

20 DECEMBER 2000

11/01

FULL ASSESSMENT REPORT
AND REGULATION IMPACT ASSESSMENT

A396 – ERYTHROSINE IN PRESERVED CHERRIES

EXECUTIVE SUMMARY

- An application was received on 10 August 1999 from Ardmona Foods Limited, requesting permission to continue the use of erythrosine to colour preserved cherries to a maximum permitted level of 200 mg/kg.
- Clause (2A) of Standard A5 – Colourings, of the Australian *Food Standards Code* (FSC) permitted the use of erythrosine to a maximum level of 290 mg/kg. This permission ceased to have effect on 9 March 2000.
- Standard 1.3.1 – Food Additives, which came into legal effect on 22 June 2000, included a permission for erythrosine to be added to preserved cherries to a maximum level of 290 mg/kg. However, this permission was subject to the outcome of this application.
- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated erythrosine in 1990 and allocated an Acceptable Daily Intake (ADI) of 0-0.1 mg/kg body weight.
- The current and proposed permitted uses of erythrosine lead to only a low level of dietary exposure which is well below the ADI and does not raise any apparent public health and safety concerns.
- There is a technological need to colour preserved cherries in order to meet consumer expectations for red coloured cherries. The colours in natural red cherries migrate to other fruits in a fruit cocktail during the cooking process. Maraschino cherries are white and are therefore dyed red to resemble a normal variety of cherry.
- Erythrosine is the only colour available that provides the appropriate colour, that does not bleed into the other fruit in a canned fruit cocktail during the cooking process, and that is stable over the shelf life of the product.
- The Regulation Impact Statement concludes the benefits to consumers, industry and governments of permitting erythrosine in preserved cherries, to a maximum level of 200 mg/kg, outweigh any costs.

BACKGROUND

Erythrosine (FD&C Red No, 3; CI 45430) is a red colorant previously used in Australia in a wide variety of foods including confectionery, biscuits, cakes, frankfurters and milk. Concerns regarding the safety of this colour were raised by the United States Food and Drug Administration (USFDA) following the publication of a report indicating that under experimental conditions erythrosine at high dose levels (4% in the diet) can affect the level of circulating thyroid hormones in rats thus leading to an increase in the incidence of thyroid tumours. The response of the USFDA in 1990 was withdrawal of permission to use erythrosine lakes (salts), (but not erythrosine) in all foods, drugs and cosmetics, and to withdraw the use of erythrosine in cosmetics and externally applied drugs. Use of erythrosine in food in the USA is permitted in amounts consistent with good manufacturing practice.

JECFA reviewed the data on erythrosine in 1990, including the data on potential carcinogenicity. Their conclusion was that the tumorigenic effects were a consequence of the effects on the thyroid hormones which occurred only at high dose levels. JECFA concluded that an ADI could be established from the effects of the thyroid function and on the basis of the human data available, an ADI of 0.1 mg/kg was established.

A proposal to restrict the use of erythrosine in foods was prepared by the National Health and Medical Research Council prior to the commencement of the Australia New Zealand Food Authority Act 1991, and continued in force by virtue of section 71 of the Act. At the 81st meeting of the Food Science and Technology Subcommittee in February 1991, it was 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 no further action was taken prior to the establishment of the Authority.

The proposal was considered by the Authority in March 1993. The decision at this time was to withdraw permission in the Australian *Food Standard Code* (FSC) for the use of erythrosine from all foods except preserved cherries and fabricated collagen casing for manufactured meats (Amendment No. 19, 9 March 1994). Permission for use of these latter two categories would be allowed for another three years (until 9 March 1997) in order to allow the development of alternative colours.

An application (A324) was received from Ardmona Foods, S.P.C Limited, and Golden Circle Ltd on 11 October 1996, to consider retaining Clause (2A) (a) (i) in Standard A5 of the Australian Food Standards Code, allowing the use of erythrosine in preserved cherries. Permission was extended until 9 March 2000 (Amendment No. 34, 15 May 1997).

Erythrosine is used to colour white cherries red prior to processing. The applicant states that alternative red colours cannot be used because the colour migrates into the other components of the can, such as pears, peaches, grapes and pineapple in cans of fruit cocktail or fruit salad.

The application requests a variation to Standard A5 – Colourings, of the Australian FSC to allow the continued use of the colour erythrosine, including its aluminium and calcium lakes, in maraschino, cocktail and glaze cherries.

Food regulations in other countries still permit the use of erythrosine in cherries, including the USFDA, New Zealand and the European Union (EU). There is a Codex standard for erythrosine in various cherries.

ISSUE

The issue is that the current permission contained in the Australian FSC for the use of erythrosine to colour preserved cherries was due to be withdrawn from 9 March 2000 and manufacturers of such products have been unable to find a suitable alternative colouring agent to colour preserved cherries used in the manufacture of canned fruit cocktail or fruit salad.

OBJECTIVE

The objective of this application was to vary Standard A5 – Colourings of the Australian FSC, to continue to permit the use erythrosine in preserved cherries at 200 mg/kg.

RELEVANT PROVISIONS

Standard A5 – Colours, of the Australian FSC, from 9 March 1997 until 9 March 2000, prescribed that erythrosine, including its aluminium and calcium lakes, was permitted for use in preserved cherries known as maraschino or cocktail cherries and glace cherries, to a maximum level of 290 mg/kg.

Standard 1.3.1 – Food Additives, came into legal effect on 22 June 2000. Schedule 1 of Standard 1.3.1, permits the use of erythrosine, to a maximum level of 290 mg/kg, in preserved cherries known as maraschino cherries, cocktail cherries or glace cherries.

Regulation 250 – Colouring Substances, of the New Zealand *Food Regulations 1984* (NZFR) lists erythrosine and its aluminium lakes as permitted colouring substances. Food may contain colourings where permitted by the NZFR without any specific restrictions.

Erythrosine has been allocated the International Numbering System (INS) number 127. Codex Standard 78-1981, for Canned Fruit Cocktail, provides that cherries used in canned fruit cocktail may be artificially coloured with erythrosine to a level limited by good manufacturing practice.

The United States of America (USA) Code of Federal Regulation, Title 21, Part 74.303, states that FD&C Red No. 3 (erythrosine) may be safely used for colouring foods generally in amounts consistent with good manufacturing practice except that it may not be used to colour foods for which standards of identity have been promulgated, unless added colour is authorised by such standards.

The applicant states that a maximum permission for erythrosine in preserved cherries of 200mg/kg has been requested as this level is consistent with current EU permissions for preserved cherries. The EU permits erythrosine to be added to cocktail berries and cherries to a level of 200 mg/kg, and to fruit cocktail to a level of 150 mg/kg.

PUBLIC CONSULTATION

Calls for public comment in relation to this application were published in the Australian and New Zealand press on 13 October 1999, with a comment period of six weeks.

Fifteen submissions were received in relation to A396. A detailed summary of submissions is at Attachment 3.

The Allergy, Sensitivity, and Environmental Health Association (ASEHA) Qld Inc, Consumers' Federation of Australia (CFA), National Council of Women of New Zealand (NCWNZ) and National Council of Women of Australia (NCWA) were opposed to the application.

The **Australian Food and Grocery Council (AFGC), Berri Limited, Del Monte International Inc., Western Australian Food Advisory Committee, SPC Limited, Food Technology Association Vic. Inc., InforMed Systems and Melbourne Kashrut** supported the application.

Queensland Health (QH) recognised that using erythrosine as prescribed was not considered a risk to public health and safety, but requested justification that the proposed level of 200 mg/kg is the minimum required to achieve the technological outcome.

The **New Zealand Ministry of Health (NZMoH)** suggested that justification would need to be given for any recommendation that is more restrictive than the current Codex standards since this represents a restriction on the current New Zealand arrangements.

The **Melbourne Kashrut** indicated that erythrosine is kosher, while the other colour carmine (or cochineal, colouring 120) was not. Therefore if carmine is used the finished product must be declared as not Kosher.

The **Office of Regulation Review** commented on the format of the Regulation Impact Statement.

OPTIONS including alternatives to regulation

Option 1 – do not permit the addition of erythrosine to preserved cherries.

Option 2 – permit the addition of erythrosine to preserved cherries at 200 mg/kg; or

Option 3 – permit the addition of erythrosine to preserved cherries at 290 mg/kg, and retain the *status quo*.

Non-regulatory options such as self-regulation and co-regulation through codes of practice, industry guidelines, information strategies etc have not been considered in relation to this application. Use of food additives is specifically regulated in order to protect public health and safety. Specific regulation of erythrosine is consistent with the regulation of all other food additives.

ASSESSMENT

Toxicology

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considered erythrosine at its 37th meeting in June 1990.

Prior to 1990, erythrosine was last evaluated by JECFA at its 33rd meeting when a temporary ADI of 0-0.05 mg/kg of body weight was established.

At the 37th meeting JECFA considered additional studies on thyroid hormone metabolism, carcinogenicity and mutagenicity studies and allocated an ADI of 0-0.1 mg/kg of body weight for erythrosine, based on the no-observed-effect level of 60 mg per person per day (equivalent to 1 mg per kg of body weight per day) and a safety factor of 10.

Dietary Modelling

In the Full Assessment report prepared in 1993, estimates of dietary intake of erythrosine indicated that the permitted uses at that time would lead to a dietary intake in excess of the ADI of 0.1 mg/kg. The subsequent withdrawal of permission for erythrosine use from all major processed foods has reduced the level of intake well below the ADI. The current permitted uses of erythrosine are considered to lead to only a low level of dietary exposure which does not raise any significant public health and safety concerns.

The Dietary Exposure Assessment Report in relation to this application (at attachment 2) concludes:

Estimated dietary exposure to erythrosine is below the ADI for mean and high consumers of preserved cherries. The estimated level of consumption of preserved cherries that is required to meet the ADI for erythrosine is well above actual consumption levels. It is unlikely that the continued addition of erythrosine to preserved cherries at (200 mg/kg) will result in the ADI for erythrosine being exceeded in Australia and New Zealand.

Issues Raised By Public Submissions

1. Safety considerations

Comment Received

ASEHA, CFA, NCWA and NCWNZ raised a range of concerns relating to the safety of erythrosine. Issues raised included interactions between erythrosine and other additives, possible increase in thyroid hormone levels affecting thyroid functions resulting in hyperthyroidism that can cause hyperactive behaviour, is associated with benign thyroid tumours in rodents, has been shown to have toxic effects on the genes of some strains of yeast cells, may cause phototoxicity, and is a suspect carcinogen.

QH stated that when cherries coloured with erythrosine are stored in plain cans, fluorescein is readily formed by the interaction of the tin-iron couple present. This does not occur in lacquered cans. **QH** suggested that 'consideration from the applicant should be given to address this outcome'.

NCWNZ also raised the issue of sensitivity to erythrosine, suggesting that about 20% of people who are sensitive to aspirin are also sensitive to azo dyes and other groups which may be affected are asthmatics and people who suffer from eczema. **InforMed Systems** considered that it is possible that individuals may have idiosyncratic response to almost anything in food and that this is a matter of individual characterisation and avoidance and cannot be legislated.

Discussion

As stated above, JECFA considered erythrosine in 1991 and assigned it an ADI of 0-0.1 mg/kg of body weight. Additionally, with restriction of permission to use erythrosine only to preserved cherries at a reduced maximum level of 200 mg/kg, dietary intake is minimal, further enhancing the safety of the additive.

There is little evidence of individuals having a sensitivity to erythrosine. Foods containing erythrosine are required to list its presence in the ingredient list in the form “colour (127)” or “colour (erythrosine)”. This provides sufficient information to allow individuals to avoid foods containing erythrosine if necessary or desired. This approach is consistent with the regulation and labelling of other food additives.

The applicant was informed of **QH’s** concerns in relation to the formation of fluorescein by the interaction of the tin-iron couple with erythrosine. The applicant has provided the following information:

- Cans currently used for canning fruit cocktail have only a lacquered top and bottom. Exposure of the tinplate to the contents of the can is necessary to prevent browning of the peaches and pears over time. Cans of fruit cocktail contain only very small amounts of erythrosine.
- Preserved cherries are supplied to the manufacturers in bulk packages made of plastic.
- Maraschino cherries are usually sold at retail bottled in glass.

Technological need for the additive

ASEHA, CFA, NCWA and **NCWNZ** considered that technological need for the additive had not been sufficiently demonstrated. Issues raised included that synthetic colouring agents such as erythrosine have no nutritive value and serve no purpose other than enhancing the aesthetic appearance of food, that other colours had been identified which could be used for colouring preserved cherries, that manufacturers showed an unwillingness to search for and use an alternative colouring reflecting a lack of will by the industry to effect change. The submission from **NCWA** also suggested that other colouring agents had been successfully used for the purposes of colouring cherries in the United Kingdom (UK).

The **AFGC** considered that there are sound technical reasons and consumer imperatives to permit the addition of erythrosine to preserved cherries. The AFGC contended that despite all the experimental work that has been carried out, it has not been possible to identify a suitable alternative to erythrosine in preserved cherries. The flesh of cherries has little intrinsic colour, and when processed the flesh becomes colourless. It is not possible to ‘fix’ other colours in the cherry flesh and they tend to ‘bleed’ into other foods with which they might be mixed, particularly in a moist environment, and in particular, in fruit salad or fruit cocktail, where pears and pineapples are left with red colour stains. The preserved cherry is seen as a key ingredient in canned fruit salad or fruit cocktail and removing it or replacing it is not seen as a viable alternative

QH suggested that they would like to see justification that the proposed level of 200 mg/kg is the minimum required to achieve the technological outcome. **QH** suggested that research into alternative colours has been progressing for a number of years and requests that the use of alternative colours be investigated to facilitate the replacement of erythrosine with a suitable alternative.

SPC Ltd stated that alternative colours which had been tested include diced papaya and carmine. Diced papaya proved unsuccessful, as consumers did not like the colour of the cherries, and preferred cherries coloured with erythrosine. Carmine coloured cherries cannot be certified as kosher, which is an extremely important marketing requirement for overseas markets, particularly North America. **SPC Ltd** contended that no red cherry varieties exist which are suitable for canning, in that they show colour fade and bleed after sterilization process in the can, and therefore erythrosine is required.

Discussion

The Codex principles for the use of food additives which set out under what conditions the use of food additives are justified are discussed below. The third principle is to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer.

Organoleptic properties include the taste, aroma and appearance of a food. Therefore, food additives, such as erythrosine, used to replace or enhance the colour of a food would be an acceptable use of a food additive as they enhance the appearance of the food.

It is not possible to use natural red cherries or coloured grapes (red or black) in a fruit cocktail as the colour bleeds profusely from both types of fruit during the cooking process. Therefore the industry has traditionally used Thompson seedless or sultana grapes that do not have any colour, and the maraschino cherry. Maraschino cherries are white and are therefore dyed red to resemble a normal variety of cherry.

The applicant provided information on the use of alternative dyes to erythrosine. The one that has had limited success is carmine. The main technological disadvantage of dyes other than erythrosine is that when fruit cocktail is cooked in the can, the alternative dye migrates (bleeds) into the other fruits, and the pears and peaches turn a pink shade. The applicant stated that this is unacceptable in many markets, particularly their major export market, Japan. The applicant further suggests that the dye bleed might be satisfactory if the product was made day by day, however, it is a seasonal product made each year from February to March. Therefore, with a three month carry on, the product can be over 15 months old before it is dispatched.

The applicant also contended that there are three other factors which make carmine an unsuitable alternative to erythrosine:

- The carmine colour is not a true cherry colour and does not resemble the colour of erythrosine;
- The Jewish community does not accept foods coloured with carmine as kosher; and
- The cost of carmine is high compared to other colours, as the colour is extracted from insects. Additionally, as the use of carmine has increased, especially since the banning of erythrosine in various products, the cost has increased.

The applicant also questioned whether the suppliers of carmine would be able to produce enough to supply the world, if the major fruit cocktail producing nations banned erythrosine.

In response to issues raised by the NCWA, regarding the use of other colourings in preserved cherries in the UK and the testing of alternative colours, the applicant supplied verification from its cherry supplier, Nicola D'Avanzo Fruit (Italy) that carmine was the only alternative red dye suitable for dyeing cherries. Other red colours available on the market provided no stability at all on cherries when mixed in fruit cocktails. Nicola D'Avanzo Fruit also stated that erythrosine gave more stable results and a longer shelf life than fruit dyed with carmine. In addition, Nicola D'Avanzo Fruit contended that using carmine instead of erythrosine increased production costs by 35%. All of their customers (in Europe, South Africa, Asia, and South America) have decided to continue using erythrosine to colour cherries, while the process of dyeing of cherries with carmine is covered by a patent in the USA.

The applicant also provided testimonial from Emery International, UK, importers of canned goods. Emery International confirmed that cocktail cherries available from Sainsbury and Tesco in the UK were labelled as being coloured with erythrosine.

Consumer choice

Both the **NCWA** and the **NCWNZ** objected to the statement in the Preliminary Assessment that that consumer choice may be restricted by removal of the permission to colour preserved cherries with erythrosine. **NCWA** argued that consumers could still have cherries in their canned fruit salad, albeit white or another more suitable colour perhaps as used by some English companies. Further, **NCWA** considered that, given an informed choice, the majority of consumers would choose colourless cherries rather than red cherries.

Discussion

The applicant states that canned fruit cocktail has been manufactured around the world for about 40 years, and cherries (coloured with erythrosine) have been a traditional ingredient.

As stated above, there is no suitable natural red cherry or red colouring which is colour fast in the long term and gives the required colour in the final product for fruit cocktail or fruit salad.

Currently, manufacturers may choose to use colourless cherries in canned fruit cocktail, and may choose to use this as a marketing advantage, thus providing greater consumer choice. However, removal of the permission to colour preserved cherries, including cocktail cherries, with erythrosine, and with no adequate alternative being available, may force manufacturers to provide inferior quality product where the colour bleeds, or only colourless cherries, or not include cherries in fruit cocktails at all. This will certainly limit the choice of consumers, particularly those consumers who are used to and prefer the traditional appearance the cherries and fruit cocktail.

Removal of the permission to use erythrosine to colour preserved cherries will certainly limit the choice of some sectors of the community. The most suitable alternative to erythrosine, carmine, is not recognised as being kosher.

International requirements

The **AFGC** stated that ANZFA must also take into account that internationally erythrosine is permitted for this use in other developed countries, including the EU and the USA, while the **NZMoH** pointed out that Codex has widespread permissions for erythrosine with maximum levels in the 300-400 mg/kg range.

NZMoH suggested that justification will need to be given for any recommendation that is more restrictive than the current Codex standards, since this represents a restriction on current New Zealand arrangements.

In contrast, the **CFA** suggested that the US FDA have de-listed certain uses of erythrosine and is considering banning its use totally, and the **NCWNZ** suggested that the US FDA has recommended that this dye be banned as a carcinogen.

Discussion

As set out in Relevant Provisions, above, erythrosine is still accepted as an approved colouring agent internationally. New Zealand and the USA permit the use of erythrosine in foods where colouring is permitted, to a level determined by good manufacturing practice. Codex permits the use of erythrosine to colour cherries used in canned fruit cocktail, also to a level limited by good manufacturing practice.

The New Zealand Food Regulations currently permit erythrosine in a range of foods (including confectionery, biscuits, cakes, soft drinks, cordials and milk) equivalent to the permitted uses in Australia prior to 1993. In the Full Assessment report prepared in 1993, estimates of dietary intake of erythrosine indicated that the permitted uses at that time could lead to intakes above the ADI of 0-0.1 mg/kg body weight. Therefore, continuation of the current permissions for the use of erythrosine in New Zealand may also lead to a dietary intake in excess of the ADI of 0.1 mg/kg. The subsequent withdrawal of erythrosine use from all major processed foods in Australia has reduced the level of intake well below the ADI. The currently permitted uses of erythrosine in the joint Food Additives Standards 1.3.1 are considered to lead to only a low level of dietary exposure which does not raise any significant public health and safety concerns.

The applicant has requested that a maximum permitted level of 200 mg/kg be prescribed, as this is consistent with current EU permissions for cocktail and candied cherries.

CODEX PRINCIPLES FOR THE USE OF FOOD ADDITIVES

The use of food additives is justified only where they serve one or more of the purposes set out from (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:

- (a) **to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified on the circumstances dealt with in sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet.**

Not applicable

- (b) **to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs.**

Not applicable

- (c) **to enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer.**

Organoleptic properties include the taste, aroma and appearance of a food. Therefore, food additives used to replace or enhance the colour of a food would be an acceptable use of food additives as colourings enhance the appearance of the food.

There is a consumer expectation that the cherries in a fruit cocktail should be red, however, there is no suitable natural red cherry or red colouring which is colour fast in the long term and gives the required colour in the final product for fruit cocktail or fruit salad. Therefore, the use of the colouring is justified to enhance the colour of the cherries to resemble a normal variety of cherry in order to meet consumer expectations.

- (d) **to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any or these activities.**

The use of erythrosine in cocktail cherries is necessary as it is the only colour available which is colour fast for the shelf life of the product, which, in the case of canned fruit cocktail, may be greater than 2 years.

REGULATION IMPACT ANALYSIS

Option 1 – do not permit the addition of erythrosine to preserved cherries.

Advantages/benefits

Industry: There are no perceived advantages for manufacturers and importers of preserved cherries and canned fruit cocktail.

Consumers: There may be benefits for those consumers who wish to avoid erythrosine in all foods. Some consumers believe there is a health and safety concern with the consumption of erythrosine and therefore may perceive a benefit in its removal from all foods. However, toxicological assessment and dietary modelling (discussed above) show there is no health and safety concern with the addition of erythrosine to preserved cherries.

Government: There are no perceived benefits for government agencies.

Disadvantages/costs

- Industry:** Manufacturers of preserved cherries and canned fruit cocktail may be disadvantaged by no longer being able to provide a product which has been traditionally made and is expected by consumers. Importers of preserved cherries and canned fruit cocktail will be disadvantaged by having access to the Australian market restricted, or by having to manufacture product specifically for the Australian market.
- Consumers:** Consumers of canned fruit cocktail may be disadvantaged by a product they are familiar with no longer meeting their expectations due to there being no cherries added at all, or the cherries not meeting their expectations. The Jewish community may be disadvantaged by no longer having access to a kosher food product.
- Government:** There may be some costs to government in the need to become familiar with and administer new requirements. There may be costs to government arising from the need to defend itself in international fora for implementing regulation which is not consistent with international regulation.

Option 2 – permit the addition of erythrosine to preserved cherries at 200 mg/kg

Advantages/benefits

- Industry:** Manufacturers and importers of preserved cherries and canned fruit cocktail will benefit by continuing to be able to manufacture or import preserved cherries coloured with erythrosine. 200 mg/kg is the level requested by the applicant, representing the maximum level necessary to colour preserved cherries, and is consistent with EU permissions for erythrosine in preserved cherries. Some submissions suggested that if consumers were properly informed, they would prefer white cherries or cherries coloured with a natural colour rather than erythrosine. Manufacturers and importers may benefit by having an increased choice of colourings to use in preserved cherries, and may benefit by having the option to use uncoloured or naturally coloured cherries as a marketing opportunity.
- Consumers:** Consumers of preserved cherries will benefit by having continued access to preserved cherries which meet their usual expectations. Jewish consumers may benefit by having continued access to kosher preserved cherries and fruit cocktail.
- Government:** Government benefits by the implementation of regulations which are less trade restrictive, and consistent with current EU permissions for erythrosine in preserved cherries.

Disadvantages/costs

- Industry:** There are no perceived costs to manufacturers or importers of preserved cherries.
- Consumers:** There are no perceived costs to consumers.
- Government:** There may be some costs to government in the need to become familiar with and administer new requirements. While this option is less restrictive than option 1, it is still more restrictive than current Australian, New Zealand and international permissions. Therefore, there may be costs to government arising from the need to defend itself in international fora for implementing regulation which is not consistent with international regulation.

Option 3 – permit the addition of erythrosine to preserved cherries at 290 mg/kg (retain the status quo).

Advantages/benefits

- Industry: As with option 2, manufacturers and importers of preserved cherries and canned fruit cocktail will benefit by continuing to be able to manufacture or import preserved cherries coloured with erythrosine.
- Consumers: Consumers of preserved cherries will benefit by having continued access to preserved cherries which meet their usual expectations. Jewish consumers may benefit by having continued access to kosher preserved cherries and fruit cocktail.
- Government: There are no perceived additional benefits to government.

Disadvantages/costs

- Industry: There are no perceived costs to manufacturers or importers.
- Consumers: There may be perceived costs to those consumers who believe there are health and safety concerns associated with the consumption of erythrosine, as this level is not the minimum level needed to meet the technical need of manufacturers. The application requests permission to add erythrosine to a level of 200 mg/kg, being the level required to meet the technical need, and being consistent with EU permissions.
- Government: This permission is still more restrictive for erythrosine than internationally, however, as it would retain the status quo for erythrosine regulation in Australian it is unlikely to result in any costs to government.

RIS Evaluation

As there are no public health and safety concerns as a result of this application, the costs of Option 1 outweigh the benefits.

The costs and benefits of Options 2 and 3 are very similar. However, as some consumers perceive there are benefits from reducing the intake of erythrosine as much as possible, then Option 2 is preferable.

ANZFA SECTION 10 OBJECTIVES

This application was received on 10 August 1999 and is therefore assessed in accordance with the section 10 objectives at that date.

a. The protection of public health and safety.

JECFA has allocated an ADI of 0-0.1 mg/kg body weight for erythrosine. Dietary modelling indicates that the highest consumers of preserved cherries will only consume a fraction of the ADI for erythrosine. Therefore there are no apparent issues in relation to public health and safety raised by this application.

b. The provision of adequate information relating to food to enable consumers to make and informed choice and to prevent fraud and deception.

Currently, as prescribed by Clause (5)(e) of Standard A1 – Labelling and Advertising, of the Australian FSC, as preserved cherries are a standardised food used as an ingredient at less than 10% of a mixed food, labelling of the presence of erythrosine in the final product may not be required. Fruit cocktail products currently on sale in Australia list erythrosine in the ingredient list.

Clause 6 of Standard 1.2.4 – Labelling of Ingredients, of the joint FSC requires the declaration of the components of compound ingredients where those ingredients make up more than 5% of the final food, or where a food additive in the compound ingredient is performing a technological function in the final food. This represents much clearer and simpler regulation of the labelling of compound ingredients. Fruit cocktail are required to list the presence of erythrosine in cherries in the ingredient list.

For preserved cherries sold as such (such as packets of glace cherries) the use of erythrosine is also required to be listed in the ingredient list.

c. The promotion of fair trading in food.

Permission to use erythrosine to colour preserved cherries will apply to all manufacturers equally. Therefore the ‘level playing field’ is maintained and fair trading in food remains unaffected.

d. The promotion of trade and commerce in the food industry.

Permission to use erythrosine in preserved cherries will promote trade and commerce in the food industry in that manufacturers will be able to continue producing and supplying canned fruit cocktail containing coloured cherries which are stable for the domestic and international markets and meet consumer expectations.

e. The promotion of consistency between domestic and international food standards.

Internationally, erythrosine is permitted in a much wider range of foods, often to a level limited by good manufacturing practice.

Permitting erythrosine in preserved cherries to a level of 200 mg/kg will go some way to promoting consistency between domestic and international food standards. However, restriction of the use of erythrosine only to preserved cherries is generally inconsistent with international standards.

CONCLUSIONS

- JECFA evaluated erythrosine in 1990 and allocated an ADI of 0-0.1 mg/kg body weight.
- The current and proposed permitted uses of erythrosine lead to only a low level of dietary exposure which does not raise any apparent public health and safety concerns.

- There is a technological need to colour preserved cherries in order to meet consumer expectations for red coloured cherries. The colours in natural red cherries migrate to other fruits in a fruit cocktail during the cooking process. Maraschino cherries are white and are therefore dyed red to resemble a normal variety of cherry.
- Erythrosine is the only colour available that provides the appropriate colour, that does not bleed into the other fruit in a canned fruit cocktail during the cooking process, and that is stable over the shelf life of the product.
- The Regulation Impact Statement concludes the benefits to consumers, industry and governments of permitting erythrosine in preserved cherries, to a maximum level of 200 mg/kg, outweigh any costs.
- Implementation of the draft variation should be from the date of gazettal.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does need to be advised to the WTO as a TBT Notification because it represents a reduction in the current permissions for use of erythrosine in Australia and New Zealand and is more restrictive than current international requirements.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

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

The following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.

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

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

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

INVITATION FOR PUBLIC SUBMISSIONS

The Authority has completed a full assessment of the application, prepared draft variations to the joint Australia New Zealand *Food Standards Code* and the Australian *Food Standards Code*, and will now conduct an inquiry to consider the draft variations and its regulatory impact.

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

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

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A406** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **2 February 2001**.

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

Attachments to the Report:

1. Draft Variation to Volume 2 of the Food Standards Code.
2. Dietary Exposure Assessment Report
3. Summary of Public Comment Received

DRAFT VARIATION TO VOLUME 2 OF THE FOOD STANDARDS CODE

A396 – ERYTHROSINE IN PRESERVED CHERRIES

To commence: On gazettal

The entry in the Max Level column in Schedule 1 in Standard 1.3.1 in the Australia New Zealand Food Standards Code, in relation to preserved cherries known as maraschino cherries, cocktail cherries or glace is varied by deleting -

290 mg/kg

substituting -

200 mg/kg

The entry for the entry in the Max Level column, in relation to preserved cherries known as maraschino cherries, cocktail cherries or glace cherries now reads as follows –

preserved cherries known as maraschino cherries, cocktail cherries or glace cherries			
127	Erythrosine	200 mg/kg	

APPLICATION A396 – ERYTHROSINE IN PRESERVED CHERRIES

DIETARY EXPOSURE ASSESSMENT REPORT

An application was received by ANZFA requesting permission to use erythrosine to colour preserved cherries to a level of 200 mg/kg. Preserved cherries include maraschino cherries, cocktail cherries and glace cherries.

A dietary exposure assessment was deemed necessary in order to determine if the requested level of use of erythrosine from the application was of public health and safety concern.

Dietary Modelling

The dietary exposure assessment was conducted using ANZFA's dietary modelling computer program, DIAMOND. The dietary exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with proposed levels of use of erythrosine in foods.

How were the dietary exposures calculated?

The DIAMOND model allows erythrosine concentrations to be assigned to food groups. Erythrosine concentrations were only assigned to preserved cherries, and this included where preserved cherries were used as an ingredient in canned fruit salad and other mixed foods.

The DIAMOND program multiplies the specified concentration of erythrosine by the amount of preserved cherries that an individual consumed in order to estimate the exposure for each individual. Population statistics (mean and high percentile dietary exposures) are then derived from the individuals' dietary exposures.

The quantity of preserved cherries that need to be consumed to meet the Acceptable Daily Intake (ADI) for erythrosine was calculated for both Australian and New Zealand populations. These calculations were based on the average weight of the respondents in both countries NNSs (67 kg and 71 kg for Australia and New Zealand respectively), and the proposed level of erythrosine in preserved cherries (200 mg/kg). These quantities were compared to the 95th percentile consumption of preserved cherries as derived from the NNS data.

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology. The dietary exposure assessment was conducted for both Australian and New Zealand populations.

Erythrosine Concentration levels

The level of erythrosine in foods used in the dietary exposure estimates was 200 mg/kg in preserved cherries. This was the level outlined in the application.

Estimating Risk

In order to determine if the level of dietary exposure to erythrosine is of public health and safety concern, the estimated dietary exposures were compared to an ADI. The ADI for erythrosine is set at 0.1 mg/kg of bodyweight.

Results

Dietary exposure estimates of erythrosine from consumption of preserved cherries from all sources were compared to the ADI of 0.1 mg/kg bodyweight for erythrosine. The estimated mean and 95th percentile erythrosine exposures for consumers of preserved cherries in Australia and New Zealand were both well below the ADI for erythrosine, as indicated in Table 1.

Table 1. Dietary exposure estimates of erythrosine as a percentage of the ADI for Australian and New Zealand consumers of preserved cherries.

Consumers	% ADI	
	Australia	New Zealand
Mean	10.2	4.4
95 th percentile	28.8	12.2

Aus - No. Consumers = 195, 1.4% of all respondents
NZ - No. Consumers = 207, 4.5% of all respondents

Based on the ADI and average body weights for the populations of Australia and New Zealand, and the proposed erythrosine level in preserved cherries, the amount of preserved cherries that need to be consumed to exceed the ADI is approximately 35 g/day. This level is approximately twice to seven times the estimated 95th percentile consumption derived from the NNS's (see Table 2).

Table 2. Consumption of preserved cherries required to meet the ADI for erythrosine compared to estimated 95th percentile consumption of preserved cherries.

Consumption	Australia (grams/day)	New Zealand (grams/day)
Required to meet ADI	34	36
Estimated 95 th percentile	15.8	4.8

Aus - No. Consumers = 41, 0.3% of all respondents
NZ - No. Consumers = 118, 2.5% of all respondents

Summary/Conclusions

Estimated dietary exposure to erythrosine is below the ADI for mean and high consumers of preserved cherries. The estimated level of consumption of preserved cherries that is required to meet the ADI for erythrosine is well above actual consumption levels. It is unlikely that the continued addition of erythrosine to preserved cherries at (200 mg/kg) will result in the ADI for erythrosine being exceeded in Australia and New Zealand.

A396 – ERYTHROSINE IN PRESERVED CHERRIES

PUBLIC COMMENT RECEIVED AT FULL ASSESSMENT

List of submitters

Submitter

- 1 Allergy, Sensitivity, and Environmental Health Association (ASEHA) Qld Inc
- 2 Australian Food and Grocery Council
- 3 Berri Limited
- 4 Consumers' Federation of Australia
- 5 Del Monte International Inc.
- 6 Food Technology Association Vic. Inc.
- 7 InforMed Systems
- 8 Melbourne Kashrut
- 9 National Council of Women of Australia
- 10 National Council of Women of New Zealand
- 11 New Zealand Ministry of Health
- 12 Office of Regulation Review
- 13 Queensland Health
- 14 SPC Limited
- 15 Western Australian Food Advisory Committee

Submitter	Comments
Allergy, Sensitivity, and Environmental Health Association (ASEHA) Qld Inc	<ul style="list-style-type: none"> - concerned about the inadequacy of the toxicological studies on erythrosine, in particular, the lack of chronic studies and limited human data - do not accept animal studies as an adequate indicator of human toxicity - concerned that children consume this colouring in frankfurter skins and are more likely to be attracted to red coloured foods than paler foods - erythrosine should not be allowed in any food children consume or are likely to consume - of further concern is interactions between erythrosine and other additives, or naturally occurring chemicals as these may cause either an additive or potentiated effect - toxicology on erythrosine currently to hand indicates that it: <ul style="list-style-type: none"> ▪ is a xanthine (alkaloid) ▪ is water soluble and 20% is absorbed across the gut into the body but may accumulate in the body if there is any blockage of the bile duct ▪ has been shown to have toxic effects on the genes of some strains of yeast cells ▪ can inhibit the uptake of dopamine and may act as an excitatory agent on the CNS causing hyperactive behaviour ▪ may affect acetyl choline release

Submitter	Comments
	<ul style="list-style-type: none"> ▪ affects the uptake of choline, GABA, glycine, glutamine, noradrenaline ▪ may cause elevation in protein-bound-iodine and affect the iodine sensitive in the community ▪ may increase thyroid hormone levels and affect thyroid functions resulting in hyperthyroidism that can cause hyperactive behaviour ▪ is associated with benign thyroid tumours in rodents ▪ may cause phototoxicity ▪ is a suspect carcinogen <p>- at risk populations include infants whose metabolism is still developing and those in the community with iodine and/or phenolic sensitivities</p> <p>- erythrosine included in foods with other additives may result in an increased dose that exceeds the ADI</p> <p>- Code Additive Breaker (Hanssen) “children consuming food with high levels of erythrosine can have intakes approaching the levels that could cause problems</p> <p>- In 1991 the US National Research Council estimated that only 2% of chemicals that are widely used have been comprehensively studied for toxic effects</p> <p>ASEHA recommends that:</p> <ul style="list-style-type: none"> • The use of erythrosine be suspended until further toxicology assessments are available, in particular, chronic studies and human studies • Erythrosine should be subject to further toxicology assessment especially for effects on the endocrine system, the central nervous system and for effects on behaviour and learning • Erythrosine should be banned in any food children are likely to eat • ANZFA should engage in more educational programs to alert the community to the use of food additives and the risk of these to some groups in the population • ANZFA should begin to gather data from the general population regarding the adverse health impacts of food additives • A system, similar to the National Registration Authority’s Existing chemical Review Process, to reassess chemicals that have not been adequately tested for health impacts
Australian Food and Grocery Council	<ul style="list-style-type: none"> - Despite all the experimental work that has been carried out, it has not been possible to identify a suitable alternative to erythrosine in preserved cherries - The flesh of cherries has little intrinsic colour, and when processed the flesh becomes colourless - Although other colours have been tried, for reasons yet to be elucidated, it is not possible to ‘fix’ them in the cherry flesh and they tend to ‘bleed’ into other foods with which they might be mixed, particularly in a moist environment, and in particular, in fruit salad or fruit cocktail, where pears and pineapples are left with red colour stains - The preserved cherry is seen as a key ingredient in canned fruit salad or fruit cocktail and removing it or replacing it is not seen as a viable alternative - Preserved cherries constitute a small proportion of fruit salad or fruit cocktail as consumed, and an even smaller proportion of the diet <i>in toto</i> - ANZFA must carry out a risk assessment into the consumption of erythrosine in this sole use of the colour in food in order to fulfill the first objective of food standards, namely to protect public health and safety - ANZFA must also take into account that internationally erythrosine is permitted for this use in other developed countries, including the EU and the USA - Supports the continued use of erythrosine in maraschino or cocktail cherries and glaze cherries, subject to an appropriate risk assessment by

Submitter	Comments
	<p>ANZFA</p> <ul style="list-style-type: none"> - Recommends that preserved cherries be permitted to contain <u>not more than 200 mg/kg</u> - There are sound technical reasons and consumer imperatives to permit the addition of erythrosine to preserved cherries
Berri Limited	<ul style="list-style-type: none"> - Supports the use of erythrosine in cocktail cherries for use in canned and glace products - Berri Limited produces shelf-stable fruit packs for use in Australian and overseas markets, and requires the continuation of the use of erythrosine in these products to be internationally competitive
Consumers' Federation of Australia	<ul style="list-style-type: none"> - Opposes the use of erythrosine in food because of unresolved concerns about its effects on animal and human health - Erythrosine has been shown to cause changes in thyroid function in rodents, and after long-term use, increased incidence of benign thyroid tumours (Klassen CD [ed] 1996 <i>Casseret and Doull's Toxicology</i> 5th edition) - Erythrosine has been shown to have toxic effects on the genes of some strains of yeast cells (Hanssen M 1989 <i>The New Additive Code Breaker</i>) - It is possible that erythrosine contributes to behavioural disturbance in some susceptible children, possibly through its demonstrated effects on neuro-transmitter uptake in animals or through its effect on thyroid function (Buist RA 1986 <i>Food Chemical Sensitivity</i>) - Understand that the US FDA have de-listed certain uses of erythrosine and is considering banning its use totally - Synthetic colouring agents such as erythrosine serve no purpose other than enhancing the aesthetic appearance of food - While there is any unresolved concern over their long-term safety, we feel there is absolutely no justification for granting yet another extension of approval for this additive
Del Monte International Inc.	<ul style="list-style-type: none"> - provided copies of SCF and JECFA reports regarding studies on erythrosine - support the continued use of erythrosine for cherries used in fruit cocktails in Australia and New Zealand
Food Technology Association Vic. Inc.	<ul style="list-style-type: none"> - agree to permit the use of erythrosine in preserved cherries at 200 mg/kg, provided that the risk assessment is satisfactory with regard to public health and safety
InforMed Systems	<ul style="list-style-type: none"> - the supposed adverse effects of this colour seem to be thyroid effects - this has been refuted as it has been shown that the absorption of iodine from this colour in humans is negligible - the US agencies have claimed some mutagenicity in the past, but subsequent studies have failed to substantiate this - the issue of hyperactivity is always raised - it is possible that individuals may have idiosyncratic response to almost anything in food - this is a matter of individual characterisation and avoidance and cannot be legislated - for these reasons, there seems to be no justification for not permitting this colour - recommend approval
Melbourne Kashrut	<ul style="list-style-type: none"> - Melbourne Kashrut is a religious Jewish organization which investigates the Kosher status of various food products and food ingredients. - Cochineal (colouring 120) is not Kosher, and therefore if this colouring is used the finished product must be declared as not Kosher, eg canned fruit cocktail or canned fruit salad etc. - This would be quite unfortunate for the Jewish communities in Australia and New Zealand. - Erythrosine is Kosher. - There is no evidence that it would be harmful at the level used in cocktail cherries (maximum 200 mg/kg).

Submitter	Comments
National Council of Women of Australia	<ul style="list-style-type: none"> - use of erythrosine in preserved cherries is not justified - reasons used to give an extension of use of erythrosine in preserved cherries and fabricated collagen casings in 1993 were as follows: <ul style="list-style-type: none"> ▪ use of erythrosine in preserved cherries leads only to a low level of dietary exposure which is below the ADI and does not raise any significant public health and safety concerns <p><i>Response:</i> continual intake of any substance known to be cancer causing, even at low levels, cannot be ruled out as a health concern</p> <ul style="list-style-type: none"> ▪ there is a technological need to colour white cherries used in canned fruit and suitable alternative colours to erythrosine have not yet been identified <p><i>Response:</i> Food Additives Campaign Team's Report on Food Additives to the MAFF Advisory Committee in 1987 identified food colours used in some English companies preserved cherries and concluded that the use of erythrosine was not technically justified (excerpts from reference included)</p> <ul style="list-style-type: none"> ▪ current review of food additives (P150) is considered to be a more appropriate mechanism to consider the issue of future use of erythrosine in foods; in the interim, extension of current permissions will allow further time for the development of alternative colours <p><i>Response:</i> the Australian industry has had 6 years to search for an alternative, which the English companies have already found; the Australian industry should be aware of the alternatives; unwillingness to search for and use an alternative colouring reflects a lack of will by the industry to effect change; no further extensions should be permitted</p> <ul style="list-style-type: none"> ▪ the proposed amendment will only apply to preserved cherries <p><i>Response:</i> if this is the only food in the food supply using erythrosine, all the more reason to remove it; maraschino cherries under P150 has no indication of erythrosine permission and the dye is not listed synthetic colours schedule</p> - questions statement in preliminary assessment report that consumer choice may be restricted; argues that consumers could still have cherries in their canned fruit salad, albeit white or another more suitable colour perhaps as used by some English companies - given an informed choice, majority of consumers would choose colourless cherries rather than red cherries - erythrosine has the ability to affect the nerve impulse transmissions quite apart from its cancer causing ability (excerpt from "Pure Facts" March 1990, Feingold Association) - any synthetic colouring has no nutritive value, but is used for cosmetic purposes only, their use should be strictly regulated and technically justified - erythrosine is not needed or justified in our food supply, and permission for the extension of use for a further three years should not be granted
National Council of Women of New Zealand	<ul style="list-style-type: none"> - Understand that erythrosine is also used in other food items such as disclosing tablets for revealing plaque on teeth, quick custard mix, biscuits, pre-packed swiss rolls, canned red cherries, strawberries and rhubarb, packet trifle mixes and frankfurter / savloy skins - Fears have been expressed that erythrosine might increase thyroid hormone levels because of its high (577 mg/g) iodine content and lead to hyperthyroidism - In experiments carried out with rats, thyroid gland weights increased abnormally, and they developed benign tumours when fed 4% erythrosine - Children consuming food high in erythrosine can have intakes approaching the levels which could cause problems

Submitter	Comments
	<ul style="list-style-type: none"> - The US FDA has recommended that this dye be banned as a carcinogen - The UK Food Advisory Committee on Mutagenicity has studied the available data and advised that there is now sufficient evidence from well constructed tests to conclude that erythrosine is probably not mutagenic - Erythrosine has been implicated in minimal brain dysfunction in children, and it can also cause phototoxicity - The ADI for erythrosine is 0 – 0.1 mg/kg body weight and we question whether the figure of 200 mg/kg is as low as possible - Object strongly to the implication that lack of such an additive would limit consumer choice; it is hardly an essential food item and as for further restricting use of this colour by the food industry – surely that is not a bad thing - About 20% of people who are sensitive to aspirin are also sensitive to azo dyes - Other groups which may be affected are asthmatics and people who suffer from eczema - The cumulative effect of children of eating cherries in conjunction with other foods outlined above may well bring the levels of erythrosine in childrens' diets above acceptable limits - Believes ANZFA should be taking minimal risks when allowing the use of erythrosine by: <ul style="list-style-type: none"> • seriously looking for alternatives and establishing a deadline for doing so • keeping levels as low as possible • not using such an additive if it is not essential
New Zealand Ministry of Health	<ul style="list-style-type: none"> - New Zealand currently permits erythrosine as a food colour without any specific restrictions under the Food Regulations - Codex has widespread permissions for erythrosine with maximum levels in the 300-400 mg/kg range - Note that a risk assessment is still to be completed - Suggest that justification will need to be given for any recommendation that is more restrictive than the current Codex standards, since this represents a restriction on current New Zealand arrangements - Any further restriction beyond Codex standards would be of considerable interest to New Zealand
Office of Regulation Review	<ul style="list-style-type: none"> - The preliminary assessment report contains some elements of a Regulatory Impact Statement (RIS) - A proper regulatory analysis needs to embody all elements of a RIS (details in submission on how to do a RIS)
Queensland Health	<ul style="list-style-type: none"> - Erythrosine used at the level prescribed is not considered a risk to public health and safety - Would like to see justification that the proposed level of 200 mg/kg is the minimum required to achieve the technological outcome - When cherries coloured with erythrosine are stored in plain cans, fluoresin is readily formed by the interaction of the tin-iron couple present. This does not occur in lacquered cans; consideration from the applicant should be given to address this outcome - Research into alternative colours has been progressing for a number of years - Requests that the use of alternative colours be investigated to facilitate the replacement of erythrosine with a suitable alternative
SPC Limited	<ul style="list-style-type: none"> - supports the use of erythrosine in preserved cherries - SPC is a major processor of fruit cocktail / fruit salad, which uses cherries coloured with erythrosine as ingredients - These products are marketed in Australia, New Zealand and to many other overseas markets - Alternatives tested include diced papaya and carmine - Diced papaya proved unsuccessful, as consumers did not like the colour

Submitter	Comments
	<p>of the cherries, and preferred cherries coloured with erythrosine</p> <ul style="list-style-type: none"> - Carmine coloured cherries cannot be certified as kosher, which is an extremely important marketing requirement for overseas markets, particularly North America - No red cherry varieties exist which are suitable for canning, in that they show colour fade and bleed after sterilization process in the can, and therefore erythrosine is required
Western Australian Food Advisory Committee	<ul style="list-style-type: none"> - Supports the proposal to continue to permit the use of erythrosine in preserved cherries at 200 mg/kg