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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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FINAL ASSESSMENT REPORT

PROPOSAL P287

REVIEW OF CYCLAMATE PERMISSIONS

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

Proposal P287 has been prepared to review the current permissions in the *Australia New Zealand Food Standards Code* (the Code) for cyclamate in food. This is in light of results from the *2003 Consumption of Intense Sweeteners* survey[1] which showed that some high consumers of foods containing cyclamates had cyclamate exposures that 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 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 This Application was withdrawn by the Applicant pending its consideration by FSANZ within this Proposal.

FSANZ has assessed the safety of cyclamate including the consideration of new data, and has concluded that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) ADI for cyclamate of 11 mg/kg body weight/day is adequately protective of consumers.

FSANZ has also undertaken revised dietary exposure assessments for a range of population groups using current manufacturers' use levels of cyclamate where available, in conjunction with current maximum permitted levels in the Code. Based on this data, 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 95th percentile dietary exposures for Australians aged 2-11 years exceeded the ADI. Additional scenarios were also modelled based on the extension of cyclamate use in tabletop sweeteners and reduced permissions for cyclamate in water-based beverages (intensely sweetened soft drinks and cordial), both with and without the extension of use in tabletop sweeteners.

At Draft Assessment, FSANZ proposed a reduction in the maximum permitted levels for cyclamate in water-based flavoured drinks from the current level of 600 mg/kg to 300 mg/kg. This reduced the estimated 95th percentile dietary cyclamate exposures for Australians aged 2-11 years to below the ADI. FSANZ also recommended the reinstatement of cyclamate permissions in tabletop sweeteners as tabletop sweeteners contributed minimally to total cyclamate exposure in children aged 2-11 years.

Whilst a number of submitters were supportive of FSANZ's preferred approach, several industry submitters commented that the proposed level of 300 mg/kg was too low from a technological perspective and would present major challenges for smaller manufacturers. These submitters proposed an alternative level of 400 mg/kg cyclamate in water-based flavoured drinks. However at this level, estimated dietary exposure to cyclamate in Australian consumers aged 2-11 years exceeds the ADI.

FSANZ has consulted closely with industry to determine an appropriate level of cyclamates that is both protective of public health and safety and provides industry with practical levels of cyclamate that can be used in sweetener blends.

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

At Final Assessment, FSANZ is amending the maximum permitted level for cyclamates in water-based flavoured drinks from 600 mg/kg to 350 mg/kg and allowing the use of cyclamates in tabletop sweeteners (Option 6). Dietary modelling based on a maximum permitted level of 350 mg/kg cyclamates in water-based flavoured drinks and the reinstatement of cyclamate permissions in tabletop sweeteners shows that high cyclamate consumers (Australian children aged 2-11 years) are at or below the ADI at the 95th percentile exposure. Option 6 is considered adequately protective of public health and safety and may also offer additional benefits to consumers associated with a permission to use cyclamate in tabletop sweeteners. Whilst all options considered will impose costs to manufacturers to meet the reductions in cyclamate permissions, Option 6 will still permit the practical use of cyclamate in intensely sweetened drinks, although this level may be problematic for some smaller manufacturers. Option 6 will also enable industry to manufacture and sell tabletop sweeteners containing cyclamate in Australia.

The variations to the cyclamate permissions in water-based flavoured drinks will take effect 12 months from the date of gazettal to allow manufacturers sufficient time for reformulation and re-labelling.

Purpose

The purpose of this Proposal is to review the current permissions in the Code for cyclamate in food following the results of the *2003 Consumption of Intense Sweeteners* survey which found that some high consumers were exceeding the Acceptable Daily Intake (ADI) for cyclamate.

Decision

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 350 mg/kg with a 12 month implementation period after gazettal, and to allow the use of cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice.

Reasons for Decision

FSANZ approves the draft variations to Standard 1.3.1 – Food Additives for the following reasons:

- The proposed draft variations to Standard 1.3.1 are consistent with the section 18 objectives of the FSANZ Act, in particular, they do not raise any public health and safety concerns, are based on risk analysis using the best available scientific evidence, and help to 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 Report **(Attachment 3)** shows that reducing permissions for cyclamate in water-based flavoured drinks to 350 mg/kg would ensure that public health and safety of high cyclamate 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 350 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 addition, FSANZ is recommending that a 12-month implementation period apply from the date of gazettal of the amendments with respect to the reduced cyclamate permissions for water-based flavoured drinks, to allow reformulation of products.

- 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. The Draft Assessment Report was advertised for public comment from 23 May 2007 to 4 July 2007. Seventeen submissions were received during this period. A summary of the submissions received in response to the Draft Assessment Report is included at **Attachment 6.**

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' comments in the preparation of this Final Assessment Report.

FSANZ has consulted with key stakeholders, including the beverages industry, regarding the recommendations proposed in this Final Assessment Report. In recognition of the impacts on industry associated with reducing cyclamate permissions in water-based flavoured drinks, FSANZ is recommending that a 12-month implementation period apply from the date of gazettal of the amendments.

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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 *Australia New Zealand Food Standards Code* (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 had 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 permissions 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 3 to 6.

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 18 of the FSANZ Act. These are:

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

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

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

4. Key Assessment Questions

FSANZ 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 intense sweetener 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 Joint FAO/WHO Expert Committee on Food Additives (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

At Draft Assessment FSANZ sought to determine whether re-analysing data from the *2003 Consumption of Intense Sweeteners* survey using current/updated manufacturers' use levels of cyclamate, where available, in conjunction with current maximum permitted levels (MPLs) 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 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 **(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 to 300 mg/kg in water-based beverages (intensely sweetened soft drinks and cordials), with and without the 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. Table 1 summarises the scenarios modelled at Draft Assessment.

Table 1: Scenarios modelled at Draft Assessment 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
**cyclamate concentration of 300 mg/kg

At Final Assessment, FSANZ conducted additional modelling on children aged 2-11 years based on MPLs of 350 mg/kg **(Scenarios 5 and 6)** and 400 mg/kg **(Scenarios 7 and 8)** of cyclamate in water-based flavoured drinks. The level of 400 mg/kg was based on comments raised in submissions to the Draft Assessment Report, whereas 350 mg/kg represented a midway point between 300 mg/kg and 400 mg/kg. Table 2 represents the scenarios modelled at Final Assessment, which have been amended from those previously modelled at Draft Assessment.

Table 2: Scenarios modelled at Final Assessment for P287: Review of Cyclamate Permissions

		Scenario parameters		
Scenario	**Population group**	**Cyclamate concentration (mg/kg)**	**Cyclamate in tabletop sweeteners included**	**Reduced cyclamate MPL in intensely sweetened soft drinks and cordials**
Scenario 5	Aust 2-11 years	350	No	Yes
Scenario 6	Aust 2-11 years	350	Yes	Yes
Scenario 7	Aust 2-11 years	400	No	Yes
Scenario 8	Aust 2-11 years	400	Yes	Yes

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 based on:

- current manufacturers' use levels after the Code permissions had come into force;
- those derived from the FSANZ *2003 Consumption of Intense Sweetener* survey; and
- revised cyclamate concentrations based on submissions to the Draft Assessment Report (400 mg/kg) and an alternative level (350 mg/kg).

Current manufacturers' use levels were obtained via submissions to the Initial Assessment Report.

The concentration of cyclamate in tabletop sweeteners for Scenarios 2, 4, 6 and 8 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 modelled at Draft Assessment, estimated 95th percentile dietary cyclamate exposures for the Australian and New Zealand population aged 12 years and above were at or below the ADI. However, estimated 95th percentile 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.

To assist FSANZ in refining dietary exposure estimates for cyclamate, FSANZ sought additional information at Draft Assessment in relation to market share data for carbonated soft drinks and cordials, as well as consumer dilution practices for cordials. However, no additional information was provided by submitters in response to this request.

At Final Assessment, dietary modelling based on 350 mg/kg cyclamate in intensely sweetened soft drinks and cordials (Scenarios 5 and 6), established dietary exposures at or below the ADI for cyclamate for Australians aged 2-11 years at the 95th percentile (ranging from 90-100%). At 400 mg/kg cyclamate (Scenarios 7 and 8), Australian children aged 2-11 years (both males and females) exceeded the ADI at the 95th percentile (ranging from 100-110%).

The reduction in cyclamate permissions for intensely sweetened soft drinks and cordials would further reduce estimated exposures to cyclamate for Australians 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) for both Draft and Final Assessments.

5.2.6 Additional dietary exposure assessments based on 90th percentile exposure

As part of this Final Assessment Report, FSANZ has undertaken additional dietary exposure estimates for cyclamate based on 90th percentile exposure as well as 95th percentile exposure. This is in light of an international peer review of FSANZ's dietary modelling procedures which recommended that FSANZ should consider reporting food chemical dietary exposures at the 90th percentile not the 95th percentile, if only one 24 hour recall record per person was used for the assessment.

The 95th percentile results are likely to be an overestimate of the average daily exposure for high consumers of cyclamate over a lifetime because the consumption of occasionally consumed foods will be overestimated and result in estimated dietary exposures that may be 2-5 fold higher than the mean for consumers. Hence the use of 95th percentile results potentially leads to an overly conservative risk management approach.

At Draft Assessment, FSANZ reported dietary exposure assessment results at the 95th percentile exposure as at that stage, the revised approach for reporting dietary exposure assessment results had not been formally adopted by FSANZ.

However, given that intensely sweetened beverages such as soft drinks and cordials could reasonably be expected to be consumed on a daily basis by children and are therefore not occasionally consumed foods, it is considered that risk management decisions for this Proposal should continue to be based on estimated dietary exposures at the 95th percentile.

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.

With reduced cyclamate levels at 400 mg/kg in water-based flavoured drinks, as suggested by some submitters (Scenarios 7 and 8), dietary exposures to cyclamate were reduced in Australians aged 2-11 years at the 95th percentile to 110% (males) and 100% (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 at 350 mg/kg in water-based flavoured drinks (Scenarios 5 and 6), dietary exposures to cyclamate were reduced in Australians aged 2-11 years at the 95th percentile to 95% (males) and 90% (females) of the ADI (Scenario 5), and 100% (males) and 90% (females) of the ADI (Scenario 6). As the dietary exposure estimates were based on conservative assumptions, no safety concerns are raised by these levels of exposure. Table 3 provides a comparison of the four scenarios modelled at Final Assessment and their impact on cyclamate exposure in children aged 2-11 years at the 95th percentile exposure.

Table 3: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years for Scenarios 5-8

Population group	Scenario	95th percentile consumers (mg/kg bw/day)	95th percentile consumers (%ADI)
Males	5	10.3	95
	6	11.0	100
	7	11.8	110
	8	12.5	110
Females	5	10.1	90
	6	10.1	90
	7	11.5	100
	8	11.2	100

Scenario 5: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg bw/day) for cyclamate in water-based beverages
Scenario 6: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg bw/day) for cyclamate in water-based beverages
Scenario 7: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages
Scenario 8: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

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 350 mg/kg. With this scenario, all consumers of cyclamate-containing products were at or 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 350 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 350 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 European Union (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 its 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 350 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.

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.

At Draft Assessment, four regulatory options were identified for this Proposal as follows:

Option 1 – Maintain the *status quo*, namely, retain current cyclamate permissions in water-based flavoured drinks with 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 (300 mg/kg) with no re-instatement of cyclamate permissions in tabletop sweeteners.

Option 4 – Reduce cyclamate permissions in water-based flavoured drinks (300 mg/kg) and re-instate cyclamate permissions for tabletop sweeteners.

In response to comments raised at Draft Assessment that the proposed MPL of 300 mg/kg cyclamate in water-based flavoured drinks was too low to achieve the technological benefit, FSANZ modelled additional scenarios based on MPLs of 350 mg/kg and 400 mg/kg cyclamate in water-based flavoured drinks. The level of 400 mg/kg was based on comments raised in submissions on the Draft Assessment Report, whereas 350 mg/kg represented a midway point between 300 mg/kg and 400 mg/kg.

At Final Assessment, Options 1 and 2 have not been considered further, given the potential public health and safety risks associated with exceedances of the ADI for cyclamate in Australian children aged 2-11 years. There was no support from submitters for either Option 1 or Option 2 at Draft Assessment. Options 3 and 4 have not been considered further at Final Assessment taking into consideration submitters' comments that a level of 300 mg/kg cyclamate in water-based flavoured drinks would present technological difficulties, particularly for smaller manufacturers.

At Final Assessment, the following regulatory options have therefore been considered as follows:

Option 5 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Option 6 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and re-instate cyclamate permissions in tabletop sweeteners.

Option 7 – Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Option 8 – Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and re-instate cyclamate permissions in 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

There are costs to industry associated with Options 5 to 8 however, quantitative information is not available. This is reflected in the Business Cost Calculator Report, in accordance with the Office of Best Practice Regulation (OBPR) guidelines which is found at **Attachment 7**.

7.2.1 Option 5 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Under Option 5, the affected parties and potential impacts are:

7.2.1.1 Industry

- Reducing cyclamate permissions from 600 mg/kg to 350 mg/kg in water-based flavoured drinks will result in 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. Smaller, regional manufacturers are likely to be most affected as they are often dependent on third party organisations to conduct reformulations.

- Discussions with some manufacturers of water-based flavoured drinks and the peak body representing the beverages industry indicate that most manufacturers will be able to reformulate to this reduced level, although reformulation is likely to be more problematic for smaller, regional manufacturers.

- If cyclamate permissions are not re-instated in tabletop sweeteners, Australian and overseas manufacturers of tabletop sweeteners would not be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia.

- As cyclamate is permitted in tabletop sweeteners under the New Zealand *Dietary Supplements Regulations 1984* and may be legally sold in Australia under the TTMRA, there would continue to be an inconsistency between Australian and New Zealand products.

7.2.1.2 Consumers

- At the level of 350 mg/kg cyclamate in water-based flavoured drinks, 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. The switch to higher cost intense sweeteners may specifically impact on lower socio-economic groups and possibly a reduction in beverage choice.

- If cyclamate permissions are not re-instated 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.

7.2.1.3 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.

7.2.2 Option 6 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and re-instate cyclamate permissions in tabletop sweeteners.

Under Option 6, the affected parties and potential impacts are:

7.2.2.1 Industry

- Reducing cyclamate permissions from 600 mg/kg to 350 mg/kg in water-based flavoured drinks will result in 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. Smaller, regional manufacturers are likely to be most-affected as they are often dependent on third party organisations to conduct reformulations.

  Discussions with some manufacturers of water-based flavoured drinks and the peak body representing the beverages industry indicate that most manufacturers will be able to reformulate to this reduced level, although reformulation is likely to be more problematic for smaller, regional manufacturers.

- If cyclamate permissions are re-instated in tabletop sweeteners, Australian and overseas manufacturers of tabletop sweeteners would be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia.

  Tabletop sweeteners containing cyclamate that are manufactured under the New Zealand *Dietary Supplements Regulations 1984* would be able to be sold as food under the Code.

7.2.2.2 Consumers

- At the level of 350 mg/kg cyclamate in water-based flavoured drinks, 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. The switch to higher cost intense sweeteners may specifically impact on lower socio-economic groups and possibly a reduction in beverage choice.

- If cyclamate permissions are re-instated in tabletop sweeteners, 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 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.

7.2.3 Option 7 – Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Under Option 7, the affected parties and potential impacts are:

7.2.3.1 Industry

- As with Options 5 and 6, reducing cyclamate permissions from 600 mg/kg to 400 mg/kg in water-based flavoured drinks will result in 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. Smaller, regional manufacturers are likely to be most affected as they are often dependent on third party organisations to conduct reformulations.

  Submissions from the beverages industry in Australia and international organisations representing manufacturers of reduced-calorie foods and beverages and intense sweeteners, requested a level of 400 mg/kg cyclamate in water-based flavoured drinks (as opposed to 300 mg/kg proposed at Draft Assessment). On this basis, it is assumed that manufacturers can reformulate to this level, although there would still be costs associated with reformulation as previously discussed

- If cyclamate permissions are not re-instated in tabletop sweeteners, Australian and overseas manufacturers of tabletop sweeteners would not be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia.

  As cyclamate is permitted in tabletop sweeteners under the New Zealand *Dietary Supplements Regulations 1984* and may be legally sold in Australia under the TTMRA, there would continue to be an inconsistency between Australian and New Zealand products.

7.2.3.2 Consumers

- At the level of 400 mg/kg cyclamate in water-based flavoured drinks, there are possible long-term public health and safety concerns if high consumers of cyclamate-containing products consistently exceed the ADI.

- There may be costs passed on to the consumer associated with the reformulation and re-labelling of products by industry. The switch to higher cost intense sweeteners may specifically impact on lower socio-economic groups and possibly a reduction in beverage choice.

- If cyclamate permissions are re-instated in tabletop sweeteners, 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.

7.2.3.3 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. However, at the level of 400 mg/kg cyclamate in water-based flavoured drinks, the public health and safety of high consumers of cyclamate-containing products would not be protected if the ADI for cyclamate is exceeded in the long term.

7.2.4 Option 8 - Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and re-instate cyclamate permissions in tabletop sweeteners.

Under Option 8, the affected parties and potential impacts are:

7.2.4.1 Industry

- As with Options 5 and 6, reducing cyclamate permissions from 600 mg/kg to 400 mg/kg in water-based flavoured drinks will result in 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. Smaller, regional manufacturers are likely to be most affected as they are often dependent on third party organisations to conduct reformulations.

Submissions from the beverages industry in Australia and international organisations representing manufacturers of reduced-calorie foods and beverages and intense sweeteners, requested a level of 400 mg/kg cyclamate in water-based flavoured drinks (as opposed to 300 mg/kg proposed at Draft Assessment). On this basis, it is assumed that manufacturers can reformulate to this level, although there would still be costs associated with reformulation as previously discussed.

- If cyclamate permissions are re-instated in tabletop sweeteners, Australian and overseas manufacturers of tabletop sweeteners would be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia.

  Tabletop sweeteners containing cyclamate that are manufactured under the New Zealand *Dietary Supplements Regulations 1984* would be able to be sold as food under the Code.

7.2.4.2 Consumers

- At the level of 400 mg/kg cyclamate in water-based flavoured drinks, there are possible long-term public health and safety concerns if high consumers of cyclamate-containing products consistently exceed the ADI. The re-instatement of cyclamate permissions in tabletop sweeteners would have minimal impact on overall cyclamate exposure.

- There may be costs passed on to the consumer associated with the reformulation and re-labelling of products by industry. The switch to higher cost intense sweeteners may specifically impact on lower socio-economic groups and possibly a reduction in beverage choice.

- If cyclamate permissions are re-instated in tabletop sweeteners, 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. However, at the level of 400 mg/kg cyclamate in water-based flavoured drinks, the public health and safety of high consumers of cyclamate-containing products would not be protected if the ADI for cyclamate is exceeded in the long term.

- 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

In comparison with Option 1 – to maintain the status quo, Options 5 to 8 will all impose costs to manufacturers associated with product development, reformulation and labelling to meet the reductions in cyclamate permissions for water-based flavoured drinks.

Compared to Options 7 and 8, Options 5 and 6 may impose greater costs to some smaller manufacturers who may have difficulties in reformulating their products to the level of 350 mg/kg cyclamate. Under Option 6, Australian and overseas manufacturers of tabletop sweeteners would be able to take advantage of market opportunities to develop and sell cyclamate-containing tabletop sweeteners in Australia.

Under Options 5 and 6, all consumers of products containing cyclamate are at or under the ADI for cyclamate, whereas under Options 7 and 8, Australian children aged 2-11 years exceed the ADI. Options 5 and 6 therefore offer greater benefits to consumers over Options 7 and 8 as public health and safety would be protected, although it is noted that there may be some manufacturers' costs that are passed onto consumers. Option 6 may also offer additional benefits to consumers associated with a permission to use cyclamate in tabletop sweeteners.

Given FSANZ's primary objective is to protect public health and safety, Options 5 and 6 are the only viable options. Option 6 is preferred over Option 5 as it would appear to provide greater benefits to consumers, while also benefiting industry to the extent that it would enable the use of cyclamate in tabletop sweeteners. Option 6 is therefore the preferred option. The draft variations to the Code as a result of Option 6 being the preferred option are provided at **Attachment 1**. The draft variations to reduce cyclamate permissions in the Code will take effect 12 months from the date of gazettal of the amendments to enable industry to reformulate and re-label existing products.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

FSANZ has proposed certain measures to address the issues highlighted in the *2003 Consumption of 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.

FSANZ has consulted with key stakeholders, including the beverages industry, regarding the recommendations proposed in this Final Assessment Report. In recognition of the impacts on industry associated with reducing cyclamate permissions in water-based flavoured drinks, FSANZ is recommending that a 12 month implementation period apply from the date of Gazettal of the amendments.

The Board's decision on the draft variation to Standard 1.3.1 will be notified to the Ministerial Council. Stakeholders will be notified of any changes to the Code in the national press and on the website.

9. Consultation

9.1 Public Consultation

The Initial Assessment Report was advertised for public comment from 20 October 2004 to 1 December 2004. A total of 13 submissions were received during this period.

The Draft Assessment Report was advertised for public comment from 23 May 2007 to 4 July 2007. Seventeen submissions were received during this period. A summary of the submissions received in response to the Draft Assessment Report is included at **Attachment 6.**

There were mixed views from submitters in response to the four regulatory options identified at Draft Assessment, possibly as the issue of cyclamate in tabletop sweeteners is also under consideration as part of this Proposal.

Four submitters supported Option 4 – to reduce cyclamate permissions in water-based flavoured drinks to 300 mg/kg cyclamate and to reinstate cyclamate in tabletop sweeteners, although two submitters qualified their comments. Two submitters supported a reduction in cyclamate permissions to 300 mg/kg but either did not provide comments or expressed a reservation with respect to the addition of cyclamate in tabletop sweeteners. Four submitters supported Option 3 – to reduce cyclamate permissions in water-based flavoured drinks to 300 mg/kg cyclamate but with no reinstatement of cyclamate permissions in tabletop sweeteners. Four submitters supported a reduction in cyclamate permissions in water-based flavoured drinks but proposed an alternative level of 400 mg/kg. These submitters did not provide comments with respect to tabletop sweeteners. One submitter supported the reinstatement of cyclamate in tabletop sweeteners but did not provide comments with respect to water-based flavoured drinks. One submitter provided comments but did not indicate a preferred regulatory option while another submitter requested that FSANZ remove permissions for cyclamate in the Code.

A number of key issues were raised by submitters in response to the Draft Assessment Report. These issues are identified and discussed below. Other comments raised by submitters have been addressed in the summary of submissions at **Attachment 6.**

9.1.1 Safety Factor Used in Determining the ADI for Cyclamate

One submitter considered that it would be appropriate for FSANZ to use a safety factor of 30 (as opposed to 100) to determine the ADI for cyclamate, in light of the extensive human data that exists on cyclamate metabolism. It was noted that only a small percentage of individuals are able to convert cyclamate to cyclohexylamine and that the level of human conversion from cyclamate to cyclohexylamine varies considerably over time, even among good converters. It was also noted that the two issues of concern, namely, possible testicular effects and cardiovascular effects have only been observed in cyclohexylamine feeding and not in cyclamate studies.

9.1.1.1 FSANZ Response

FSANZ has considered the available data on the safety of cyclamate, and retained the ADI of 11 mg/kg bw per day. The safety assessment recognised that most individuals do not metabolise cyclamate to cyclohexylamine and therefore exceeding the ADI somewhat would not represent a health risk for these individuals. Further, the uncertainty factor of 100 built into the ADI calculations means that the ADI is a somewhat conservative estimate of safety and intakes exceeding this may be safe for many consumers. However, at this time FSANZ does not believe that the ADI should be increased by reducing the safety factor. Therefore the ADI of 11 mg/kg bw per day has been used in this Proposal.

9.1.2 Proposed Level of 300 mg/kg Cyclamate in Water-Based Flavoured Drinks

The majority of submitters supported the recommendation at Draft Assessment to reduce the MPLs of cyclamate in water-based flavoured drinks from 600 mg/kg to 300 mg/kg, although noting that this reduction will require development by industry to ensure that alternative intense sweetener preparations achieve the appropriate sweetness levels. It was also noted that the proposed reduction will mean that Australian and New Zealand permissions will be closer to the EU and UK limit of 250 mg/kg.

Three submitters disagreed with the proposed reduction in the MPLs of cyclamate in water-based flavoured drinks from 600 mg/kg to 300 mg/kg and proposed an alternative level of 400 mg/kg. It was stated that at levels below 400 mg/kg the benefits of cyclamate become negligible, or are substantially reduced. These benefits include cost-effectiveness, stability, synergism with other sweeteners and improved taste. It was also stated that some product formulations are complex and not all products may be reformulated to a limit of 300 mg/kg. Furthermore, it was suggested that the proposed reduction to 300 mg/kg cyclamate would present major challenges for smaller manufacturers.

One submitter commented that data from 24 hour recall studies are known to be less accurate and more likely to overestimate dietary exposure than seven or 14 day studies. It was suggested that a reduction to 400 mg/kg would be sufficient to ensure that the ADI of 11 mg/kg is not regularly exceeded by any age group, including those 2-11 years of age. Two submitters stated that exceedances of the ADI should not be automatically viewed as a safety concern, given the safety margin that is built into the ADI.

One submitter noted that the proposed reduction in cyclamate levels will still result in dietary exposure estimates that exceed the European ADI for cyclamate. They also questioned whether FSANZ should consider reducing cyclamate levels to less than 300 mg/kg, given the availability of numerous alternative sweeteners and noting that the EU has reduced cyclamate levels to 250 mg/kg in water-based flavoured drinks.

One WTO member commented that the proposed amendment to the MPL for cyclamate in water-based flavoured drinks differs from the Codex standard of 400 mg/kg, and suggested that Australia adopts the Codex limit to harmonise with international standards and to avoid unnecessary barriers to trade.

9.1.2.1 FSANZ Response

At Draft Assessment, FSANZ considered that the European Union limit of 250 mg/kg cyclamate in non-alcoholic drinks was not justified as this limit was based on an ADI of 7 mg/kg body weight. FSANZ's safety assessment concluded that the JECFA ADI of 11 mg/kg was adequately protective of consumers and that the proposed reduction in cyclamate permissions to 300 mg/kg was sufficient for safety.

With respect to the WTO member's comments, the Codex General Standard for Food Additives permits cyclamate in fruit nectar and concentrates of fruit nectar at a MPL of 400 mg/kg, however there are no permissions for cyclamate in the category of water-based flavoured drinks. Maximum levels for cyclamates in a range of food categories, including water-based flavoured drinks, are being considered by the Codex Committee on Food Additives (CCFA) and are currently at Step 6.

As noted in Section 9.2, FSANZ considers that reducing 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.

In response to submitters' concerns that 300 mg/kg cyclamate may not be achievable in all cases, FSANZ has undertaken further dietary modelling at the suggested level of 400 mg/kg cyclamate in water-based flavoured drinks, both with and without the inclusion of cyclamate in tabletop sweeteners. However, at this higher level, the estimated dietary exposures for Australian children aged 2 to 11 years exceeded the ADI at the 95th percentile exposure **(Attachment 3).** An exposure above the ADI should not be considered acceptable if it occurs over a prolonged period of time, as is potentially the case for young children.

Subsequent to this, FSANZ undertook further dietary modelling based on a MPL of 350 mg/kg cyclamate in water-based flavoured drinks. At this level, the estimated dietary exposures for Australian children aged 2 to 11 years were at or below the ADI at the 95th percentile exposure **(Attachment 3).** FSANZ also sought advice from the beverages industry in terms of its capacity to reduce cyclamate levels in water-based flavoured drinks to a level of between 300 and 400 mg/kg without adversely affecting characteristics such as taste and product stability. It is understood that reducing cyclamate levels to below 400 mg/kg is achievable for most manufacturers, although there will be a significant cost imposition to do so.

Based on the above, FSANZ is recommending a reduction in the MPL for cyclamate in water-based flavoured drinks to 350 mg/kg.

9.1.3 Reinstatement of Cyclamates in Tabletop Sweeteners

Six submitters supported the recommendation to reinstate cyclamate permissions in tabletop sweeteners at GMP levels. It was noted that permitting the use of cyclamates in tabletop sweeteners would not result in an exceedance of the ADI for cyclamate in 2 to 11 year olds. Submitters also stated that the inclusion of tabletop sweeteners would provide benefits for industry and consumers and would also enable products manufactured in New Zealand under the dietary supplements regulations to be sold as foods under the Code. It was also noted that permission for the use of cyclamate at GMP levels has been proposed for adoption in the Codex General Standard for Food Additives (GSFA).

Four submitters did not support the recommendation to reinstate cyclamate permissions in tabletop sweeteners at GMP level. One submitter advised caution in this regard and suggesting that the issue of cyclamates on water-based flavoured drinks and tabletop sweeteners be considered as two separate proposals. Comments raised by submitters on this issue are identified below.

One submitter highlighted that the figures from the *1995 National Nutrition Survey* (NNS) used to estimate dietary exposure for 2 to 11 year olds are outdated, and may actually be significant underestimates as the consumption of intensely sweetened products has changed substantially since 1995. Two submitters raised issues in relation to the potential for extended usage of cyclamate by children arising from the addition of cyclamate-containing tabletop sweeteners to hot beverages, cereals, fruit and in cooking. Several submitters also commented that there is no consumption or exposure data for New Zealand children and that this data should be obtained as part of the risk assessment process.

One submitter requested clarification in relation to the dietary exposure assessment to cyclamate from tabletop sweeteners, specifically:

- it is not clear what the likely cyclamate content of the tabletop sweeteners is, and therefore how average daily intake is modelled; and
- how the maximum permitted level of cyclamate in tabletop sweeteners translates into daily consumption of cyclamate for heavy users of tabletop sweeteners such as individuals with diabetes and impaired glucose intolerance.

Two submitters suggested that tabletop sweeteners containing cyclamate should be limited to single serve portions as this would reduce the risk of high consumers over-consuming cyclamate in foods and beverages that are prepared in the home.

One submitter suggested that a reduction in cyclamate permissions in water-based beverages and reinstatement of permissions for cyclamate could be perceived as a contradictory regulatory measure.

9.1.3.1 FSANZ Response

FSANZ acknowledges that there are a number of limitations associated with the data used to calculate dietary exposure to cyclamate in Australian children aged 2 to 11 years. These limitations are discussed in Section 5.2.5 of Appendix 2 of the Dietary Exposure Assessment Report and relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. However, as children were not included in the *2003 Consumption of Intense Sweetener* survey, the 1995 NNS food consumption data, in conjunction with manufacturers' use data (where available), provides the best estimate of cyclamate exposure in this population group. In the dietary exposure assessment for cyclamate in Australian children aged 2 to 11 years, FSANZ has taken into account where intense sweeteners were reported as being:

- added to beverages, breakfast cereals etc
- added during the preparation or cooking of foods in the home e.g. intensely sweetened stewed fruit
- as part of a commercially available food/beverage e.g. intensely sweetened soft drink, intensely sweetened cordial.

The issue of the absence of consumption and dietary exposure data for New Zealand children is discussed in Section 9.1.5 of this report.

A detailed discussion of the methodology used to determine dietary exposure to cyclamates is provided in Sections 5.1 and 5.2 of Appendix 2 of the Dietary Exposure Assessment Report. There is currently no permission in the Code for the use of cyclamates in tabletop sweeteners. However, cyclamates were permitted in tabletop sweeteners under the former Australian *Food Standards Code* although no maximum levels were specified. The concentration level of cyclamate in tabletop sweeteners used for Scenarios 2, 4, 6 and 8 of the dietary modelling was the manufacturers' use levels prior to the introduction of the new Code and the relevant concentrations are listed in Table 3 in the Dietary Exposure Assessment Report.

These concentrations, combined with consumption data from either the *2003 Consumption of Intense Sweetener* survey or the 1995 NNS as appropriate, were used to estimate cyclamate exposure from tabletop sweeteners in Australian and New Zealand adults 12 years and above and Australian children, respectively.

Dietary exposure assessment results for all population groups (including individuals with diabetes and glucose intolerance), based on the addition of cyclamate to tabletop sweeteners (Scenario 2) are reported in Section 6.2 of Appendix 2 of the Dietary Exposure Assessment Report.

Whilst the inclusion of cyclamates in tabletop sweeteners contributed to increased cyclamate exposures in some population groups, estimated 95th percentile exposures are still at or below the ADI. For the population group that is most at risk of high cyclamate exposure, namely Australian children aged 2 to 11 years, there is minimal change to cyclamate exposure with the inclusion of a permission to use cyclamate in tabletop sweeteners at GMP levels, as the major contributor to cyclamate exposure was intensely sweetened soft drinks and cordials. On this basis, and taking into consideration the benefits to both industry and consumers, FSANZ considers that the reinstatement of cyclamate in tabletop sweeteners is justified. It is not considered necessary to limit tabletop sweeteners containing cyclamate to single serve portions as there is no evidence to suggest that this would be an effective means of reducing cyclamate consumption, given that consumers will consume an amount that is necessary to obtain the desired sweetening effect.

9.1.4 Transitional Period

Several submitters noted that the 12-month stock-in-trade provision only permits the product manufactured prior to the date of gazettal and complying with the previous levels to be sold for a period of 12 months from the date of gazettal. This provision does not relate to the ongoing manufacture of the product. It was therefore proposed that a transitional period of 12 to 18 months be implemented from the date of gazettal of the amendments to allow manufacturers sufficient time to reformulate products and implement labelling changes.

9.1.4.1 FSANZ Response

FSANZ recognises that manufacturers will be required to invest resources in reformulating products and possibly changing labels to meet the reduced cyclamate levels, and that the 12-month stock-in-trade provision does not address this issue. Therefore, FSANZ proposes to allow a transitional period of 12 months to assist in the changeover to the reduced cyclamate permissions. The 12-month stock-in-trade provisions under subclause 3(2) of Standard 1.1.1 of the Code will also apply.

9.1.5 Dietary Exposure Estimates for New Zealand Children

Two submitters considered that cyclamate dietary exposure data estimates for New Zealand children aged 2-11 years should be provided as it is not appropriate to make assumptions about health and safety in the absence of data.

9.1.5.1 FSANZ Response

Due to the New Zealand 1997 NNS collecting data for individuals 15 years and above, an exposure assessment for New Zealand children was not possible. Data from the 2002 New Zealand Children's Nutrition Survey were not in the correct format at the time of this assessment to enable dietary exposure to be estimated. However, based on knowledge about food consumption patterns in the two countries, it is assumed that Australian children are representative of New Zealand children of the same age (2-11 years for this dietary exposure assessment).

9.1.6 Ongoing Monitoring of Intense Sweeteners

Two submitters recommended that ongoing monitoring of intense sweeteners should be conducted to determine the impact on the consumption of other intense sweeteners and to determine whether the proposed risk management strategies for cyclamates have been effective.

9.1.6.1 FSANZ Response

A further follow-up survey on intense sweeteners is planned as part of FSANZ's Evaluation Strategy 2004-2008. Under the Strategy, this survey is scheduled to be undertaken on a five-yearly cycle and is therefore due to commence in 2008. However, given that this review of cyclamates is not yet complete, and a 12-month transitional period is proposed, a follow up sweetener survey may not be appropriate until a later date, possibly after 2009.

9.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

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. However, as the requirements in other countries were unknown, notification of the proposed changes to the Code was made to the WTO in accordance with the Sanitary and Phytosanitary Measures (SPS). This enabled other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

One comment was received in response to the notification. It was noted that the proposed amendment to the MPL for cyclamate in water-based flavoured drinks differs from the Codex Alimentarius Commission standard of 400 mg/kg, and suggested that Australia adopts the Codex limit to harmonise with international standards and to avoid unnecessary barriers to trade. This issue is addressed in Section 9.1.2.

CONCLUSION

10. Conclusion and Decision

FSANZ agrees to reduce cyclamate permissions in water-based flavoured drinks from 600 mg/kg to 350 mg/kg and also to allow the use of cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice. This variation would be achieved by varying Schedule 1 of Standard 1.3.1.

Decision

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 350 mg/kg with a 12 month implementation period after gazettal, and to allow the use of cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice.

10.1 Reasons for Decision

FSANZ approves the draft variations to Standard 1.3.1 – Food Additives for the following reasons:

- The proposed draft variations to Standard 1.3.1 are consistent with the section 18 objectives of the FSANZ Act, in particular, they do not raise any public health and safety concerns, are based on risk analysis using the best available scientific evidence, and help to 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 Report **(Attachment 3)** shows that reducing permissions for cyclamate in water-based flavoured drinks to 350 mg/kg would ensure that public health and safety of high cyclamate 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 350 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 addition, FSANZ is recommending that a 12 month implementation period apply from the date of gazettal of the amendments with respect to the reduced cyclamate permissions for water-based flavoured drinks, to allow reformulation of products.

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

11. Implementation and Review

It is proposed that the draft variations relating to reinstating permissions for tabletop sweeteners commence from the date of gazettal. The draft variations to reduce the levels of cyclamate in water based flavoured drinks is to commence 12 months from gazettal to enable affected manufacturers to reformulate and re-label products.

A further follow-up survey on intense sweeteners is planned as part of FSANZ's Evaluation Strategy 2004-2008. It is anticipated that this survey would evaluate the impact of any amendments to cyclamate permissions as a result of this Proposal, including any corresponding increase in the consumption of other intense sweeteners.

ATTACHMENTS

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

Attachment 1

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

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

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	

To commence: 12 months from Gazettal

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

952	Cyclamates	600	mg/kg

substituting –

952	Cyclamates	350	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:

1. A metabolism study in humans
2. Two repeat-dose studies
3. A long-term toxicity study
4. 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[6], 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.

[6] 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).

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Attachment 3

Dietary Exposure Assessment Report

1. Executive Summary

A Proposal was initiated by FSANZ to consider cyclamate permissions in the *Australia New Zealand Food Standards Code* (the Code) in response to the FSANZ *2003 Consumption of Intense Sweetener* survey (FSANZ 2004*)*, which investigated the exposure to intense sweeteners for 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).

At Draft Assessment, dietary exposures to cyclamate were calculated for various Australian and New Zealand population groups including children aged 2-11 years. This 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. The major contributor to dietary exposures for this population group was water-based flavoured drinks (intensely sweetened soft drink and cordial). For further detail about the findings of the Draft Assessment Report, please see Appendix 2 for a full review.

Based on the findings at Draft Assessment as well as submissions received thereafter, Final Assessment dietary modeling was conducted on children aged 2-11 years with reduced cyclamate permissions for water-based flavoured drinks, both with and without the addition of cyclamate permissions for tabletop sweeteners.

To address the comments raised at Draft Assessment around the proposed MPL of 300 mg/kg for cyclamate in water-based flavoured drinks being too low to achieve the technological benefit, FSANZ modelled additional scenarios for the Final Assessment based on MPLs of 350 mg/kg (Scenarios 5 and 6) and 400 mg/kg (Scenarios 7 and 8) of cyclamate in water-based flavoured drinks with and without the addition of cyclamate permissions for tabletop sweeteners.

Under both Scenarios 5 and 6, Australian children aged 2-11 years were below the ADI for mean, 90th and 95th percentile dietary exposures for cyclamates. When cyclamate concentrations for water based beverages were increased to 400 mg/kg for Scenarios 7 and 8, dietary exposures for males exceeded the ADI at the 95th percentile (110%) while females were at 100% of the ADI. The addition of tabletop sweeteners (Scenarios 6 and 8) had little impact on overall dietary exposures to cyclamate for this age group.

Major contributors to cyclamate dietary exposure were intensely sweetened soft drinks (ranging from 45-65% for both genders), intensely sweetened cordials were the next highest contributor (ranging from 25-50%) and tabletop sweeteners (for Scenarios 6 and 8) contributed 9-10% to cyclamate dietary exposure.

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 especially for occasionally consumed foods.

In this case, it is likely that estimated dietary exposure based on 24-hour recall reflects the dietary exposure for a longer time period as intensely sweetened soft drinks and cordials are frequently consumed by this population group.

In conclusion, the dietary exposure assessment revealed that estimated cyclamate dietary exposures based on reduced cyclamate levels for water based flavoured drinks result in exposures below the ADI for children aged 2-11 years, except for males for Scenarios 7 and 8 where consumers exceeded the ADI at the 95th percentile (110%).

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 (300-400 mg/kg) be implemented.

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 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 5.5.

4. Dietary Exposure Assessments Conducted to Date

A full review of the dietary exposures conducted to date can be found in Appendix 2.

5. Dietary Exposure Assessment for P287: Review of Cyclamate Permissions

At Final Assessment, scenarios were only conducted for children 2-11 years of age as it was this group who were found to have the highest cyclamate exposures for scenarios 1-4 in Draft Assessment. It was assumed that if this group was found to have dietary exposures to cyclamate below the ADI for scenarios modelled at Final Assessment, then Australians and New Zealanders 12 years and above would also have dietary exposures below the ADI.

In response to comments raised at Draft Assessment that the proposed MPL of 300 mg/kg for cyclamate in water-based flavoured drinks was too low to achieve the technological benefit, FSANZ modelled additional scenarios based on MPLs of 350 mg/kg and 400 mg/kg of cyclamate in water-based flavoured drinks.

The level of 400 mg/kg was based on comments raised in submissions to the DAR, whereas 350 mg/kg represented a midway point between 300 mg/kg and 400 mg/kg.

The following regulatory options have therefore been considered as follows:

Option 5 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Option 6 – Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and re-instate cyclamate permissions in tabletop sweeteners.

Option 7 – Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners.

Option 8 – Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and re-instate cyclamate permissions in tabletop sweeteners.

Table 2: Scenarios modelled for Final Assessment for P287: Review of cyclamate permissions

		Scenario parameters		
Scenario	**Population group**	**Cyclamate concentration (mg/kg)**	**Cyclamate in tabletop sweeteners included**	**Reduced cyclamate MPL in intensely sweetened soft drinks and cordials**
Scenario 5	Aust 2-11 years	350	×	✓
Scenario 6	Aust 2-11 years	350	✓	✓
Scenario 7	Aust 2-11 years	400	×	✓
Scenario 8	Aust 2-11 years	400	✓	✓

5.1 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.

Due to the New Zealand 1997 NNS collecting data for individuals 15 years and above, an exposure assessment for New Zealand children was not possible. Data from the 2002 New Zealand Children's Nutrition Survey were not in the correct format at the time of this assessment to enable dietary exposure to be estimated. However, it is assumed that Australian children are representative of New Zealand children of the same age (2-11 years) for this dietary exposure assessment.

This population group was assessed based on the findings for cyclamate dietary exposures at Draft Assessment. Children were found to have higher dietary exposures based on body weight compared to the adult population, thus further modelling was warranted to determine the risk to public health and safety.

5.2 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 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 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 4 and 6 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 3) 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 CIC reasons.

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

DIAMOND Food Code	Commodity	Cyclamate concentration level (mg/kg)			
		Scenario 3	Scenario 4	Scenario 5	Scenario 6
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**	**350**	**350**	**400**	**400**
14.1.3.7	**Cordials, intensely sweetened**	**350**	**350**	**400**	**400**
14.1.3.9	**Cola type drinks, intensely sweetened**	**350**	**350**	**400**	**400**
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

5.3 Food Consumption Data

DIAMOND contains food consumption data from the 1995 NNS 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.

5.4 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 mL 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 4 and 6;
- 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; and
- all intensely sweetened beverages have been assumed to contain cyclamate.

These assumptions are likely to lead to a conservative estimate for cyclamate dietary exposure for Australian children aged 2–11 years.

5.5 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 does have its 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, Rutishauser and Allsopp, 2000). 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 is 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.
- 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 complimentary 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 1,921 Australians aged 2-11 years were included in the 1995 NNS. The breakdown of consumers versus respondents for males and females for all scenarios is presented in Table 4.

Table 4: Number of consumers of cyclamate and proportion to total respondents for Australians aged 2-11 years included in the 1995 NNS

Scenario	2-11 years male Consumers (n)	Proportion cons/resp (%)	2-11 years female Consumers (n)	Proportion cons/resp (%)
5 and 7	99	10	76	8
6 and 8	103	10	79	8

Scenario 5 and 7: Excluded cyclamate-containing tabletop sweeteners
Scenario 6 and 8: Included cyclamate-containing tabletop sweeteners

The proportion of consumers of foods containing cyclamate for Australians aged 2-11 years was approximately 10%.

6.2 Estimated Dietary Exposures to Cyclamate

Recently FSANZ began using the 90th percentile as a default reporting value to provide a more realistic estimation of longer term high consumer exposures based on a single day of food consumption data. 90th percentile estimates are presented in this report as well as 95th percentile estimates which were presented for the Draft Assessment Report (*see Appendix 2 for further details*).

6.2.1 Estimated Dietary Exposures to Cyclamate Concentrations of 350 mg/kg for Water Based Beverages

Mean dietary exposure for males and females for both scenarios modelled were between 3.6 mg/kg bw/day and 4.1 mg/kg bw/day. Estimated 90th percentile dietary exposures for males and females for both scenarios ranged from 8.1 mg/kg bw/day to 8.9 mg/kg bw/day. Ninety-fifth percentile dietary exposures to cyclamate were between 10.1 mg/kg bw/day and 11 mg/kg bw/day. For full details, refer to Table 5 and Figure 1.

Table 5: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years

Population group	Scenario	Mean consumers (mg/kg bw/day)	90th percentile consumers (mg/kg bw/day)	95th percentile consumers (mg/kg bw/day)
Males	5	3.6	8.1	10.3
	6	4.0	8.6	11.0
Females	5	3.9	8.2	10.1
	6	4.1	8.9	10.1

Scenario 5: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg bw/day) for cyclamate in water-based beverages
Scenario 6: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg bw/day) for cyclamate in water-based beverages

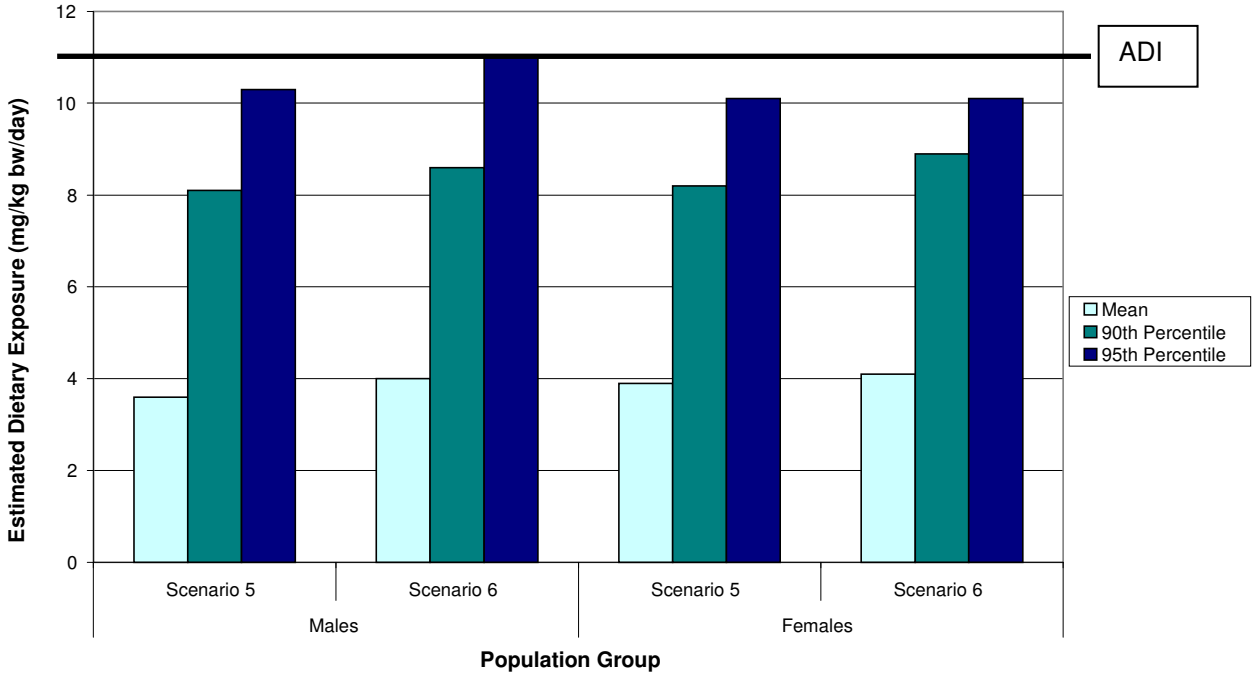

Figure 1: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate (350 mg/kg) aged 2-11 years

6.2.2 Estimated Dietary Exposures to Cyclamate Concentrations of 400 mg/kg for Water Based Flavoured Drinks

Mean dietary exposure for males and females for both scenarios were between 4.1 mg/kg bw/day and 4.6 mg/kg bw/day. Estimated 90th percentile dietary exposures for both genders and scenarios ranged from 9.3 mg/kg bw/day to 10.0 mg/kg bw/day. Ninety-fifth percentile dietary exposures to cyclamate for both population groups and scenarios were above 11 mg/kg bw/day. For full details, refer to Table 6 and Figure 2.

Table 6: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years

Population group	Scenario	Mean consumers (mg/kg bw/day)	90th percentile consumers (mg/kg bw/day)	95th percentile consumers (mg/kg bw/day)
Males	7	4.1	9.3	11.8
	8	4.5	9.8	12.5
Females	7	4.5	9.4	11.5
	8	4.6	10.0	11.2

Scenario 7: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

Scenario 8: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

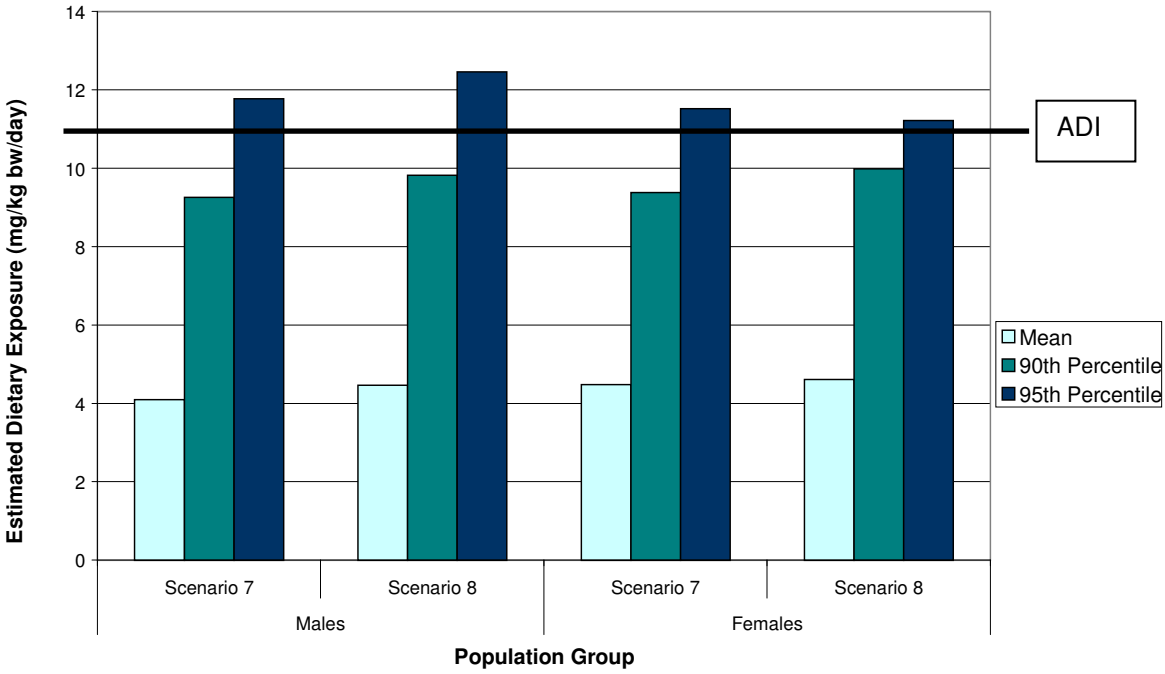

Figure 2: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate (400 mg/kg) aged 2-11 years

6.3 Major Contributing Foods to Total Estimated Dietary Exposures

A selection of the contributing foods to total estimated cyclamate dietary exposures for Australian children aged 2-11 years are presented in Table 7 .

Table 7: Contributors to estimated cyclamate dietary exposures for Australians aged 2-11 years for scenarios modelled at Final Assessment

	Scenario 5		Scenario 6		Scenario 7		Scenario 8	
Commodity	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**	**Male**	**Female**
Cordials, intensely sweetened	30	50	25	45	30	50	25	45
Soft drinks, intensely sweetened	65	50	55	45	65	50	60	45
Tabletop sweeteners	0	0	10	10	0	0	10	9
Prunes	2	1	2	1	2	1	2	1
Sauces, toppings, mayonnaise, salad dressing, intensely sweetened	2	1	2	1	2	1	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 5: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg) for cyclamate in water-based beverages

Scenario 6: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg) for cyclamate in water-based beverages

Scenario 7: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg)for cyclamate in water-based beverages

Scenario 8: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

For Scenarios 5-8 the major contributors (≥5%) to estimated cyclamate intakes for both males and females, 2-11 years of age, were cordials (ranging from 25-50%) and soft drinks (ranging from 45-65%). When tabletop sweeteners were included in Scenarios 6 and 8, they were a major contributor to cyclamate dietary exposures (9-10%).

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 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 Dietary Exposures to Cyclamate Concentrations of 350 mg/kg for Water Based Beverages

The estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI are presented in Table 8 and Figure 3.

Table 8: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

Population group	Scenario	Mean consumers	90th percentile consumers	95th percentile consumers
Males	Scenario 5	35	75	95
	Scenario 6	35	80	100
Females	Scenario 5	35	75	90
	Scenario 6	35	80	90

Scenario 5: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg) for cyclamate in water-based beverages

Scenario 6: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (350 mg/kg) for cyclamate in water-based beverages

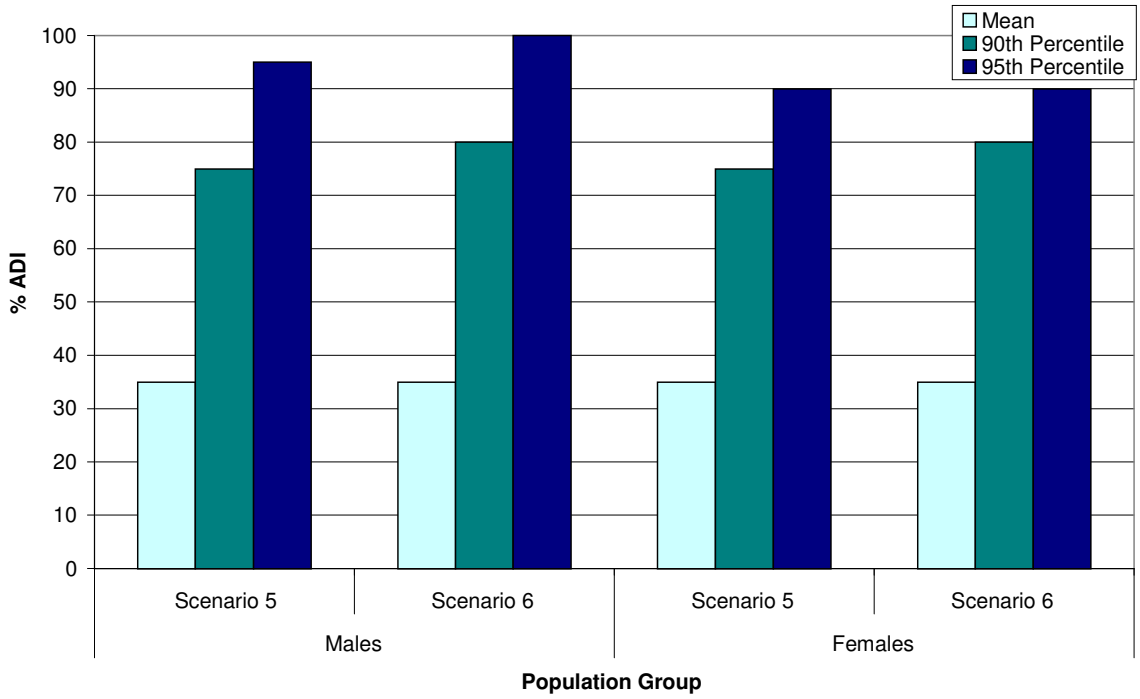

Figure 3: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate (350 mg/kg) aged 2-11 years as a proportion of the ADI (%)

For Australian children 2-11 years estimated mean dietary exposures were approximately 35% of the ADI in Scenarios 5 and 6. Estimated 90th percentile dietary exposures ranged from 75-80% of the ADI for both scenarios and genders. For dietary exposures at the 95th percentile, males in Scenario 6 had the highest percentage of the ADI at 100%.

7.3 Characterisation of Dietary Exposures to Cyclamate Concentrations of 400 mg/kg for Water Based Beverages

When cyclamate concentrations were increased to 400 mg/kg for water based beverages, mean dietary exposures for Australian children 2-11 years ranged from 35-40% of the ADI for both scenarios and genders. Estimated 90th percentile dietary exposures increased to 85-95% of the ADI and 95th percentile dietary exposures were at or above 100% of the ADI. See Table 9 and Figure 4 for further details.

Table 9: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate (400 mg/kg) aged 2-11 years as a percent of the ADI (%)

Population group	Scenario	Mean consumers	90th percentile consumers	95th percentile consumers
Males	Scenario 7	35	85	110
	Scenario 8	40	90	110
Females	Scenario 7	40	85	100
	Scenario 8	40	90	100

Scenario 7: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

Scenario 8: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

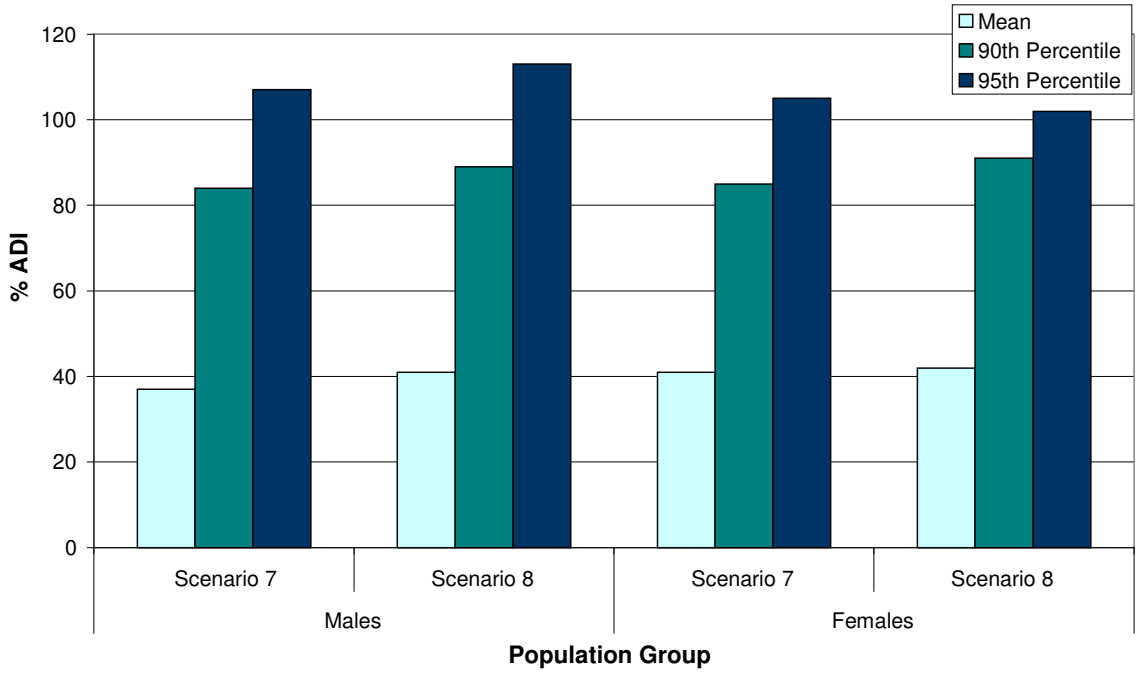

Figure 4: Estimated mean, 90th and 95th percentile dietary exposures for Australian consumers of cyclamate (400 mg/kg) aged 2-11 years as a proportion of the ADI (%)

7.4 Proportion of Consumers Exceeding the ADI

The proportion of Australian children aged 2-11 years exceeding the ADI is shown in Table 10.

Table 10: Proportion (%) of Australian consumers of cyclamate aged 2-11 years who exceeded the ADI at the 95th percentile

	Population group	
Scenario	**2-11 years male**	**2-11 years female**
7	5	5
8	7	5

Scenario 7: Exclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

Scenario 8: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL (400 mg/kg) for cyclamate in water-based beverages

As no children aged 2-11 years exceeded the ADI for cyclamate when concentrations were 350 mg/kg for water based beverages, these scenarios have therefore not been included here for discussion. When cyclamate concentrations were increased to 400 mg/kg for water based beverages for Scenarios 7 and 8, both genders exceeded the ADI at the 95th percentile. The proportion of males exceeding the ADI was 5% for Scenario 7 and 7% for Scenario 8. The proportion of females exceeding the ADI was 5% for both scenarios.

8. Conclusions

Estimated dietary exposures to cyclamate, based on current revised MPLs for cyclamate of 350 mg/kg and 400 mg/kg for water-based flavoured drinks, resulted in dietary exposures below the ADI for mean and 90th percentile dietary exposures, however, at the 95th percentile exposure, 2-11 year old males exceeded the ADI for Scenarios 7 and 8 (400 mg/kg cyclamate in water-based flavoured drinks without and with the addition of tabletop sweeteners, respectively).

The major contributor to dietary exposures for this population group assessed was water-based flavoured drinks (intensely sweetened soft drinks and cordials) and tabletop sweeteners.

Overall, the dietary exposure assessment revealed there is minimal change to exposure to cyclamate with the inclusion of a permission to use cyclamate in tabletop sweeteners. 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.

Estimated dietary cyclamate exposures and the proportion of the population exceeding the ADI for the 2-11 year age group would be reduced with the implementation of lower cyclamate permissions for intensely sweetened soft drinks and cordials (300-400 mg/kg).

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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, 90th 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.

Reporting of dietary exposure assessment results for high consumers

Under the FSANZ Science Strategy 2006-2009, FSANZ agreed to review its dietary modelling procedures. As part of this review an international peer review was sought. FSANZ has previously reported dietary exposures for high consumers at the 95th percentile. The recommendation of the peer review by an international dietary exposure assessment expert from the US Food and Drug Administration was that FSANZ should consider reporting food chemical dietary exposures at the 90th percentile not the 95th percentile, if only one 24 hour recall record per person was used for the assessment. This is because the 95th percentile results are likely to be an overestimate because they will include dietary exposure for high consumers of irregularly consumed foods which are 2-5 fold higher than the mean (Lambe *et al.,* 2000) and hence potentially result in an overly conservative risk management approach.

Appendix 2

Dietary Exposure Assessment Report – Draft Assessment

1. Executive Summary

A Proposal was initiated by Food Standards Australia New Zealand (FSANZ) to consider cyclamate permissions in the *Australia New Zealand Food Standards Code* (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 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 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 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)**.

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 larger 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 A2.1.

Table A2.1: Current MPLs for cyclamate in the 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. 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 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.[7]

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 Appendix 3*). 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.

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.

[7] DIAMOND was not used for this process.

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 A2.2 summarises the scenarios modelled for P287: Review of cyclamate permissions.

Table A22: Scenarios modelled for P287: Review of cyclamate permissions

Scenario	Population group	Scenario parameters: Cyclamate in tabletop sweeteners included	Scenario parameters: 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 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 'commercial in confidence' (CIC) 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 mL is equal to 1 g 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 A2.1) were matched to the most appropriate ANZFSC code(s).

Table A2.3 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 CIC reasons.

Table A2.3: Cyclamate concentrations used for estimating dietary exposure 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**

DIAMOND Food Code	Commodity	Cyclamate concentration level (mg/kg)			
		Scenario 1	Scenario 2	Scenario 3	Scenario 4
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 A2.3;
- 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 beverages 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 does have its 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*., 2001). 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 is 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 complimentary 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* survey. The breakdown of consumers versus respondents for various population groups is presented in Table A2.4.

Table A2.4: Number of consumers of cyclamate and proportion to total respondents for Australian and New Zealanders aged 12 years in the 2003 Consumption of Intense Sweeteners survey

	AUS	**NZ**	**Australia and New Zealand**						
Measurement	**12+ years**	**12+ years**	**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 A2.5.

Table A2.5: Number of consumers of cyclamate and proportion to total respondents for Australians aged 2-11 years included in the 1995 NNS

Scenario	2-11 years male Consumers (n)	Proportion cons/resp (%)	2-11 years female Consumers (n)	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. 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

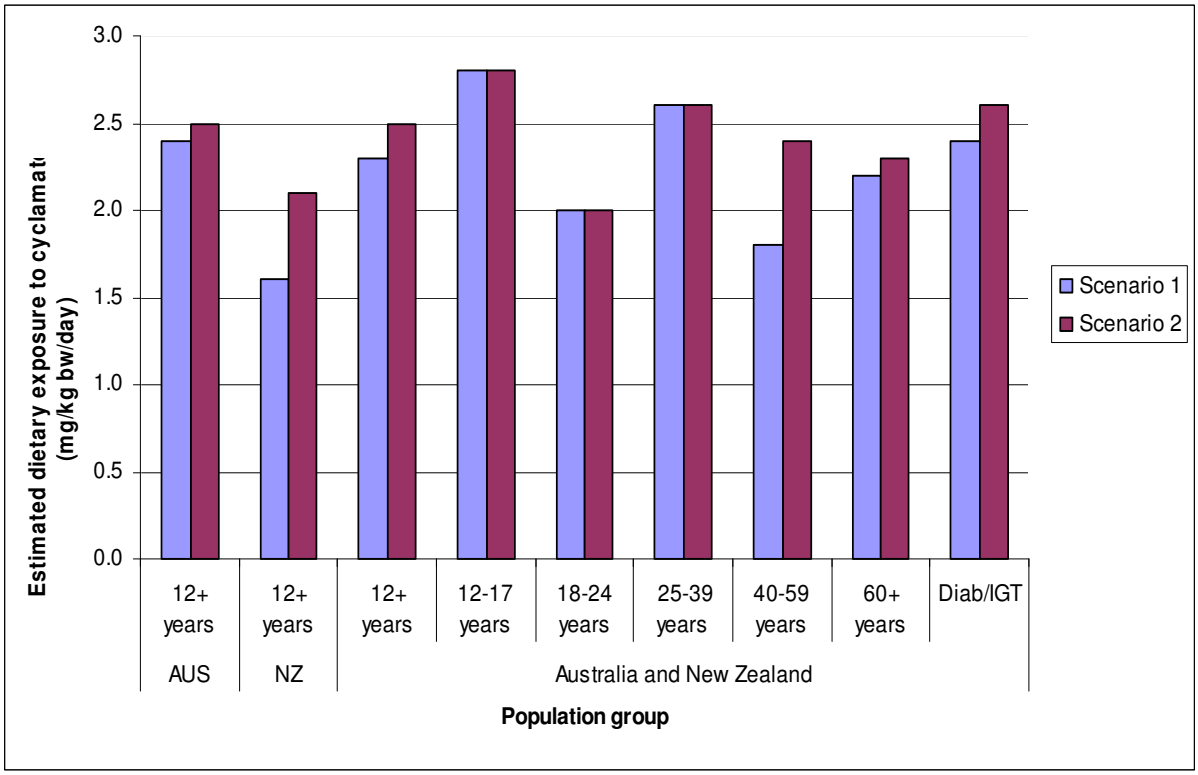
6.2.1 Estimated Mean Dietary Exposures

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 A2.6 and Figure A2.1. 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 A2.6: 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

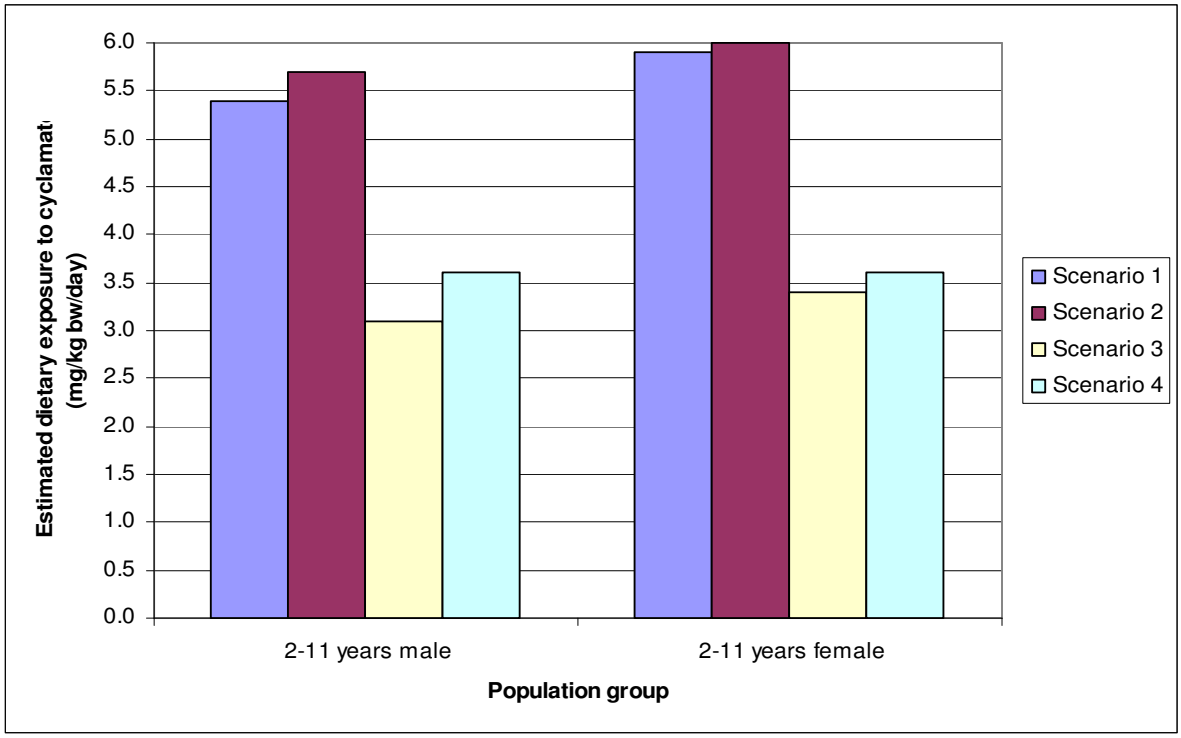
Figure A2.1: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

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 A2.7 and Figure A2.1. 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 A2.7: 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages



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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

Figure A2.2: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years (mg/kg bw/day)

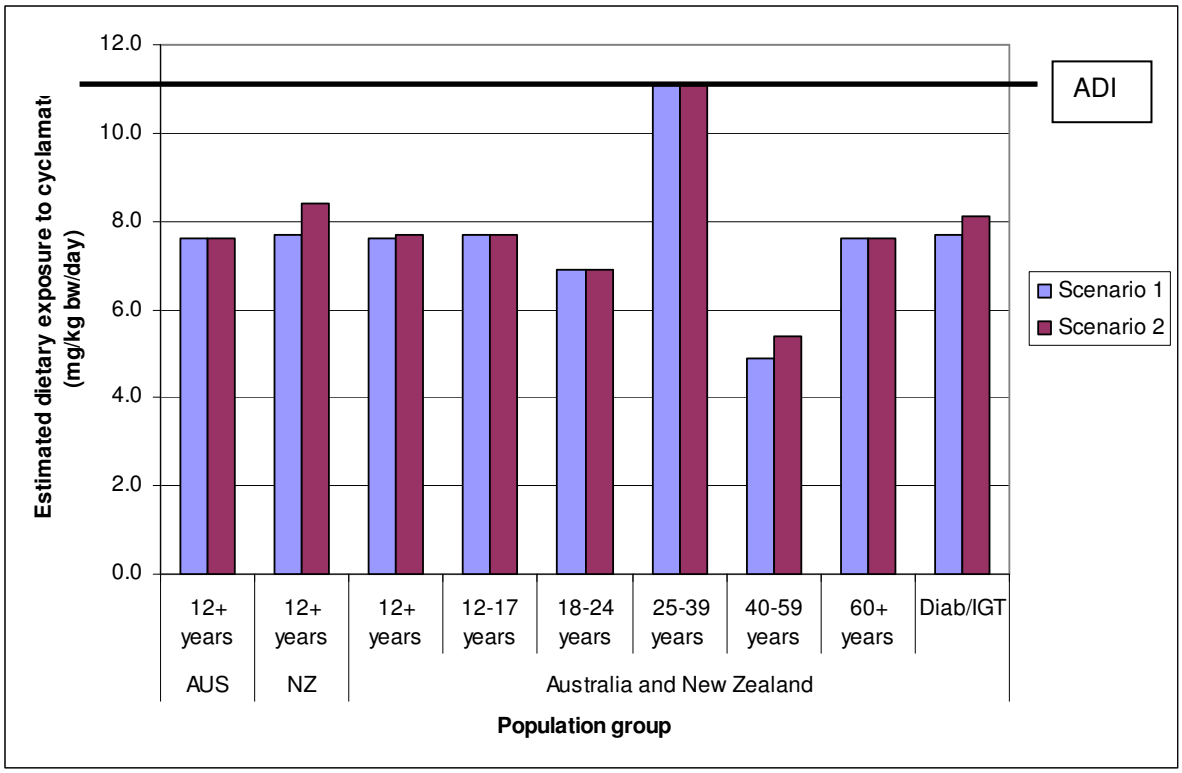
6.2.2 Estimated 95th Percentile Dietary Exposures

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 A2.8 and Figure A2.3. 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 A2.8: 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

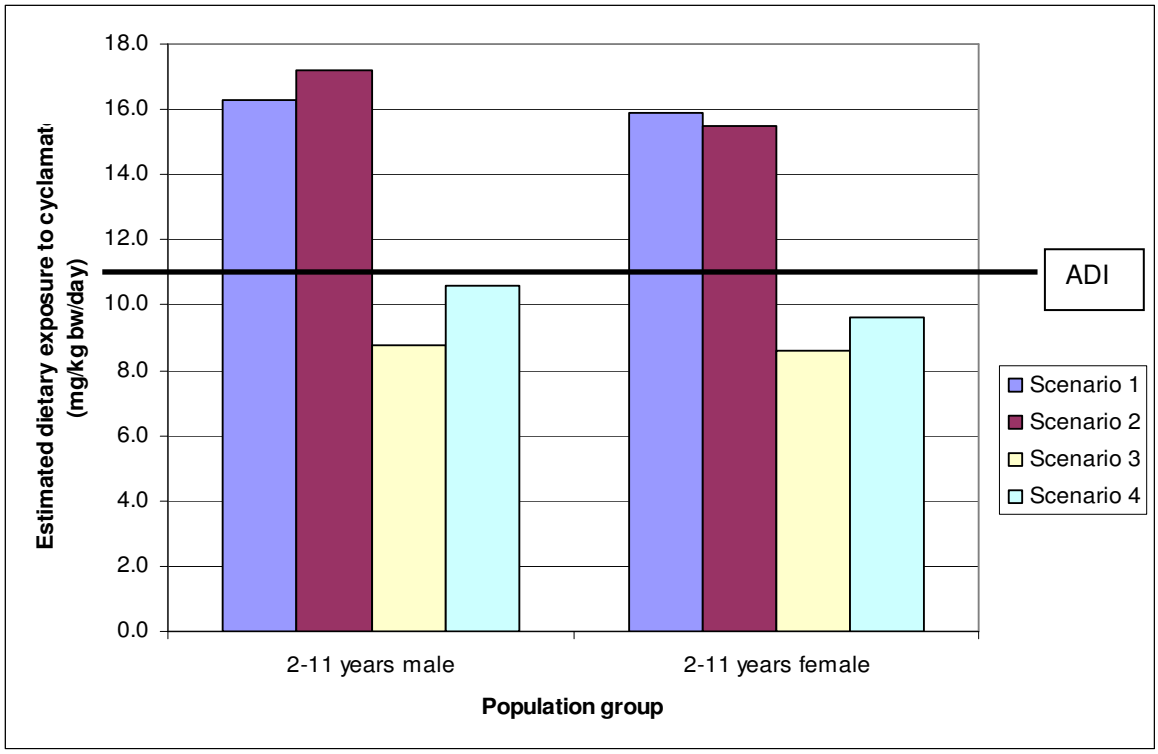
Figure A2.3: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above (mg/kg bw/day)

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 Figure A2.4. 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 A2.9: 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages



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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

Figure A2.4: 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 A2.8*). 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 A2.8*).

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 A2.4*).

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 beverages (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 A2.10.

Table A2.10: 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 A2.11.

Table A2.11: 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

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 A2.10*). 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 A2.11*). 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 A21.2 and Figure A2.5.

Table A2.12: 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

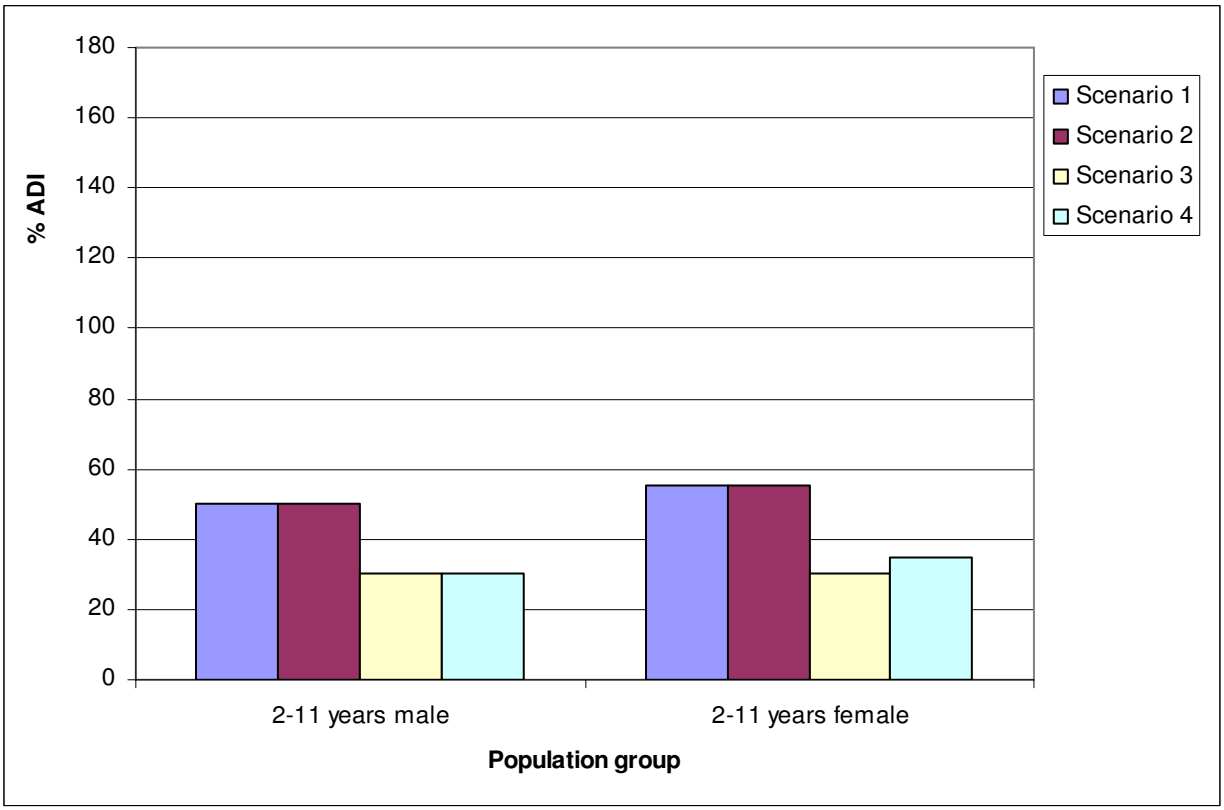
Figure A2.5: Estimated mean dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

The estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI are presented in Table A2.13 and Figure A2.6.

Table A2.131: Estimated mean dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

Scenario	Population group 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages



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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

Figure A2.6: 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.

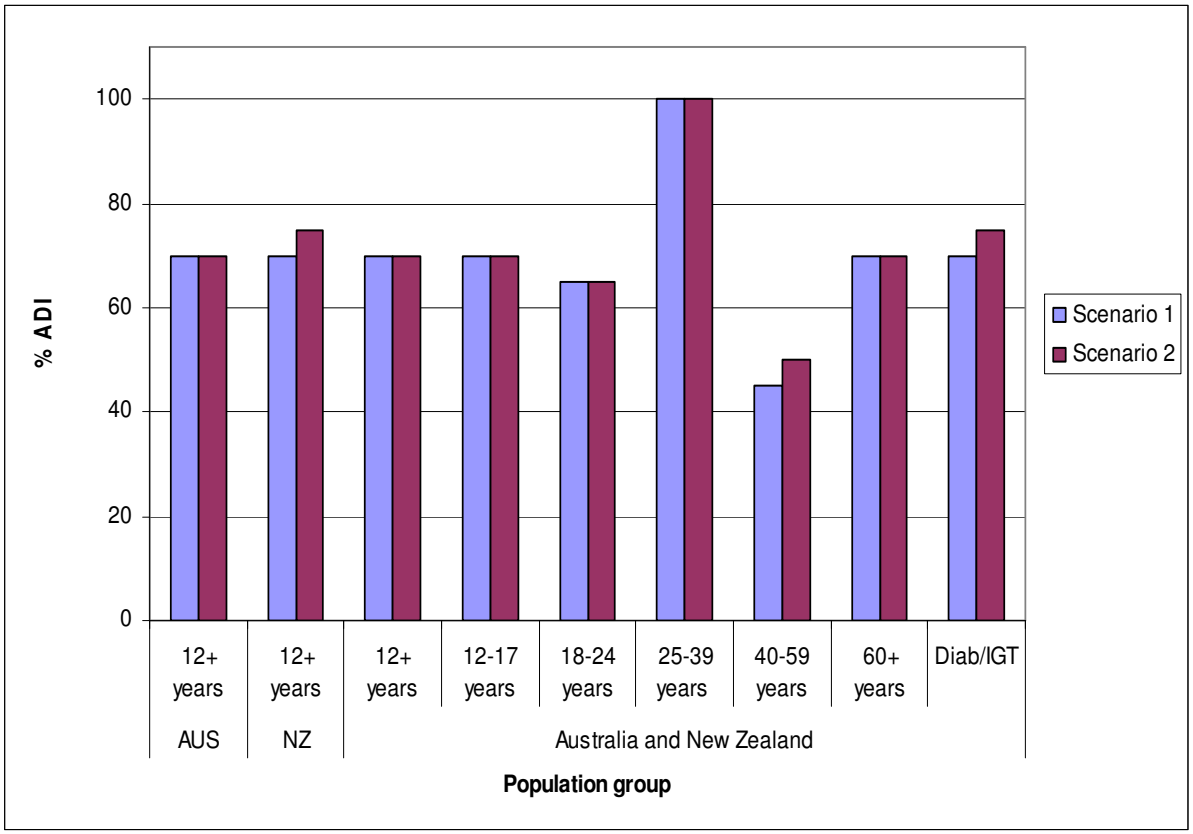
7.3 Characterisation of Estimated 95th Percentile Dietary Exposures

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 A2.14 and Figure A2.7.

Table A2.14: 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

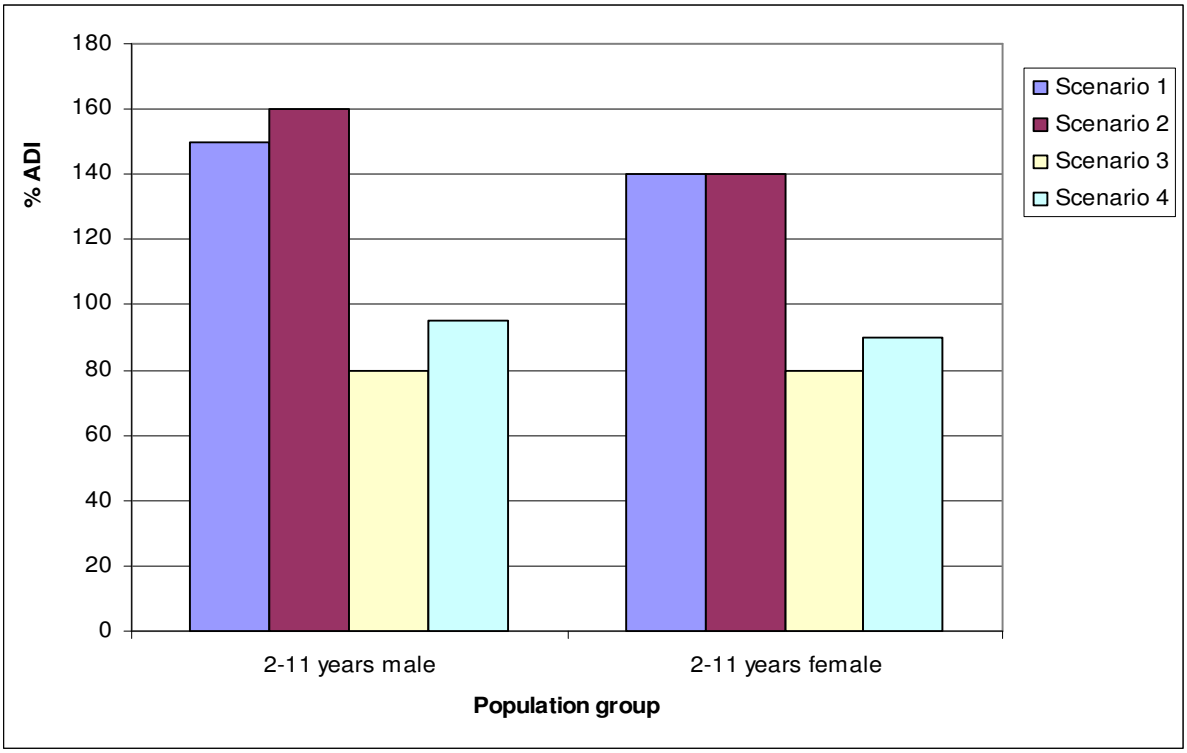
Figure A2.7: Estimated 95th percentile dietary exposures for Australian and New Zealand consumers of cyclamate aged 12 years and above as a percent of the ADI (%)

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 A2.15 and Figure A2.8.

Table A2.152: Estimated 95th percentile dietary exposures for Australian consumers of cyclamate aged 2-11 years as a percent of the ADI (%)

Scenario	Population group 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages



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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

Figure A2.8: 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. 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 A2.15*).

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 A2.16.

Table A2.16: 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 A2.17.

Table A2.17: 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 beverages
Scenario 4: Inclusion of cyclamate-containing tabletop sweeteners and a reduced MPL for cyclamate in water-based beverages

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 Table A2.16 and Table A2.17*). 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 A2.18.

Table A2.18: Estimated mean and 95th percentile dietary exposures for consumers of cyclamate aged 12-17 years

Scenario	Mean consumer exposure mg/kg bw/day		% ADI		95th percentile consumer exposure mg/kg bw/day		% 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. This is because, in this case, it is likely that estimated dietary exposure based on 24-hour recall reflects that for a larger time-period as intensely sweetened soft drinks and cordials are frequently consumed by this population group.

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.

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.

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Appendix 3

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 A3.1: 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

Population group	Country	Mean consumer exposure mg/kg bw/day	% ADI	95th percentile consumer exposure 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, when results were combined for Australia and New Zealand this was not the case.

Attachment 4

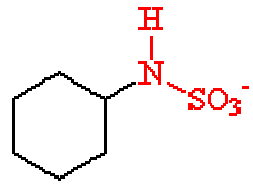
Food Technology Report

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 (1 g/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

Food category #	Food category	Max permitted level (mg/kg)
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 350 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 350 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 350 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 350 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 will have a 12 month transition period post gazettal of the change as well as 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 350 mg/kg cyclamate is technologically feasible in water-based flavoured drinks.

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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[8]. It has an ADI of 0-11 mg/kg bw/day as assessed by JECFA[9]. 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[10].

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'[11] 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[12]. 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)[13]. 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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[8] 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

[9] 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.

[10] 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

[11] 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.

[12] 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

[13] 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[14], 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[15].

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[16].

[14] 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

[15] 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.

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

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

Canada

Currently cyclamate is only approved as a tabletop sweetener[17], but not as an intense sweetener for general food use, i.e. it is not approved as a food additive[18].

The Canadian Food and Drug Regulations[19] 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)[20], 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

[17] 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

[18] 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

[19] 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

[20] 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

Second Round of Public Consultation

1. Calorie Control Council, Atlanta

- Is concerned about FSANZ's recommendation to reduce cyclamates in water-based flavoured drinks from 600 mg/kg to 300 mg/kg.
- Notes that the reductions are based on estimations from the 1995 Australian National Nutrition Survey, a 24-hour recall study, and that data from 24-hour recall studies are known to be less accurate and more likely to overestimate usage than 7 or 14 day studies.
- An ADI is a conservative safe exposure level, which anticipates a continuous lifetime exposure and should not be regarded as a specific point at which safety ends and possible health concerns begin.
- Considers that the extensive human data on cyclamate metabolism obviates the need for the full factor of 10 historically related to intra-species differences and that a safety factor of 30 would more than adequately assure human safety i.e.:

    - only a small percentage of persons have other than insignificant capability to convert cyclamate to cyclohexylamine.
    - the level of human conversion from cyclamate to cyclohexylamine varies considerably over time, even among good human converters (very few individuals will convert 20% and no individual will be exposed to cyclohexylamine at 20% level for more than a small part of his life).
    - the demonstrated loss of ability to convert whenever cyclamate is not consumed for a few days further makes it unlikely under real-life intake conditions that any individual will convert anywhere near the benchmark conversion figure for other than a small part of his life. Animal studies on which the no effect level was determined are premised on continuous exposure of cyclohexylamine.

- Notes that the toxicity of cyclamate per se is not in question but that of its metabolite, cyclohexylamine and that toxic effects have only been observed in cyclohexylamine feeding studies, not cyclamate studies.
- Doubts whether the high dose testicular effects in rats are relevant to human safety given the exaggerated dose levels at which such effects occur, rat-man differences, and the limited extent to which cyclamate is metabolised to cyclohexylamine in man.
- Considers that it is improbable that any adverse effect would ever be observed in humans, even high converters, at the 95th percentile of use.
- Believes that the public is more than adequately protected by the current 600 mg/kg maximum level of cyclamate permitted for use in water-based flavoured drinks. However, if FSANZ finds it necessary to reduce the level, the Council would support a reduction from 600 mg/kg to 400 mg/kg rather than 300 mg/kg.

2. Food Technology Association of Victoria (FTA)

- Agrees with Option 3 – to reduce cyclamate permissions in water-based flavoured drinks and no reinstatement of cyclamate permissions in tabletop sweeteners.

3. New Zealand Food Safety Authority (NZFSA)

- Supports Option 4 subject to refining the dietary exposure assessment and including New Zealand children.
- Believes a dietary assessment on New Zealand children should be carried out 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.
- The inclusion of tabletop sweeteners under Option 4 will enable products manufactured in New Zealand that are currently sold as a dietary supplement to be sold under the Code.

4. Paul Elwell-Sutton

- Requests that FSANZ cancels permission for cyclamates in any food available for purchase by the public in New Zealand unless prescribed by a qualified health professional.
- States that cyclamates are recognised carcinogens, have been implicated in liver, thyroid, circulatory system and reproductive system dysfunction and have been banned in some countries.

FSANZ response

The safety of cyclamate has been extensively studied and there is no scientific evidence to suggest that cyclamate is implicated in the above conditions at the levels that are currently permitted in the Code, or indeed at the reduced levels that are proposed in water-based flavoured drinks. A detailed safety assessment is provided at **Attachment 2**.

Whilst cyclamate is not permitted in foods in the United States, it is however approved for use as an intense sweetener in food in over 50 countries.

5. Dietitians Association of Australia (DAA)

- Supports, with qualification, Option 4, 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).
- States that children in the 2-11 year old group may not be significant users of tabletop sweeteners but notes the following concerns:

    - a heat stable low-joule sweetener such as cyclamate may be substituted for sugar for tabletop use for fruit, cereal and hot beverages.
    - as a heat stable sweetener, cyclamate can also be used in cooking and this may change the results from the food modelling that was used in the risk assessment.

- Recommends that the tabletop sweetener is limited to forms that are packaged as single serve portions as this would reduce the risk of 2-11 year old children over-consuming cyclamate in foods and beverages prepared in the home.

6. Hermes Sweeteners

- Supports FSANZ's proposed amendment as per the provisions of Proposal P287.
- Notes that permission for use of cyclamate at GMP level in tabletop sweeteners could be granted without regard to the maximum use levels in other food categories, namely soft drinks.
- States that permission for use of cyclamate at GMP level has been proposed for adoption in the Codex General Standard for Food Additives (GSFA) (Step 8 at the 39th session of the Codex Committee on Food Additives, Beijing, 24-28 April 2007).

7. International Sweeteners Association

- Welcomes the conclusions that the ADI of 11 mg/kg is adequately protective of consumers and supports the inclusions of permissions for cyclamate in tabletop sweeteners.
- Supports a level of 400 mg/kg cyclamate for use in water-based flavoured drinks. At levels under 400 mg/kg, the improvement of taste becomes negligible and the synergistic effects of cyclamate are substantially reduced. A level of 300 mg/kg would also require significant reformulations.

8. Cadbury Schweppes

- Generally supports the proposal to reduce the permission levels for cyclamates in water-based flavoured beverages from 600 mg/kg to 300 mg/kg.
- Cadbury Schweppes has been continually reviewing the cyclamate levels in their water-based flavoured beverage products and has been able to reduce usage levels below the current maximum permitted level of 600 mg/kg for most products, and in most cases has been able to achieve a level below 300 mg/kg.
- Notes that some additional development is still required for some water-based flavoured beverages products to ensure that alternative intense sweeteners provide the appropriate sweetness levels and that there is still continued consumer preference for Cadbury Schweppes branded products.
- Has some concerns with a 12 month stock-in-trade provision and would prefer a minimum 18 month provision to allow sufficient time for the required development work.

9. Environmental Health Unit, Queensland Health

- Notes that additional data is being sought relative to carbonated soft drinks and cordials and that there may be additional dietary modelling required and a further report. Would like to see the dietary modelling finalised before giving support for any of the options currently being proposed.

- This is particularly the case in view of the statement in the Draft Assessment Report (DAR) '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.'
- Seeks advice as to why cyclamate is not permitted for use in the USA and why Canada only permits cyclamate in tabletop sweeteners.

FSANZ response

At Draft Assessment, FSANZ sought additional data to assist in refining the dietary modelling however, no additional information was provided by submitters. Therefore, the dietary modelling is based on the best available data.

In the United States, cyclamate was first introduced in foods and beverages in the early 1950s prior to the requirement for a pre-market review of food additives. In 1970, the FDA 'banned' the use of cyclamates following a review of scientific studies which appeared to indicate that cyclamate could cause bladder tumours in rats and mice. In 1985, the Cancer Assessment Committee of FDA's Center for Food Safety and Applied Nutrition and the National Academy of Sciences both concluded that cyclamate is not a carcinogen, however, other issues in relation to cyclamate remained unresolved and permissions for cyclamate were not reinstated.

FSANZ has been unable to obtain information as to why Canada only permits cyclamate in tabletop sweeteners.

10. Australian Food and Grocery Council (AFGC)

- Supports Option 4 – to reduce cyclamate permissions in water-based flavoured drinks and reinstate cyclamate permissions for tabletop sweeteners.
- Notes that this option provides an appropriate level of risk management for 2-11 year olds from excessive consumption of cyclamate in water-based flavoured drinks. Permitting cyclamate in tabletop sweeteners will provide greater opportunity and choice for industry and consumers and provides an opportunity for increased competitiveness and reduced cost.
- Proposes that the draft variation to omit permission to use cyclamate in water-based flavoured drinks at a level of 600 mg/kg take effect 12 months from the date of gazettal. This will allow industry sufficient time to evaluate and reformulate products, and implement labelling changes.
- Notes that stock-in-trade provisions only permit the product manufactured prior to the date of gazettal and complying with the previous levels to be sold for 12 months from the date of gazettal and does not relate to the ongoing manufacture of products. As such, there is no period of grace under this Proposal. Section 9.1 of the DAR implies that manufacturers would have 12 months from the date of gazettal to reformulate products, however this intent is not reflected in the drafting.
- Is advised that a minimum level of 300 mg/kg cyclamate is necessary to accommodate high temperatures across a range of climatic conditions in Australia and to achieve an effective shelf-life.
- Supports the decision not to reduce the maximum permitted level to 250 mg/kg as adopted in the EU as it is too low for Australian and New Zealand conditions.

- Notes that reducing the level of cyclamate by 50% will require research by industry to develop the appropriate combination of sweeteners to achieve the desired effect.
- Also notes that Application A540 for the use of Steviol Glycoside as a new intense sweetener is currently being assessed and if approved, may have applications that could reduce the current use levels of cyclamate.

11. Tasmanian Department of Health and Human Services

- Supports Option 3 – reduce cyclamate permissions in water-based flavoured drinks from 600 mg/kg to 300 mg/kg and no re-instatement of cyclamate permissions in tabletop sweeteners.
- Recommends ongoing surveys of intense sweeteners to determine whether the proposed risk management strategies for cyclamates have been effective.
- Notes that modelling of tabletop sweeteners was limited to current usage, however, as cyclamate is more heat stable than some other sweeteners, the tabletop usage may be extended. This could include tabletop use for fruit, cereal and hot beverages and in cooking, and this might change the results from the food modelling in the risk assessment.
- Considers that limiting cyclamate-containing tabletop sweeteners to single serve or small packs would reduce the risk of young children and 25-39 year old male high consumers over-consuming cyclamate in foods and beverages prepared in the home.

12. The Cancer Council NSW

- Supports Option 3 - reduce cyclamate permissions in water-based flavoured drinks from 600 mg/kg to 300 mg/kg and no re-instatement of cyclamate permissions in tabletop sweeteners.
- Believes that the regulatory measures for water based beverages and tabletop sweeteners should be consistent. A reduction in cyclamate permissions in water-based beverages and reinstatement of permissions for cyclamate in tabletop sweeteners could be perceived as a contradictory regulatory measure.
- Believes it is necessary that food regulation supports the Dietary Guidelines which encourage water as the main beverage of choice, and also recommend the consumption of milk over other types of beverages, especially for children.
- Is concerned about the high consumption of soft drinks on the market, both sugar sweetened and artificially sweetened, which displace more desirable beverages from the diets of both adults and children.
- Considers it is essential that food regulatory measures take into account the necessity for such beverages which include artificial sweeteners, as well as ensuring public health and safety.

13. NSW Food Authority

- Supports Option 4 to reduce the cyclamate permissions in water-based flavoured drinks and re-instate permissions for tabletop sweeteners.
- Recognises that there is likely to be a lower proportion of respondents exceeding the ADI than the reported 3-5% of 2-11 year as the dietary modelling may result in a slight overestimate of the population's exposure to cyclamates.

- Considers that, in light of the age of the consumption data used, FSANZ should consider providing a market share weighted estimate of cyclamate exposure from soft drinks and/or a comparison of intensely sweetened soft drinks available now and in 1995, in the FAR.
- Believes that consultation with industry is required to address the following questions in the FAR:

    - Whether manufacturers intend to reduce cyclamate levels at the expense of increasing other intense sweeteners.
    - How often do manufacturers alter the level of and type of intense sweetener used in their products?
    - Was the External Advisory Group consulted on such issues?

- Questions whether the full set of results from the *2003 Consumption of Intense Sweeteners Survey* could be included in the FAR.

FSANZ response

At Draft Assessment FSANZ sought additional information in relation to market share data for carbonated soft drinks and cordials, however, no additional information was provided by submitters in response to this request. Therefore, the dietary modelling is based on the best available data.

FSANZ has consulted with industry on numerous occasions during the development of this Proposal. Based on these consultations and FSANZ's own research, if the level of cyclamates are to be reduced or removed from a product, then it is necessary to alter the ratios of other intense sweeteners that are used in the product or to introduce alternative sweeteners to obtain the desired flavour and to maintain shelf-life. The External Advisory Group (EAG) was consulted in the initial stages of the Proposal however, it was not considered necessary to reconvene the EAG as FSANZ consulted the various representative industry bodies separately, as required, during the various stages of the Proposal.

FSANZ does not consider that it is appropriate to include the full results of the *2003 Consumption of Intense Sweeteners Survey* in the FAR. Since the survey was undertaken, FSANZ has undertaken revised dietary exposure estimates using manufacturers current use levels of cyclamates and it is these results that are presented and discussed in this Proposal. The *2003 Consumption of Intense Sweeteners Survey* can be obtained from FSANZ's website at
http://www.foodstandards.gov.au/newsroom/publications/intensesweetenerssurveymarch2004/index.cfm

14. NSW Centre for Public Health Nutrition (CPHN)

- Supports FSANZ's preferred option to reduce the cyclamate content of cordials and soft drinks, however, advises caution in the proposed option for maximum permitted levels of cyclamate in tabletop sweeteners.
- Notes that lowering cyclamates in water-based flavoured beverages will lead to changes in the formulation of intensely sweetened drinks and that FSANZ believes there is no public health risk when the use of other sweeteners is increased to compensate for the reduced use of cyclamate.

- Believes that unless consumption/sales data for those intensely sweetened drinks are made available, public health and safety cannot be ensured.
- Recommends that post-enforcement dietary modelling of the intake of other intense sweeteners should be carried out to ensure that the ADI for other intense sweeteners is not exceeded.
- Suggests that any possible harmful synergistic effects of combined intense sweeteners, particularly from newer combinations, need to be considered.
- Notes that there is no information provided about how the maximum permitted level of cyclamate in tabletop sweeteners translates into daily consumption of cyclamate for heavy users of tabletop sweeteners (e.g. diabetes/impaired glucose tolerance and dieters) and would like to see this information in the FAR.
- States that the likely cyclamate content of tabletop sweeteners is unclear and it is therefore difficult to model average daily intake. Cyclamate would probably be mixed with saccharin (or other sweetener) to obtain sufficient sweetness and this would be a preferred outcome.
- Recommends that the two components of the proposed changes to the cyclamate food standards be considered as two separate proposals.
- Supports public health interventions that promote consumption of water as the beverage of choice.

FSANZ Response

As discussed in Section 9.1.6, a further follow-up survey on intense sweeteners is planned as part of FSANZ's Evaluation Strategy 2004-2008. It is anticipated that this survey would evaluate the impact of any amendments to cyclamate permissions as a result of this Proposal, including any corresponding increase in the consumption of other intense sweeteners. Following an evaluation of this data, any risks to public health and safety would be considered and risk management options identified.

FSANZ acknowledges that the consideration of cyclamate in tabletop sweeteners adds a degree of complexity to this Proposal. However, FSANZ has previously provided an undertaking to Hermes Sweeteners (UK) (the applicant for the former Application A515) that it would consider their Application as part of Proposal P287.

15. Department of Human Services Victoria (DHS)

- Supports the proposal to 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.
- Does not support the proposal to allow the use of cyclamates in tabletop sweeteners at the level of Good Manufacturing Practice (GMP).
- Considers that the cyclamate dietary exposure estimates for children aged 2-11 years may be significant underestimates as the data is derived from the 1995 NNS and the consumption of intensely sweetened products has changed substantially over the last 12 years. This is concerning, given that this sub-population has the highest exposure rates per kilogram body weight and potentially will have the longest lifetime exposures.
- Considers that consumption or exposure data for New Zealand children aged 2-11 years should be obtained - it is not acceptable to make assumptions in the absence of data when undertaking a health and safety risk assessment.

- Is concerned that the proposed reduction in cyclamate levels will still result in dietary exposure estimates that exceed the European ADI for cyclamate.
- Notes that the consumption rates of tabletop sweeteners for young children are not known.
- Notes that the minimum quantity of cyclamate needed to achieve the technological purpose is not provided in the DAR.
- Questions whether FSANZ should consider reducing cyclamate levels to less than 300 mg/kg, given the increased availability of numerous alternative intense sweeteners that may be safer and the overseas practice of 0-250 mg/kg levels of cyclamate in water-based drinks.
- Requests that the FAR explain why there is a downward trend favouring the elimination of cyclamate in water-based drinks.
- States that the reduction of cyclamate permissions in water-based flavoured drinks from 600 mg/kg to 300 mg/kg will mean that Australian and New Zealand permissions will be nearer to the EU and UK permissions of 250 mg/kg.

FSANZ response

Some manufacturers have chosen to replace cyclamate with alternative sweeteners but not all. It is not known specifically why this is the case, however this may be due to a combination of factors such as the development of alternative low-cost sweeteners or for trade reasons.

16. Australian Beverages Council Ltd (ABCL)

- Supports FSANZ's risk assessment and outcomes confirming the use of 11 mg/kg body weight as the appropriate limit for the ADI for cyclamate. This is consistent with the ADI established by JECFA.
- Accepts the basis for the recommendation by FSANZ for the reduced maximum permitted limit for cyclamate to 300 mg/kg, however, is seeking a maximum limit of 400 mg/kg.
- Does not agree that all products may be reformulated to a limit of 300 mg/kg. Reformulation has been done for products that are seen as "easier" to reformulate, however, those formulations that are considered to be more complex are yet to be addressed.
- Notes that the proposed reduction to just 50% of the current limit is a substantial reduction and will be a major challenge for some products, particularly smaller manufacturers.
- Notes the comments and the technical assessment submitted to FSANZ from the Calorie Control Council in support of the higher limit.
- States that cyclamate is a stable intense sweetener. As part of a blend of sweeteners, its synergistic effects allows bottlers to minimise the total amounts of sweeteners added to low joule beverages.
- Exceedance of the ADI should not be automatically viewed as a safety concern.
- Believes that the benefits (of cyclamate) do not outweigh the costs of reformulation. Acceptable cyclamate/saccharin blends provide lower cost, low joule products and the switch to higher cost intensive sweeteners may result in a negative impact on lower socio-economic groups, with a reduction in beverage choice or a switch to less appropriate products.

- Considers that the 12-month stock-in-trade provision does not allow sufficient time for product reformulation and the requirements, for new labels and associated materials, particularly for smaller manufacturers and therefore seeks a minimum of 18 months from gazettal to implement changes.
- Notes that smaller, regional manufacturers are often dependent on third party organisations to conduct reformulations. It was further noted that reformulations involving such substantial reductions in sweetener levels are not simple projects, particularly when such formulations involve the use of additional sweeteners. The synergistic effects of the combination of sweeteners will need to be addressed.

17. National SPS Enquiry Point of China

- Notes that Australia is proposing to modify the limit of cyclamate in water-based drinks from the present 600 mg/kg to 300 mg/kg, which is different from the CAC standard of 400 mg/kg.
- Suggests that Australia adopts the CAC limit of 400 mg/kg based on the principle of harmonisation with international standards and to avoid unnecessary barriers to trade.

Attachment 7

Business Cost Calculator Report

P 287 – Review of Cyclamate Permissions

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.
Objective:	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.

Policy Options

Option Name	Quickscan Result
Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners	FALSE
Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and re-instate cyclamate permissions in tabletop sweeteners	FALSE
Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners	FALSE
Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and re-instate cyclamate permissions in tabletop sweeteners	FALSE

Compliance Cost Summary

Option Name:	Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners
Businesses Affected:	N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Option Name:	Reduce cyclamate permissions in water-based flavoured drinks to 350 mg/kg and re-instate cyclamate permissions in tabletop sweeteners
Businesses Affected:	N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Option Name:	Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and do not re-instate cyclamate permissions in tabletop sweeteners
Businesses Affected:	N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Option Name:	Reduce cyclamate permissions in water-based flavoured drinks to 400 mg/kg and re-instate cyclamate permissions in tabletop sweeteners
Businesses Affected:	N/A

Type	Cost per Business	Total Cost of Regulation
N/A	N/A	N/A

Caution should be used comparing options and interpreting results over time. The Business Cost Calculator does not estimate the future values of ongoing costs. Refer to the User Guidelines for further information.

This report contains summaries of compliance costs only. An assessment on the compliance cost in itself does not provide an answer to which policy option is the most effective and efficient one. Rather, it provides information which needs to be considered alongside other relevant factors and issues when deciding between alternative policy options.