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

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[11-10]

FINAL ASSESSMENT REPORT

APPLICATION A603

RED 3 ERYTHROSINE IN FOOD COLOURING PREPARATIONS

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 colouring preparations containing the colour erythrosine which would be added to icing and frostings.

Erythrosine is a cherry-pink food dye with international permissions varying widely from highly restricted (EU) to generally permitted in foods following GMP (USA). Australia and New Zealand, the European Union, and the Codex Alimentarius, currently restrict the use of erythrosine to preserved cherries up to a maximum of 200 mg/kg.

The Applicant is seeking to extend the current use of erythrosine to food colouring preparations which would be added to icing and frostings used in the decoration of foods such as cakes and biscuits etc. The maximum level sought is 2 mg/kg, 1/100th of the level currently permitted in preserved cherries. Extending permissions for erythrosine would allow food suppliers to sell a wider range of products and increase consumer choice. The technological function of erythrosine is to add or restore colour. The intent of the proposed extension of use is to improve the visual appearance of iced and frosted products (e.g. cakes and other baked goods). More specifically, addition of erythrosine to food provides precise visual effects and unique colour shades unattainable by using currently permitted red 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 significantly 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 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 for erythrosine in icings and frostings set out in the amendments to Standard 1.3.1 are adequate to provide for continued safe use of erythrosine. 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.

Purpose

The purpose of the Application is to amend Standard 1.3.1 – Food Additives, to permit the sale of foods containing icings and frostings coloured with erythrosine (INS 127) at a proposed maximum level of 2 mg/kg.

Decision

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

Reasons for Decision

This Application has been assessed against the requirements for Final Assessment in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ approves the 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 this Application was sought from 15 September 2008 to 28 October 2008 for the Initial Assessment Report and from 16 December 2009 to 10 February 2010 for the Draft Assessment Report. In the first round of public comment, nine submissions were received, with almost all the submissions supporting rejecting the Application. In the second round, seventeen submissions were received; three of which addressed issues related to genetically modified foods and labelling. Consequently these were not given further consideration as erythrosine is not a GM food issue.

Of the fourteen relevant submissions, six opposed the Application; one did not state support or opposition, while seven supported either the preferred approach or progression of the Application. Those who supported the Application cited reasons including: erythrosine's superior technological function, including hue and tinctorial strength; increased market access; increased market competitiveness and strong consumer demand from cake decorators. Issues identified in the submissions have been addressed in this Report.

Amendments to the Draft Variation after Consultation

The draft variation at Draft Assessment included an entry for erythrosine under item 0.1 of Schedule 1 of Standard 1.3.1. The purpose of item 0.1 is to allow the sale of any food additive in the form of a preparation with other additives allowed where technologically justified relative to their use in the preparation.

If the initial draft had been approved, it may have had unintentional consequences on the use of erythrosine to colour other food additive preparations. Clause 8 of Standard 1.3.1 provides for foods to act as delivery vehicles for additives into a food product where permission for the additive in the final food exists in the Standard. Therefore, FSANZ has removed the entry for erythrosine from item 0.1 Preparations of food additives in Schedule 1 of Standard 1.3.1.

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SUPPORTING DOCUMENTS

The following documents were used in the preparation of this Final Assessment Report, and 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

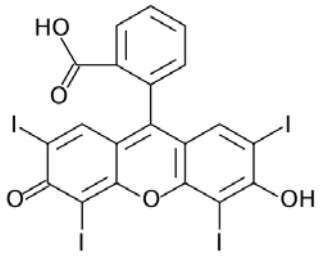
Introduction

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 erythrosine (INS 127) which would be added to icing and frostings used 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 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 confectionery 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 only permitted to be added to preserved cherries 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
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- erythrosine was the only colour available that provided 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 commented that in assessing the risk of exceeding the ADI, non-food sources of erythrosine should be considered as contributors to chronic exposure, such as use of pharmaceutical products over extended time periods. However they concluded that models based on the maximum levels of use give overestimates of actual exposure, because erythrosine will be used in only a limited number of red foods. The Committee concluded that it was unlikely that long-term dietary exposure to erythrosine would exceed the ADI, even if non-food sources of exposure were taken into account.

1.3.2 Codex Alimentarius

In the current version of the 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) at its 41st Session (2009) forwarded draft and proposed draft food additive provisions of the GSFA to the 32nd session of the Codex Alimentarius Commission (CAC) for adoption at Step 8 and 5/8, respectively (para. 109 and Appendix IV,[1]). These included provisions for addition of erythrosine to 22 categories of food (Table 1). One of the permissions proposed was 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'.

The 32nd Session of the CAC noted the concerns of many delegations on the safety of erythrosine and returned the draft and proposed draft provisions to the CCFA for further discussion at its next session in the context of a refined exposure assessment by JECFA.[2] The CCFA at its recent 42nd Session (2010) did not recommend seeking a review of dietary exposure by JECFA.

1.3.3 Regulation in countries other than Australia and New Zealand

For permitted synthetic 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.

1.3.1.1 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 prior to 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] 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

1.3.1.2 European Union

Food additives are authorised at EU level for all the Member States, 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.

1.3.1.3 Japan

According to the Japanese standards for use of food additives, erythrosine is generally permitted in food except: 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, and 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, administered by the Korea Food and Drug Administration (KFDA), takes a similar approach to the Japanese standard. Forty-six foods are excluded from the permissions for erythrosine use[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.

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 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 process involved an assessment of the following evidence:

- toxicological data, food intolerance data and hazard assessment

[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 confectionery (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).

- 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 identified a number of considerations 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.

- Some alternate red colourings (i.e. Carmine) 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 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 colouring 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 colouring 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. In humans, at doses above 1.0 mg/kg bw/day, the levels are 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 does not see any reason to amend the ADI of 0.1 mg/kg bw/day established by JECFA. Therefore, an ADI of 0.1 mg/kg bw/day is appropriate for dietary risk assessment purposes.

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

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**.

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

- 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 Final 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**.

Erythrosine is a reddish-pink synthetic food dye used globally in various foods and food ingredients, ingested drugs and as a biological stain. The technological function of food colourings is to add or restore colour to food products. The intent of the proposed extension for the use of erythrosine in food colouring preparations is to improve the visual appearance of iced products such as cakes and other baked goods.

The Applicant claims that there is a technical need to extend the use of erythrosine in Australia and New Zealand from preserved cherries to food colouring preparations used to colour icings and frostings used for decorating cakes for the technological purpose of achieving colour enhancement. This claim has been substantiated with claims that food colouring preparations containing erythrosine possess superior colouring characteristics to alternative red colours including; colour strength, longevity, lack of bleeding and quality of the finished product. Consequently this allows for a greater range of colouring effects to be achieved including a wider range of pinks, lavenders and violets, royal blue and true black.

The colour hue and intensity is directly affected by the amounts added and the proposed amounts are consistent in achieving the intended result – to colour food. Addition of erythrosine is self-limiting as overuse of this colour leads to less appealing shades.

The merits of using erythrosine are strongly supported by some companies, in particular, Americolor™ Corporation and CK Products, two of the largest producers of erythrosine products used for cake decorating purposes.

Currently in Australia and New Zealand, alternative red colourings include combinations of artificial food colours such as Allura Red AC, Ponceau 4R, Azorubine / Carmoisine and Amaranth, and natural red colours such as cochineal/carmine, anthocyanins and beet red. There is some published and anecdotal evidence supporting the claims that erythrosine possesses superior technological properties including lack of bleeding, colour hue, colour strength, stability and colouring ability to other red colours used in cake decorating and/or icing manufacturing.

Erythrosine is an effective red food colouring thereby fulfilling a technological function in foods.

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 colouring preparations?

The use of erythrosine under the proposed conditions does not raise any public health and safety concerns. It is highly unlikely that any food coloured with erythrosine at a concentration of 2 mg/kg of erythrosine which is not consumed in large amounts on a daily basis would pose a significant health risk. Comparisons with the ADI indicated that 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 and Draft Assessment Reports.

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 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.

- The sale of food colouring preparations is provided for by item 0.1 Preparations of food additives in Schedule 1 of Standard 1.3.1. Food colouring preparations are not foods that are intended to be consumed in their own right but are used in the preparation of other foods. Clause 8 of Standard 1.3.1, Food for use in preparation of another food, allows food additives to be present in foods intended for use in the preparation of a food provided the level in the final food complies with maximum permitted levels in the Standard. 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. Setting a maximum limit for the colouring concentrate will not control the level of the colouring in the final food for the consumer.

- 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. 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 should 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 adequate information to enable consumers to make informed choices.

On the basis of the risk assessment, FSANZ considers the general labelling requirements of the Code as they currently stand are appropriate for all foods permitted to contain erythrosine. No additional mandatory labelling is proposed.

6.4.1. Labelling of ingredients

The general labelling requirements of the Code applicable to foods for retail sale required to bear a label include the mandatory declaration of food additives (Standard 1.2.4 – Labelling of Ingredients). In accordance with these existing requirements, where a food for retail sale is required to bear a label and contains icing or frosting coloured with erythrosine, the food colouring must be declared in the ingredient list by its class name ‘colour’ followed by its specific name ‘erythrosine’ or code number in brackets ‘(127)’. This requirement will also apply to the retail sale of food colouring preparations containing erythrosine.

The declaration of erythrosine on the label of a food will therefore alert consumers to its presence and may be used by consumers to avoid foods containing erythrosine if they so wish.

Where foods for retail sale are exempt from the requirement to bear a label, such as unpackaged foods, the Code does not require the presence of non-allergenic food additives to be declared. Therefore, as for other non-allergenic food additives, consumers will not be able to identify the presence of erythrosine from the label of the food. However, the risk assessment concludes that the use of erythrosine in icings and frostings at the proposed maximum level of 2mg/kg does not raise any public health and safety concerns. This proposed maximum level will apply to all icings and frostings used in foods prepared for retail sale, including foods exempt from the requirement to bear a label. Likewise, the requirement to follow GMP will apply to the sale of all food colouring preparations containing erythrosine. As these proposed conditions provide for the safe use of erythrosine regardless of whether or not the food is required to bear a label, FSANZ considers the current food additive declaration requirements in Standard 1.2.4 are appropriate for all foods permitted to contain erythrosine.

Consumers who wish to avoid erythrosine in foods that are not required to bear a label may request information from the food provider about its presence or otherwise, although provision of this information is not mandated by the Code. This approach is consistent in the Code for the use of all permissible non-allergenic food additives in foods that are not required to bear a label. The colour of the icing or frosting in a food would also alert consumers to the possible presence of the food colouring.

6.4.2 Labelling for food intolerances

FSANZ acknowledges that some consumers may be sensitive to erythrosine in food. The requirement to declare food additives in the ingredient list of foods for retail sale required to bear a label, will enable consumers who may be sensitive to erythrosine to identify those products containing the food colouring. For foods exempt from the requirement to bear a label, FSANZ recognises that erythrosine will not be required to be declared. As such, consumers will not be able to identify the presence of the food colouring from the label of the food. However, the hazard assessment supported by expert opinion (see **Supporting Document 1**) concludes that the potential for intolerance reactions from small amounts of erythrosine in the diet would be very low. FSANZ therefore considers the current declaration requirements for non-allergenic food additives, regardless of whether or not the food is required to bear a label, to be commensurate with the level of risk posed from intolerances to erythrosine.

6.4.3 Labelling of directions for use

As the Applicant's intended use for the retail 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 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 as proposed does not raise any public health and safety concerns. FSANZ does not therefore consider the inclusion of directions for use within Standard 1.2.6 to be appropriate for food colouring preparations containing erythrosine.

Whilst commercial use of erythrosine will be limited to icings and frostings and preserved cherries, FSANZ acknowledges that some consumers may use food colouring preparations containing erythrosine in the home for other purposes. As such, FSANZ's risk assessment has taken a number of home-prepared foods that may conceivably be coloured with red food colouring into consideration. The dietary exposure assessment (see **Supporting Document 2**) concludes that should the home use of erythrosine be in foods other than icing, it is highly unlikely it would be consumed in sufficient quantities on a daily basis to lead to levels of dietary exposure that pose a significant health risk.

On the basis of the risk assessment, FSANZ considers that mandating any additional labelling within the Code (e.g. within Standard 1.2.6 – Directions for Use or Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations) to regulate for the possibility of unusual consumption patterns in the home is not justified.

6.4.4 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 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 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 iced and frosted 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 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.

6.6 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 *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.

6.6.1 The sale of food colour preparations containing erythrosine

Food colouring preparations which are sold to consumers to colour food, are regulated as foods under item 0.1 in Schedule 1 of Standard 1.3.1. The purpose of item 0.1 is to allow any food additive to be sold in the form of a food additive preparation, with other additives specifically permitted which perform appropriate technological functions in the actual preparations. There is no need to explicitly permit erythrosine in food colouring preparations as they are not added with the intent to colour the preparation i.e. perform their technological function.

Food colouring preparations act as a vehicle to allow colouring to be added to food provided there is a permission for the colouring in that food. This is provided for by clause 8 of Standard 1.3.1 which states:

> *Any food additive permitted in a food may be added to an ingredient intended for use in the preparation of that food provided that the level in the final food when prepared complies with the maximum permitted level in this Standard.*

6.6.2 The sale of icing and frostings containing erythrosine

Currently the only permission in the Code for use of erythrosine is 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*

Option 2 Approve a variation to the Code to permit the sale of foods containing icing and frostings coloured with erythrosine up to a maximum of 2 mg/kg

This Application must be assessed against the requirements for a Final 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.

8.1 Affected Parties

The identified affected parties are:

1. Retailers of food colouring 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 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:* Approve a variation to the Code to permit the sale of foods containing icing and frostings coloured with erythrosine up to a maximum of 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 discussed 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, being permitted in 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).

In regard to concerns over any adverse reactions, health impacts or associated costs to sensitive individuals, FSANZ invited further feedback from affected parties at Draft Assessment. No additional costs or issues were identified through this public consultation process.

As a matter of good process FSANZ resubmitted the Draft Assessment to the OBPR to comment on the adequacy of the Regulation Impact Statement and in particular unintended consequences for FSANZ as a result of approving a further food colouring (e.g. loss of reputation or goodwill) without more fully exploring the adverse effects to consumers intolerant to erythrosine or food colourings in general.

The OBPR's response was that FSANZ's emphasis on population wide safety of this additive was appropriate. It supported FSANZ's assessment that any impact on sensitive individuals is able to be managed through provision of label information. In the case of unlabelled products, consumers who are intolerant to food colourings in general are likely to avoid such products anyway, which further reduces the possibility of any intolerance or sensitive reactions due to erythrosine *per se*. This approach is considered consistent with a principle of applying minimum necessary regulation and managing risks in a way commensurate with the level and nature of the risk. Furthermore, the OBPR commented that critics of providing permission for the additive appear to be advocating adoption of a 'precautionary principle', which is generally going to be at odds with a principle of minimum necessary regulation.

Finally, comments from the OBPR also acknowledged that it would be difficult to quantify the benefits and costs given the uncertainties around the number of sensitive individuals to erythrosine only and the impacts to them. However, if the additive is used in accordance with the proposed standards, the impacts appear to be relatively small on a community-wide basis and there is probably a net benefit from approving the additive.

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. One submission stated that several products had lost market share or ceased production due to restrictions in erythrosine use. Other submissions suggested there would be increased market access and market competitiveness associated with the proposed extended erythrosine permissions.

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 some other alternate red colourings such as cochineal/carmine. Some submissions on the Draft Assessment Report indicated that strong demand for cake decorating products containing erythrosine exists from the cake decorating community.

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.

Feedback from the OBPR also acknowledged that it would be difficult to quantify the benefits and costs given the uncertainties around the number of sensitive individuals to erythrosine only and the impacts to them. However if the additive was used in accordance with the proposed standard, the impacts appeared to be relatively small on a community-wide basis and there was probably a net benefit from approving the additive.

Amending Standard 1.3.1 to approve the retail sale of foods containing icing and frostings 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 Final Assessment, Option 2 i.e. approving a draft variation to Standard 1.3.1 to permit the retail sale of foods containing icing and frostings containing the colour erythrosine, has a greater net benefit and is the preferred option.

Communication and consultation strategy

9. Communication

FSANZ developed an appropriate communication strategy for Application A603. This involved advertising the availability of the Assessment Reports for public comment in the national press and making the Reports available on the FSANZ website.

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

10. Consultation

Public comment on the Draft Assessment Report was sought from 16 December 2009 to 10 February 2010. Seventeen submissions were received in response to the second round of public consultation. Three submissions addressed issues related to genetically modified foods and GM food labelling. Consequently these have not been given further consideration as erythrosine is not a GM food issue.

Of the remaining fourteen submissions, six submissions opposed the Application; one did not state support or opposition, whilst seven responses supported the proposed extended permissions for erythrosine. Those who supported the Application cited reasons including: erythrosine's superior technological function, including usage levels, colour hue, stability and colouring ability; increased market access; increased market competitiveness and strong consumer demand from cake decorators.

A summary of submissions received is provided at **Attachment 2.** FSANZ has taken submitters' comments into account in preparing the Final Assessment Report for this Application. Discussed below are specific concerns raised in submissions for further consideration.

10.1 Issues raised in submissions

10.1.1 Non-food sources of erythrosine

Some jurisdictions questioned why non-food sources of erythrosine were not included in the dietary exposure assessment, particularly when noting erythrosine's inclusion as a permitted ingredient on the Australian Register of Therapeutic Goods and the possibility of chronic exposure to erythrosine from consumption of pharmaceuticals.

10.1.1.1 FSANZ Response

JECFA (2000) commented that in assessing the risk of exceeding the ADI for erythrosine, non-food sources should be considered as contributors to chronic exposure, such as use of pharmaceutical products over extended time periods. FSANZ has considered the risk of exceeding the ADI for erythrosine if pharmaceuticals were included in exposure estimates and concluded that this risk is very low.

Food is the principal relevant source of exposure to erythrosine and all estimated dietary exposures for the population groups assessed are below 50% of the ADI, even when highly protective assumptions are made. Pharmaceuticals are unlikely to be a substantial contributor to overall chronic exposure and their inclusion as an input in models of exposure would not largely alter exposure estimates.

In Australia, erythrosine may be used as an excipient in orally administered (prescription, over the counter and complementary) medicines, without the requirement for sponsors to submit an application for evaluation by the TGA[6]. Other products that contain erythrosine include dental disclosure tablets. While pharmaceuticals are a possible contributor to exposure to erythrosine, this contribution is unlikely to be substantial. Exposure from pharmaceuticals is usually intermittent, while the hazard posed by erythrosine relates to chronic rather than acute exposure. In pharmaceuticals, the colour intensity of erythrosine, and the small dose volumes of long term medicines, is such that tablets, syrups and dental disclosing solutions would be unlikely to be a notable source of exposure.

[6] Australian Government, Department of Health, Therapeutic Goods Administration (2004) Colourings Permitted in Medicines for Oral Use http://www.tga.gov.au/meds/colourings.pdf

10.1.2 Scientific references omitted from Hazard Assessment

One submitter, in expressing the view that erythrosine was an unsafe food additive claimed that FSANZ had failed to consider a number of references in its Hazard Assessment Report.

10.1.2.1 FSANZ Response

Six journal articles on erythrosine were highlighted which had been identified from the Feingold Association website. Three of these articles were further identified as not being included in the Hazard Assessment Report. The first of these, by Tsuda et al (2001), was incorrectly identified as relating to erythrosine (Red 3) when in fact it related to a number of other red dyes. On this basis it is not considered a relevant inclusion in the Hazard Assessment Report, particularly when there is an extensive toxicological database on erythrosine. Indeed, a study conducted by this same group on the *in vivo* genotoxicity of erythrosine in mice (Sasaki et al 2002) was evaluated in the Hazard Assessment Report (see Section 2.3.9).

The two other journal articles described *in vitro* studies where erythrosine was added to isolated neurons from frogs or rat brain homogenates (Levitan 1980; Lafferman & Silbergeld 1979). By virtue of their publication dates, these studies clearly fall outside the scope of the Hazard Assessment, which was to evaluate supplementary studies published in the scientific literature since JECFA's most recent assessment of erythrosine (1990). Additionally, these studies are considered to have limited regulatory value for a number of reasons:

- The study by Levitan (1980) was conducted on isolated frog neurons. Amphibians are not an appropriate model to assess mammalian toxicity and are not used to inform human health risk assessments.

- As outlined in the Hazard Assessment Report (Section 2.4.1), erythrosine cannot cross the blood brain barrier (Levitan et al 1984) and therefore has limited potential to interact with the nervous system. Pharmacokinetic data also support this contention (Mailman & Lewis 1981). The addition of erythrosine directly to rat brain homogenates is not a relevant route of exposure to assess dietary risk.

- As discussed in the Hazard Assessment Report (Section 1.3), the apparent perturbation of dopamine uptake in rat brain homogenates reported by Lafferman and Silberg (1979) is attributable to non-specific binding of erythrosine to neural membranes (Mailman 1980). This non-specific binding is considered to be an experimental artefact, which has no bearing on human behaviour (Mailman and Lewis, 1981).

On the basis of the above considerations, the three studies identified by the submitter have not been included in the Hazard Assessment Report.

10.1.3 Intolerance to erythrosine

The safety of erythrosine was questioned by a number of submitters particularly its relationship to intolerance reactions.

10.1.3.1 FSANZ Response

As part of the hazard assessment, FSANZ considered 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. In some of the studies, symptoms were reported with doses of erythrosine many times higher than the ADI. A study by the Royal Prince Alfred Hospital research group (Loblay and Swain, 1985) reported adverse effects in patients tested with erythrosine at an oral dose of 30 mg. Such a high dose of erythrosine is not likely to be consumed as part of a normal diet. However, the doses used are chosen so as to maximize diagnostic sensitivity, specificity and predictive value in the particular patient group (Loblay, personal communications).

The maximum permitted level sought is 2 mg/kg of food such as icing and frostings used in cakes, biscuits and fancy breads. In relation to unpackaged food, given the concentration of 2mg/kg, a consumer would need to eat 15 kg of icing and frosting to reach the 30 mg dose used in the study. In addition, FSANZ notes that erythrosine is poorly absorbed from the gastrointestinal tract, which further reduces the exposure resulting from the small amounts of erythrosine that would be expected in a normal diet. Therefore, exposure to erythrosine from such packaged or unpackaged foods would be very low.

10.1.4 Adverse thyroid effects

A concern was raised by one submitter that studies indicate erythrosine disrupts thyroid function and that this is not fully considered in the allocated ADI.

10.1.4.1 FSANZ Response

The submitter cited a JECFA monograph on erythrosine and on this basis expressed concern that erythrosine causes thyroid tumours and disrupts thyroid function. Further, the use of a temporary JECFA ADI (of 0.05 mg/kg bw/day), the absence of a NOAEL for a tumorigenic effect and that laboratory studies have only covered 60-days exposure, were raised.

As discussed at length in the Hazard Assessment Report (Sections 2.4.3 & 2.4.6), the occurrence of benign thyroid tumours in a minority of laboratory animal studies is not relevant to humans based on well-established interspecies differences in thyroid physiology.

The current JECFA ADI is not temporary as stated by the submitter and is in fact 0.1 mg/kg bw/day. While JECFA could not establish a NOAEL for thyroid tumours in rats, the ADI is based on a more sensitive endpoint in humans (elevated TSH). Laboratory animal studies have actually run for up to 30 months of exposure to erythrosine.

10.1.5 Effects on behaviour

Concern was raised in a number of submissions regarding the adverse effects of erythrosine on behavioural and/or learning dimensions especially in children. Further, it was claimed that using an ADI, which does not consider these behavioural issues, to assess the safety of erythrosine is unrelated to the real issue.

10.1.5.1 FSANZ Response

The JECFA ADI for erythrosine of 0.1 mg/kg bw/day is based on a sensitive endpoint (elevated TSH) in a human volunteer study. The use of a 10-fold safety factor to derive this ADI is actually designed to cover the full spectrum of variability in response to a chemical within the human population, including sensitive subpopulations such as children. It is worth noting that the doses of erythrosine typically used to test for intolerance were higher than the ADI (see Section 1.2 of the Hazard Assessment Report).

In relation to intolerance reactions, the majority of consumers – including children – are not affected by erythrosine. All available information on the potential effect of erythrosine on children's behaviour is considered in the hazard assessment. During its deliberations, FSANZ consulted with Dr Robert Loblay, Director of the Allergy Unit at the RPAH. His expert medical view is that natural food chemicals provoke symptoms more frequently than artificial additives and that patients sometimes mistakenly incriminate the most obvious food component, such as additives, as being responsible for their symptoms.

10.1.6 Technological justification

Some submissions questioned the validity of the stated technological need for erythrosine, arguing that a purely cosmetic effect is not sufficient to warrant extending permissions in light of safety concerns.

10.1.6.1 FSANZ Response

In assessing whether to grant permissions for use of new food additives, or extensions of use for already permitted food additives, FSANZ is required to conduct a pre-market safety assessment. FSANZ also has to have regard to the Ministerial Policy Guideline for substances added to achieve a purely technological function, such as food additives. The Guideline states that these should be permitted where the substance is safe for human consumption, the purpose of addition is achieving a solely technological function and that the amounts and form prescribed are consistent with achieving the stated purpose.

Food additives are regulated in Standard 1.3.1 of the Code which 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 technological function as a function set out in Schedule 5.

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. The Food Technology assessment concluded that erythrosine is an effective colouring and that its use is technologically justified in the form and amounts prescribed for the stated purpose. Further, the Hazard Assessment concluded there is unlikely to be an appreciable public health risk from the proposed use of erythrosine.

10.1.7 Labelling of unpackaged foods

Some concerns were raised regarding the lack of consumer information for certain foods, such as unpackaged foods, that are not required to declare the presence of erythrosine. One submitter claimed the lack of labelling does not protect public health and safety.

10.1.7.1 FSANZ Response

FSANZ acknowledges that consumers are not able to identify the presence of erythrosine in certain foods that are not required to bear a label, such as unpackaged foods. In response to submitter concerns, FSANZ has considered the use of erythrosine in such foods as part of the Final Assessment (see Section 6.4 – Labelling and consumer information of this Final Report).

The risk assessment concludes that the use of erythrosine in icings and frostings at the proposed maximum level of 2mg/kg does not raise any public health and safety concerns. As discussed in Section 6.4, this proposed maximum level will apply to all icings and frostings used in foods for retail sale, including foods that are not required to bear a label.

Furthermore, FSANZ's hazard assessment concludes that the potential for intolerance reactions from small amounts of erythrosine in the diet would be very low. The safety of erythrosine in relation to intolerance reactions and unpackaged foods has been further addressed in response to submission issues in Section 10.1.3 – Intolerance to erythrosine.

Based on the risk assessment, FSANZ maintains the current declaration requirements for non-allergenic food additives in Standard 1.2.4 – Labelling of Ingredients are appropriate for all foods permitted to contain erythrosine, regardless of whether or not the food is required to bear a label.

10.1.8 Comparison of food allergens and erythrosine risk management strategies

One submitter disagreed with the statement used by FSANZ in Section 6.3.2 – Labelling for food intolerances of the Draft Assessment Report: '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.'

10.1.8.1 FSANZ Response

FSANZ accepts this statement may have been phrased inappropriately. We do not intend to apply the food allergens risk management strategy to erythrosine per se, as the level of risk posed from food allergens and from intolerance to erythrosine differ (i.e. allergens pose a high level of risk to public health and safety, whereas, the potential for intolerance reactions to erythrosine would be very low). Section 6.4.2 – Labelling for food intolerances of this Final Report reflects our intention.

10.1.9 Directions of Use

A concern was reiterated by one submitter that the retail sale of food colouring preparations containing erythrosine may lead to the home-use of erythrosine beyond icings and frostings and preserved cherries with implications to the dietary exposure assessment. The submitter therefore requested FSANZ further consider labelling of directions for use.

10.1.9.1 FSANZ Response

In the Draft Assessment Report, FSANZ acknowledged that some consumers may use food colouring preparations containing erythrosine in the home for purposes other than icings and frostings. As such, FSANZ considered home-prepared foods that may conceivably be coloured with erythrosine as part of the risk assessment. As discussed in Section 6.4.3 – Labelling of directions for use, the risk assessment concludes that should erythrosine be used in the home for purposes other than icing, it is highly unlikely to pose a significant health risk. FSANZ therefore maintains the inclusion of directions for use on the label of food colouring preparations containing erythrosine is not justified.

10.1.10 Drafting

One submission sought clarification on the operation of item 0.1 'Preparations of food additives' in Schedule 1 of Standards 1.3.1 in relation to the inclusion of a specific entry for erythrosine. It was suggested the draft variations appear to allow erythrosine to be used in any other food additive preparation which is not the intention.

10.1.10.1 FSANZ Response

FSANZ considered the issues raised about the draft variations at Draft Assessment and accepts the draft variations may have had unintentional consequences on the use of erythrosine and other non Schedule 3 and 4 colours in food additive preparations.

The intent of item 0.1 in Schedule 1 of Standard 1.3.1 is to allow any food additive to be sold in the form of a food additive preparation (for example in liquid form). Specific permission for other additives are also provided where those additives perform an appropriate technological function in the food additive preparation.

Food colouring preparations may act as a vehicle to allow colouring to be added to a food provided there is a permission for the colouring in that food. This is provided for by Clause 8 of Standard 1.3.1 which states:

> *Any food additive permitted in a food may be added to an ingredient intended for use in the preparation of that food provided that the level in the final food when prepared complies with the maximum permitted level in this Standard.*

Erythrosine is not added to food colouring preparations with the intent to colour the preparation i.e. to perform a technological function in the preparation; therefore no permission is required under item 0.1 and the draft variations at Final Assessment reflect this.

FSANZ proposed the variations to create a separate category for colourings and to add to the flavourings category in order to dispense with the need for entries in the qualifications column. The additive limits included in the colourings and flavourings categories is considered consistent with the current Standard 1.3.1. These current requirements are that ethanol is permitted at GMP in 'preparations of colours and flavours only' and the current prohibition on Schedule 3 and 4 additives in food additive preparations does not apply to preparations of colours or flavours.

10.1.11 Scope of Application

The scope of the application was questioned by one submitter who claimed that although not requested by the Applicant, the drafting included permission for use of erythrosine by any food manufacturers. It was further questioned why wider consultation was not undertaken with a view to broaden permissions in applications such as confectionary and suggested that FSANZ would now be open to an influx of applications.

10.1.11.1 FSANZ Response

The Applicant seeks to extend permissions for erythrosine to allow its sale in food colouring preparations which are to be used in icings and frostings used to decorate cakes. As discussed in Section 6.7 the proposed amendments to Standard 1.3.1 would permit foods containing icing and frostings where the concentration of erythrosine in the icing sold does not exceed a maximum level of 2 mg/kg. No other extensions to current permissions of use for erythrosine are allowed.

In assessing whether to grant permissions for use of new food additives, or extensions of use for already permitted food additives, FSANZ is required to conduct a pre-market safety assessment. Therefore any further requests for extension of use for erythrosine would be conducted on a case-by-case basis.

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 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 was not 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 Decision

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

Decision

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

11.1 Reasons for Decision

FSANZ approves 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

1A. Draft variation to the *Australia New Zealand Food Standards Code* (at Final Assessment Report)
1B. Draft variation to the *Australia New Zealand Food Standards Code* (at Draft Assessment Report)
2. Summary of issues raised in public submissions

Attachment 1A

Draft variations to the *Australia New Zealand Food Standards Code* (at Final Assessment Report)

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	

[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

Overall seventeen submissions were received in response to the second round of public consultation on Application A603 Red 3 Erythrosine in food colouring preparations. Three submissions addressed issues related to genetically modified foods and GM food labelling. Consequently these have not been given further consideration as erythrosine is not a GM food issue.

Of the remaining fourteen submissions, six submissions opposed the Application; one did not state support or opposition, whilst seven responses supported the proposed extended permissions for erythrosine.

A summary of all submissions received is provided in the below table.

Submitter	Group	Comments
SA Health	Government	• Does not support preferred approach • FSANZ does not present strong arguments in favour of extending permissions – Cites industry move away from use of erythrosine and artificial colours generally 'due to community concerns relating to allergies and intolerances, particularly in children' • Believes extending permissions appears in contrast to intent of decreasing artificial colours in food supply • States approval is not justified as industry does not appear to want it; the only real benefit is purely cosmetic and potential risks to individuals and community via an increased intake.
CHOICE	Consumer Association	• Supports Option 1 – *Status Quo* • Rationale: – No vital technological function – use is purely cosmetic – Alternate colours are available – Safety is still questionable, particularly in relation to children – Parent and community concerns regarding artificial additives, particularly in children's food and drink – Proposed food commonly consumed by children – Proposed use is likely in products exempt from labelling requirements – Undermines '*responsible'* food businesses' move away from use of artificial colours <u>Consumer Demand</u> • Not aware of consumer need or want for more choice in available red/pink food colours – Cites no consumer submissions received from IAR supporting extension.

Submitter	Group	Comments
		• Notes consumer concern over use of artificial colours • Notes voluntary industry move away from use of artificial colours due to consumer concerns • Cites no consumer benefit in extending permissions for use of erythrosine and no detriment in rejecting Application • Approval may result in costs for sensitivity testing <u>Labelling</u> • Disagrees with FSANZ opinion that current ingredient labelling requirements are adequate to protect consumers • Concern regarding use of erythrosine in unpackaged product in bakeries and product supplied by caterers which are exempt from labelling requirements. <u>Consumer Use</u> • Home use is unregulated • Believes that the proposed home use fact sheets should be available at point-of-sale to have any influence on home use. <u>Additional issues</u> • Queries the extent to which 'other decorations' have been considered in dietary modelling • Highlights 'loophole' which permits colours to be added to flavourings, thereby bypassing labelling requirements and restrictions on addition to broader range of foodstuffs – Suggests permitting addition of colours to flavours that are used for home use only, not commercial use.
Dietitians Association of Australia	Industry Association	• Does not support • Cites anecdotal experience from RPAH Allergy Clinic that erythrosine produces stronger reaction in sensitive individuals than tartrazine. • Believes it is worth considering that evidence of adverse effects can only really be seen once approvals are given or extended. • Expresses concerns about consumer exposure from unpackaged products which have no labelling requirement • Believes the stated purpose (visual appearance) does not warrant extended permissions given consumer and health professional concern over individual reactions to this and other colours.
Hollywood Cake Decorations	Importer	• Supports extended permissions • Allows use levels to achieve true "red" colour and at the same time comply with maximum limits • Believes permissions would speed up importing process and allow Australia access to larger range of products allowed to be imported • Believes we are currently "market restricted" and states American companies won't manufacture products in colours other than Red 3 (i.e. Red 40) for small markets such as Australia.

Submitter	Group	Comments
		• States the market is 'crying out' for domestic suppliers to be able to supply products (Decorations and Colour additives) which are available in the US but not here. • Believes extending permissions would allow increased market potential, increased imports of products and allow competition.
Paramark International P/L	Importer	• Supports Application to extend permissions • Believes there is discordance between what can be produced in the US and here which puts Australia at a disadvantage. – US products have better colouring ability, better products available – Availability of alternate reds to Australian market is reduced because the quantities required do not meet minimum production run requirements in US • Notes that 'years ago' AQIS allowed icing colours and decorations in because colour concentration was very low. • Notes that consumers in Australia are ordering products online from US • Believes there are lost business opportunities (i.e. sales) because businesses cant import products • Believes there are lost employment opportunities because of limited business expansion due to limited commercial opportunities • Believes FSANZ presented a balanced assessment of erythrosine and strongly supports the advantages stated
Shirley Collins	Private	• Requests embargo on GM food
Jo Douglas	Private	• Requests proposal squashed • Dangers of chemical additives, particularly when used in combinations • Ban all additives unless they are shown to be beneficial to people's health
Paul Elwell-Sutton	Private	• Opposes Application • Believes erythrosine is an unsafe food additive – Cites studies which have demonstrated tumorigenic effects of erythrosine on thyroid and which disrupt thyroid function – Notes JECFA set a temporary ADI, however states this is a no-effect level for tumorigenic effect on thyroid, and only 60day exposure was used.
Food Intolerance Network	Association	• Opposes Application • Believes erythrosine is an unsafe additive (as all artificial colours are), which is known to affect children's health, learning and behaviour • States the ADI used by FSANZ doesn't include any behavioural or learning dimensions nor any direct testing upon children • Believes the Hazard Assessment and Dietary Exposure assessments are irrelevant to this main issue (above point)

Submitter	Group	Comments
		• Claims E127 is regarded by RPAH Allergy Unit as an unacceptable food additive and listed in their publication as 'Avoid' due to its effects on children • Refers to the Feingold Association's collection of scientific references regarding safety of Red 3 and claims none of the news is good. • Cites three safety studies not included in our Hazard Assessment • Questions why current permission to colour 'white cherries red' is not considered to breach Trade Practices Act (1974, Section 52) with regards to misleading and deceptive conduct. • States FSANZ claim of potential benefits to consumers is unfounded • Disagrees with conclusion that no safety issue exists • Claims E127 is a 'dangerous and unnecessary food additive'
NZFSA	Government	• Notes the dietary exposure assessment indicates that the level of addition proposed does not represent a risk to public health • Agrees extended permissions should be restricted to where there is technological justification • Agrees a technological justification exists for use of erythrosine in icings, frostings and colour preparations used to make icings and frostings • Concerned that permissions for use in colour preparations may lead to use at retail in non-approved end foods • Recommends further consideration be given to specific naming and directions for use for food colouring preparations (i.e. colour for icing and frosting) • Estimates costs for this to industry would be minimal, as product is not currently in the market and imported products are already required to bear country specific labelling. Therefore specific labelling could be imposed without significant regulatory impact • Seeks clarification of the operation of category 0.1 'preparations of food additives' in Schedule 1 of Standard 1.3.1 • Suggests it is not necessary to list permission for erythrosine under category 0.1, but would be more appropriately placed under category 5.4 'icings and frostings', in Schedule 1 of Standard 1.3.1 only. • Believes the proposed drafting [1.1] to [1.4] means that the additives listed under 'preparations of food additives' can be added to preparations of food additives used as baking compounds as well as the following to food colouring preparations; Additives in Schedule 3 and 4, ethanol, and erythrosine. • Believes the proposed drafting is overly restrictive as not all colours permitted by the Code for use in confectionery and baking in Schedule 1 are covered.

Submitter	Group	Comments
Michelle Denise	Private	• Defer approval until Food Labelling Review and Dr Judy Carman report considered
NSWFA	Government	• Neither supports nor opposes Application • Requests FSANZ consider non-food sources of Red 3 in dietary exposure assessment • Alternatively, suggests FSANZ supply evidence/information to support assumption that non-food sources contribute little to exposure.
Department of Health, Victoria	Government	• No objection to application proceeding at this stage. • Notes that if approved may ultimately lead to permissions in a wider variety of foods. • Cognizant of community concern regarding colours even though current scientific evidence regarding possible adverse effects is unclear.
Queensland Health (whole of government response)	Government	• Notes previous issues raised have been addressed • No objection to progressing Application • Notes that erythrosine and its aluminium lake are permitted ingredients on Australian Register of Therapeutic Goods and that the dietary exposure assessment appear to have not considered non-food sources
AFGC	Industry Assoc	• Supports Option 2 – preferred approach • Supports FSANZ principles in assessing food additive permissions i.e. no unacceptable risk, demonstrable need, fulfils technological function that benefits consumers, used only at levels that achieve the technological function. • Supports proposed maximum limits in icing • Notes that extending the permission to use erythrosine is a voluntary permission, providing the manufacturer or cake decorator the option to use erythrosine • Supports the need to provide consumers with information via ingredient labelling to enable informed purchasing decisions • Supports conclusion that proposed use of erythrosine is technologically justified, does not raise any public health and safety concerns and notes there is a net benefit to both consumers and industry in providing greater opportunity to use the colour • Supports the analysis of benefit and cost
Lynn MacLaren MLC	Greens (WA)	• Opposes any new submission that pre-empts release/outcomes of labelling review. • Claims the Biotech industry failed to demonstrate safe ethical procedures/practices • Cites support for consumer driven approach to labelling particularly in relation to GM labelling

Submitter	Group	Comments
Food Technology Association of Australia	Industry Association	• Supports Option 2 – preferred approach • Questions the scope of the Application – Applicant requested permission only for food suppliers, not manufacturers, but draft variation permits use in any food manufacture. Questions why the scope wasn't broadened for a wider range of products i.e. confectionery. Suggests it appears obvious that confectionery industry will now seek separate approvals.