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INFORMATION SUMMARY

APPLICATION A410

PHYTOSTEROL ESTERS AS NOVEL FOOD INGREDIENTS

The Australia New Zealand Food Authority has received an application to amend the Australian *Food Standards Code* on the above matter. The Authority's Preliminary Assessment Report is provided below and provides further detail. The Authority now invites public submissions on any issue raised in the Report for the purposes of making a full assessment.

PRELIMINARY ASSESSMENT REPORT

Applicant: Unilever Foods **Date received:** 14 March 2000

BACKGROUND:

An application has been received from Unilever Foods to amend Standard A19 – Novel Foods – to approve the continued use of phytosterol esters derived from vegetable oils as novel food ingredients in table spreads.

Phytosterol esters are currently being added (to a total of 13.7%) to two brands of table spread in Australia. It is claimed by the manufacturers that incorporation of additional phytosterol esters into the diet may be an effective way of lowering total and LDL cholesterol levels. The naturally occurring level of phytosterols in table spreads is 0.3 – 0.4%.

Standard A19 – Novel Foods – came into effect on 16 December 1999. The standard prohibits the sale of these foods unless they are listed in the Table to clause 2, and comply with any special conditions in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, a warning statement or other advice, or the need to meet specific requirements of composition or purity.

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

The Authority will assess the safety for human consumption of each novel food in accordance with the Authority's safety assessment guidelines.

In order to allow a period of time to assess any foods currently on the market that are deemed to be novel, clause 2 of the Standard, which prohibits the sale of novel foods does not come into force until 16 June 2001 (18 months after gazettal of the Standard).

OBJECTIVE:

The objective of the application is to allow the continued use of phytosterol esters in table spreads. This is likely to be achieved by amending (i) the Table to Clause 2 in Standard A19 – Novel Foods – to include phytosterol esters derived from vegetable oils, and (ii) by amending Clause 1 of Standard G3 to permit the addition of phytosterol esters to table spread. In the proposed joint Australia New Zealand Food Standards Code, the permission to add phytosterol esters to table spread would be achieved by amending Clause 1 of Standard 2.4.2.

REGULATORY IMPACT ASSESSMENT

The regulatory impact assessment below is preliminary only and based on available information or on information provided by the applicant. The assessment is designed to assist in identifying the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions. This preliminary assessment invites public comment on these areas.

OBJECTIVE OF THE REGULATORY IMPACT ASSESSMENT

To assess the risks and benefits associated with adopting the proposed regulator change to permit the continued use of phytosterol esters in table spreads.

Potential regulatory impacts

The potential impact of the various regulatory options are as follows:

Option 1. Not approve the use of phytosterol esters as novel foods.

This option would require food manufacturers currently marketing this product to cease sale on 16 June 2001 when Clause 2 of Standard A19 becomes effective. Consumers would no longer have access to a product that is reported to lower blood cholesterol.

Option 2. Approve the use of phytosterol esters from vegetable oils as novel foods.

This option would allow the sale of table spreads containing phytosterol esters to continue. Consumers would have access to a product that is reported to lower blood cholesterol. Enforcement agencies may be required to monitor use of this novel food.

Identification of affected parties

Parties affected by the options outlined above include:

1. Food industry wishing to promote table spreads containing phytosterol esters.
2. Consumers who may benefit from the use of phytosterol ester-containing products.
3. Government agencies enforcing the food regulations.

CONSIDERATION OF ISSUES UNDER SECTION 13

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, and is not so similar to a previous application that it ought not be accepted.

Costs and benefits arising for any food regulatory measure or other measures developed or varied as a result of this application, will be considered at full assessment.

OTHER RELEVANT MATTERS

Codex. There are no Codex standards in relation to phytosterol esters.

APPROVAL IN OTHER COUNTRIES

In the USA, phytosterol esters from vegetable oils have Generally Recognised As Safe (GRAS) status. In the European Union, phytosterol esters are currently being assessed under the EU Novel Food Regulations. Phytosterol esters are approved in Switzerland and Brazil.

CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, as provided for in section 13 of the *ANZFA Act 1991*. Cost arising from any food regulatory measure so developed will be assessed at Full Assessment.

Accordingly the Authority has decided to accept the application and will now make a full assessment of it.

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the Code would allow the addition of phytosterol esters derived from vegetable oils to table spreads. Conditions of use such as a requirement to comply with specifications for identity and purity, and to comply with a maximum percentage addition to table spreads may be required.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand Food Regulations 1984*.
- **Food imported into New Zealand from Australia** must comply with either the *Australian Food Standards Code* or the *New Zealand Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*
- **Food imported into New Zealand from Australia** must comply with either the *Australian Food Standards Code* or the *New Zealand Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the *Australian Food Standards Code*. However, under the provisions of the *Trans-Tasman Mutual Recognition Arrangement*, food may be imported into Australia from New Zealand if it complies with the *New Zealand Food Regulations 1984* or *Dietary Supplements Regulations 1985*.

- **Food manufactured in Australia and sold in Australia** must comply solely with the Australian *Food Standards Code*, except for exemptions granted in Standard T1.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority 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.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A410** at one of the following addresses:

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| Australia New Zealand Food Authority PO Box 7186 Canberra Mail Centre ACT 2610 AUSTRALIA Tel (02) 6271 2222 Fax (02) 6271 2278 | Australia New Zealand Food Authority PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 Fax (04) 473 9855 |
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The Authority should receive submissions by **16 August 2000**.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on <slo@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.