SUBMISSION
23.01.2017

RAISIO

Food Standards Australia New Zealand
PO Box 7186
Canberra ACT.

RE: Call for submissions on Application A1134, Increased Concentration of Plant Sterols in Breakfast Cereals

Dear Sir,

Raisio Nutrition Ltd. (later Raisio), the international manufacturer of phytostanol ester commercially marketed in consumer products under the Benecol brand since 1995, wish to make a submission supporting FSANZ accepting Application A1134 to increase the concentration of plant sterols in breakfast cereals. Raisio use the same terminology as FSANZ for the purpose of this submission: Phytosterols, phytostanols and their esters, are collectively termed plant sterols.

Raisio welcomes the assessment made by FSANZ and wants to offer more information on the issues summarized below.

1. Nutrition assessment: The studies from Gylling *et al.* 2010 and Davidson *et al.* 2001 that play an important role in the FSANZ assessment have been referenced incorrectly. Both studies reported the intake as plant sterol equivalents – not as esters.
2. Nutrition assessment: A third study with high daily intake of plant sterols (as phytostanol ester) exists: Mensink *et al.* 2010.
3. Additional analytical method for detection of plant sterols: US FDA researchers have published a validated method for determination of plant sterols (Srigleya & Haileb, 2015).
4. Proposal to streamline the legislation: the same increase of plant sterols per portions should be set for yogurts.

In addition, Raisio respectfully makes the following request:

5. Code revision proposal P1025 agrees to the removal of tall oil phytosterols esters from the Code. However, this has not yet been executed.

1. Nutrition assessment, Gylling *et al.*, 2010 and Davidson *et al.*, 2001

The study from Gylling *et al.*[1] is discussed in the *Nutrition assessment* chapter of the Risk assessment report by FSANZ. This Gylling *et al.* study does, together with the study of Davidson *et al.*[2], set the "safe to use level" for the *Dietary exposure assessment* as the reported intake levels of plant sterols did not affect the blood concentration of fat soluble vitamins.

Raisio wishes to point out a significant error made by FSANZ in the evaluation of these two studies: Both the Gylling *et al.* and the Davidson *et al.* study reported the intake of plant sterols as free equivalents, not as their corresponding esters.

- Gylling *et al.*: A daily intake of 8.8 g of phytostanols was studied. This corresponds to a daily intake of 14.7 g/day of phytostanol ester (using the same 0.6 conversion factor based on molecular weights as FSANZ did in the Dietary exposure assessment).

- Davidson *et al.*: A daily intake of 3.0 g, 6.0 g or 9.0 g of phytosterols was studied. This corresponds to a daily intake of 5.0 g, 10.0 g and 15.0 g of phytosterol ester (using the same 0.6 conversion factor based on molecular weights as FSANZ did in the Dietary exposure assessment).

FSANZ incorrectly recalculate the daily intake from these studies, to correspond to a "safe to use level" of 5.4 g plant sterol equivalents when the correct figure in fact is 9.0 g of plant sterol equvivalents.

Raisio urges FSANZ to correct the mistake made and correctly reference the two studies throughout the risk assessment report. Especially the *Executive summary* and chapter *5.4.3 Estimated total dietary plant sterol exposure - scenario modelling approach* needs to be revised. However, this mistake does not change the outcome of the Dietary exposure assessment nor the conclusions of the risk assessment that addition of plant sterols at 2.2 g/serve to breakfast cereals would not pose a safety risk to the Australian and New Zealand populations.

2. Nutrition assessment: an additional study exists

Raisio wants to highlight the existence of an additional supportive study for the safety of high intake of phytostanol ester: Mensink *et al.*[3] (Mensink, et al., 2010) performed a randomized, double-blind, placebo-controlled dose-response study of phytostanol ester in 93 healthy individuals with baseline serum total cholesterol between 5 and 8 mmol/L and no history of cardiovascular diseases or other severe medical conditions. During a 3-week run-in period, subjects consumed a placebo margarine and soy-based yogurt. After this period, subjects were randomized to one of four groups and administered, for 4 weeks, either (intakes are presented as free phytostanol equivalents):

(i) Placebo (0 g phytostanols/day) – continued to consume the placebo margarine and soy-based yoghurt;

(ii) ~3 g phytostanols/day – consumed margarine supplemented with phytostanol ester plus placebo yogurt

(iii) ~6 g phytostanols/day – consumed placebo margarine plus yogurt supplemented with phytostanol ester; or

(iv) ~9 g phytostanols/day – consumed margarine plus yogurt supplemented with phytostanol ester.

Fasting blood samples were collected at baseline and at weeks 2 and 3 of the run-in period, and weeks 6 and 7 of the treatment period; lipid results were based on average data from samples collected at weeks 2 and 3 and at weeks 6 and 7. Clinical biochemistry indicators of kidney and liver function were not altered by the consumption of phytostanol ester, and no differences in the marker of inflammation (hs-CRP) were reported. The placebo-adjusted LDL-cholesterol reductions were 7.5, 12, and 17.4% for individuals in the 3, 6, and 9 g/day phytostanol groups, respectively. Thus, LDL-cholesterol seems to be dose-dependently reduced by phytostanols (as phytostanol ester), although it is notable that the LDL-

cholesterol reduction in the 6 g/day phytostanols group was not statistically significant relative to the 3 g/day group. Changes in total cholesterol among the treatment groups were similar to those observed for LDL-cholesterol. Phytostanol consumption had no effects on HDL-cholesterol or triglyceride levels, and no substantial changes in nutrient status of antioxidants (β-carotene, lutein) and fat-soluble vitamins (α-tocopherol) were reported.

Raisio suggests that FSANZ also considers the study by Mensink *at al.* as pertinent data.

3. Additional analytical method for detection of plant sterols

A method for determination of plant sterols in food products was validated and published in 2015 by US FDA researchers[4] (Srigleya & Haileb, 2015). This method is very similar to the methods mentioned by FSANZ.

4. Proposal to streamline the legislation

The FSANZ Act requires FSANZ to have regard, among other matters, to the objective of achieving consistency between domestic and international food standards when it is considering the development of the Food Standards Code.

Raisio suggest that the FSANZ should consider, for the sake of consistency, to streamline the approvals for the use of plant sterols and at the same time also revise requirements set for the plant sterol content and package capacity for yoghurts. If the application A1134 is accepted, yoghurts would be the only permitted product in Australia from which the daily required intake of plant sterols could not be obtained from a convenient portion.

Currently the consumption of at least two packages of yoghurt with added plant sterols is needed to achieve the reduction of cholesterol absorption as one package with maximum capacity of 200 g of yogurt can contain no less than 0.8g and no more than 1.0 g of plant sterol equivalents (STANDARD 2.5.3 *Fermented milk products*).

Sanitarium presented several justifications on why a single serving product is preferred (See Sanitarium application Chapter *1.3 Justification for the application*). All those same arguments can be used for single serving yoghurts too. In order to make the legislation more consistent and in order to achieve consistency between domestic and international food standards it is proposed to allow flexibility in the dosing of plant sterols also in yogurts so that the daily intake of plant sterols can be consumed from one serving.

Currently no yoghurt products with added plant sterols are present on the Australian market whilst single yoghurts and especially single serving drinking yoghurts are one of the most sold products on other main markets such as Europe (please see appendices 4 and 10 of application A1134 by Sanitarium for further details). The probable reason for this is that it is currently not possible due to the regulatory limitations to market yogurts or yogurt drinks providing the daily dose of plant sterols in one single serving in Australia / New Zealand. The current restriction regarding the yoghurts is clearly an inconsistency between the domestic and international food standards.

Currently yoghurt with added plant sterols can be sold only in packages with a capacity of no more than 200 g. The restriction of the package size has already been removed for milk (application A1065) and the

same should be done for yoghurts. Like for milk there is no advantage of restricting the size of the package for yoghurts.

Raisio respectfully proposes that FZANZ consider updating the dosing of plant sterols in yoghurts simultaneously with the possible Gazettal of application A11034. The standard 2.5.3 Fermented milk products is suggested to be updated in the following way:

Phytosterol. Phytostanol and their esters may only be added to yoghurt -
(a) that contains no more than 1.5g of total fat per 100g; and
(c) no less than 0.5 and no more than 2.2 g total plant sterol equivalents per serving.

5. Proposal P1025: removal of tall oil phytosterols esters from the Code.

The report by FSANZ for the old Proposal P1025[5] for code revision agrees to the removal of tall oil phytosterols esters from the Code. However, this has not yet been executed. Raisio suggests that this already agreed change is made simultaneously with the possible Gazettal of application A11034.

In summary

Raisio urges FSANZ to adopt Application A1134 and consider further expansion of plant sterol enriched products so that Australian consumers can conveniently consume and nutritionally benefit from plant sterol products similarly to their overseas fellow men.

Yours sincerely,

[redacted]

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List of references

1 Gylling H, Hallikainen M, Nissinen MJ, Miettinen TA (2010) The effect of a very high daily plant stanol ester intake on serum lipids, carotenoids, and fat-soluble vitamins. Clin Nutr 29:112–118.

2 Davidson MH, Maki KC, Umporowicz DM, Ingram K a, et al (2001) Safety and Tolerability of Esterified Phytosterols Administered in Reduced-Fat Spread and Salad Dressing to Healthy Adult Men and Women. J Am Coll Nutr 20:307–319.

3 Mensink RP, de Jong A, Lütjohann D, Haenen GRMM, Plat J (2010) Plant stanols dose-dependently decrease LDL-cholesterol concentrations, but not cholesterol-standardized fat-soluble antioxidant concentrations, at intakes up to 9 g/d. Am J Clin Nutr 92:24-33.

4 Srigleya CT, Haileb EA. Quantification of plant sterols/stanols in foods and dietary supplements containing added phytosterols. Journal of Food Composition and Analysis. 2015, 40;163–176

5 Approval Report – Proposal P1025 Code Revision
http://www.foodstandards.gov.au/code/proposals/Documents/P1025-CodeRevision-ApprR.docx