



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

1-07

21 March 2007

INITIAL ASSESSMENT REPORT

APPLICATION A596

VEGETABLE OIL PHYTOSTEROL ESTERS IN LOW-FAT YOGHURT MINI-DRINKS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 2 May 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

FSANZ received an Application from Unilever Australasia on 22 December 2006 to amend the *Australia New Zealand Food Standards Code* (the Code) to approve the use of phytosterol esters derived from vegetable oils in low-fat yoghurt mini-drinks at a level of 3.35 g (equivalent to 2 g of free phytosterols) in a single serve product to be consumed once a day. The Applicant indicates that low-fat yoghurt mini-drinks will be sold in bottles with a capacity of between 80 and 150 mL.

Phytosterol esters are considered to be a novel food according to the definitions in Standard 1.5.1 – Novel Foods. Standard 1.5.1 requires that novel foods undergo a safety assessment before being permitted in the food supply and prohibits the sale of novel foods or novel food ingredients unless they are listed in the Table to clause 2. Phytosterol esters are included in the Table to clause 2 and may be added to yoghurt only if in accordance with Standard 2.5.3 – Fermented Milk Products.

Standard 2.5.3 permits the addition of phytosterol esters to low-fat yoghurt at levels between 1.3 and 1.6 g per serve. Low-fat yoghurt mini-drinks meet the definition of yoghurt in Standard 2.5.3 and are therefore permitted to contain added phytosterol esters at the levels approved for yoghurt. This Application is requesting the approval of a higher level of addition of phytosterol esters, specifically for low-fat yoghurt mini-drinks. If approved, Standard 2.5.3 would be amended to include specific conditions for the addition of phytosterol esters to low-fat yoghurt mini-drinks.

Phytosterol esters and tall oil phytosterols have been approved for use in edible oil spreads in Australia and New Zealand since 2001. Phytosterol esters have recently been approved for use in high-fibre breakfast cereals, low-fat milk and low-fat yoghurt. Tall oil phytosterols have also recently been approved for use in low-fat milk. The Applications (A433, A434 and A508) for the recent approvals for use of phytosterols were the subject of First and Second Reviews requested by the Ministerial Council. FSANZ addressed the issues raised in these Reviews and Standard 1.5.1 was subsequently amended (9 November 2006) to include the additional permissions for the addition of phytosterols to high-fibre breakfast cereals, low-fat milk and low-fat yoghurt.

In order to assess the merits of this Application, data on the efficacy and nutritional effects of phytosterols when added to low-fat yoghurt mini-drinks at 3.35 g per serve is required. The Applicant has supplied details of a clinical study and additional scientific information relevant to a safety assessment supporting the extended use of phytosterols in low-fat yoghurt mini-drinks. The assessment will consider the potential dietary impact of a more concentrated source of phytosterols on target and non-target consumers.

This Application also requests permission to use the food additive tocopherol as an antioxidant in a fermented milk product containing added phytosterol esters. If approved, a variation to Standard 1.3.1 – Food Additives, would be warranted.

This Initial Assessment report is not an assessment of the merits of this Application, but rather is an appraisal of whether the Application warrants further consideration according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). It is the conclusion of this assessment that, having regard to the requirements of section 13 of the FSANZ Act, this Application should be accepted.

This Report outlines the relevant issues necessary to proceed with assessment of the Application and also provides the general community with relevant information supplied by the Applicant to assist in identifying the issues and parties that may be affected by a decision.

Public submissions are invited on this Initial Assessment report. Comments are specifically sought on the public health and safety aspects of this application, and the costs and benefits to the food industry in general. Should any submissions be received, those will be considered as part of the assessment process.

Purpose

The purpose of the Application is to assess whether it is appropriate to approve the use of a higher level of phytosterol esters per serve of low-fat yoghurt mini-drinks than currently permitted in the Code.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the use of phytosterol esters derived from vegetable oil in low-fat yoghurt mini-drinks at a level of 3.35 g per serve. Such an approval, if accepted, would warrant a variation to Standard 2.5.3 – Fermented Milk Products.
- The current permission for the addition of phytosterol esters to low-fat yoghurt permits a level of 1.3 to 1.6 g per serve.
- The Application also seeks approval for the use of the food additive tocopherols as an antioxidant in a fermented milk product containing added phytosterol esters. If approved, a variation to Standard 1.3.1 – Food Additives, would be warranted.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to the Code that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments are requested on any aspect of this Application, and in particular, information relevant to the potential costs and benefits of the proposed regulatory options.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 2 May 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

FSANZ received an Application from Unilever Australasia on 22 December 2006 to amend the Code to approve the use of phytosterol esters derived from vegetable oils in low-fat yoghurt mini-drinks at a level of 3.35 g (equivalent to 2 g of free phytosterols) in a single serve product to be consumed once a day. The Applicant indicates that low-fat yoghurt mini-drinks will be sold in bottles with a capacity of between 80 and 150 mL.

This Application also requests permission to use the food additive tocopherol as an antioxidant in a fermented milk product.

1. Background

It is now well established that consumption of plant sterols from either a vegetable oil or tall oil source, in amounts between 1-3 g per day can lead to reduced total and low-density lipoprotein (LDL) cholesterol levels in consumers. Phytosterols compete with cholesterol for uptake into the bloodstream leading to less absorption of dietary cholesterol from the intestine.

Phytosterols (plant sterols) are naturally present in many varieties of fruits, vegetables, nuts and cereals. The most common and major sterols in vegetable oils are sitosterol, campesterol and stigmasterol. Free phytosterols are structurally related to cholesterol (found only in animals) and occur naturally at low levels (up to 0.9%) in common edible vegetable oils. Phytosterols can be esterified by reaction with fatty acid methyl esters or free fatty acids to produce phytosterol esters.

1.1 Current Standards

Under Standard 1.5.1, novel foods are required to undergo a pre-market safety assessment. The purpose of this Standard is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia and New Zealand.

Novel Food is defined in clause 1 of Standard 1.5.1, as:

***novel food** means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account –*

- (a) the composition or structure of the product; or*
- (b) levels of undesirable substances in the product; or*
- (c) known potential for adverse effects in humans; or*
- (d) traditional preparation and cooking methods; or*
- (e) patterns and levels of consumption of the product.*

***non-traditional food** means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.*

Standard 1.5.1 prohibits the sale of novel foods or novel food ingredients unless they are listed in the Table to clause 2.

Phytosterol esters are included in the Table to clause 2 and may be added to yoghurt only if in accordance with Standard 2.5.3 – Fermented Milk Products.

Standard 2.5.3 defines and sets compositional requirements for fermented milk, including yoghurt. Clause 4 of Standard 2.5.3 states:

Phytosterol esters may only be added to yoghurt –

- (a) *such that the yoghurt contains no more than 1.5 g total fat per 100 g; and*
- (b) *that is supplied in a package, the capacity of which is no more than 200 g; and*
- (c) *where the total phytosterol ester added is no less than 1.3 g and no more than 1.6 g.*

Standard 1.3.1 regulates the use of food additives in the production and processing of foods. A food additive may only be added to food where expressly permitted in Standard 1.3.1.

1.2 Historical Background

Phytosterol esters and tall oil phytosterols have been approved for use in edible oil spreads in Australia and New Zealand since 2001. Phytosterol esters have recently been approved for use in high-fibre breakfast cereals, low-fat milk and low-fat yoghurt. Tall oil phytosterols have also recently been approved for use in low-fat milk. The Applications (A433, A434 and A508) for the recent approvals for use of phytosterols were the subject of First and Second Reviews requested by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). FSANZ addressed the issues raised in these Reviews and Standard 1.5.1 was subsequently amended (9 November 2006) to include the additional permissions for the addition of phytosterols to high-fibre breakfast cereals, low-fat milk and low-fat yoghurt.

FSANZ is currently assessing an Application (A560) for the use of phytosterols in fruit juice and fruit juice drinks.

2. The Issue / Problem

Novel foods are required to undergo a pre-market safety assessment under Standard 1.5.1 - Novel Foods, to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk based safety assessment before they are offered for retail sale in Australia or New Zealand.

This Application seeks permission to extend the use of phytosterol esters in low-fat yoghurt to a level of 3.35 g per serve, specifically for low-fat yoghurt mini-drinks, which would be marketed as a single serve food product to be consumed once per day.

Currently, phytosterol esters are permitted to be used in edible oil spreads, high-fibre breakfast cereal, low-fat milk and low-fat yoghurt. Standard 1.5.1 permits phytosterol esters to be added to yoghurt in accordance with Standard 2.5.3 – Fermented Milk Products. Clause 4 of Standard 2.5.3 limits the quantity of phytosterol esters that may be added to yoghurt to between 1.3 g and 1.6 g per package (with a capacity of no more than 200 g).

The addition of phytosterol esters to low-fat yoghurt mini-drinks at 3.35 g per serve must therefore be assessed. If approved, Standard 2.5.3 would be amended to include specific conditions for the addition of phytosterol esters to low-fat yoghurt mini-drinks.

Standard 1.3.1 currently does not permit the addition of tocopherols to renneted milk products; therefore the addition of tocopherols to low-fat yoghurt mini-drinks must also be assessed.

3. Objectives

The objective of this assessment is to determine whether or not it is appropriate to amend the Code to extend the use of phytosterol esters in low-fat yoghurt mini-drinks to a level of 3.35 g per serve. In addition, this assessment will also determine whether or not it is appropriate to approve the use of tocopherols as a food additive in low-fat yoghurt mini-drinks containing added phytosterols. Such amendments would need to be consistent with section 10 objectives of the FSANZ Act.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Questions

These are the key questions FSANZ will consider at Draft Assessment:

What would be the potential dietary intake of phytosterol esters for mean and high consumers if they were approved for use at a level of 3.35 g per serve in low-fat yoghurt mini-drinks?

Considering the information provided by the Applicant, other available information (including from previous assessments of phytosterol esters by FSANZ), and FSANZ's dietary exposure assessment, would the approval of phytosterol esters at a level of 3.35 g per serve in low-fat yoghurt mini-drinks pose any risk to public health and safety?

What are the food technology implications of this Application with respect to the request for approval of the food additive tocopherol in a fermented milk product (low-fat yoghurt mini-drinks) containing added phytosterols?

RISK ASSESSMENT

5. Safety Assessment

The safety of phytosterols when consumed in low-fat yoghurt mini-drinks at a level of 3.35 g per serve will be evaluated in relation to the following:

- the potential for adverse health effects in the target group of consumers through higher levels of consumption of phytosterols; and
- the potential health impacts on non-target consumers.

The assessment of this Application will entail consideration of the safety of phytosterols in the context of existing permissions for phytosterol-enriched products. In addition to the information provided by the Applicant, FSANZ will refer to other relevant information including from the published scientific literature, other regulatory agencies and the general community.

The safety of use of tocopherols as a food additive in a fermented milk product (low-fat yoghurt mini-drinks) containing added phytosterols will also be evaluated in the assessment of this Application.

6. Efficacy of phytosterols in low-fat yoghurt mini-drinks

The Applicant has submitted a publication of a clinical study that investigated the efficacy of phytosterols in low-fat yoghurt based drink (with similar levels of phytosterols added as requested in this Application) on serum lipids. Evidence for the efficacy of phytosterols at the proposed levels in low-fat yoghurt mini-drinks is required for this assessment to ensure that any labelling statements used by manufacturers would not be misleading or deceptive for consumers.

RISK MANAGEMENT

6. Options

6.1 Option 1 – do not approve the use of phytosterol esters in low-fat yoghurt mini-drinks at a level of 3.35 g per serve and the use of the food additive tocopherol as an antioxidant in a fermented milk product containing added phytosterols

This option maintains the *status quo* by not increasing the permitted level of use of phytosterol esters per serve of low-fat yoghurt mini-drinks in Standard 2.5.3, thereby retaining the current limitations on the level of use of phytosterols in this category of foods.

This option also maintains the *status quo* by not permitting the use of tocopherols in fermented milk products, containing added phytosterols, in Standard 1.3.1.

6.2 Option 2 – approve the use of phytosterol esters in low-fat yoghurt mini-drinks at a level of 3.35 g per serve and the use of the food additive tocopherol as an antioxidant in a fermented milk product containing added phytosterols

This option will result in an amendment to the Code to permit the sale of low-fat yoghurt mini-drinks containing phytosterol esters at a level of 3.35 g per serve and to permit the use of tocopherols in fermented milk products containing added phytosterols.

7. Impact Analysis

7.1 Affected Parties

Parties possibly affected by the regulatory options outlined in Section 6 include:

- consumers, especially the target groups such as adults over 40 years of age with health concerns about high serum cholesterol;
- dietitians and allied health professionals providing dietary advice to consumers;
- the manufacturing and retail sectors of the food industry; and
- Government generally, and State, Territory and New Zealand enforcement agencies.

7.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, including the likely health, economic and social impacts.

To develop the analysis of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

- What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?
- What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, etc?
- What are the costs or benefits for business – compliance, reporting, costs, savings, increased market opportunities both domestically and overseas?
- What are the costs or benefits for government – administration, enforcement, public health and safety, etc?

COMMUNICATION

8. Communication and Consultation Strategy

FSANZ has applied a basic communication strategy to Application A596. This will involve advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. We will issue a media release drawing journalists' attention to the matter.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

At this stage FSANZ is seeking public comment to assist it in assessing this Application.

The Applicant and individuals and organisations who make submissions on this Application will be notified at each stage of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, we will notify the Ministerial Council. The Applicant and Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the website.

9. Consultation

All stakeholders must observe the relevant due date for submissions.

The purpose of the Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the Application.

All stakeholders who make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for public consultation.

9.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated 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, namely a Codex standard for phytosterol esters. Amending the Code to permit a higher level of use of an approved novel food ingredient (phytosterol esters) may have a liberalising effect on international trade. However, at this stage of the assessment this does not appear to warrant notification to the WTO as either a TBT or SPS issue.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

10. Conclusion

This Initial Assessment Report is based mainly on information provided by the Applicant and discusses relevant issues in relation to approving a higher level of use of phytosterol esters as a novel food ingredient in low-fat yoghurt mini-drinks. After having regard to the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the use of phytosterol esters derived from vegetable oil in low-fat yoghurt mini-drinks at a level of 3.35 g per serve. Such an approval, if accepted, would warrant a variation to Standard 2.5.3 – Fermented Milk Products.
- The current permission for the addition of phytosterol esters to low-fat yoghurt permits a level of 1.3 to 1.6 g per serve.
- The Application also seeks approval for the use of the food additive tocopherols as an antioxidant in a fermented milk product containing added phytosterol esters. If approved, a variation to Standard 1.3.1 – Food Additives, would be warranted.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than a variation to the Code that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.