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

3-07
23 May 2007

DRAFT ASSESSMENT REPORT

PROPOSAL P287

REVIEW OF CYCLAMATE PERMISSIONS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 July 2007.
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

Purpose

The purpose of this Proposal is to develop food regulatory measures to ensure that the dietary exposure to foods containing cyclamate does not result in any unacceptable risks to public health and safety. This is in light of the findings of a survey[1] on the consumption of intense sweeteners in Australia and New Zealand, which concluded that the estimated dietary exposure for some consumers of cyclamate products currently for retail sale on the market exceeded the acceptable daily intake (ADI) for cyclamate.

As part of this Proposal, FSANZ has also considered the issues in an Application from Hermes Sweeteners (UK), to amend the *Australia New Zealand Food Standards Code* (the Code) to permit cyclamate as an intense sweetener in tabletop sweeteners (liquid preparations and portion-sized packages). This Application was withdrawn by the Applicant pending its consideration by FSANZ as part of this Proposal.

This Proposal seeks to amend the maximum permitted level for cyclamates in water-based flavoured drinks (e.g. soft drinks, cordials) and to allow the use of cyclamates in tabletop sweeteners. The measures proposed by FSANZ are intended to protect public health and safety while permitting the appropriate and practical use of cyclamate in foods.

Submissions are now invited to assist FSANZ to complete the Final Assessment.

Preferred Approach

Amend Schedule 1 of Standard 1.3.1 – Food Additives, to reduce the maximum permitted level for cyclamates in water-based flavoured drinks from 600 mg/kg to 300 mg/kg and to allow the use of cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice (GMP).

Reasons for Preferred Approach

FSANZ recommends the proposed draft variation to Standard 1.3.1 – Food Additives for the following reasons:

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act, in particular, it does not raise any public health and safety concerns, it is based on risk analysis using the best available scientific evidence, and helps promote an efficient and internationally competitive food industry.

- FSANZ has conducted an assessment of the safety of cyclamate **(Attachment 2)** which concludes that the ADI of 11 mg/kg body weight is adequately protective of consumers.

[1] Consumption of Intense Sweeteners in Australia and New Zealand. Prepared by Roy Morgan Research, 2004

The dietary exposure assessment **(Attachment 3)** shows that reducing permissions for cyclamate in water-based flavoured drinks to 300 mg/kg would ensure that public health and safety of high consumers (Australians aged 2-11 years) is protected, and the inclusion of permissions for cyclamate in tabletop sweeteners would have minimal effect on cyclamate exposure in this population group.

- The Food Technology Report **(Attachment 4)** concludes that the use of cyclamate in foods is technologically justified. Reducing permissions for cyclamate in water-based flavoured drinks to 300 mg/kg would still enable manufacturers to produce commercial products, however, reformulations are likely to be required to achieve appropriate sweetness and shelf-life properties. Manufacturers will have the usual 12 month stock-in-trade provisions under subclause 1(2) of Standard 1.1.1 in the Code, in which to reformulate their products if the Code is amended to reduce cyclamate permissions in water-based flavoured drinks.

- The regulatory impact statement concludes that the benefits of the proposed regulatory approach outweigh the costs.

Consultation

The Initial Assessment Report was advertised for public comment between 20 October 2004 and 1 December 2004. A total of 13 submissions were received during this period and a summary of these is attached to this Report.

In addition, FSANZ established an External Advisory Group (EAG), comprising key industry and consumer stakeholders in Australia and New Zealand, to assist in the assessment of Proposal P287. FSANZ has considered submitters' and the EAG's comments in the preparation of this Draft Assessment Report.

FSANZ has had preliminary discussions with several Australian and New Zealand manufacturers of water-based flavoured drinks regarding the implications of the proposed reduction in cyclamate permissions, and will continue to consult with these and other affected parties during the consultation period for this Draft Assessment Report. This will ensure that manufacturers are fully consulted and given ample opportunity to reformulate their products prior to the introduction of any amendments to Standard 1.3.1.

Public submissions are now invited on this Draft Assessment Report. Responses to this Draft Assessment Report will be used to develop the next stage of the Proposal and the preparation of the Final Assessment Report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variations to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
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Submissions need to be received by FSANZ by 6pm (Canberra time) 4 July 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

Proposal P287 has been prepared to review the use of the intense sweetener cyclamate across the whole food supply. This is in light of a survey[2] conducted on behalf of FSANZ on the consumption of intense sweeteners in Australia and New Zealand, which concluded that the estimated dietary exposure for some consumers of cyclamate products currently for retail sale on the market exceeded the acceptable daily intake (ADI)[3] for cyclamate.

This Proposal will highlight the survey findings, examine the issues and detail appropriate options for regulation of cyclamate-containing foods to ensure that public health and safety is protected.

As part of this Proposal, FSANZ has also considered issues raised in an Application (Application A515) from Hermes Sweeteners (UK), namely, to amend the Code to permit cyclamate as an intense sweetener in tabletop sweeteners (liquid preparations and portion-sized packages) (refer Section 1.3).

1. Background

1.1 Review of Food Additives in Australia and New Zealand

Between 1998 and 2000, FSANZ undertook a review of food additive permissions (Proposal P150) during the broader review of food standards in Australia and New Zealand. As a result of this review, a revised food additive standard was developed, Standard 1.3.1 – Food Additives. The new Standard simplified the regulation of food additives by reducing prescriptiveness and bringing together food additives that may be used in all foods into one generic standard. As part of this review, cyclamate permissions in low joule products were made more restrictive and cyclamates were no longer permitted in tabletop sweeteners. The review process also identified several sweeteners, including cyclamates, for inclusion on a priority list for further monitoring following implementation of the new Standard.

Current permissions in the Code under Standard 1.3.1 for cyclamate are as follows:

Food	Maximum permitted level (mg/kg)
Commercially sterile fruit and vegetables in hermetically sealed containers	1350
Fruit and vegetable spreads including jams, chutneys and related products	1000
Low joule chewing gum	20000
Low joule fruit and vegetable juice products	400
Water based flavoured drinks	600
Brewed soft drinks	400
Jelly	1600
Sauce, topping, mayonnaise, salad dressing	1000

[2] Consumption of Intense Sweeteners in Australia and New Zealand. Prepared by Roy Morgan Research, 2004
[3] The current ADI for cyclamate is 11 mg/kg bw/day. The ADI is an estimate of the amount of a substance in food that can be ingested daily over a lifetime without appreciable health risk.

Currently there are no permissions for cyclamate use in tabletop sweeteners in Standard 1.3.1, however, in New Zealand, tabletop sweeteners are marketed as dietary supplements under the New Zealand *Dietary Supplements Regulations 1984* and are permitted to contain cyclamates. These products may be legally sold in Australia under the *Trans-Tasman Mutual Recognition Arrangement 1997* (TTMRA). It should be noted that the New Zealand *Dietary Supplements Regulations 1984* are currently under review and in the future tabletop sweeteners are likely to be regulated as foods.

In the Code, cyclamate (or cyclamates) refers to cyclamate or calcium cyclamate or sodium cyclamate, with the food additive number INS 952[4].

1.2 Evaluation of Intense Sweeteners

As part of the FSANZ Evaluation Strategy 2001-2003, FSANZ undertook an evaluation of Standard 1.3.1 to assess if the change from a prescriptive food additive standard in the former Australian Food Standards Code to a more generic one in the Code had resulted in an impact on public health and safety. FSANZ chose to evaluate the impact of the new Standard by assessing consumer use of intense sweeteners because these additives are in wide use in the food supply, the regulation of intense sweeteners had changed considerably following the review of the Code and several of the sweeteners were on a priority list for future monitoring.

1.2.1 2003 Consumption of Intense Sweeteners Survey

A survey of the use of intensely sweetened foods by Australians and New Zealanders aged 12 years and above was undertaken, using the services of Roy Morgan Research, between August 2002 and February 2003.

The survey was conducted in three phases:

1. a computer assisted telephone interviewing (CATI) survey of 3,529 people (2,514 in Australia and 1,015 in New Zealand) weighted to represent the population distribution of each country. This survey phase aimed to record consumption patterns of intense sweetened foods and to identify users of these foods to participate in subsequent survey phases;
2. a seven-day, brand specific, self-completed diary of consumption amounts of intense sweetened foods among 400 respondents (263 in Australia and 137 in New Zealand), who were identified as consumers of these foods. Food consumption data reported in the diary were matched with sweetener concentration data supplied by industry; and

3. a separate diary survey of 298 people (223 in Australia and 75 in New Zealand) with either diabetes or impaired glucose tolerance.

The first two phases of the survey repeated a similar survey conducted by the then National Food Authority in 1994 among Australians aged 12-39 years. No similar survey has previously been conducted in New Zealand.

[4] INS – International Numbering System for Food Additives

1.2.1.1 Dietary exposure to cyclamate as measured in the survey

Some high consumers of foods containing cyclamate were found in this survey to have cyclamate exposures that exceeded the ADI. Soft drinks and cordials were the major contributors to cyclamate exposure in both countries, with tabletop sweeteners also contributing to cyclamate exposure among New Zealanders, particularly older New Zealanders[5].

Across the 71% of diary survey participants who consumed foods containing cyclamate during the 7-day diary survey, estimated 95th percentile exposure to cyclamate represented 85% of the ADI. However, exposure varied between age and country. In Australia, 25-39 year olds and the small base of 12-17 year olds (29 respondents) exceeded the cyclamate ADI at the 95th percentile (150% and 245% respectively). In New Zealand, the small base of 25-39 year olds (30 respondents) met the ADI at the 95th percentile and those aged 60 years and over exceeded the cyclamate ADI at the 95th percentile (110%). It is of note that this population group (n=400) who completed the diary survey had already been identified as being potential high consumers of intensely sweetened foods, as determined through a screener survey.

Dietary exposure to cyclamates, expressed as a proportion of the ADI, had not decreased since the 1994 survey.

It should be noted that the survey was conducted during the transition period to the Code when products were still available for sale that conformed to the requirements of the former Australian *Food Standards Code* and the New Zealand *Food Regulations* 1984. Further revised dietary exposure estimates have since been undertaken using manufacturers current use levels of cyclamate and these results are discussed in Section 5.2 and **Attachment 3**.

1.2.1.2 Dietary exposure to cyclamate in children

Children under 12 years of age were not included in the survey, for methodological and cost reasons. Dietary exposure of Australian children aged 2-11 years to cyclamate was therefore estimated using the food consumption data measured in the 1995 National Nutrition Survey and mean cyclamate levels collected in the 2002-2003 survey. Using this approach, mean and 95th percentile exposure to cyclamate among Australian children aged 2-11 years who were consumers of cyclamate-containing foods was estimated to be approximately 50% and 200% of the ADI respectively.

1.3 Application A515 – Cyclamate Level in Tabletop Sweeteners

FSANZ received an Application on 14 October 2003 from Hermes Sweeteners (UK), to amend the Code to permit cyclamate as an intense sweetener in tabletop sweeteners (liquid preparations and portion-sized packages). The Application sought to amend Schedule 1 of Standard 1.3.1 to approve the use of cyclamate at GMP (Good Manufacturing Practice) levels under category 11.4 – Tabletop sweeteners for 11.4.1 (liquid preparations) and 11.4.2 (tablets or powders or granules packed in portion sized packages).

[5] The Code does not currently permit the use of cyclamate in tabletop sweeteners. The former Australian *Food Standards Code* and the *New Zealand Food Regulations 1984* did permit the use of cyclamate in tabletop sweeteners prior to December 2002. Tabletop sweeteners are currently marketed as dietary supplements in New Zealand and are permitted to contain cyclamates.

Intense sweeteners that are currently approved for use at GMP in tabletop sweeteners include acesulphame potassium (INS 950), alitame (INS 956), aspartame-acesulphame salt (INS 962) and saccharin (INS 954), aspartame (INS 951), sucralose (INS 955), neotame (INS 961) and thaumatin (957). The Applicant requested that cyclamate also be approved at GMP levels, as their use by consumers is self-limiting (i.e. used only to the level needed to sweeten food).

In April 2005, Hermes Sweeteners decided to formally withdraw Application A515, pending consideration being given to reinstating cyclamate permissions in tabletop sweeteners as part of Proposal P287 on the Review of Cyclamate Permissions.

1.4 International Regulations on Cyclamate

Cyclamate is currently approved for use in more than 50 countries. Cyclamate is a permitted food additive (as a sweetener) in the Codex Alimentarius. Cyclamate (E 952, cyclamic acid and its sodium and calcium salts) is approved in the EU and the UK as a sweetener for a variety of food products, including for tabletop sweeteners. However, cyclamate is not permitted for use in the USA, while Canada only permits cyclamate use in tabletop sweeteners. A comparison of cyclamate permission between the EU, UK, Canada, Codex and Australia/New Zealand is contained in **Attachment 5**.

2. The Issue / Problem

Two issues have been identified in this Proposal. Firstly, the intense sweetener survey identified subgroups of the Australian and New Zealand populations that were high consumers of cyclamate-containing foods and at possible risk from exceeding the ADI. Secondly, FSANZ is considering a request from Hermes Sweeteners (UK) to permit cyclamate in tabletop sweeteners. Studies in animals have shown adverse effects on the reproductive tract of male rats following administration of cyclamate in the diet. Therefore, the potential long-term effects on health in humans of cyclamate consumption over the ADI need to be considered.

Due to the common objective and similarity of issues being considered, this report addresses both matters concurrently, except for the dietary exposure assessment **(Attachment 3)** which of necessity separates the two issues, as reflected in Scenarios 1 to 4.

3. Objectives

The objective of this Proposal is to ensure that dietary consumption of foods containing cyclamate does not result in any public health and safety concerns from the levels of cyclamate permitted in a range of foods in the Code.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Questions

At Draft Assessment FSANZ has considered the following key questions:

- What is the estimated dietary exposure to cyclamate for at-risk population groups who are high consumers of cyclamate?
- What are the possible public health and safety consequences of exceeding the ADI for high consumers of cyclamate?
- What are the implications of reducing the permitted levels of cyclamate as an ingredient in certain foods?

RISK ASSESSMENT

5. Risk Assessment Summary

5.1 Safety Assessment

As part of this Proposal, FSANZ has assessed the safety of cyclamate including consideration of new data in order to fully characterise the public health and safety risks.

Cyclamate has very low acute toxicity. It has a laxative effect in humans at high doses (6 – 16 g/day). However, its metabolite, cyclohexylamine, which is formed by bacterial fermentation in the colon, causes testicular atrophy in a number of animal species. The no-observed-effect level (NOEL) for cyclohexylamine-induced testicular atrophy in rats was 100 mg/kg body weight /day. Based on this, the ADI for cyclamate is 11 mg/kg body weight/day.

A critical factor in the establishment of the ADI is the level of conversion of cyclamate to cyclohexylamine in the gastrointestinal tract, as this varies considerably between and within individuals. New data on the metabolism of cyclamate in humans has been published since the 1982 JECFA evaluation. FSANZ has assessed these data and other recent studies on cyclamate toxicity and determined that the ADI established by JECFA in 1982 is adequately protective of consumers. The JECFA ADI for cyclamate was established as 11 mg/kg body weight/day.

A full report on the safety of cyclamate is provided at **Attachment 2**.

5.2 Dietary Exposure Assessment

5.2.1 Background

As a result of the findings from the *2003 Consumption of Intense Sweeteners* survey, FSANZ sought to determine under this Proposal whether re-analysing the data from the survey using current/updated manufacturers' use levels of cyclamate, where available, in conjunction with current maximum permitted levels (MPLs) outlined in the Code, would impact upon the level of exposure to cyclamate. Current manufacturers' use levels are frequently well below MPLs. The population aged 2-11 years were not included in the *2003 Consumption of Intense Sweeteners* survey; therefore, additional dietary modelling was performed for this population.

A revised dietary exposure assessment for a range of population groups was performed based on current manufacturers' use levels of cyclamate, in conjunction with the current MPL outlined in Standard 1.3.1 (Food Additives) of the new Code **(Scenario 1)**. Additional scenarios were assessed based on a previous Application to extend the use of cyclamate to tabletop sweeteners **(Scenario 2)**; and the effect on estimated dietary exposures of reducing MPLs for cyclamate in water-based beverages such as intensely sweetened soft drinks and cordials, both with and without the extension of use of cyclamate in tabletop sweeteners **(Scenarios 3 and 4)**.

Scenarios 3 and 4 were only conducted on children aged 2-11 years as they are the population group that have higher exposures to cyclamate per kilogram of body weight. Therefore, they are the group against which the effectiveness of potential risk management options, such as the reduction in MPLs, was tested for effectiveness.

Table 1 summarises the Scenarios modelled for P287: Review of Cyclamate Permissions.

Table 1: Scenarios modelled for P287: Review of Cyclamate Permissions

		Scenario parameters	
Scenario	**Population group**	**Cyclamate in tabletop sweeteners included**	**Reduced cyclamate MPL in intensely sweetened soft drinks and cordials**
Scenario 1	Aust and NZ 12+ years	No	No
	Aust 2-11 years	No	No
Scenario 2	Aust and NZ 12+ years	Yes	No
	Aust 2-11 years	Yes	No
Scenario 3	Aust and NZ 12+ years	N/A*	N/A*
	Aust 2-11 years	No	Yes
Scenario 4	Aust and NZ 12+ years	N/A*	N/A*
	Aust 2-11 years	Yes	Yes

*Scenarios 3 and 4 were only modelled for Australian children aged 2-11 years

5.2.2 Food consumption data

The food consumption data used for those aged 12 years and above were 7-day diary data from the *2003 Consumption of Intense Sweetener* survey. For those aged 2-11 years, data were sourced from the 1995 Australian National Nutrition Survey (NNS), which was based on a 24-hour recall.

5.2.3 Cyclamate concentration levels

The concentrations of cyclamate in food that were used in the dietary exposure assessment were: current manufacturers' use levels after the Code permissions had come into force; and those derived from the FSANZ *2003 Consumption of Intense Sweetener* survey. Current manufacturers' use levels were obtained via submissions to the Initial Assessment Report (IAR). The use of manufacturers' data, in conjunction with current MPLs listed in Standard 1.3.1 of the Code, provides a more realistic estimate of the current exposure to cyclamate than MPLs alone.

The concentration of cyclamate in tabletop sweeteners for Scenarios 2 and 4 was the manufacturers' use level prior to the new Code coming into force in December 2000, as used in the *2003 Consumption of Intense Sweetener* survey.

5.2.4 Estimated dietary exposures to cyclamate

Based on current manufacturer use levels of cyclamate, estimated 95th percentile dietary cyclamate exposures for the Australian and New Zealand population aged 12 years and above were at or below the ADI, whilst estimated dietary exposures for Australians aged 2-11 years exceeded the ADI (Scenarios 1 and 2).

Reducing the MPL for intensely sweetened soft drinks and cordials (from 600 mg/kg to 300 mg/kg) (Scenarios 3 and 4) reduced estimated 95th percentile dietary cyclamate exposures for Australians aged 2-11 years to below the ADI. The reduction in cyclamate permissions for intensely sweetened soft drinks and cordials would further reduce estimated exposures to cyclamate for Australian and New Zealanders aged 12 years and above.

Overall, there is a minimal change to exposure to cyclamate with the inclusion of a permission to use cyclamate in tabletop sweeteners. Of those aged 12 years and above, the sub-group most likely to consume tabletop sweeteners were those aged 60 years and above, not the younger population groups who were more likely to exceed the ADI for cyclamate. For the population aged 2-11 years, the 1995 National Nutrition Survey outlined there were no consumers of liquid tabletop sweeteners and only 14 consumers of tablet/powdered tabletop sweeteners.

5.2.5 Contributing foods to total estimated dietary exposures

The major contributors to estimated dietary cyclamate exposures for all population groups were water-based flavoured drinks (intensely sweetened soft drinks and cordials).

5.2.6 Additional data required

To assist in refining the dietary exposure assessment for this Proposal, FSANZ seeks data on the following:

5.2.6.1 Carbonated soft drinks

- the total volume of all carbonated soft drinks sold in Australia (cola and non-cola separately);
- the total volume of all carbonated soft drinks and cordials that are intensely sweetened sold in Australia (cola and non-cola separately); and
- the total volume of all intensely sweetened carbonated soft drinks that contain cyclamate sold in Australia (cola and non-cola separately).

5.2.6.2 Cordials

- the total volume of all cordials sold in Australia;
- the total volume of all cordials that are intensely sweetened sold in Australia;
- the total volume of all intensely sweetened cordials that contain cyclamate sold in Australia; and
- current market research on how consumers make up cordial, specifically for children aged 2-11 years.

5.3 Risk Characterisation

Dietary modelling using current manufacturers' use levels, with and without the inclusion of cyclamate-containing tabletop sweeteners (Scenarios 1 and 2), indicate that only Australians aged 2-11 years exceed the ADI at the 95th percentile. Under Scenario 1, estimated 95th percentile exposures were 150% and 140% of the ADI for males and females respectively. The inclusion of cyclamate-containing tabletop sweeteners (Scenario 2), made little difference to exposures for this age group, with 95th percentile exposures at 160% (males) and 140% (females) of the ADI.

An exposure above the ADI should not be considered to be acceptable if it occurs over a prolonged period of time. Since the exposures for children at the 95th percentile would exceed the ADI for a period of up to nine years, the erosion of the uncertainty factor incorporated in the ADI is of concern.

With reduced cyclamate levels in water-based flavoured drinks (Scenarios 3 and 4), dietary exposures to cyclamate were reduced in Australians aged 2-11 years at the 95th percentile to 80% of the ADI (both males and females) (Scenario 3), and 95% (males) and 90% (females) of the ADI (Scenario 4). No safety concerns are raised by these levels of exposure.

Figure 1 below provides a comparison of the four scenarios modelled and their impact on cyclamate exposure in children aged 2-11 years at the 95th percentile exposure, as a proportion of the ADI.

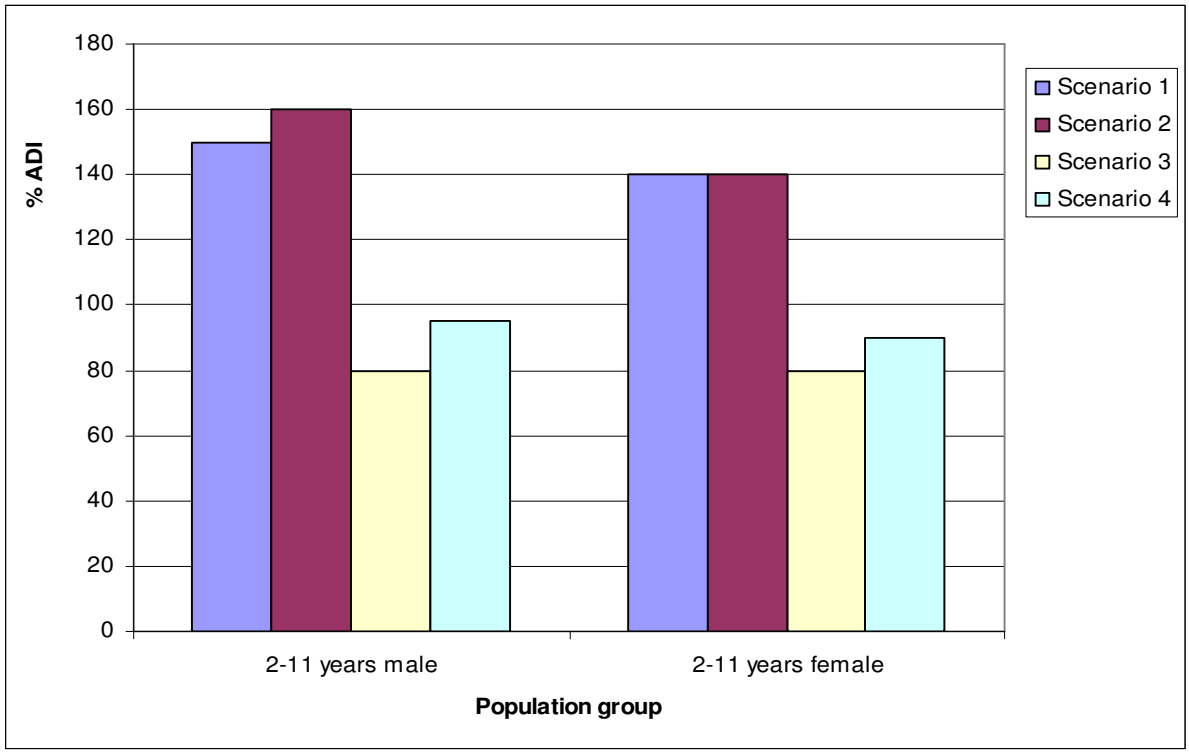

Figure 1: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a proportion of the ADI (%)

5.4 Food Technology Assessment

Cyclamate (or cyclamic acid) is a white crystalline powder that is quite soluble in water (1 g/7.5 ml). Cyclamate solutions are stable to heat, light and air throughout a wide pH range.

Cyclamate is not considered to be very sweet relative to other intense sweeteners. It is between 30-80 times as sweet as sucrose (common sugar). Its relative sweetness depends on the food matrix, pH, concentration and other flavouring agents.

The sweetness from cyclamate builds to a maximal level more slowly and persists longer than sweetness due to sucrose. High concentrations of cyclamate also produce increased levels of bitterness and aftertaste, but this is not usually considered a problem at normal use concentrations.

Cyclamate is used as an intense sweetener in a variety of food products, though it is generally used in combination with other sweeteners, specifically saccharin and more recently acesulphame potassium. A mixture of 10:1 (cyclamate:saccharin) has a synergistic effect producing a sweetness greater than expected from adding the effects of the individual sweeteners. This 10:1 intense sweetener blend is used for a variety of products including soft drinks to produce a pleasant sweetness, minimising the aftertastes of both intense sweeteners.

Cyclamate has claimed advantages over other currently permitted intense sweeteners in various food applications. Cyclamate:

- is heat stable, so suitable for addition to products that require cooking and baking;
- is water soluble;

- has a long shelf-life;
- provides a pleasant taste profile, especially in conjunction with other intense sweeteners;
- is non-proprietary so is readily available; and
- has lower costs to other alternatives.

It is claimed that these properties make cyclamate suitable for tabletop sweeteners both in liquid preparations and in solid preparations such as tablets, powdered or granular forms. A full Food Technology Report is provided at **Attachment 4**.

5.4.1 Reduced cyclamate permissions

Section 5.2 above indicates that some high level consumers (particularly the 95th percentile exposure for Australian children aged 2-11 years) currently consume cyclamate at levels which exceed the ADI. To reduce dietary exposure, scenario dietary modelling was undertaken using a reduced MPL for water-based flavoured drinks from 600 mg/kg to 300 mg/kg. With this scenario, all consumers of cyclamate-containing products were below the ADI, including those consumers at the 95th percentile dietary exposure.

This then raises the question as to whether manufacturers of intensely sweetened water-based flavoured drinks can still produce commercially acceptable products using a reduced MPL of 300 mg/kg cyclamate. To respond to this question, FSANZ has sought industry advice, conducted literature searches, communicated with relevant food technology experts and undertaken research in relation to comparable international regulations for cyclamate. The outcomes of these investigations are summarised below.

5.4.1.1 Use of alternative sweetener blends

Other than the commonly used 10:1 cyclamate:saccharin blend, it is possible to use alternative sweetener blends to produce synergistic sweetness. These include blends of cyclamate with aspartame and acesulphame potassium (as dual or even triple blends). These blends can also improve the product stability, so the possible issue of reduced shelf life should not be a concern. Further information regarding this issue is also contained in the Food Technology Report provided at **Attachment 4**.

Personal communication with one manufacturer of intensely sweetened fruit juices has confirmed that as many as four intense sweeteners, including cyclamate, are currently used in their product range. This manufacturer advised that a reduction in the MPL for cyclamate would have implications for the flavour profile of their products, and that to maintain the current flavour profile it would be necessary to alter the various blends of intense sweeteners that are used.

FSANZ notes that a number of manufacturers of water-based flavoured drinks are no longer using cyclamates in their intensely sweetened product range and have chosen to use alternative blends of sweeteners. Personal communication with one major manufacturer across Australia and New Zealand has confirmed that development work is in hand to phase out the use of cyclamates in their cordials and soft drink range, although this will be at a significant cost to the industry. This manufacturer also advised that the proposed reduction of the MPL for cyclamates in water-based flavoured beverages from 600 mg/kg to 300 mg/kg would be acceptable from their perspective.

5.4.1.2 Relevant International Regulations

Comparable international regulations for cyclamate are provided at **Attachment 5**. It is noted that the EU reduced permissions for cyclamate in water-based flavoured drinks in 2004, following the results of dietary modelling which indicated that a number of young children exceeded the ADI for cyclamate. An example of such dietary modelling work was performed in the UK which indicated that some young children between the ages of 1 ½ years and 4 ½ years were consuming twice the ADI of cyclamate.

The EU reduced their permission for cyclamate in water-based flavoured drinks from 400 to 250 mg/l in 2004. Before this amendment was incorporated into The Sweeteners in Food (Amendment) (England) Regulations 2004, the UK Food Standards Agency consulted with the British Soft Drink Association and the main UK manufacturer of cyclamate-containing soft drinks in 2003. These industry discussions in the UK indicated that it would still be feasible to produce water-based flavoured drinks containing cyclamate at levels of 200-250 mg/l. It was indicated that reformulations of the products affected would probably be required, possibly with other intense sweeteners, in addition to saccharin (which is nearly always used as a blend with cyclamate).

5.4.1.3 Conclusion

It is understood that a reduction of the MPL for cyclamate in water-based flavoured beverages from 600 mg/kg to 300 mg/kg should still allow manufacturers to produce commercially suitable products. However reformulations are likely to be required, using alternative intense sweeteners in the blends. Such blends should not compromise product stability so the possible issue of reduced shelf-life should not be an issue. Reformulations would require research and development by the manufacturers to replicate appropriate sweetness for their product, as well as shelf-life assessments. Ultimately, commercial interests will decide which intense sweeteners manufacturers will use for their products, as there are a range of intense sweeteners and blends available, all with their advantages and disadvantages. Manufacturers would have the usual 12 month stock-in-trade provisions under subclause 1(2) of Standard 1.1.1 in the Code, in which to reformulate their products if the Code is amended to reduce the MPLs for cyclamate.

FSANZ will continue to have discussions with Australian and New Zealand manufacturers of water-based flavoured drinks regarding the food technology implications of the proposed reduction in MPLs for cyclamate. Further comment is invited from industry as part of this Draft Assessment Report.

RISK MANAGEMENT

6. Options

Given the long term risk to public health and safety associated with current cyclamate exposures, the main focus of risk mitigation was reducing exposure in the population group that is most at risk, specifically children aged 2-11 years. This raised a number of technological and feasibility issues.

Four regulatory options are identified for this Proposal:

Option 1 – Maintain the *status quo*, namely, retain current cyclamate permissions in water-based flavoured drinks and no re-instatement of cyclamate permissions in tabletop sweeteners.

Option 2 – Retain current cyclamate permissions in water-based flavoured drinks and re-instate cyclamate permissions in tabletop sweeteners.

Option 3 – Reduce cyclamate permissions in water-based flavoured drinks and no re-instatement of cyclamate permissions in tabletop sweeteners.

Option 4 – Reduce cyclamate permissions in water-based flavoured drinks and re-instate cyclamate permissions for tabletop sweeteners.

7. Impact Analysis

7.1 Affected Parties

Parties likely to be affected by the regulatory options outlined above include:

- those sectors of the food industry that manufacture and/or market cyclamate-containing food products.
- consumers of cyclamate-containing products.
- Australian, State, Territory and New Zealand Government agencies that enforce the food regulations.

7.2 Benefit Cost Analysis

7.2.1 Option 1 – Maintain the status quo

Under Option 1, the affected parties and potential impacts are:

7.2.1.1 Industry

- There are no perceived costs or benefits to current manufacturers of cyclamate-containing food products as such products would continue to be permitted for sale and re-formulation would not be required.
- Manufacturers and importers of tabletop sweeteners would be disadvantaged as they would be unable to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia and New Zealand.

7.2.1.2 Consumers

- There are possible long-term public health and safety concerns if high consumers of cyclamate-containing products consistently exceed the ADI.

- Under this option, cyclamate would not be permitted in tabletop sweeteners and consumers of these products would be unable to take advantage of qualities such as improved taste profile, a wider choice and form of sweeteners and potentially reduced costs.

7.2.1.3 Government

- There is no benefit to government agencies that enforce the food regulations. There is a potential cost to government as public health and safety would not be protected if the ADI for cyclamate is exceeded in the long term.

7.2.2 Option 2 – Retain current cyclamate permissions in water-based flavoured drinks and re-instate cyclamate permissions in tabletop sweeteners

Under Option 2, the affected parties and potential impacts are:

7.2.2.1 Industry

- There are no perceived costs or benefits to current manufacturers of water-based flavoured drinks as such products would continue to be permitted for sale and re-formulation would not be required.

- As cyclamate would be permitted in tabletop sweeteners, manufacturers in Australia and importers of tabletop sweeteners to Australia would be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners.

7.2.2.2 Consumers

- The re-instatement of cyclamate permissions in tabletop sweeteners would have minimal impact on overall cyclamate exposure. Therefore, the impacts on consumers would be similar to Option 1, that is, there are possible long-term public health and safety concerns if high consumers of cyclamate-containing products consistently exceed the ADI.

- Under this option cyclamate would be permitted in tabletop sweeteners and consumers of these products would be able to take advantage of qualities such as improved taste profile, a wider choice and form of sweeteners and potentially reduced costs.

7.2.2.3 Government

- There is a cost to government as public health and safety would not be protected if the ADI for cyclamate is exceeded in the long term. Additionally, the re-instatement of cyclamate permissions in tabletop sweeteners may be viewed as contradictory if there are still population groups that exceed the ADI.

7.2.3 Option 3 - Reduce cyclamate permissions in water-based flavoured drinks and no re-instatement of cyclamate permissions in tabletop sweeteners

Under Option 3, the affected parties and potential impacts are:

7.2.3.1 Industry

- With reduced cyclamate permissions in water-based flavoured drinks, there are likely to be costs to manufacturers associated with reformulation of products containing cyclamate and possible re-labelling. Cyclamate is generally used in conjunction with another sweetener, and additional sweeteners or changes to blends of existing sweeteners may be required to obtain the desired flavour profile. Labelling changes would be required if reformulation results in the use of an additional sweetener or where an existing sweetener is no longer used.

- Under this option manufacturers in Australia and importers of tabletop sweeteners to Australia would be disadvantaged as they would be unable to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners.

- Potentially there may be restrictions in overseas trade of cyclamate-containing products, although it has been noted by industry that the affected products are primarily for the domestic market.

7.2.3.2 Consumers

- Under this option, the public health and safety of all consumers of cyclamate-containing products would be protected.

- There may be costs passed on to the consumer associated with the reformulation and re-labelling of products by industry.

- As cyclamate would not be permitted in tabletop sweeteners, consumers of these products would be unable to take advantage of qualities such as improved taste profile, a wider choice and form of sweeteners and potentially reduced costs.

7.2.3.3 Government

- There is a benefit to government under this option in that it is reacting to new data demonstrating possible public health and safety concerns and implementing appropriate regulatory action.

- Alternatively, the government may be perceived as introducing a regulatory measure that is unnecessarily restrictive and confined to protecting a small group of high consumers, whilst the majority of consumers are already protected.

7.2.4 Option 4 - Reduce cyclamate permissions in water-based flavoured drinks and re-instate cyclamate permissions for tabletop sweeteners

Under Option 4, the affected parties and potential impacts are:

7.2.4.1 Industry

- With reduced cyclamate permissions in water-based flavoured drinks, there are likely to be costs to manufacturers associated with reformulation of products containing cyclamate and possible re-labelling.

Cyclamate is generally used in conjunction with another sweetener, and additional sweeteners or changes to blends of existing sweeteners may be required to obtain the desired flavour profile. Labelling changes would be required if reformulation results in the use of an additional sweetener or where an existing sweetener is no longer used.

- Potentially there may be restrictions in overseas trade of cyclamate-containing products, although it has been noted by industry that the affected products are primarily for the domestic market.

- As cyclamate would be permitted in tabletop sweeteners under this option, manufacturers in Australia and importers of tabletop sweeteners to Australia would be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners.

7.2.4.2 Consumers

- Under this option, the public health and safety of all consumers of cyclamate-containing products would be protected.

- There may be costs passed on to the consumer associated with the reformulation and re-labelling of products by industry.

- As cyclamate would be permitted in tabletop sweeteners manufactured in Australia or imported to Australia, consumers of these products would be able to take advantage of qualities such as improved taste profile, a wider choice and form of sweeteners and potentially reduced costs.

7.2.4.3 Government

- There is a perceived benefit to government in that it is reacting to new data demonstrating possible public health and safety concerns and implementing appropriate regulatory action.

- Alternatively, the government may be perceived as introducing a regulatory measure that is unnecessarily restrictive and confined to protecting a small group of high consumers, whilst the majority of consumers are already protected.

- A further cost to government is that the re-instatement of cyclamate permissions in tabletop sweeteners may be viewed as contradictory to a regulatory measure to reduce permissions in water-based beverages.

7.3 Comparison of Options

Option 1 does not impose any costs to current manufacturers of water-based flavoured drinks, although some manufacturers and importers of tabletop sweeteners may be disadvantaged. Under this option, there are possible long-term public health and safety concerns for a small group of the population (children aged 2-11 years) that is at risk of exceeding the ADI for cyclamate. Given FSANZ's primary objective is to protect public health and safety, Option 1 is not preferred.

Under Option 2, the costs to manufacturers are similar to Option 1 although there may be benefits to manufacturers and importers of tabletop sweeteners. Similarly, there are potential public health and safety implications for some consumers associated with Option 2 although there may be some benefits to consumers if permissions are given for cyclamate in tabletop sweeteners. As for Option 1, Option 2 cannot be sustained in view of the potential public health and safety risks to high consumers of cyclamate-containing foods.

Option 3 is likely to impose costs on manufacturers, in terms of the requirement to reduce cyclamate permissions in water-based flavoured drinks and the inability to manufacture and import tabletop sweeteners containing cyclamates. Under this option, there is a benefit to consumers as public health and safety would be protected, although there may be some manufacturers' costs that are passed on to the consumer.

Option 4 imposes similar costs on manufacturers as Option 3, although there are potential benefits to manufacturers and importers of tabletop sweeteners. The benefits to consumers under Option 4 are similar to Option 3, although under Option 4 there may be an additional benefit associated with the use of cyclamate in tabletop sweeteners.

Given FSANZ's primary objective is to protect public health and safety, Options 3 and 4 are the only viable options. FSANZ is aware that Options 3 and 4 are likely to impose costs on industry although these costs have not been quantified to date. Option 4 is preferred over Option 3 as it would appear to provide greater benefits to consumers, while imposing fewer costs to industry. Option 4 is therefore the preferred option. The draft variations to the Code as a result of Option 4 being the preferred option are provided at **Attachment 1**.

COMMUNICATION

FSANZ has proposed certain measures to address the issues highlighted in the 2002-2003 intense sweetener survey that highlighted that the dietary exposure of specific subgroups of the population could exceed the ADI for cyclamate. The measures proposed by FSANZ are intended to protect public health and safety while permitting the appropriate and practical use of cyclamate in foods. The proposed measures are based upon the best available scientific evidence.

This is the second opportunity for public consultation on this Proposal and FSANZ is calling for submissions to assist FSANZ toward a Final Assessment. FSANZ will ensure that relevant stakeholders and other interested parties are made aware of the regulatory measures proposed, and their comments sought, particularly manufacturers of artificially sweetened beverages and tabletop sweeteners, and jurisdictions which ensure compliance with the Code.

FSANZ has had preliminary discussions with several Australian and New Zealand manufacturers of water-based flavoured drinks regarding the recommendations proposed in this Draft Assessment Report and will continue to consult with these and other affected parties during the consultation period for this Draft Assessment Report. This will ensure that manufacturers are fully consulted and given ample opportunity to reformulate their products prior to the introduction of any amendments to Standard 1.3.1. If any additional issues are identified, FSANZ will consider targeting key stakeholder groups to seek additional views on available risk management options.

8. Consultation

8.1 Public Consultation

FSANZ sought public comment from the period 20 October 2004 to 1 December 2004 in order to assist in assessing this Proposal. A total of 13 submissions were received at Initial Assessment and are summarised in **Attachment 6**.

The Initial Assessment Report sought comment on a range of issues concerning cyclamate, including the scientific aspects of this Proposal, the parties that might be affected by this Proposal and the potential costs and benefits to stakeholders of the risk management options identified.

A number of issues were raised by submitters in response to the Initial Assessment Report. These issues are identified and discussed below.

8.1.1 Safety of Cyclamate

Several industry submitters considered that there were minimal public health and safety issues due to the safety factors inherent in establishing an ADI. Additionally, it was noted that the dietary exposure calculations indicated that only some age groups exceeded the ADI and not all, and that this was only for those consumers in the 95th percentile.

In contrast to this assertion, some stakeholders suggested that children, adolescents and young adults are of most concern if the ADI is exceeded due to the possibility of long-term adverse effects. For example, it was noted by one stakeholder that increased exposure may have an impact on the fertility of young men, which is already in decline in Australia.

Any reduction in the permitted levels of cyclamates in food need to be considered in terms of possible increased dietary exposure to other sweeteners and the potential to exceed the ADIs of other sweeteners.

8.1.1.1 FSANZ Response

FSANZ's safety assessment concluded that the JECFA ADI of 11 mg/kg body weight is adequately protective of consumers. However, the conversion of cyclamate to cyclohexylamine varies considerably between and within individuals, therefore, to protect public health, it is preferable that the intake levels of all consumers be at or below the ADI for most of their lifetime.

In terms of the possibility that the ADI for other sweeteners could be exceeded if cyclamate permissions were reduced, the results of the 2003 Intense Sweeteners Survey[6] showed that, at the upper end of the ranges of exposure (90th and 95th percentile), cyclamate was the only sweetener surveyed that had the potential to exceed the ADI for specific population groups. The large margin in exposures between cyclamate and other sweeteners would make it unlikely that the ADIs for other sweeteners would be exceeded due to changes in usage patterns.

[6] Consumption of Intense Sweeteners in Australia and New Zealand. Prepared by Roy Morgan Research, 2004

8.1.2 Potential dietary exposure for Australian and New Zealand consumers

Several submitters agreed that more precise data on levels of cyclamates used by manufacturers was required to enable better estimates of dietary exposure. The New Zealand Food Safety Authority (NZFSA) also advised that the New Zealand Dietary Supplements Regulations permit the use of cyclamates, therefore the dietary exposure estimates will need to consider exposure from dietary supplement use.

8.1.2.1 FSANZ Response

As discussed in Section 5.2 and **Attachment 3**, since the Initial Assessment Report was released, FSANZ has undertaken a revised dietary exposure assessment based on manufacturers' use levels of cyclamate where available. This reduced the estimated 95th percentile exposures for consumers of cyclamate (Scenarios 1 and 2) to a level at or below the ADI for Australian and New Zealanders aged 12 years and above. However, the 95th percentile dietary exposure for consumers of cyclamate was above the ADI for Australians aged 2-11 years (males: 150% ADI for Scenario 1 and 160% for Scenario 2; females 140% ADI for Scenarios 1 and 2).

FSANZ contacted the NZFSA about exposure to cyclamates through use in dietary supplements. NZFSA advised FSANZ that tablets and capsules sweetened with cyclamate are very limited, although there are no quantitative exposure data for New Zealand consumers available for FSANZ to incorporate into the dietary exposure assessment report. NZFSA was not aware of any drinks sweetened with cyclamates/saccharin sold as dietary supplements. However, cyclamate/saccharin tabletop sweeteners are currently marketed as a dietary supplement in New Zealand. Exposure from this source is taken into account in Scenario 2 of the Dietary Exposure Assessment. There was no exceedance of the ADI for cyclamate following inclusion of tabletop sweeteners for Australian or New Zealand consumers.

8.1.3 Technological need for cyclamate in foods

Several public health agencies commented on the technological need for cyclamate in foods, stating that there are considerably better alternatives to cyclamate available in Australia/New Zealand that can be used by industry, e.g. aspartame. In this regard, consumers would not be adversely affected by the removal of cyclamate from the food supply.

Industry submitters argued that cyclamate is unique among low-calorie sweeteners due to its stability at high temperatures, low pH, longer shelf-life and lower cost, particularly when used in blends with other more expensive sweeteners. Additionally, when used as part of a blend of sweeteners, the synergistic effects allows bottlers to minimise the total amounts of sweeteners added to low joule beverages.

8.1.3.1 FSANZ Response

The technological benefits of cyclamate as an intense sweetener in foods are well established and are discussed in the Food Technology Report (**Attachment 4**). These benefits include its solubility in water, heat stability, long shelf-life and pleasant taste profile when used in blends with other sweeteners. Additionally, cyclamate is readily available and at lower costs to other sweeteners and has a long history of safe use.

For these reasons FSANZ considers that the ongoing use of cyclamate is technologically justified and provides manufacturers with an alternative sweetener that can be used depending on their specific requirements.

8.1.4 Risk management strategies

Some stakeholders proposed that industry should be encouraged, possibly over a reasonable timeframe, to reduce or remove cyclamate from their products or to consider a reduction in the maximum permitted levels of cyclamate in specific foods such as beverages.

8.1.4.1 FSANZ Response

As discussed in the Dietary Exposure Assessment Report (**Attachment 3**), the major contributors to cyclamate exposure in children are soft drinks, cordials and cola beverages. To reduce levels of intake, FSANZ is proposing to reduce the MPL of cyclamate in the category 'water based flavoured drinks' in Standard 1.3.1 in the Code (Regulatory Option 4). Any amendments to cyclamate permissions would be introduced in conjunction with a standard 12 month stock-in-trade provision.

For the reasons discussed in Section 8.1.3.1 above, it is not considered appropriate to remove cyclamate permissions in the Code in their entirety, and removing cyclamate permissions for other foods would have minimal impact on overall cyclamate exposure in children.

8.1.5 Harmonisation with EU regulations

One industry submitter, Hermes Sweetener Ltd, the Applicant for Application A515 seeking cyclamate permissions for tabletop sweeteners, suggested harmonising permissions for cyclamate in Australia and New Zealand with current EU regulations. These regulations have lower maximum use levels in specific categories of foods (250 mg/kg cyclamate for non-alcoholic drinks), and also permit the use of cyclamate in tabletop sweeteners. It was noted that harmonisation with EU regulations would reduce levels of intake, allow for a better trans-national comparison of consumption habits and levels of intake, and would facilitate international trade.

By comparison, several submitters advised that a reduction in cyclamate permissions would have a limited impact on international trade as products are primarily for the domestic market.

8.1.5.1 FSANZ Response

The maximum level of 250 mg/kg cyclamate in non-alcoholic drinks in Europe was based on an ADI of 7 mg/kg body weight (discussed in **Attachment 2**) rather than the JECFA ADI of 11 mg/kg body weight. As discussed in the Safety Assessment Report, FSANZ has determined that the ADI of 11 mg/kg body weight established by JECFA in 1982 is adequately protective of consumers, and dietary modelling indicates that reducing cyclamate permissions to the level of 300 mg/kg is sufficient for safety. It is also noted by several submitters that products containing cyclamate are primarily for the domestic market, therefore any benefits in terms of international trade may not be realised. On this basis, FSANZ considers that reducing the level of cyclamate to 250 mg/kg is not justified.

The reinstatement of cyclamate in tabletop sweeteners in line with EU regulations could promote international trade for these products with Europe.

8.2 External Advisory Group

FSANZ established an External Advisory Group (EAG), comprising key industry and consumer stakeholders in Australia and New Zealand, to assist in the assessment of Proposal P287. The list of EAG participants and their terms of reference are provided at **Attachment 7**.

The EAG met by teleconference on 14 February 2006. At this meeting a number of issues relating to the assessment of this Proposal were discussed, and comments provided by the EAG have been incorporated in the Draft Assessment Report.

8.3 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.

While there are relevant international standards, amending cyclamate permissions in the Code is unlikely to have a significant effect on international trade as the proposed amendments are no more restrictive than requirements in the EU, UK, the United States and Canada. As the requirements in other countries are unknown, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures (SPS) Agreement.

CONCLUSION

9. Conclusion and Preferred Approach

It is proposed to reduce cyclamate permissions in water-based flavoured beverages from 600 mg/kg to 300 mg/kg and also to permit the use of cyclamates in tabletop sweeteners.

Preferred Approach

Amend Schedule 1 of Standard 1.3.1 – Food Additives, to reduce permissions for cyclamates in water-based flavoured drinks from 600 mg/kg to 300 mg/kg and to include permissions for cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice (GMP).

9.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variation to Standard 1.3.1 – Food Additives for the following reasons:

- The proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act, in particular, it does not raise any public health and safety concerns, it is based on risk analysis using the best available scientific evidence, and helps promote an efficient and internationally competitive food industry.

- FSANZ has conducted an assessment of the safety of cyclamate **(Attachment 2)** which concludes that the ADI of 11 mg/kg body weight is adequately protective of consumers. The dietary exposure assessment **(Attachment 3)** shows that reducing permissions for cyclamate in water-based flavoured drinks to 300 mg/kg would ensure that public health and safety of high consumers (Australians aged 2-11 years) is protected, and the inclusion of permissions for cyclamate in tabletop sweeteners would have minimal effect on cyclamate exposure in this population group.

- The Food Technology Report **(Attachment 4)** concludes that the use of cyclamate in foods is technologically justified. Reducing permissions for cyclamate in water-based flavoured drinks to 300 mg/kg would still enable manufacturers to produce commercial products, however, reformulations are likely to be required to achieve appropriate sweetness and shelf life properties. Manufacturers will have the usual 12 month stock-in-trade provisions under subclause 1(2) of Standard 1.1.1 in the Code, in which to reformulate their products if the Code is amended to reduce cyclamate permissions in water-based flavoured drinks.

- The regulatory impact statement concludes that the benefits of the proposed regulatory option outweigh the costs.

10. Implementation and Review

It is proposed that the draft variation come into effect on the date of gazettal.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Dietary Exposure Report
4. Food Technology Report
5. International permissions for cyclamate
6. Summary of issues raised in public submissions
7. EAG membership and Terms of Reference

Attachment 1

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

To commence: on gazettal

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

[1.1] *inserting in* Schedule 1 *under item* 11.4 Tabletop Sweeteners* –

952	Cyclamates	GMP	

[1.2] *omitting from* Schedule 1, *under item* 14.1.3 Water based flavoured drinks* –

952	Cyclamates	600	mg/kg

substituting –

952	Cyclamates	300	mg/kg

Attachment 2

Safety Assessment Report

1. Introduction

Cyclamate is a non-caloric, non-cariogenic sweetener, which is approximately 30 times sweeter than sugar with a lemon-sour sweetness. A recent FSANZ survey indicated that some Australian and New Zealand consumers of food products containing cyclamate, especially children aged between two and 11 years, are exceeding the acceptable daily intake (ADI) for this sweetener (FSANZ, 2004; Roy Morgan Research, 2005). FSANZ has undertaken to conduct a review of the cyclamate permissions in the Code with the view to reducing exposure. As part of this re-consideration, the basis of the existing ADI will be reviewed to include any new data which may have become available.

Data related to the safety of cyclamate has been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) a number of times since 1967, most recently in 1982. An ADI of 11 mg/kg body weight has been established, based on testicular effects observed in rats.

In this safety assessment report, FSANZ has reviewed six new studies. These are:

- A metabolism study in humans
- Two repeat-dose studies
- A long-term toxicity study
- Two epidemiological studies

The information below is a summary of the key toxicological properties of cyclamate together with a review of more recently available studies.

2. Hazard Identification and characterisation

2.2 Absorption, distribution, metabolism and excretion

2.2.1 Summary of previously evaluated studies

Data from clinical trials indicate approximately 37% of ingested cyclamate is absorbed (JECFA, 1982). Once absorbed, cyclamate is distributed evenly in body water and excreted unchanged in the urine.

Non-absorbed cyclamate may be converted to cyclohexylamine by bacteria in the gastrointestinal tract. The extent of conversion varies substantially between individuals and within individuals over time. Not all individuals are able to convert cyclamate. Previous studies in humans indicate that around 25% of individuals are able to convert cyclamate to cyclohexylamine (converters), however the proportion of converters may be slightly lower in European and North American populations and higher among Japanese populations (Bopp and Price, 2001).

Among converters, the extent of conversion is variable and can range from <0.1% to >60%. It is estimated that only 3% of individuals convert more than 20%, and <1% convert 60% or more (Bopp and Price, 2001).

Within individuals, the extent of conversion varies from day-to-day and appears to depend on duration of exposure. A single dose of cyclamate may not be converted to cyclohexylamine; however, daily exposure appears to induce the ability to convert. If cyclamate exposure ceases for a number of days, the ability to convert may be diminished and lost (Bopp and Price, 2001).

Once conversion has occurred, cyclohexylamine is rapidly and completely absorbed from the large intestine and primarily excreted unchanged in the urine.

As the toxic effects of cyclamate are due to cyclohexylamine, the proportion of cyclamate converted to cyclohexylamine is a critical factor in establishing the ADI. A recent study on the metabolism of cyclamate to cyclohexylamine in humans during long-term administration has been summarised below.

2.2.2 The metabolism of cyclamate to cyclohexylamine in humans during long-term administration (Renwick et al., 2004)

The aim of this study was to provide data that defined the variations in cyclamate metabolism during long-term administration in humans. An initial 1-week screening study of 261 volunteers (125 males and 136 females) was undertaken to identify individuals that converted cyclamate to cyclohexylamine. The study was conducted in the United Kingdom at a time when cyclamate containing products were not commonly available.

Of the 261 initial participants, 30 (13 male and 17 females) were able to convert > 0.2% cyclamate based on excretion of cyclohexylamine in the urine. Seven males and seven females with the ability to convert cyclamate to cyclohexylamine (>0.2% of the daily dose of cyclamate excreted in urine as cyclohexylamine) and 31 subjects who lacked this ability (<0.2% conversion) were recruited for the 13-week study.

Subjects were given calcium cyclamate tablets equivalent to a total of 750 mg cyclamic acid daily for 13 weeks. The degree of conversion of cyclamate to cyclohexylamine was determined based on urinary excretion of cyclohexylamine (measured in daily 20 mL urine specimens and twice weekly timed 3-hour urine collection in weeks 1-3 and 7-13). Blood samples were collected once weekly and analysed for cyclohexylamine.

Of the 31 non-converters, 30 remained non-converters. One subject showed an increased conversion rate, however this was low and variable, with the highest rate being 1%. This was probably due to changes in gastrointestinal microflora and/or the conversion ability of the microflora. For all non-converters in the 13-week study the average percentage metabolism at steady state remained <0.25%.

Of the converters, one subject was found to be a non-converter (with an average conversion during steady state of 0.03%). Four subjects showed a consistent average conversion rate of 3-4%, another four subjects showed an average conversion rate of 8-20% and the remaining five subjects converted on average between 25 and 46% of the dose.

Large intra-individual variations were observed in all converters. Only six of the initial 261 subjects analysed in the 1-week screen were found to convert greater than 18.9% of ingested cyclamate to cyclohexylamine (the value used by JECFA to establish an ADI). The greatest metabolism observed was 85.4%, by one individual on day 60. The average conversion rate for the same subject over days 7-91 was 26%. The highest metabolism at steady state was 45.80% in a different subject. The highest individual average conversion over a seven day period based on daily urine samples was 58.3%.

Conclusion

Very few individuals have the ability to convert cyclamate to cyclohexylamine. Only approximately 11% of subjects were able to convert >0.2% cyclamate. Most of the subjects in the initial screen (89% of the initial 261) lacked or had low, variable conversion rates. Only six subjects had consistently high rates of conversion (>18.9%). The results supported the findings of previous shorter studies that showed conversion rates vary considerably between and within individuals.

2.3 Toxicity studies

2.2.1 Summary of previously evaluated studies

Numerous animal and human studies have been conducted with both cyclamate and cyclohexylamine, and a number of reviews of the toxicological data have been published (see for example (Bopp *et al*., 1986; O'Brien Nabors and Miller, 1989; Bopp and Price, 2001). JECFA has considered the safety of calcium cyclamate, sodium cyclamate and cyclohexylamine on a number of occasions (JECFA 1967, 1970, 1976, 1977, 1980 and 1982).

Cyclamate has very low acute toxicity. The main effect produced by cyclamate at high doses (6 – 16 g/day in humans) is a softening of stools and diarrhoea (JECFA, 1977; JECFA, 1982). Numerous genotoxicity studies have been performed with both cyclamate and cyclohexylamine and while results of early studies were equivocal, later studies indicated that neither cyclamate nor cyclohexylamine are mutagenic or clastogenic (JECFA, 1970; Bopp and Price, 2001).

In 1970, a 2-year chronic toxicity study of sodium cyclamate (combined with sodium saccharin at a ratio of 10:1, and supplemented with cyclohexylamine from week 79) in rats implicated cyclamate as a cause of bladder cancer (Bopp and Price, 2001), which led to approval being withdrawn in the United States. JECFA evaluated this study in 1970 and concluded that the findings were only tentative pending a complete evaluation (JECFA, 1970). It is not clear from the following JECFA reports if this occurred. Further studies on the carcinogenic potential of cyclamate and cyclohexylamine were performed and provided strong evidence that neither of these chemicals is carcinogenic in animals.

Cyclohexylamine produces greater toxicity and it is therefore this toxicity on which the ADI for cyclamate is based. The two main effects of interest regarding cyclohexylamine are testicular atrophy and cardiovascular effects.

Testicular atrophy

Testicular atrophy has been shown in numerous toxicological studies in rats and it is clear that this organ is the most sensitive to cyclohexylamine. JECFA and others have used the endpoint of testicular atrophy in establishing an ADI for cyclamate.

Testicular effects due to cyclohexylamine were initially defined in three 90-day studies in rats conducted by Collings and Kirkby (1974), Gaunt et al. (1974) and Mason and Thompson (1977) (cited in (JECFA, 1977; Bopp *et al.,* 1986; Bopp and Price, 2001). In these studies, rats were given cyclohexylamine hydrochloride in the diet at concentrations ranging from 0.01 to 1.0%.

Results showed that body weight gain was not affected at dietary concentrations up to 0.1%; a slight decrease was seen at 0.2% (equivalent to 100 mg/kg bw per day), and significant, dose related decreases in body weight were seen at higher concentrations (0.5 – 1%). The testes did not appear affected at doses of 0.2% and below, but were clearly affected at 0.6% (equivalent to 300 mg/kg bw per day).

In another study, conducted by Brune et al. (1978, cited in (Bopp *et al.,* 1986; Bopp and Price, 2001) groups of 100 male rats were given cyclohexylamine in the diet at levels of 0, 50, 100, 200 or 300 mg/kg/day for 90 days. This study confirmed 100 mg/kg/day as a NOEL, slight but significant changes were seen in the testes histopathology of rats in the 200 mg/kg/day group and marked effects were seen at 300 mg/kg/day.

Chronic studies (Gaunt et al., 1976; Oser et al., 1972 and Oser et al., 1976, cited in (Bopp *et al.,* 1986) have supported these findings. Although results for doses between 100 and 200 mg/kg bw/day have indicated that the NOEL may be closer to 175 mg/kg/day, these results have been equivocal and therefore the NOEL for cyclohexylamine-induced testicular atrophy is currently accepted as 100 mg/kg bw/day.

Other species may not be as sensitive to the effects of cyclohexylamine as the rat; mice are clearly less sensitive, but testicular effects have been observed in dogs (Bopp *et al.,* 1986).

Cardiovascular effects

The other main toxicological effect of cyclohexylamine is its pressor effect in humans and animals. It is a well characterised indirectly acting sympathomimetic agent, similar to tyramine, however more than 100 times less potent (Bopp and Price, 2001). In humans a single oral dose of 5-10 mg/kg has been shown to increase blood pressure: no significant change in blood pressure occurred following a 2.5 mg/kg dose. In affected subjects, blood pressure quickly returned to normal even at plasma concentrations that initially were associated with pressor effects, indicating a rapid desensitisation, further supported by the observation that unlike acute studies in animals, most chronic studies have failed to demonstrate any significant cardiovascular effects (Bopp *et al.,* 1986).

Nor have hypertensive effects been observed following administration of cyclamate. This appears to be due to the kinetics of cyclamate metabolism, which would not cause a rapid increase in plasma cyclohexylamine concentrations even in individuals with high conversion ability ingesting large amounts of cyclamate (Bopp and Price, 2001).

2.3.2 Recent toxicity studies

Long-term toxicity and carcinogenicity study of cyclamate in nonhuman primates (Takayama *et al*., 2000).

Male and female cynomolgus, rhesus and African green monkeys were fed sodium cyclamate in the diet five days a week, starting shortly after birth and continuing for up to 24 years. Ten monkeys (4 cynomolgus, 5 rhesus, and 2 African green) were in the low dose group and received 100 mg/kg; 11 monkeys (5 cynomolgus, 5 rhesus and 1 African green) were in the high dose group and received 500 mg/kg. An age-matched control group contained 8 cynomolgus and 8 rhesus monkeys.

Seven monkeys from the two dose groups died during the study, including two 15-year old females (one from each dose group) that were put down due to severe pelvic endometriosis. None of these deaths were attributed to cyclamate. At the end of the 24-year study, the remaining monkeys (8/10 low dose monkeys, 6/11 high dose and 16/16 control monkeys) were sacrificed and complete necropsies were performed on all animals.

Six tumours were observed in five of the cyclamate treated monkeys. In the low dose group two females had benign neoplasms (one adenoma of the thyroid and one leiomyoma of the uterus) and one male had a papillary adenocarcinoma of the prostate. In the high dose group, a metastatic hepatocellular carcinoma was observed in one male, and one female had a metastatic adenocarcinoma of the colon as well as a benign neoplasm (leiomyoma of the uterus). No tumours were observed in the control animals.

Testicular function was evaluated in 12 cyclamate-treated monkeys and the age matched controls mid-way through the study (after 12 years of dosing). Semen analysis, measurements of testosterone and gonadotrophin levels, and testicular biopsies did not reveal any differences between the treated and control groups. At study termination, 10 cyclamate-treated males remained. For all but one animal, testicular size, colour and consistency were similar between the test and control animals. One monkey (low dose group) had severe atrophy of the right testis, however a biopsy taken from the same testis 10 years prior had shown normal spermatogenesis. This monkey had gastrointestinal problems throughout the study period and it was concluded that the testicular atrophy might not have been cyclamate related. Two monkeys in the high dose group showed focal germ cell aplasia mixed with areas showing normal spermatogenesis. The consensus by the three pathologists that examined the testicular sections was that these changes were probably not related to cyclamate exposure.

Conclusions

The authors concluded that these findings do not provide clear evidence of a toxic or carcinogenic effect of sodium cyclamate in monkeys. Due to the small number of animals used, the relatively low doses of cyclamate (9 and 45 times the ADI of 11 mg/kg), and the incidence of a variety of tumours of different types, the results of this study were inconclusive and it does not provide information that could be used in this risk assessment.

Cyclamate intake and cyclohexylamine excretion are not related to male fertility in humans (Serra-Majem *et al*., 2003)

A case-control study was conducted with 405 Spanish men attending a male infertility clinic because of infertility lasting >12 months and 379 control subjects attending the clinic for a vasectomy. Semen evaluation, urine analysis for cyclamate and cyclohexylamine excretion and dietary questionnaires were compared between the two groups. Mean estimated cyclamate intake was 0.72 mg/kg bw per day for the case group and 0.55 mg/kg bw per day for the control group. Urinary cyclamate excretion was 0.19 and 0.22 mg/kg bw per day in the cases and controls respectively. 13% of cases and 12% of controls had detectable levels of cyclohexylamine in their urine (average values of 0.035 and 0.053 mg/kg bw per day respectively). No statistically significant differences were found between the groups for any of the variables measures.

Under the conditions of this study, consumption of low levels of cyclamate had no effect on male fertility.

Other studies on cyclamate and cyclohexylamine

An epidemiology study of the fertility of 18 workers involved in cyclamate manufacture was assessed by the SCF (SCF, 2000), but was determined to be of little significance for the safety assessment of cyclamate as it related to occupational exposure and the workers were exposed to a number of factors that may have affected their fertility including elevated working temperature, high alcohol consumption and smoking.

Two repeat dose studies with cyclohexylamine in male cynomolgus monkeys were assessed by the SCF in 1995. In the first study, five male monkeys received cyclohexylamine twice daily in gelatine capsules. The dose was gradually increased from 2 x 17 mg/kg bw per day for one week to 2 x 34 mg/kg bw per day for 1 week and then 2 x 50 mg/kg bw per day for 5 weeks. In the second study, the five male monkeys that had formed the control group in the first study were dosed with 2 x 17 mg/kg bw per day cyclohexylamine for 4 weeks.

In the first study, the high doses of cyclohexylamine were not well tolerated by the test group and reduced food and water intake by the animals was observed, as was some testicular damage. The second study showed minimal effects on spermatogenesis in two of the five monkeys. It was concluded that the dose of 34 mg/kg bw per day was a minimal effect level and therefore a clear NOEL could not be established from this study (SCF, 1995).

2.4 Acceptable Daily Intake

JECFA considered the safety of calcium cyclamate, sodium cyclamate and cyclohexylamine at its meetings in 1967, 1970, 1976, 1977, 1980 and 1982. An ADI of 0-11 mg/kg bw (expressed as cyclamic acid) was established at the meeting in 1982. As no adequate sub-chronic rat study has been conducted with cyclamate, this ADI is based on the NOEL for cyclohexylamine-induced testicular atrophy in rats (100 mg/kg bw/day). From clinical studies it was shown that approximately 37% of ingested cyclamate is absorbed and in converters on average 30% of the remaining cyclamate (63%) is converted to cyclohexylamine. This leads to an estimate that on average 18.9% of the cyclamate dose may be converted to cyclohexylamine in converters and absorbed.

Allowing for the difference in molecular weights between cyclamate and cyclohexylamine and using a safety factor of 100, the ADI of 11 mg/kg bw was established.

More recently, the Scientific Committee on Food (SCF) of the European Commission considered the safety of cyclamate and established its own ADI of 7 mg/kg bw (SCF, 2000). This was based on the same NOEL used by JECFA in 1982; however, in its calculations, the SCF suggested that 85% of cyclamate intake may be metabolised to cyclohexylamine. This was the maximum conversion observed by Renwick et al. (2004) in one individual on one day of the 13-week study. A safety factor of 32 was applied[7], which led to the establishment of an ADI for cyclamate of 7.35 (rounded down to 7 mg/kg bw).

FSANZ has reviewed the new data since JECFA's evaluation in 1982, and concluded that the new evidence, in particular from the metabolism study by Renwick et al., does not warrant changing the ADI established at this time. Using the highest conversion rate seen in one individual on one day in the recent study by Renwick et al (2004), as was done by the SCF in 2000, is considered to be very conservative. As testicular atrophy is unlikely to be a C_{max} effect, a single day of high exposure to cyclohexylamine is of no particular concern. If the highest conversion rate averaged over 7 days (58%) were used and a safety factor of 32 applied, the ADI derived would be similar to the original JECFA ADI (10.78 compared to 10.58). Therefore FSANZ has retained the JECFA ADI.

3. Overall Conclusions

FSANZ has retained the ADI for cyclamate of 11 mg/kg bw as established by JECFA in 1982. This is considered to be adequately protective of individuals with consistently high cyclamate metabolising ability, based on a recent study on the metabolism of cyclamate to cyclohexylamine.

Most individuals (89%) do not metabolise cyclamate to cyclohexylamine and therefore exceeding the ADI somewhat would not represent a health risk for these individuals. For individuals with metabolising ability, if occasionally the ADI were slightly exceeded, no adverse effects would be anticipated. The uncertainty factor built into the ADI calculations means that the ADI is a somewhat conservative estimate of safety, and intakes exceeding the ADI may be safe for many consumers.

However, to protect public health an appropriate degree of conservatism must be adopted to guard against uncertainties, therefore it is preferable that the intake levels of all consumers be at or below the ADI for most days of their lifetimes.

[7] This safety factor consists of 10 for inter-species extrapolation for the NOEL, 3.2 for inter-individual variations in toxicodynamics and 1 for inter-individual variations in toxicokinetics (as the maximum conversion value was used).

References

Bopp, B. and Price, P. (2001) Cyclamate. In: O'Brien Nabors L. eds. *Alternative Sweeteners: Third Edition, Revised and Expanded*. Chapter 5. Marcel Dekker Inc, New York, pp63-85.

Bopp, B., Sonders, R. and Kesterson, J. (1986) Toxicological Aspects of Cyclamate and Cyclohexlamine. *CRC Critical Reviews in Toxicology* 16(3):213-306.

FSANZ (2004) *Consumption of Intense Sweeteners in Australia and New Zealand – Roy Morgan Research Report*., Canberra.

JECFA (1970) *Calcium and sodium cyclamates*. WHO/FOOD ADD/70.39, World Health Organization, Geneva.

JECFA (1977) *Sodium and calcium cyclamates*. WHO FAS 12, WHO TRS No. 617, World Health Organization, Geneva.

JECFA (1982) *Calcium cyclamate, sodium cyclamate and cyclohexylamine*. WHO FAS 17. World Health Organization, Geneva.

O'Brien Nabors, L. and Miller, W. (1989) Cyclamate - A Toxicological Review. *Comments Toxicology* 3(4):307-315.

Renwick, A.G., Thompson, J.P., O'Shaughnessy, M. and Walter, E.J. (2004) The metabolism of cyclamate to cyclohexylamine in humans during long-term administration. *Toxicol Appl Pharmacol* 196(3):367-380.

Roy Morgan Research (2005) *Consumption of Intense Sweeteners in Australia and New Zealand – Extra Cyclamate Analysis*.

SCF (1995) *Opinion on cyclamic acid and its sodium and calcium salts*. Reports of the Scientific Committee for Food (Thirty-eighth Series). Scientific Committee on Food , 37-43. http://www.europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_38.pdf.

SCF (2000) *Revised opinion on cyclamic acid and its sodium and calcium salts*. European Commission, Scientific Committee on Food.

Serra-Majem, L., Bassas, L., Garcia-Glosas, R., Ribas, L., Ingles, C., Casals, I., Saavedra, P. and Renwick, A.G. (2003) Cyclamate intake and cyclohexylamine excretion are not related to male fertility in humans. *Food Addit.Contam* 20(12):1097-1104.

Takayama, S., Renwick, A.G., Johansson, S.L., Thorgeirsson, U.P., Tsutsumi, M., Dalgard, D.W. and Sieber, S.M. (2000) Long-term toxicity and carcinogenicity study of cyclamate in nonhuman primates. *Toxicol Sci* 53(1):33-39.

Attachment 3

Dietary Exposure Assessment Report

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APPENDIX 2 **66**

1. Executive Summary

A proposal was initiated by FSANZ to consider cyclamate permissions in the Code in response to the FSANZ 2003 Consumption of Intense Sweetener survey (FSANZ 2004), which investigated the exposure to intense sweeteners in Australians and New Zealanders aged 12 years and above. From this survey, it was concluded that some consumers of cyclamate containing products exceeded the Acceptable Daily Intake (ADI).

The 2003 Consumption of Intense Sweetener survey was conducted during the transition period between the old Australian *Food Standards Code* and the New Zealand Food Regulations and the new Joint Code. Therefore, a revised dietary exposure assessment for a range of population groups was deemed necessary based on current manufacturers' use levels of cyclamate where available, in conjunction with the current maximum permitted levels (MPL) outlined in Standard 1.3.1 (Food Additives) of the new Code (Scenario 1). Additional scenarios were assessed based on a previous Application to extend the use of cyclamate to tabletop sweeteners (Scenario 2); and the effect on estimated dietary exposure of reducing MPLs for cyclamate in water-based flavoured drinks such as intensely sweetened soft drinks and cordials, both with and without the extension of use of cyclamate in tabletop sweeteners **(Scenarios 3 and 4)**.

Dietary exposures to cyclamate were calculated for various Australian and New Zealand population groups:

- the Australian and New Zealand populations aged 12 years and above; and the combined Australian and New Zealand sub-groups of 12-17 years, 18-24 years, 25-39 years, 40-59 years and 60 years and above;
- diabetic/impaired glucose tolerant consumers in Australia and New Zealand; and
- Australians aged 2-11 years.

The food consumption data used for those aged 12 years and above were 7-day diary data from the *2003 Consumption of Intense Sweetener* survey. For those aged 2-11 years, data were sourced from the 1995 Australian National Nutrition Survey (NNS), which was based on a 24-hour recall. The concentration data were current manufacturer's use levels and scenario Code permissions.

Under Scenarios 1 and 2, estimated mean dietary exposures for all population groups were below the reference health standard (ADI):

- Estimated mean dietary exposure for Australians aged 12 years and above was 2.4 mg/kg bw day (Scenario 1) and 2.5 mg/kg bw/day (Scenario 2), and New Zealanders aged 12 years and above were 1.6 mg/kg bw/day (Scenario 1) and 2.1 mg/kg bw/day (Scenario 2).
- The highest estimated mean dietary exposure to cyclamate was for Australians aged 2-11 years. Estimated mean dietary exposure for males was 5.4 mg/kg bw/day (Scenario 1) and 5.7 mg/kg bw/day (Scenario 2), and females were 5.9 mg/kg bw/day (Scenario 1) and 6.0 mg/kg bw/day (Scenario 2).

Under both Scenarios 1 and 2 at the 95th percentile:

- the Australian and New Zealand populations aged 12 years and above had estimated dietary exposures at or below the ADI;
- under Scenario 2, three percent of Australians and less than 1% of New Zealanders aged 12 years and above had estimated dietary exposures above the ADI;
- Australians aged 2-11 years had estimated dietary exposures that exceeded the ADI. Under Scenario 1, males had an estimated dietary exposure at 150% of the ADI and females at 140% of the ADI. Under Scenario 2, males had an estimated dietary exposure at 160% of the ADI and females at 140% of the ADI; and
- under Scenario 2, 16% of Australian males and 19% of females aged 2-11 years had an estimated dietary exposure above the ADI.

Scenarios 3 and 4 were not assessed for the Australian and New Zealand populations aged 12 years and above, as exposure under Scenarios 1 and 2 was within the ADI; however, any reduction in permissions would further reduce estimated dietary exposures for this population.

Under Scenarios 3 and 4, estimated 95th percentile dietary exposures for Australians aged 2-11 years were below the ADI:

- Males had an estimated dietary exposure at 80% of the ADI under Scenario 3; and 95% of the ADI under Scenario 4.
- Females had an estimated dietary exposure at 80% of the ADI under Scenario 3; and 90% of the ADI under Scenario 4.
- Under Scenario 4, five percent of males and 3% of females had an estimated dietary exposure above the ADI.

For the Australian and New Zealand population aged 12 years and above, the major contributors to estimated dietary cyclamate exposure in both Scenarios 1 and 2 were intensely sweetened cordials and fruit drinks, which contributed approximately half of estimated dietary exposure. Intensely sweetened soft drinks and jellies and milk-based puddings made up most of the remaining contributions, with the exception of tabletop sweeteners for the New Zealand population in Scenario 2.

For Australian males aged 2-11 years, across Scenarios 1-4, intensely sweetened soft drinks was the major contributor (range of 55%-65%), with cordials making up most of the remaining contribution (range of 26%-32%), with the exception of tabletop sweeteners in Scenarios 2 (8%) and 4 (13%). For Australian females aged 2-11 years, intensely sweetened soft drinks and cordials made a contribution of between 42% and 51% towards estimated dietary cyclamate exposure across Scenarios 1-4. Tabletop sweeteners contributed 7% in Scenario 2 and 11% in Scenario 4.

Estimated dietary exposures for Australians aged 2-11 years were based on food consumption data for one day only, and generally it is recognised that 24-hour recall data overestimate consumption over time for high consumers.

In this case, it is likely that estimated dietary exposure based on 24-hour recall reflects that for a longer time-period as intensely sweetened soft drinks and cordials are frequently consumed by this population group. When estimated dietary exposures based on 24-hour recall data were compared to exposures based on 7-day diary data for Australian and New Zealanders aged 12-17 years to determine the validity of using 24-hour recall data for long-term estimates, it was found that estimated 95th percentile dietary exposures were 80% of the ADI for exposure based on 24-hour recall; and 70% of the ADI for 7-day exposure, representing a 10% difference. Even taking this difference into account, under Scenarios 1 and 2, it is likely that at the 95th percentile, cyclamate exposures for Australians aged 2-11 years using 7-day diary data could still exceed the ADI.

However, it must also be noted that whilst 7-day diary data were collected for the Australian and New Zealand population aged 12 years and above which ensures a more accurate estimate of longer term, or chronic, exposure than 24-hour data, diary respondents were already identified as being high consumers of products containing intense sweeteners from the screener survey. Hence, dietary exposure may be overestimated across the whole population.

Overall, the dietary exposure assessment revealed that estimated cyclamate dietary exposures based on current uses by manufacturers result in an exceedance of the ADI for Australian children aged 2-11 years. For the Australian and New Zealand population aged 12 years and above, there was a lower exposure estimated compared to the *2003 Consumption of Intense Sweetener* survey. The major contributor to dietary exposures for all population groups assessed was water-based flavoured drinks (intensely sweetened soft drink and cordial).

Estimated dietary cyclamate exposures and the proportion of the population exceeding the ADI for the 2-11 year age group would be reduced should lower cyclamate permissions in intensely sweetened soft drinks and cordials (from 600 mg/kg to 300 mg/kg) be implemented. Any reduction in permissions for this food group would further reduce estimated dietary cyclamate exposures for Australian and New Zealanders aged 12 years and above.

Of those aged 12 years and above, the sub-group most likely to consume tabletop sweeteners were those aged 60 years and above. For the population aged 2-11 years, tabletop sweeteners were not a significant contributor to total dietary cyclamate exposures. This would suggest that reinstating permissions for the inclusion of cyclamate in tabletop sweeteners would have little effect on the exposure to cyclamate in the younger population groups who have higher levels of exposure on a body weight basis.

2. BACKGROUND

Cyclamate has been used for over 30 years as an intense sweetener in Australia and New Zealand and is currently approved for use in more than 50 countries. However, it is not permitted for use in the USA, and Canada only permits cyclamate use in tabletop sweeteners.

Cyclamate is a widely used intense sweetener due to its flexible functionality and cost competitiveness. It is one of the most heat-stable of sweeteners and ideal for cooking and baking. Being only 30 times sweeter than sugar, cyclamate is often used in combination with other sweeteners. Cyclamate also provides body, mouthfeel and general rounding out of flavour to the end product and has a relatively high shelf-life (Schweppes and Hansells submissions, 2004).

2.1 Existing Permissions

The current maximum permitted levels (MPL) for cyclamate in the Code (Standard 1.3.1 – Food Additives) are listed in Table 1.

Table 1: Current MPLs for cyclamate in the *Australia New Zealand Food Standards Code*

Commodity	MPL (mg/kg)
Commercially sterile fruit and vegetables in hermetically sealed containers	1,350
Fruit and vegetable spreads including jams, chutneys and related products	1,000
Low joule chewing gum	20,000
Low joule fruit and vegetable juice products	400
Water based flavoured drinks	600
Brewed soft drinks	400
Jelly	1,600
Sauce, topping, mayonnaise, salad dressing	1,000

An Application (A515) was received by FSANZ in October 2003 to amend the Code in order to permit the use of cyclamate in tabletop sweeteners. This Application was subsequently withdrawn pending a review of current cyclamate permissions as part of this Proposal.

3. DIETARY EXPOSURE ASSESSMENTS

3.1 What are Dietary Exposure Assessments?

Dietary exposure assessments are tools used to estimate exposures to food chemicals from the diet as part of the risk assessment process. To estimate dietary exposure to food chemicals, records of what foods people have eaten (food consumption) is multiplied by the amount of the food chemical in each food (food chemical concentration).

Dietary exposure = food chemical concentration x food consumption

The accuracy of these exposure estimates depend on the quality of the data used in the dietary exposure assessment models. Sometimes not all of the data required are available or there is uncertainty about the accuracy. Therefore assumptions are made either about the foods eaten or about chemical levels, based on previous knowledge and experience.

The models are generally set up according to international conventions for food chemical exposure estimates, however each modelling process requires decisions to be made about how to set up the model and what assumptions to make. A different decision may result in a different answer. Therefore, FSANZ clearly documents all such decisions and model assumptions to enable the results to be understood in the context of the data available and so that risk managers can make informed decisions.

The dietary exposure assessment is conducted using the FSANZ dietary modelling computer program, DIAMOND. DIAMOND contains food consumption data for Australia from the 1995 National Nutrition Survey (NNS) that surveyed 13,858 people aged 2 years and above, as well as for New Zealand from the 1997 NNS that surveyed 4,636 people aged 15 years and above. The NNSs used a 24-hour food recall methodology.

It is recognised that these food consumption data have several limitations. For a complete list of limitations see Section 5.1.6 on *Limitations*.

4. SUMMARY OF DIETARY EXPOSURE ASSESSMENTS CONDUCTED TO DATE

4.1 1994 Survey of Intense Sweetener Consumption

In 1994, a survey of intense sweetener consumption by Australians aged 12-39 years was administered by the then National Food Authority (now FSANZ) (National Food Authority, 1995). Estimated 90th percentile dietary exposure to cyclamate was at 110% of the ADI. Consumption of cordial containing intense sweetener was most likely to produce high cyclamate dietary exposures. The survey concluded that further investigation of the potential for high cyclamate exposures was warranted.

4.2 Review of the Code and Proposal P150

Between 1998-2000, FSANZ undertook an evaluation of food additive permissions during the Review of the Food Standards Code as a part of Proposal P150, to assess if the change from a prescriptive food additive standard in the former Australian *Food Standards Code* to a more horizontal standard (Standard 1.3.1) in the *Australia New Zealand Food Standards Code*, would have an impact on public health and safety. Cyclamate permissions were changed as a result of the Review with a decrease in MPLs for some foods and removal of MPLs for others.

4.3 2003 Consumption of Intense Sweeteners Survey

The *2003 Consumption of Intense Sweetener* survey (FSANZ, 2004) was conducted during the two-year transition period before the Code became fully implemented from December 2002. As a result, products containing cyclamate conforming to the requirements of the former Australian *Food Standards Code* and the New Zealand Food Regulations were still available for sale, and subsequently consumed by some survey participants.

Tabletop sweeteners were permitted to contain cyclamate in the old Australian *Food Standards Code* and the New Zealand Food Regulations and are no longer permitted in the current Code.

The *2003 Consumption of Intense Sweeteners* survey conducted by Roy Morgan Research extended survey parameters to include Australians aged 40 years and above and the New Zealand population. A total of 3,529 people were interviewed using a 'screener' survey. From this survey sample, 400 respondents were identified as potential high consumers of products containing intense sweeteners. These potential high consumers completed a 7-day brand specific food diary, providing data on individual respondents' weekly consumption of intensely sweetened foods. A separate diary survey of 298 people (223 in Australia and 75 in New Zealand) with either diabetes or impaired glucose tolerance (IGT) was also administered.

Estimated dietary exposures were calculated by multiplying food consumption data with the level of cyclamate in each food that had a permission. Either current manufacturer use levels or the MPL as specified in the Code were used. Population statistics (mean and 95th percentile estimated dietary exposures) for each population group were derived from the individuals' ranked exposures.[8]

The evaluation for the combined Australian and New Zealand population indicated no public health and safety concerns for most sweeteners with the exception of cyclamate (see Table A2.1 in Appendix 2). For the 71% of diary survey participants who consumed foods containing cyclamate during the 7-day diary survey, estimated 95th percentile dietary exposure to cyclamate represented 85% of the ADI. However, dietary exposure varied between age and country. In Australia, the small number of 12-17 year olds and 25-39 year olds exceeded the cyclamate ADI at the 95th percentile of dietary exposure (245% and 150% respectively). In New Zealand, the small base of 25-39 year olds met the ADI at the 95th percentile and those aged 60 years and over exceeded the cyclamate ADI at the 95th percentile (110%). It is of note that this population group (n=400) had already been identified as being potential high consumers of intensely sweetened foods.

For the Diabetic/IGT population group, the estimated dietary exposure exceeded the ADI at the 95th percentile (110%).

4.3.1 Major Contributors

The major contributors to the estimated dietary exposure to cyclamate in the *2003 Consumption of Intense Sweetener* survey were intensely sweetened cordials and soft drinks. When compared to the 1994 survey, which focused solely on 12-39 year old Australians, the 2003 survey indicated that for this age group there was a significant increase in the average daily consumption amount of soft drinks containing intense sweeteners.

[8] DIAMOND was not used for this process.

The 2003 data indicated that in terms of age, the younger age groups were more likely to be consumers of cordials and fruit drinks containing cyclamate. Those aged 60 years and above were more likely to have consumed jams and canned fruits containing cyclamate, as well as tabletop sweeteners (New Zealand only).

4.4 Estimated Dietary Exposures for Children Under 12 Years

Children under 12 years of age were not included in the *2003 Consumption of Intense Sweeteners* survey, for methodological and cost reasons. Exposure of Australian children aged 2-11 years to cyclamate was therefore estimated through DIAMOND, using food consumption data collected in the 1995 NNS and mean cyclamate levels collected in the *2003 Consumption of Intense Sweeteners* survey. Consumption data for New Zealand children were not available. Using this approach, mean and 95th percentile exposure to cyclamate among Australian children aged 2-11 years who were consumers of cyclamate-containing foods was estimated to be approximately 50% and 200% of the ADI respectively.

5. DIETARY EXPOSURE ASSESSMENT FOR P287: REVIEW OF CYCLAMATE PERMISSIONS

As a result of the findings from the *2003 Consumption of Intense Sweeteners* survey, FSANZ sought to determine under this Proposal whether re-analysing the data from the survey using current/updated manufacturers' use levels of cyclamate, where available, in conjunction with current MPLs outlined in the Code, would impact upon the level of exposure to cyclamate. Current manufacturers use levels are frequently well below MPLs. In addition, FSANZ sought to determine cyclamate exposure levels taking into consideration an extension of use of cyclamate to tabletop sweeteners (based on a previous Application: A515), as well as considering a reduction in the MPL for cyclamate in intensely sweetened soft drinks and cordials (assessment undertaken for Australians aged 2-11 years only).

Four scenarios were modelled for the purpose of this Proposal:

Scenario 1:

Exposure to cyclamate with the ***exclusion*** of cyclamate in tabletop sweeteners for Australians and New Zealanders aged 12 years and above and Australians aged 2-11 years, using current manufacturers' use levels of cyclamate.

***Scenario 2*:**

Exposure to cyclamate with the ***inclusion*** of cyclamate in tabletop sweeteners for Australians and New Zealanders aged 12 years and above and Australians aged 2-11 years, using current manufacturers' use levels of cyclamate, plus previous manufacturers' use levels for cyclamate in tabletop sweeteners.

***Scenario 3**:*

Exposure to cyclamate with the ***exclusion*** of cyclamate in tabletop sweeteners for Australians aged 2-11 years, using current manufacturers' use levels of cyclamate and assuming a proposed reduced MPL for cyclamate for intensely sweetened soft drinks and cordials.

***Scenario 4**:*

Exposure to cyclamate with the ***inclusion*** of cyclamate in tabletop sweeteners for Australians aged 2-11 years, using current manufacturers' use levels of cyclamate plus previous manufacturers' use levels for cyclamate in tabletop sweeteners and assuming a proposed reduced MPL for cyclamate for intensely sweetened soft drinks and cordials.

Scenario 3 and 4 were only conducted on children aged 2-11 years as they are the population group that have higher exposures to cyclamates per kilogram of body weight. Therefore they are the group against which the effectiveness of potential risk management options, such as the reduction in MPLs, was tested for effectiveness.

Table 2 summarises the scenarios modelled for P287 – Review of cyclamate permissions.

Table 2: Scenarios modelled for P287 - Review of cyclamate permissions

		Scenario parameters	
Scenario	**Population group**	**Cyclamate in tabletop sweeteners included**	**Reduced cyclamate MPL in intensely sweetened soft drinks and cordials**
Scenario 1	Aust and NZ 12+ years	×	×
	Aust 2-11 years	×	×
Scenario 2	Aust and NZ 12+ years	✓	×
	Aust 2-11 years	✓	×
Scenario 3	Aust and NZ 12+ years	N/A	N/A
	Aust 2-11 years	×	✓
Scenario 4	Aust and NZ 12+ years	N/A	N/A
	Aust 2-11 years	✓	✓

5.1 Methods for Dietary Exposure Assessment: Australians and New Zealanders aged 12 years and above

The dietary exposure assessment for Australians and New Zealanders aged 12 years and above was conducted on behalf of FSANZ by Roy Morgan Research.

5.1.1 Population Groups Assessed

The dietary exposure assessment was conducted for the general diary survey respondents (identified high consumers of intensely sweetened products; n=400) from the *2003 Consumption of Intense Sweetener* survey. Results were also analysed for Australians only, New Zealanders only and for the combined Australian and New Zealand age groups: 12-17 years; 18-24 years; 25-39 years; 40-59 years; and 60 years and above.

A dietary exposure assessment was also conducted for the total diabetic/IGT diary sample group from the *2003 Consumption of Intense Sweetener* survey, as this group were thought likely to consume more intensely sweetened foods than the general population.

5.1.2 Cyclamate Concentration Levels

The concentration levels of cyclamate in food used in the dietary exposure assessment were obtained from current manufacturers' use levels after the Code permissions had come into force, in addition to those derived from the FSANZ *2003 Consumption of Intense Sweetener* survey. Current manufacturers' use levels were obtained via submissions to the Initial Assessment Report (IAR). The use of manufacturers' data, in conjunction with current MPLs listed in Standard 1.3.1 of the Code, provides a more realistic estimate of the current exposure to cyclamate than MPLs alone.

Where manufacturers provided new information on a range of possible cyclamate concentrations, the highest level in the range was used in order to assume a worst-case scenario. Concentrations were assigned to individual foods by brand and flavour. If the levels of current use of cyclamate in foods were provided by the manufacturers as percentages, these were converted to mg/kg concentrations for the purpose of the exposure calculations. Where it was established that manufacturers do not use cyclamate in food items where permissions exist, a cyclamate concentration of zero was assigned in the exposure assessment for that particular food group (e.g. low joule chewing gum). Where there were no new manufacturers' use data available or submitted, concentrations from the 2003 survey were used, but if these data exceeded the current MPL (mg/kg), the concentration value was capped at the current MPL.

The concentration of cyclamate in tabletop sweeteners for Scenario 2 was the manufacturers' use level prior to the new Code coming into force in December 2000, as used in the *2003 Consumption of Intense Sweetener* survey. Cyclamate concentrations were only assigned to tabletop sweeteners known to contain cyclamate, predominantly those available for sale in New Zealand.

Individual concentration values for each product by brand and flavour are unable to be shown in this document for commercially confidential (CCI) reasons.

5.1.3 Food Consumption Data

Data on food consumption for the Australian and New Zealand population aged 12 years and above were obtained from the *2003 Consumption of Intense Sweeteners* survey, in which participants completed 7-day, brand specific food diaries.

5.1.4 Calculation of Estimated Dietary Exposures

Estimated dietary exposures to cyclamate were calculated by multiplying cyclamate concentration levels with the amount of individual commodities that the individual consumed (by brand and flavour). For further detailed procedure see the *Consumption of Intense Sweeteners in Australia and New Zealand – Roy Morgan Research Report* (FSANZ, 2004).

5.1.5 Assumptions in the Dietary Exposure Assessments

Assumptions made in the dietary exposure assessments include:

- where submissions indicated that manufacturers do not use cyclamate in food items where MPLs exist, the food was assigned a zero concentration e.g. low joule chewing gum;
- all cyclamate present in food is absorbed by the body;
- there are no reductions in cyclamate concentrations from food preparation or due to cooking;
- the food category 'soft drinks' included 'home prepared' carbonated beverages;
- for the purpose of this exposure assessment, it is assumed that *light* cordial is equivalent to the *diet* cordial varieties consumed in *2003 Consumption of Intense Sweetener* study. *Diet* varieties for some brands are no longer available for retail sale on Australian supermarket shelves;
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. salad dressings and toppings); and
- a cyclamate concentration was only assigned to those brands of tabletop sweeteners known to contain cyclamate, not all tabletop sweeteners (applies mainly to products available in New Zealand).

5.1.6 Limitations of the Dietary Exposure Assessments

Limitations of the dietary exposure assessments include:

- since the 2003 sweetener survey data were collected, there have been changes in the food supply. New cyclamate containing products have come onto the market and others may have been replaced with non-cyclamate containing sweeteners, thus representing a limitation with the consumption data. This was dealt with in some situations by applying concentrations for new foods to consumption of like foods in the diary survey; and
- dietary exposure assessments for populations aged 12 years and above were performed on a group of consumers who had already been identified as potential high consumers of intense sweeteners and therefore may not be representative of the general population.

5.2 Methods for Dietary Exposure Assessments: Australians aged 2-11 years

As children under the age of 12 were not included in the *2003 Consumption of Intense Sweetener* survey, dietary exposure assessments for Australians aged 2-11 years were performed using the DIAMOND computer program. Further details on how the dietary exposure assessments were conducted using DIAMOND can be found in Appendix 1.

5.2.1 Population Groups Assessed

A dietary exposure assessment to cyclamate was of interest for those aged 2-11 years as children generally have higher exposures to food chemicals on a body weight basis. This is due to their smaller body weight and higher consumption of food per kilogram of body weight compared to adults.

Children may also consume a significant proportion of the food types that can contain cyclamate, such as intensely sweetened soft drinks, cordials and jelly. Only the Australian population was assessed as FSANZ does not currently have access to data on the food consumption of the New Zealand population under the age of 15 years.

In addition, the estimated dietary exposure to cyclamate for Australians aged 12-17 years was assessed using DIAMOND so that results could be compared with the *2003 Consumption of Intense Sweetener* survey of the same group. This was to ascertain whether differences existed in cyclamate exposure levels based on consumption data collected via the two different methods (7-day diary versus 24-hour recall used in DIAMOND), thus assessing the validity of using 24-hour recall data for Australians aged 2-11 years to represent longer-term consumption patterns.

5.2.2 Cyclamate Concentration Levels

Cyclamate concentrations were not able to be assigned to individual foods by brand and flavour. This is because: a) the 1995 NNS describes foods in a more generic way (e.g. soft drinks, fruit flavours, artificially sweetened); and b) DIAMOND is set up to calculate dietary cyclamate exposures using groups of foods, rather than by individual foods. Therefore, a mean cyclamate concentration (mg/kg) was derived from the manufacturers' use data (as used for the assessments for the population aged 12 years and above) and assigned to each food group known to contain cyclamate. Where a single manufacturer provided a range of possible cyclamate concentrations for a food, the highest level in the range was used for deriving the mean for use in calculating the estimated dietary exposures, in order to assume a worst-case scenario. If the levels of current use of cyclamate in foods were provided by the manufacturers as percentages, these were converted to mg/kg concentrations for the purpose of the exposure calculations.

Where it was established that manufacturers do not use cyclamate in food items where permissions exist, a cyclamate concentration of zero was assigned in the exposure assessment for that particular food group (e.g. low joule chewing gum). Where there were no new manufacturers' use data, concentrations from the *2003 Consumption of Intense Sweetener* survey were used, but if these data exceeded the current MPL (mg/kg), the concentration value was capped at the current MPL.

The concentration of cyclamate in tabletop sweeteners for Scenarios 2 and 4 was the manufacturers' use level prior to the review of the Code in December 2000, as used in the *2003 Consumption of Intense Sweetener* survey.

Concentrations of cyclamate were assigned to food groups using DIAMOND food classification codes. These codes are based on the Australian New Zealand Food Classification System (ANZFCS) used in Standard 1.3.1 Food Additives (for example 11.4.1 represents Tabletop sweeteners – liquid preparations). Foods known to contain cyclamate (as shown in Table 1) were matched to the most appropriate ANZFSC code(s).

Table 3 outlines the cyclamate concentrations used in DIAMOND for the exposure assessment for Australians aged 2-11 years. The value for prunes, being the only value for a food group, could not be displayed due to CCI reasons.

Table 3: Cyclamate concentrations used for estimating dietary exposure to cyclamates for Australians aged 2-11 years

DIAMOND Food Code	Commodity	Cyclamate concentration level (mg/kg)			
		Scenario 1	Scenario 2	Scenario 3	Scenario 4
4.3.1.2	Prunes	*	*	*	*
4.3.3.2	Commercial sterile fruit & veg, intensely sweetened	400	400	400	400
4.3.4.1	Chutneys, low joule jam & low joule spread	790	790	790	790
5.2.1.1	Bubble & chewing gum, intensely sweetened	0	0	0	0
11.4.1	Tabletop sweeteners, liquid preparations	0	48,000	0	48,000
11.4.2	Tabletop sweeteners, tablets, powder, granules/portions	0	80,000	0	80,000
14.1.2	Fruit & vegetable juices and fruit & vegetable juice products	0	0	0	0
14.1.3.1	Brewed soft drinks	0	0	0	0
14.1.3.6	Soft drinks, intensely sweetened	417	417	300	300
14.1.3.7	Cordials, intensely sweetened	552	552	300	300
14.1.3.9	Cola type drinks, intensely sweetened	553	553	300	300
20.2.1.4	Jelly, intensely sweetened only	1,346	1,346	1,346	1,346
20.2.4.4	Sauces, toppings, mayo & salad dressing, intensely sweetened	400	400	400	400

*not displayed due to Commercial In Confidence

5.2.3 Food Consumption Data

DIAMOND contains food consumption data for 13,858 Australians aged 2 years and above of which 1,921 are aged 2-11 years, which were collected via a 24-hour food recall.

5.2.4 Assumptions in the Dietary Exposure Assessments

The aim of the dietary exposure assessment was to make as realistic an estimate of cyclamate dietary exposure as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessment did not underestimate exposure.

Assumptions made in the dietary exposure assessments include:

- where a MPL is given to a food classification code, all foods in that group contain cyclamate;
- all the foods within the group contain cyclamate at the levels specified in Table 3;
- unless otherwise specified, the mean concentration of cyclamate in each food category has been used;
- consumption of foods as recorded in the NNS represents current food consumption patterns;
- consumers always select the intensely sweetened products containing cyclamate;
- consumers do not increase their consumption of foods/food groups (g/day) upon foods/food groups containing cyclamate becoming available;
- all cyclamate present in food is absorbed by the body;

- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of cyclamate;
- where a food has a specified cyclamate concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. intensely sweetened apples used to make an apple crumble;
- there are no reductions in cyclamate concentrations from food preparation or due to cooking;
- where foods in the NNS were reported as being the 'intensely sweetened' version of a food, only those foods were used in the exposure assessment for that food group. For example, intensely sweetened soft drinks were used in the model, not all sweetened soft drinks;
- for some food groups, there were no 'intensely sweetened' versions of the food reported as being consumed in the NNS. For the purpose of this exposure assessment, the whole food group was assigned a cyclamate concentration. For example, sweet cured prunes, a cyclamate concentration was assigned to all prunes consumed in the NNS. Brands were not identified for foods in the NNS, and flavours were only identified in some cases;
- dietary exposure to cyclamate through the use of complementary medicines (Australia) was not considered;
- for the purpose of this exposure assessment, it is assumed that 1 millilitre is equal to 1 g for all liquid and semi-liquid foods (e.g. salad dressings and toppings);
- a cyclamate concentration was assigned to all tabletop sweeteners consumed in the NNS in order to assume a worst case scenario for Scenarios 2 and 4;
- New Zealand children would eat similarly to Australian children and have similar dietary exposures to cyclamate, given that consumption data were not available in DIAMOND for this population group;
- all intensely sweetened flavoured drinks have been assumed to contain cyclamate; and
- for Scenarios 3 and 4, the MPL for cyclamate is 300 mg/kg for cordial and soft drinks and cyclamate is used at the maximum level in all intensely sweetened cordial and soft drink.

These assumptions are likely to lead to a conservative estimate for cyclamate dietary exposure for Australian children aged 2–11 years (and 12-17 years).

5.2.5 Limitations of the Dietary Exposure Assessments

Dietary exposure assessments based on 1995 NNS food consumption data provide the best estimate of actual consumption of a food and the resulting estimated dietary exposure to a food additive for the population. However, it should be noted that the NNS data do have limitations. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diets, is unlikely to have changed markedly since 1995 (Cook *et al*., 2001a; Cook *et al.*, 2001b). However, there is uncertainty associated with the consumption of foods that may have changed in consumption since 1995, or that have been introduced to the market since 1995.

Limitations of the dietary exposure assessments include:

- as only 24-hour dietary survey data are available through the NNS this represents a limitation of estimating dietary exposure over a period of time. Twenty four-hour recall data tends to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime. The results for Australians aged 2-11 years are therefore not directly comparable to those aged 12 years and above;
- daily food consumption amounts for occasionally consumed foods based on 24-hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time. This specifically affects the food groups in this assessment such as jelly;
- over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian NNS, there have been significant changes to the Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary exposure assessment is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995;
- where the NNS collected data on the use of complementary medicines (Australia), it was either not in a robust enough format to include in DIAMOND or has simply not been included in the DIAMOND program. Consequently, exposure to food additives from complementary medicines or dietary supplements could not be included in the dietary exposure assessment;
- while the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food; and
- FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate.

6. DIETARY EXPOSURE ASSESSMENT RESULTS

6.1 Proportion of Consumers versus Respondents

A total of 400 Australia and New Zealanders aged 12 years and above participated in the *2003 Consumption of Intense Sweeteners* diary survey. The breakdown of consumers versus respondents for various population groups is presented in Table 4.

Table 4: Number of consumers of foods containing cyclamate and proportion to total respondents for Australian and New Zealanders aged 12 years in the *2003 Consumption of Intense Sweeteners* diary survey

Measurement	AUS 12+ years	NZ 12+ years	Australia and New Zealand 12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab /IGT
Consumers (n)	189	96	284	31	19	79	75	80	229
Proportion of consumers/resp (%)	72	70	71	65	77	81	69	66	77

A total of 1,921 Australians aged 2-11 years were included in the 1995 NNS. The breakdown of consumers versus respondents for males and females for Scenarios 1 and 3, and 2 and 4 is presented in Table 5.

Table 5: Number of consumers of foods containing cyclamate and proportion to total respondents for Australians aged 2-11 years included in the 1995 NNS

Scenario	2-11 years male Consumers (n)	2-11 years male Proportion cons/resp (%)	2-11 years female Consumers (n)	2-11 years female Proportion cons/resp (%)
1 and 3	99	10	76	8
2 and 4	103	11	79	8

Scenario 1 and 3: Excluded cyclamate-containing tabletop sweeteners
Scenario 2 and 4: Included cyclamate-containing tabletop sweeteners

The proportion of consumers of cyclamate compared to the total number of respondents for Australians aged 2-11 years (approximately 10%) was lower than that for Australians and New Zealanders aged 12 years and above (71%). This may be attributed to the two methods used for collecting food consumption data, i.e. 7-day food diary versus 24-hour food recall as well as different food consumption patterns. A respondent may not have consumed products containing cyclamate on the day of the recall; however, over a 7-day period, they are more likely to be consumers of products containing cyclamate.

6.2 Estimated Dietary Exposures to Cyclamate

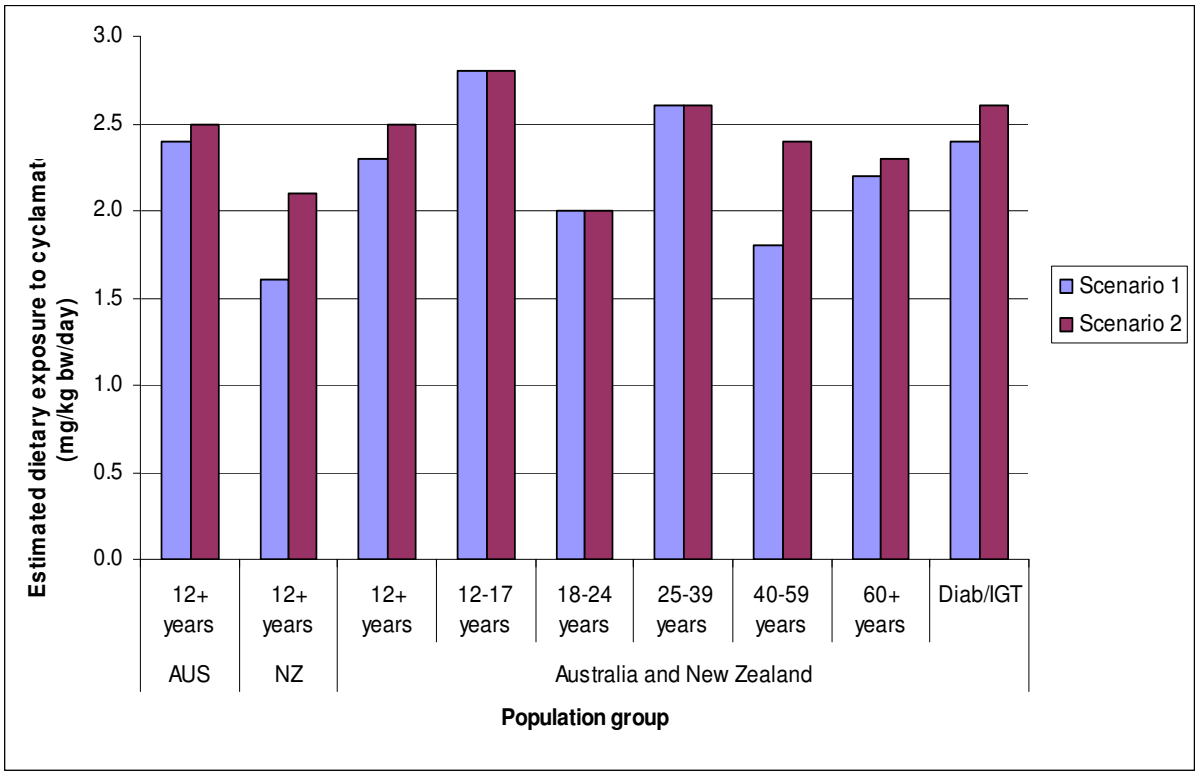
6.2.1 Estimated Mean Dietary Exposures

The estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day) for Scenarios 1 and 2 are shown in Table 6 and Figure 1. Estimated dietary exposures ranged between 1.6 and 2.8 mg/kg bw/day for Scenario 1 depending on the population group assessed, and between 2.0 and 2.8 mg/kg bw/day for Scenario 2 depending on the population group assessed.

Table 6: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

	Population group								
	AUS	NZ	Australia and New Zealand						
Scenario	12+ years	12+ years	12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab/IGT
1	2.4	1.6	2.3	2.8	2.0	2.6	1.8	2.2	2.4
2	2.5	2.1	2.5	2.8	2.0	2.6	2.4	2.3	2.6

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

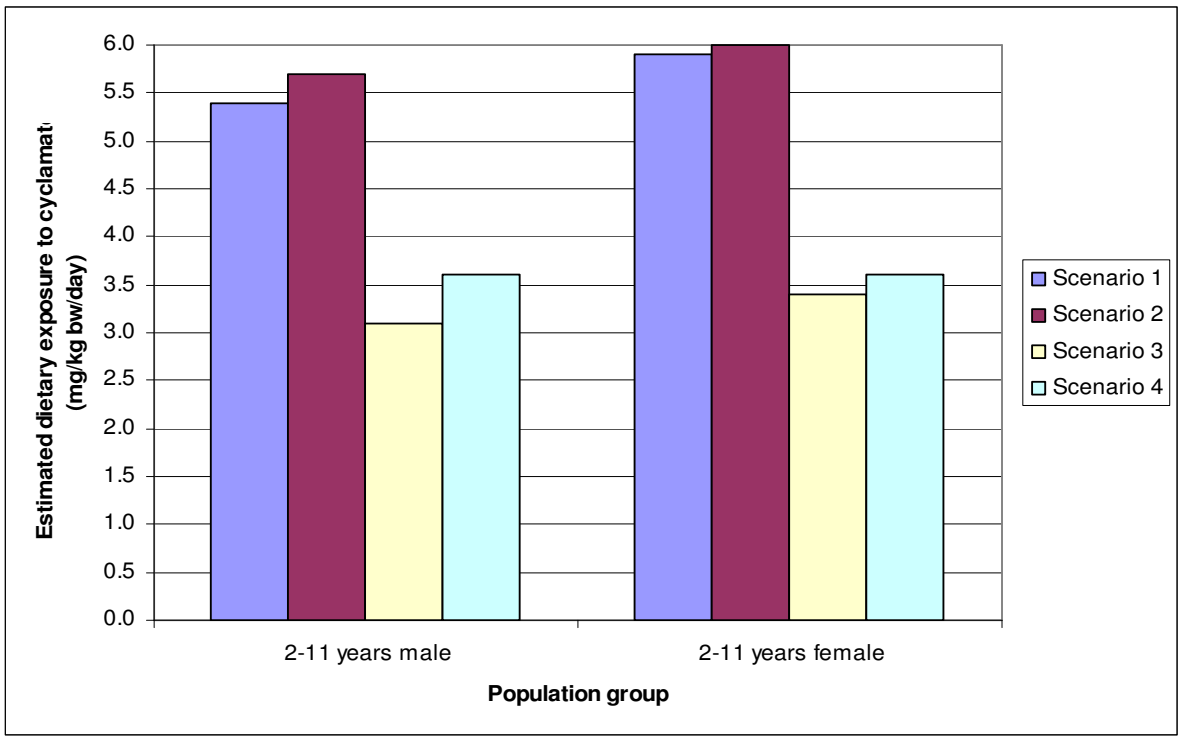
Figure 1: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

The estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day) for Scenarios 1-4 are shown in Table 7 and Figure 1. Estimated dietary exposures ranged between 5.4 and 6.0 mg/kg bw/day for Scenarios 1 and 2 and between 3.1 and 3.6 mg/kg bw/day for Scenarios 3 and 4, depending on the gender assessed.

Table 7: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day)

	Population group	
Scenario	**2-11 years male**	**2-11 years female**
1	5.4	5.9
2	5.7	6.0
3	3.1	3.4
4	3.6	3.6

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

Figure 2: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day)

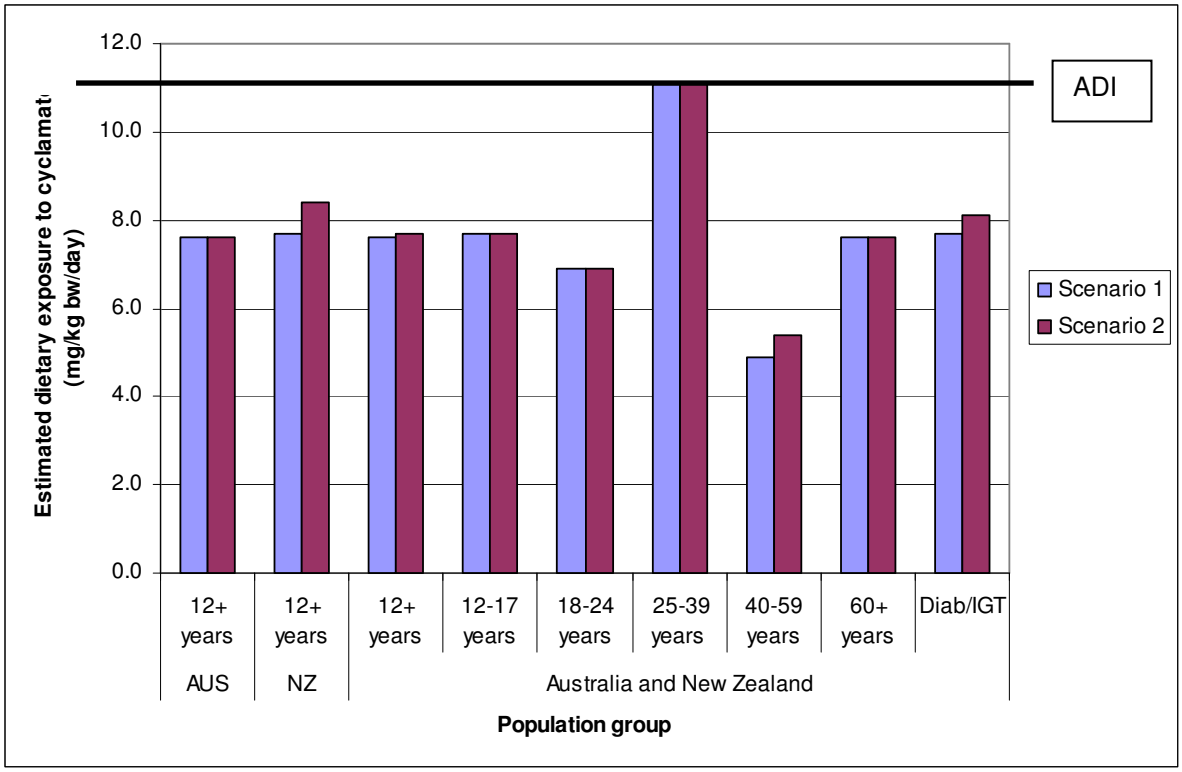
6.2.2 Estimated 95th Percentile Dietary Exposures

The estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day) for Scenarios 1 and 2 are shown in Table 8 and Figure 3. Estimated dietary exposures ranged between 4.9 and 11.1 mg/kg bw/day for Scenario 1 depending on the population group assessed, and between 5.4 and 11.1 mg/kg bw/day for Scenario 2 depending on the population group assessed.

Table 8: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

	Population group								
	AUS	NZ	Australia and New Zealand						
Scenario	12+ years	12+ years	12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab/IGT
1	7.6	7.7	7.6	7.7	6.9	11.1	4.9	7.6	7.7
2	7.6	8.4	7.7	7.7	6.9	11.1	5.4	7.6	8.1

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

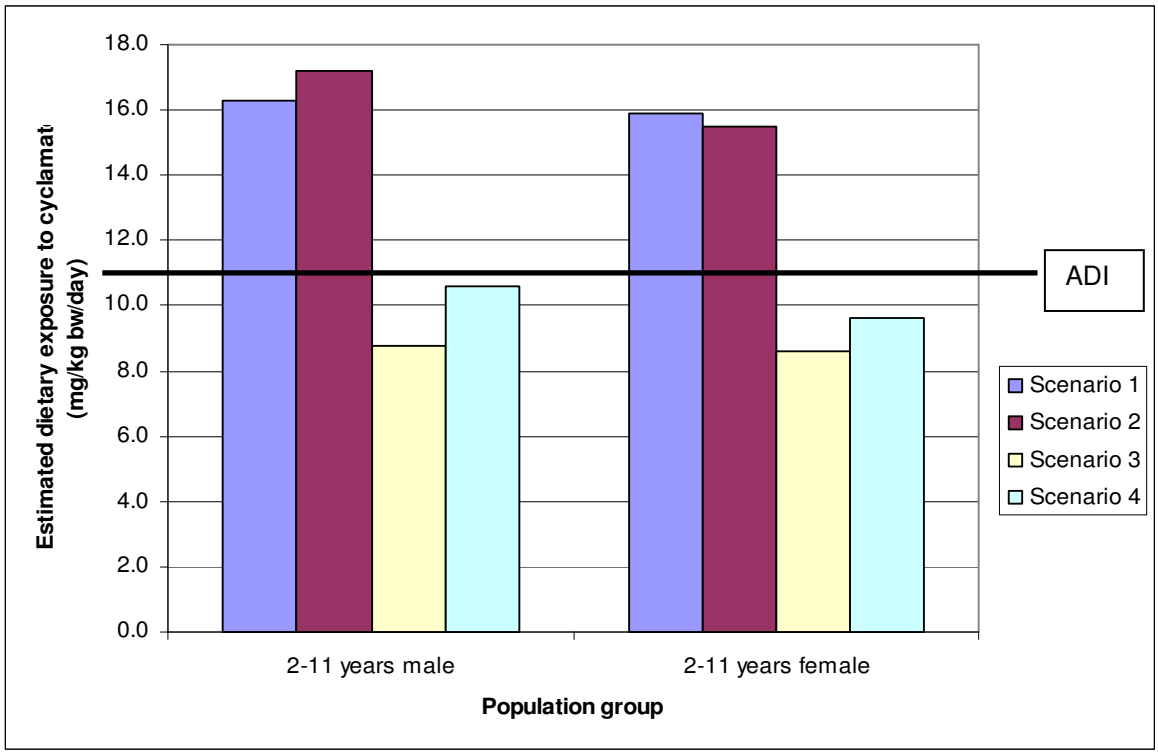
Figure 3: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

The estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day) for Scenarios 1-4 are shown in Table 9 and Figure 4. Estimated dietary exposures ranged between 15.9 and 17.2 mg/kg bw/day for Scenarios 1 and 2 and between 8.6 and 10.6 mg/kg bw/day for Scenarios 3 and 4, depending on the gender assessed.

Table 9: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day)

	Population group	
Scenario	**2-11 years male**	**2-11 years female**
1	16.3	15.9
2	17.2	15.5
3	8.8	8.6
4	10.6	9.6

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

Figure 4: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day)

For the population sub-groups aged 12 years and above at the 95th percentile, consumers aged 25-39 years had the highest estimated dietary exposure to cyclamate (Scenarios 1 and 2: 11.1 mg/kg bw day), whilst consumers aged 40-59 had the lowest (Scenario 1: 4.9 mg/kg bw/day; Scenario 2: 5.4 mg/kg bw/day) (see Table 8). Minimal differences were observed between the remaining population groups, with intakes between 7-8 mg/kg bw/day. However, an increase in cyclamate dietary exposure from Scenario 1 to Scenario 2 was observed for New Zealanders.

This can be attributed to the reported consumption of tabletop sweeteners known to contain cyclamate in the 2003 study period that were predominantly available in New Zealand only.

The total diabetic/IGT group were identified as a population sub-group that were more likely to consume intensely sweetened foods. Although the proportion of people in this group consuming intensely sweetened foods was higher than the general population, the amount they ate was similar therefore their estimated dietary exposure to cyclamate at the 95th percentile were similar to that of the general population who consume intensely sweetened foods (Scenario 1: 7.7 mg/kg bw/day; Scenario 2: 8.1 mg/kg bw/day) (see Table 8).

For the population aged 2-11 years, estimated 95th percentile dietary exposures were higher on a body weight basis compared to the adult population (Scenario 1: males 16.3 mg/kg bw/day; females 15.9 mg/kg bw/day) (Scenario 2: males 17.2 mg/kg bw/day; females 15.5 mg/kg bw/day) (see Table 9). This may be attributed to their high consumption amounts per kilogram of bodyweight, and/or the fact that assessments for children 2-11 years used single 24-hour recall consumption data to estimate exposures, compared to 7-day diary data matched by brand and flavour for the age groups 12 years and above, which provide a better estimate of long term consumption patterns.

With reduced permissions for cyclamate in water-based flavoured drinks (Scenarios 3 and 4), estimated dietary exposures to cyclamate for Australians aged 2-11 years at the 95th percentile were reduced from Scenarios 1 and 2 (Scenario 3: males 8.8 mg/kg bw/day; females 8.6 mg/kg bw/day) (Scenario 4: males 10.6 mg/kg bw/day; females 9.6 mg/kg bw/day).

6.3 Major Contributing Foods to Total Estimated Dietary Exposures

A selection of the contributing foods to total estimated cyclamate dietary exposures for the Australian and New Zealand population aged 12 years and above are presented in Table 10.

Table 10: Contributors to estimated cyclamate dietary exposures for Australians and New Zealanders aged 12 years and above

	Scenario 1			Scenario 2		
Product group	**AUS**	**NZ**	**Diab/IGT**	**AUS**	**NZ**	**Diab/IGT**
Cordials and fruit drinks, intensely sweetened	53	55	49	50	39	44
Soft drinks, intensely sweetened	33	20	24	31	14	21
Jellies and milk-based puddings, intensely sweetened	14	25	28	14	18	25
Tabletop sweeteners	0	0	0	6	29	10
Condiments (incl. jam), intensely sweetened	<1	<1	<1	<1	<1	<1
Other desserts/breakfasts, intensely sweetened	<1	<1	<1	<1	<1	<1

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

A selection of the contributing foods to total estimated cyclamate dietary exposures for Australians aged 2-11 years and above are presented in Table 11.

Table 11: Contributors to estimated cyclamate dietary exposures for Australians aged 2-11 years

	Scenario 1		Scenario 2		Scenario 3		Scenario 4	
Commodity	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
Cordials, intensely sweetened	32	51	30	43	30	49	26	48
Soft drinks, intensely sweetened	65	47	59	42	64	48	55	43
Tabletop sweeteners	0	0	8	11	0	0	13	7
Prunes	1	<1	1	1	2	2	2	<1
Sauces, toppings, mayonnaise, salad dressing, intensely sweetened	<1	<1	1	1	2	2	2	<1
Condiments (incl. jam), intensely sweetened	<1	<1	<1	<1	<1	<1	<1	<1
Canned fruit, intensely sweetened	<1	0	<1	0	<1	0	<1	0

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

For the Australian and New Zealand population aged 12 years and above, the major contributors to estimated cyclamate dietary exposure in both Scenarios 1 and 2 were intensely sweetened cordials and fruit drinks, which contributed approximately half of estimated dietary exposure (see Table 10). Intensely sweetened soft drinks and jellies and milk-based puddings made up most of the remaining contributions, with the exception of tabletop sweeteners for the New Zealand population in Scenario 2. A zero contribution means that either the food was not consumed by that population group, or there was a zero concentration assigned to that food.

For Australian males aged 2-11 years, across Scenarios 1-4, intensely sweetened soft drinks was the major contributor to estimated cyclamate dietary exposure (range of 55%-65%), with cordials making up most of the remaining contribution (range of 26%-32%), with the exception of tabletop sweeteners in Scenarios 2 (8%) and 4 (13%) (see Table 11). However, as this model did not match consumption brand for brand it is likely that this is an overestimate as the whole food category of intensely sweetened water-based flavoured drinks was assumed to contain cyclamate. For Australian females aged 2-11 years, intensely sweetened soft drinks and cordials made a contribution of between 42% and 51% towards estimated cyclamate dietary exposure across Scenarios 1-4. Tabletop sweeteners contributed 7% in Scenario 2 and 11% in Scenario 4. A zero contribution means that either the food was not consumed by that population group, or there was a zero concentration assigned to that food.

7. RISK CHARACTERISATION

7.1 Current Acceptable Daily Intake for Cyclamate

In order to determine whether the level of estimated dietary exposures to cyclamate will be a public health and safety concern, they were compared to the established Acceptable Daily Intake (ADI) of 11 mg/kg bw/day (JECFA, 1982).

The ADI was set by the Joint Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) Expert Committee on Food Additives (JECFA). The ADI is defined as an estimate of the amount of a chemical that can be ingested daily over a lifetime without appreciable risk to health (WHO 2001).

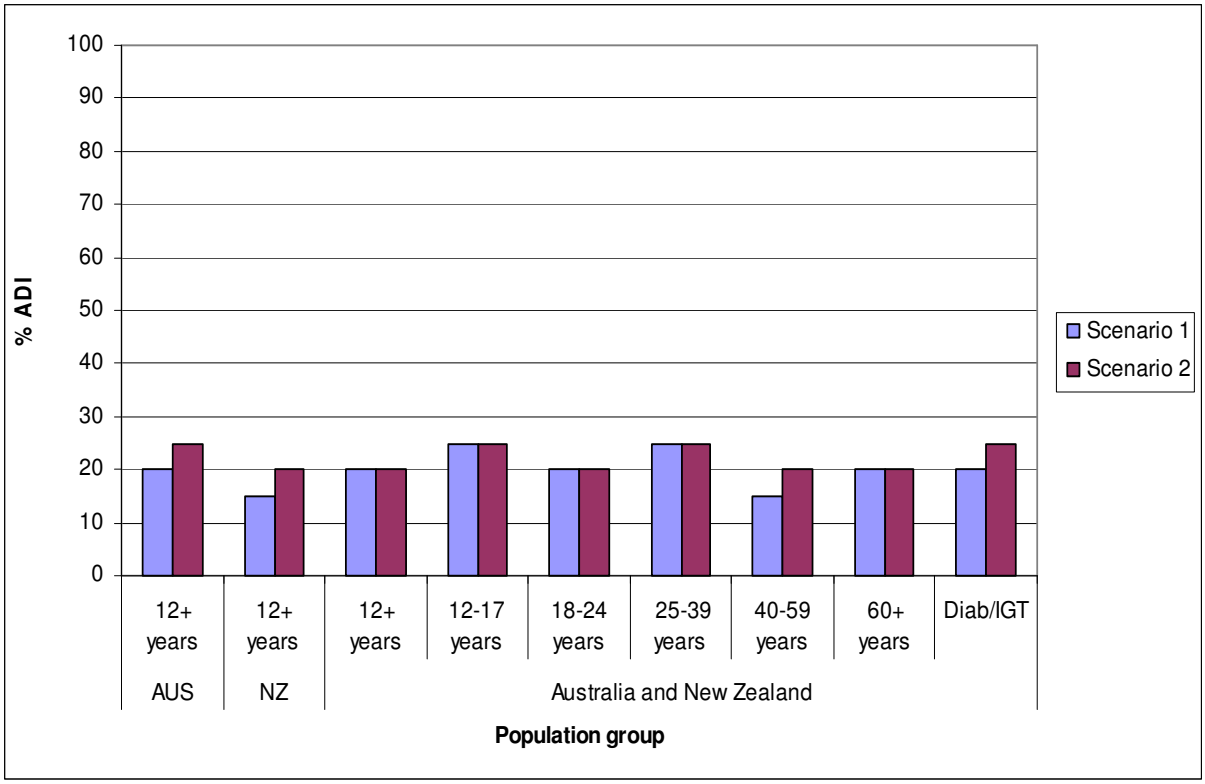
7.2 Characterisation of Estimated Mean Dietary Exposures

The estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI are presented in Table 2 and Figure 1.

Table 2: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

	Population group								
	AUS	NZ	Australia and New Zealand						
Scenario	12+ years	12+ years	12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab/IGT
1	20	15	20	25	20	25	15	20	20
2	25	20	20	25	20	25	20	20	25

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

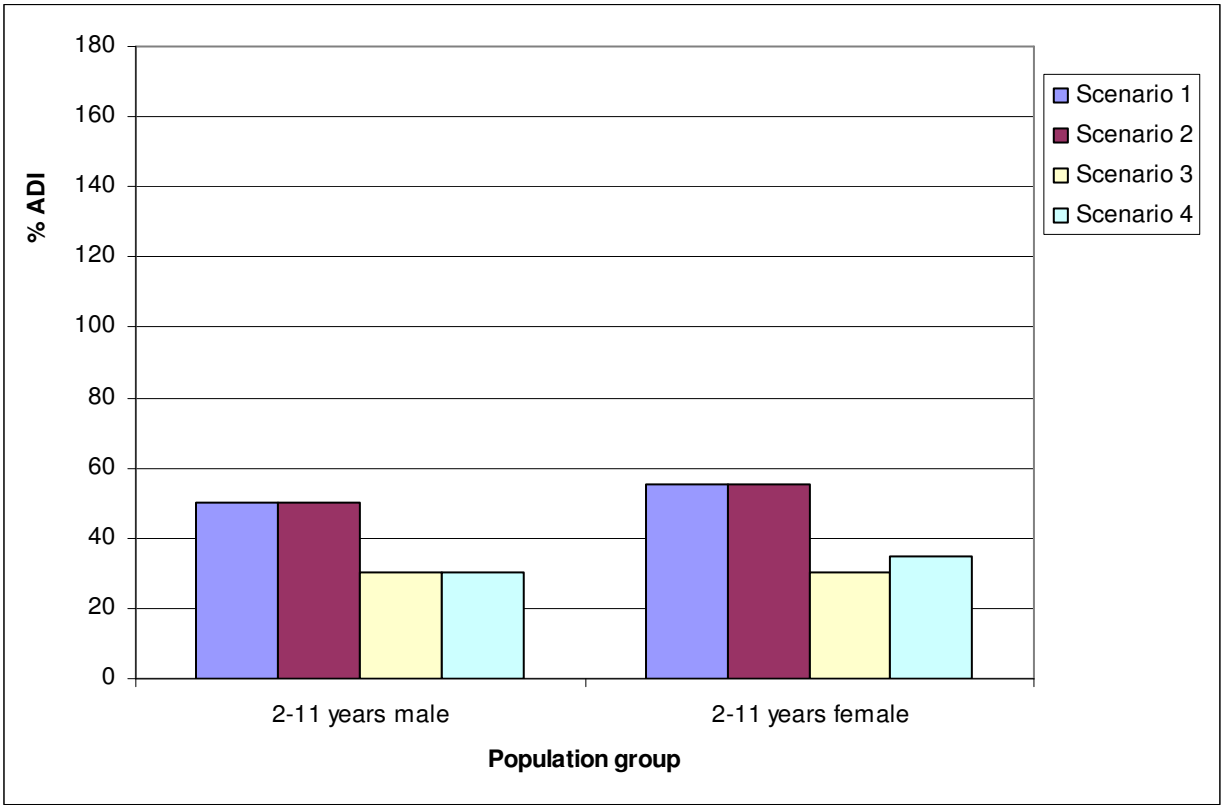
Figure 1: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

The estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI are presented in Table 3 and Figure 2.

Table 3: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

	Population group	
Scenario	**2-11 years male**	**2-11 years female**
1	50	55
2	50	55
3	30	30
4	30	35

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

Figure 2: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

For all population groups and scenarios, estimated mean dietary exposures were well below 100% of the ADI (see Table 2 and Table 3).

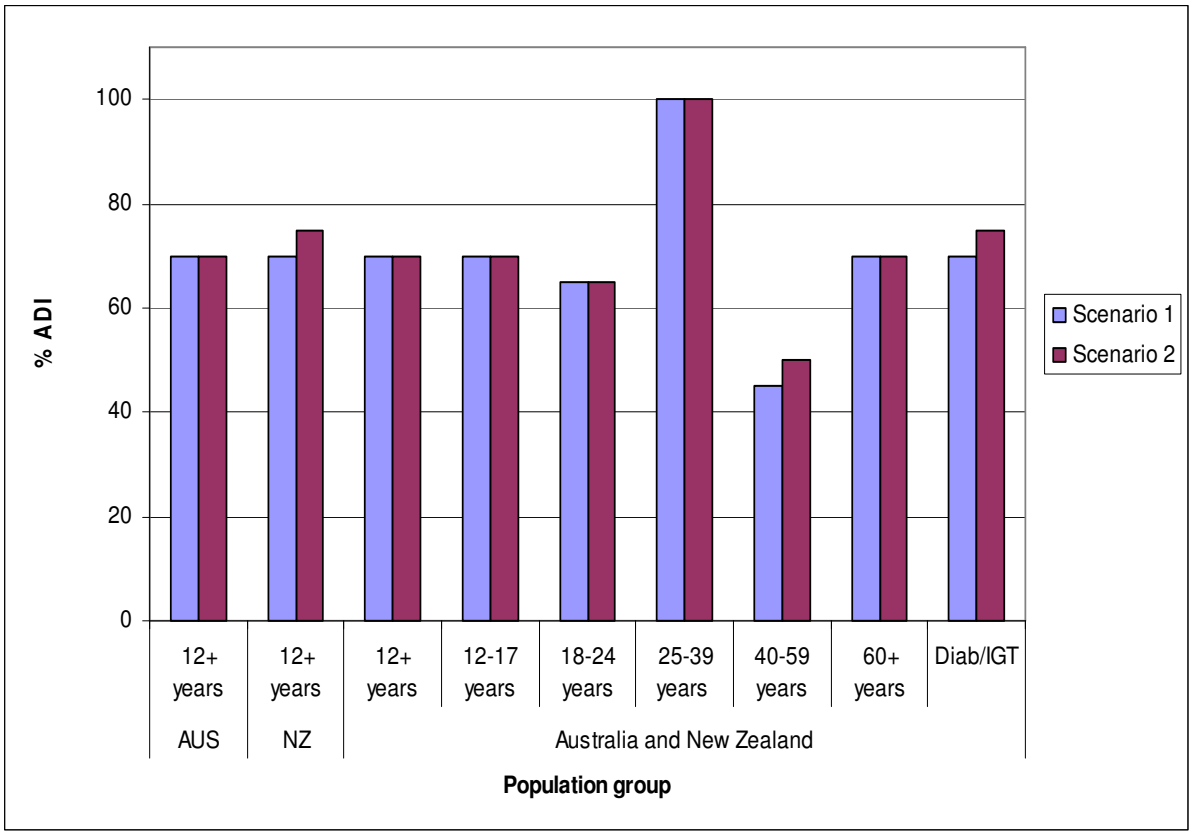
7.3 Characterisation of Estimated 95th Percentile Dietary Exposures

The estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI are presented in Table 4 and Figure 3.

Table 4: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

	Population group								
	AUS	NZ	Australia and New Zealand						
Scenario	12+ years	12+ years	12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab/IGT
1	70	70	70	70	65	100	45	70	70
2	70	75	70	70	65	100	50	70	75

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

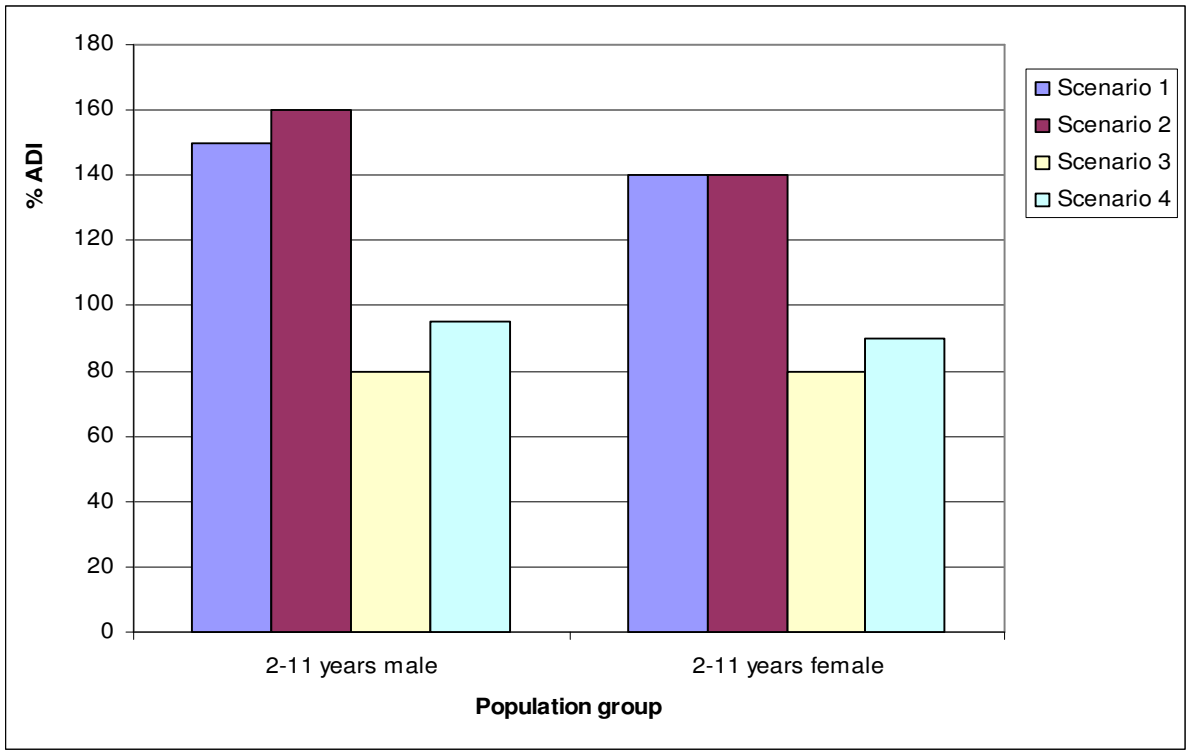
Figure 3: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

The estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI are presented in **Table** and *Figure*.

Table 5: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

	Population group	
Scenario	**2-11 years male**	**2-11 years female**
1	150	140
2	160	140
3	80	80
4	95	90

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks



Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

Figure 4: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a proportion of the ADI (%)

For the Australian and New Zealand population aged 12 years and above, estimated 95th percentile dietary exposure was at 70% of the ADI (see Table 4). However, for consumers aged 25-39 years, estimated dietary exposure was 100% of the ADI.

For Australians aged 2-11 years, estimated 95th percentile dietary exposures were approximately 150% of the ADI in Scenarios 1 and 2 (see Table 5).

With reduced permissions for cyclamate in intensely sweetened soft drinks and cordials (Scenarios 3 and 4), estimated 95th percentile dietary exposures were reduced to below 100% of the ADI, with the highest being 95% of the ADI for male consumers with the inclusion of cyclamates in tabletop sweeteners (Scenario 4).

7.4 Proportion of Consumers of Exceeding the ADI

The proportion of Australian and New Zealand consumers of cyclamate aged 12 years and above who exceeded the ADI is presented in Table 6.

Table 6: Proportion (%) of Australian and New Zealand consumers of cyclamate aged 12 years and above who exceeded the ADI

	Population group								
	AUS	NZ	Australia and New Zealand						
Scenario	12+ years	12+ years	12+ years	12-17 years	18-24 years	25-39 years	40-59 years	60+ years	Diab/IGT
1	3	0	2	4	0	6	0	0	2
2	3	<1	3	4	0	6	3	<1	2

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners

The proportion of Australian consumers of cyclamate aged 2- 11 years who exceeded the ADI is presented in Table 7.

Table 7: Proportion (%) of Australian consumers of cyclamate aged 2-11 years who exceeded the ADI (%)

	Population group	
Scenario	2-11 years male	2-11 years female
1	13	17
2	16	19
3	3	3
4	5	3

Scenario 1: Exclusion of cyclamate-containing tabletop sweeteners
Scenario 2: Inclusion of cyclamate-containing tabletop sweeteners
Scenario 3: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based flavoured drinks

For Australians aged 2-11 years, a higher proportion exceeded the ADI in Scenarios 1 and 2 compared to consumers aged 12 years and above (see Tables 6 and 7). The highest proportion of consumers exceeding the ADI for the population groups aged 12 years and above was 25-39 year olds at 6%. In comparison, 19% of female consumers aged 2-11 years exceeded the ADI. With reduced permissions for cyclamate in intensely sweetened soft drinks and cordials (Scenarios 3 and 4), the proportion of consumers aged 2-11 years exceeding the ADI was reduced to between 3% and 5%.

The higher proportion exceeding the ADI for Australians aged 2-11 years could be attributed to the higher exposures per kilogram of body weight for the 2-11 year age group and also to the use of 24-hour recall data to estimate the exposures.

It would be expected that dietary exposures over a longer period of time, such as those derived using 7-days of food consumption data for the 12 years and above age groups, would be lower, particularly for the dietary exposures at the top end of the distribution, meaning that in reality there would be a lower proportion of respondents exceeding the ADI.

8. COMPARISON OF ESTIMATED DIETARY EXPOSURES WITH 2003 DATA

8.1 Comparison of 2003 Consumption of Intense Sweetener Survey Data and Current Estimates of Exposure (Australians and New Zealanders aged 12 years and above)

Roy Morgan Research performed significance testing between the original dietary exposure estimates from the *2003 Consumption of Intense Sweetener* survey and the revised dietary exposure estimates for all adult population groups (Scenario 1 only). This was to determine whether the use of cyclamate following the existence of the new Code only (and more restrictive permissions for cyclamates in foods), made any statistically significant difference to estimated dietary exposures. Whilst there was a reduction in both mean and 95th estimated dietary exposure to cyclamate since the *2003 Consumption of Intense Sweetener* survey, it was not a significant difference.

8.2 Comparison of 2003 Consumption of Intense Sweetener Survey Data and DIAMOND

The additional dietary exposure assessment conducted for Australians aged 12-17 years using DIAMOND allowed a direct comparison to the dietary exposure assessment results based on the *2003 Consumption of Intense Sweetener* survey data for the same population group, to determine the validity of using 24-hour recall data for long-term estimates.

A comparison of the estimated mean and 95th percentile dietary exposures for consumers of cyclamate aged 12-17 years from the DIAMOND program and the *2003 Consumption of Intense Sweetener* survey are presented in Table 8.

Table 8: Estimated mean and 95th percentile dietary exposures for consumers of cyclamate aged 12-17 years

Scenario	Mean consumer exposure mg/kg bw/day		Mean consumer exposure % ADI		95th percentile consumer exposure mg/kg bw/day		95th percentile consumer exposure % ADI	
	DIAMOND	Sweet'er Survey	DIAMOND	Sweet'er Survey	DIAMOND	Sweet'er Survey	DIAMOND	Sweet'er Survey
1	3.6	2.8	35	25	9.4	7.7	85	70
2	3.4	2.8	30	25	8.9	7.7	80	70

Under Scenario 2, estimated 95th percentile dietary exposures were 80% of the ADI for exposure based on 24-hour recall; and 70% of the ADI for 7-day exposure, representing a 10% difference. Even taking this difference into account, under Scenarios 1 and 2, it is likely that at the 95th percentile, cyclamate exposures for Australians aged 2-11 years using 7-day diary data could still exceed the ADI.

However, it must also be noted that whilst 7-day diary data were collected for the Australian and New Zealand population aged 12 years and above which ensures a more accurate estimate of longer term, or chronic, exposure than 24-hour data, diary respondents were already identified as being high consumers of products containing intense sweeteners from the screener survey. Hence, dietary exposure may be overestimated across the whole population. In this case it is likely that estimated dietary exposure based on 24 hour recall data is realistic because intensely sweetened soft drinks and cordials are frequently consumed by this population group on a regular basis.

9. CONCLUSIONS

Estimated dietary exposures to cyclamate, based on current uses by manufacturers, result in an apparent exceedance of the ADI for children aged 2-11 years.

For the Australian and New Zealand population aged 12 years and above, there was a lower estimated dietary exposure to cyclamate in comparison to the *2003 Consumption of Intense Sweetener* survey.

The major contributor to dietary exposures for all population groups assessed was water-based flavoured drinks (intensely sweetened soft drinks and cordials).

Estimated dietary cyclamate exposures and the proportion of the population exceeding the ADI for the 2-11 year age group would be reduced should lower cyclamate permissions in intensely sweetened soft drinks and cordials (from 600 mg/kg to 300 mg/kg) be implemented. Any reduction in permissions for this food group would further reduce estimated exposure for Australian and New Zealanders aged 12 years and above.

Overall, the dietary exposure assessment revealed there is a minimal change to exposure to cyclamate with the inclusion of a permission to use cyclamate in tabletop sweeteners. Of those aged 12 years and above, the sub-group most likely to consume tabletop sweeteners were those aged 60 years and above, not the younger population groups who were more likely to exceed the ADI for cyclamate. For the population aged 2-11 years, there were no consumers of liquid tabletop sweeteners and only 14 consumers of tablet/powdered tabletop sweeteners. This would suggest that reinstating permissions for the inclusion of cyclamate in tabletop sweeteners would have little effect on the dietary exposure to cyclamate in the younger population groups who have higher cyclamate dietary exposures on a body weight basis.

10. References

Cook, T., Rutishauser, I., Seelig, M. (2001) *Comparable data on food and nutrient and physical measurements from the 1983, 1985 and 1995 national nutrition surveys*.

Cook, T., Rutishauser, I., Allsopp, R. (2001) *The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys*. Commonwealth of Australia: Canberra.

Food Standards Australia New Zealand (FSANZ) (2004) *Consumption of Intense Sweeteners in Australia and New Zealand – Roy Morgan Research Report*, Canberra, available at: http://www.foodstandards.gov.au/_srcfiles/Intense_sweetener_Report_feb04.pdf#search=%22consumption%20of%20intense%20sweeten%22

JECFA (1982) *Calcium cyclamate, sodium cyclamate and cyclohexylamine*, WHO FAS 17. World Health Organization, Geneva.

McLennan, W., Podger, A. (1998) National Nutrition Survey Nutrient Intakes and Physical Measurements Australia 1995. Australian Bureau of Statistics.

National Food Authority (NFA) (1995) *Survey of Intense Sweetener Consumption in Australia – Final Report prepared in co-operation with Roy Morgan Research Centre*, FSANZ, Canberra.

Roy Morgan Research (2005) *Consumption of Intense Sweeteners in Australia and New Zealand – Extra Cyclamate Analysis*.

Rutishauser I., (2000) *Getting it right:- how to use the data from the 1995 National Nutrition Survey*. Commonwealth of Australia: Canberra.

World Health Organization (2001) *Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 1956-2001) (First through fifty-seventh meetings) Internet Edition*, ILSI Press International Life Sciences Institute, Washington DC.

Appendix 1

Calculation of Estimated Dietary Exposure through DIAMOND

The DIAMOND program allows cyclamate concentrations to be assigned to specific food groups and concentrations were only assigned to intense sweetened food groups, where available.

Dietary exposure to cyclamate was calculated for each individual in the NNS using his or her individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of cyclamate by the amount of food that the individual consumed from the group in order to estimate the exposure to each food. Once this has been completed for all of the foods specified to contain cyclamate, the total amount of cyclamate consumed from all the food is summed for the individual. Population statistics (mean and 95th percentile exposures) are then derived from the individuals' ranked exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individual's total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary exposures that are expressed per kilogram of body weight.

Where estimated dietary exposures are expressed as a percentage of the ADI, each individual's total exposure is calculated as a percentage of the ADI (in units per kilogram of body weight per day), the results are then ranked, and population statistics derived.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, intensely sweetened stewed apples used to make an apple crumble are all included in the consumption of intensely sweetened stewed apples.

In DIAMOND, all mixed foods, i.e. those in classification codes 20 and 21, have a recipe. Recipes are used to break down mixed foods into component ingredients which are in classification codes 1-14 (e.g. sauces will be broken down to sugar, flavours, vegetables, water etc). The data for consumption of the ingredients from the recipe are then used in models and multiplied by cyclamate concentrations for each of the raw ingredients. This only occurs if the *Mixed food* classification code (classification code 20) is not assigned its own cyclamate permission. If the *Mixed foods* classification is assigned a cyclamate concentration, the total consumption of the mixed food is multiplied by the proposed level, and the recipes are not used for that food group.

In DIAMOND, hydration and raw equivalence factors are applied to some foods to convert the amount of food consumed in the dietary survey to the equivalent amount of the food in the form to which a food chemical concentration is assigned. Factors are only applied to individual foods, and not major food group codes. For example, consumption figures for concentrated cordial syrup are converted into the equivalent quantities of cordial made up ready to drink.

Percentage contributions of each food group to total estimated dietary exposures are calculated by summing the exposures for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the exposures of all individuals from all food groups containing cyclamate, and multiplying this by 100.

Appendix 2

The following results are from the *2003 Consumption of Intense Sweeteners Survey* as published and not the new analysis for P287 with new manufacturer use data.

Table A2.1: Mean and 95th percentile estimated dietary exposures for male and female consumers of cyclamate (mg/kg bw/day and % ADI) of combined Australian and New Zealand population groups

		Mean consumer exposure		95th percentile consumer exposure	
Population group	**Country**	**mg/kg bw/day**	**% ADI**	**mg/kg bw/day**	**% ADI**
12+ years	Australia	3.1	30	9.9	90
	New Zealand	2.2	20	8.8	80
	Aus/NZ	2.9	25	9.3	85
12-17 years	Australia	4.6	40	27.0	245
	New Zealand	2.5	25	7.8	70
	Aus/NZ	4.1	35	10.2	95
18-24 years	Australia	2.5	25	10.3	95
	New Zealand	1.0	10	4.5	40
	Aus/NZ	2.2	20	10.3	95
25-39 years	Australia	3.4	30	16.6	150
	New Zealand	2.3	20	11.4	100
	Aus/NZ	3.2	30	11.4	100
40-59 years	Australia	2.3	20	8.0	75
	New Zealand	1.7	15	8.8	80
	Aus/NZ	2.3	20	8.3	75
60+ years	Australia	2.9	25	9.2	85
	New Zealand	3.1	30	12.3	110
	Aus/NZ	2.9	25	11.1	100
Diab/IGT	Australia	3.6	35	11.9	110
	New Zealand	2.1	20	8.8	80
	Aus/NZ	3.3	30	11.6	110

Note: Exposure for Australia was higher for some population groups however averaged out with NZ

Attachment 4

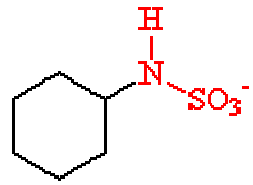
Food Technology Report

Introduction

Proposal P287 has been prepared to review the use of the intense sweetener cyclamate across the whole food supply. FSANZ initiated this review Proposal following the results of the *2003 Consumption of Intense Sweetener Survey* conducted by Roy Morgan Research on behalf of FSANZ, on the consumption of intense sweeteners in Australia and New Zealand. This survey concluded that the estimated dietary exposure for some consumers of cyclamate containing products exceeded the acceptable daily intake (ADI) for cyclamate. The reinstatement of permissions for tabletop sweeteners in accordance with Application A515, is also being considered as part of this Proposal.

Physico-chemical properties of cyclamate

Cyclamic acid (also referred to as cyclohexylsulphamic acid) is a white crystalline powder with molecular weight of 179.24. 'Cyclamate' in this report refers to both cyclamic acid and the sodium and calcium salts of the acid. It is an intense sweetener (non-nutritive sweetener) and is listed as INS 952. For its use as an intense sweetener the maximum permitted levels given are calculated as the free acid, that is cyclamic acid.



Cyclamic acid (as the negative ion)

It has a melting point of 169-170ºC. It is quite soluble in water (1 g/7.5 ml) and has a lemon-sour sweetness. It is a strong acid with the pH of a 10% aqueous solution being 0.8-1.6. Both the sodium and calcium cyclamate salts are white crystalline powders that are also freely water soluble (1g/4-5 ml). The sodium and calcium salts are more neutral in aqueous solution (10% solution pH 5.5-7.5). Cyclamate solutions are stable to heat, light and air throughout a wide pH range (Bopp and Price, 2001).

Cyclamate use as an intense sweetener

Cyclamate is considered the least sweet intense sweetener, being between 30-80 times as sweet as sucrose (common sugar) in food applications (Lawrence, 2003). Its relative sweetness depends on the food matrix, pH, concentration and other flavouring agents. Cyclamate is about 40 times as sweet as a 2% sucrose solution but only about 24 times as sweet as a 20% solution (Bopp and Price, 2001). The literature often uses a rough guide of cyclamate being 30 times as sweet as sugar.

The sweetness from cyclamate builds to a maximal level more slowly and persists longer than that due to sucrose.

High concentrations of cyclamate also produce increased levels of bitterness and aftertaste, but this is usually not considered a problem at normal use concentrations. The sodium salt has better properties compared to the calcium salt since it is sweeter and the off-taste response occurs at a higher concentration (Bopp and Price, 2001).

Cyclamate is used as an intense sweetener in a variety of food products, though it is generally used in combination with other sweeteners, specifically saccharin and more recently acesulphame potassium. A mixture of 10:1 (cyclamate:saccharin) has a synergistic effect producing a sweetness greater than expected from adding the effects of the individual sweeteners. This 10:1 intense sweetener blend is used for a variety of products including soft drinks to produce a pleasant sweetness, minimising the aftertastes of both intense sweeteners. Cyclamate also has synergistic effects with aspartame and acesulphame potassium. Therefore other blends other than the common cyclamate:saccharin are also commercially available such as the binary combinations of cyclamate:aspartame and cyclamate:acesulphame potassium and the ternary blends of cyclamate:saccharin:aspartame and cyclamate:acesulphame potassium:aspartame. Such blends are claimed to give good taste quality and a blend can also improve product stability (The Beverage Institute for Health and Wellness, 2006).

Cyclamate has claimed advantages over other currently permitted intense sweeteners in various food applications. Cyclamate:

- is heat stable, so suitable for addition to products that require cooking and baking;
- is water soluble;
- has a long shelf-life;
- provides a pleasant taste profile, especially in conjunction with other intense sweeteners;
- is non-proprietary so is readily available; and
- has lower costs to other alternatives.

Current permissions for cyclamate in the Code

Cyclamates is an approved food additive in the *Australia New Zealand Food Standards Code* (the Code) as an intense sweetener with INS number 952. It has specific approvals for a range of food products detailed in Schedule 1 of Standard 1.3.1, which are summarised in Table 1.

Table 1: Cyclamate permissions in the Code (Australia and New Zealand)

Food category #	Food category	Max permitted level (mg/kg)
4.3.3	Commercially sterile fruits and vegetables in hermetically sealed containers	1,350
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	1,000
5.2	Sugar confectionery, low joule chewing gum	20,000
14.1.2.2	Fruit and vegetable juice products, low joule fruit and vegetable juice products	400
14.1.3	Water based flavoured drinks	600
14.1.3.1	Brewed soft drinks	400
20.2	Food other than beverages, jelly	1,600
20.2	Food other than beverages, sauces and toppings (including mayonnaises and salad dressings)	1,000

In the Code cyclamates includes cyclamic acid and the sodium and calcium salts. The maximum permitted levels of cyclamate and its salts are calculated as cyclohexyl-sulphamic acid (the free acid).

Tabletop sweeteners

Background

There is currently no approval in the Code for cyclamate as a tabletop sweetener (food categories 11.4; 11.4.1 (liquid preparation) and 11.4.2 (tablets, powders or granules) in Schedule 1 of Standard 1.3.1). Cyclamate was approved for use in tabletop sweeteners in the former regulations before the formation of the joint Code in Australia (as discussed below) and New Zealand.

The former Australian *Food Standards Code* contained Standard A8 – Artificial sweetening substances. Standard A8 did not have a defined section or clause within this Standard that mentioned or dealt explicitly with tabletop sweeteners. Standard A8 provided a definition of an artificial sweetener and listed the permitted food additives.

Clause 3 of A8 defined an artificial sweetener in the subclauses as listed below.

> *(3) (a) An artificial sweetener is the product of any permitted artificial sweetening substance or permitted artificial sweetening substances and a base in tablet, granular, powder or liquid form.*
>
> *(d) Subject to paragraph (e), an artificial sweetener in granular or powder form for retail sale must be packed so that discrete quantities thereof, each having a sweetness equivalent to 1 level metric teaspoon (4.4 g) or two level metric teaspoons (8.8 g) of sugar, are separately contained in sealed sachets or like packages.*

The definitions above defined and thereby provided permissions for food additives in tabletop sweeteners (both liquid preparations and tablet, granular or powder form).

Cyclamate (cyclohexylsulphamic acid or its sodium or calcium salt) was permitted in clause 2 of Standard A8 as an artificial sweetening substance.

The former permissions relating to tabletop sweeteners in New Zealand were contained in the *New Zealand Food Regulations 1984*, in Regulation 251 – Artificial sweeteners. Again, there was no specific mention or direct permission for tabletop sweeteners, but permissions by definition and approvals for artificial sweeteners were provided. Sodium and calcium cyclamate were approved as artificial sweeteners.

Technological justification for use in tabletop sweeteners

Technological justification for reinstating cyclamate permissions in tabletop sweeteners has been provided by industry. The reasons provided meet the Codex General Principles for the Use of Food Additives, being technological need (c) in section 3.2 – Justification for the Use of Additives, to enhance the keeping quality or stability or enhance the organoleptic properties of the food (Codex Alimentarius, 2006).

Liquid preparations of tabletop sweeteners are used in home cooking and baking, for sweets and desserts with a reduced sugar requirement, particularly in diets for diabetics and for weight management. Heat stability, taste and cost are paramount in these applications.

Cyclamate is stable in cooking and baking and has a pleasant taste profile, particularly when used in synergistic association with other sweeteners such as saccharin or acesulphame potassium. These properties, in addition to its long shelf-life and low cost make it highly suitable in liquid preparations of tabletop sweeteners.

While existing regulations allow for the use of aspartame, sucralose, acesulphame potassium, alitame, saccharin and the recently approved combined salt aspartame-acesulphame, only acesulphame potassium and saccharin are considered practical alternatives to cyclamate in liquid tabletop sweeteners for the following reasons:

- **Aspartame** is not heat stable and only poorly soluble and therefore is not suited to liquid formulations and for use in cooking and baking. It also has a relatively high cost and controversial public profile.

- **Sucralose** currently has not been made available to third party manufacturers of tabletop sweeteners by the patent owners.

- **Alitame** is not currently commercially available.

- Both **acesulphame potassium** and **saccharin** show a similar taste profile. Acesulphame potassium is a higher priced alternative to saccharin without providing significant advantages.

- **Aspartame-acesulphame salt** has the advantages and disadvantages of the individual sweeteners (aspartame and acesulphame potassium) as listed above.

In terms of tabletop sweeteners formulated as tablets, powders or granules, the use of cyclamate in a synergistic blend with other intense sweeteners such as saccharin, when compared to aspartame and/or acesulphame potassium:

- allows for an improved taste profile as compared to pure saccharin and/or acesulphame potassium;
- excellent heat stability;
- long shelf-life; and
- lower cost.

Reduced levels in water-based beverages

The results of the dietary exposure assessment indicates that some high level consumers (particularly the 95th percentile exposure for Australian children aged 2-11 years) currently consume cyclamate at levels which exceed the ADI. To reduce dietary exposure, scenario dietary modelling was undertaken using a reduced MPL for water-based flavoured drinks from 600 mg/kg to 300 mg/kg. With this scenario, all consumers of cyclamate-containing products were below the ADI, including those consumers at the 95th percentile dietary exposure (Section 5.2 and **Attachment 3**).

This then raises the question as to whether manufacturers of intensely sweetened water-based flavoured drinks can still produce commercially acceptable products using a reduced MPL of 300 mg/kg cyclamate. To respond to this question, FSANZ has sought industry advice, conducted literature searches, communicated with relevant food technology experts and undertaken research in relation to comparable international regulations for cyclamate. The outcomes of these investigations are summarised below.

Use of alternative sweetener blends

Other than the commonly used 10:1 cyclamate:saccharin blend, it is possible to use alternative sweetener blends to produce synergistic sweetness. These include blends of cyclamate with aspartame and acesulphame potassium (as dual or even triple blends). These blends can also improve the product stability (The Beverage Institute for Health and Wellness, 2006) so the possible issue of reduced shelf-life should not be a concern.

Personal communication with one manufacturer of intensely sweetened fruit juices has confirmed that as many as four intense sweeteners, including cyclamate, are currently used in their product range. This manufacturer advised that a reduction in the MPL for cyclamate would have implications for the flavour profile of their products, and that to maintain the current flavour profile it would be necessary to alter the various blends of intense sweeteners that are used.

FSANZ notes that a number of manufacturers of water-based flavoured drinks are no longer using cyclamates in their intensely sweetened product range and have chosen to use alternative blends of sweeteners. Personal communication with one manufacturer has confirmed that development work is in hand to phase out the use of cyclamates in their cordials and soft drink range, although this will be at a significant cost to the industry. This manufacturer also advised that the proposed reduction of the MPL for cyclamates in water-based flavoured beverages from 600 mg/kg to 300 mg/kg would be acceptable from their perspective.

Relevant international regulations

Comparable international regulations for cyclamate are provided at **Attachment 5.**

The EU reduced their permissions for cyclamate in water-based flavoured drinks in 2004 from 400 mg/l to 250 mg/l following the results of surveys and dietary modelling which indicated that a number of young children exceeded the ADI (7 mg/kg bw/day) for cyclamate. For example, the United Kingdom Food Standards Agency (FSA) had undertaken a survey in 2003 on intense sweetener consumption from soft drinks in young children. This survey indicated that high level consumers (at the 97.5 percentile) were consuming twice the ADI for cyclamate (Food Standards Agency, 2003).

As a consequence of the dietary modelling work, the FSA sought to reduce cyclamate permissions for soft drinks. As part of this work the FSA consulted with the soft drink industry who advised that it would still be feasible to manufacture drinks containing cyclamate at levels of 200-250 mg/l (Food Standards Agency, 2004). This consultation concluded that the reduction in cyclamate permission would require some reformulation, with possibly other additional intense sweeteners being required in addition to saccharin, (which is nearly always used as a blend with cyclamate). Industry discussions indicated that one possible option, that is, to reduce permission to 100 mg/l, would be impractical as at this level cyclamate would have insufficient technological effect and alternative intense sweeteners would be needed to reformulate their products.

Conclusion

Cyclamate is technologically justified as an intense sweetener for use in a variety of food products where it has a number of advantages over other intense sweeteners. One of these food products is tabletop sweeteners - both solid and liquid preparations. Often cyclamate is used with saccharin in a 10:1 (cyclamate:saccharin) mixture, or in blends with other intense sweeteners. Such blends should not compromise product stability so the possible issue of reduced shelf-life should not be an issue.

European information indicates that levels of 200-250 mg/l are commercially acceptable and in Australia and New Zealand, information to date indicates that a reduction in cyclamate levels to 300 mg/kg can be achieved, although reformulations with other intense sweeteners would be required. It is also noted that cyclamate is not always used in intensely sweetened beverages and its use is currently being phased out by one major manufacturer.

Reformulations would require research and development by manufacturers to replicate appropriate sweetness for their product, as well as shelf-life assessments. Ultimately commercial decisions will determine which intense sweeteners manufacturers will use for their products. Manufacturers would have the usual 12 month stock-in-trade provisions under subclause 1(2) of Standard 1.1.1 in the Code in which to reformulate their products if the Code is amended to reduce the MPLs for cyclamate. FSANZ concludes that the MPL of 300 mg/kg cyclamate is technologically feasible in water-based flavoured drinks.

References

Bopp, B.A. and Price, P. (2001) Cyclamate. In: O'Brien Nabors, L., ed. *Alternative Sweeteners: Third Edition, Revised and Expanded.* Chapter 5. Marcel Dekker Inc. New York, pp 63-85.

Codex Alimentarius, Codex General Standard on Food Additives 2006, CODEX STAN 192-1995, Rev. 7-2006 section 3.2, page 3. http://www.codexalimentarius.net/download/standards/4/CXS_192e.pdf. Accessed on 6 March 2007.

Food Standards Agency (2003) *Diary survey of the intake of intense sweeteners by young children from soft drinks*. Food Survey Information Sheet Number 36/03. http://www.food.gov.uk/multimedia/pdfs/36softdrink.pdf. Accessed on 18 January 2007.

Food Standards Agency (2004) Full Regulatory Impact Assessment. http://www.food.gov.uk/multimedia/pdfs/sweetners2004ria.pdf. Accessed on 2 March 2007

Lawrence, J.F. (2003) Cyclamates. In: Caballero, B., editor-in-chief. *Encyclopedia of Food Sciences and Nutrition, second edition*, Academic Press, Oxford, pp 1712-1714.

The Beverage Institute for Health and Wellness, Cyclamate (2006) at http://www.beverageinstitute.org/ingredients/cyclamate.shtml. Accessed on 5 March 2007

Attachment 5

International Permissions for Cyclamate in Food

Cyclamate is a currently permitted food additive, as a sweetener, in Codex Alimentarius, with INS 952[9]. It has an ADI of 0-11 mg/kg bw/day as assessed by JECFA[10]. Cyclamate is also approved in Europe but with a reduced ADI of 0-7 mg/kg bw/day, determined by the European Commission's Scientific Committee on Food[11].

Cyclamate is available for use as an intense sweetener in food in over 50 countries, but 'it was banned in the United States from use in all foods, beverages, and drugs'[12], in 1970 after earlier being approved.

EU

Cyclamate (E 952, cyclamic acid and its sodium and calcium salts) is approved in the EU as a sweetener for a variety of food products. This approval is contained in the European Parliament and Council Directive 94/35/EC[13]. European Parliament and Council Directive 2003/115/EC of 22 December 2003, as an amendment to Directive 94/35/EC produced a reduction in the maximum usable dose for cyclamate in water-based flavoured drinks from 400 to 250 mg/l (along with other amendments)[14]. The EU (and therefore the UK) uses the units of mg/l while the Code uses mg/kg. For drinks the units are expected to be very similar since the density of the drinks is likely to be approximately that of water, which has a density of 1.0 gm/ml (or kg/l).

The current EU permissions are detailed in Table 1.

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[9] CAC/GL 36-1989, Rev. 6 -2001, Amd. 2006, Class names and the international numbering system for food additives, http://www.codexalimentarius.net/download/standards/7/CXG_036e.pdf. Accessed on 18 January 2007

[10] World health Organization (1982) 26th Report of the Joint FAO/WHO Expert Committee on Food Additives. Evaluation of certain food additives, April 19-28, 1982, Technical Report Series, p 683.

[11] Scientific Committee on Food, *Revised opinion on cyclamic acid and its sodium and calcium salts,* SCF/CS/ADD/EDUL/192, Brussels, European Commission, 2000. Found at: http://europa.eu.int/comm/food/fs/sc/scf/out53_en.pdf. Accessed on 18 January 2007

[12] Bopp, B.A. and Price, P. (2001) Chapter 5 Cyclamate. In: O'Brien Nabors, L. ed. *Alternative Sweeteners, third edition* Marcel Dekker, Inc. N.Y. USA. p 64.

[13] European Parliament and Council Directive 94/35/EC on sweeteners for use in foodstuffs. Official Journal of the European Communities, No. L 237/3, 1994. A consolidated version including various amendments (current at 29/1/04) is found at: http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/consleg/1994/L/01994L0035-20040129-en.pdf. Accessed on 18 January 2007

[14] European Parliament and Council Directive 2003/115/EC of 22 December 2003 amending Directive 94/35/EC on sweeteners for use in foodstuffs. Official Journal of the European Communities L24/65, 2004, found at http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_024/l_02420040129en00650071.pdf. Assessed on 2 March 2007

Table 1: Cyclamate permissions for food in the EU

Food	Maximum permitted level (mg/l) (termed maximum usable dose)
Non-alcoholic drinks	
Water-based flavoured drinks, energy-reduced or with no added sugar	250
Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	250
Desserts and similar products	
Water-based flavoured desserts, energy-reduced or with no added sugar	250
Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar	250
Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	250
Egg-based desserts, energy-reduced or with no added sugar	250
Cereal-based desserts, energy-reduced or with no added sugar	250
Fat-based desserts, energy-reduced or with no added sugar	250
Confectionery	
Confectionery with no added sugar	500
Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	500
Starch-based confectionery, energy-reduced or with no added sugar	500
Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar	500
Chewing gum with no added sugar	1,500
Edible ices, energy-reduced or with no added sugar	250
Canned or bottled fruit, energy-reduced or with no added sugar	1,000
Energy-reduced jams, jellies and marmalades	1,000
Energy-reduced fruit and vegetable preparations	250
Fine bakery products for special nutritional uses	1,600
Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC	400
Dietary foods for special medical purposes as defined in Directive 1992/21/EC	400
Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	400
Food supplements as defined in Directive 2002/46/EC supplied in a solid form	500
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	250
Breath-freshening micro-sweets, with no added sugar	2,500
Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	1,250

The consolidated document, Directive 94/35/EC (amended and current to 29/1/04) confirms that the sweeteners are approved as tabletop sweeteners (as well as having the permissions and limits as food additives for various foods)[5]. Therefore cyclamate is approved as a tabletop sweetener in the EU.

UK

The permissions for cyclamate (E952, cyclamic acid and its sodium and calcium salts) in food in the UK is contained in The Sweeteners in Food Regulations 1995[15], with subsequent amendments. Schedule 1 contains the permitted maximum dose for the sweeteners and the different food types, with those for cyclamate listed in Table 2. The amendment to permissions for cyclamate came from The Sweeteners in Food (Amendment) (England) Regulations 2004[16].

Table 2: Cyclamate permissions for food in the UK

Food	**Maximum permitted level (mg/l) (Maximum usable dose)**
Non-alcoholic drinks	
Water-based flavoured drinks, energy-reduced or with no added sugar	250
Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	250
Desserts and similar products	
Water-based flavoured desserts, energy-reduced or with no added sugar	250
Milk and milk-derivative-based preparations, energy-reduced or with no added sugar	250
Fruit and vegetable-based desserts, energy-reduced or with no added sugar	250
Egg-based desserts, energy-reduced or with no added sugar	250
Cereal-based desserts, energy-reduced or with no added sugar	250
Fat-based desserts, energy-reduced or with no added sugar	250
Miscellaneous	
Cocoa-, milk-, dried-fruit or fat-based sandwich spreads, energy-reduced or with no added sugar	500
Canned or bottled fruit, energy-reduced or with no added sugar	1,000
Energy-reduced jams, jellies and marmalades	1,000
Energy-reduced fruit and vegetable preparations	250
Fine bakery products for special nutritional uses	1,600
Complete formulae for weight control intended to replace total daily food intake or an individual meal	400
Complete formulae and nutritional supplements for use under medical supervision	400
Liquid food supplements/dietary integrators	400
Solid food supplements/dietary integrators	400

Cyclamate is also approved as a tabletop sweetener in the UK, similarly to the EU Directive 94/35/EC, under The Sweeteners in Food Regulations 1995[7].

The UK Food Standards Agency (FSA) performed a survey of intense sweeteners in soft drinks for young children (1.5-4.5 years) in 2003, to gather data on the concentration of intense sweeteners in drinks as consumed[17].

[15] The Sweeteners in Food Regulations 1995 (Statutory Instrument 1995, No. 3123), http://www.opsi.gov.uk/si/si1995/Uksi_19953123_en_1.htm#tcon. Accessed on 18 January 2007 and various amendments

[16] The Sweeteners in Food (Amendment) (England) Regulations 2004 (SI 2004 No. 3348) http://www.opsi.gov.uk/si/si2004/20043348.htm. Accessed on 18 January 2007 and comparable regulations for Scotland, Northern Ireland and Wales.

[17] Diary survey of the intake of intense sweeteners by young children from soft drinks. Food Survey Information Sheet Number 36/03, Food Standards Agency, UK, 2003, found at:

The survey indicated that for 'high level' (97.5th percentile) consumers of cyclamate the daily consumption was 14.07 mg/kg bw, being twice the acceptable daily intake (ADI), which in the UK (and the EU) is 7 mg/kg bw.

Due to these results and the adoption of Directive 2003/115/EC by the EU, which reduced cyclamate permissions, the UK adopted an amendment to the Sweeteners In Food Regulation in 2004[8] which included amended permissions for cyclamate as detailed in the extract below, and the summary table, Table 3.

Amended permissions for cyclamate:

b) in the entries relating to 'E952 Cyclamic Acid and its Na and Ca salts' –

(i) in the entry under the heading 'non-alcoholic drinks' relating to 'Water-based flavoured drinks, energy-reduced or with no added sugar', for the entry '400 mg/l' in Column 4 there shall be substituted the following entry -

' 250 mg/l',

(ii) in the entry under that heading relating to 'Milk and milk-derivative based or fruit juice-based energy-reduced or with no added sugar', for the entry '400 mg/l' in Column 4 there shall be substituted the following entry -

' 250 mg/l',

(iii) the entries listed in Columns 3 and 4 under the heading 'Confectionery' shall be omitted, and

(iv) the entry in Columns 3 and 4 under the heading 'Miscellaneous' relating to 'Edible ices, energy-reduced or with no added sugar' shall be omitted;

Table 3: Amendment to cyclamate permissions in the UK, 2004

Food	**Original maximum permitted levels (mg/l)**	**Amended maximum permitted levels (mg/l)/permissions**
Non-alcoholic drinks		
Water-based flavoured drinks, energy-reduced or with no added sugar	400	250
Milk and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	400	250
Confectionery		
Confectionery with no added sugar	500	No permission
Cocoa or dried-fruit-based confectionery, energy-reduced or with no added sugar	500	No permission
Starch-based confectionery, energy-reduced or with no added sugar	500	No permission
Chewing gum with no added sugar	1,500	No permission
Miscellaneous		No permission
Edible ices, energy-reduced or with no added sugar	250	No permission

http://www.food.gov.uk/multimedia/pdfs/36softdrink.pdf. Accessed on 18 January 2007

Canada

Currently cyclamate is only approved as a tabletop sweetener[18], but not as an intense sweetener for general food use, i.e. it is not approved as a food additive[19].

The Canadian Food and Drug Regulations[20] do not mention cyclamate. Specifically Division 16 – Food Additives and relevant tables were searched.

Codex

The Codex Alimentarius (Codex) has a standard of food additive permissions, the General Standard for Food Additives (GSFA)[21], which contains permissions for cyclamate (this includes cyclamic acid and the sodium, potassium and calcium salts) listed in Table 4. The permissions for cyclamate were added into the GSFA in 2005.

Table 4: Cyclamate permissions in the Codex GSFA

Food category number and category	Maximum permitted level (mg/kg)
14.1.3.1 Fruit nectar	400
14.1.3.3 Concentrates for fruit nectar	400

[18] Canadian regulation titled 'Cyclamate and Saccharin Sweeteners', found at http://www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/legislation/reg_p_e_sweeteners-edulcorants_e.pdf. Accessed on 18 January 2007

[19] Artificial Sweeteners section found in: http://www.hc-sc.gc.ca/fn-an/nutrition/prenatal/national_guidelines-lignes_directrices_nationales-06g_e.html#2. Accessed on 18 January 2007

[20] Canadian Food and Drug Regulations found at http://www.hc-sc.gc.ca/fn-an/legislation/acts-lois/fdr-rad/index_e.html. Accessed on 18 January 2007

[21] General Standard for Food Additives, *CODEX STAN 192-1995 (Rev. 7-2006)*, http://www.codexalimentarius.net/download/standards/4/CXS_192e.pdf. Accessed on 18 January 2007

APPENDIX 1

Comparison of cyclamate permissions between the EU, UK, Canada and Codex (and Australia and New Zealand)

Food (EU nomenclature unless otherwise indicated)	**Maximum permitted limits (mg/kg)**				
	EU	**UK**	**Codex**	**Canada**	**Australia and New Zealand**
Non-alcoholic drinks					
Water-based flavoured drinks, energy-reduced or with no added sugar	250	250			
Water based flavoured drinks (ANZ)[a]					600
Brewed soft drinks(ANZ)[a]					400
Fruit and vegetable juice products, low joule fruit and vegetable juice products (ANZ)[a]					400
Milk- and milk-derivative-based or fruit-juice-based drinks, energy-reduced or with no added sugar	250	250			
Desserts and similar products					
Water-based flavoured desserts, energy-reduced or with no added sugar	250	250			
Milk- and milk-derivative-based preparations, energy-reduced or with no added sugar	250	250			
Fruit- and vegetable-based desserts, energy-reduced or with no added sugar	250	250			
Egg-based desserts, energy-reduced or with no added sugar	250	250			
Cereal-based desserts, energy-reduced or with no added sugar	250	250			
Fat-based desserts, energy-reduced or with no added sugar	250	250			
Jelly (ANZ)[a]	1,000	1,000			1,600
Confectionery					
Confectionery with no added sugar	500	-			
Cocoa- or dried-fruit-based confectionery, energy-reduced or with no added sugar	500	-			
Starch-based confectionery, energy-reduced or with no added sugar	500	-			
Cocoa-, milk-, dried-fruit- or fat-based sandwich spreads, energy-reduced or with no added sugar	500	-			
Chewing gum with no added sugar	1,500	-			20,000
Edible ices, energy-reduced or with no added sugar	250	-			
Canned or bottled fruit, energy-reduced or with no added sugar	1,000	1,000			1,350
Energy-reduced jams, jellies and marmalades	1,000	1,000			1,000
Energy-reduced fruit and vegetable preparations	250	250			
Fine bakery products for special nutritional uses	1,600	1,600			

Food (EU nomenclature unless otherwise indicated)	Maximum permitted limits (mg/kg)				
	EU	**UK**	**Codex**	**Canada**	**Australia and New Zealand**
Sauces and toppings (including mayonnaises and salad dressings) (ANZ)[a]					1,000
Foods intended for use in energy-restricted diets for weight reduction as referred to in Directive 96/8/EC	400	400			
Dietary foods for special medical purposes as defined in Directive 1992/21/EC	400	400			
Food supplements as defined in Directive 2002/46/EC supplied in a liquid form	400	400			
Food supplements as defined in Directive 2002/46/EC supplied in a solid form	500	400			
Drinks consisting of a mixture of a non-alcoholic drink and beer, cider, perry, spirits or wine	250	-			
Breath-freshening micro-sweets, with no added sugar	2,500	-			
Food supplements as defined in Directive 2002/46/EC, based on vitamins and/or mineral elements and supplied in a syrup-type or chewable form	1,250	-			
Fruit nectar (GSFA)[b]	-	-	400		
Concentrates for fruit nectar (GSFA)[b]	-	-	400		
Tabletop sweetener	Approved	Approved		Approved	No permission

Notes:

a. ANZ – refers to Australia and New Zealand, the *Australia New Zealand Food Standards Code*, Schedule 1 of Standard 1.3.1 – Food Additives

b. GSFA – refers to the Codex General Standard for Food Additives (GSFA), CODEX STAN 192-1995 (Rev. 7-2006).

Attachment 6

Summary of Submissions

1. Calorie Control Council, Atlanta

- Submitted scientific papers on toxicology and dietary exposure of cyclamate for consideration by FSANZ.
- Referred to the definition of an ADI and that there was a sufficiently large safety margin to ensure that there were no concerns about occasional exceedance of the ADI.

2. Food Technology Association of Victoria (FTA)

- The FTA agreed that FSANZ should continue with the development of a realistic risk management strategy.
- Mandatory removal or reduction of the use of Cyclamate would result in huge costs to industry that would be reflected in increased product pricing due to reformulation, new labels, evaluation tests, changes in market performance and consumer perceptions and preferences, market share, etc.
- Industry should be encouraged, over a reasonable time frame, to reduce and remove cyclamate from their products.

3. Dietitians Association of Australia (DAA)

- The DAA supported the progression of P287 to Draft Assessment. While no regulatory options were presented in the Initial Assessment Report, the DAA suggested as an option, removal of permission for the use of cyclamates in foods in Australia and New Zealand. The prohibition could be phased in over the period of several years to allow industry to source alternate sweeteners and to sell existing stock. The reasons for this recommendation were as follows:

    - There was now a large range of alternative sweeteners available in Australia/New Zealand that can be used instead of cyclamate. Consumers would not be adversely affected by its removal from the food supply.
    - People with diabetes were no longer advised to consume sugar-free or low-sugar diets.
    - Previous efforts to reduce consumers' exposure to cyclamates have not had any demonstrable effects.
    - The current epidemic of overweight/obesity, particularly among children, adolescents and young adults, might lead to increased consumption of products sweetened with cyclamates, increasing the proportion exceeding the ADI.
    - From FSANZ's research on sweetener use in Australia, adolescents and young adults were the group most at risk of exceeding the ADI for cyclamate. From research on animal models, there was some evidence that increased exposure may have an impact on the fertility of young men, which is already in decline in Australia. (Food labelling issues: Quantitative Research with Consumers. Evaluation report series No. 4. FSANZ, June 2003.)

- Removal of permission for the use of cyclamate in Australia/New Zealand food would have little effect on trade with North America, given that cyclamate was banned in the USA and only allowed as a table-top sweetener in Canada.

4. New Zealand Food Safety Authority

- Agreed with FSANZ's approach to seek more precise data on levels of cyclamates used by industry, to enable better estimates of dietary exposure. It would be important to consider changes to the dietary exposure of other sweeteners, particularly any increased consumption of alternative sweeteners that might be of concern, if cyclamate permissions were restricted.
- In New Zealand, consumption of cyclamates was not limited to foods. The Dietary Supplements Regulations permitted the use of cyclamates. Dietary exposure from dietary supplement use would need to be taken into account in the FSANZ review.

5. Australian Food and Grocery Council (AFGC)

- As the dietary exposure calculations currently indicated that high consumers exceeded the ADI for some age groups, but not consistently for all age groups, and only marginally in others, and that the ADI was set as a safe level for lifetime exposure which already included a 100-fold safety factor, the AFGC considered the risk to public health and safety was minimal.
- AFGC agreed that information on current manufacturers' levels of cyclamate in foods was essential to perform an appropriate risk assessment.
- AFGC considered that it was too early to identify risk management options until further dietary exposure assessment is performed using the most up-to-date manufacturers' levels.
- Any reductions in permissions for use of cyclamate and replacement with alternative intense sweeteners would involve considerable research and development by industry to find appropriate new combinations.

6. Food Liaison

- Considered that where the ADI was exceeded, that the calculations needed to be considered in the context of the sweetener survey, which was a survey of high users only, and not of the general population. The 95th exposure calculations were the highest percentile of individuals already identified as high users of sweeteners.
- Due to the conservative nature of the exposure estimates, exceeding the ADI for a very small proportion of the population might not be a public health and safety issue.
- As FSANZ reinstated permission for use of cyclamate in jellies in December 2003 (Amendment 69), this might now be considered a premature action in light of the EU's proposal to lower the ADI to 7 mg/kg bw/day.
- Submitted data on how each individual food contributes to the ADI of 11 mg/kg bw/day (current ADI) or 7 mg/kg bw/day (proposed by EU). Canned fruit, water-based drinks and jelly were products that only require a small number of serves to reach the ADI.
- It might be prudent to consider repealing permissions for use that were not currently being used by the food industry.

7. Hermes Sweeteners Ltd

- Compared to European (EC) regulation, current permissions for cyclamate in Australia and New Zealand, although restrictive as to the categories of foods, allowed for much higher maximum use levels in specific categories of foods, including categories of foods likely to be heavily consumed by children.
- On the other hand, under present FSANZ regulation, the use of cyclamate was not permitted in tabletop sweeteners, whereas it was permitted according to current EC regulations. (Directives 2003/115/EC and 96/83/EC in amendment of Directive 94/35/EC on sweeteners for use in foodstuffs).
- Therefore suggested harmonising permissions for the use of cyclamate in Australia and New Zealand with current EC regulations.
- Harmonisation of categories of foods and maximum use levels as laid down in the EC would not only reduce levels of intake, but would allow for a better trans-national comparison of consumption habits and levels of intake, and would facilitate international trade and exchange of goods, allowing namely for marketing of Australian and New Zealand food products containing cyclamate in Europe without reformulation.
- Specifically petitioned for permission for the use of cyclamate in tabletop sweeteners, in particular in liquid preparations and in portion-sized packages (FSANZ Standard 1.3.1, schedule 1, items 11.4.1 and 11.4.2), as per their Application A515.

8. Hansells (NZ) Ltd

- The ADI was set on a precautionary basis to protect the most sensitive individuals and allow for uncertainties in the scientific evidence. However, the ADI was not a threshold value above which harmful effects were even likely to occur in humans.
- FSANZ survey results had indicated that cyclamate consumption levels had not increased since 1994. Their marketing data showed that in fact there had been a slight decline in market volumes of some product categories. They could also confirm that Hansells product range had not changed during the last three years. If the consumption levels had not changed what was FSANZ trying to achieve by changing the permissions?
- FSANZ survey had not clearly identified at risk groups. Who were the high consumers? If it was a small minority who had not responded to the reduction in permissions in 2001, would they respond to further reduction in permissions? What implications would further reduction to permissions have on the other consumers? Hansells recommended that FSANZ identify the 'at risk' group and key attributes of their dietary patterns. Perhaps the solution was health education.
- FSANZ survey results showed that cyclamate was not over-consumed by population groups suffering from diseases such as diabetes. Hence they would also like to take this opportunity to propose that cyclamate should be permitted in tabletop sweeteners, a format of sweeteners generally consumed by those who suffered from diabetes.
- Typical consumers used intense sweetener products for either medical or healthy choice reasons even though they were expensive compared with the sugar equivalent products. Those with medical reasons had limited choices as it is: removing choices or increasing costs, which would in turn restrict choices, and did not encourage the consumer to make informed choices for their health and well-being.

- Cyclamate was unique among low-calorie sweeteners. Only 30 times sweeter than sugar, a fraction of the sweetness of most low-calorie sweeteners, it is nearly always used in combination with another sweetener(s). In addition to its sweet taste, cyclamate provided body, mouthfeel and general rounding out of flavour to the end product, a quality not seen with other low-calorie sweeteners. It also had a longer shelf-life and was stable at high temperatures.
- What do FSANZ aim to achieve by restricting the use of a consumer-friendly, cost-effective product, which had not been proven to pose a health risk? Any reduction to current permission level would have major cost implications to the industry and the consumer. It would clearly impose a barrier to international trade.
- The WTO recognised Codex Alimentarius as the international standard and the Codex standards are based on the ADI of 11 mg/kg body weight. As a WTO member state, Australia/New Zealand should comply with Codex standards unless there was clear evidence for variation.

9. Department of Human Services Victoria

- The review should also consider the potential effects of any reduction in the permitted levels of cyclamates in food.
- Would such a move lead to an increase in the consumption of other artificial sweeteners beyond the ADI and what human health implications would arise from such a scenario?

10. International Sweeteners Association (ISA)

- Attached a copy of a recent study on cyclamate in humans.

11. Environmental Health Unit of Queensland Health

- After considering the Report, it strongly supported FSANZ proceeding with the detailed assessment.
- Surveys indicated that children are at significant risk of exceeding the Acceptable Daily Intake (ADI) for cyclamate. This was of concern as there was probably greater potential for them to develop adverse effects later in life than is the case with adults.
- There were considerably better alternatives to cyclamate available now in terms of both flavour and intensity than used to be the case e.g. aspartame.
- It was questionable whether artificial sweeteners should be allowed in any products other than those described as ‘low joule’. This was particularly the case for cyclamate where excessive intake was a possibility.
- It seemed that the most urgent need was to reduce permitted levels of cyclamate in beverages or else eliminate it altogether, as that is the main source of dietary intake and would be expected to be even more significant for children.
- Methods of analysis for artificial sweeteners other than cyclamate were considerably easier and more sensitive, so chemical surveillance would be easier if qualitative screening to verify absence of cyclamate was all that needed to be done in most cases.

12. Australian Beverages Council (ABC)

- Cyclamate is a stable intense sweetener and the benefit of its stability cannot be under-estimated for many parts of Australia. It was also important to consider the benefits of cyclamate as part of a blend of sweeteners, where the synergistic effects allows bottlers to minimise the total amounts of sweeteners added to low joule beverages.
- The ABC, whilst always cognisant of any safety concerns that may arise, did not support the lowering of the permitted limits for cyclamates in beverages.
- It was imperative that FSANZ used only the most up-to-date data, reflective of the products being offered for sale, and hence being consumed, by each population sub-group.
- FSANZ needed to consider the number of individuals who might exceed the ADI and the number of other individuals who benefited from the availability of cyclamate sweetened products.
- Exceedence of the ADI should not automatically be viewed as a safety concern.
- Current market data was provided to FSANZ as commercial-in-confidence data.
- The major impact of a reduction in the permitted limits for cyclamate in water-based beverages would be local in nature with no envisaged effects on international trade.
- The benefits outweighed the costs to many consumers. Consumers in northern parts of Australian might find stable, low joule products less available, should the permitted limits in foods be reduced.
- Given the safety margin built into the ADI, ABC believed that the benefits would not outweigh the costs of reformulation and supply management of less stable low joule products to some consumers.
- Believed that consumer information was clearly identified under existing labelling regulations.
- The issue of costs and benefits to both targeted and non-targeted groups must be also viewed in its social-economic context. Acceptable cyclamate/saccharin blends provided lower cost, low joule products. In some cases, the forcible switch to higher cost intensive sweetener would result in a negative impact on lower socio-economic groups, with a resulting reduction in beverage choice to those groups. Such a reduction might see, in less well-informed socio-economic groups, a switch to less appropriate products.
- ABC saw no additional costs to government.

13. Cadbury Schweppes

- Cadbury Schweppes was concerned that the trend indicated a reduction in the permissible levels of cyclamates.
- While Cadbury Schweppes acknowledged that there were sections of the population who were at risk with excessive intake of cyclamates it also noted that cyclamates performed an important technological function in many low joule type products, due to their stability in low pH still and carbonated products. Cyclamates also provided a low-cost alternative when used in blends with other, more expensive, intense sweeteners.
- A significant amount of work had been done on some of their products in an attempt to reduce the level of cyclamates, particularly in their beverages products, but they were concerned that they might not be able to reduce the levels further without impacting on product quality and cost.

Attachment 7

EAG Membership and Terms of Reference

Name	Organisation
Mr Kim Leighton	Australian Food and Grocery Council
Ms Melanie McPherson	Australian Beverages Council
Mr David Panasiak	Food Liaison Pty Ltd
Ms Pauline Leech	Hansells, New Zealand
Ms Brenda Cutress	New Zealand Food and Grocery Council
Ms Jacqui Dobbs	Frucor Beverages, New Zealand

Terms of Reference for the External Advisory Group

Within the scope of Proposal P287, the terms of reference for the External Advisory Group are to:

Provide technical advice specifically in relation to

- On the basis of safety, the appropriateness and technological justification of the current maximum permitted limits (MPLs) of cyclamate in foods. In particular, whether reduced MPLs or reduced permissions for cyclamate in specific foods could be accommodated by industry; and
- The justification for FSANZ to consider reinstatement of permissions for cyclamate in table top sweeteners which were repealed when the Australia New Zealand Food Standards Code was adopted.

In undertaking the above, members should note the following:

Confidentiality provisions applying to the External Advisory Group

Confidential Information means all information that:
(a) by its nature is confidential;
(b) is designated by FSANZ as confidential;
(c) an External Advisory Group member knows or ought to know is confidential; or
(d) is confidential commercial information as defined under section 3 of the *Food Standards Australia New Zealand Act 1991.*

External Advisory Group member includes officers and employees of the External Advisory Group member.

1. Obligations

External Advisory Group members agree to:

a. keep Confidential Information confidential;
b. only use or copy the Confidential Information as strictly necessary for External Advisory Group meetings;
c. not disclose the Confidential Information to any other person without written approval by FSANZ; and
d. immediately notify FSANZ if the External Advisory Group member becomes aware that any of the Confidential Information:
    i. has been used, copied or disclosed other than in accordance with paragraph (c); or
    ii. is required to be disclosed by law.

External Advisory Group members also acknowledge that they are aware of and subject to non-disclosure obligations under section 39 of the *Food Standards Australia New Zealand Act 1991* with respect to confidential commercial information in respect of food that has been acquired by the member because of being a member of the External Advisory Group.

2. Exceptions

The obligation of confidentiality does not apply to information that is:

a. in the public domain;
b. independently developed or acquired by a External Advisory Group member; or
c. required to be disclosed by law.

3. Return or destruction of Confidential Information

External Advisory Group members must return to FSANZ, or destroy all copies or delete electronic forms of Confidential Information, within 14 days of receiving a written request from FSANZ.