26 March 2012
[7-12]

Call for submissions – Application A1065

Packaging Size for Phytosterol-enriched Milk

FSANZ has assessed an Application made by Lion Dairy and Drinks (formerly National Foods) to remove the current restriction on package size for milk enriched with phytosterols, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist its consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

Under the Information Publication Scheme all submissions on applications and proposals, will be published on our website. We will not publish any material provided in-confidence. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 7 May 2012

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

Table of Contents

Supporting documents

The following document which informed the assessment of this Application is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm

SD1 Risk Assessment Report

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Lion Dairy and Drinks (formerly National Foods) on 28 July 2011. The Applicant requested a variation to Standard 2.5.1 – Milk, in the *Australia New Zealand Food Standards Code* (the Code), to remove the 1 litre volume restriction on milk enriched with phytosterols. No other changes to the Code, including labelling requirements or compositional change, are requested in this application.

FSANZ has reviewed the rationale for the volume restriction, current scientific evidence on the safety of phytosterols, consumer behaviour information, as well as approaches to regulating phytosterol-enriched foods in the United States of America (USA) and the European Union (EU).

Based on data provided in the Application, and other available information, there are not believed to be any public health or safety concerns relating to removing the volume restriction.

Removing the volume restriction aims to allow additional package size options, potentially leading to more convenient and cost effective delivery of phytosterol enriched milk to consumers.

Based on the outcome of the risk assessment and the expected benefits to consumers regarding supply, FSANZ has prepared a draft variation to the Code to remove the volume restriction clause for phytosterol enriched milk from Standard 2.5.1.

This Application is being assessed under the General Procedure.

2. Introduction

2.1 The Applicant

Lion Dairy and Drinks (formerly National Foods) is a food and beverage provider in Australia and New Zealand.

2.2 The Application

Application A1065 – Packaging Size for Phytosterol Enriched Milk was submitted by National Foods (now Lion Dairy and Drinks) on 28 July 2011. It sought to remove the volume restriction from phytosterol-enriched milk, subclause 5(b) of Standard 2.5.1 – Milk, in the *Australia New Zealand Food Standards Code* (the Code).

Removal of the volume restriction aims to allow additional pack size options potentially leading to more convenient and cost effective delivery of phytosterol-enriched milk to consumers.

2.3 The current Standard

Standard 2.5.1 – Milk currently restricts the package size for phytosterol-enriched milk to 1 litre. A Code amendment is required before this restriction can be removed. Standard 1.2.3, clause 2 requires certain labelling statements to be used.

The volume restriction was one of the risk management measures included in the approval of adding phytosterols to milk arising from Application A434[1]. A volume restriction was included to discourage general household use because it was considered unlikely that everyone in a multiple person household would benefit from consumption of phytosterol-enriched milk. The volume restriction was recommended by FSANZ at the time of the Initial Assessment to help ameliorate concerns that arose because phytosterols were a relatively new addition to Australian and New Zealand diets.

The mandatory advisory label statements advise that the product should be consumed as part of a healthy diet, may not be suitable for children under the age of five years and pregnant or lactating women and that plant sterols do not provide additional benefit when consumed in excess of 3 g per day.

Before the then Australia and New Zealand Food Regulation Ministerial Council[2] approved the permission to allow the addition of phytosterols in milk there were had been two reviews. The proposed volume restriction was not a matter considered in the review requests.

2.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

---

1 http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfatmilkandlowfatyoghurt/

2 Now known as the COAG Legislative and Governance Forum on Food Regulation (the Forum)

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

The risk assessment relevant to this Application is provided in Supporting Document 1 and includes the following key elements:

- assessment of any new information about the safety of phytosterols which has become available since the last FSANZ review in 2010
- assessment of consumer behaviour data provided as part of the Application
- assessment of the effectiveness of the risk management measures in Australia and New Zealand, Europe and the USA regarding phytosterol-enriched foods.

There is no new toxicological, clinical or epidemiological evidence indicating the need to change the previous safety assessments. Therefore the conclusion of previous safety assessment stands, that is, the consumption of phytosterol enriched foods raises no safety concerns and a reference health standard is not warranted. This conclusion is supported by available information from Europe and the USA on the use of phytosterol-enriched foods.

The previous risk assessments were based on national nutrition survey data (consumption data), and there was an assumption that consumers replaced all non-enriched products with enriched products. The volume of the package was not used to determine the dietary intake of phytosterols. Therefore, removing the package size restriction has no impact on previous dietary intake assessments, including nutritional assessment.

It is expected that removing the volume restriction from phytosterol-enriched milk is likely to increase the consumption of such milk by target and possibly non-target populations (mainly children). However, based on current usage data, indicating most consumers fall within the target-population, any increased consumption in children is likely to be low and there is no evidence to suggest this will have an adverse health effect. Any increased consumption occurring in the target population is likely to be of additional benefit as there is evidence, that at least some of this population may not be receiving the minimum effective amount of phytosterols required due to the current volume restriction.

3.2 Risk management

The current volume restriction was one of several risk management measures aimed at encouraging appropriate use by target consumers and discouraging use by non-target consumers in the same household.

The risk assessment included consideration of the effectiveness of the current restriction on package size and what risk might arise to target and non-target consumers by removing it. As the volume restriction was part of a range of measures it is difficult to assess its contribution, if any, to risk mitigation.

Market research information provided in the Application indicates most consumers of phytosterol-enriched milk in Australia are in the target population and children are generally absent from target consumer households. Purchasers of phytosterol-enriched milk also purchase other milk types.

Europe and the USA have a wider variety and longer history of use of phytosterol-enriched foods than Australia or New Zealand. Therefore, to help address the question of the risk management value of the volume restriction in milk, FSANZ reviewed the risk management measures in these international areas as well as the history of reported adverse events from the consumption of phytosterol-enriched foods.

The information from Europe and the USA indicates that the absence of a volume restriction does not lead to adverse health effects from consumption of phytosterol-enriched foods (neither jurisdiction has a volume restriction on phytosterol-enriched foods).

Question for submitters:

Q1. Are you aware of any additional information on the safety of phytosterol-enriched foods?

Q2. Do you have any additional information on the consumption of phytosterol-enriched milk by target and non-target consumers?

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.

FSANZ considers it is appropriate to retain the other risk management measures of mandatory advisory statements as these assist in encouraging appropriate use.

3.3 Regulatory options and impacts

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure, developed or varied as a result of the application, outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- there are no other measures that would be more cost-effective than a variation to a Standard that could achieve the same end

- any relevant New Zealand standards

- any other relevant matters.

3.3.1 Cost/benefit analysis

Two regulatory options were considered:

(1) prepare a draft variation to Standard 2.5.1 to remove the volume restriction clause for milk.
(2) reject the Application

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 6 October 2011 (reference 13135), confirmed that a Regulation Impact Statement (RIS) was not required for this Application. The proposed variation to the Code is considered minor and machinery in nature. However FSANZ has performed an impact assessment, see below.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value.

Rather, the assessment seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

3.3.1.1 Option 1 – Prepare a draft variation to Standard 2.5.1

Consumers:

The proposed variation to the Code could advantage the target-consumer by:

- enabling a broader availability of phytosterol-enriched milk as many retailers give preference to larger size packages due to limitations on available shelf space (see below)

- potentially enabling phytosterol-enriched milk to be more affordable (bigger packs of the same product may provide lower unit cost to the purchaser)

- making access to phytosterol-enriched milk more convenient and affordable, thereby enabling consumers to meet the target consumption level for efficacy and potentially enabling more consumers to obtain the benefits

- enabling more efficient storage as it is often easier to store a few bulky items than several smaller ones.

The proposed variation to the Code could disadvantage the non-target-consumer from mixed consumer households by:

- increasing their consumption because more phytosterol-enriched milk is available in the household than previously

Such consumption by non-target consumers is not expected to have an adverse health effect.

Government:

Allowing the draft regulation is essentially de-regulation. This would potentially have a minor benefit for the Government as there would be no requirement for any compliance monitoring of package size.

Industry:

The proposed draft variation could advantage industry by:

- enabling phytosterol-enriched milk to be supplied to outlets where 1 litre containers are not currently sold
- allowing for increased production efficiency by supplying larger packs
- potential increase in market volumes, as indicated in the Application.

3.3.1.2 Option 2 – Reject the Application

Consumers:

There are no benefits to target-consumers from this Option.

Rejecting the Application has potential to reduce the availability of the product in retail outlets as it may lose out to more economically attractive chiller cabinet products.

Industry:

Rejecting the Application may have an adverse effect on the Applicant and other providers of phytosterol-enriched milk by limiting or reducing the market off take. The general preference of outlets for fresh white milk is to provide shelf-space for volumes greater than 1 litre (1 litre packs account for approximately 12% of fresh milk sales in Australia and 30% in New Zealand).

Government:

There are no benefits to governments in maintaining a restriction as there are no public health or safety issues; or perceived costs on jurisdictions that enforce the food regulations.

3.3.1.3 Comparison of Options

FSANZ anticipates that the removal of the volume restriction would provide increased product availability and convenience to consumers, and advantages to the industry (more cost effective packaging and greater market volume) with no expected impacts on government enforcement agencies. The removal of the restriction, however, will not prevent phytosterol-enriched milk from continuing to being sold in 1 litre packages if there is sufficient consumer pressure to do so.

Compared with the current situation, amending the Code does not provide any adverse effects on public health and safety; it may have some health benefit in target-consumers. It may also result in a better value for money product for the consumer.

In households which have a mix of target and non-target consumers, proceeding with an amendment has potential to result in greater consumption in non-target groups than currently occurs. However, FSANZ's risk assessment did not identify any potential health risks to non-target consumers and therefore the only potential adverse outcome of increased consumption by this subpopulation is an economic one.

An assessment of the costs and benefits of the two options indicated that there would be a net benefit in removing the package size restriction on phytosterol-enriched milk.

3.3.2 Other measures

There are no other measures which could achieve the same result other than an amendment to Standard 2.5.1.

3.3.3 Relevant New Zealand standards

Standard 2.5.1 applies to New Zealand. There are no New-Zealand-only standards.

3.3.4 Any other relevant matters

None were identified.

3.3.5 Addressing FSANZ's objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.3.5.1 Protection of public health and safety

The consumption of phytosterol-enriched milk raises no public health or safety concerns.

3.3.5.2 The provision of adequate information relating to food to enable consumers to make informed choices

Current mandatory advisory statements, which will remain, assist consumers in appropriate use of phytosterol-enriched milks.

3.3.5.3 The prevention of misleading or deceptive conduct

No issues were identified

3.3.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2) as addressed below:

- *the need for standards to be based on risk analysis using the best available scientific evidence*

FSANZ has previously assessed and characterised the risk from the consumption of foods containing added phytosterols, phytostanols and their fatty acid esters. Collectively, these risk assessments have considered all available information (national and international), including animal toxicity data and epidemiological data, relevant to the safety of phytosterols, phytostanols and their fatty acid esters.

FSANZ conducted a search of the scientific literature published since previous assessments and concluded that there were no new publications indicating a potential for safety concerns in any population group consuming foods enriched with phytosterols, phytostanols and their fatty acid esters.

- *the promotion of consistency between domestic and international food standards*

The requirements in the EU and USA for package size for phytosterol-enriched milk have been taken into consideration. Similar package size restrictions do not apply in the above mentioned countries/jurisdictions.

- *the desirability of an efficient and internationally competitive food industry*

There is no significant international trade in fresh liquid milks and the removal or retention of the current volume restriction is unlikely to have a significant impact on international trade.

- *the promotion of fair trading in food*

The Application questions the consistency, logic and fairness in the differences in volume restriction for the foods which are currently allowed to contain phytosterols. In particular they challenge the fairness between the absence of a volume restriction for "Edible Oil Spreads" enriched with phytosterols compared with milk. Both milk and edible spreads are often consumed throughout the day i.e. have similar patterns of use, however a typical size tub of spread (250g) can contain around 25 individual serves compared to a 1 litre package of milk which contains 4 serves. Removing the package size restriction eliminates this impediment.

- *any written Ministerial policy guidelines*

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.

Question for submitters:

Q3. Do you have any information of potential costs and benefits of the proposed change i.e. removal of the volume restriction?

3.4. Risk communication

FSANZ developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the *Food Standards News*.

Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

Documents relating to A1065 are available on the website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

The Applicant and individuals and organisations that make submissions on this Application, will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum. If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.4.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards, and amending the Code to remove the package size restriction for phytosterol-enriched milk is unlikely to have a significant effect on international trade as it would permit phytosterol-enriched milk in any size package to be imported into Australia and New Zealand and sold, whereas currently sale can only be in containers of 1 L or less. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement was not considered necessary.

4. Draft variation

The draft variation to Standard 2.5.1 is at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variation will take effect on gazettal.

5. References

Code of Federal Regulations - Title 21: Food and Drugs (2011). § 101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD). Available http://edocket.access.gpo.gov/cfr_2011/aprqtr/pdf/21cfr101.83.pdf. Accessed 17/02/2012.

EFSA (2008). Consumption of food and beverages with added plant sterols in the European Union. A report from the data collection and exposure unit in response to a request from the European Commission. *The EFSA Journal 133: 1-21.*

Food and Drug Administration, (2010). 21 CFR Part 101 – Food Labeling; Health Claim; Phytosterols and Risk of Coronary Heart Disease; Proposed Rule. *Federal Register*, Vol. 75, No. 235.

Attachments

A. Draft variation to the *Australia New Zealand Food Standards Code*
B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1065 – Packaging size for Phytosterol-enriched Milk) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated TO BE COMPLETED

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards* (*Application A1065 – Packaging size for Phytosterol-enriched Milk) Variation.*

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standard 2.5.1 in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on **the date of gazettal**.

SCHEDULE

[1] ***Standard 2.5.1*** *is varied by deleting* paragraph 5(b*)*.

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1065 which seeks to remove the current restriction on package size for milk enriched with phytosterols. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to Standard 2.5.1.

2. Purpose and operation

The Authority has prepared a draft variation of Standard 2.5.1 by deleting paragraph 5(b), which refers to the package size being restricted to 1 L.

The variation will remove the restriction on package size for phytosterol enriched milk so that phytosterol-enriched milk can be sold in any volume, consistent with other forms of liquid milk packaging.

Allowing phytosterol-enriched milk to be sold in larger containers is expected to be more attractive to retail outlets. This is then expected to lead to increased availability of the product.

The volume restriction was one of several risk management measures designed to encourage appropriate use and consumption of phytosterol enriched milk by target consumers and discourage use by non-target consumers. Other remaining risk management measures, including mandatory advisory label requirements, are considered by FSANZ to be sufficient for achieving those aims.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1065 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for Submissions (which includes the draft variation) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 2.5.1 is likely to have a minor impact on business and individuals and is deemed to be a de-regulation.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 97 of the FSANZ Act.

6. Variation

The variation removes the restriction on package size for phytosterol enriched milk, enabling phytosterol-enriched milk to be sold in any volume.