



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

11/03

13 August 2003

INITIAL ASSESSMENT REPORT

APPLICATION A 508

PHYTOSTEROLS DERIVED FROM TALL OILS AS INGREDIENTS IN LOW FAT AND NO FAT LIQUID MILK

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

24 September 2003

(See 'Invitation for Public Submissions' for details)

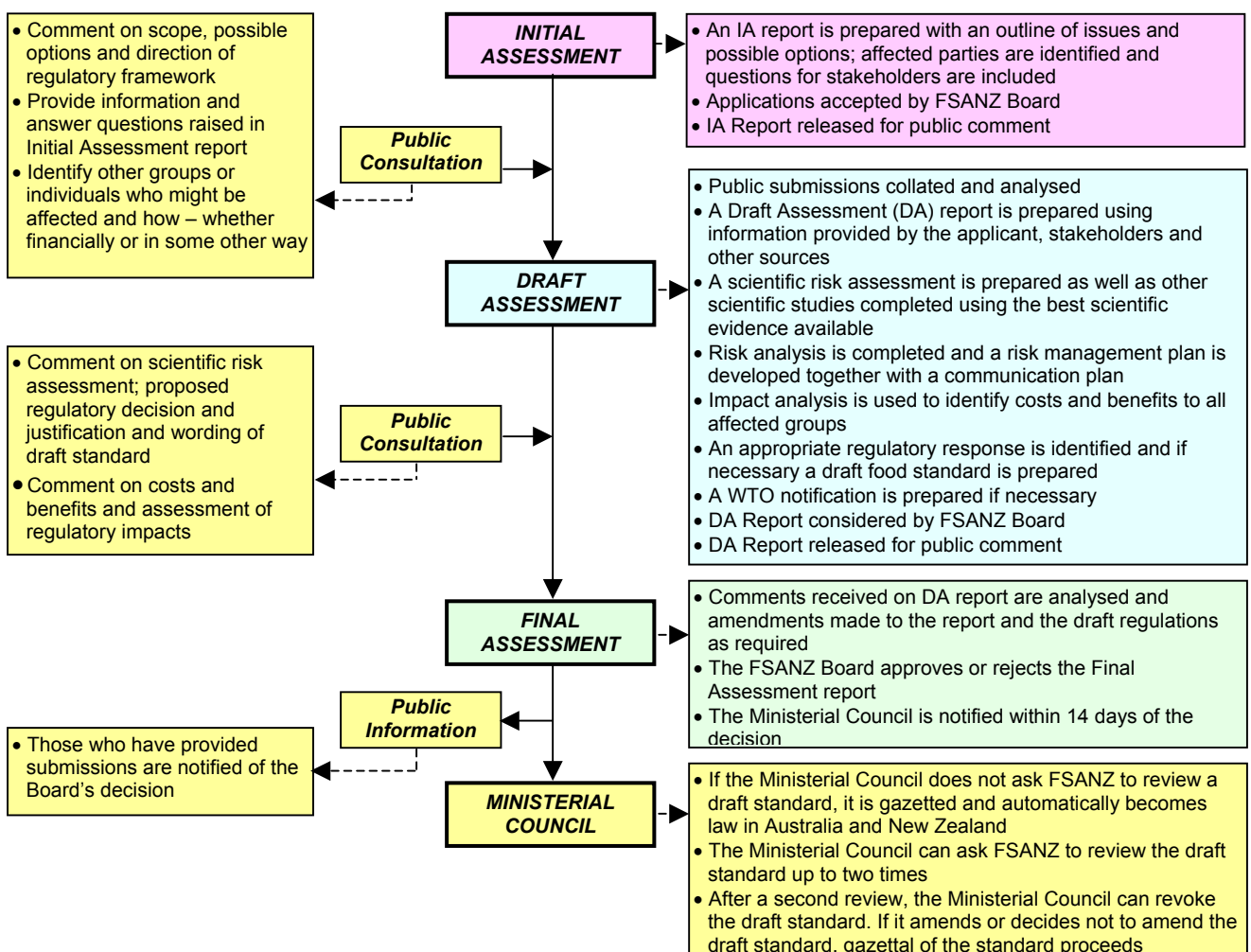
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A508, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report based on regulation impact principles 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/Final Assessment for 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 should be received by FSANZ by **24 September 2003**

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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 Liaison 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.

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Executive Summary

Parmalat Australia Ltd has submitted an application to FSANZ seeking approval for the use of tall oil phytosterols¹ (TOPs) as a novel food ingredient in low-fat and no-fat liquid milk products under Standard 1.5.1 – Novel Foods-in the *Australia New Zealand Food Standards Code* (the Code). Standard 1.5.1 requires that novel foods undergo a safety assessment before being permitted in the food supply. If approved, the novel food is listed in the Table to the Standard and must comply with any special conditions of use also listed in the Table.

Prior consideration by FSANZ of the use of TOPs and phytosterol esters derived from vegetable oils as novel food ingredients resulted in permission for their use in one food type only, namely edible oil spreads and margarines, where the level of consumption is self-limiting. Further safety data and additional scientific information was deemed to be necessary to extend the permission for their use in a broader range of food products.

The applicant has supplied additional scientific information relevant to a safety assessment supporting the use of TOPs in milk products. This will be assessed by FSANZ in the draft assessment stage.

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, consumers and Government in general. Should any submissions be received, those will be considered as part of the assessment process.

¹ i.e. phytosterols derived from tall oils

1. Introduction

1.1 Nature of Application

An application was received from Parmalat Australia Pty Ltd, on 25 June 2003 seeking approval for the use of tall oil phytosterols (TOPs) as novel food ingredients in a low-fat and no fat liquid milk products under Standard 1.5.1 – Novel Foods-of the Code.

2. Regulatory Problem

In the Code, Standard 1.5.1 Novel Foods requires that non-traditional foods which have features or characteristics that may raise safety concerns, undergo a risk-based safety assessment before they are offered for retail sale in Australia and New Zealand. Novel foods or novel food ingredients that have been assessed under the Standard, when approved, are listed in the Table to clause 2 of the Standard.

In 1999, following consultation between FSANZ and Senior Food Officers (SFOs) in each of the Australian States and Territories and New Zealand, it was agreed that phytosterol esters derived from vegetable oils ought to be regarded as novel food ingredients because of the lack of a history of significant consumption by the broad community at the proposed levels of dietary exposure. Non-esterified phytosterols derived from tall oils are also considered to be novel for similar reasons.

In June 2000, FSANZ received an Application (A417) to amend the Code to include TOPs in edible oil spreads as novel foods at a level of 8% w/w. Approval was granted by the Ministerial Council in June 2002. The permissions were limited to edible oil spreads at that time primarily because of a lack of information relating to the safety of phytosterols at the higher levels of exposure in a broader range of foods. There is currently no permission in the Code to add phytosterol esters or TOPs to other foods.

FSANZ is currently considering two other related applications:

- **A 434 from Dairy Farmers**-is seeking to extend the approval for the use of phytosterol esters derived from vegetable oils to a low-fat liquid milk product and a low-fat yoghurt.
- **A 433 from Goodman Fielder Ltd**-is seeking to extend the approval for the use of phytosterol esters derived from vegetable oils to a fibre-increased bread and breakfast cereal bars.

The present Application (A508) seeks permission to add TOPs to low fat and no fat milk products as currently there are no permissions in the Code.

3. Objective

The objective of this application is to establish if the food regulations should be changed to allow the use of TOPs in low-fat and no-fat liquid milk products. Before this broader range of foods containing TOPs can enter the food supply in Australia and New Zealand, FSANZ must undertake a safety assessment that specifically considers (a) the potential health impact of higher dietary exposure to these compounds on target consumers and (b) the potential

effects on non-target consumers. For approval, an amendment to the Code must be agreed by the FSANZ Board, and subsequently be notified to the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC). An amendment to the Code may only be gazetted once the Ministerial Council process has been finalised.

In addressing the proposed variation to Standard 1.5.1 to approve an extension of the use of TOPs as novel food ingredients, FSANZ is required by its legislation to meet three primary objectives in developing and varying food standards that 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. Background

4.1 Nature of tall-oil phytosterols

Phytosterols are found naturally in plants at low levels. TOPs are predominantly a mixture of four phytosterols: sitosterol, sitostanol, campesterol and campestanol, extracted from tall oil soap which is a bi-product of the pulping process used for coniferous trees in North America and Europe. They are then purified in a three-step process. The free phytosterols are structurally related to cholesterol and occur naturally at low levels (up to 0.9%) in common vegetables. TOPs are reported to reduce plasma cholesterol levels. It is claimed by the applicant that incorporation of additional phytosterols, namely, TOPs into the diet may be an effective way of lowering total and low-density lipoprotein (LDL) cholesterol levels.

4.2 Related Applications

An application (Application A434) has also been submitted to FSANZ seeking permission to use phytosterol esters derived from vegetable oils in a low-fat liquid milk product and a low-fat yogurt. Due to significant similarities in terms of the safety assessment, issues that arise in relation to A434 will also be considered within this application.

5. Relevant Issues

5.1 Safety assessment

The safety of phytosterols when consumed in a broader range of foods will be evaluated according to the Authority's section 10 objectives in terms of the following:

- potential for adverse health effects from consumption of higher amounts of phytosterols in the target group of consumers;
- potential health impacts of phytosterols on non-target consumers;
- potential nutritional effects of phytosterols on absorption of certain fat-soluble vitamins and carotenoids in particular;
- efficacy of phytosterols in relation to labelling statements when present in a low-fat or no-fat milk matrix;
- proposed manner of marketing of phytosterol-containing products.

In support of this application to extend the use of TOPs, the applicant has submitted efficacy studies including the data and results from clinical studies involving mildly hypercholesterolaemic individuals in a variety of food matrixes, including milk. The applicant has also provided detailed marketing information² in relation to specific dairy-based products that are the subject of this application. In addition to the information supplied by the applicant, FSANZ will also have regard to dietary modelling and other relevant information including from published scientific literature, other regulatory agencies and the general community.

5.2 Purpose of TOPs in low-fat and no-fat liquid milk products

TOPs are added to foods with the intended purpose of lowering cholesterol absorption in humans. It is proposed that each liquid milk product will contain 0.9g of TOPs/250 mL serving size and will

The Applicant has proposed that the products will carry labelling statements to indicate that consumption of two serves/day is the recommended limit for individual daily consumption and that, further consumption above the recommended levels does not significantly lead to any further reductions in cholesterol absorption

5.3 Conditions of use

If approved, permission to use TOPs in low fat and no fat liquid milk products will be listed in the Table to clause 2 of the standard. Any special conditions of use, for example maximum permitted levels and reference to appropriate specifications³, will also be listed in the Table in Column 2. The conditions of use may also include the requirement for distinctive labelling of products to provide information for consumers. The special conditions of use will be determined on completion of the comprehensive risk analysis.

² FSANZ has assessed this as commercially-in-confidence material and as such is not available on the public register

³ Preliminary analysis of the specifications indicate that they meet the requirements for TOPs already existing in Standard 1.3.4 Identity and Purity for edible oils.

5.4 International Regulations for TOPs and free phytosterols

Codex

There are no Codex standards in relation to TOPs.

Approval in other countries

In the USA, vegetable oil-based spreads containing TOPs at a level up to 12% have self-confirmed Generally Recognised as Safe (GRAS) status.

In the European Union, an application for use in table spreads is still being considered under the Novel Food Directorate.

Other applications for use of free phytosterols in a range of foods⁴ (bakery products, grain-based snack products and gum arabic pastills) are currently being considered under the Novel Food Directorate. A variety of foods containing plant sterols (both phytosterol and phytostanol esters) are reportedly currently on the market in the EU. Examples of these include yoghurts (natural and flavoured), semi-skimmed milk, chicken meat products, sausages, mayonnaise-based salads, cereal bars, and soft cream cheeses in addition to the permitted yellow fat spreads.

6. Regulatory Options

Option 1 – prohibit the use of TOPs in a low-fat and no fat milk product

This option maintains the status quo by not including these foods in the Table to clause 2 of Standard 1.5.1, thereby retaining the current limitations on the use of TOPs to edible oil spreads only.

Option 2 – approve the use of TOPs in a low-fat and no fat milk product

This option will result in an amendment to the Code to permit the sale and use of TOPs at specified levels in a low-fat and no fat milk products. However, restrictions on the future use of such products as ingredients in other foods may be required and will be further assessed at Draft Assessment.

Option 3 – approve the general use of TOPs

This option will result in an amendment to the Code to permit the use of TOPs as ingredients in any food to a maximum permitted level.

⁴ It could not be ascertained whether the source was from tall oils or vegetable oils.

7. Impact Analysis

7.1 Affected parties

- Consumers, especially target groups such as adults over 40 years of age with health concerns about high serum cholesterol, pregnant and lactating women and children;
- Dietitians and allied health professionals providing dietary advice to consumers;
- The manufacturing and retail sectors of the food industry; and
- Government generally, where a regulatory decision may impact on trade or WTO obligations, and State, Territory and New Zealand enforcement agencies.

7.2 Impact 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.

The following initial assessment of the costs and benefits of the three regulatory options identified so far is based on a preliminary assessment of the information supplied by the applicant and knowledge of previous considerations relating to the use of phytosterols in the food supply.

Option 1

There is a potential cost to consumers with this option in terms of the lack of availability and choice of phytosterol-enriched food products. Similarly, there is an identifiable cost to the food industry in terms of a loss of product range and marketing opportunities. There would be no immediate impact on government.

Options 2 and 3

There are potential benefits to consumers associated with these options in terms of access to a greater range of phytosterol-enriched food products and potential benefits to food manufacturers in terms of increased product range and greater market share. There are potential increasing marketing opportunities for food retailers. There would be no direct impact on Government as either of these options is unlikely to have any impact on monitoring resources.

To further develop the impact analysis in terms 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 terms of public health and safety, consumer information and labelling? Do any identified health benefits for the targeted group of consumers outweigh any costs to non-target groups?
- What are the costs or benefits for business – increased market opportunities both domestically and overseas, production costs, marketing costs including providing advice to consumers, additional labelling requirements?
- What are the costs and benefits for government – administrative, public health and safety?

8. Consultation

This Initial Assessment Report is intended to seek early input from the general community on a range of issues concerning the availability of a low-fat and/or no fat milk products containing TOPs. Comment is also invited on a broader permission for food products containing phytosterols than is currently permitted in the food supply in Australia and New Zealand.

All individuals, groups or organisations who make a submission in relation to this application will be included on a mailing list to receive further FSANZ documents pertaining to this application. Readers are encouraged to bring this Initial Assessment Report to the attention of others with an interest in the application. FSANZ will also add other interested parties to the mailing list for public consultation as they come to hand.

At this stage, FSANZ is seeking public comment to assist with assessment of the application. Such comments could cover:

- scientific aspects of the application, in particular, any information relevant to the safety assessment;
- Information that would assist in an assessment of the appropriateness and effectiveness of current labelling statements on edible spreads containing phytosterol esters derived from vegetable oils and/or phytosterols derived from tall oils;
- parties that might be affected by having this application approved or rejected;
- potential costs and benefits to consumers, industry and government.

8.2 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 TOPs. Amending the Code to allow TOPs as novel food ingredients may have a liberalising effect

on international trade via removal of the prohibition on the sale of these novel food ingredients. 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.

9. Conclusion and Recommendation

Section 13 of the FSANZ Act prescribes those matters that must be taken into account by FSANZ in making an Initial Assessment. FSANZ has taken those matters into account, and accepts the application.

Accordingly, FSANZ now seeks public comment in order to proceed to the Draft Assessment Report. If subsequently approved by FSANZ and agreed by the Ministerial Council, Standard 1.5.1 would allow the use of TOPs as a novel food ingredient in the manufacture of low-fat and no fat milk products or approval in a range of other foods at specified maximum levels.