

### 7 September 2012 [20-12]

# **Call for submissions – Application A1070**

# Packaging Size for Phytosterol-enriched Lower Fat Cheese

FSANZ has assessed an Application made by Kraft Foods to remove the current restriction on portion weights of cheese and processed cheese 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 consideration of the draft food regulatory measure.

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

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. 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 <u>information for submitters</u>.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct 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 <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

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) 19 October 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 <u>standards.management@foodstandards.gov.au</u>.

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

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#### Supporting documents

The following documents, referred to in the report and used to assist the assessment of this Application, are available on the FSANZ website at <a href="http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm">http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm</a>

Application A1065 – Packaging Size for Phytosterol-enriched Milk (including the Call for Submissions, Supporting Document 1 and the Approval Report)

# 1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from Kraft Foods Australia on 19 March 2012. The Applicant seeks a variation to Standard 2.5.4 – Cheese in the *Australia New Zealand Food Standards Code* (the Code) to remove the current requirement that phytosterol-enriched cheese and processed cheese (containing no more than 12 g of fat per 100 g) be supplied in an individual portion, the weight of which is not greater than 50 g (the portion weight restriction).

The request to remove the portion weight restriction for phytosterol-enriched cheese and cheese products is comparable to Application A1065 (Packaging size for phytosterol-enriched milk), which sought to remove the package volume restriction for phytosterol-enriched milk. FSANZ has assessed A1065 and proposed removing the volume restriction. The Approval Report for A1065 was completed in July 2012.

The issues raised in this Application are very similar to those addressed during consideration of A1065. Therefore, FSANZ did not perform a new risk assessment for this Application but refers to the recently completed risk assessment for A1065.

FSANZ believes it is appropriate to remove the portion weight restriction for phytosterolenriched cheese and cheese products. This is based on the information provided in the Application, the current scientific evidence on the safety of phytosterols added to food, consumer purchasing and consuming behaviour and the international regulatory approaches to phytosterol-enriched cheese and cheese products.

Removing the portion weight restriction is likely to lead to the sale of additional larger portion weight options that could lead to greater availability of, and more convenient access to, phytosterol-enriched cheese and cheese products for consumers with additional cost savings and market benefits for industry.

# 2. Introduction

# 2.1 The Applicant

Kraft Foods Australia is a producer of processed food products including various cheese products produced in Australia and available in New Zealand.

# 2.2 The Application

The Application was received by FSANZ on 19 March 2012. The purpose of the Application is to remove the current portion weight restriction for cheese and processed cheese that can be enriched by the addition of tall oil phytosterol esters. Currently these cheese products need to be produced and sold in individual portions that are not greater than 50 g.

The Applicant claims the current portion weight restriction limits market access for consumers who wish to purchase such products. It further claims removal of the portion weight restriction will allow manufacturers to produce a more convenient, cost effective and environmentally responsible portion; and that this will provide consumer benefits in terms of better access and choice of products to obtain the health benefits of reduced cholesterol levels associated with consuming food products containing added phytosterols.

## 2.3 The current Standard

Paragraph 3(b) of Standard 2.5.4 – Cheese contains the portion weight restriction for cheese and processed cheese to which tall oil phytosterol esters may be added:

#### 3 Tall Oil Phytosterol Esters

Tall oil phytosterol esters may only be added to cheese and processed cheese -

- (a) that contains no more than 12 g total fat per 100 g; and
- (b) that is supplied in an individual portion, the weight of which is no more than 50 g; and
- (c) where the tall oil phytosterol ester is added at no less than 70 g / kg and no more than 90 g / kg.

The portion weight restriction was included as a risk management approach when the original permission to add tall oil phytosterol esters was first granted to lower fat cheese and processed cheese products as an outcome of Application A1019, from the same Applicant, in 2010.

Currently phytosterol-enriched processed cheese products (such as spreadable cheese) are sold as packs of  $4 \times 40$  g containers with the individual portion weight of the product being less than 50 g. The product can also be individually purchased as 40 g containers. Processed cheese slices are sold as packages of individually wrapped single slices of 20 g. Both types of products are compliant with paragraph 3(b).

The justification for the portion weight restriction was to ensure appropriate consumption of the phytosterol-enriched products. The risk management measure was to ensure a consistent approach to how phytosterol permissions were granted to low fat milk and yoghurts (FSANZ, 2006). It allowed consumers to easily determine their daily consumption (i.e. number of serves) of phytosterols. It was also to limit consumption by non-target consumers, especially in households that could contain both types of consumers.

While the current restriction to smaller portions of cheese and processed cheese may encourage consumers to limit their serving size of the product, there is no restriction on the number of sets of portions that can be purchased.

#### 2.3.1 Overseas situation

The Application notes that there are no portion weight restrictions for cheese products enriched with phytosterols in Europe and many other countries including the USA.

In Europe, the European Commission Decision 2004/333/EC permits the addition of various phytosterols to different food categories including cheese type products (EC, 2004). This EC Decision requires that products containing phytosterols must be presented in such a manner that they can be easily divided into portions (either one portion per day or three portions per day). The Applicant has provided information identifying twelve cheese products enriched with phytosterols available in Europe. All the spreadable cheese products are available in multi-serve containers.

In the USA, there are a range of phytosterol-enriched cheese products sold in 8 oz (227 g) blocks. Promotional material for these products states that two 1 oz (28 g) serves of cheese per day will meet the recommended amount necessary to achieve the beneficial cholesterol reduction (CFR, 2005).

# 2.4 Reasons for accepting Application

The Application was accepted for assessment because:

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

### 2.5 **Procedure for assessment**

The Application is being assessed under the General Procedure.

# 3. Summary of the assessment

## 3.1 Risk assessment

FSANZ recently completed an assessment of a comparable application that sought to remove the volume restriction for phytosterol-enriched milk (A1065) (FSANZ, 2012). A detailed risk assessment report (Supporting Document 1, SD1) was written for the assessment. The risk assessment questions, discussion and conclusions for that application apply to this current Application. A new risk assessment report for this Application was therefore deemed unnecessary. FSANZ referred to A1065 SD1 when it determined the risk assessment conclusions for this assessment.

The following risk assessment questions that were slightly amended from those used for A1065 were used to formulate the risk assessment conclusions.

- 1. (a) Who is the target population?
  - (b) Who are the non-target population groups?
- 2. (a) What were the assessed health risks from consumption of phytosterols for the target and non-target sub-populations?

- (b) What assumptions and uncertainties were associated with the risk assessment? Have these assumptions and uncertainties changed since approval of the application with the packaging restriction? If so how?
- 3. The 50 g portion weight restriction was aimed at encouraging individual use (i.e. target consumer) and discouraging use by non-target population, e.g. by those in the same household.
  - (a) What were the evidence/assumptions/uncertainties in relation to the risk of phytosterol-enriched cheese and cheese products when consumed by non-target consumers? Has this altered? If so how?
  - (b) What evidence/assumptions show that the portion weight restriction was successful in mitigating that risk? What are uncertainties around this?
- 4. (a) What are the consequences of the portion weight restriction for:
  - target consumers?
  - non-target consumers?
  - manufacturers?
  - (b) What were the evidence/assumptions/uncertainties in relation to these consequences for each identified group?
- 5. Based on the evidence, assumptions and uncertainties from question 4), what are the likely consequences of removing the portion weight restriction for:
  - target consumers?
  - non-target consumers?

#### 3.1.1 Safety assessment conclusions

There is no new toxicological, clinical or epidemiological evidence indicating the need for FSANZ to revise the previous safety assessments on phytosterol-enriched foods. Therefore, the conclusions of previous safety assessments remain valid, that is, the consumption of phytosterol-enriched foods raises no safety concerns and a health-based guidance value (i.e. acceptable daily intake, ADI) is not warranted. This conclusion is supported by available information from Europe and the USA on the use of phytosterol-enriched foods. There have been no new references related to the safety of phytosterol-enriched foods since FSANZ updated its assessment in July 2012 for A1065.

FSANZ also concluded in an earlier safety assessment that a reduction in the absorption of beta-carotene with consumption of phytosterols is expected, however this was considered to have no significant nutritional impact (FSANZ, 2010).

In general, pregnant and lactating women and children under 5 years of age do not need to lower their cholesterol levels and so derive no benefit from consuming phytosterol-enriched foods. Safety data for pregnant women, lactating women, and children under 5 years of age is relatively limited compared to the extensive data available for the target population. However, based on knowledge of the mechanisms of phytosterol action, the now extensive experience of use of phytosterol-enriched foods in the general population and the absence of effects in pregnant animals and their offspring, there is no basis for postulating a risk to these population subgroups.

#### 3.1.2 Dietary intake conclusions

The previous dietary intake assessments for phytosterols 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 portion weight of the product was not used to determine the dietary intake of phytosterols. Therefore, removing the portion weight restriction has no impact on previous dietary intake assessments, including nutritional assessments.

#### 3.1.3 Consumer purchasing and consumption behaviour

FSANZ did not perform a unique assessment of consumer purchasing behaviour for phytosterol-enriched cheese and processed cheese but has largely referred to the analysis performed for phytosterol-enriched milk as part of A1065. It is expected that removing the portion weight restriction from phytosterol-enriched cheese and processed cheese may increase consumption of such cheese products by target and possibly non-target populations (mainly children). Current use data supplied in the Application, suggests that 85% of phytosterol-enriched cheese purchasers fall within the target-population. The supplied data show that 53% of purchasers buy this product as their sole source of enriched phytosterol products, and another 32% purchase the cheese in combination with cholesterol-reducing spreads. Sales data indicate that senior couples and independent singles are the main life stage groups of purchasers, and the primary shopper tends to be aged 55+ years.

In younger households where a phytosterol-enriched cheese is bought, the non-enriched product is bought more frequently. This information suggests that the purchase of phytosterol-enriched cheese by younger households is for specific family members, and an alternative non-enriched cheese is purchased for non-target members of the household. Therefore 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 shown to have a positive effect on lowering cholesterol levels.

## 3.2 Risk management

The safety assessment concluded that removing the portion weight restriction would not have a significant effect on the consumption of phytosterol-enriched cheese and processed cheese products and therefore did not raise any safety concerns. Therefore the appropriate risk management approach is to remove the portion weight restriction in the absence of increased risk. The other current risk management measures were also considered as discussed below.

There are mandatory advisory statements that must be provided on the labels of phytosterolenriched foods as noted in the Table to clause 2 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations. These current risk management requirements will still apply for phytosterol-enriched cheese and cheese products. The statements are to the effect that:

- when consuming this product, it should be consumed as part of a healthy diet
- this product may not be suitable for children under the age of five years and pregnant and lactating women
- plant sterols do not provide additional benefits when consumed in excess of three grams per day.

These statements, combined with the higher relative price of the phytosterol-enriched cheese, will help limit the degree to which non-target consumer households purchase this type of cheese.

Another risk management approach that remains unchanged requires that tall oil phytosterol esters may only be added to cheese and processed cheese products that contain no more than 12 g of total fat per 100 g.

FSANZ communicated with the Applicant to determine what consumer education strategies it could undertake if the Application is successful. One specific issue is how to educate consumers to determine their daily consumption of phytosterols consumed from a spreadable cheese product taken from a large volume package, compared to the easier calculation when consumed from smaller portion controlled packages.

Kraft has committed to updating its consumer information and informing consumers of the appropriate amount of phytosterol-enriched spreadable cheese product to be eaten when using non-portion controlled packs. For example, Kraft will provide information on the larger pack size products indicating that 40 g (being two tablespoons) of the product is required to achieve the benefit. Kraft provides information for consumers about their phytosterol-enriched cheese products on its website <u>www.kraft.com.au/liveactive.aspx</u>.

### 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. These are discussed below.
- Whether other measures (whether available to FSANZ or not) would be more costeffective than a food regulatory measure developed or varied as a result of the Application. There are no other measures which could achieve the same result other than an amendment to Standard 2.5.4.
- Any relevant New Zealand standards. Standard 2.5.4 applies to New Zealand and there are no New Zealand only standards.
- Any other relevant matters. None were identified. Section 18 matters are considered below.

#### 3.3.1 Cost/benefit analysis

Two regulatory options were considered:

- (1) prepare a draft variation to Standard 2.5.4 to remove the portion weight restriction for cheese and cheese products enriched with tall oil phytosterol esters
- (2) reject the Application.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 2 April 2012 (reference 13700), 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 a summary 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 effects that are considered cannot be assigned a dollar value.

Rather, the assessment seeks to highlight the qualitative effects 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 2.5.4

#### Consumers:

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

- enabling a broader availability of phytosterol-enriched cheese and processed cheese products as many retailers give preference to larger weight packages due to limitations on available shelf space (see below)
- potentially enabling phytosterol-enriched cheese and processed cheese products to be more affordable (bigger packs of the same product may provide lower unit cost to the purchaser), noting they are more expensive than comparable non-phytosterol-enriched products
- potentially enabling more consumers to obtain the potential benefits due to the above two points
- enabling more efficient storage as it is often easier to store a few bulky items than several smaller ones.

Removing the restriction will permit phytosterol-enriched cheese and processed cheese products to continue to be sold in smaller 4 x 40 g containers while allowing for alternative portion weights to be produced.

Consumption by non-target consumers is not expected to have an adverse health effect (see the risk assessment conclusions in section 3.1.1 and A1065 SD1).

#### Government:

Allowing the draft variation is de-regulation. This would potentially have a minor benefit for governments as there would be no requirement for any compliance monitoring of portion weight.

#### Industry:

The proposed draft variation could advantage industry by:

- enabling phytosterol-enriched cheese and processed cheese products to have better market access and supermarket presence where the smaller containers are not currently sold
- allowing for increased production efficiency by supplying larger packs
- potentially increasing 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 the potential to reduce the availability of the products in retail outlets as they may lose out to more economically attractive products in larger package sizes in the highly competitive retail shelf space.

#### Industry:

Rejecting the Application may have an adverse effect on the Applicant and other providers of phytosterol-enriched cheese and processed cheese products by limiting or reducing the market of such products. This option reduces the growth potential for phytosterol-enriched cheese products due to their reduced availability on supermarket shelves and higher unit cost of production. The 4 x 40 g containers represent only a 7% market penetration for non-phytosterol-enriched cheese products compared to larger size packages, so are less popular with consumers.

#### 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 removing the portion weight 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 effects on government enforcement agencies.

Compared with the current situation, amending the Code does not create any adverse effects on public health and safety; it may have some potential health benefits for 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.

An assessment of the costs and benefits of the two options indicated that there would be a net benefit in removing the portion weight restriction on phytosterol-enriched cheese and processed cheese.

#### 3.3.2. 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.

#### 3.3.2.1 Protection of public health and safety

The consumption of phytosterol-enriched cheese and processed cheese raises no public health and safety concerns.

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

Current mandatory advisory statements, which will remain, help consumers make informed choices and promote appropriate use of phytosterol-enriched cheese and processed cheese products.

#### 3.3.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

#### 3.3.2.4 Subsection 18(2) considerations

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

• 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 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 found no new information indicating a need to revise previous conclusions that the consumption of tall oil phytosterol esters raises no safety concerns at the expected levels of consumption.

• the promotion of consistency between domestic and international food standards

There are no portion weight restrictions for similar products in other parts of the world, so removing the portion weight restriction means more consistency of the Australian and New Zealand standard with international food standards.

• the desirability of an efficient and internationally competitive food industry

Removing the portion weight restriction for Australian and New Zealand phytosterol-enriched cheese and processed cheese products may improve their possible international trade, though it is likely different countries will have different permissions for addition of phytosterols to cheese products.

• the promotion of fair trading in food

Removing the portion weight restriction for phytosterol-enriched cheese products enables these products to be traded in a similar way to other phytosterol-enriched food products that do not have any restriction on portion weight such as edible oil spreads or milk products (if proposed amendment is gazetted).

any written policy guidelines formulated by the Ministerial Council<sup>1</sup>

The Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals<sup>2</sup> is relevant in the consideration of permitting new novel food ingredients to food or extending the permission of novel foods. The current Application is not an extension of use of tall oil phytosterol esters in cheese and cheese products, but a removal of a portion weight restriction for such already permitted products. FSANZ's assessment of the earlier application (A1019) permitting the addition of tall oil phytosterols to cheese products considered and addressed the policy guidelines, including the safety and cumulative consumption of phytosterols from different food categories. The dietary exposure assessment performed for A1019 used conservative assumptions that are not dependent on the portion weight of the product.

<sup>&</sup>lt;sup>1</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

http://www.foodstandards.gov.au/\_srcfiles/Addition%20to%20Food%20of%20Substances%20other%2 Othan%20Vitamins%20and%20Minerals%20May%202008.pdf

Therefore, the assessment of the cumulative consumption of phytosterols is not changed due to this Application.

### 3.4. Risk communication

FSANZ developed and is applying 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 A1070 are available on the website at <a href="http://www.foodstandards.gov.au/foodstandards/applications/applicationa1070pack5512.cfm">http://www.foodstandards.gov.au/foodstandards/applications/applicationa1070pack5512.cfm</a>

The draft variation will be considered for approval by the FSANZ Board, taking into account any public comments received.

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 no relevant international standards and amending the Code to remove the portion weight restriction for phytosterol-enriched cheese or processed cheese is unlikely to have a significant effect on international trade. Approving the Application will potentially open up trade of phytosterol-enriched cheese products into Australia and New Zealand by removing one current restriction. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

# 4. Draft variation

The conclusion of the assessment is that the portion weight restriction for phytosterolenriched cheese and processed cheese is not a necessary risk management measure. Therefore, it is appropriate to remove paragraph 3(b) from Standard 2.5.4, as requested by the Application.

The draft variation to Standard 2.5.4 is at Attachment A.

A draft Explanatory Statement is at Attachment B.

# 4.1 Implementation

The variation will take effect on gazettal.

# 5. References

CFR (2005) US FDA Code of Federal Regulations Title 21 Ch. I § 101.83 Health Claims: plant sterol/stanol esters and risk of coronary heart disease (CHD). http://edocket.access.gpo.gov/cfr\_2011/aprqtr/pdf/21cfr101.83.pdf

EC (2004) European Commission Decision 2004/333/EC of 31 March 2004 authorising the placing on the market of yellow fat spreads, salad dressings, milk type products, fermented milk type products, soya drinks and cheese type products with added phytosterols/phytostanols as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and the Council. http://eur-

lex.europa.eu/smartapi/cgi/sga\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004D 0333&model=guichett

FSANZ (2006) Reports for Application A434 – Phytosterol esters in low fat milk and low fat yoghurt <u>http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfat</u> <u>milkandlowfatyoghurt/index.cfm</u>

FSANZ (2010) Reports for Application A1019 – Exclusive use of phytosterol esters in low-fat cheese including Approval Report available at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1019phyt4161.cfm

FSANZ (2012) Reports for Application A1065 – Packaging size for phytosterol-enriched milk Supporting Document 1 – Risk Assessment Report, available at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm

### Attachments

- A. Draft variations 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 A1070 – Packaging Size for Phytosterol-enriched Lower Fat Cheese) 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 A1070 – Packaging Size for Phytosterol-enriched Lower Fat Cheese) Variation.

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

The Schedule varies Standard 2.5.4 in the Australia New Zealand Food Standards Code.

#### 3 Commencement

This variation commences on gazettal.

#### SCHEDULE

[1] **Standard 2.5.4** is varied by omitting paragraph 3(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 A1070 which seeks to remove the current restrictions on portion weights for cheese and processed cheese enriched with tall oil phytosterol esters. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to Standard 2.5.4.

#### 2. Purpose and operation

The Authority has prepared a draft variation to Standard 2.5.4 by deleting paragraph 3(b) which requires the phytosterol-enriched cheese and processed cheese to be supplied in an individual portion, the weight of which is not greater than 50 g.

The variation removing the individual portion and maximum weight requirement will enable phytosterol-enriched cheese and processed cheese products to be sold in comparable portion weights to non phytosterol-enriched products.

Removing the portion and maximum weight requirement for phytosterol-enriched cheese products is expected to allow manufacturers to produce portion weights that are more attractive to retailers, and hence an increased availability and visibility of product for consumers.

The portion and maximum weight requirement was originally proposed as one of the risk management options to limit the consumption of phytosterol-enriched cheese and cheese products by non-target consumers, comparable to the earlier restrictions applied to milk and yoghurt. The other risk management measures, including the mandatory advisory label requirements, are considered by FSANZ to be sufficient for this purpose. Recently FSANZ supported the removal of the package volume restriction for phytosterol-enriched milk.

#### 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 A1070 will include one round of public consultation following an assessment and the preparation of a draft variation. A call for submissions (including the draft variation) will occur for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 2.5.4 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 94 of the FSANZ Act.

#### 6. Variation

The variation deletes paragraph 3(b) of Standard 2.5.4. In doing so, the variation removes the individual portion and maximum weight requirement for phytosterol-enriched cheese and processed cheese so they can be sold in any appropriate portion weight, determined by commercial considerations.