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

16 December 2009
[20-09]

DRAFT ASSESSMENT REPORT

APPLICATION A603

RED 3 ERYTHROSINE IN FOOD COLOURING PREPARATIONS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 10 February 2010
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/foodstandards/changingthecode/

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. Permissions for addition of erythrosine range from highly restricted (EU) to use in all foods following GMP (USA), with other countries positions in-between. In Australia, New Zealand, the European Union, and in the Codex Alimentarius, the use of erythrosine is currently restricted to preserved cherries (known as maraschino cherries, cocktail cherries or glacé 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.

The Applicant is seeking to extend the use of erythrosine from a single food that is consumed in low amounts (i.e. preserved cherries) to a food additive preparation that would be added to products such as icing and frostings used in other foods such as cakes, biscuits and fancy breads. The maximum permitted level sought is 2 mg/kg, 1/100th of the level currently permitted in cherries. This would allow food suppliers to sell a wider range of products and increase consumer choice. The technological purpose of the proposed extension for the use of erythrosine would be to improve the visual appearance of cakes and other baked goods. In particular, the purpose of adding erythrosine to food is to achieve a precise visual effect and unique shades which are unattainable by using other food colours.

The toxicity of erythrosine is well-defined. The acceptable daily intake (ADI) for erythrosine is 0.1 mg/kg body weight/day. Studies evaluated as part of the current Application process provided no indication of any new safety issues related to erythrosine consumption. The risk assessment re-affirmed the ADI which remains appropriate for dietary risk assessment purposes.

Comparisons with the ADI of 0.1 mg/kg bw/day indicated that for all groups of Australian and New Zealand consumers assessed (including children), estimated dietary exposures are below 50% of the ADI, even when highly protective assumptions are made. At a concentration of 2 mg of erythrosine per kg of food, only foods that are consumed every day and in large amounts could notably contribute to exposure. Icing, and other foods that might conceivably be coloured at home, are typically eaten occasionally and only in low or moderate amounts. Therefore, exposure to erythrosine from such foods is unlikely to pose a significant health risk. It should also be noted that addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

In addition to assessing toxicity and dietary exposure, FSANZ reviewed the published evidence on intolerance reactions to erythrosine. An extensive search of the medical database revealed only a few clinical studies on the potential role of erythrosine in intolerance reactions. In some of the studies, symptoms were reported with doses of erythrosine many times higher than the ADI.

FSANZ consulted with Dr Robert Loblay, Director of the Allergy Unit at the Royal Prince Alfred Hospital, based on his medical expertise in the area of food intolerance and his extensive involvement with the diagnosis and management of intolerance patients.

Dr Loblay considered the FSANZ review to be an accurate summary of the published literature on erythrosine intolerance. Dr Loblay also noted that 'almost all patients with documented food intolerance are sensitive to more than one substance (natural and/or added)'; and cautions that 'without medical testing, patients sometimes mistakenly incriminate the most obvious food component as being responsible for their symptoms'.

On this basis, FSANZ's risk assessment concluded that the use of erythrosine as a food colouring in food colouring preparations and food containing icing at the proposed levels, does not raise any public health and safety concerns. On the available evidence supported by expert opinion, the potential for intolerance reactions resulting from small amounts of erythrosine in the diet is estimated to be very low.

The maximum levels of use set out in the amendments to Standard 1.3.1 are adequate to provide for safe use of erythrosine in preserved cherries and icing. In addition, the generic requirements of the Code are appropriate for providing consumers with information regarding foods coloured with erythrosine. FSANZ considers that any potential risk to individual consumers, who may be intolerant to erythrosine, is implicitly addressed by the requirement to label all food additives. To further assist consumers, FSANZ will publish a fact sheet on the home use of food colouring preparations to provide advice on the appropriate use of these products.

A comparison of options indicates that there are no additional costs or benefits from maintaining existing restrictions on the use of erythrosine in foods. While FSANZ did not identify any significant additional costs from the proposed amendments FSANZ invites specific feedback on any costs or benefits that could arise from this Application and how they might be described quantitatively or qualitatively.

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 decorations so that the concentration of erythrosine in the icing made does not exceed a proposed maximum use level of 2 mg/kg.

Preferred Approach

To prepare draft a draft variation to Schedule 1 of Standard 1.3.1 – Food Additives, to permit the use of the food colouring erythrosine in food colouring preparations and icing and frostings.

Reasons for Preferred Approach

This Application has been assessed against the requirements for a Draft Assessment in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ recommends the proposed draft variation to Standard 1.3.1 for the following reasons:

- A detailed hazard assessment has concluded that the use of erythrosine under the proposed conditions does not raise any public health and safety concerns. In particular, a review of the toxicity of erythrosine provided no indication of any safety issues related to its proposed use and the dietary exposure assessment indicated that estimated dietary exposures were below the safe level. Addition of erythrosine to food is self-limiting as overuse of this colour leads to less appealing shades.

- Use of erythrosine is technologically justified as a food colouring. In particular, its use to colour icing and frostings, may have certain advantages over other food colourings.

- The regulatory impact analysis concludes that there are potential benefits for both consumers and industry in extending the use of erythrosine as a food colouring and there are no specifically identified costs.
-
- The proposed draft variations to Standard 1.3.1 are consistent with the section 18 objectives of the FSANZ Act. In particular, the proposed amendments:

    - are based on risk analysis using the best available scientific evidence and ensure the protection of public health and safety by imposing maximum limits for the use of erythrosine which do not pose any safety concerns
    - do not compromise the provision of adequate information relating to food to enable consumers to make informed choices
    - are consistent with the desirability of an efficient and internationally competitive food industry and the promotion of fair trading in food
    - are consistent with written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council.

Consultation

Public comment on the Initial Assessment Report was sought from 15 September 2008 to 28 October 2008. Nine submissions were received, with almost all the submissions supporting rejecting the Application. The issues raised in the submissions have been addressed in this Report.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code 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 further considering this Application/Proposal. 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 Changing the Code 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.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 10 February 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5630

CONTENTS

INTRODUCTION **8**

1. BACKGROUND 8
1.1 Current Standard *8*
1.2 Historical Background *8*
1.3 International experience *9*
1.5 Approach to Assessment of the Application *12*
1.6 Issues Raised by the Applicant *12*
2. THE ISSUE 13
3. OBJECTIVES 13
4. KEY ASSESSMENT QUESTIONS 14

RISK ASSESSMENT **14**

5.1 RISK ASSESSMENT SUMMARY 14
5.2 DIETARY EXPOSURE ASSESSMENT 15
5.3 FOOD INTOLERANCE 16
5.4 RISK CHARACTERISATION 17
5.5 TECHNOLOGICAL JUSTIFICATION 17
5.6 ANSWERS TO RISK ASSESSMENT QUESTIONS 18
5.6.1 Are there any public health and safety issues with approving the use of erythrosine in food additive preparations? *18*
5.6.2 What is the published scientific literature and clinical evidence on intolerance reactions to erythrosine in food? *18*
5.6.3 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? *18*
5.6.4 What is the potential dietary exposure to erythrosine if food colouring products are used contrary to accepted practice in the domestic kitchen? *19*

RISK MANAGEMENT **19**

6. RISK MANAGEMENT ISSUES 19
6.1 Erythrosine as a food colouring *19*
6.2 Technological justification *20*
6.3 Potential change in consumer behaviour *20*
6.4 Labelling and consumer information *20*
6.5 Other Risk Management options considered *22*
6.6 Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals *22*
6.7 Purpose of the proposed amendments to the Code *23*
7. REGULATORY OPTIONS 24

COMMUNICATION AND CONSULTATION STRATEGY **28**

9. COMMUNICATION 28
10. CONSULTATION 29
10.1 Issues raised in submissions *29*
10.2 World Trade Organization (WTO) *32*

CONCLUSION **32**

11. CONCLUSION AND PREFERRED APPROACH 32
11.1 Reasons for Preferred Approach *33*
12. IMPLEMENTATION AND REVIEW 33
ATTACHMENT 1 - DRAFT VARIATIONS TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE* 35
ATTACHMENT 2 - SUMMARY OF ISSUES RAISED IN PUBLIC SUBMISSIONS 36

SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Assessment Report, are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa603red3e4006.cfm:

SD1: Hazard Assessment Report
SD2: Dietary Exposure Assessment Report
SD3: Food Technology Report

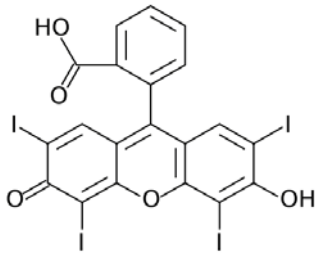
Introduction

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 Figure 1) is a cherry-pink, coal-based fluorone food dye (Figure 1). In Australia and New Zealand, 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 a variety of other foods, including cake frosting and cake-decorating gels.



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

Figure 1: Erythrosine chemical structure and synonyms

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 Ltd, SPC Ltd, 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 Ltd, 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
-
- 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.

1.3.2 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.

The Codex Committee on Food Additives (CCFA) held its Forty-first Session in Shanghai (China) from 16 to 20 March 2009. The Committee forwarded draft and proposed draft food additive provisions of the GSFA, for adoption at Step 8 and 5/8, respectively (para. 109 and Appendix IV,[1]) to the 32nd session of the Codex Alimentarius Commission. This included provisions for addition of erythrosine to 22 categories of food (Table 1). One of the permissions proposed is the addition of erythrosine to a maximum level of 300 mg/kg to category 05.4 'Decorations (e.g., for fine bakery wares), toppings (non-fruit) and sweet sauces'.

CCFA also called for information on the technological justification for use of erythrosine in food categories 08.2 'Processed meat, poultry, and game products in whole pieces and cuts' and 08.3 'Processed comminuted meat, poultry, and game products' (para. 103).

The 32nd Session of the Codex Alimentarius Commission noted the concerns of many delegations on the safety of erythrosine. In view of these concerns, the Commission returned the draft and proposed draft provisions for erythrosine to the CCFA for further discussion at its next session in the context of a refined exposure assessment by JECFA.[2]

1.3.3 Regulation in countries other than Australia and New Zealand

For synthetic permitted colours, permissions vary widely between countries. Some synthetic colours have wide permissions in one country, but are not permitted as a food additive in others. Permissions for addition of erythrosine range from highly restricted (EU) to use in all foods following GMP (USA), with other countries positions in-between.

[1] Report of the Forty-First Session of the Codex Committee on Food Additives, Shanghai, China,16-20 March 2009 http://www.idfa.org/news/stories/2009/03/2009_ccfa_rpt.pdf

[2] Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission 32nd Session, Report ftp://ftp.fao.org/codex/Alinorm09/al32REPe.pdf

1.3.1.1 Canada

In the Canadian system, synthetic food colours are the only additives that must be certified by the Health Products and Food Branch, Health Canada before being used in foods. Regulations concerning food colours are listed in Division 6, and Table III of Division 16 of the Food and Drug Regulations. Erythrosine is permitted in a wide variety of foods including icing sugar, as well as staples such as bread, dairy products and fish. Maximum levels of use vary from 80 mg/kg to 600 mg/kg. However, in Canada erythrosine primarily has limited use in various unstandardised, non-staple foods at a maximum level of 300 mg/kg.

1.3.1.2 European Union

Food additives are authorised at EU level for all the Member States (including the UK), as well as for Norway and Iceland. Erythrosine is permitted in the EU only 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.

Norway used to regulate colourings different than the EC countries. In 2001, Norway implemented the EC Directives on food additives, and today the there is no difference between the food additives legislation in Norway and the other EU Member States.

1.3.1.3 Japan

According to the Japanese standards for use of food additives, erythrosine is permitted to use in any food except for: fish pickles, fresh fish/shellfish (including whale meat), kasutera (a type of pound cake), kinako (roasted soybean flour), konbu (kelp)/wakame (sea weed) (both Laminariales), legumes/pulses, marmalade, meat, meat pickles, miso (fermented soybean paste), noodles (including wonton), nori (laver), soy sauce, sponge cakes, tea leaves, vegetables, or whale meat pickles.

There are no maximum limits of use. It should be noted that the intake of artificial colours is thought to be limited in Japan.

1.3.1.4 Korea

The Korea Food Additive Code which is administered by the Korea Food and Drug Administration (KFDA) takes a similar approach to the Japanese standard. It lists 46 foods in which erythrosine cannot be used[3]. More recently, the KFDA proposed to add 12 additional foods[4] to the current positive list.

1.3.1.5 Switzerland

Since 1 January 2006, the Swiss authorities have applied a revised food law, adapted in principle to European food law. In Switzerland, erythrosine is permitted in cherries and cocktail cherries to a maximum of 200 mg/kg.

[3] For the full listing see: http://fa.kfda.go.kr/foodadditivescode.html

[4] Dairy products including ice cream, ice cream mix and ice cream powder, fruit and vegetable drinks, fish processed products, breads, ready to eat products, dry confectionary (including biscuits, cookies, crackers, chips and other but excluding Korean traditional cookies), candies, chocolates, ice candy, carbonated drinks, mixed drinks, toasted cereal flakes (so called breakfast cereal).

1.3.1.6 USA

In the US, erythrosine may be used as a colouring in any food in amounts consistent with Good Manufacturing Practice (GMP). In 1990, the United States Food and Drug Administration (USFDA) withdrew 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.

1.5 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:

- toxicological data, food intolerance data and hazard assessment
- expert advice on intolerance to erythrosine
- food technology report
- dietary exposure assessment
- impact analysis (cost-benefit).

1.6 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 bw/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 (according to Jewish dietary law) and therefore unsuitable for some consumers.
- Extending the permission for use of erythrosine would increase consumer choice.
- 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.

2. The Issue

The Applicant is seeking to extend the use of erythrosine from a single food that is consumed in low amounts (i.e. preserved cherries) to a food colouring 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
- 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; and
- 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 is the published scientific literature and clinical evidence on intolerance reactions to erythrosine in food?

3. 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?

4. What is the potential dietary exposure to erythrosine if food colouring products are used contrary to accepted practice in the domestic kitchen?

RISK ASSESSMENT

5.1 Risk Assessment Summary

A hazard assessment was conducted as part of this Application. For the full Hazard Assessment Report see **Supporting Document 1**[5].

The toxicological database for erythrosine is extensive and adequate to establish a suitable health standard for regulatory purposes. The current acceptable daily intake (ADI) for erythrosine, as established in 1990 by JECFA is 0.1 mg/kg bw/day.

FSANZ has evaluated a range of supplementary studies published since the last comprehensive toxicological evaluation of erythrosine by JECFA in 1990. The studies covered metabolism, reproduction and developmental toxicity, genotoxicity, in addition to a range of other studies.

The toxicity profile of erythrosine is well-defined. It is poorly absorbed from the digestive tract in both rats and humans and distributes almost entirely to the liver, where it is excreted unchanged in the bile. Erythrosine has low acute oral toxicity, does not cause reproductive or developmental toxicity, and the weight-of-evidence indicates that it is unlikely to be genotoxic. In both humans and rats, repeated ingestion results in elevated serum thyroid stimulating hormone (TSH) levels.

[5] http://www.foodstandards.gov.au/foodstandards/applications/applicationa603red3e4006.cfm

In humans, at doses above 1.0 mg/kg bw/day this is associated with increased serum iodine, while in rats, there is compelling evidence that this is due to the inhibition of the peripheral metabolism of thyroxine (T_4) to tri-iodothyronine (T_3) in the liver at and above doses of 2.5 mg/kg bw. Erythrosine does not directly act on the thyroid gland in either species. The weight-of-evidence indicates that erythrosine is not carcinogenic, however, benign thyroid tumours have been observed at very high doses (>2500 mg/kg bw/day) in a minority of long-term feeding studies in rats. It is most likely that the occurrence of these tumours was secondary to the compound's hormonal effects and is not relevant to humans based on well-recognised interspecies differences in thyroid physiology.

Based on a consideration of all of the available studies, including the supplementary ones published since 1990 when JECFA last considered the toxicity of erythrosine, FSANZ is unable to find a basis to amend the ADI of 0.1 mg/kg bw/day established by JECFA. This evaluation re-affirms the ADI established by JECFA in 1990. Therefore, an ADI of 0.1 mg/kg bw/day is appropriate for dietary risk assessment purposes.

As part of the hazard assessment, FSANZ considered information published in the medical literature on intolerance reactions to erythrosine. An extensive search of the medical database revealed only a few clinical studies on the potential role of erythrosine in intolerance reactions. The studies investigated the effect of erythrosine on a number of clinical patients with various symptoms. The patients were challenged with various doses of erythrosine, from 1 mg up to 30 mg. In some of the studies, symptoms were reported with the higher doses of erythrosine, many times higher than the ADI. Although it is not possible to estimate, based on the available evidence, the prevalence of intolerance reactions to erythrosine in the general population, it is unlikely to be common. As erythrosine is poorly absorbed from the gastrointestinal tract, the exposure and, therefore the potential for intolerance reactions resulting from the small amounts of erythrosine in the diet, would be very low.

5.2 Dietary Exposure Assessment

FSANZ conducted a dietary exposure assessment for the food colouring erythrosine based on the information provided by the Applicant. For the full Dietary Exposure Assessment Report see **Supporting Document 2**[6].

The purpose of the dietary exposure assessment was to estimate dietary exposure to the food colouring erythrosine for the Australian and New Zealand populations if the permitted use of erythrosine is extended as proposed. Dietary exposure was estimated for the addition of erythrosine according to existing and proposed permissions, at levels not exceeding the maximum use level and also assuming that poorly controlled conditions in home cooking result in using ten times the proposed maximum amount of erythrosine in icing.

The exposure assessment shows that:

- if the use of erythrosine is extended to foods with icing, consumers including children are highly unlikely to exceed the Acceptable Daily Intake (ADI) for erythrosine of 0.1 mg/kg bodyweight/day
-

[6] http://www.foodstandards.gov.au/foodstandards/applications/applicationa603red3e4006.cfm

- all estimated dietary exposures for the population groups assessed are below 50% of the ADI, even when highly protective assumptions are made

- consumption of iced foods coloured with erythrosine would increase erythrosine exposure only marginally, because the vast majority of exposure rests with the existing permissions
-
- home use of erythrosine is unlikely to lead to exposure of concern even if erythrosine is used at ten times the proposed maximum level in all iced home cooked foods

- at a concentration of 2 mg of erythrosine per kg of food, only foods that are consumed every day and in large amounts could notably contribute to exposure. Icing, and other foods that might conceivably be coloured at home, are typically eaten occasionally and only in low or moderate amounts. Therefore, exposure to erythrosine from such foods is unlikely to pose a significant health risk.

Contributors to dietary erythrosine exposure are canned fruit with cherries, preserved cherries, commercial food with icing, home cooked food with icing, and coloured icing that consumers reported consuming as a standalone food item. Canned fruit salads containing cherries are the most important contributor to erythrosine dietary exposures, even if the use of the colouring is extended to iced foods. This reflects the much higher permitted concentration of erythrosine in preserved cherries.

Should the requested uses of erythrosine be approved, mean consumer dietary exposures are estimated at no more than 0.3 mg/day or up to 0.02 mg/kg bw/day. Dietary exposures for consumers at the 90th percentile would be less than 1 mg/day or 0.05 mg/kg bw/day.

5.3 Food Intolerance

Adverse reactions to food are well recognized, and many heterogeneous mechanisms have been identified, not only immunological (IgE-mediated) food allergy, but also non-immunological reactions like pseudo-allergy, enzyme deficiencies, toxic effects of food constituents and intolerance reactions. In the assessment of this Application, FSANZ has gathered and reviewed the published scientific literature on intolerance reactions to erythrosine in food. This information has been considered as part of the risk assessment included in this Draft Assessment Report.

Whereas the toxicological effects of a substance are predominantly a consequence of the nature of that substance, with some degree of variation in individual sensitivity, and are therefore largely predictable, intolerances by contrast are primarily a manifestation of the physiology of the affected individual and only secondarily a consequence of the substance itself. Thus, individuals with food intolerances will generally react to a range of unrelated natural and synthetic substances which can be consumed by other individuals without problems. For this reason, the long established national and international approach to managing toxicological hazards is to limit the amounts of a substance that can be added to food to ensure that consumers do not ingest sufficient to produce harmful effects, and the risk of food intolerances are managed by giving consumers the information necessary to identify ingredients in food and to make informed choices about what they eat.

5.4 Risk Characterisation

The toxicity of erythrosine is well defined. Supplementary studies published since JECFA last considered the toxicity of erythrosine were evaluated as part of the current Application. The new studies provided no indication of any safety issues related to erythrosine. This evaluation supports the ADI established by JECFA in 1990.

Comparisons with the ADI of 0.1 mg/kg bw/day indicated that for all groups of Australian and New Zealand consumers assessed (including children) estimated dietary exposures are below 50% of the ADI, even when highly protective assumptions are made. At a concentration of 2 mg of erythrosine per kg of food, only foods that are consumed every day and in large amounts could notably contribute to exposure. Icing, and other foods that might conceivably be coloured at home, are typically eaten occasionally and only in low or moderate amounts. Therefore, exposure to erythrosine from such foods is unlikely to pose a significant health risk.

An extensive search of the medical database revealed only a few clinical studies on the potential role of erythrosine in intolerance reactions. In some of the studies symptoms were reported with doses of erythrosine many times higher than the ADI. On the available evidence, the potential for intolerance reactions resulting from small amounts of erythrosine in the diet is estimated to be very low.

On this basis, it is concluded that there is unlikely to be an appreciable public health risk from the proposed use of erythrosine.

5.5 Technological Justification

A food technology review was undertaken as part of this Application. For the complete Food Technology Report see **Supporting Document 3**[7].

The red colouring erythrosine is used around the world in various foods and food ingredients, ingested drugs and as a biological stain. Food colourings are used in food products for the maintenance and restoration of natural colourings lost during processing and for general improved visual appearance to produce aesthetically and psychologically pleasing foods. The proposed extension for the use of erythrosine in food colouring preparations would be to aesthetically improve the visual appearance of cakes and other baked goods.

The Applicant claims that there is a technical need to extend the use of the red food colouring erythrosine in Australia and New Zealand from its current usage in preserved cherries to food additive preparations primarily used to colour icing and other cake decorations. This has been substantiated with the Applicant's claims and some industry experience that erythrosine food colouring preparations have superior colouring characteristics compared to alternative red food colourings. Included in these claims are properties such as the colour strength, longevity, lack of bleeding and overall quality of the finished product.

In particular, Americolor™ Corporation and CK Products are two of the largest companies who use erythrosine in products for cake decorating purposes.

[7] http://www.foodstandards.gov.au/foodstandards/applications/applicationa603red3e4006.cfm

They have advised the Applicant that the purpose of adding erythrosine to food is to achieve a precise visual effect and unique shades which are unattainable by using any other food colours. The colour hue and intensity is directly affected by the amounts of erythrosine added and the proposed amounts are consistent in achieving the intended result – to colour the food. Colour combinations are individually weighed and added to the mix for each single recipe so that a consistent final effect is obtained. Addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

Currently in both Australia and New Zealand, red colourings used in cakes and cake decorating include combinations of artificial food colouring such as Allura Red AC, Ponceau 4R, Azorubine/Carmoisine and Amaranth, with permitted natural red food colourings also including Carmine and Beetroot Red. There is limited published evidence, although there is some industry experience that suggests that the bleeding properties and strength of erythrosine are superior to other available red food colourings used in cake decorating and/or icing manufacturing.

However, unlike preserved cherries, heat stability of the red colouring is not an issue in cake icings and cake decorating. Colouring is added after the baking process; therefore erythrosine does not undergo a high heat retort treatment as in the case of preserved cherries in canned fruit salads.

5.6 Answers to Risk Assessment Questions

5.6.1 Are there any public health and safety issues with approving the use of erythrosine in food additive preparations?

The use of erythrosine under the proposed conditions does not raise any public health and safety concerns. At a concentration of 2 mg/kg of erythrosine any food that is not consumed in large amounts on a daily basis is highly unlikely to pose a significant health risk. Comparisons with the ADI indicated that for all estimated dietary exposures are below 50% of the ADI, even when highly protective assumptions are made.

5.6.2 What is the published scientific literature and clinical evidence on intolerance reactions to erythrosine in food?

There are only a few clinical studies on the potential role of erythrosine in intolerance reactions. In some of the studies, symptoms were reported with doses of erythrosine many times higher than the ADI. As erythrosine is poorly absorbed from the gastrointestinal tract the potential for intolerance reactions resulting from small amounts of erythrosine in the diet would be very low.

5.6.3 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?

Should the requested uses of erythrosine be approved, mean consumer dietary exposures are estimated at no more than 0.3 mg/day or up to 0.02 mg/kg bw/day. Dietary exposures for consumers at the 90th percentile would be less than 1 mg/day or 0.05 mg/kg bw/day.

5.6.4 What is the potential dietary exposure to erythrosine if food colouring products are used contrary to accepted practice in the domestic kitchen?

Home use of food colouring preparations containing erythrosine is unlikely to lead to exposure of concern even if erythrosine is used at ten times the proposed maximum level in all iced home cooked foods. It is highly unlikely that foods other than icing to which erythrosine could be added in the home would be consumed in sufficient quantities on a daily basis to lead to levels of dietary exposure that pose a significant health risk.

Risk management

FSANZ has considered the management of any risks identified through the risk assessment and submissions received during the public consultation period following the Initial Assessment Report.

6. Risk management issues

6.1 Erythrosine as a food colouring

Following the conclusions of the risk assessment, the purpose of risk management is to provide a regulatory mechanism for the safe use of erythrosine in a wider variety of foods than currently permitted and to manage any risks or issues identified from the risk assessment. FSANZ's risk assessment concludes that the use of erythrosine as an ingredient in food colouring preparations following GMP and food containing icing at the proposed level of 2 mg/kg does not raise any public health and safety concerns.

The maximum levels of use set out in the proposed amendments to Standard 1.3.1 (in **Attachment 1**) are adequate to provide for safe use of erythrosine in preserved cherries and icing. In addition, the general requirements of the Code are appropriate for providing consumers with information regarding foods coloured with erythrosine. To further assist consumers, FSANZ will publish a fact sheet on the home use of food colouring preparations to provide advice on the appropriate use of these products. No other additional risk management measures are proposed.

It is proposed to allow the use of erythrosine under GMP in food colouring preparations (under the food additive category of 0.1 Preparation of food additives) rather than setting a maximum permitted level for the following reasons:

- Food colouring preparations are not foods that are intended to be consumed in their own right. Therefore setting a maximum limit for the colouring concentrate will not control the level of the colouring in the final food for the consumer.
-
- There is no toxicity risk that needs to be managed by setting a maximum permitted level in food colouring preparations.

- Maximum permitted levels are not intended for foods prepared and consumed at home. The provisions of the Code apply only to food products sold or prepared for sale in Australia or New Zealand or imported into Australia or New Zealand (clause 1(1) of Standard 1.1.1). Food prepared and consumed at home falls outside the application of the Code.

- It allows manufacturers to formulate food colouring preparations that, when used following manufacturer's instructions, suit a variety of food applications.

- The usage of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

There will be a maximum permitted level of 2 mg/kg for icing and frostings, which will apply to all food that contains icing or frostings sold to the public. Use of erythrosine in foods sold to the public other than icing and preserved cherries remains prohibited. This provides the appropriate regulatory mechanism for the safe use of erythrosine.

6.2 Technological justification

The Applicant has highlighted the superior technological properties of erythrosine compared with other food colours. The FSANZ Food Technology Report (see **Supporting Document 3**) partially supports these claims. However, it also indicates that alternative food colourings are available to industry and for home cooking. Therefore some stakeholders could argue that FSANZ could propose to reject this Application. However, the risk assessment conclusion does not indicate that there are public health and safety concerns that would form the basis for rejecting the Application. As outlined in section 7, the availability of other red food colourings may not offer sufficient grounds to reject the Application under the FSANZ Act. In addition, the Food Technology Report supports the claim that erythrosine has particular advantages over alternative colours by providing a precise visual effect and unique shades unattainable from other colours.

6.3 Potential change in consumer behaviour

There is no evidence to suggest that food consumption behaviour would change through permitting the use of erythrosine as a food colouring in icing and frostings. However, the assumptions made in the assessment are sufficiently protective to take account of some potential changes in consumer behaviour: all iced foods are assumed to be coloured with erythrosine, and at ten times the level permitted in food sold to the public. Regardless, consumers including children are still unlikely to exceed the ADI of 0.1 mg/kg bw/day. No risk management options are therefore required since the Dietary Exposure Assessment Report (**Supporting Document 2**, summarised in section 5.2) concludes that there is no risk to consumers at the proposed use levels of erythrosine.

6.4 Labelling and consumer information

Labelling provisions are included within the Code to protect public health and safety and to provide an important source of information for consumers. Labelling enables consumers to make informed decisions regarding their consumption of food additives, including food colourings.

On the basis of the risk assessment, FSANZ considers the general labelling requirements of the Code as they currently stand appropriately manage the risk and provide adequate information to consumers regarding foods containing erythrosine. No additional mandatory labelling is proposed.

6.3.1. Labelling of ingredients

The general labelling requirements of the Code applicable to packaged foods that contain food additives include the mandatory listing of ingredients (Standard 1.2.4 – Labelling of Ingredients). In accordance with these existing requirements, foods sold to the public that have been coloured with erythrosine must declare the food additive in the ingredient list.

This requirement will also apply to the sale of food colouring preparations containing erythrosine. In the case of a food colouring preparation where erythrosine is the only ingredient, the preparation will be required to be labelled with the additive which would otherwise be listed in the ingredient list. The declaration of erythrosine will therefore alert consumers to the presence of erythrosine in foods and may be used by consumers to avoid foods containing erythrosine if they so wish.

6.3.2 Labelling of directions for use

As the Applicant's intended use for the sale of food colouring preparations containing erythrosine is to colour icings and frostings, FSANZ considered mandating such directions for use on the label by amending Standard 1.2.6 – Directions for Use. The purpose of Standard 1.2.6, as defined in the Code, is to provide directions where, for reasons of health and safety, the consumer should be informed of specific use requirements. FSANZ's risk assessment, however, concludes that the use of erythrosine in food colouring preparations following GMP does not raise any public health and safety concerns. FSANZ does not therefore consider the inclusion of directions within Standard 1.2.6 to be appropriate for this Application.

FSANZ acknowledges that some consumers may use food colouring preparations in the home for purposes other than icings and frostings. FSANZ considered a number of foods that may conceivably be coloured with red food colouring in the home. The dietary exposure assessment shows that consumption of beverages coloured with erythrosine, such as milk and cordials, might potentially lead to exposures close to the ADI for erythrosine. However, at a concentration of 2 mg/kg, even small children would have to consume three 300 mL serves of beverages that have been coloured with erythrosine daily, over a lifetime, to exceed the ADI. However, it was noted that there is no evidence that such behaviour is likely to occur. Taking these factors into account, FSANZ considers that mandating any additional labelling within the Code (e.g. within Standard 1.2.6 or Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations) to regulate for the possibility of unusual consumption patterns in the home, without evidence of this behaviour, is not justified.

6.3.2 Labelling for food intolerances

FSANZ acknowledges that some consumers may be sensitive to erythrosine in food. The current general labelling requirement to declare food additives in the ingredient list will enable consumers who may be sensitive to erythrosine to identify those products containing erythrosine. This labelling requirement can be likened to the declaration requirement for allergens in food (Standard 1.2.3), which provides a comparable risk management strategy. The Hazard Assessment Report (see **Supporting Document 1**) concludes that the potential for intolerance reactions from the small amounts of erythrosine in the diet, would be very low. FSANZ, therefore, considers the current declaration requirement for food additives to be commensurate with the level of risk posed from intolerances to erythrosine.

6.3.3 Additional consumer information

To further assist consumers, FSANZ will publish a fact sheet on the home use of food colouring preparations to provide advice on the appropriate use of these products. In addition, FSANZ has recently published 'Choosing the Right Stuff - the official shoppers' guide to food additives and labels, kilojoules and fat content' which is available in bookshops.

This guide provides consumers with the information they need to purchase products that do not contain the food additives they wish to avoid. Lists of food additives are also available from FSANZ's website under the link to 'the Code' or under 'food additives' from the 'quick links' toolbar on the homepage. The New Zealand Food Safety Authority has also produced a pocket sized booklet entitled 'Identifying Food Additives' available from their website.

6.5 Other Risk Management options considered

The conclusion of the risk assessment conducted by FSANZ does not support any alternative or more detailed risk management options than proposed in the sections above. FSANZ is aware from public submissions received and consultation conducted on this Application that there is some opposition and disquiet from a number of stakeholders to the extension of use of the colouring, erythrosine, to other foods.

Because of this concern FSANZ further investigated other risk management strategies, over and above those discussed earlier. These alternative options are discussed below.

6.5.1 Explicit maximum permitted limit for erythrosine in colour preparations, not GMP

FSANZ considered the use of a maximum permitted limit for erythrosine in colour preparations within item 0.1 – Preparations of food additives in Schedule 1 of Standard 1.3.1 rather than GMP. (GMP refers to using the minimum amount of the food additive required to perform the technological function). A maximum permitted level could be set for the colouring concentrate but it would need to be practical for commercial colouring preparations. However, having a maximum permitted limit for the concentrated colouring would have no impact on the final use of the colouring to colour icing or frosting. As section 5.4 and the Food Technology Report (**Supporting Document 3**) indicates use of the colouring is self limiting since addition of too much colour produces less appealing colours.

6.6 Policy Guideline on the Addition to Food of Substances other than Vitamins and Minerals

In developing or reviewing food regulatory measures and variations of food regulatory measures FSANZ must have regard to any relevant written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council

The Policy Guideline on *The Addition to Food of Substances other than Vitamins and Minerals* (the Guideline) provides guidance on the addition to food of substances other than vitamins and minerals. This includes substances intentionally added solely for a technological purpose, such as food additives and processing aids.

Food colourings, including erythrosine, are food additives used in food products to improve the visual appearance and to produce aesthetically and psychologically pleasing foods. The proposed extension for the use of erythrosine in food colouring preparations would be for the sole technological purpose to improve the visual appearance of cakes and other baked goods.

The Guideline states that the addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where the substance meets a number of safety and technological objectives.

Having given due regard to the Guideline, FSANZ concluded that the addition of erythrosine should be permitted as proposed for the following reasons:

- the purpose for adding erythrosine to food as proposed has been articulated clearly by the manufacturer as achieving a solely technological function of a food colouring (see section 5.4 and Supporting Document 3)

- the proposed addition of erythrosine to food is safe for human consumption (see sections 5.1 and 5.2; Supporting Documents 1 and 2)

- the proposed amounts of erythrosine added are consistent with achieving the technological function (see section 5.4 and Supporting Document 3)

- erythrosine would be added in a quantity and a form which is consistent with delivering the stated purpose of aesthetically improving the visual appearance of cakes and other baked goods (see section 5.4 and Supporting Document 3)

- no nutrition, health or related claims are to be made in regard to erythrosine.

6.7 Purpose of the proposed amendments to the Code

Permission for the use of food colourings are set out in Schedules 1, 3 and 4 of Standard 1.3.1.

The purpose of the proposed amendments to Standard 1.3.1 is to permit the sale of two categories of food:

1. *food colour preparations* containing an amount of erythrosine that, following GMP, is suitable for use in home cooking and for commercial use

2. *icing and frostings* containing erythrosine so that the concentration of erythrosine in the icing sold does not exceed a proposed maximum use level of 2 mg/kg.

6.7.1 The sale of food colour preparations containing erythrosine

Food colouring preparations which are sold to consumers to colour food, are regulated as foods. The food additive permissions for these products are under item 0.1 Preparations of food additives within Schedule 1 of Standard 1.3.1. Currently only the colours within Schedule 3 and 4 of this Standard are permitted in colour preparations.

Erythrosine is not listed in either Schedule 3 or 4, so there is currently no permission in the Code for erythrosine to be added to colouring preparations. Therefore an amendment to item 0.1 is required to permit erythrosine colour concentrates to be sold.

The purpose of the amendments to item 0.1 is to permit the sale of food additive preparations containing erythrosine following GMP (see **Attachment 1**).

6.7.2 The sale of icing and frostings containing erythrosine

Currently the only permission in the Code for use of erythrosine to colour preserved cherries known as maraschino cherries, cocktail cherries or glacé cherries within the food category 4.3 Processed fruits and vegetables in Schedule 1 of Standard 1.3.1. Erythrosine is not permitted to colour any other types of food within this Schedule.

Erythrosine is currently permitted to be added to preserved cherries only up to a maximum of 200 mg/kg (item 4.3 of Schedule 1). Schedule 1 permissions for additives in icing and frostings are set out in item 5.4. The purpose of amendments to this item is to permit the addition of erythrosine to icings and frostings to a maximum permitted level of 2 mg/kg (see **Attachment 1**).

7. Regulatory Options

Two regulatory options have been identified for this Application: to permit the use of erythrosine as proposed by the Applicant with appropriate risk management in place or to reject the Application and maintain the *status quo:*

Option 1 To reject the Application and maintain the *status quo* and restrict erythrosine to preserved cherries only up to a maximum of 200 mg/kg (Standard 1.3.1, Schedule 1, section 4.3).

Option 2 Permit the sale of food colouring preparations containing erythrosine for use in home cooking and for commercial use. The intended use of the food additive preparations is to colour icing and other cake decorations so that the concentration of erythrosine in the icing does not exceed 2 mg/kg.

This Application must be assessed against the requirements for a Draft Assessment in the FSANZ Act. The FSANZ Act sets out the possible grounds for rejection of an Application. If FSANZ decides to reject an Application this needs to be done for sound reasons, based on solid evidence, must be legally defensible and may require one or more of the following:

- A detailed hazard assessment has concluded that the use of erythrosine under the proposed conditions raises public health and safety concerns.
- Use of erythrosine as proposed does not achieve its purpose, i.e. erythrosine is unsuitable for colouring icing.
- The regulatory impact analysis concludes that the potential cost exceeds the potential benefit.

- The proposed draft variations to Standard 1.3.1 are inconsistent with one of the section 18 objectives of the FSANZ Act, in particular, the proposed amendments:

    - do not ensure the protection of public health and safety
    - compromise the provision of adequate information to enable consumers to make informed choices
    - are inconsistent with the desirability of an efficient and internationally competitive food industry and the promotion of fair trading in food
    - are not consistent with written policy guidelines formulated by Ministerial Council.

Standard 1.3.1 states that *Additives can only be added to food in order to achieve an identified technological function according to Good Manufacturing Practice*. It further defines that *technological function means a function set out in Schedule 5*, where Schedule 5 sets out the functional classes of food additives. Erythrosine falls within the functional class of Colouring, and therefore must add or restore colour to food to satisfy the requirements of Standard 1.3.1.

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

The permissions for the use of food colours (being food additives in the Code) used in Australia and New Zealand are set out in Standard 1.3.1, and it is therefore not appropriate to consider non-regulatory options.

8. Impact Analysis

In the course of developing food regulations for adoption in Australia and New Zealand, FSANZ considers the impact of the regulatory options put forward on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates the advantages and disadvantages of each Option, and their economic impacts. Where medium to significant impact or compliance costs are likely, FSANZ will estimate compliance costs of regulatory options and consult further with the Office of Best Practice Regulation (OBPR) regarding the Regulatory Impact Statement. The level of analysis is determined by the nature of the Application or Proposal.

FSANZ has consulted the OBPR with regard to Application A603- Red 3 Erythrosine in Food Colouring Preparations, and they have deemed the Regulatory Impact Statement to be adequate.

8.1 Affected Parties

The affected parties identified at Draft Assessment 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 and caterers.
3. Artisan and specialist cake decorators and caterers

4. Importers of foods containing erythrosine.
5. Consumers who purchase and consume the above.
6. Government agencies involved in enforcing the Food Standards Code.

8.2 Benefit Cost Analysis

8.2.1 Option 1: Status Quo

There are no additional costs or benefits associated with maintaining the status quo. Erythrosine in foods would be restricted to preserved cherries known as maraschino cherries, cocktail cherries or glacé cherries.

8.2.2 *Option 2: Permit the sale of food colouring preparations containing erythrosine for use in home cooking and for commercial use. The intended use of the food additive preparations is to colour icing and other cake decorations so that the concentration of erythrosine in the icing does not exceed 2 mg/kg.*

8.2.2.1 Costs

A detailed risk assessment has concluded that the use of erythrosine under the proposed conditions does not raise any public health and safety concerns. However, some submissions expressed concern over the safety of erythrosine as a food additive. In particular, they were concerned with adverse effects for sensitive individuals. However, on the available evidence supported by expert opinion, the potential for intolerance reactions resulting from small amounts of erythrosine in the diet is estimated to be very low and sensitive individuals would be likely to have intolerance reactions to a range of foods, including other food colourings.

As was shown in Section 6, labelling is an effective risk management measure to provide protection from substances that may cause intolerance, sensitivities or allergic reactions. FSANZ therefore considers that any potential risk to individual consumers, who may be intolerant to erythrosine, is implicitly addressed by the requirement to declare food additives in the statement of ingredients. The labelling and information requirements set out in the Code allow consumers who are sensitive and/or intolerant to erythrosine to avoid products containing erythrosine and any associated discomfort due to their consumption.

In cases where foods are displayed unpackaged for retail sale, there may be some potential costs to consumers through the inability of those consumers to identify and therefore avoid erythrosine in particular. However, consumers can readily identify where a food colouring has been added to icing and avoid such foods. Moreover, as stated above, the risk assessment indicates that it is highly unlikely that an individual would be intolerant just to erythrosine and not other food colourings. This view was supported by Dr Loblay, the director of the Allergy Unit at the Royal Prince Alfred Hospital, who noted that ‘almost all patients with documented food intolerance are sensitive to more than one substance (natural and/or added)’. Therefore, sensitive individuals most likely would avoid such foods in any case, which further reduces any potential additional costs related with extending the use of erythrosine as proposed *per se*.

It is acknowledged that identifying and dealing with issues of food intolerance may have costs for affected individuals and their families. It can take years of medical analysis to identify sources of intolerance and to identify appropriate management strategies.

As noted above, it is unlikely that such intolerances could be attributed to erythrosine alone. Therefore, it would be difficult to identify the proportion of costs associated with food intolerance from granting an extension of use for erythrosine.

Some submitters expressed a concern that granting a permission to extend the use of erythrosine may lead some consumers to avoid products with other food colourings, given recent interest in food colours. While no detail was provided, the comments may have reflected a concern that there could be a reduction in sales of foods that do not contain erythrosine, if consumers develop a desire to avoid all food colours as a result of this Application, increasing their concerns about food colours as a group.

FSANZ estimates that there will be only minor additional cost impost on jurisdictions to determine compliance with the proposed amendment compared with current monitoring and compliance activities of foods containing erythrosine.

Overall, additional costs from Option 2 are expected to be low as the use of erythrosine is highly restricted to few foods, the amounts added are very low, and consumers who are intolerant to erythrosine will be able to avoid it in packaged products, as this is a voluntary permission. As stated above, consumers with intolerance to erythrosine are also likely to be intolerant to other colours and are likely to be avoiding those products, whether labelled or unlabelled.

At Initial Assessment, FSANZ requested information from stakeholders and affected parties detailing any costs associated with this option. No specific quantitative estimates were provided and/or available. Subsequently, FSANZ consulted the OBPR, who advised that the approach taken to this cost benefit analysis was suitable for this Application (OBPR ID: 9856).

However, prior to finalising this Application FSANZ will be considering whether it can better assess less tangible costs, such as some of those identified above. To assist in that process, we seek specific feedback on any costs (or benefits) that could arise from this Application and how they might be described quantitatively or qualitatively.

8.2.2.2 Benefits

Use of erythrosine is technologically justified as a food colouring agent and has better functionality in certain foods compared to alternative red colourings. Therefore its extended use could potentially benefit the food industry and consumers. A submission stated that several products had lost market share or ceased production due to restrictions in erythrosine use.

Quantitative estimates regarding benefits and increased market growth opportunities were not provided.

Consumers would benefit from increased choice in availability of foods containing erythrosine. For example, erythrosine can be certified as Kosher unlike other red colourings such as cochineal/carmine.

8.3 Comparison of Options

A comparison of options indicates that there are no additional costs or benefits from maintaining existing restrictions on the use of erythrosine in foods.

Amending Standard 1.3.1 to approve the retail sale of food additive preparations containing the colour erythrosine (INS 127) does not have any significant additional costs. Further, the Application is technologically justified and has potential benefits for food manufacturers and consumers. Therefore at Draft Assessment, Option 2 i.e. amending Standard 1.3.1 to approve the retail sale of food additive preparations containing the colour erythrosine, has a greater net benefit and is the preferred option.

FSANZ would like to invite stakeholders and affected parties to provide quantitative estimates (if available) as well as any other information or comments in regard to the following questions:

What are the potential costs and/or benefits of the proposed risk management options to you as a stakeholder?

Are there other affected parties that have not been identified in this regulatory impact statement that you feel should be included?

Are there other costs or benefits that you feel should be considering in the regulatory impact statement?

Do you consider that the benefits of approving this application outweigh the costs? If you have any data or information to support your view, FSANZ would welcome the opportunity to consider it.

Are there other costs or benefits for consumers that have not been covered in the regulatory impact statement?

Do you consider that any identified health costs i.e.: consumers with intolerances and/or sensitivities outweigh the benefits to others?

Are there other costs or benefits for business that have not been covered in the regulatory impact statement??

Are there other costs or benefits for government that have not been considered in the regulatory impact statement?

Communication and consultation strategy

9. 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 for Application A603. This involves advertising the availability of the Draft 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.

10. Consultation

Public comment on the Initial Assessment Report was sought from 15 September 2008 to 28 October 2008. Nine submissions were received, with almost all the submissions supporting rejecting the Application. **Attachment 2** summarises the submissions received during this first round of public comment. Issues raised in these submissions and FSANZ's response to these are discussed in section 10.1.

FSANZ is seeking further public comment on this Application to assist in finalising the assessment. The purpose of this Draft Assessment Report is to seek further input on a range of issues known to be of interest to stakeholders. FSANZ will seek public comment following Draft Assessment to assist in finalising the assessment.

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.

10.1 Issues raised in submissions

Several issues were raised in submissions to the Initial Assessment Report, which have been addressed at Draft Assessment. They have been dealt with in the body of the Report and in the attachments, but will be summarised here as well.

10.1.1 Safety concerns with extending the use of erythrosine

10.1.1.1 Submitters' views

Some submitters were concerned about reactions to erythrosine in sensitive individuals. There was a view that erythrosine was a dangerous and unnecessary food additive, and its use should therefore remain restricted.

10.1.1.2 FSANZ evaluation

The toxicological database for erythrosine is extensive and adequate to establish a suitable health standard. FSANZ assessment re-affirms the ADI of 0.1 mg/kg bw/day established by JECFA in 1990 as appropriate for dietary risk assessment purposes. The dietary exposure assessment shows that if the use of erythrosine was extended to foods with icing, all estimated dietary exposures for the population groups assessed were below the ADI, even when it is assumed that erythrosine is used at ten times the proposed maximum level in home cooked foods.

In summary, FSANZ's risk assessment concludes that the use of erythrosine as a food colouring in food colouring preparations and food containing icing at the proposed level does not raise any public health and safety concerns.

10.1.2 Move by industry away from the use of erythrosine

10.1.2.1 Submitters' views

Industry submissions suggested that there had been a move by industry away from the use of erythrosine and that any extension of current permissions would not be helpful.

10.1.2.2 FSANZ evaluation

FSANZ recognises that some consumers wish to avoid foods containing certain additives. In response to consumer demand, some Australian food suppliers appear to be moving towards removing artificial colours from their formulations, in particular in foods for children. This would be helpful to those consumers who wish to avoid those additives by increasing the range of foods available to these consumers. Approving this Application would not impede food suppliers from removing artificial food colourings from their products.

10.1.3 International regulation of erythrosine

10.1.3.1 Submitters' views

Several submitters pointed out that, while the US allows erythrosine to be used under GMP, the restriction to the use of erythrosine in Australia and New Zealand are consistent with Codex and the European Union.

10.1.3.2 FSANZ evaluation

As pointed out by submitters, there is no internationally consistent approach to the use of erythrosine.

The FSANZ assessment is based on the internationally accepted ADI of 0.1 mg/kg bw/day established by JECFA in 1990 as appropriate for dietary risk assessment purposes and Australian and New Zealand food consumption data. CCFA forwarded draft and proposed draft food additive provisions for addition of erythrosine to 22 categories of food in the GSFA to the Codex Alimentarius Commission.

This included the proposed addition of erythrosine to a maximum level of 300 mg/kg to decorations for fine bakery wares and non-fruit toppings. The proposed extension of erythrosine permission in the Code is consistent with proposed extension of permissions in the Codex GSFA, however, the proposed concentration of at 2 mg/kg for icings and frostings is considerably lower than the levels proposed for the GSFA.

10.1.4 Technological need for extending the use of erythrosine

10.1.4.1 Submitters' views

Most submitters questioned the technological need for extending the use of erythrosine.

10.1.4.2 FSANZ evaluation

The proposed extension for the use of erythrosine in food colouring preparations fulfils the technological need to improve the visual appearance of cakes and other baked goods.

FSANZ acknowledges that, unlike preserved cherries in canned fruit salad, heat stability of the red colouring is not an issue in cake icings and cake decorating as the colouring is added after the baking process has been completed.

10.1.5 Consumer benefit

10.1.5.1 Submitters' views

Several submitters were of the opinion that there was no evidence that consumers wanted foods containing erythrosine, and that on the contrary, there was a growing consumer demand for foods using natural food colouring.

10.1.5.2 FSANZ evaluation

Synthetic and natural colours are routinely added to food and beverages as a visual cue for quality, to induce the perception of flavour and to meet consumer expectations. Additives (including colours) may not be included in foods unless they are approved and included in the Code.

FSANZ recognises that some consumers wish to avoid certain food additives. Food additives, including food colours, must be identified on the label with either its name or its specific code number. As is the case under existing permissions, foods that have been coloured with erythrosine must list erythrosine in the ingredient list. Consumers can use this information to make informed purchasing decisions.

10.1.6 Issues with non-commercial use

10.1.6.1 Submitters' views

Several submissions stated that, unlike industrially produced preserved cherries, it would be difficult to regulate the use of a food additive in home cooking.

10.1.6.2 FSANZ evaluation

It should be noted that the provisions of the Code apply only to food products sold or prepared for sale in Australia or New Zealand or imported into Australia or New Zealand (clause 1(1) of Standard 1.1.1). Food preparation for other purposes falls outside the application of the Code. For example, the microbiological limits set for food in the Code apply to food sold to the public, but are not intended for foods prepared at home. This equally applies to chemical limits set for food, such as the proposed ML for erythrosine in icing.

However, FSANZ's risk assessments take home-prepared foods into consideration where appropriate. In the case of this Application, the dietary exposure assessment shows that if the use of erythrosine was extended to foods with icing, consumers including children were unlikely to exceed the ADI of 0.1 mg/kg bw/day, even when it was assumed that erythrosine is used at ten times the proposed maximum level in home cooked foods. This assumption is highly protective of consumers.

In addition, FSANZ provides food handling advice to consumers in the form of fact sheets and a range of other materials. FSANZ will publish a fact sheet on the home use of food colouring preparations to provide consumers with advice on the appropriate use of these products.

10.2 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.

Amending the Code to permit the use of the food colouring erythrosine in food colouring preparations and icing and frosting is unlikely to have a significant effect on international trade. The erythrosine preparation is consistent with the international specifications for erythrosine so there does not appear to be a need to notify the WTO. For these reasons, FSANZ has decided not to notify the WTO under the either the Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements.

Conclusion

11. Conclusion and Preferred Approach

This Application has been assessed against the requirements for Draft Assessment in the FSANZ Act. FSANZ recommends the proposed draft variation to Standard 1.3.1 set out in **Attachment 1**.

Preferred Approach

To prepare draft a draft variation to Schedule 1 of Standard 1.3.1 – Food Additives, to permit the use of the food colouring erythrosine in food colouring preparations and icing and frostings.

11.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.3.1 for the following reasons:

- A detailed hazard assessment has concluded that the use of erythrosine under the proposed conditions does not raise any public health and safety concerns. In particular, a review of the toxicity of erythrosine provided no indication of any safety issues related to its proposed use and the dietary exposure assessment indicated that estimated dietary exposures were below the safe level.

- Use of erythrosine is technologically justified as a food colouring. In particular, its use to colour icing and frostings, may have certain advantages over other food colourings. FSANZ acknowledges that, unlike preserved cherries in canned fruit salad, heat stability of the red colouring is not an issue in cake icings and cake decorating as the colouring is added after the baking process has been completed. Also, there are already other food colourings available that can colour icing red. However, this does not constitute sufficient grounds for rejection because the proposed extension for the use of erythrosine fulfils a technological function as it is defined in the Code.

- The regulatory impact analysis concludes that there are potential benefits for both consumers and industry in extending the use of erythrosine as a food colouring and there are no specifically identified costs.

- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act, in particular, the proposed amendments:

    - ensure the protection the protection of public health and safety by imposing maximum limits for the use of erythrosine which, after rigorous assessment by FSANZ, do not pose any safety concerns
    - do not compromise the provision of adequate information relating to food to enable consumers to make informed choices
    - are based on risk analysis using the best available scientific evidence
    - are consistent with the desirability of an efficient and internationally competitive food industry and the promotion of fair trading in food
    - are consistent with written policy guidelines formulated by the Australia and New Zealand Food Regulation Ministerial Council.

12. Implementation and Review

If this Application is successful, the variations to the Code will take effect on gazettal and would be subject to existing compliance arrangements.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Summary of issues raised in public submissions

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act 2003 and are not subject to disallowance or sunsetting.

[1] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from the* Qualifications *column in* Schedule 1 *under item* 0.1 Preparations of food additives –

			Does not apply to preparations of colours or flavours

[1.2] *omitting from* Schedule 1 *under item* 0.1 Preparations of food additives –

-	Ethanol	GMP	Preparations of colours and flavours only

[1.3] *inserting in* Schedule 1, *under item* 0.1, *sub-item* baking compounds –

colourings

	Additives in Schedule 3 and 4	
-	Ethanol	GMP
127	Erythrosine	GMP

[1.4] *inserting in* Schedule 1, *under item* 0.1, *sub-item* flavourings –

	Additives in Schedule 3 and 4	
-	Ethanol	GMP

[1.5] *inserting in* Schedule 1 *under item* 5.4 icings and frostings* –

127	Erythrosine	2	mg/kg

Attachment 2

Summary of issues raised in public submissions

FSANZ received 8 submissions in response to the Initial Assessment Report on Application A603 – Red 3 Erythrosine in Food Colouring Preparations. A list of submitters and a summary of submitter comments is provided below.

1. List of Submitters

No	Submitter	Name
1	Private	Elaine Attwood
2	New Zealand Food Safety Authority	Jenny Reid
3	National Council of Women of Australia	Hean Bee Wee
4	Confectionery Manufacturers of Australasia Ltd	Jennifer Thompson
5	Queensland Health	Gary Bielby
6	Lanxess Deutschland GmbH	David Lueddeke
7	Dietitians Association of Australia	Annette Byron
8	Department of Health SA	Joanne Cammans

2. Summary of submissions

There were nine submissions to Application A603: three from government organisations, two from industry, two from professional organisations and two from consumer representatives. Almost all the submissions supported rejecting the Application.

Some submissions questioned the safety of erythrosine as a food additive, and provided some references on the toxicology of erythrosine[8]. In particular, submitters were concerned about reactions to erythrosine in sensitive individuals. There was a view that erythrosine was a dangerous and unnecessary food additive, and its use should therefore remain restricted. They argued that any increase in exposure to erythrosine, in particularly in children, would be undesirable and that increasing use may lead to unsafe exposure to erythrosine. Submitters commented that erythrosine had a low ADI and its use is therefore limited to very few foods. One submitter pointed out that the extended permission for use sought by the Applicant would mean erythrosine would be added to nutrient poor and energy dense foods. The increased consumption of such foods is inconsistent with public health messages.

Industry submissions suggested that there had been a move by industry away from the use of erythrosine, including industry in the US, and that any extension of current permissions would not be helpful. Submitters stated that the food industry is removing artificial colours from their products, in particular those consumed by children, and that use of erythrosine in preserved cherries is declining. On the other hand, one submitter argued that several products lost market share or ceased production due to the restriction placed on erythrosine use and extended use would be of benefit to the food industry and consumers.

[8] The references provided in submission form part of the risk assessment provided in the Draft Assessment Report. The toxicology of erythrosine is discussed in detail in the food safety report (Attachment 2).

Several submitters pointed out that, while the US allows erythrosine to be used under GMP, the restriction to the use of erythrosine in Australia and New Zealand is consistent with Codex and the European Union. Even if the proposed changes were gazetted, this would not create a level playing field, as the US permits use following GMP.

The submitters concluded that it would be unlikely that Australian or New Zealand businesses would gain any advantages from the proposed changes to the Code. In contrast, one submitter argued that extending the permission to use erythrosine would make Australian and New Zealand businesses more competitive.

Most submitters questioned the technological need for extending the use of erythrosine. They argued that the current range of red colourings available to food suppliers is adequate, and that any technological need (if any) is restricted to applications where bleeding of colour is an issue, such as preserved cherries in canned fruit salads. They stated that bleeding was not an issue in cake decorations and that a range of natural additives that provide bright attractive colours are available. One submission called for further evidence from suppliers of cake decorations, bakers and other specialists on the technological need to permit erythrosine based food colouring for cake decorating.

Some submitters argued that there was little evidence that extending the permission for erythrosine would lead to an overall decrease in the use of food colouring. They raised concerns that granting permission to use erythrosine for cake decorations may ultimately lead to permissions in a wider variety of products.

In contrast, one submitter argued that, for many applications, erythrosine is irreplaceable. The submission pointed out that erythrosine has high colour strength and that, depending on the depth of shade required, erythrosine could be used in much lower concentrations than other food colourings.

Several submitters were of the opinion that there was no evidence that consumers wanted foods containing erythrosine, and that on the contrary, there was a growing consumer demand for foods using natural food colouring rather that erythrosine. They stated that red food colourings for home use are already available to consumers. Some submitters asked for data demonstrating that consumers wanted extended use of food colours. Two submitters, including a food colouring manufacturer, stated that kosher food colourings were currently available and that there had been no application for kosher food dyes.

Several submissions stated that, unlike industrially produced preserved cherries, it would be difficult to regulate the use of a food additive in home cooking. Submitters argued that it is likely that domestic users would use erythrosine at much higher concentrations than those intended in the Application. Some submitters suggested possible risk management strategies, should the permission to use erythrosine be extended, could include limiting permissions strictly to icing on cakes or bakery products and providing additional labelling on products to clarify the intended use.

Submitters suggested the following possible additional sources of exposure to erythrosine: therapeutic goods, disclosure tablets used in dentistry, oral and other cosmetics, hair dyes and play dough where food preparations had been used in the home to colour the dough.