Comments from the Department of Health, Victoria 19 October 2012

The Department of Health, Victoria (DH) welcomes the opportunity to comment on Application A1070 to vary Standard 2.5.4 –Cheese in the *Australian and New Zealand Food Standards Code* to remove the individual portion size restriction of 50 g maximum weight for phytosterol-enriched cheese.

On the basis of the information provided in the FSANZ report on the assessment of A1070, DH is of the view that further work is needed on the cumulative effects of phytosterol-enriched foods. In that regard, DH seeks advice from FSANZ about its plans to undertake such work.

In the interim, DH wishes to make comments about Application 1070 along similar lines to those made in response to the assessment of A1065 which sought approval for the removal of the 1 litre restriction of phytosterol-enriched reduced fat milk. This is because the issues raised previously were not resolved satisfactorily and therefore have now re-emerged with the current application A1070.

DH's comments are as follows:

(i) Applicability of existing Ministerial Policy Guidelines

Phytosterol-enriched margarine was introduced to Australia in 2000, followed by a substantial expansion of phytosterol-enriched products in 2006 that included low fat milks, high-fibre breakfast cereals, low-fat yoghurts and reduced-fat cheese. Phytosterol-enriched products are considered to be dietary staples which are consumed on a daily basis.

DH understands that portion weight restriction was intended as a risk management measure when permission was granted to add physterols to milk and yoghurt in 2006 (A434), and to add tall oil phytosterols to lower fat cheese and processed cheese products in 2010. That measure was introduced as a way of ensuring appropriate consumption of phytosterol-enriched products and a consistent approach to how phytosterol permissions were granted for other products. It was also intended that such a measure would allow consumers to easily determine their daily consumption of phytosterols and to limit consumption by non-target consumers.

It is noted that FSANZ recognises that liberalising individual portion sizes has the potential to result in greater consumption in non-target groups than currently occurs. It is also noted that FSANZ risk assessment did not identify any potential health risks to non-target consumers.

In light of that conclusion, it is unclear then why the current mandatory statements advising, for instance, that phytosterol-enriched products *may not be suitable* for children under the age of five years and pregnant and lactating women, remain necessary. If a statement was necessary to assist consumers then, arguably, information about why it may be unsuitable would be more appropriate.

Further, the packaging restrictions along with the price premium afforded to the phytosterol-enriched products were considered to be barriers to excessive intakes in the general population. The Application acknowledges that the increased packaging size will reduce the cost of the product to the consumer. There is a body of research that shows that larger packages of products encourage the

consumption of greater quantities, in part due to perceived lower food cost[1]. Consequently, it may be possible that, irrespective of the information provided to consumers in terms of mandatory statements, economic considerations may be a significant factor in driving consumer choice.

The proposed liberalisation of the packaging size of phytosterol-enriched cheese and the predicted lower product price are collectively likely to increase consumer exposure levels in both target and non-target groups. In terms of the latter, DH reiterates the concerns raised in relation to A1065 about the absence of any assessment of the cumulative impact on intakes of added phytosterols to multiple food products in the Australian market.

Under the "Implementation" section of the *Policy Guidelines on the Addition to Food of Substances other than Vitamins and Minerals* (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.

It is noted that FSANZ maintains that the recently completed assessment of A1065 and the detailed risk assessment report written for that assessment apply to this current Application. It is also noted that the assessment process for this current application did not identify any new toxicological, clinical or epidemiological evidence and therefore the conclusions of the previous safety assessment remain. However, DH suggests that FSANZ uses caution is drawing definitive conclusions about safety in the absence of evidence about potential cumulative effects of increased consumption and continuous daily exposure of phytosterol-enriched foods.

Further, DH does not agree that it was unnecessary to update previous dietary estimates for this Application. The last dietary estimates for phytosterols was undertaken in 2010 and although the dietary modelling included many of the currently permitted products which, at that time, did not include cheese products.

In light of these concerns, DH again 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.

(ii) Reliance on short-term studies to inform FSANZ risk assessments.

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

DH has observed that short-term studies form the bulk of research to inform the risk assessments undertaken by FSANZ. It is understood that this is because of the paucity of long term studies.

DH appreciates that the consumption of these products with added phytosterols is a fairly new phenomenon and so long term studies are rarely available. The absence of long term studies however should not translate to an assumption that there is no risk.

FSANZ has asserted that, after considering all of the available research, there are no long term health concerns. However, authors of some of the short term

[1] French, SA 2003, Pricing Effects on Food Choices, *The Journal of Nutrition*, 133(3): 841S-843S

studies that have been reviewed for the Application have called for longer term studies to discount any potential future health risk such as the absorption and metabolism of vitamins and minerals[2,3], induction of hypertension[4] and increased cardiovascular risk[5].

DH acknowledges that FSANZ has relied upon updated dietary intake data from 2007 and the manufacturer's own data to conclude that there are no concerns for children's cumulative intake of products with added phytosterols. However, DH's concerns centre on higher prolonged intakes for non-target consumers comprising teenagers to young adults who may be unnecessarily exposed to these substances for many years in multiple person households.

The European Food Safety Authority, in providing its Scientific Opinion-*Plant Stanol Esters and Blood Cholesterol*[6]*,* stated that the consumption of higher quantities of phytosterols can significantly reduce levels of beta-carotene in blood. As a result, it recommended that plant sterol intakes should not exceed 3 grams per day as a prudent precaution for target consumers.

However, non-target consumers will also be subjected to the beta-carotene lowering effects in the absence of any other health benefit. This problem becomes even more pronounced when the inherently low population intake of fruit and vegetables is considered. Beta-carotene is obtained from fruit and vegetables. The recent *Victorian Health Monitor-Food and Nutrition Report*[7] has found that around 85 per cent of adult Victorians consume less than the daily recommended number of serves of fruit and vegetables. Essentially, the longer term effects of reduced beta-carotene blood levels raise a health concern within the context of an already low fruits and vegetable intake. It is therefore inaccurate for FSANZ to state that there is no long term risk associated with phytosterol-enriched products for both target and non-target consumers.

(ii) Data used to inform dietary monitoring

It is of concern that FSANZ continues to rely on dated 1995 consumption data to inform adult dietary intake estimates on the basis that intakes have changed little over time. With increasing consumer knowledge and interest in health, and the changing food supply, including the price of food products, it is unlikely that the consumption of phytosterol-enriched dietary staples has in fact remained the same. For example, evidence from reduced fat milk sales in March 2012 shows an increase of 8.7 per cent compared with the same time last year[8].

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[2] Tuomilehto, J., Tikkanan, M.J., Hogstrom, P., Keinanen-Kiukaanniemi, S., Piironrn, V., Toivo, J., Salonen, J.T., Nyyssonen, K., Stenman, U-H., Alfthan, H. and Karppanen, H. 2009. Safety assessment of common foods enriched with natural nonesterified plant sterols, *European Journal of Clinical Nutrition*, 63(5): 684-691.

[3]Richelle, M., Enslen, M., Hager, C., Groux, M., Tavazzi, I. and Godin J.P. 2004. Both free and esterified plant sterols reduce cholesterol absorption and the bioavailability of beta-carotene and alhpa-tocopherol in normocholesterolaemic humans, *America Journal of Clinical Nutrition,* 80: 171-177.

[4] Kreuzer, J. 2011. Phytosterols and phytostanols: is it time to rethink that supplemented margarine?, *Cardiovascular Research*, 90(3): 397-398.

[5] Kelly, E.R., Jogchum, P., Mensink, R. and Berendschot T.T.J.M. 2011. Effects of long term plant sterol and - stanol consumption on the retinal vasculature: a randomized controlled trial in statin users, *Atherosclerosis,* 214(1): 225-230.

[6] European Food Safety Authority. 2008. Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from McNeil Nutritionals Ltd. on plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease (EFSA-Q-2008-118). *The EFSA Journal,* 825: 1-13.

[7] http://docs.health.vic.gov.au/docs/doc/Victorian-Health-Monitor-Food-and-Nutrition-report

[8] http://www.xcheque.com/news/articles/5423-australian-milk-sales-up.html

DH agrees with the advice provided by FSANZ in its assessment of A1065 that sales data do not provide details that can drill down to intake at the individual level. However, DH contends that sales data can serve as an indicator that could trigger when a change has occurred and which warrants further investigation.

Relying on dated consumption data to inform current assessment risks cannot be considered to be good practice. DH agrees with FSANZ that a National Nutrition Survey is ideal for the purpose of obtaining comprehensive, updated individual consumption data. However, in its absence it should not be unreasonable for the applicant or FSANZ to provide updated intake data to supplement this deficit.

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