



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

5-06

9 August 2006

INITIAL ASSESSMENT REPORT

APPLICATION A555

DECLARATION OF ANTIOXIDANTS IN FATS AND OILS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 September 2006

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

An Application has been received by FSANZ from the Food Intolerance Network to amend Standard 1.2.4 – Labelling of Ingredients, in the *Australia New Zealand Food Standards Code* (the Code), to require antioxidants present in fats and oils to be declared on the label of the final food containing such fats and oils as ingredients.

Currently, Standard 1.2.4 provides an exemption from ingredient labelling for ingredients in compound ingredients (including food additives) when the compound ingredient comprises less than 5% of the final food. This exemption does not apply to food additives in compound ingredients that perform a technological function in the final food. Therefore, under the proposed amendment, antioxidants in fats and oils, when used in compound ingredients, would be required to be declared at all times, irrespective of whether they are performing a technological function in the final food.

Standard 1.3.1 – Food Additives in the Code currently permits six antioxidants, propyl gallate, octyl gallate, dodecyl gallate, tertiary butylhydroquinone (tBHQ), butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT) to be added to fats and oils up to the maximum levels specified in the Standard. The amendment is being sought by the Applicant on the basis that these antioxidants contribute to food intolerance reactions in certain individuals, and therefore labelling of foods containing these substances will enable consumers to make an informed choice regarding their purchase and use.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Purpose

The purpose of the Application is to determine whether Standard 1.2.4 should be amended to require the declaration of the antioxidants contained in fats and oils in the final food, when such fats and oils are used as compound ingredients in these foods.

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 to require labelling for the presence of antioxidants in fats and oils at all times. Such an approval, if accepted, would warrant a variation to Standard 1.2.4.
- There is currently no requirement in the Code for the labelling of food additives in a compound ingredient where the compound ingredient comprises less than 5% of the final food, and the food additive is not performing a technological function in the final food.

- 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 Standard 1.2.4 that could achieve the same end.

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments are specifically sought on the safety issues associated with antioxidants used in fats and oils and the costs and benefits to stakeholders of labelling for the presence of these antioxidants at all times.

Responses to this Initial Assessment Report will be used to assist FSANZ in progressing the Application to the next stage and the preparation of the Draft Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

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 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) 20 September 2006.

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

On 23 November 2004, the Food Intolerance Network submitted an Application to amend Standard 1.2.4 – Labelling of Ingredients, in the Code to require antioxidants present in fats and oils to be declared on the label at all times. Currently, the Code provides an exemption from ingredient labelling for ingredients in compound ingredients (including food additives) when the compound ingredient comprises less than 5% of the final food. This exemption does not apply to food additives in compound ingredients that perform a technological function in the final food. Therefore, under the proposed amendment, antioxidants in fats and oils, when used in compound ingredients, would be required to be declared at all times, irrespective of whether they are performing a technological function in the final food.

Standard 1.3.1 – Food Additives, in the Code currently permits six antioxidants, to be added to fats and oils up to the maximum levels specified in the Standard. These antioxidants are as follows:

INS Number	Additive Name
310	Propyl gallate
311	Octyl gallate
312	Dodecyl gallate
319	Tertiary butylhydroquinone (tBHQ)
320	Butylated hydroxyanisole (BHA)
321	Butylated hydroxytoluene (BHT)

The amendment is being sought by the Applicant on the basis that these antioxidants contribute to food intolerance reactions in certain individuals, and therefore labelling of foods containing these substances will enable consumers to make an informed choice regarding their purchase and use.

In support of their Application, the Applicant has provided limited data relating to the adverse effects on health, behaviour and learning in certain individuals following consumption of these antioxidants in food.

1. Background

1.1 Current Standard

1.1.1 Standard 1.3.1

Standard 1.3.1 - Food Additives, in the Code regulates the use of food additives in the production and processing of food. The permitted uses of food additives by food type are listed in Schedule 1 of Standard 1.3.1. In relation to the food type ‘Edible oils and oil emulsions’, there are six antioxidants that are permitted to be added as follows:

INS Number	Additive Name	Maximum Permitted Level
310	Propyl gallate	100 mg/kg
311	Octyl gallate	100 mg/kg
312	Dodecyl gallate	100 mg/kg
319	Tertiary butylhydroquinone (tBHQ)	200 mg/kg
320	Butylated hydroxyanisole (BHA)	200 mg/kg
321	Butylated hydroxytoluene (BHT)	100 mg/kg

1.1.2 *Standard 1.2.4*

Clause 8 of Standard 1.2.4 in the Code requires that food additives are declared in the ingredients list by their class name, followed by the additive's specific name or code number in brackets.

Under clause 6 of Standard 1.2.4, a food additive is exempt from ingredient labelling if the following conditions are met:

- the food additive is added to a food as part of a compound ingredient;
- the compound ingredient is present in the final food at less than 5%;
- the food additive is not performing a technological function in the final food; and
- the name of the compound ingredient is declared in the ingredient list rather than the separate declaration of all the ingredients in the compound ingredient.

However, this exemption does not apply if the food additive in the compound ingredient contains a substance listed in the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations in the Code, given the potential for these substances to cause severe adverse reactions in sensitive individuals, even when present in food at very low levels.

1.2 **Antioxidants in Fats and Oils**

Antioxidants are a class of food additives which prolong the shelf-life of foods by protecting them against deterioration caused by oxidation, such as fat rancidity and colour changes.

A detailed food technology report with respect to antioxidants in fats and oils will be provided at Draft Assessment.

1.2.1 *Propyl gallate, octyl gallate and dodecyl gallate*

Propyl gallate, octyl gallate and dodecyl gallate are frequently used in combination with BHA and BHT. They are typically found in fats and oils, dairy foods, cereals and snack foods and may also be found in packaging material. However, due to their instability at high temperatures, their use is limited.

The safety of propyl gallate, octyl gallate and dodecyl gallate was last evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1996. The 1993 JECFA evaluation of propyl gallate produced an acceptable daily intake (ADI) of 0-1.4 mg/kg body weight which was maintained at the 1996 evaluation. No ADI was allocated for octyl gallate and dodecyl gallate.

1.2.2 *Tertiary butylhydroquinone (tBHQ)*

tBHQ is an effective antioxidant in both vegetable oils and in most other fats. It is found in a range of oils, margarines and fat containing foods and retains its antioxidant capability in baking and frying.

The safety of tBHQ was last evaluated by JECFA in 1997. This JECFA evaluation produced an ADI of 0-0.7 mg/kg body weight.

1.2.3 Butylated hydroxyanisole (BHA)

BHA is an effective antioxidant in animal fats used in baked products. It is stable at high temperatures.

The safety of BHA was last evaluated by JECFA in 1988. This JECFA evaluation produced an ADI of 0-0.5 mg/kg body weight.

1.2.4 Butylated hydroxytoluene (BHT)

BHT has similar characteristics to BHA and is also an effective antioxidant in animal fats, although it has limited use in oils.

The safety of BHT was last evaluated by JECFA in 1995. This JECFA evaluation produced an ADI of 0-0.3 mg/kg body weight.

1.3 Historical Background

1.3.1 Proposal P150 – Australia New Zealand Standard for Food Additives

The current regulations in Standard 1.3.1 in relation to the use of food additives were finalised in 2000, following a comprehensive review of food standards in Australia and New Zealand. As part of Proposal P150, each additive in Standard 1.3.1 underwent a detailed risk analysis. Of the 397 additives evaluated, a total of 13 additives warranted further consideration regarding risk management options. The antioxidants propyl gallate, octyl gallate, dodecyl gallate, tBHQ, BHA, and BHT were included in a group comprising a number of additives assessed as being of no risk, assuming the exclusive use of the additive in foods at the maximum permitted levels.

1.3.2 Proposal P143 – Review of the Statement of Ingredients

The current provisions in Standard 1.2.4 in relation to compound ingredient labelling were developed during the review of the Code as part of Proposal P143. As a result of this Proposal, the threshold for compound ingredient labelling was reduced from 25% for ingredients, and 10% for food additives, down to 5% for those food additives that are not performing a technological function in the final food. This approach was preferred as it aligned internationally. Furthermore, the technological function of a food additive in the final food is considered a direct indicator of a food additive's concentration and significance in the final food.

During the development of Standard 1.2.4, FSANZ acknowledged that whilst declaring each ingredient in a compound ingredient in the ingredient list would provide more information to consumers, it would also complicate and lengthen ingredient lists, which is unlikely to promote consumers' understanding and use of the ingredient list.

Additionally, a requirement to declare food additives that are not performing a technological function in the final food would not align with international requirements and consequently would result in a barrier to trade, would result in increased costs of labelling to manufacturers and could not be justified in terms of public health and safety.

1.4 Relevant International Requirements

In assessing whether regulatory intervention is warranted, FSANZ must have regard to the promotion of consistency between domestic and international food standards so that there is, no undue impediment to trade.

1.4.1 Codex Alimentarius

The Codex General Standard for Food Additives (GSFA)¹ contains permissions for the antioxidants propyl gallate, tBHQ, BHA and BHT. These additives are permitted in a broader range of food categories than those specified in the Code. In terms of those food categories that relate to the category of 'Edible Oils and Oil Emulsions' in the Code, these antioxidants are permitted to be added up to a maximum level of 200 mg/kg. There are no specific permissions for the antioxidants octyl gallate or dodecyl gallate in the Codex Standard.

With respect to compound ingredient labelling, the Codex General Standard for the Labelling of Prepackaged Foods² requires that all ingredients in the compound ingredient be labelled. However, if the compound ingredient constitutes less than 5% of the food, Codex only requires that food additives performing a technological function in the final food be declared.

1.4.2 European Union

The European Union permits the addition of propyl gallate, octyl gallate, dodecyl gallate, BHA and BHT to broad range of foodstuffs, including fats and oils. There is no specific permission for tBHQ. Gallates and BHA can be added to 'fats and oils for the professional manufacture of heat-treated substances', either singly or in combination, up to a maximum level of 200 mg/kg. BHT can be added to 'frying oil and frying fat, excluding olive pomace oil', up to a maximum level of 100 mg/kg³.

The European Union provides an exemption from ingredient labelling for those additives which are contained in an ingredient of a foodstuff but serve no technological function in the finished product⁴.

¹ CODEX STAN 192-1995 (Rev. 6-2005)

² CODEX STAN 1-1985 (Rev.1-1991)

³ European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners.

⁴ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

1.4.3 United States

The United States Code of Federal Regulations (CFR) permits the addition of dodecyl gallate, octyl gallate, propyl gallate, tBHQ, BHA and BHT to fats and oils. They may be used in foods providing the total content of antioxidants does not exceed 0.02% of the oil or fat content of the food⁵.

The United States provides an exemption from ingredient labelling for incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. The term incidental additives incorporates *substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.*⁶

2. The Issue / Problem

The Applicant has requested an amendment to the Code so that antioxidants present in fats and oils are declared on the label at all times. The Applicant's request is based on concerns that these substances have an adverse effect on health, behaviour and learning in certain individuals, therefore labelling of foods containing these substances will enable consumers to make an informed choice regarding their purchase and use.

As discussed under the preceding Section, the existing requirements in Standard 1.3.1 relating to the permissions for the addition of antioxidants in fats and oils, and Standard 1.2.4 relating to the labelling exemption for food additives in compound ingredients, were based on several factors, including:

- a detailed safety assessment of the permitted additives;
- the presence of low concentrations of the additives which have an insignificant function in the final food;
- limiting unnecessarily long and complex ingredient lists;
- minimising additional costs to industry and associated flow-on costs to consumers; and
- alignment with international regulations.

An assessment of this Application therefore requires:

- an evaluation of the available evidence in relation to these antioxidants and food intolerance reactions;
- an assessment of the costs and benefits to consumers of additional labelling for the presence of antioxidants in fats and oils; and
- an assessment of the costs and benefits to industry of additional labelling.

3. Objectives

The specific objective of the Application is to determine whether an amendment to Standard 1.2.4 is required to protect the health and safety of individuals who may potentially suffer from adverse reactions to antioxidants when present in fats and oils.

⁵ 21 CFR Ch. 1 (4-1-04), s166.110, s172.115, s182.3169, s182.3173, s184.1660.

⁶ 21 CFR Ch.1 (4-1-04 Edition), Sec. 101.100

A secondary objective of the Application is to determine whether such labelling is required to provide adequate information to consumers to enable informed choices about the presence of low levels of antioxidants in foods.

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

Is there scientific evidence that the antioxidants propyl gallate (310), octyl gallate (311), dodecyl gallate (312), tBHQ (319), BHA (320), (BHT (321) are associated with adverse reactions in certain individuals following consumption of foods containing these substances? In considering this question, the assessment will need to specifically consider the level and concentration of the antioxidant present in the final food as a result of carry-over, when the compound ingredient constitutes less than 5% of the final food.

What are the costs and benefits to stakeholders of labelling for the presence of antioxidants in fats and oils at all times? In assessing whether regulatory intervention is warranted, FSANZ must be satisfied that the benefits of labelling outweigh the costs.

Can the outcome sought by the Applicant be achieved via alternative measures, for example, consumer education strategies?

RISK ASSESSMENT

5. Safety Assessment

As discussed in Section 2.1, the safety of the antioxidants that are the subject of this Application, have been previously evaluated by JECFA.

At Draft Assessment, FSANZ will undertake a further assessment of these antioxidants with respect to their potential role in food intolerance reactions in susceptible individuals.

RISK MANAGEMENT

6. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and Governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

The two regulatory options available for this Application are:

- Option 1.** Maintain the current provisions in clause 6 of Standard 1.2.4. Under this option, antioxidants present in fats and oils will continue to be exempt from ingredient labelling if the amount of compound ingredient in the food is less than 5% and the antioxidant is not performing a technological function in the final food.
- Option 2.** Amend Standard 1.2.4 in the Code so that antioxidants present in fats and oils, when used as compound ingredients, are required to be declared in the ingredient list of the final food.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. consumers, specifically those who suffer from intolerances to certain substances in food;
2. public health professionals;
3. food manufacturers and importers, specifically those using fats and oils containing antioxidants in the manufacture of foods; and
4. Australian Government, State, Territory and New Zealand Government agencies that enforce food regulations.

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. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, and its health, economic and social impacts.

The regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

COMMUNICATION

8. Communication and Consultation Strategy

FSANZ intends issuing this Initial Assessment Report to elicit information and evidence from stakeholders on the public health and safety aspects associated with antioxidants in fats and oils and on the likely costs and benefits to stakeholders of declaring the presence of antioxidants in fats and oils at all times. The Assessment Report will be advertised for public comment in the national press and will be made available on the FSANZ website. FSANZ Communication will monitor media reaction, if any, and advise on appropriate communication strategies.

During the assessment of this Application, FSANZ will work closely with food intolerance associations, public health professionals and consumer organisations in Australia and New Zealand.

9. Consultation

Public comment is sought on the Initial Assessment Report for this Application.

All stakeholders that 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.

Comments that would be useful could cover:

- **the safety of antioxidants in fats and oils;**
- **which food products are likely to be affected;**
- **the levels of antioxidants that are likely to be present;**
- **the cost and benefits to stakeholders of labelling; and**
- **information on food intolerance in relation to the six named antioxidants (scientific studies).**

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 relevant international standards in relation to compound ingredient labelling and amending the Code to require the declaration of antioxidants in fats and oils at all times is likely to have a significant effect on international trade, as the Australia/New Zealand requirements will be inconsistent with international requirements.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's 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

Having regard to the criteria for Initial Assessments in section 13 of the FSANZ Act, FSANZ recommends that the Application be accepted for the following reasons:

- The Application is seeking an amendment to the ingredient labelling requirements in Standard 1.2.4 so that antioxidants present in fats and oils are required to be declared in the ingredient list at all times.
- The Application relates to a matter that may warrant a variation of a food regulatory measure in Standard 1.2.4, if further assessment supports such a variation.
- The Application is not so similar to a previous application that it ought not be accepted.
- At this stage of the assessment, FSANZ is not able to determine whether the costs that would arise from a variation to Standard 1.2.4 would outweigh the direct and indirect benefits to the community, Government or industry. FSANZ will call for specific submissions on this issue and re-address the matter at Draft Assessment.
- There are no alternative measures available to address the Applicant's issue.

It is recommended that this Application now be progressed to Draft Assessment. 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.