

RE: 2nd call for submissions – Proposal P1025 Code Revision

Dear recipient,

Raisio Nutrition Ltd. (Raisio) greatly appreciates the opportunity to comment on the Proposal P1025-Code Revision. Raisio is the inventor and manufacturer of the cholesterol lowering ingredient plant stanol ester, the owner of the Benecol® brand and the "father" of the whole plant sterol/plant stanol category. Benecol® food products with added plant stanol ester are available in around 30 countries and thus we are well aware of the international regulatory status of plant sterols/plant stanols.

Our comments concern the specifications given for phytosterols in the "Attachment A - Chapters 1-5 - Draft variations to the Australia New Zealand Food Standards Code"¹. In the proposal there are two separate specifications given for phytosterols: (A) phytosterols, phytostanols and their esters and (B) tall oil phytosterol esters. This is at odds with previous decisions by FSANZ.

Raisio's view is that there is no need to have a separate specification for tall-oil phytosterols and the specification ended up there by force of circumstances.

Elaboration:

In the proposal two different specifications are presented:

S3–24 Specification for phytosterols, phytostanols and their esters	S3–27 Specification for tall oil phytosterol esters
<p>Subject to subsections (2) and (3), phytosterols, phytostanols and their esters must comply with a monograph specification in section S3–2 or section S3–3.</p> <p>i.e. FAO JECFA Monographs 5 (2008)</p>	<p>For tall oil phytosterol esters, the specifications are the following:</p> <p>(a) phytosterol content:</p> <p>(i) phytosterol esters plus free phytosterols—no less than 97%; and</p> <p>(ii) free phytosterols after saponification—no less than 59%; and</p> <p>(iii) free phytosterols—no more than 6%; and</p> <p>(iv) steradienes—no more than 0.3%; and</p> <p>(b) sterol profile based on input sterols:</p> <p>(i) campesterol—no less than 4.0% and no more than 25.0%; and</p> <p>(ii) campsteranol*—no more than 14.0%; and</p> <p>(iii) B-sitosterol—no less than 36.0% and no more than 79.0%; and</p> <p>(iv) B-sitostanol—no less than 6.0% and no more than 34%; and</p> <p>(v) fatty acid methylester—no more than 0.5%; and</p>

	(vi) moisture—no more than 0.1%; and (vii) solvents—no more than 50 mg/kg; and (viii) residue on ignition—no more than 0.1%; (c) heavy metals: (i) iron—no more than 1.0 mg/kg; and (ii) copper—no more than 0.5 mg/kg; and (iii) arsenic—no more than 3 mg/kg; and (iv) lead—no more than 0.1 mg/kg; (d) microbiological: (i) total aerobic count—no more than 10 000 cfu/kg; and (ii) combined moulds and yeasts—no more than 100 cfu/g; and (iii) coliforms—negative; and (iv) <i>E. coli</i> —negative; and (v) <i>salmonella</i> —negative.
--	---

* This should probably read "Campestanol"

The background for these two specifications derives from two applications to change the Code:

- Application A1024 EQUIVALENCE OF PLANT STANOLS, STEROLS & THEIR FATTY ACID ESTERS (by Raisio Nutrition Ltd)²
- Application A1019 EXCLUSIVE USE OF PHYTOSTEROL ESTERS IN LOWER-FAT CHEESE PRODUCTS (Kraft Foods Limited)³

The aim of the Application A1024 was to establish a single generic specification for phytosterols, phytostanols and their esters irrespective of the particular type (free or ester form), source (vegetable or tall oil) and specific specification of the preparation, in line with the JECFA specification. The outcome of the A1024 was a decision by FSANZ:

To approve draft variations to Standard 1.5.1 – Novel Foods so that specific source based permissions for phytosterols esters and tall oil phytosterols are amended into a single generic permission for phytosterols, phytostanols and their esters, for the current four food vehicles to which plant sterols can be added.

FSANZ recommended amendments to the Code to reflect one set of generic permissions and specifications for phytosterols, phytostanols and their esters, based on the following reasons:

- All forms of plant sterols are equally safe for human consumption
- The amendments do not raise any additional nutritional safety concerns
- Any plant sterol that meets the specifications, including the extra conditions, is capable of lowering LDL-cholesterol
- Most plant sterol mixtures can be incorporated into currently approved foods
- Existing measures are likely to ensure that only suitable plant sterol mixtures are added to the foods
- The amendments are consistent with relevant Ministerial Council Policy Guidelines
- The amendments support industry innovation

² <http://www.foodstandards.gov.au/code/applications/documents/A1024%20Plant%20Stanols%20AppR.pdf>

³ <http://www.foodstandards.gov.au/code/applications/documents/A1019%20Phytosterol%20esters%20in%20lower%20fat%20cheese%20AppR.pdf>

- The amendments provide net benefits to affected parties
- No other measures would be more effective at achieving this outcome.

However at the same time the Application A1019 was being processed parallel to the A1024. Application A1019 was seeking an exclusivity for the "lower fat cheeses" category. During the assessment FSANZ could not make an assumption that the A1024 would go through so they could not reference the general specification set in the decision of A1024 in the decision of A1019 so A1019 fell out of the scope. Also A1019 was seeking exclusivity.

For the Application A1019 FSANZ concluded that approval of tall-oil phytosterol esters in lower-fat cheese and lower-fat processed cheese poses no increased health risk when compared to currently approved plant sterol-fortified foods and decided:

To amend Standard 1.3.4 – to insert a specification for phytosterol esters derived from tall oils to cover the Exclusivity period of 15 months from the date of gazettal

The exclusivity period ended in 2012.

Our proposal:

The JECFA specification in the proposed Code for phytosterols, phytostanols and their esters (S3—24) covers also the specification for tall oil phytosterol esters so there is no need for the section "S3—27 Specification for tall oil phytosterol esters" in the revised Code. There is no scientific or regulatory reason to have two different specifications in the Code for phytosterols from different sources as stated by FSANZ in the decision of A1024.

Our suggestion is that the section "S3-27 Specification for tall oil phytosterol esters" is removed from the Code.

Thank you for considering our comments. If you have any questions about plant sterols/plant stanols, Raisio is always available to provide information and assistance.

Yours Sincerely,



12.09.2014

Malin Keto-Tokoi
Regulatory Manager
Raisio Nutrition Ltd., Benecol Unit

