients on foods to enable consumers to identify these added ingredients.

Overseas approvals

18. A detailed assessment of studies on toxicity, reproductive toxicity, genotoxicity and estrogenicity of phytosterol and phytostanol esters was carried out by the 69th meeting of

the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (World Health Organisation, 2009). JECFA found no evidence for genotoxicity of phytosterols or phytostanols and their esters and no indication of potential for carcinogenicity from the available toxicity studies.

19. While there is legislation in several countries for plant sterols in oils and spreads (eg the USA, Canada, Switzerland and EU) other dietary sources are not so common. However, the EU Scientific Committee on Food (SCF) considered that phytosterols from multiple dietary sources should avoid plant sterol intakes exceeding 3 g/day (SCF, 2002a). The Scientific Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority (EFSA) recommended that sterol-containing foodstuffs should not be consumed in amounts resulting in total phytosterol intakes exceeding 3 g/day.

Exclusivity

20. The Applicant has requested exclusivity on the basis they have invested significant financial resources in research, technical and regulatory arenas in support of their Application.
21. The draft variation specifies that the total plant sterol equivalents content of 0.5–2.2 g per serving permitted to be added to breakfast cereals would apply exclusively to the 'Sanitarium Health and Wellbeing' and the 'Weet-Bix' brands only, for an exclusive use period of 15 months commencing on the date of gazettal of the variation, as requested by the Applicant.

Draft amendment

22. FSANZ proposes varying Schedule 25 by omitting clause 3 from the entry for '*Phytosterols, phytostanols and their esters' in the table to section S25—2 and replacing it with new clauses 3, 3A and 3B. The entry only has three further brief clauses (clause 4, 5 and 6). Given the Revised Code is less than a year old, it would seem much 'cleaner' to replace the entire entry for '*Phytosterols, phytostanols and their esters' from clause 3 and replace it with clause numbered sequentially from clause 3 to 8.

Conclusions

23. NZFGC notes and concurs with the FSANZ conclusion that there is no safety issue with increased levels of plant sterols and their esters in cereals whether portion controlled or not. We note that there may be a consumer preference for portion-controlled serves so that consumers might better manage their total daily consumption. Labelling requirements will inform consumers as to the products containing plant sterols. We support the exclusivity period for the 'Sanitarium Health and Wellbeing' and the 'Weet-Bix' brands only, for an exclusive use period of 15 months commencing on the date of gazettal of the variation.

References

EU Scientific Committee on Food (2002a). General view on the long-term effects of the intake of elevated levels of phytosterols from multiple dietary sources ...

http://europa.eu.int/comm/food/fs/sc/scf/out143_en.pdf

EU Scientific Committee on Food (2003a). Opinion on applications for approval of a variety of plant sterol-enriched foods.

http://europa.eu.int/comm/food/fs/sc/scf/out174_en.pdf

WHO (2009). Safety evaluation of certain food additives / prepared by the sixty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Phytosterols, phytostanols and their esters, pp 117-164.

http://whqlibdoc.who.int/publications/2009/9789241660600_eng.pdf