

## **Comments from the Department of Health, Victoria 7 May 2012**

The Department of Health, Victoria (DH) welcomes the opportunity to make comment on Application A1065 to vary Standard 2.5.1 – Milk to remove the 1 litre volume restriction on milk enriched with phytosterols.

On the basis of the information provided in the assessment report on Application A1065 undertaken by FSANZ, DH considers the assessment to be incomplete and wishes to raise the following concerns:

### **(i) Applicability of existing Ministerial Policy Guidelines**

According to FSANZ (Call for Submissions – Application A1065: page 8),  
No Policy Guideline is applicable. Specifically the Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals does not apply because the application does not relate to a new permission for adding phytosterols to foods.  
However, DH is of the view that the *Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals* (the Policy Guideline) is in fact a relevant consideration in the assessment of the Application.

Under the “Implementation” section of the Policy Guideline it is stated that  
there needs to be consideration of the cumulative impact of particular substances being added to multiple food products.

The volume restriction of 1 litre was one of the risk management measures included in the approval of adding phytosterols to milk arising from Application A434<sup>1</sup>. It has been six years since this original product was introduced into the Australian market. There are now a number of products on the market that are enriched with phytosterols (for instance, in addition to milk there are margarines, yoghurt and cheese).

Liberalising the volumes of phytosterol enriched milk for sale will in itself increase consumer exposure levels. DH is concerned that an assessment of the cumulative impact on intakes by target and non-target population groups of added phytosterols to multiple food products in the Australian market has not been undertaken. DH therefore considers that it would be premature to grant approval of the Application without an assessment being undertaken by FSANZ on the cumulative exposure of these substances in the different foods in Australia, as required in the Ministerial Policy Guideline.

### **(ii) Health impact assessment of long term exposure**

This concerns builds upon that raised in point (i).

The request to remove the current volume restriction to enable the availability and sale of larger product volumes provides a purely economic benefit largely to the manufacturer and to a lesser degree to consumers. DH understands that the amount of phytosterol in excess of 2-3g per day does not provide any additional health benefit in terms of the cholesterol lowering effects. The cholesterol lowering capacity of added phytosterols is in the order of 10-15 per cent<sup>2,3</sup>.

Milk is a perishable product. The increased volumes for sale at a reduced cost to the consumer will encourage an increased consumption of phytosterol-enriched milk. There are no short term health concerns with phytosterol-enriched milk. However, as raised

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<sup>1</sup><http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfatmilkandlowfatyoghurt/index.cfm>

<sup>2</sup> Kreuzer, J 2011, ‘Phytosterols and phytosterols: is it time to rethink that supplemented margarine?’, *Cardiovascular Research*, vol. 90, no. 3, pp. 397-398.

<sup>3</sup> <http://www.heartactive.com.au/heartactive>

above, long term exposure has not been assessed. A lack of evidence does not equate to safety of these substances when consumed in larger quantities with continuous daily exposure in the longer term, that is, chronic years of exposure to phytosterols enriched foods. DH suggests that it would be more accurate to acknowledge that studies are currently unavailable to inform a decision on the Application at this time and that FSANZ would need to undertake a thorough intake assessment. DH suggests that in the interim the current volume restriction should be maintained.

Higher prolonged intakes are especially of concern for younger consumers not in the target group (that is, over 40 year olds with cholesterol concerns) who may be unnecessarily exposed to these substances for many years in multiple person households. The possible effects of chronic exposure to added phytosterols on the absorption and metabolism of vitamins and minerals<sup>4,5</sup>, induction of hypertension<sup>6</sup> and increase cardiovascular risk<sup>7</sup> are of particular concern. Such consumption is likely to increase if volume restrictions are removed.

## **(ii) 'Fair trading in foods': comparators**

FSANZ has accepted the Applicant's rationale that the *promotion of fair trading in food* to supports the Application. Phytosterol enriched-margarines that are commonly sold in quantities that contain numerous servings are cited by the Applicant as the comparator.

DH suggests that such a comparison is not equal. Milk and margarine are two very different products in terms of consumption patterns and shelf lives. Milk being highly perishable has a very short shelf life and can be consumed alone (that is, a glass of milk) or as part of a mixed meal. Conversely, margarine has an extended shelf life and is consumed as part of a mixed meal only and this aspect has a limiting effect on intakes. As a result, it can be expected that removing the volume restriction will increase consumer intakes but importantly this increase will not correspond with any additional health benefit to consumers.

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<sup>4</sup> Tuomilehto, J Tikkanen, MJ Hogstrom, P Keinanen-Kiukaanniemi, S Piironen, V Toivo, J Salonen, JT Nyyssonen, K Stenman, U-H Alfthan, H Karppanen, H 2009, 'Safety assessment of common foods enriched with natural nonesterified plant sterols', *European Journal Of Clinical Nutrition*, vol. 63, no. 5, pp. 684-691.

<sup>5</sup> Richelle, M Enslen, M Hager, C Groux, M Tavazzi, I Godin JP 2004, 'Both free and esterified plant sterols reduce cholesterol absorption and the bioavailability of beta-carotene and alpha-tocopherol in normocholesterolaemic humans', *American Journal of Clinical Nutrition*, vol. 80, pp. 171-177.

<sup>6</sup> Kreuzer, J 2011, 'Phytosterols and phytostanols: is it time to rethink that supplemented margarine?', *Cardiovascular Research*, vol. 90, no. 3, pp. 397-398.

<sup>7</sup> Kelly, ER Jogchum, P Mensink, R Berendschot TTJM 2011, 'Effects of long term plant sterol and -stanol consumption on the retinal vasculature: a randomized controlled trial in statin users', *Atherosclerosis*, vol. 214, no. 1, pp. 225-230.