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Dear Sir/Madam

Re: Application A1065 Packaging size for Phytosterol-enriched Milk

The National Heart Foundation of Australia (NHFA) welcomes the opportunity to comment on the FSANZ proposal to remove the volume restriction on phytosterol-enriched milks.

We note that Section 2.5.1 of the Food Standards Code¹ currently only permits phytosterols in milk volumes of 1L and this has been cited as a barrier to consumption². The original intent of volume restriction was to ensure milks enriched with phytosterols were not available in "family sized" volumes, thus reducing the likelihood of consumption by non target members of the community (in particular, children, and pregnant and lactating women).

The NHFA is supportive of the addition of phytosterol esters to margarine spreads, low-fat yoghurt and drinking yoghurts, reduced-fat cheese, fruit juice and fruit juice drinks. The NHFA has previously submitted responses to FSANZ on phytosterol Applications (A1024 and A434)³⁻⁴.

The NHFA **remains unconvinced** that there is a compelling argument to change the current restriction. The FSANZ Risk Assessment Report (Supporting Document 1) suggests that there is a consumer demand for larger pack sizes⁵. However, this is based on 24 enquiries to Lion Dairy and Drinks (formerly National Foods) from Australian consumers over a 10 month period⁶. Independent market research is needed to provide an accurate picture of demand.

The argument that larger volume sizes will be relatively cheaper and reduce economic barriers to consumption needs further testing. Roy Morgan research suggests that current consumers tend to live in households with a medium-to-high income and have disposable income⁷. Further research is needed to examine whether price is prohibitive for those in lower income groups who would benefit from phytosterol-enriched milk or whether other socio-economic factors are at play (e.g. education and self-efficacy).

Most importantly, the NHFA believes there are still unresolved safety concerns associated with the consumption of phytosterol enriched milks by non-target consumers. Our Position Statement (2009) currently recommends that Australians with '*high absolute risk of CVD consume 2-3 g of phytosterols per day from margarine, breakfast cereal, low fat yoghurt or milk enriched with phytosterols*' (as part of a cardio-protective diet). The position statement also states that '*children*

(other than those with familial hypercholesterolaemia) and lactating or pregnant women do not need phytosterol enriched products because it is not appropriate to reduce cholesterol absorption in these situations.’ Our position paper also concludes that there are ‘no reported adverse effects from daily consumption of phytosterol/stanol enriched foods although long-term safety information is not available⁸.

We are unaware of any further evidence providing insight into consumption trends of target and non-target consumers and no new evidence confirming the long term safety of consumption by non-target groups. We note that the FSANZ Risk Assessment has also found no new evidence. The NHFA would like to emphasise that *no evidence of risk* does not by default imply *no risk* or confer *safety*.

As such, the NHFA recommends that FSANZ adopts the precautionary principle and **maintain the current restriction**. This should only be reviewed:

1. At such a time when we have better intelligence on consumption trends. The National Health Survey (2011) results will be able to provide a clearer picture of consumption; and
2. When sound evidence is available confirming long term safety.

We are grateful for the opportunity to submit this brief response to Application A1065. Please do not hesitate to contact our National Policy Officer (Beth Thomas at Beth.Thomas@heartfoundation.org.au) if you require any further information. We look forward to seeing the outcome of the Application.

Yours faithfully



Dr Lyn Roberts AM
Chief Executive Officer – National

¹ Commonwealth of Australia (2011) *Australia New Zealand Food Standards Code (the Code) Standard 2.5.1* accessed at <http://www.comlaw.gov.au/Details/F2011C00620> on April 27, 2012.

² Food Standards Australia New Zealand (2012) *Supporting Document 1 Risk Assessment Report* accessed at <http://www.foodstandards.gov.au/srcfiles/A1065%20Packaging%20size%20of%20milk%20with%20phytosterols%20SD1%20Risk%20assess.pdf>

³ National Heart Foundation of Australia (2009) Submission to FSANZ Application A1024 Equivalence of plant stanols, sterols & their fatty acid esters, Melbourne NHFA

⁴ National Heart Foundation of Australia (2004) Submission to FSANZ Application A434 – Phytosterol esters derived from vegetable oils in low fat milk and low fat yoghurt. Sydney NHFA.

⁵ Food Standards Australia New Zealand (2012) *Supporting Document 1 Risk Assessment Report* accessed at <http://www.foodstandards.gov.au/srcfiles/A1065%20Packaging%20size%20of%20milk%20with%20phytosterols%20SD1%20Risk%20assess.pdf>

⁶ Lion Dairy and Drinks (2011) Application to amend the Australia New Zealand Food Standards Code - Removal of package size restrictions for milk with added phytosterols, phytostanols and their esters accessed at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm> on April 27 2012

⁷ Roy Morgan Single Source as cited in Lion Dairy and Drinks (2011) Application to amend the Australia New Zealand Food Standards Code - Removal of package size restrictions for milk with added phytosterols, phytostanols and their esters accessed at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm> on April 27 2012

⁸ NHFA Position statement Phytosterol/stanol enriched foods 2007 (Updated December 2009) accessed at <http://www.heartfoundation.org.au/SiteCollectionDocuments/Stanol-enriched-foods-position-statement.pdf> on April 27, 2012