

**Meier, David**

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**From:** standards.management@foodstandards.gov.au  
**Sent:** Monday, 7 May 2012 5:47 PM  
**To:** standards.management  
**Subject:** FSANZ: Applications and Submissions - Submission [SEC=INCONFIDENCE]  
**Attachments:** Application A1065 UANZ response 7 May 2012.doc  
  
**Categories:** Yellow Category



**FSANZ: Applications and Submissions - Submission**

Monday, 7 May, 2012

1. **Assessment Report Number:** Application A1065
2. **Assessment Report Title:** Packaging Size for Phytosterol-enriched Milk
3. **Organisation Name:** Unilever Australia Ltd
4. **Organisation Type:** Individual
5. **Representing:** Unilever Australia zlted
6. **Street Address:** 20-22 Cambridge St Epping NSW 2121
7. **Postal Address:** As above
8. **Contact Person:** [REDACTED]
9. **Phone:** [REDACTED]
10. **Fax:** [REDACTED]
11. **Email Address:** [REDACTED]
12. **Submission Text:** 7th May 2012 Project Manager Application A1065 Food Standards Australia New Zealand Unilever Australia Ltd Submission in response to: Application A1065 Packaging Size for Phytosterol-enriched Milk Dear Project Manager As an interested stakeholder over the past 12 years, we have keenly and actively participated in regulatory developments for phytosterol, and the more recently defined plant sterol, products in Australia and New Zealand. We would like to take this opportunity to provide our submission in response to this most recent application and support the FSANZ proposed recommended regulatory outcome: FSANZ recommends the removal of the volume restriction for phytosterol-enriched milk based on: - Lack of evidence of public health or safety issues arising from the consumption of phytosterols; - The market research information provided in the Application indicating that consumers may be disadvantaged by a restricted range of package sizes; - Consistency with the risk management approach in the EU and USA; - The availability of other risk management measures. Risk Assessment Report The FSANZ Supporting Document 1 Risk Assessment Report Application A1065 Packaging Size for Phytosterol-enriched Milk clearly states that there have been a significant number of very thorough scientific evaluations on plant sterols to date, the most recent in 2010. FSANZ concluded that consumption of phytosterol enriched foods raises no safety concerns and that a reference health standard is therefore not warranted. At this time FSANZ also assessed the potential for phytosterol enriched foods to increase the risk

of cardiovascular disease and concluded that added phytosterols are not present in sufficient amounts to be considered as an additional risk factor for CHD under normal conditions. There are two new published pieces of information FSANZ have assessed as part of the current review: Kelly ER, Plat J, Mensink RP, Berenschot TT(2011) Effects of long term plant sterol and stanol consumption on the retinal vasculature: a randomised controlled trial in statin users. *Atherosclerosis* 214(1):225-230 Genser B, Silbernagel G, De Backer G, Bruckert E, Carmena R, Chapman MJ, Deanfield J, Descamps OS, Rietzschel ER, Dias KC, Marz W (2012) Plant Sterols and cardiovascular disease: a systematic review and meta-analysis. *European Heart Journal* 33(4):444-451 FSANZ have reviewed these studies and concluded: FSANZ has not located any studies published since its previous risk assessment in 2010 that would indicate a potential for safety concerns in any population group consuming foods enriched with phytosterols, phytosterols and their fatty acid esters. Additional comments in this review: FSANZ considers there is no less uncertainty in the data supporting the safety of phytosterols in food since the approval of the addition of phytosterols to reduced-fat milk in 2006. The nature of plant sterols together with their chemical and physical properties are well described in scientific literature. Detailed toxicity studies in animals are available. In addition there are many published studies examining the safety, efficacy and nutritional effects in humans following consumption of phytosterol-enriched foods. Phytosterols have a history of safe use in the food supply of more than ten years. Areas of uncertainty continue to diminish as additional data supporting the safety of phytosterols accumulate in the published literature. We congratulate FSANZ on the strong scientific basis of its risk assessment, and the balanced approach in reviewing the totality of evidence for these much-studied substances. Should FSANZ be interested in further Unilever positions on these studies, please do not hesitate to contact me. Yours sincerely [REDACTED]  
Regulatory Manager Unilever Australasia

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7<sup>th</sup> May 2012  
Project Manager Application A1065  
Food Standards Australia New Zealand

Unilever Australia Ltd Submission in response to:  
Application A1065 Packaging Size for Phytosterol-enriched Milk

Dear Project Manager

As an interested stakeholder over the past 12 years, we have keenly and actively participated in regulatory developments for phytosterol, and the more recently defined plant sterol, products in Australia and New Zealand. We would like to take this opportunity to provide our submission in response to this most recent application and support the FSANZ proposed recommended regulatory outcome:

FSANZ recommends the removal of the volume restriction for phytosterol-enriched milk based on:

- Lack of evidence of public health or safety issues arising from the consumption of phytosterols;
- The market research information provided in the Application indicating that consumers may be disadvantaged by a restricted range of package sizes;
- Consistency with the risk management approach in the EU and USA;
- The availability of other risk management measures.

#### **Risk Assessment Report**

The FSANZ Supporting Document 1 *Risk Assessment Report Application A1065 Packaging Size for Phytosterol-enriched Milk* clearly states that there have been a significant number of very thorough scientific evaluations on plant sterols to date, the most recent in 2010.

FSANZ concluded that consumption of phytosterol enriched foods raises no safety concerns and that a reference health standard is therefore not warranted. At this time FSANZ also assessed the potential for phytosterol enriched foods to increase the risk of cardiovascular disease and concluded that added phytosterols are not present in sufficient amounts to be considered as an additional risk factor for CHD under normal conditions.

There are two new published pieces of information FSANZ have assessed as part of the current review:

Kelly ER, Plat J, Mensink RP, Berenschot TT(2011) Effects of long term plant sterol and stanol consumption on the retinal vasculature: a randomised controlled trial in statin users. *Atherosclerosis* **214**(1):225-230

Genser B, Silbernagel G, De Backer G, Bruckert E, Carmena R, Chapman MJ, Deanfield J, Descamps OS, Rietzschel ER, Dias KC, Marz W (2012) Plant Sterols and cardiovascular disease: a systematic review and meta-analysis. *European Heart Journal* **33**(4):444-451

FSANZ have reviewed these studies and concluded:

*FSANZ has not located any studies published since its previous risk assessment in 2010 that would indicate a potential for safety concerns in any population group consuming foods enriched with phytosterols, phytostanols and their fatty acid esters.*

Additional comments in this review:

*FSANZ considers there is no less uncertainty in the data supporting the safety of phytosterols in food since the approval of the addition of phytosterols to reduced-fat milk in 2006. The nature of plant sterols together with their chemical and physical properties are well described in scientific literature. Detailed toxicity studies in animals are available. In addition there are many published studies examining the safety, efficacy and nutritional effects in humans following consumption of phytosterol-enriched foods. Phytosterols have a history of safe use in the food supply of more than ten years. Areas of uncertainty continue to diminish as additional data supporting the safety of phytosterols accumulate in the published literature.*

We congratulate FSANZ on the strong scientific basis of its risk assessment, and the balanced approach in reviewing the totality of evidence for these much-studied substances.

Should FSANZ be interested in further Unilever positions on these studies, please do not hesitate to contact me.

Yours sincerely

  
Regulatory Manager  
Unilever Australasia