



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

15 September 2008
[16-08]

INITIAL ASSESSMENT REPORT

APPLICATION A603

RED 3 ERYTHROSINE IN FOOD COLOURING PREPARATIONS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 27 October 2008
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 Golding Handcrafts on 20 March 2007 seeking to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code). The Applicant seeks to modify the schedule of the Standard to permit the sale of food additive preparations containing the colour erythrosine.

Erythrosine is a cherry-pink food dye. In Australia, New Zealand, the European Union, and in the Codex Alimentarius, the use of erythrosine is restricted to preserved cherries (known as maraschino cherries, cocktail cherries or glace cherries) up to a maximum of 200 mg/kg. Other red colours are not in common use for this purpose because the colour migrates into other food components. In the USA, erythrosine is permitted for general use, and is commonly used in sweets and foods marketed to children.

The current acceptable daily intake (ADI) for erythrosine is 0.1 mg/kg body weight/day. This is based on the No Observed Effect Level (NOEL) of 1 mg/kg bw/day (60 mg per person per day) for effects on thyroid function in humans observed at the next highest dose of 3.3 mg/kg bw/day, and using a 10-fold safety factor.

The Applicant is seeking to extend the use of erythrosine from a single food that is consumed in low amounts (i.e. maraschino cherries) to a food additive preparation that would be added to products such as icing and frostings used in other foods that are more widely consumed (e.g. cakes, biscuits, fancy breads). This would allow food suppliers to sell a wider range of products and increase consumer choice. However, extending the permission for using erythrosine must not compromise public health and safety.

The role of FSANZ is to identify any risks associated with increasing the use of erythrosine and, if appropriate, provide a regulatory mechanism for its safe use in a wider variety of foods. The risk assessment will consider the information provided by the Applicant but will also have regard to other available information, including from the scientific literature, general technical information, from independent scientists, from other regulatory agencies and international bodies, and the general community.

Purpose

The purpose of the Application is to amend Standard 1.3.1 – Food Additives to permit the sale of food additive preparations containing the colour erythrosine (INS 127) to the public, i.e. for use in home cooking and for commercial use. The intended use of the food additive preparations is to colour icing and other cake decoration so that the concentration of erythrosine in the icing made does not exceed a proposed maximum use level of 2 mg/kg.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) (as was in force prior to 1 July 2007), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval to permit the sale of food colouring preparations containing the colour erythrosine. Such an approval, if accepted, would warrant a variation to Standard 1.3.1.
- There is currently no permission in the Code for the use of erythrosine in foods other than preserved cherries (known as maraschino cherries, cocktail cherries or glace cherries).
- The Application is sufficiently different to previous applications.

Consultation

The purpose of this Initial Assessment Report is to seek input from stakeholders in relation to the Application. At this stage, FSANZ is seeking public comment to assist the assessment of this Application. FSANZ is particularly interested in receiving further information in response to the questions asked throughout this 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 18 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

Submissions need to be received by FSANZ by 6pm (Canberra time) 27 October 2008.

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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
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NEW ZEALAND
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INTRODUCTION

FSANZ received an Application from Golding Handcrafts on 20 March 2007 seeking to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code).

The Applicant seeks to modify the schedule of the Standard to permit the sale of food colouring preparations containing the colour erythrosine (INS 127). The intended primary use for these products is the colouring of icing and decorations for decorating cakes.

1. Background

Erythrosine (tetraiodofluorescein, for synonyms refer to Table 1) is a cherry-pink, coal-based fluorone food dye (Figure 1). In Australia, the Code restricts the use of erythrosine in foods to preserved cherries known as maraschino cherries, cocktail cherries or glacé cherries. Erythrosine is used to colour these cherries red prior to processing. Other red colours are not in common use for this application because the colour migrates into other food components, such as to pears, peaches, grapes and pineapple in cans of fruit cocktail or fruit salad. In the USA, erythrosine is permitted for general use, and is commonly used in sweets and foods marketed to children such as candies, popsicles, cake frosting and cake-decorating gels.

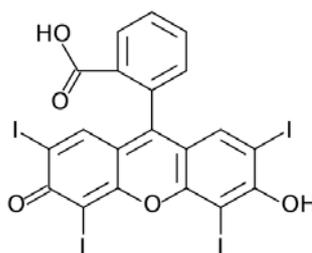


Figure 1: Erythrosine chemical structure

Table 1: Synonyms of erythrosine

Erythrosine synonyms
FD&C Red No. 3
E number E127 (C.I Food Red 14)
Colour Index (1975) no. 45430 (C.I. Acid Red 51)
INS No. 127
Erythrosine BS
Erythrosine B
Red 3

1.1 Current Standard

Erythrosine is currently permitted to be added to preserved cherries only up to a maximum of 200 mg/kg (Standard 1.3.1, schedule 1, section 4.3).

1.2 Historical Background

Before 1991, a wide variety of Australian and New Zealand foods including confectionery, biscuits, cakes, frankfurters and milk contained erythrosine. The National Health and Medical Research Council (NHMRC) prepared a proposal to restrict the use of erythrosine in foods before the commencement of the *Australia New Zealand Food Authority Act 1991* (FSANZ Act). The 81st meeting of the Food Science and Technology Subcommittee in February 1991 recommended that erythrosine use be limited to frankfurter skins, fish paste, and cocktail and maraschino cherries. The Australian Food Standards Executive Committee supported this proposal in May 1991, but there was no further action at this time. Prior to the commencement of the Australia New Zealand joint food standards-setting system, the New Zealand Food Regulations had no specific restrictions on the use of erythrosine.

In March 1993, the then National Food Authority (NFA) decided to withdraw permission for the use of erythrosine from all foods sold in Australia and New Zealand, except for preserved cherries and fabricated collagen casing for manufactured meats for another three years (until 9 March 1997) to allow development of alternative colours. After assessment of an Application (A324) from Ardmona Foods, SPC Limited, and Golden Circle Ltd in 1996, permission to use erythrosine in preserved cherries to a maximum level of 290 mg/kg was extended until 9 March 2000.

FSANZ received a new Application in August 1999 from Ardmona Foods Limited, requesting permission to continue the use of erythrosine to colour preserved cherries to a maximum permitted level of 200 mg/kg. FSANZ concluded that:

- this use of erythrosine led to a low level of dietary exposure and did not raise any apparent public health and safety concerns;
- there was a technological need to colour preserved cherries in order to meet consumer expectations; and
- erythrosine was the only colour available that provides the appropriate colour, that does not bleed into the other fruit in a canned fruit cocktail during the cooking process, and that is stable over the shelf life of the product.

Consequently, since 2001, erythrosine can be added to preserved cherries sold in Australia and New Zealand up to a maximum of 200 mg/kg, but to no other foods.

1.3 International experience

1.3.1 Joint FAO/WHO Expert Committee on Food Additives

Erythrosine has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) at a number of meetings. JECFA reviewed the data on erythrosine in 1990, including the data on potential carcinogenicity. The Committee concluded that erythrosine was not genotoxic and the occurrence of thyroid tumours in rats was secondary to the compound's hormonal effects. At its 37th meeting (1990), JECFA established an ADI of 0-0.1 mg/kg body weight. At its 53rd meeting in 2000, JECFA assessed national dietary exposure assessments for erythrosine. At the time, erythrosine was considered for use in a wide range of solid foods, in water-based flavoured non-alcoholic drinks, and in spirits and liqueurs in the draft General Standard for Food Additives (GSFA) being established by the Codex Committee on Food Additives and Contaminants.

JECFA found that the national estimates of erythrosine dietary exposures were below the ADI of 0.1 mg/kg body weight. The Committee concluded that in assessing the risk of exceeding the ADI, non-food sources of erythrosine should be considered, such as use in pharmaceutical products, which may contribute significant amounts to the total dietary exposure if consumed over a long period. The dietary exposure to erythrosine could exceed the ADI if the maximum levels in the GSFA were to be widely accepted at the national level; however, models based on the maximum levels of use proposed in the draft General Standard gave overestimates of actual dietary exposure, because erythrosine was likely to be used in only a limited number of red foods. Therefore, the Committee concluded that it was unlikely that long-term dietary exposure to erythrosine would exceed the ADI.

1.3.3 Codex Alimentarius

In the current version of the General Standard for Food Additives (GSFA), Codex permits the use of erythrosine in candied fruit (cocktail cherries and candied cherries only) at the maximum level of 200 mg/kg. No other permissions for use of erythrosine are given.

1.3.2 Regulation in countries other than Australia and New Zealand

Food regulations in other countries permit the use of erythrosine in cherries, including the United States of America (USA) and the European Union (EU).

1.3.2.1 United States of America

The United States of America (USA) Code of Federal Regulation, Title 21, Section 74.303, states that FD&C Red No. 3 (Erythrosine) may be safely used as a colouring in general foods in amounts consistent with good manufacturing practice (GMP). Concerns regarding the safety of this colour were raised by the United States Food and Drug Administration (USFDA) following the publication of a report indicating that under experimental conditions erythrosine at high dose levels (4% in the diet) can affect the level of circulating thyroid hormones in rats thus leading to an increase in the incidence of thyroid tumours. The response of the USFDA in 1990 was withdrawal of permission to use erythrosine lakes (salts), (but not erythrosine) in all foods, drugs and cosmetics, and to withdraw the use of erythrosine in cosmetics and externally applied drugs.

1.3.2.2 European Union

Erythrosine is permitted in the EU in preserved cherries (cocktail and glacé cherries) at the maximum level of 200 mg/kg and in bigarreaux cherries in syrups and in cocktails at the maximum level of 150 mg/kg.

1.4 Approach to Assessment of the Application

In order to evaluate the merits of this Application, FSANZ must take account of certain factors. The initial process will involve an assessment of the outcomes resulting from the following evidence:

- food technology report
- toxicological data and safety assessment
- dietary exposure assessment
- impact analysis (cost-benefit)

1.5 Issues Raised by the Applicant

The Applicant has raised a number of issues regarding the use of erythrosine as a food colouring. The Applicant argues that:

- food colours containing erythrosine have superior colouring characteristics and colours without erythrosine cannot match the strength of colour or provide the same result;
- the amount of erythrosine used by the manufacturer of the food colours is minimal and the proposed maximum level is 2 mg/kg in the prepared food;
- children are unlikely to consume enough icing to exceed the Acceptable Daily Intake of 0.1 mg erythrosine/kg body weight/day;
- erythrosine is used at lower concentrations than other food colourings; this could reduce the amount of food colourings consumed overall;
- in the USA, erythrosine is permitted for colouring foods generally consistent with GMP. Extending the use of erythrosine permitted by the Code would allow Australian and New Zealand manufacturers to compete on a more level playing field;
- other red colourings are not kosher and therefore unsuitable for some consumers;
- extending the permission for use of erythrosine would increase consumer choice; and
- the intended market for food colouring preparations containing erythrosine is primarily the home cake decorator making one-off projects for family occasions. A less important market segment are professionals (e.g. cake decorators, commercial bakeries) using food colouring preparations to prepare and sell cakes and similar products.

Questions for submitters:

1. What evidence is there that erythrosine has superior colouring characteristics?
2. Would you consider using colour preparations containing erythrosine, at home or in your food business?
3. Would the availability of food colouring preparations containing erythrosine reduce your use of other food colours?
4. How would the availability of erythrosine-based food colourings increase the competitiveness of Australian and New Zealand businesses?
5. How great is the consumer demand for food products coloured with erythrosine based food colour preparations?

2. The Issue / Problem

The Applicant is seeking to extend the use of erythrosine from a single food that is consumed in low amounts (i.e. maraschino cherries) to a food additive preparation that would be added to products such as icing and frostings used in other foods that are more widely consumed (e.g. cakes, biscuits, fancy breads).

The Applicant argues that food colours containing erythrosine have superior colouring characteristics and colours without erythrosine cannot match the strength of colour or provide the same result. Therefore, the existing permissions for the use of erythrosine are too restrictive, and amending the Code to permit the sale of food colouring preparations containing erythrosine would allow food suppliers to supply a wider range of products and increase consumer choice.

However, extending the permission for using erythrosine must not compromise public health and safety. FSANZ's role is to identify any risks associated with increasing the use of erythrosine and, if appropriate, provide a regulatory mechanism for its safe use in a wider variety of foods.

3. Objectives

The specific objectives of FSANZ's assessment of this Application are to:

- protect the public health and safety of consumers in relation to the proposed extended use of erythrosine,
- ensure that any permitted use of food additives is based on risk analysis using the best available scientific evidence , and
- promote consistency between domestic and international food standards regarding the use of erythrosine.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 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

There are four key assessment questions requiring investigation as part of FSANZ's consideration of this Application:

1. Are there any public health and safety issues with approving the use of erythrosine in food additive preparations?
2. What would be the potential dietary exposure to erythrosine for mean and high consumers of foods containing products such as icings or frostings made with food additive preparations containing erythrosine?
3. What oral sources of erythrosine exposure other than food, such as use in pharmaceutical products, should be considered?
4. Is there a technological justification for seeking the approval of an extension of use of erythrosine?

Questions for submitters:

6. What non-food sources of erythrosine should FSANZ consider in the assessment of this Application?

RISK ASSESSMENT

5. Risk Assessment Summary

The risk assessment will consider the information provided by the Applicant in relation to risk assessment issues but will also have regard to other available information, including from the scientific literature, general technical information, from independent scientists, from other regulatory agencies and international bodies, and the general community. If required, FSANZ will seek additional information from the Applicant.

The objective of the risk assessment for this Application is to describe the toxicology and safety of use of erythrosine. A dietary exposure assessment will be undertaken to compare estimated erythrosine dietary exposures with the ADI. Food technology consideration will include the technological need for using erythrosine as well as how food additive preparations containing erythrosine are used in practice.

5.1 Toxicology and safety of use

The current ADI for erythrosine of 0.1 mg/kg bw/day was established by JECFA in 1990. This ADI is based on the NOEL of 60 mg per person per day (equivalent to 1 mg/kg bw/day) in a 14-day human study for effects on thyroid function at the next highest dose of 200 mg per person per day (equivalent to 3.3 mg/kg bw/day) and using a 10-fold safety factor for intraspecies variability. Given that a reasonable period of time has passed since the toxicology of erythrosine was reviewed by JECFA, the scope of the current safety assessment will include an evaluation of supplementary toxicity studies published in the scientific literature since 1990.

Questions for submitters:

7. Do you have any scientific information or data on the safety of use of food colouring preparations containing erythrosine for home use or food manufacture?

5.2 Dietary exposure assessment approach

Dietary modelling is a tool used to estimate dietary exposure to food chemicals, including food colours, from the diet as part of the FSANZ risk assessment process. To estimate dietary exposure to erythrosine, records of what foods people have eaten are needed, along with estimates of how much erythrosine is in each food.

The dietary exposure assessment will be conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data in order to estimate the exposure to erythrosine from the diet. This will be achieved by using FSANZ's dietary modelling computer program, DIAMOND.

A dietary exposure assessment will be conducted for the whole population in Australia and New Zealand and population sub groups, such as children. Children generally have higher dietary exposures to food chemicals when expressed on a body weight basis because they consume more food per kilogram of body weight compared to adults due to their increased energy needs for growth and development.

The dietary exposure to erythrosine will be estimated by combining usual patterns of food consumption, as derived from national nutrition survey data from Australia and New Zealand, with current concentrations of erythrosine in food, in addition to the estimated use levels of erythrosine in foods.

The accuracy of the dietary exposure estimates depends on the quality of the data used in the dietary models. In the case of this Application, the amount of erythrosine that might be added to food, and the type of foods it is added to, is uncertain. Therefore, assumptions will have to be made, both about the foods eaten and about the levels of erythrosine in the food. These will be based on the food technology report, previous knowledge and experience, information supplied by the Applicant, and information supplied by stakeholders.

Dietary models are generally set up according to international conventions for food chemical dietary exposure estimates. Each modelling process requires decisions to be made about how to set the model parameters and what assumptions to make.

Different decisions may result in different answers. Therefore, FSANZ will clearly document all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the data available and so that FSANZ risk managers can make informed decisions.

Questions for submitters:

8. The intended use of the food colour preparations is to colour icing and other cake decorations. Are you aware of any other foods or ingredients that may be coloured with these products, either in the home or for commercial use?

9. Do you think it likely that erythrosine in icings or any other foods made with food colouring preparations (home and/or commercial use) could exceed the proposed maximum use level of 2 mg/kg?

5.3. Food technology considerations

The scope of the current food technology assessment will include an evaluation of material about the manufacture of food colouring preparations containing erythrosine supplied by the Applicant (HACCP program, Material Safety Data Sheets, and the 1993 JECFA Erythrosine monograph and other associated material) and any relevant material published in the scientific literature. The Food Technology Report will consider the evidence that erythrosine has superior colouring characteristics and whether the availability of food colouring preparations containing erythrosine reduces the use of other food colours. Issues concerning the use of food colouring preparations in home cooking and in food businesses will also be considered. Finally, the report will determine if there is a technological justification for the sale of food colouring preparations containing erythrosine.

The Application states that there is a technological need for the use of food colouring preparations containing erythrosine for colouring icing, in sprays to colour icing, in coloured sanding sugar and other related colourings for cake decorations. The Applicant notes that these products are currently available for this purpose in the USA.

The Applicant argues that erythrosine has significant advantages over alternative red colours (i.e. Red 40 Allura, Carmine) as it possesses superior colouring characteristics such as strength, longevity, lack of bleeding, the quality of the final colour, and subsequently the visual quality of the food. For example, the Applicant states that use of colour preparations containing Red 40 Allura results in foods with an orange/red colour. To achieve bright pinkish/red colours, colour preparations containing erythrosine are needed. Overall, the Applicant argues that the use of food colouring preparations containing erythrosine allows for a wider range of colours in decorating cakes (including ranges of pinks, lavenders, violets, royal blue and black), with less total colourings required to be added due to the inherent stability provided by Red 3 Erythrosine.

Additionally, other alternative colouring preparations containing Carmine (which is extracted from beetles), are not kosher, and therefore do not meet the needs of some consumers and food suppliers.

Question for submitters:

10. What is the technological need for the use of erythrosine in food colouring preparations?

RISK MANAGEMENT

6. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, including consumers, food industries and governments.

FSANZ has identified two options that are available for proceeding with assessment of Application A603. The regulatory options available for this Application are as follows:

1. Rejecting the Application so that the use of erythrosine in foods is restricted to preserved cherries known as maraschino cherries, cocktail cherries or glacé cherries (the *status quo*).
2. Amend Standard 1.3.1 to approve the retail sale of food additive preparations containing the colour erythrosine (INS 127).

7. Impact Analysis

FSANZ is required, in the course of developing regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options on all sectors of the community, including consumers, the food industry and governments in both countries. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will consult the Office of Best Practice Regulation to estimate compliance costs of regulatory options. The regulatory impact assessment identifies and evaluates the advantages and disadvantages of amendments to the standards, and their economic impacts.

7.1 Affected Parties

The potentially affected parties are:

1. Retailers of food additive preparations, such as businesses selling cake decorations;
2. Suppliers of foods that contain food colourings, such as bakeries, confectioners, caterers;
3. importers of foods containing erythrosine; and
4. consumers that use food additive preparations and consumers that purchase and consume foods made with food additive preparations

7.2 Benefit Cost Analysis

FSANZ will collect information following the release of the Initial Assessment Report that will be used to develop a regulatory impact analysis for the Draft Assessment. Stakeholders are encouraged to present data in response to this Application, considering all affected parties wherever possible.

7.3 Comparison of Options

A comparison of options will be presented following the completion of the impact analysis.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

This Application seeks the extension of the permission for the use of erythrosine set out in Standard 1.3.1. As a result, FSANZ has developed a communication strategy to Application A603. This involves advertising the availability of the Initial Assessment Report for public comment in the national press and making the Report available on the FSANZ website.

The aim of the communication strategy is to inform the food industry and consumers about the issues raised in the Application and to communicate with health professionals about the proposed change to the standard and provide them with information for their clients if this should become necessary.

The process by which FSANZ considers food standards matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ's assessment reports.

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

FSANZ provides an advisory service to the jurisdictions on changes to the Code. General information on food additives and a User Guide are available from the FSANZ website. *The official shopper's guide to food additives and labels* is also available from book stores. These publications will be updated if this should become necessary.

9. Consultation

FSANZ has a commitment towards community involvement and recognises that community involvement is a two-way process. Effective consultation begins with FSANZ being very open about food standards under development and informing the community about the processes and issues pertinent to each application and proposal. FSANZ is also very welcoming of comments on each application and proposal, either as formal submissions on assessment reports or through participation at stakeholder forums.

The purpose of this Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to stakeholders. During the assessment process, FSANZ will carry out consultation of key stakeholders. FSANZ will seek public comment following Initial Assessment in order to proceed to Draft Assessment of 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 the Initial Assessment Report know of other stakeholders who might have an interest in this Application, they should bring it 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 even if they do not provide a submission.

9.2 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.

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 Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (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 and Preferred Approach

Subsection 13(2) of the FSANZ Act prescribes those matters that FSANZ must have regard to in making an Initial Assessment. FSANZ has considered these matters and has accepted the Application.