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Standards Management Officer  
Food Standards Australia New Zealand  
PO Box 7186  
Canberra BC ACT 2610

Dear Sir / Madam

**Submission – Application A1065 – Packaging Size for Phytosterol-enriched Milk**

Thank you for the opportunity to provide a submission on the Call for Submissions for Application A1065.

This submission provides technical advice and comments related to this issue. It was prepared with advice from other relevant Queensland Government agencies. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government when notification is made by the FSANZ Board to the Legislative and Governance Forum on Food Regulation.

The restriction on package size was one of the risk management measures arising from Application A434 – Phytosterol esters in low fat milk and low fat yoghurt. This measure was aimed at encouraging appropriate use by target consumers and discouraging use by non-target groups such as children and pregnant and lactating women.

Another of the risk management measures is the requirement for mandatory advisory statements that advise that foods containing phytosterols and their esters may not be suitable for children less than five years of age and pregnant and lactating women.

It is noted that FSANZ considers that there is no new clinical or epidemiological evidence that raises public health or safety concerns about the consumption of phytosterol-enriched foods. Also, it was noted that specific safety data in relation to pregnant women, lactating women and children less than 5 years remains very limited and that FSANZ has not justified how it was concluded that 'There is no basis for postulating a risk to these populations subgroups based on toxicological data'.

Based on the work undertaken by FSANZ it appears that additional research needs to be undertaken into the health effects on consumption of phytosterols by pregnant women, their unborn children, infants and children.

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As noted in the FSANZ Call for Submissions Reports, increasing the package size is likely to lead to increased consumption by non-target groups. This places greater importance on the second strategy for limiting consumption by non-target groups through use of mandatory advisory statements and declarations.

Concern is expressed that the current requirements for mandatory advisory statements and declarations are weak in relation to minimum font size (ie. not prescribed), to comprehension (eg. typically written in capitals) and placement on the package. Examination of two milk products containing plant sterols (Devondale Reduce Cholesterol Absorption and Heart Active) has occurred. While the advisory statements / declarations on these products appear to be adequate, some other foods containing phytosterols or phytostanols include advisory statements that are unlikely to be identified and read by most consumers. For example, displayed on the bottom of the product, in a large block of text in capitals surrounded by other 'technical' information. As such, we believe that any permission, such as increasing the maximum package size, that increases the exposure to non-target groups should be supported by a strengthened requirements for the legibility and placement of the mandatory advisory statement and declarations.

Concern has already been expressed in past submissions about the need to address the cumulative impact over time of extending permissions to new food products. When the *Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals* was endorsed by the Australia and New Zealand Food Regulation Ministerial Council in May 2008, Ministers agreed that the *Policy Guideline* should apply to new applications or proposals and should not trigger a review of existing permissions in the Australia New Zealand Food Standards Code. However, the policy guideline states under the heading Implementation 'It may be necessary to review existing standards that are impacted by this policy in order to achieve optimal public health outcomes over time. Particularly, there needs to be consideration of the cumulative impact of particular substances being added to multiple food products'.

It is considered that removing the restriction on the package size of milk in effect provides an additional permission for phytosterols in milk in package sizes greater than one litre. Therefore Application 1065 would appear to be a new application and FSANZ needs to have regard to the policy guidelines in accordance with Section 18 of the *Food Standards Australia New Zealand Act 1991*.

In the Call for Submission report the assessment by FSANZ appears to have mainly examined the issues related to phytosterols and their esters and not phytostanols and their esters. However the Risk Assessment Report considers both. Consideration should be given to clarifying the assessment relates to both in the Final Assessment report.

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