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

4-05
25 May 2005

FINAL ASSESSMENT REPORT

APPLICATION A469

SACCHARIN IN WATER-BASED FLAVOURED DRINKS

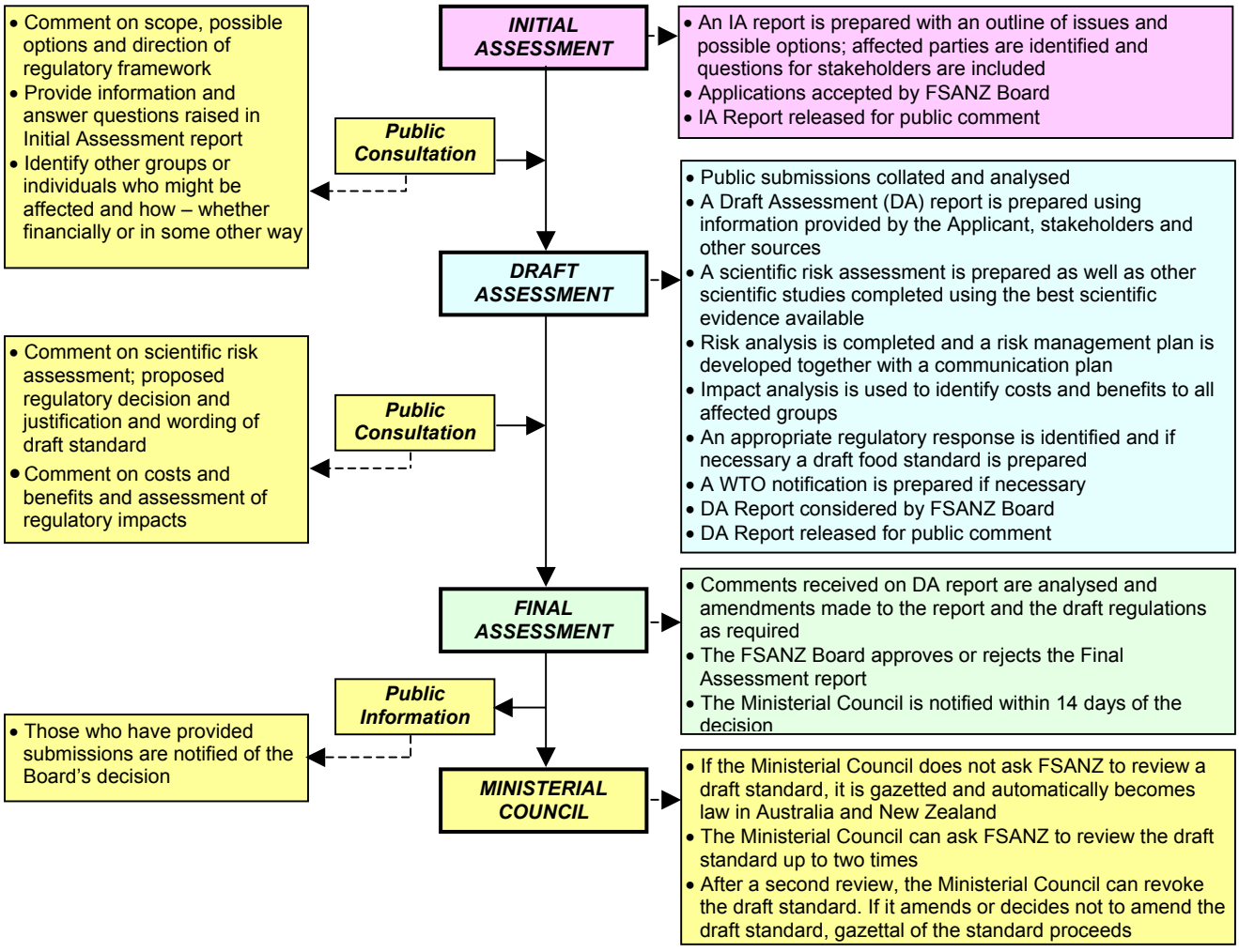
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

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Executive Summary and Statement of Reasons

The Australasian Soft Drinks Association Ltd (ASDA) submitted an Application on 6 June 2002 to amend category 14.1.3 of Schedule 1 in Standard 1.3.1 – Food Additives, in the *Australia New Zealand Food Standards Code* (the Code) to increase the maximum permitted levels of saccharin and cyclamate in water-based flavoured drinks, including soft drinks and cordials.

On 14 April 2004 ASDA, which is now known as the Australian Beverages Council, withdrew the request to increase the maximum permitted level of cyclamate in water-based flavoured drinks. The Application is now restricted to consideration of an amendment to increase the maximum permitted level of saccharin in water-based flavoured drinks from 80 mg/kg to 150 mg/kg.

The Applicant originally requested amendment to the current permissions for the maximum levels of saccharin (150 mg/kg) and cyclamate (1,200 mg/kg) for inclusion in diet cordials and diet soft drinks. The Applicant claimed that the requested levels are considerably lower than those permitted for use in the former Australian *Food Standards Code* and that were permitted for use during the transition period until the end of December 2002 (i.e. saccharin 1.5 g/kg or 1,500 mg/kg and cyclamate 20 g/kg or 20,000 mg/kg). However they are higher than those adopted in the current Code (saccharin 80 mg/kg and cyclamate 600 mg/kg). The Applicant claimed that current permitted levels would force some beverage manufacturers to either withdraw their products from the market place or to reformulate to the legally permitted levels, which are insufficient for acceptable sweetness.

The risk assessment for this Application concluded that there are no expected public health and safety concerns for Australian and New Zealand consumers if permission is provided to increase the maximum saccharin levels to 150 mg/kg in diet cordials and diet soft drinks. This conclusion is based on dietary exposure assessment using manufacturers' data on levels used by the food industry, which provides a more realistic estimate of current dietary exposure to saccharin rather than using maximum permitted levels for the whole category in the Code. The Food Technology Report concludes that the requested maximum permitted level of 150 mg/kg for saccharin in water-based flavoured drinks is technologically justified.

The regulatory impact analysis concluded that amending Standard 1.3.1 – Food Additives, to permit saccharin to a maximum level of 150 mg/kg in water-based flavoured drinks potentially provides benefits to the food industry and consumers with very little associated impact on any sector.

Statement of Reasons

The draft variation to Standard 1.3.1 – Food Additives, approving the use of saccharin to a maximum permitted level of 150 mg/kg in water-based flavoured drinks, is recommended for the following reasons:

- there are no expected public health and safety concerns for Australian and New Zealand consumers if the maximum permitted level of saccharin in water-based flavoured drinks is increased from 80 to 150 mg/kg;

- the addition of saccharin as an intense sweetener in water-based flavoured drinks is technologically justified;

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act;

- the regulation impact assessment has concluded that the benefits of increasing the maximum permitted level of saccharin in water-based flavoured drinks outweigh any costs; and

- there are no alternatives that are more cost effective than a variation to Standard 1.3.1. to achieve what the Application seeks, namely permission to increase the maximum level of saccharin in water based flavoured drinks to 150 mg/kg.

If approved, the variation to the Code will come into effect on the date of gazettal.

1. Introduction

The Australian Soft Drinks Association Ltd (ASDA) submitted an Application on 6 June 2002 to amend category 14.1.3 of Schedule 1 of Standard 1.3.1 – Food Additives, in the Code to increase the maximum permitted levels of saccharin and cyclamate in water based flavoured drinks, including soft drinks and cordials. The Applicant is now known as the Australian Beverages Council. The Applicant withdrew the request for an increase in cyclamate levels on 14 April 2004 and the Application is now restricted to consideration of an increase in saccharin levels in water-based flavoured drinks.

2. Regulatory Problem

The Applicant requests increased maximum levels of permission for saccharin (to 150 mg/kg) for inclusion in diet cordials and diet soft drinks. The requested level is higher than the current level in the Code (80 mg/kg). The Applicant claims that the requested level is considerably lower than the maximum level permitted for use in the former Australian *Food Standards Code* and during the transition period until the end of December 2002 (i.e. 1.5 g/kg or 1,500 mg/kg).

The Applicant claims that the current permitted level will force some beverage manufacturers to either withdraw their products from the market place or to reformulate to the legally permitted level, which is insufficient for acceptable sweetness.

2.1 Current Regulations

Category 14.1.3 of Schedule 1 to Standard 1.3.1 - Food Additives, provides a maximum permitted level of 80 mg/kg for saccharin in water-based flavoured drinks.

2.2 Regulatory Situation Overseas

2.2.1 International

The draft Codex General Standard for Food Additives (GSFA, 2001) listed saccharin (954) in categories 14.1.4.1 – Carbonated beverages, and 14.1.4.2 – Non-carbonated, including punches and ades, at a level of 500 mg/kg. This listing is not present in the latest version of the draft GSFA (rev. 3, 2004) as saccharin has not yet been reviewed for this purpose by the Codex Committee on Food Additives and Contaminants (CCFAC). The level in the former draft GSFA was provided as *prima facie* evidence of technological need based on permitted levels in at least 2 countries.

2.2.2 United States - Code of Federal Regulations

The following information has been extracted from the United States – Code of Federal Regulations, related to permissions for use of saccharin in food.

21CFR180.37 The food additives saccharin, ammonium saccharin, calcium saccharin and sodium saccharin may be safely used as sweetening agents in food in accordance with the following conditions, if the substitution for nutritive sweeteners is for a valid special dietary purpose and is in accord with current special dietary food regulations and policies or if the use or intended use is for an authorized technological purpose other than calorie reduction:

(a) Saccharin is the chemical, 1,2-benzisothiazolin-3-one-1,1-dioxide. The named salts of saccharin are produced by the additional neutralization of saccharin with the proper base to yield the desired salt.
(b) The food additives meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22, 62, 266-267, 297-299.
(c) Authority for such use shall expire when the Commissioner receives the final reports on the ongoing studies in Canada and publishes an order on the safety of saccharin and its salts based on those reports and other available data.
(d) The additives are used or intended for use as a sweetening agent only in special dietary foods, as follows:

(1) In beverages, fruit juice drinks, and bases or mixes when prepared for consumption in accordance with directions, in amounts not to exceed 12 milligrams of the additive, calculated as saccharin, per fluid ounce *(i.e. about 400 mg/Litre).*
(2) As a sugar substitute for cooking or table use, in amounts not to exceed 20 milligrams of the additive, calculated as saccharin, for each expressed teaspoonful of sugar sweetening equivalency.
(3) In processed foods, in amounts not to exceed 30 milligrams of the additive, calculated as saccharin, per serving of designated size.

2.2.3 European Union directive 94/35/EC of 30 June 1994 - on sweeteners for use in foodstuffs

Saccharin and its sodium, potassium and calcium salts (E954) are permitted in energy reduced water-based flavoured drinks or water-based flavoured drinks with no added sugar to a maximum usable dose of 80 mg/l. E954 is also listed at 100 mg/l for 'Gaseosa', a non-alcoholic drink with carbon dioxide, sweeteners and flavourings.

3. Objective

The objective of this assessment is to determine if it is appropriate to increase the permitted level of saccharin in water based flavoured drinks.

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

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

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

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;

- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Historical Background

FSANZ has conducted two major dietary exposure assessments for saccharin and cyclamate over the last 10 years. The first of these was a detailed, brand-level study in 1994 of the consumption of intense sweetened foods by Australians aged 12-39 years. The second was an estimate of exposure prepared using food consumption data derived from the 1995 Australian National Nutrition Surveys (NNS), prepared as part of the review of food additives during the development of the joint standard on food additives (P150 – Review of Food Additives).

In both of these assessments, the Acceptable Daily Intake (ADI) used was 5 mg/kg body weight (bw) for saccharin. The results for cyclamate are not relevant for the revised Application.

5. Relevant Issues

5.1 The review of the former Australian *Food Standards Code* following dietary exposure assessment

During the review of the former Australian *Food Standards Code*, the permitted levels for cyclamates and saccharin were determined for the broad category of water-based flavoured drinks. Safety concerns were raised for the use of both sweeteners at the high levels formerly permitted and the maximum permitted levels were significantly reduced based on the results of dietary modelling at the time of the review.

5.2 Safety Assessment

Saccharin is a condensed heterocyclic ortho-sulfobenzimide, discovered in the late 1870s by chemists in the USA. It is commercially available in four forms: acid saccharin, sodium saccharin, ammonium saccharin and calcium saccharin. Sodium saccharin is the most commonly used form because of its high solubility, stability and low production costs[1]. Saccharin is excreted unchanged predominantly in the urine, and no evidence suggests that it is metabolised in animals or humans[2].

[1] O'Brien Nabors L., (2001). Alternative Sweeteners. Third Edition. Marcel Dekker Inc., New York.
[2] Sweatman T.W. and Renwick A.G., (1980) The tissue distribution and pharmacokinetics of saccharin in the rat. Toxicol. Appl. Pharmacol., 55, 18-31. In: O'Brien Nabors L. Alternative Sweeteners. Third edition. Marcel Dekker Inc, New York. 2001

Saccharin has been in use for over a century and the Joint FAO/WHO Committee on Food Additives (JECFA) has considered the data on saccharin on several occasions. JECFA allocated a temporary acceptable daily intake (ADI) of 0 to 2.5 mg/kg bw/day at its 21st meeting in 1977, due to concerns over the carcinogenic potential in animals following high dietary doses of saccharin[3].

Saccharin in its sodium form has been tested in numerous chronic feeding studies and in all single-generation studies there was no evidence of tumour formation. However, a statistically significant increase in urinary bladder tumours was found in male rats in two-generation feeding studies at high dose levels (>3% in diet). Saccharin also produced pathological changes (formation of urinary calcium-phosphate precipitates, cytotoxicity and hyperplasia) in the bladder prior to the development of tumours at high dose levels and it is generally considered that the bladder changes, which occurred, were a direct precursor to the formation of tumours. At lower dose levels, there was no tumour formation, nor evidence of pathological changes in the bladder. Saccharin has not been shown to bind to DNA *in vivo,* although sodium saccharin has exhibited clastogenic activity *in vitro* and *in vivo* (animal studies) at high concentrations suggesting that clastogenic activity may be due to ionic imbalances at the chromosomal level at high concentrations[3].

Extensive epidemiological studies in human populations have shown no increased risk of bladder cancer in humans and in 1997 the International Agency for Research on Cancer (IARC) concluded that the bladder tumours in male rats following high dietary exposure to saccharin was not relevant to humans[3].

JECFA's most recent evaluation, considered that the 1% dietary level in the most recent 2-generation feeding study in rats (equivalent to 500 mg/kg bw/day) was the No Observed Effect Level (NOEL). A similar NOEL of 500 mg/kg bw/day was observed in long-term toxicity studies in monkeys. Consequently, JECFA allocated an ADI of 0-5 mg/kg bw/day to saccharin and its calcium, potassium, and sodium salts, based on a 2-generation feeding study in rats incorporating a safety factor of 100[3].

5.3 Dietary Exposure Assessment

A Dietary Exposure Assessment (**Attachment 3)** was undertaken to determine the potential exposure to saccharin for the specific request from the Applicant to increase levels of permission for saccharin (from 80 mg/kg to 150 mg/kg) for inclusion in diet cordials and diet soft drinks.

Four scenarios were modelled for the purpose of this Application.

- Scenario 1 ('baseline' scenario) assumes that saccharin is present in foods at the maximum permitted levels (MPLs) currently listed in the Code;

- Scenario 2 ('baseline plus request by Applicant) assumes that saccharin is present in foods at the MPLs currently listed in the Code, with the exception of intense sweetened soft drinks and intense sweetened cordials that were assigned the maximum permitted saccharin concentrations that were requested by the Applicant;

[3] WHO (1993) Evaluation of certain food additives and contaminants. WHO Technical Report Series. 837

- Scenario 3 ('baseline manufacturer's use' scenario) is based on saccharin concentrations derived from the intense sweetener survey carried out by FSANZ (FSANZ, 2004)[4]. If no manufacturers' use levels were available, then the MPL in the Code was used. Intense sweetened cordials and artificially sweetened soft drinks were assigned the current MPLs to enable a comparison with proposed MPLs from the Application in Scenario 4; and

- Scenario 4 ('baseline manufacturers use plus request by Applicant) is based on manufacturers use levels (as discussed for Scenario 3) and assesses the potential exposure should the MPLs for saccharin requested in the Application be approved.

Scenario 1 ('baseline') estimated mean dietary exposures for consumers of saccharin were the lowest for Australians aged 2 years and above at 29% ADI and were the highest for Australian children aged 2-6 years at 42% ADI. The estimated 95th percentile dietary exposures were lowest at 109% ADI and highest at 132% ADI for Australians aged 2 years and above and 2-6 years, respectively.

Scenario 2 ('baseline plus request by Applicant') estimated mean dietary exposures for consumers of saccharin were lowest at 31% ADI for Australians aged 2 years and above and highest at 43% ADI for Australian children aged 2-6 years. Estimated 95th percentile dietary exposures for consumers of saccharin for Scenario 2 range were lowest for Australians aged 2 years and above at 111% ADI and highest for Australian children aged 2-6 years at 132% ADI.

Scenario 3 ('baseline manufacturers use levels') estimated mean dietary exposures for consumers of saccharin were lowest at 17% ADI for Australians aged 2 years and above and highest for Australian children aged 2-6 years at 19% ADI. Estimated 95th percentile dietary exposures for consumers of saccharin were lowest at 45% ADI for Australian children aged 2-6 years and highest for New Zealanders aged 15 years and above at 95% ADI.

When Scenario 4 ('manufacturers use level plus A469') estimated mean dietary exposures for consumers of saccharin were considered, the lowest dietary exposure was estimated at 18% ADI (for Australians aged 2 years and above) and the highest at 21% ADI (for Australian children aged 2-6 years). Estimated 95th percentile dietary exposures for consumers of saccharin for Scenario 4 were lowest at 61% ADI (for Australian children aged 2-6 years) and highest at 95% ADI (for New Zealanders aged 15 years and above).

Higher exposures for children are due to their lower body weights and their higher food consumption per kilogram of body weight compared to adults.

Scenarios 3 and 4 provide the more realistic estimates of dietary exposure to saccharin since they are based on the saccharin levels that are actually used in the manufacture of food products rather than the MPLs listed in the Code. When Scenarios 3 and 4 are considered, mean and 95th percentile dietary exposures are below the ADI for all population groups examined.

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

5.4 Risk Characterisation

The conclusions from the Safety Assessment (section 5.2) and Dietary Exposure Assessment (section 5.3 and **Attachment 3**) analysis are as follows:

- Although toxicological concerns have been identified following high dietary exposure of saccharin in the diets of rats, this appears to be a species-specific effect in male rats only, with no evidence of a public health and safety concerns for humans.

- JECFA established an ADI of 5 mg/kg bw/day which is considered the safe level of exposure for humans.

- For the population groups assessed, mean consumers were below the ADI for all four scenario's modelled.

- Scenario's 1 and 2 demonstrated that high consumers (95th percentile) of saccharin exceeded the ADI with the highest exposure of 132% for Australian children aged 2-6 years. However, conservative assumptions were used in the modelling for both these scenarios, which would overestimate consumption in the populations assessed. In addition, there are limitations inherent in the dietary modelling (e.g. 24 hour food consumption data estimates are higher than would be consumed over a longer period of time)[5].

- When manufacturer's levels were used to calculate dietary exposure to saccharin, high consumers for all populations groups were below the ADI.

The use of manufacturers' data provides a more realistic estimate of dietary exposure to saccharin in the current market place, as the assessment is based on saccharin levels that are used in the food manufacturing industry rather than the MPLs listed in the Code. There are no expected public health and safety concerns for Australian and New Zealand consumers if the permission to increase saccharin levels to 150 mg/kg for inclusion in diet cordials and diet soft drinks is granted.

5.5 Reformulation for New Sweetener Levels

The Applicant contended that revised maximum permitted level of 80 mg/kg for saccharin would require some manufacturers of soft drinks and cordials to reformulate or withdraw their products from the marketplace. The industry considers that this is not necessary, given that products containing up to the requested level of 150 mg/kg have had a history of safe consumption in the market place for a number of years.

The Applicant contended that reformulating existing products not only uses up valuable time and resources, but can result in a loss of sales and market share for the products concerned. In the case of low joule cordials and diet soft drinks, which use mainly a combination of saccharin and cyclamate for sweetening purposes, reformulation would be a lengthy process, primarily due to having to obtain a new combination of sweeteners with the right synergistic properties.

[5] Refer to Dietary Exposure Assessment Report for a fuller discussion of assumptions and limitations in the modelling.

Sweeteners have a great impact on the acceptance of beverages, affecting not only the taste but also their texture. Beverage manufacturers have been using sweetener blends instead of single sweeteners in reduced calorie beverages for a long time with many successful products well established in the market place. The first commercial sweetener blend was saccharin and cyclamate.

The primary advantage of a saccharin and cyclamate blend is that saccharin (300 times sweeter than sucrose) boosts the sweetening power of cyclamate (30 times sweeter than sucrose), while cyclamate masks the aftertaste some people associate with saccharin.

The significance of the costs of reformulation has diminished as the request for an increase in the cyclamate level was withdrawn and 2 years have passed since the initial Application was received.

5.6 Intense Sweetener Exposure in Australia and New Zealand

FSANZ conducted a detailed survey of use of intense-sweetened foods in Australia and New Zealand in 2004, which included revised estimates of exposure to intense sweeteners, including saccharin. Information on saccharin from the detailed survey is included in the Dietary Exposure Assessment Report for this Application (**Attachment 3**).

5.7 Technological Justification

Saccharin is used in more than 100 countries in soft drinks, confectionery, preserves, salad dressings, desserts and combined with bulking agents in baked products. Saccharin has other food applications and is also a popular choice in oral-hygiene products. To replace the sweetness in soft drinks containing up to 15% sugars, at a conversion rate of 300 to 1, up to 1,500 mg/kg of saccharin would be required. Saccharin is typically formulated with other sweeteners or masking agents to avoid the bitter after-taste perceived by some individuals at higher concentrations.

The Food Technology Report concludes that the use of saccharin as a sweetener in water-based flavoured drinks at 150 mg/kg is technologically justified (**Attachment 4**).

5.8 Issues Raised in Public Submissions

Eleven submissions were received in response to the Initial Assessment Report for A469. Three submissions supported the Application and another submission provided tentative support if the safety concerns were addressed.

Five submissions opposed the Application, while another submission contained information from a website opposing another sweetener, aspartame. The last submission deferred comment until Draft Assessment.

Eleven submissions were received in response to the Draft Assessment Report. All submissions, including that of the Applicant, supported the Application.

The summary of submissions is at **Attachment 2**.

5.8.1 Safety Assessment Required

The Australian Food and Grocery Council (AFGC) supported the Application subject to safety assessment. The Food Technology Association (FTA) of Victoria also supported the Application but expressed concerns about excess consumption of cyclamate from cordials. Queensland Public Health Services (QPHS) tentatively supported the Application, but mentioned safety concerns raised in FSANZ's review of additives, the USA not permitting cyclamate and concern for sensitive subgroups; children, adolescents and pregnant women.

The opposing submissions were also concerned about safety assessment, particularly for the requested cyclamate increase. The New Zealand Food Safety Authority (NZFSA) noted dietary advice from the EU limiting cyclamate intakes. The State Chemistry Laboratory of Victoria noted the action of the EC in lowering cyclamate levels. The Western Australian Food Advisory Committee will reconsider after assessment and the Department of Human Services in South Australia queried the justification for increased levels. The Dietitians Association of Australia (DAA) felt that enough opportunity for comment was provided in the review of additives and the Applicant could reapply if the FSANZ survey and dietary modelling indicated consumption was within safe limits.

After the Initial Assessment Report was circulated for comment and the submissions were received, the Applicant withdrew the request relating to increasing the maximum permission level for cyclamate. Issues raised in submissions relating to cyclamate permissions are no longer relevant for this Application.

Dietary modelling indicates that the increase in the maximum permitted level of saccharin does not raise health concerns.

The comments in Round 2 confirmed that the previous concerns about safety assessment in comments at Round 1 were mainly about cyclamate rather than saccharin. The AFGC, FTA, NZFSA, QPHS and DAA now fully support the Application. The Department of Human Resources Victoria supported the safety assessment and the technological justification. The NZFSA pointed out that the New Zealand Dietary Supplements Regulations also permit saccharin in drinks sold as dietary supplements and that the levels of saccharin in tablets and capsules should not significantly increase dietary intake.

5.8.2 Costs of Reformulation

The AFGC submitted that achieving sweetness profiles with combinations of sweeteners is difficult, time consuming and that storage tests are required. Product development work doesn't guarantee market success. The Calorie Control Council highlighted the costs of reformulation, packaging and labelling.

The NZFSA on the other hand, did not accept that time and resources for reformulation was sufficient justification for increasing levels. The DAA thought it was untimely and inappropriate to request amendment on the basis of need to reformulate or withdraw products, when opportunity for comment had been provided in the review of food additives.

The Food Technology Report addresses some of the difficulties associated with reformulation of intensely sweetened products and concludes that the increase in the maximum permitted level requested for saccharin is technologically justified.

The Department of Human Services in South Australia queried in its Round 2 comments why the Application was occurring now, two years after the current level was established. The Applicant did not object to the revised level established during the review of food additives. The original Application requesting increases in both saccharin and cyclamate levels for soft drinks, was received in June 2002. The Applicant withdrew the request for cyclamate in April 2004.

The significance of the costs of reformulation has diminished as 2 years have passed since the original Application was received and the Application is now for an increase in the maximum permitted level only for saccharin.

5.8.3 Different Levels for Cordials

The Food Technology Association (FTA) of Victoria suggested that separate levels of permission for sweeteners in soft drinks and cordials should be considered.

Standard 1.3.1 addresses this matter in clause 5 – Maximum permitted levels of additives. Where maximum levels are prescribed, unless otherwise stated, the level refers to the maximum amount which may be present in the food as sold or, where there are directions for preparation, when prepared for consumption.

This principle applies generically for dilution or concentration of foods containing all permitted food additives. There is no need to specify alternative levels for individual additives in the various food categories.

6. Regulatory Options

Options available are:

Option 1 Maintain the status quo, that is the maximum permitted level for saccharin in water based flavoured drinks remains unchanged.

Option 2 Amend Standard 1.3.1 - Food Additives, to permit saccharin to a maximum level of 150 mg/kg in water-based flavoured drinks.

7. Impact Analysis

Parties affected by the options outlined above include:

1. Those sectors of the beverage industry manufacturing and selling water-based flavoured drinks containing saccharin as a sweetener.

2. Consumers of water-based flavoured drinks containing saccharin as a sweetener.

3. Government agencies enforcing the food regulations.

7.1 Impact of Regulatory Options

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments.

7.1.1 Option 1

There are no perceived benefits to the food industry, consumers or government agencies if this option is taken. Parties potentially disadvantaged by not allowing for an increase in saccharin levels are those sectors of the food industry that market diet soft drinks and diet cordials.

7.2.2 Option 2

This option is likely to deliver a benefit to the food industry and consumers in that it will allow for an improved range of diet soft drinks and diet cordials to be marketed.

There would be little or no direct impact on government.

7.2.3 Conclusion

Option 2 is the preferred option. This option potentially provides benefits to both the food industry and consumers with very little associated negative impact on any sector.

8. Consultation

8.1 Public consultation

Public comment on the Initial Assessment Report was sought from 21 May 2003 to 2 July 2003. Eleven submissions were received in response to the Initial Assessment Report for A469, prior to receipt of the Applicant's letter of 14 April 2004 withdrawing the request to increase the maximum permitted level of cyclamate in water-based flavoured drinks.

Public comment on the Draft Assessment Report was sought from 15 December 2004 to 9 February 2005. Eleven submissions were received which all supported the Application.

Attachment 2 summarises the submissions received from both rounds of public comment. Issues raised in the submissions are discussed in section 5.8 above.

8.2 World Trade Organization (WTO) Notification

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

As amending the Code is unlikely to have a significant effect on trade, notification was not made to either the WTO Technical Barrier to Trade (TBT) and Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusion and Recommendation

This Final Assessment Report concludes that amending the Code to approve the use of saccharin to a maximum permitted level of 150 mg/kg in water based flavoured drinks is not expected to raise any public health and safety concerns. Therefore, it is recommended that Standard 1.3.1 be amended to increase the maximum permitted level of saccharin in water-based flavoured drinks from 80 mg/kg to 150 mg/kg for the following reasons:

- there are no expected public health and safety concerns for Australian and New Zealand consumers if the maximum permitted level of saccharin in water-based flavoured drinks is increased from 80 to 150 mg/kg;

- the addition of saccharin as an intense sweetener in water-based flavoured drinks is technologically justified;

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act;

- the regulation impact assessment has concluded that the benefits of increasing the maximum permitted level of saccharin in water-based flavoured drinks outweigh any costs; and

- there are no alternatives that are more cost effective than a variation to Standard 1.3.1. to achieve what the Application seeks, namely permission to increase the maximum level of saccharin in water based flavoured drinks to 150 mg/kg.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Summary of Submissions
3. Dietary Exposure Assessment Report
4. Food Technology Report

Attachment 1

DRAFT VARIATION TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard 1.3.1*** *of the Australia New Zealand Food Standards Code is varied by omitting from* Schedule 1, *under item* 14.1.3 Water based flavoured drinks*, *the entry for* Saccharin, *substituting* –

954	Saccharin	150	mg/kg

Attachment 2

Summary of Submissions

A 469 – Saccharin in Water-Based Flavoured Drinks

Round one

Note that submissions commented on both cyclamate and saccharin as the comment period closed on 2 July 2003 while Applicant's letter deleting the request for cyclamate was dated 14 April 2004

#	Submitter organisation	Name
1	Australian Food and Grocery Council	Tony Downer
2	Calorie Control Council	Lyn O'Brien Nabors
3	Food Technology Association of Victoria Inc	David Gill
4	Queensland Public Health Services	Gary Bielby
5	New Zealand Food safety Authority	Carole Inkster
6	Western Australian Food Advisory Committee	Virginia McLaughlin
7	Department of Human Services – South Australia	Joanne Cammans
8	Dietitians Association of Australia	Sue Cassidy
9	State Chemistry Laboratory, Victoria	Paul Lawicki
10	Brennan Dunn, Queensland	Brennan Dunn
11	Australian Quarantine and Inspection Service	Peter Maple

Submitter	Comment
1. Australian Food and Grocery Council	The AFGC supported the Application to increase the levels of both cyclamate and saccharin in water-based flavoured drinks, subject to safety assessment. It is an AFGC policy principle that provided an additive is safe it should be available for use in necessary quantities to fulfil its technological function and permit innovation and competitiveness in the food industry. The levels are significantly lower than in the former Australian Standard at 1.5 g/kg for saccharin. Achieving a sweetness profile with combinations of intense sweeteners is a difficult and time-consuming process. Storage tests in excess of a year may be necessary to ensure appropriate product quality throughout product shelf life. The market success of product development work for reformulation is uncertain.
2. Calorie Control Council	The international association of companies that make and use low-calorie sweeteners supported the application. Both saccharin and cyclamate have a long history of safe use. CCC quoted from FSANZ's assessment of Proposal P273 – intense sweeteners in jelly – about the excellent taste profile of saccharin/cyclamate blends and synergy leading to lower levels of use. The costs of reformulation as well as new packaging and labelling were highlighted.

Submitter	Comment
3. Food Technology Association of Victoria	FTA supported the application but suggested separate levels for soft drinks and undiluted cordials. Concern about excess consumption of cyclamate from cordials was expressed and FSANZ's sweetener survey was mentioned.
4. Queensland Public Health Services	QPHS tentatively supports the application if the safety concerns raised in the review of the Code about saccharin and cyclamate are addressed. The USA does not permit cyclamate in food. FSANZ must consider consumption by specific subgroups children, adolescents and pregnant women. If there is any question of public safety the application should not proceed.
5. New Zealand Food Safety Authority	NZFSA was concerned with the applicant's request to increase levels of both cyclamate and saccharin, noting dietary advice from the European Union regarding limiting cyclamate intakes. Risk assessment using dietary modelling and considering the FSANZ survey on the use of intense sweeteners was advised. NZFSA did not accept that time and resources for reformulation was sufficient justification for increasing levels.
6. Western Australian Food Advisory Committee	The committee supports rejection of the application, but will reconsider when additional data on exposure and health risk assessments are done.
7. Department of Human Services – South Australia	There does not appear to be much justification for supporting amendment of the permitted levels if the safety assessment supports the current levels.
8. Dietitians Association of Australia	The DAA supports rejection of the application. The current levels should stand until the FSANZ survey results are available. All manufacturers were given the opportunity to comment prior to adoption of the additive standard in 2002. It is therefore untimely and inappropriate to request amendment on the basis of the need to reformulate or withdraw products. The applicant can reapply if the survey and dietary modelling indicate that the likely consumption will be well within safe limits.
9. State Chemistry Laboratory, Victoria	The EU Scientific Committee for Food has lowered the ADI for cyclamate from 11 to 7 mg/kg bw. The European Commission reduced the level of cyclamate in soft drinks from 400 to 350 mg/L.
10. Brennan Dunn, Queensland.	This comment contains information from a website opposing the use of aspartame.
11. Australian Quarantine and Inspection Service	AQIS deferred comment until the draft assessment report is available

Round two

#	Submitter Organisation	Name
1	Calorie Control Council	Lyn O'Brien Nabors
2	New Zealand Juice & Beverage Association	John Robertson
3	Cadbury Schweppes Pty Ltd	Neil Smith
4	Dietitians Association of Australia	Sue Cassidy
5	Department of Health, South Australia	Kirsten Potoczky
6	Food Technology Association of Victoria Inc.	David Gill
7	Australian Beverages Council Ltd	Tony Gentile
8	New Zealand Food Safety Authority	Carole Inkster
9	Queensland Health	Gary Bielby
10	Dept of Human Services Victoria	Victor Di Paola
11	Australian Food and Grocery Council	Tony Downer

Submitter	Comment
Calorie Control Council	The Council supports the option to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks (option 2). The submission states that the proposed increase in permissions should not raise any public health and safety concerns and is technologically justified, as stated in the Draft Assessment Report.
New Zealand Juice & Beverage Association	The submission supports the option to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks (option 2). This recommendation is because the Dietary Exposure Assessment Report indicates public health and safety is protected and the proposed amendment is technologically justified (Food Technology Report).
Cadbury Schweppes Pty Ltd	The submission supports the option to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks. (option 2).
Dietitians Association of Australia	The Association supports option 2 (to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks).
Department of Health, South Australia	The department can not see any public health and safety reason why the Application should not proceed to final assessment. However the submission queried why the Application to increase the saccharin limits is occurring now, 2 years after the current level was established, that will require expensive reformulation and which the Applicant was trying to avoid in the first instance.
Food Technology Association of Victoria Inc.	The submitter supports option 2 – to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks.
Australian Beverages Council Ltd	The submitter (who is the Applicant) supports the recommendation to raise the maximum permitted level for saccharin in beverages from 80 mg/L to 150 mg/L (option 2). They agree with the conclusion of page 55 of the Draft Assessment Report that the proposed change is technologically justified.
New Zealand Food Safety Authority	The submitter supports option 2 – to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks. They point out that saccharin is also permitted in dietary supplements in the New Zealand Dietary Supplements Regulations. Levels in capsules and tablets should not significantly increase dietary intake, drinks sold as dietary supplements may contain saccharin, which needs to be acknowledged in the final assessment.

Submitter	Comment
Queensland Health	The submitter supports option 2 – to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks. They base their support on the fact that the Risk Assessment concluded that there are no expected public health and safety concerns with the proposed amendment. As well the Food Technology Report concluded that the requested increase in permitted levels is technologically justified.
Dept of Human Services Victoria	The submission supports option 2 (to amend the Code to permit saccharin to a maximum of 150 mg/kg in water-based flavoured drinks). Concerns around adverse health outcomes as a result of excess saccharin consumption appear to be unsubstantiated. For Australians to exceed the Acceptable Daily Intake (ADI) of saccharin, intake would have to increase ten-fold. As well saccharin is not metabolised in the human gut with the majority readily excreted, so unable to accumulate to toxic levels. The sweetener does not interact with human DNA and therefore is unable to act as a carcinogen. There are also positive technological functions of saccharin, such as lower production costs, improved taste and texture, and greater consumer choice.
Australian Food and Grocery Council	The AFGC now fully supports the Application, now that a satisfactory safety assessment has been performed in the Draft Assessment Report (they had given provisional support at Initial Assessment dependent to a satisfactory safety assessment at draft assessment). This concludes that there are no expected public health and safety concerns with permitting the amendment. They support the conclusion in the Food Technology Report that the use of saccharin in water-based flavoured drinks at 150 mg/kg is technologically justified. They note that approving the requested amendment will fulfil the requirement that FSANZ consider the need for food standards to promote consistency with international standards and the desirability of an efficient and internationally competitive food industry.

Attachment 3

Dietary Exposure Assessment Report

A469 – Permissions for saccharin in water based flavoured drinks
Draft Assessment

An Application was received by FSANZ requesting the amendment of Category 14.1.3 of Schedule 1 in Standard 1.3.1 of the *Australia New Zealand Food Standards Code* (the Code) to increase the maximum permitted levels (MPLs) of saccharin in water based flavoured drinks from 80 mg/kg to 150 mg/kg.

Summary

A dietary exposure assessment was undertaken to determine the impact of allowing the levels of saccharin in the Code to be increased in water based flavoured drinks.

Food consumption data were derived from the 1995 National Nutrition Survey (NNS) and the 1997 New Zealand NNS. A number of manufacturers submitted data on the intense sweetener concentrations of their products for use in the analysis of the recently released *Consumption of Intense Sweeteners in Australia and New Zealand – Roy Morgan Research Report* (FSANZ 2004) conducted by FSANZ. The manufacturers' data used in the exposure assessments were based on the mean intense sweetener concentration plus two standard deviations for each food group in order to assume a worst-case scenario.

Dietary exposure assessments for saccharin were calculated for the Australian and New Zealand populations and were compared to the Acceptable Daily Intake (ADI). A dietary exposure assessment was also carried out for the population group of children aged 2-6 years (Australia only).

When manufacturers' data on the saccharin levels used in the manufacture of food products were used in the dietary exposure assessment, mean and 95th percentile dietary exposures to saccharin were below the ADI for all population groups examined. The use of manufacturers' data provides a more realistic estimate of dietary exposure to saccharin since the assessment is based on saccharin levels that are used in the food manufacturing industry rather than the MPLs listed in the Code.

For all population groups assessed, the major contributors to saccharin dietary exposure were sauces, toppings, mayonnaise and salad dressings; saccharin tabletop sweeteners, tablets, powders and granules; dry soup mix; and fruit & vegetable spreads including jams and chutneys.

Background

The aim of this Application was to increase the MPLs of saccharin in water based flavoured drinks in the Code from 80 mg/kg to 150 mg/kg (see Table 1). The requested level is lower than that previously allowed in the old Code prior to the full implementation on 20 December, 2002 (1500 mg/kg).

The Applicant indicated that if saccharin permissions are not increased, some manufacturers may be forced to withdraw their products from the market. They have indicated that re-formulating these products can be a potentially lengthy process and may be expensive.

Saccharin is a non-nutritive food substance, which has a long history of use worldwide.

Table 1: Proposed uses of saccharin in foods, as provided by the Applicant

Food Name	Concentration Level (mg/kg)
Diet soft drinks	150
Diet cordials	150

Two studies have been conducted previously by FSANZ on intense sweetener consumption: *Survey of intense sweetener consumption in Australia* (National Food Authority 1995), and *Consumption of Intense Sweeteners in Australia and New Zealand – Roy Morgan Research Report* (FSANZ 2004). Results from this exposure assessment are compared to the results of the most recent study in the results section.

Dietary exposure assessment provided by the Applicant

No detailed dietary exposure assessment was provided by the Applicant for the purpose of this Application, therefore, FSANZ conducted a dietary exposure assessment.

Dietary modelling

The dietary exposure assessment was conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data to estimate the exposure to the food chemical from the diet. The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary exposure = food chemical concentration x food consumption

The exposure was estimated by combining usual patterns of food consumption, as derived from national nutrition survey (NNS) data, with proposed levels of use of saccharin in foods.

Dietary survey data

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

Where foods in the NNS were reported as being the 'artificially sweetened' version of a food, only those foods were used in the exposure assessment for that food group, for example, artificially sweetened soft drinks were used not all sweetened soft drinks. For some food groups, there were little or no 'artificially sweetened' version of the foods, were reported as being consumed in the NNS. For the exposure assessments, the whole food group consumption amounts, for example, all sauces, toppings and salad dressings, and all dry soup mixes.

Population groups assessed

Dietary exposure assessments were conducted for both Australian and New Zealand populations. Dietary exposure assessments were conducted for the whole population (Australia 2 years and above and New Zealand 15 years and above) as a proxy for exposure over a lifetime. A dietary exposure assessment was conducted for children aged 2-6 years (Australia only) because children generally have higher exposures due to their smaller body weight, and they consume more food per kilogram of body weight compared to adults. It is important to note that, while children aged 2-6 years have been assessed as a separate group, this group has also been assessed in the whole population's dietary exposure assessment.

Saccharin concentration levels

The levels of saccharin in intense sweetened foods that were used in the dietary exposure assessment were derived from the Application and those derived from the recently completed FSANZ intense sweetener survey. The foods and proposed levels of use used in the exposure assessments are shown below in Table 2.

FSANZ recently completed an evaluation of intense sweeteners in foods (FSANZ 2004). As a part of this evaluation, data on the levels of use of intense sweeteners in foods were collected from manufacturers. Summary data have subsequently been used in this Application to attempt to provide a more realistic estimate of the potential impact of the increase of the levels of saccharin in the diet. All manufacturers' saccharin data have been used in a pooled format of mean or mean plus 2 standard deviations for each food group.

Concentrations of saccharin 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 14.1.3 represents water-based flavoured drinks). The foods proposed by the Applicant to contain increased levels of saccharin (as shown in Table 1) were matched to the most appropriate ANZFSC code(s) for dietary modelling purposes.

Scenarios for dietary modelling

Four scenarios were modelled for the purpose of this Application.

- Scenario One ('baseline' scenario) assumes that saccharin is present in foods at the MPLs currently listed in the Code;

- Scenario Two ('baseline plus A469' scenario) assumes that saccharin is present in foods at the MPLs currently listed in the Code, with the exception of intense sweetened soft drinks and intense sweetened cordials that were assigned the maximum permitted saccharin concentrations that were requested by the Applicant;

- Scenario Three ('baseline manufacturers use' scenario) is based on saccharin concentrations derived from the intense sweetener survey carried out by FSANZ (FSANZ 2003). If no manufacturers' use levels were available, then the MPL in the Code was used. Intense sweetened cordials and artificially sweetened soft drinks were assigned the current MPLs to enable a comparison with proposed MPLs from the Application in Scenario 4; and

- Scenario Four ('baseline manufacturers use plus A469) is based on manufacturers use levels (as discussed for Scenario 3) and assesses the potential exposure should the MPLs for saccharin requested in the Application be approved.

How were the estimated dietary exposures calculated?

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

Where estimated dietary exposures are expressed per kilogram of body weight, each individuals' 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 were not included in this calculation.

Where estimated exposures are expressed as a percentage of the reference health standard, each individual's total exposure is calculated as a percentage of the reference health standard (using the total exposures 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, saccharin sweetener used in coffee and home prepared intense sweetened stewed fruit are all included in the consumption of saccharin sweeteners. Where a higher-level food classification code (e.g. 14.1.3 Water based flavoured drinks) is given a saccharin concentration, as well as a sub-category (e.g. 14.1.3.1 Brewed soft drinks), the consumption of the foods in the sub-classification is not included in the higher-level classification code.

In DIAMOND, all mixed foods 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. The data for consumption of the ingredients from the recipe are then used in models and multiplied by saccharin concentrations of each of the raw ingredients. This only occurs if the *Mixed food* classification code (classification code 20) is not assigned its own saccharin permission. If the *Mixed foods* classification is assigned a saccharin concentration, the total consumption of the mixed food is multiplied by the proposed level, and the recipes for that food group are not used.

When a food that does not have a recipe is classified in two food groups in classification codes 1-14, and these food groups are assigned different permissions, DIAMOND will assume the food is in the food group with the highest assigned saccharin level to assume a worst-case scenario. If the food groups have the same permitted saccharin level, DIAMOND will assume the food is in the food group that appears first, based numerically on the ANZFCS.

Percentage contributions of each food group to total estimated exposures were 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 saccharin, and multiplying this by 100.

Table 2: Use of saccharin in foods and levels of use used in the dietary exposure assessments

DIAMOND Food Code	Food Name	Concentration Level (mg/kg)			
		Maximum permitted level (MPL)		Manufacturers' use level	
		Baseline	Baseline plusA469	Baseline manufacturers' use levels	Baseline manufacturers' use levels plus A469
		(Scenario 1)	(Scenario 2)	(Scenario 3)	(Scenario 4)
4.3.3	Commercially sterile fruits & vegetables	110	110	65	65
4.3.4	Fruit & vegetable spreads including jams, chutneys and related products	1 500	1 500	604	604
5.2.1.1	Bubble & chewing gum, artificially sweetened	1 500	1 500	0	0
11.4.1	Tabletop sweeteners, liquid preparation	86 130	86 130	86 130	86 130
11.4.2.2	Saccharin tabletop sweeteners, tablets, powder, granules	890 553	890 553	890 553	890 553
14.1.3.1	Brewed soft drinks	50	50	50	50
14.1.3.6	Soft drinks, artificially sweetened	80	150	80	150
14.1.3.7	Cordials, artificially sweetened	80	150	80	150
20.2.1.3	Jelly only	160	160	123	123
20.2.4	Sauces, toppings, mayonnaise & salad dressings	1 500	1 500	304	304
20.2.9.1	Soup, dry mix	1 500	1 500	1 500	1 500

Assumptions in the dietary modelling

The aim of the dietary exposure assessment was to make as realistic an estimate of 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 modelling include:

- where a permission is given to a food classification, all foods in that group contain saccharin;
- all the foods within the group contain saccharin at the levels specified in Table 2;
- while 14.1.3 Water based flavoured drinks are permitted to contain saccharin, it was assumed that saccharin would only be used in intense sweetened soft drinks and intense sweetened cordials;
- where manufacturers' data was not provided for a product it was assumed to contain the maximum amount of saccharin specified in the Code;
- where foods have a MPL of 'Good Manufacturing Practice' (GMP) in the Code, it was assumed that the maximum concentration were equivalent to the 'mean + 2 SD' manufacturers' saccharin concentration for that food type for Scenario's 1, 2, 3 and 4;
- consumption of foods as recorded in the NNS represent current food consumption patterns;
- consumers always select the products containing saccharin;
- consumers do not alter their food consumption habits besides to substitute non-saccharin containing products with saccharin containing products;
- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of saccharin;
- consumers do not increase their consumption of foods upon foods containing increased saccharin becoming available;
- where a food has a specified saccharin concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. saccharin sweetener used in coffee;
- all mixed foods with recipes in DIAMOND were assumed to be prepared in the home (and not produced commercially). Therefore, if a recipe uses an ingredient that is permitted to contain saccharin, the quantity of saccharin from the ingredient will carry-over into the mixed food. It was assumed that carry-over would not occur for cakes;

- there are no reductions in saccharin concentrations from food preparation or due to cooking;

- dietary exposure to saccharin through non-food products such as over-the-counter medicines and personal hygiene products (e.g. toothpaste) was not considered; and

- for the purpose of this assessment, it was assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. milk, yoghurt).

These assumptions are likely to lead to a conservative estimate for saccharin dietary exposure.

Limitations of the dietary modelling

A limitation of estimating dietary exposure over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend 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 tabletop sweeteners, sauces, toppings, salad dressings and mayonnaise.

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 and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, another limitation of the dietary modelling 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 1995/1997.

While the results of NNSs 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.

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. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand National Nutrition Survey so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards this population group in the dietary exposure assessment because population weights were not used.

Results

Estimated dietary exposures to saccharin

The estimated consumer dietary exposures for each scenario for saccharin for Australia and New Zealand are shown in Figures 1 and 2 (full results in Table A1.1 - A1.4 in Appendix 1).

When the current saccharin MPLs in the Code are considered (Scenario 1), estimated mean dietary exposures for consumers of saccharin were 1.5 milligrams/kilogram body weight/day (mg/kg bw/day) for Australians aged 2 years and above, 2.1 mg/kg bw/day for Australian children aged 2-6 years and 1.7 mg/kg bw/day for New Zealanders aged 15 years and above. Estimated 95th percentile exposures for consumers of saccharin are 5.4 mg/kg bw/day for Australians aged 2 years and above, 6.6 mg/kg bw/day for Australian children aged 2-6 years and 6.3 mg/kg bw/day for New Zealanders aged 15 years and above. When it is assumed that the saccharin MPLs requested in the Application are approved (Scenario 2), estimated mean and 95th percentile exposure (as assessed in mg/kg bw/day) remained the same for all population groups assessed except for Australian 2-6 year olds whose mean dietary exposure for consumers of saccharin changed from 2.1 mg/kg bw/day to 2.2 mg/kg bw/day, and Australians aged 2 years and above whose 95th percentile exposure for consumers changed from 5.4 mg/kg bw/day to 5.6 mg/kg bw/day.

When baseline manufacturers' use levels were considered in conjunction with current MPLs for saccharin in intense sweetened soft drinks and cordials (Scenario 3), estimated mean exposures for consumers of saccharin were 0.8 mg/kg bw/day for Australians aged 2 years and above, 0.9 mg/kg bw/day for Australian children aged 2-6 years and 0.9 mg/kg bw/day for New Zealanders aged 15 years and above. Estimated 95th percentile exposures for consumers of saccharin were 3.5 mg/kg bw/day for Australians aged 2 years and above, 2.2 mg/kg bw/day for Australian children aged 2-6 years and 4.7 mg/kg bw/day for New Zealanders aged 15 years and above.

When manufacturers use levels were considered in conjunction with the proposed MPLs for saccharin in intense sweetened soft drinks and cordials (Scenario 4), estimated mean exposures for consumers of saccharin were 0.9 mg/kg bw/day for Australians aged 2 years and above, 1.0 mg/kg bw/day for Australian children aged 2-6 years and 0.9 mg/kg bw/day for New Zealanders aged 15 years and above. Estimated 95th percentile exposures for consumers of saccharin were 3.8 mg/kg bw/day for Australians aged 2 years and above, 3.1 mg/kg bw/day for Australian children aged 2-6 years and 4.8 mg/kg bw/day for New Zealanders aged 15 years and above.

The higher 95th percentile exposures for the New Zealand population 15 years and above compared to Australian aged two years and above can be attributed to some consumers in New Zealand with higher consumption of 'table top' sweeteners.

Major contributing foods to total estimated dietary exposures

The major contributors (>5%) to total saccharin dietary exposures for each scenario are shown in Figure 3 for Australians aged 2 years and above, Figure 4 for Australians aged 2-6 years and Figure 5 for New Zealanders aged 15 years and above for all scenarios.

For all population groups assessed, the major contributors to saccharin dietary exposure were sauces, toppings, mayonnaise and salad dressings; saccharin tabletop sweeteners, tablets, powders and granules; dry soup mix; and fruit & vegetable spreads including jams and chutneys. A full list of all the food groups and their contributions to total dietary exposure to saccharin can be found in Tables A1.5 – A1.8 for Australia and New Zealand in Appendix 1.

The majority of food groups that were major contributors were those where is was assumed that the whole food group contained intense sweetener, not just the intense sweetened versions of the food within the group.

Risk characterisation

In order to determine if the levels of dietary exposure to saccharin are likely to be of a public health and safety concern, the estimated dietary exposures were compared to an Acceptable Daily Intake (ADI) of 5 mg/kg bw/day that was set by the FAO/WHO Joint Expert Committee on Foods Additives (JECFA) (WHO 1993). The ADI is defined as amount of a chemical that can be ingested daily over a lifetime without appreciable risk to health (WHO 2001).

Comparison of the estimated dietary exposures with the reference health standard

The estimated dietary exposures for saccharin, as compared to ADI, are shown in Figures 6 and 7 for Australia and New Zealand for each scenario assessed (full results in Table A2.1 - A2.4 in Appendix 2).

Scenario 1 ('baseline') estimated mean dietary exposures for consumers of saccharin were the lowest for Australians aged 2 years and above at 29% ADI and were the highest for Australian children aged 2-6 years at 42% ADI. The estimated 95th percentile dietary exposures were lowest at 109% ADI and highest at 132% ADI for Australians aged 2 years and above and 2-6 years, respectively.

Scenario 2 ('baseline plus A469') estimated mean dietary exposures for consumers of saccharin were lowest at 31% ADI for Australians aged 2 years and above and highest at 43% ADI for Australian children aged 2-6 years. Estimated 95th percentile dietary exposures for consumers of saccharin for Scenario 2 range were lowest for Australians aged 2 years and above at 111% ADI and highest for Australian children aged 2-6 years at 132% ADI.

Figure 1: Estimated mean dietary exposures for consumers of saccharin for different scenarios for Australia and New Zealand population groups.

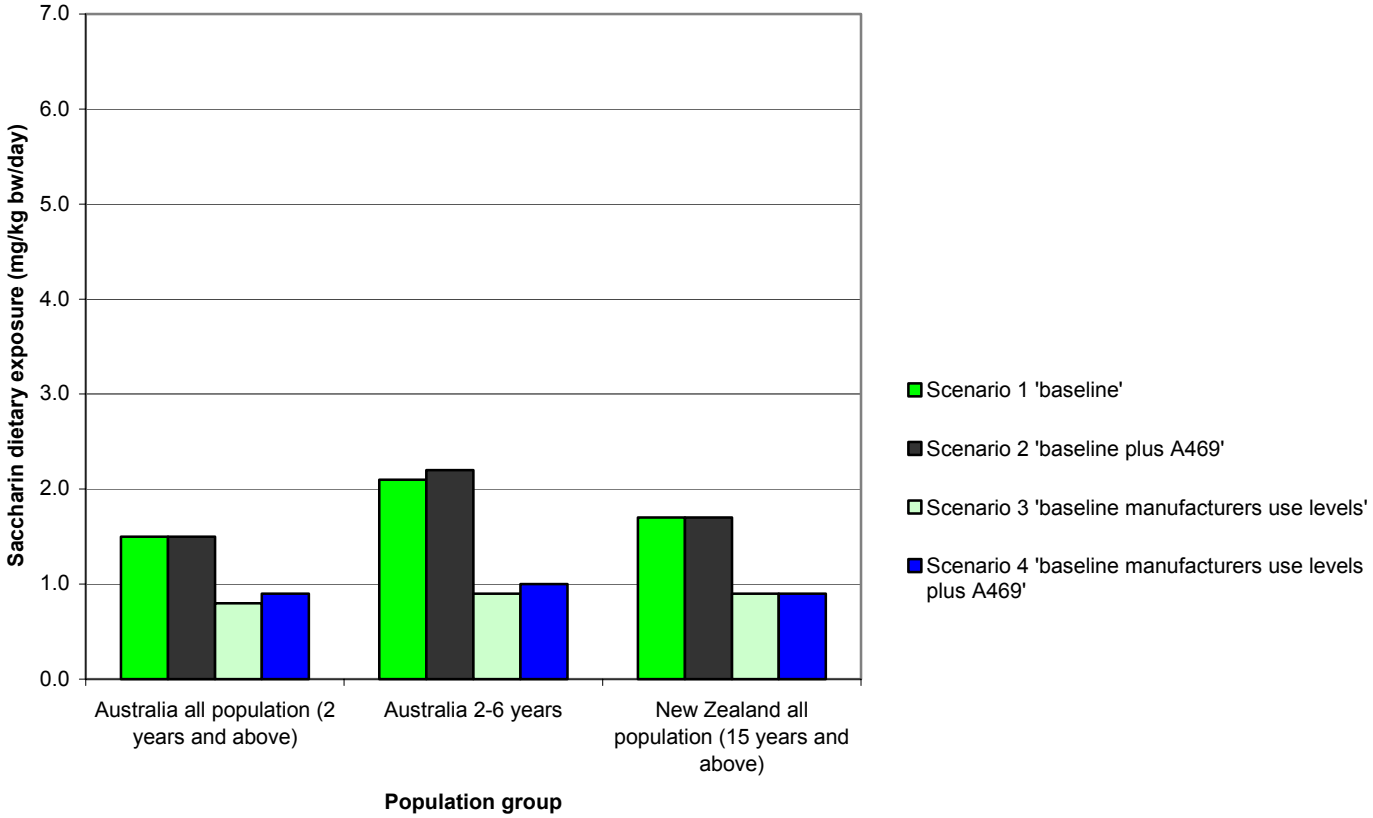


Figure 2: Estimated 95th percentile dietary exposures for consumers of saccharin for different scenarios for Australia and New Zealand population groups.

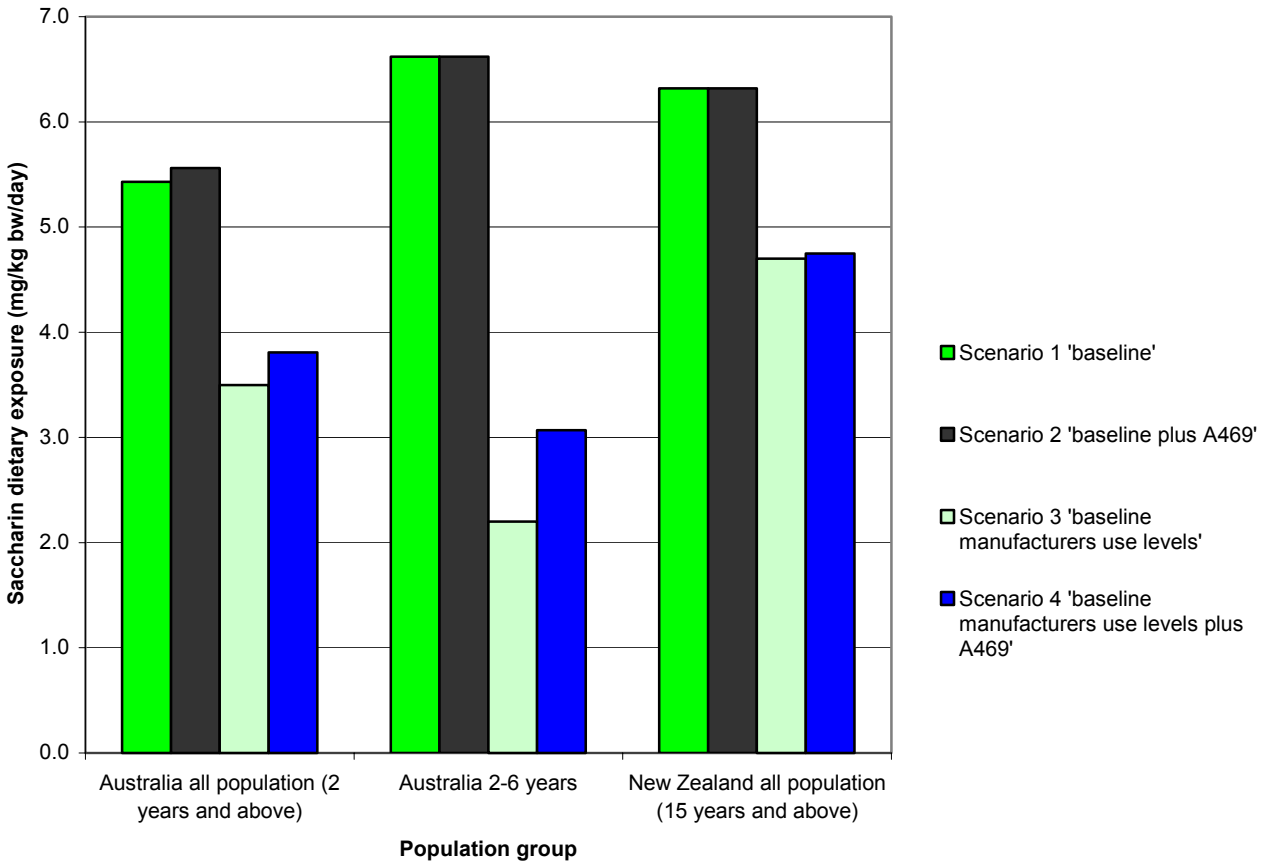
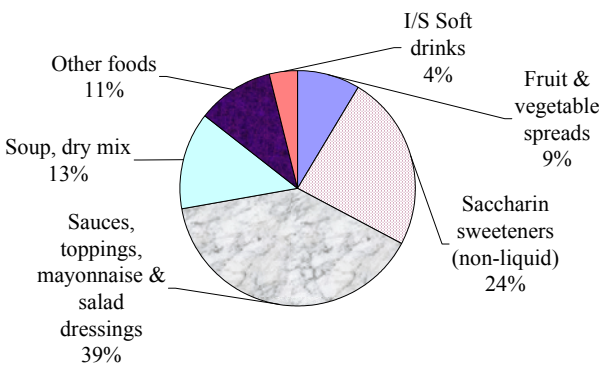
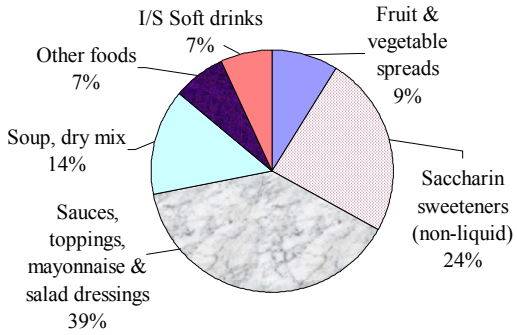


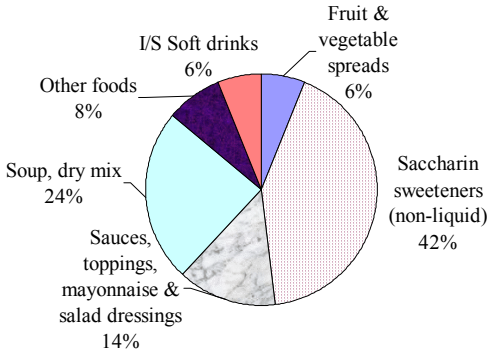
Figure 3: Major contributors to total saccharin dietary exposures for Australians aged 2 years and above for different scenarios



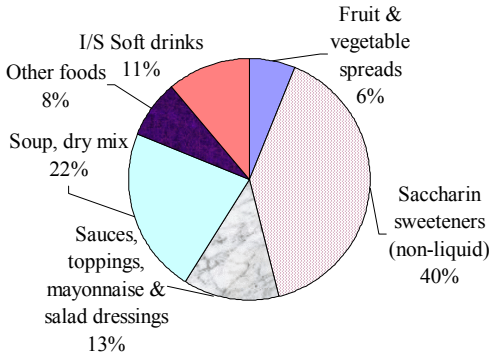
Scenario 1
(1.5 mg/kg bw/day)



Scenario 2
(1.5 mg/kg bw/day)



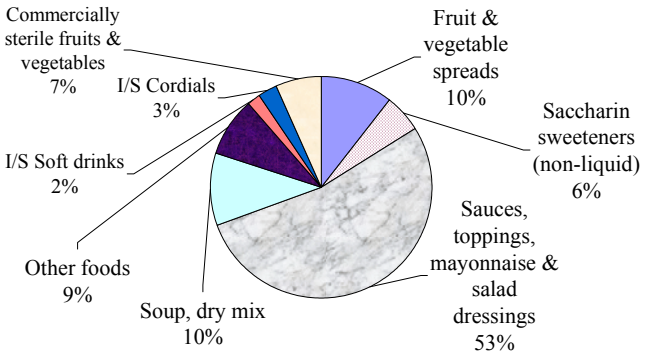
Scenario 3
(0.8 mg/kg bw/day)



Scenario 4
(0.9 mg/kg bw/day)

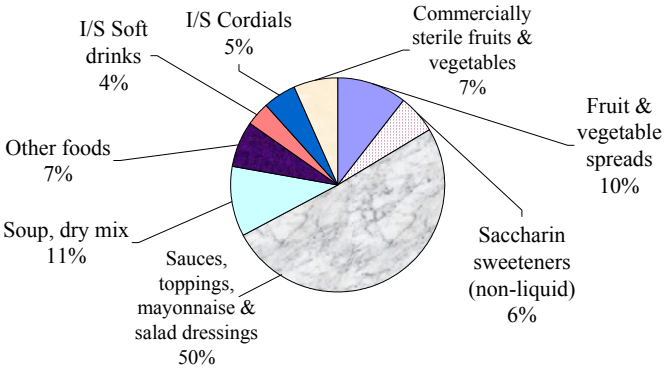
Note: in the above diagrams, Saccharin tabletop sweeteners, tablets, powder, granules are referred to as 'Saccharin sweeteners (non-liquid)'; Fruit & vegetable spreads, including jams, chutneys and related products are referred to as 'Fruit & vegetable spreads'; and Soft drinks, artificially sweetened are referred to as 'I/S Soft drinks'.

Figure 4: Major contributors to total saccharin dietary exposures for Australians aged 2-6 years for different scenarios



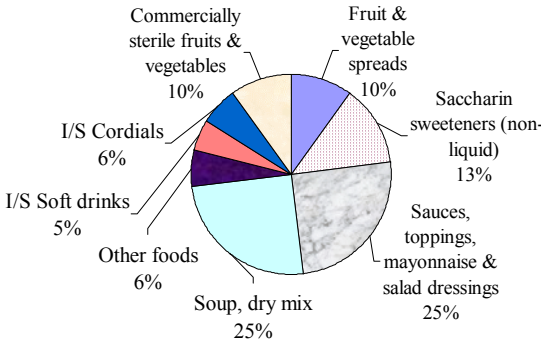
Scenario 1

(2.1mg/kg bw/day)



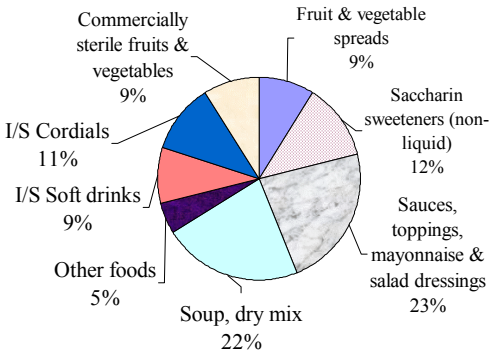
Scenario 2

(2.2 mg/kg bw/day)



Scenario 3

(0.9 mg/kg bw/day)

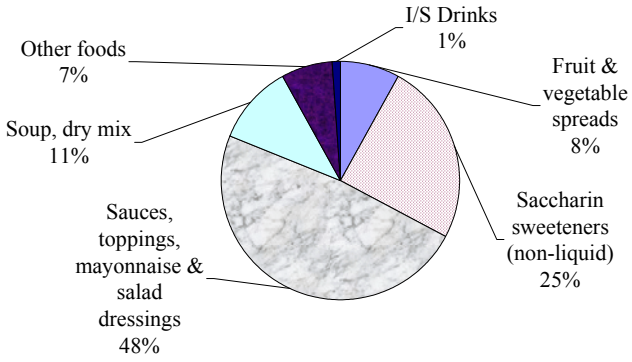


Scenario 4

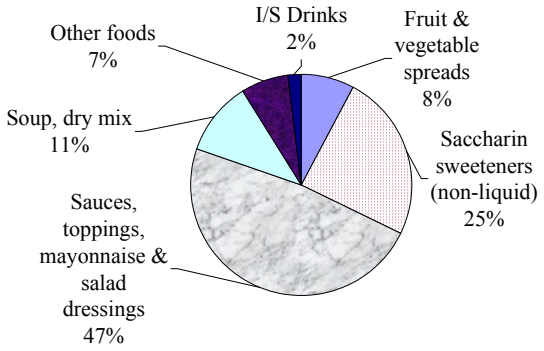
(1.0 mg/kg bw/day)

Note: in the above diagrams, Saccharin tabletop sweeteners, tablets, powder, granules are referred to as 'Saccharin sweeteners (non-liquid)'; Fruit & vegetable spreads, including jams, chutneys and related products are referred to as 'Fruit & vegetable spreads'; Soft drinks, artificially sweetened are referred to as 'I/S Soft drinks'; and Cordials, artificially sweetened are referred to as 'I/S Cordials'.

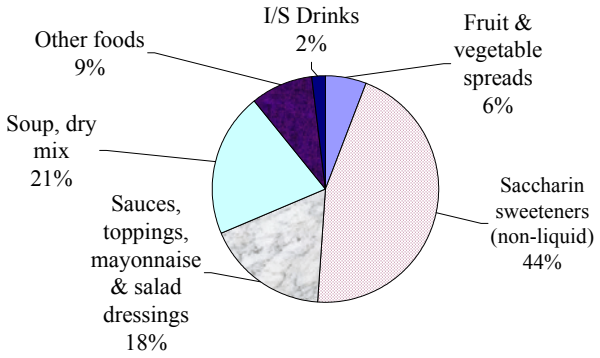
Figure 5: Major contributors to total saccharin dietary exposures for New Zealanders aged 15 years and above for different scenarios



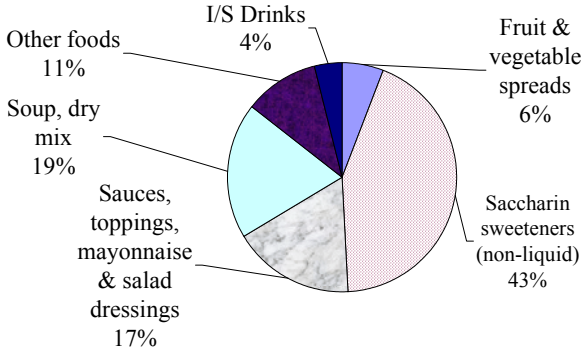
Scenario 1
(1.7 mg/kg bw/day)



Scenario 2
(1.7 mg/kg bw/day)



Scenario 3
(0.9 mg/kg bw/day)



Scenario 4
(0.9 mg/kg bw/day)

Note: in the above diagrams, Saccharin tabletop sweeteners, tablets, powder, granules are referred to as 'Saccharin sweeteners (non-liquid)'; and Fruit & vegetable spreads, including jams, chutneys and related products are referred to as 'Fruit & vegetable spreads'; Soft drinks, artificially sweetened and Cordials, artificially sweetened are referred to as 'I/S Drinks'.

Scenario 3 ('baseline manufacturers use levels') estimated mean dietary exposures for consumers of saccharin were lowest at 17% ADI for Australians aged 2 years and above and highest for Australian children aged 2-6 years at 19% ADI. Estimated 95th percentile dietary exposures for consumers of saccharin were lowest at 45% ADI for Australian children aged 2-6 years and highest for New Zealanders aged 15 years and above at 95% ADI.

When Scenario 4 ('manufacturers use level plus A469') estimated mean dietary exposures for consumers of saccharin were considered, the lowest dietary exposure was estimated at 18% ADI (for Australians aged 2 years and above) and the highest at 21% ADI (for Australian children aged 2-6 years). Estimated 95th percentile dietary exposures for consumers of saccharin for Scenario 4 were lowest at 61% ADI (for Australian children aged 2-6 years) and highest at 95% ADI (for New Zealanders aged 15 years and above).

Higher exposures for children are due to their lower body weights and their higher food consumption per kilogram of body weight compared to adults.

Scenarios 3 and 4 provide the more realistic estimates of dietary exposure to saccharin since they are based on the saccharin levels that are actually used in the manufacture of food products rather than the MPLs listed in the Code. When Scenarios 3 and 4 are considered, mean and 95th percentile dietary exposures are below the ADI for all population groups examined.

Comparison of estimated dietary exposure with other studies of saccharin exposure

In 1994, the then National Food Authority (now FSANZ) commissioned Roy Morgan Research to undertake research into intense sweetener consumption patterns of 12-39 year old Australians (NFA 1995). This survey estimated dietary exposure to intense sweeteners by combining survey data on individual respondents' weekly consumption of different foods for high consumers of intense sweeteners with data on the level of intense sweetener in each product by brand and flavour.

In 2003, FSANZ commissioned Roy Morgan Research to undertake a similar follow up survey on the consumption of intense sweeteners in Australia and New Zealand (FSANZ 2004). This survey found that there has been a significant increase in the average daily amount of consumption of carbonated soft drinks and cordials containing intense sweeteners in Australians aged 12-39 years since the 1994 survey.

The 1994 NFA intense sweetener survey results for saccharin, the 2003 FSANZ intense survey results for saccharin and the results for Scenario 3 ('baseline manufacturers use') for this Application are given in Table 3. It would appear that the saccharin dietary exposure assessment for A469 has over-estimated dietary saccharin exposure, thereby being a more conservative assessment.
The Intense sweetener surveys would be expected to be the most accurate for the age groups considered because:

- saccharin data were used rather than summary data as in the A409 dietary exposure estimate;

- selection of the people who were higher consumers of intense sweetened products is a 'worst-case' scenario; and

- a 7-day consumption data better reflect long time dietary habits than a 24-hour recall record.

However, the dietary exposure assessment for Application A469 examined different population groups to those examined in the NFA and FSANZ intense sweetener surveys. The intense sweetener surveys were conducted on potential 'high consumers' of intense sweeteners so that the A469 dietary exposures cannot be directly compared. Additionally, the methodology for collection of food consumption data also varies (seven day diary for sweetener surveys; 24-hour recall for the NNSs).

Figure 6: Estimated mean dietary exposures for consumers of saccharin as a % of the ADI for different scenarios for Australia and New Zealand population groups

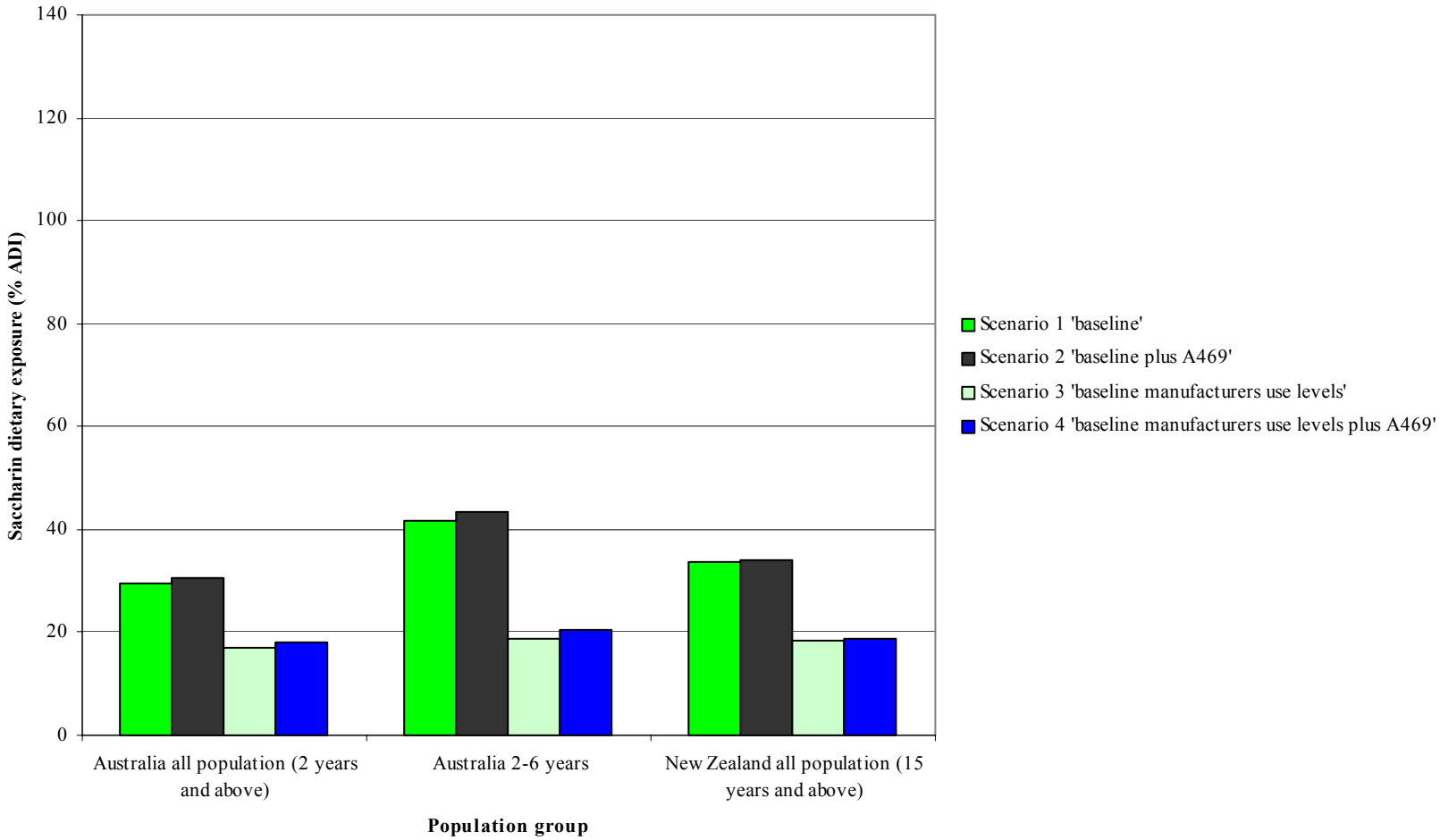


Figure 7: Estimated 95th percentile dietary exposures for consumers of saccharin as a % of the ADI for different scenarios for Australia and New Zealand population groups

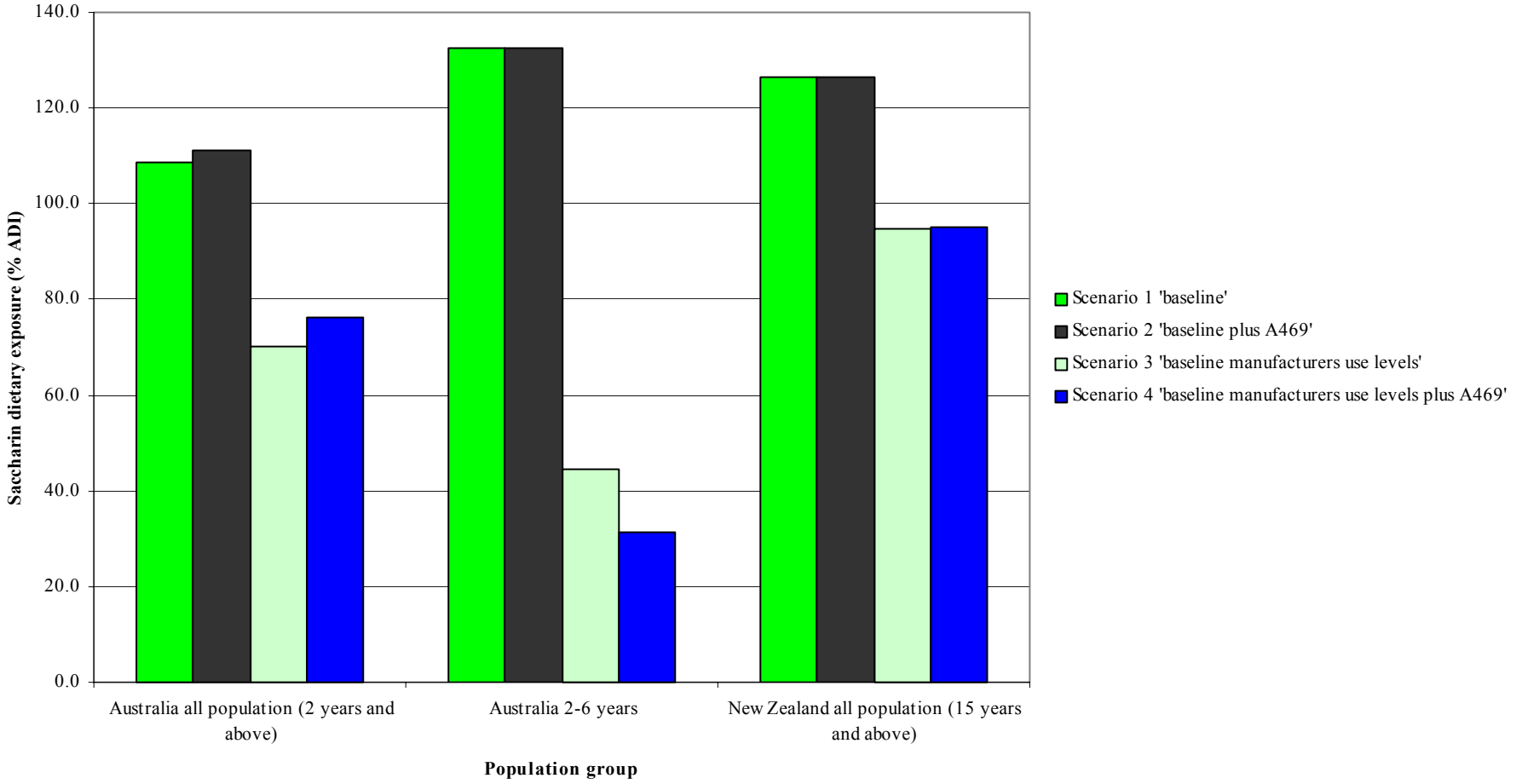


Table 3: Results for dietary exposure assessments for saccharin from different FSANZ sources

Country	Population group	Mean consumers (%ADI)			90th percentile (%ADI)		95th percentile (%ADI)		
		1994 NFA study[6]	2003 FSANZ study[7]	A469 modelling (Scenario 3)	1994 NFA study	2003 FSANZ study	1994 NFA study	2003 FSANZ study	A469 modelling (Scenario 3)
Australia	Whole population (2 years+)	n/a	n/a	17	n/a	n/a	n/a	n/a	70
	2-6 years	n/a	n/a	19	n/a	n/a	n/a	n/a	45
	12-17 years	16	9	n/a	85	17	n/a	17	n/a
	18-24 years	3	6	n/a	-	18	n/a	20	n/a
	25-39 years	9	8	n/a	47	28	n/a	51	n/a
	12-39 years	9	8	n/a	56	18	n/a	45	n/a
New Zealand	Whole population (15 years+)	n/a	n/a	18	n/a	n/a	n/a	n/a	95
	12-17 years	n/a	4	n/a	n/a	16	n/a	20	n/a
	18-24 years	n/a	2	n/a	n/a	3	n/a	7	n/a
	25-39 years	n/a	6	n/a	n/a	24	n/a	24	n/a
	12-39 years	n/a	4	n/a	n/a	15	n/a	20	n/a

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

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

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COMPLETE INFORMATION ON DIETARY EXPOSURE ASSESSMENT RESULTS

Table A1.1: Scenario 1 ('baseline') estimated dietary exposures to saccharin

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (mg/day)	Mean consumers mg/kg bw/day (mg/day)	95th percentile consumers mg/kg bw/day (mg/day)
Australia	Whole population (2 years+)	11 219	81.0	1.2 (76.6)	1.5 (94.7)	5.4 (375.0)
	2-6 years	742	75.0	1.6 (29.0)	2.1 (38.6)	6.6 (132.0)
New Zealand	Whole population (15 years+)	3 875	83.6	1.4 (103.0)	1.7 (123.3)	6.3 (450.0)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.

Table A1.2: Scenario 2 ('baseline plus A469') estimated dietary exposures to saccharin

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (mg/day)	Mean consumers mg/kg bw/day (mg/day)	95th percentile consumers mg/kg bw/day (mg/day)
Australia	Whole population (2 years+)	11 219	81.0	1.2 (79.6)	1.5 (98.4)	5.6 (375.0)
	2-6 years	742	75.0	1.6 (30.3)	2.2 (40.4)	6.6 (133.8)
New Zealand	Whole population (15 years+)	3 875	83.6	1.4 (104.2)	1.7 (124.7)	6.3 (450.0)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.

Table A1.3: Scenario 3 ('baseline manufacturers use') estimated dietary exposures to saccharin

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (mg/day)	Mean consumers mg/kg bw/day (mg/day)	95th percentile consumers mg/kg bw/day (mg/day)
Australia	Whole population (2 years+)	11 219	81.0	0.7 (45.9)	0.8 (56.8)	3.5 (259.1)
	2-6 years	742	75.0	0.7 (13.1)	0.9 (17.4)	2.2 (41.0)
New Zealand	Whole population (15 years+)	3 875	83.6	0.8 (56.5)	0.9 (67.6)	4.7 (379.4)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.

Table A1.4: Scenario 4 ('baseline manufacturers use plus A469') estimated dietary exposures to saccharin

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (mg/day)	Mean consumers mg/kg bw/day (mg/day)	95th percentile consumers mg/kg bw/day (mg/day)
Australia	Whole population (2 years+)	11 219	81.0	0.7 (48.9)	0.9 (60.5)	3.8 (291.4)
	2-6 years	742	75.0	0.8 (14.4)	1.0 (19.2)	3.1 (54.6)
New Zealand	Whole population (15 years+)	3 875	83.6	0.8 (57.7)	0.9 (69.0)	4.8 (380.9)

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.

Table A1.5: Scenario 1 ('baseline') % contribution of each food group to total saccharin dietary exposure for different population groups

Food Name	% Contribution to saccharin dietary exposure		
	Australia 2 years and above	Australia 2-6 years	New Zealand 15 years and above
Commercially sterile fruits & vegetables	4.1	**7.4**	2.4
Fruit & vegetable spreads including jams and chutneys	**9.4**	**11.3**	**8.2**
Bubble & chewing gum, artificially sweetened	0.04	0.1	0.01
Tabletop sweeteners, liquid preparation	0.4	-	2.2
Saccharin tabletop sweeteners, tablets, powder, granules	**25.3**	**6.0**	**25.2**
Brewed soft drinks	0.5	0.4	-
Soft drinks, artificially sweetened	3.7	2.3	1.2
Cordials, artificially sweetened	0.8	2.9	0.07
Jelly only	0.6	2.8	0.2
Sauces, toppings, mayonnaise & salad dressings	**40.9**	**55.7**	**49.2**
Soup, dry mix	**14.3**	**11.0**	**11.3**

Table A1.6: Scenario 2 ('baseline plus A469') % contribution of each food group to total saccharin dietary exposure for different population groups

Food Name	% Contribution to saccharin dietary exposure		
	Australia 2 years and above	Australia 2-6 years	New Zealand 15 years and above
Commercially sterile fruits & vegetables	4.0	**7.1**	2.4
Fruit & vegetable spreads including jams and chutneys	**9.0**	**10.8**	**8.1**
Bubble & chewing gum, artificially sweetened	0.04	0.1	0.01
Tabletop sweeteners, liquid preparation	0.4	-	2.1
Saccharin tabletop sweeteners, tablets, powder, granules	**24.3**	**5.8**	**24.9**
Brewed soft drinks	0.5	0.4	-
Soft drinks, artificially sweetened	**6.7**	4.1	2.3
Cordials, artificially sweetened	1.4	**5.2**	0.1
Jelly only	0.6	2.7	0.2
Sauces, toppings, mayonnaise & salad dressings	**39.3**	**53.3**	**48.6**
Soup, dry mix	**13.8**	**10.6**	**11.2**

Table A1.7: Scenario 3 ('baseline manufacturers use') % contribution of each food group to total saccharin dietary exposure for different population groups

Food Name	% Contribution to saccharin dietary exposure		
	Australia 2 years and above	Australia 2-6 years	New Zealand 15 years and above
Commercially sterile fruits & vegetables	4.1	**9.7**	2.6
Fruit & vegetable spreads including jams and chutneys	**6.3**	**10.1**	**6.0**
Bubble & chewing gum, artificially sweetened	0	0	0.0-
Tabletop sweeteners, liquid preparation	0.7	-0	4.0
Saccharin tabletop sweeteners, tablets, powder, granules	**42.2**	**13.4**	**46.0**
Brewed soft drinks	0.9	0.9	-
Soft drinks, artificially sweetened	**6.2**	**5.1**	2.3
Cordials, artificially sweetened	1.3	**6.4**	0.1
Jelly only	0.7	4.9	0.3
Sauces, toppings, mayonnaise & salad dressings	**13.8**	**25.1**	**18.2**
Soup, dry mix	**23.9**	**24.5**	**20.6**

Table A1.8: Scenario 4 ('baseline manufacturers use plus A469') % contribution of each food group to total saccharin dietary exposure for different population groups

Food Name	% Contribution to saccharin dietary exposure		
	Australia 2 years and above	Australia 2-6 years	New Zealand 15 years and above
Commercially sterile fruits & vegetables	3.8	**8.9**	2.6
Fruit & vegetable spreads including jams and chutneys	**5.9**	**9.2**	**5.9**
Bubble & chewing gum, artificially sweetened	0	0	0.0
Tabletop sweeteners, liquid preparation	0.7	-	3.9
Saccharin tabletop sweeteners, tablets, powder, granules	**39.6**	**12.1**	**45.1**
Brewed soft drinks	0.9	0.8	-
Soft drinks, artificially sweetened	**10.9**	**8.6**	4.2
Cordials, artificially sweetened	2.2	**10.9**	0.2
Jelly only	0.7	4.4	0.3
Sauces, toppings, mayonnaise & salad dressings	**13.0**	**22.8**	**17.8**
Soup, dry mix	**22.4**	**22.3**	**20.2**

Complete information on risk characterisation

Table A2.1: Scenario 1 ('baseline') estimated dietary exposures to saccharin, as a percentage of the ADI

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (% ADI*)	Mean consumers mg/kg bw/day (% ADI*)	95th percentile consumers mg/kg bw/day (% ADI*)
Australia	Whole population (2 years+)	11 219	81.0	23.8	29.4	108.8
	2-6 years	742	75.0	31.2	41.6	132.4
New Zealand	Whole population (15 years+)	3 875	83.6	28.3	33.8	126.3

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.
* Acceptable Daily Intake = 5 mg/kg bw/day

Table A2.2: Scenario 2 ('baseline plus A469') estimated dietary exposures to saccharin, as a percentage of the ADI

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (% ADI*)	Mean consumers mg/kg bw/day (% ADI*)	95th percentile consumers mg/kg bw/day (% ADI*)
Australia	Whole population (2 years+)	11 219	81.0	24.7	30.6	111.3
	2-6 years	742	75.0	32.5	43.3	132.5
New Zealand	Whole population (15 years+)	3 875	83.6	28.6	34.1	126.3

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.
* Acceptable Daily Intake = 5 mg/kg bw/day

Table A2.3: Scenario 3 ('baseline manufacturers use') estimated dietary exposures to saccharin, as a percentage of the ADI

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents (% ADI*)	Mean consumers (% ADI*)	95th percentile consumers (% ADI*)
Australia	Whole population (2 years+)	11 219	81.0	13.7	16.9	70.3
	2-6 years	742	75.0	14.0	18.7	44.7
New Zealand	Whole population (15 years+)	3 875	83.6	15.4	18.3	94.8

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.
* Acceptable Daily Intake = 5 mg/kg bw/day

Table A2.4: Scenario 4 ('baseline manufacturers use plus A469') estimated dietary exposures to saccharin, as a percentage of the ADI

Country	Population group	Number of consumers of saccharin	Consumers♦ as a % of total respondents#	Mean all respondents mg/kg bw/day (% ADI*)	Mean consumers mg/kg bw/day (% ADI*)	95th percentile consumers mg/kg bw/day (% ADI*)
Australia	Whole population (2 years+)	11 219	81.0	14.6	18.0	76.2
	2-6 years	742	75.0	15.3	20.5	61.4
New Zealand	Whole population (15 years+)	3 875	83.6	15.7	18.7	95.0

Total number of respondents for Australia: whole population = 13 858, 2-6 years = 989; New Zealand: whole population = 4 636. Respondents include all members of the survey population whether or not they consumed a food that contains saccharin.
♦ Consumers only – This only includes the people who have consumed a food that contains saccharin.
* Acceptable Daily Intake = 5 mg/kg bw/day

ATTACHMENT 4

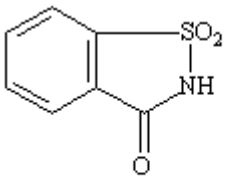
Food Technology Report

Saccharin

The name saccharin is derived from the Latin *saccharum* for sugar. Saccharin is chemically named 1,2-benzisothiazole-3(2H)-one-1,1-dioxide (chemical formula $C_7H_5NO_3S$), and is also called ortho-benzoic acid sulfimide. Saccharin is the oldest intense sweetener. It was accidentally discovered in 1878 by Fahlberg and Remsen and manufactured 5 years later. Saccharin was first used as an antiseptic and preservative. It has been used as a food sweetener for over 100 years and is currently the largest volume alternative sweetener produced.

Saccharin was produced commercially from toluene, but it can be produced from methyl anthranilate, which is a substance naturally occurring in grapes.

The structure of saccharin is diagrammatically represented as below:



Sweetness

The sodium salt is the usually available form, with good stability under a wide range of processing conditions and low cost, but it has a disadvantage of a bitter, metallic after-taste. The sweetness of the forms of saccharin have been variously determined to be 200-800 times sweeter than sucrose, depending on the saccharin concentration. It is reported as approximately 300 times as sweet as sugar dissolved in water at 7% concentration.

Saccharin's sweetening power relative to sucrose increases with decreasing concentration. Additive effects have been achieved with blends of saccharin with other sweeteners. In addition, blends are often sweeter than predicted by the additive effect. This enhanced sweetening effect is called synergism.

Saccharin is typically formulated with other sweeteners or masking agents to avoid the bitter after-taste perceived by some individuals at higher concentrations. In blends, the calcium salt of saccharin can provide a cleaner after-taste with less bitterness. During the 1960s saccharin and cyclamate were blended into diet drinks as the first application of the combined sweetener approach. Saccharin, at 300 times sweeter than sucrose boosted the sweetening power of cyclamate, which is usually considered to be 30 times sweeter than sucrose, while cyclamate masked the aftertaste that some people associate with saccharin.

Stability

In its bulk form saccharin and its salts show no detectable decomposition over several years. Saccharin is also stable in aqueous solutions over a high pH range. Severe heat and pH conditions over extended periods are required to hydrolyse saccharin, so it is highly stable in most food processing applications.

Saccharin is used in more than 100 countries in soft drinks, confectionery, preserves, salad dressings, desserts and combined with bulking agents in baked products. It is used in table-top preparations either as a single sweetener in tablet or liquid form or in combination with other sweeteners, and incorporated into chewing gum on its own or with other sweeteners. Saccharin is also a popular choice in oral-hygiene products, such as toothpastes and mouthwashes.

Combination Effects

Alternative sweeteners are replacing some uses of saccharin in foods and its survival as a food additive may depend on its use in combination with other sweeteners. The food industry continues to develop new sweeteners, as not even sugar is the best sweetener for all purposes. The ideal sweetener should be sweet, colourless, odourless and non-cariogenic. The developments throughout the 1990s have led to more use of combined sweeteners. With the availability of numerous low-calorie and calorie-reduced sweeteners and improved technologies more products are emerging.

The use of low calorie sugar-free products tripled in the final 2 decades of the 20th century. The more a sweetener tastes and functions like sucrose, the greater the consumer acceptability. If the low-calorie food can be processed on conventional equipment it is more desirable to industry. The sweetener must be stable to food processing and storage requirements, preferably soluble in water and compatible with a wide range of food ingredients.

Product Development

In reduced calorie product development, replacement of the sweetness provide by caloric sweeteners is not the only task. Sugars provide bulk, texture and mouthfeel and processing sugars produces flavours and chemical changes. Sucrose is also very soluble in water and readily forms concentrated syrups.

The polyols are important adjuncts for the development of sugar-free products, but they have different functional properties and some adverse dietary effects. Reducing calories is more easily achieved by replacing fats rather than sugars, due to their higher energy values. Fat replacers and low calorie bulking agents, such as polydextrose, can also be combined with intense sweeteners to provide mouthfeel and texture normally provided by sucrose while meeting requirements for energy reduction.

Concentrations Required for Soft Drinks

This Application requests an increase in the permitted level of saccharin in water-based flavoured drinks from 80 mg/kg to 150 mg/kg. Soft drinks contain up to 15 % sugar, which at a conversion rate of 300 to 1 would require 500 mg/kg of saccharin.

Conclusion

The use of saccharin as a sweetener in water-based flavoured drinks at 150 mg/kg is technologically justified.

References

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