

**17 December 2012**  
**[29-12]**

Approval Report – Application A1070

## Packaging Size for Phytosterol-enriched Lower Fat Cheese

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Kraft Foods Australia to remove the current restriction on portion weights of cheese and processed cheese enriched with phytosterols and has prepared a draft food regulatory measure.

On 7 September 2012, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation to the Standard on 6 December 2012. The COAG Legislative and Governance Forum on Food Regulation<sup>1</sup> (the Forum) was notified of FSANZ's decision on 13 December 2012. The Forum has 60 days to request FSANZ to review the draft variations or to inform FSANZ that they do not intend to request a review.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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<sup>1</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

# Table of Contents

<b>1. EXECUTIVE SUMMARY .....</b>	<b>2</b>
<b>2. INTRODUCTION .....</b>	<b>3</b>
2.1 THE APPLICANT .....	3
2.2 THE APPLICATION .....	3
2.3 THE CURRENT STANDARD AND MARKET SITUATION .....	3
2.4 REASONS FOR ACCEPTING THE APPLICATION.....	4
2.5 PROCEDURE FOR ASSESSMENT .....	4
2.6 DECISION .....	4
<b>3. SUMMARY OF THE FINDINGS .....</b>	<b>5</b>
3.1 RISK ASSESSMENT .....	5
3.2 RISK MANAGEMENT.....	6
3.3 SUMMARY OF SUBMISSIONS .....	7
3.4 RISK COMMUNICATION .....	9
<b>4. REASONS FOR DECISION .....</b>	<b>9</b>
4.1 SECTION 29 OF THE FSANZ ACT MATTERS .....	10
4.1.1 <i>Cost Benefit Analysis</i> .....	10
4.2 ADDRESSING FSANZ'S OBJECTIVES FOR STANDARDS-SETTING .....	12
4.2.1 <i>Protection of public health and safety</i> .....	12
4.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i> .....	12
4.2.3 <i>The prevention of misleading or deceptive conduct</i> .....	12
4.2.4 <i>Subsection 18(2) considerations</i> .....	12
4.3 IMPLEMENTATION.....	13
<b>5. REFERENCES .....</b>	<b>13</b>
ATTACHMENT A – APPROVED VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE .....	16
ATTACHMENT B – EXPLANATORY STATEMENT.....	18

## 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 <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1065pack5285.cfm>

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 sought 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 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 was comparable to Application A1065 (Packaging size for phytosterol-enriched milk), which sought to remove the package volume restriction for phytosterol-enriched milk. FSANZ completed the assessment of A1065 in July 2012 with the volume restriction removed from the Code in October 2012.

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

FSANZ considered it appropriate to remove the portion weight restriction for phytosterol-enriched cheese and cheese products. This was 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 cost savings and market benefits for industry.

Six submissions were received following the call for submissions. Five submissions supported FSANZ's recommendation to remove the portion weight restriction, while one submission did not and asked that a number of issues be addressed. These have been addressed in the approval report. FSANZ did not change its conclusions or the draft variation due to issues raised in the submission.

## **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 was 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 claimed the current portion weight restriction limited market access for consumers who wish to purchase such products and that removing the restriction would allow manufacturers to produce a more convenient, cost effective and environmentally responsible portion. The Application stated that removing the portion weight restriction would provide consumers with better access and choice of products and help them obtain the health benefits of reduced cholesterol levels associated with consuming food products containing added phytosterols.

### **2.3 The current Standard and market situation**

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 to lower fat cheese and processed cheese products was first granted 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 4x40 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 implemented to ensure a consistent approach to other permissions for phytosterols in 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 include both target and non-target 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 United States of America (USA).

In Europe, the European Commission (EC) 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 the 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 was assessed under the General Procedure.

## **2.6 Decision**

The approved variation is the same as the draft variation on which submissions were sought (Attachment A). This removes the portion weight restriction for phytosterol-enriched lower fat cheese and processed cheese products.

## **3. Summary of the findings**

### **3.1 Risk assessment**

#### **3.1.1 Safety assessment conclusions**

There have been no new references related to the safety of phytosterol-enriched foods since FSANZ updated its assessment in July 2012 for A1065<sup>2</sup>. There was 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) was not warranted. This conclusion was supported by available information from Europe and the USA on the use of phytosterol-enriched foods.

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 was 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 had 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 largely referred to the analysis performed for phytosterol-enriched milk as part of A1065. It was 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, suggested 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.

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<sup>2</sup> Risk Assessment Report (SD1) for A1065  
[http://www.foodstandards.gov.au/\\_srcfiles/A1065\\_SD1.pdf](http://www.foodstandards.gov.au/_srcfiles/A1065_SD1.pdf)

In younger households, where a phytosterol-enriched cheese is bought, the non-enriched product is bought more frequently. This information suggested 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 was no evidence to suggest this will have an adverse health effect. Any increased consumption occurring in the target population was 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 was to remove the portion weight restriction since there is no change in the risk profile. 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 phytosterol-enriched 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 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 or 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, 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 was 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 also provides information for consumers about their phytosterol-enriched cheese products on its website [www.kraft.com.au/liveactive.aspx](http://www.kraft.com.au/liveactive.aspx).

### 3.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments can be directly addressed during the process, they are valued and all contribute to the rigour of our assessment.

FSANZ called for public comment between 7 September and 19 October 2012 following assessment of the Application.

Six submissions were received, four from the food industry or industry associations and two from enforcement jurisdictions. Five submissions supported FSANZ's recommendation to remove the portion weight restriction for phytosterol-enriched cheese and cheese products and raised no issues. The submission from the Victorian Department of Health did not support FSANZ's draft variation and raised a number of issues it claims were not appropriately addressed in the Approval Report for A1065, or in the Call for Submissions document for this Application. The issues raised and how FSANZ addressed the issues are summarised in Table 1.

**Table 1: Summary of issues raised in the Victorian Department of Health submission**

Issue	FSANZ Response
<p><b>In accordance with the relevant Ministerial policy guideline, FSANZ should adopt a cautious approach regarding the potential for cumulative effects from increased consumption of phytosterol-enriched foods and possible daily exposures.</b></p>	<p>The available evidence indicates there are no cumulative effects from consuming phytosterol-enriched foods. There is an optimum cholesterol lowering effect between 2-3 grams per day; however there is no increased cholesterol-lowering effect with consumption above 3 grams per day. This is the reason for the mandatory advisory statement to this effect, to ensure that consumers do not assume that increased consumption will lead to an increased effect.</p> <p>Concerning the possible safety impact of increased consumption of phytosterol containing foods, there is no health-based guidance value for phytosterols. Consumption of phytosterol-enriched foods is not associated with any adverse effects, and these have been in the food supply now for more than 10 years.</p> <p>FSANZ has always adopted a cautious approach to the assessment of phytosterols. Permissions have been broadened incrementally over a period of more than 10 years, and only after comprehensive reviews of the literature and consideration of consumer behaviour. This gradual process has helped consumers to become more familiar with the appropriate use of phytosterol-enriched foods. Dietary information on phytosterols is now accessible through health professionals, various non-government organisations, media and advertising of products, and from experience using products already on the market.</p>
<p><b>Why is it necessary for an advisory statement to the effect that consumption of phytosterols may not be suitable for children under 5 years and pregnant and lactating women? If deemed necessary, FSANZ should provide further information for consumers on why these</b></p>	<p>This point refers to one of the three mandatory advisory statements for labelling of phytosterol-enriched foods:</p> <ul style="list-style-type: none"> <li>• <i>This product may not be suitable for children under the age of five years and pregnant or lactating women.</i></li> </ul> <p>Children under five years of age and pregnant or lactating women do not need to consume foods with the explicit purpose of lowering their cholesterol level. However, based on knowledge of the mechanisms of action, the extensive experience in the general population and absence of effects in pregnant animals and their offspring there is no basis for</p>



Issue	FSANZ Response
<p><b>products are not suitable for those population groups.</b></p>	<p>postulating a risk to these population subgroups. As stated in previous assessment reports (e.g. the Second Review Report for A433, A434 and A508 at <a href="http://www.foodstandards.gov.au/srcfiles/A508%20TOPs%20SRR%20FINAL.pdf">http://www.foodstandards.gov.au/srcfiles/A508%20TOPs%20SRR%20FINAL.pdf</a>), the purpose of this statement is largely educational, to assist consumers to use the products appropriately and cost effectively. The statement is therefore intended to reduce the possibility of use by consumers who would gain no benefit from the foods. In this context, FSANZ does not consider that further explanation relevant to these population groups on food labels is warranted. FSANZ's Fact Sheet on phytosterols does contain a summary of our response to this issue for interested consumers and stakeholders at <a href="http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/plantsterols2011.cfm">http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets/plantsterols2011.cfm</a>.</p>
<p><b>Limited long term studies available. Specifically concerned about consumption of products by teenagers and young adults over extended time.</b></p>	<p>FSANZ has addressed the safety of phytosterols in both short and long term studies in a series of risk assessments conducted over recent years. In addition, phytosterol-enriched foods have now been in the food supply for over 10 years. There is an abundance of published research articles on the safety of phytosterols and post market monitoring in Europe has not identified any safety concerns for the general population. FSANZ notes that the target population group is adults wanting to lower cholesterol levels through their diet. The available evidence indicates no safety concerns regardless of age, except in rare circumstances where an individual has the medical condition known as phytosterolaemia. These special cases have already been discussed in detail in the assessment of Application A1019. On balance, FSANZ considers that removing package size restrictions on a narrow product range is likely to have only a modest impact on the pattern of consumption of these foods. Detailed safety assessments on phytosterols added to food is contained in section 5 of the Risk Assessment Reports for A1019<sup>3</sup> and A1024<sup>4</sup>.</p>
<p><b>Concern that consumption of phytosterol-enriched foods reduces the levels of beta-carotene, since many consumers already fail to meet the recommended serves of fruit and vegetables (dietary source of beta-carotene).</b></p>	<p>FSANZ has addressed this issue in other assessments of phytosterol-enriched foods. The evidence consistently shows that the reduction in serum beta-carotene is not indicative of any nutritional deficiency and is within natural variation (see section 5.4 of Risk Assessment Report for A1019)<sup>3</sup>. The mandatory advisory statement to the effect that the product should be consumed as part of a <i>healthy diet</i> also reinforces other public health messages in relation to food choices and diet, and recommendations to consume more fruits and vegetables.</p>
<p><b>It is a concern that FSANZ continues to rely on dated 1995 consumption data to perform the dietary intake analysis.</b></p> <p><b>It is reasonable to expect the Applicant or FSANZ to provide updated intake data to reflect current consumption.</b></p>	<p>FSANZ acknowledges the age of the consumption data in the National Nutrition Surveys. The 1995 and 2007 (children) Australian NNSs, and the 1997 and 2002 (children) New Zealand NNSs, are the most recent comprehensive sets of quantitative data on food consumption patterns currently available to FSANZ until the 2011-13 Australian Health Survey data becomes available in late 2013. Conducting dietary modelling using the available food consumption data provides the best estimate available of dietary exposure across our populations because they are national studies, across wide age ranges, of all foods and beverages consumed.</p> <p>Use of this data does not invalidate the conclusions of risk assessments which are based on information for staple food items such as milk,</p>

<sup>3</sup> Risk Assessment Report (SD1) for Application A1019 – Exclusive use of phytosterol esters in lower-fat cheese products

<http://www.foodstandards.gov.au/srcfiles/A1019%20AppR%20SD1%20Risk%20Assess.pdf>

<sup>4</sup> Risk Assessment Report (SD1) for Application A1024 – Equivalence of plant stanols, sterols & their fatty acid esters

<http://www.foodstandards.gov.au/srcfiles/A1024%20Plant%20Stanols%20AppR%20SD1%20Risk%20Assess.pdf>

Issue	FSANZ Response
	<p>breakfast cereal and cheese which are not likely to have changed significantly. While the older NNSs may not include information regarding food products that are available in the market right now, for staple foods such as breads, cereals and milk, the data derived from the full 1995 and 1997 NNSs are likely to be still representative today.</p> <p>For more details please refer to the <a href="#">Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes</a> and the <a href="#">International Peer Review of FSANZ Dietary Modelling Team Practices and Procedures</a>.</p>

### 3.4 Risk communication

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

Subscribers and interested parties were 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. The issues raised in the public submissions were evaluated and addressed in this Report.

Documents relating to A1070 are available on the website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1070pack5512.cfm>

The variation was approved by the FSANZ Board taking into account public comments received from the call for submissions.

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

The FSANZ Board decision has been 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.

## 4. Reasons for decision

The draft variation to Standard 2.5.4, as proposed following assessment, was approved without change on the basis of the available evidence and for the following reasons:

- no public health or safety issues have been identified arising from consumption of phytosterols
- the market research information provided in the Application indicates 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 and compositional limits for products permitted to have tall oil phytosterol esters added to them as these assist in encouraging appropriate use of the products by consumers and manufacturers.

## **4.1 Section 29 of the FSANZ Act matters**

FSANZ had regard to the following matters under 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
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards
- any other relevant matters.

FSANZ concluded that:

- The cost benefit analysis provided below indicated there would not be any significant costs imposed on government agencies, consumers or manufacturers by removing the portion weight restriction for cheese and cheese products enriched with tall oil phytosterol esters.
- There are no measures other than a variation to Standard 2.5.4 that would achieve the same end.
- Standard 2.5.4 applies to New Zealand and there are no New Zealand only standards that would impact on the decision to amend the Code.
- There are no other relevant matters other than those considered at section 4.2.

### **4.1.1 Cost Benefit Analysis**

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 2 April 2012 (reference 13700), confirmed that a Regulation Impact Statement was not required for this Application. The proposed variation to the Code is considered minor and machinery in nature. However, FSANZ performed a qualitative assessment of the costs and benefits for the two regulatory options.

#### **4.1.1.1 Option 1 – Prepare a draft variation to Standard 2.5.4**

*Consumers:*

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

- enabling a broader availability of phytosterol-enriched cheese and processed cheese products in a market preferred package as many retailers give preference to larger weight packages due to limitations on available shelf space
- 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.

Removing the portion weight restriction will permit phytosterol-enriched cheese and processed cheese products to continue to be sold in smaller 4x40 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.

**4.1.1.2 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 continue to 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 4x40 g containers represent only a 7% market penetration for non-phytosterol-enriched cheese products compared to larger size packages, indicating they are less popular with consumers.

*Government:*

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

## **4.2 Addressing FSANZ's objectives for standards-setting**

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

### **4.2.1 Protection of public health and safety**

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

### **4.2.2 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.

### **4.2.3 The prevention of misleading or deceptive conduct**

No issues were identified.

### **4.2.4 Subsection 18(2) considerations**

FSANZ has also had regard to the objectives set out 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 consuming foods containing added phytosterols, phytosterols 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, phytosterols 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.

- any written policy guidelines formulated by the Ministerial Council<sup>5</sup>.

The Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*<sup>6</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 the 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.

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

### 4.3 Implementation

The variation will come into 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/aprqrtr/pdf/21cfr101.83.pdf](http://edocket.access.gpo.gov/cfr_2011/aprqrtr/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/phytosterols 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=32004D0333&model=guichett](http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32004D0333&model=guichett)

FSANZ (2006) Reports for Application A434 – Phytosterol esters in low fat milk and low fat yoghurt

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa434phytosterolestersinlowfatmilkandlowfatyoghurt/index.cfm>

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>

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<sup>5</sup> Now known as the COAG Legislative and Governance Forum on Food Regulation

<sup>6</sup> [http://www.foodstandards.gov.au/\\_srcfiles/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf](http://www.foodstandards.gov.au/_srcfiles/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf)

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. Approved variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement



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



### **Food Standards (Application A1070 – Packaging Size for Phytosterol-enriched Lower Fat Cheese) Variation**

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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 – 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 approved a draft variation to Standard 2.5.4.

Following consideration by COAG Legislative and Governance Forum on Food Regulation<sup>7</sup>, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

### **2. Purpose and operation**

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

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

Removing the portion weight restriction 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 weight restriction 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 approved the removal of the package volume restriction for phytosterol-enriched milk which was gazetted in October 2012.

### **3. Documents incorporated by reference**

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<sup>7</sup> Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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 has included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 5 September 2012 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 2.5.4 was likely to have a minor impact on business and individuals and was 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 weight restriction for phytosterol-enriched cheese and processed cheese so they can be sold in any appropriate portion weight, determined by commercial considerations.