

8-04
20 October 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P287

REVIEW OF CYCLAMATE PERMISSIONS

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

1 December 2004

(See 'Invitation for Public Submissions' for details)

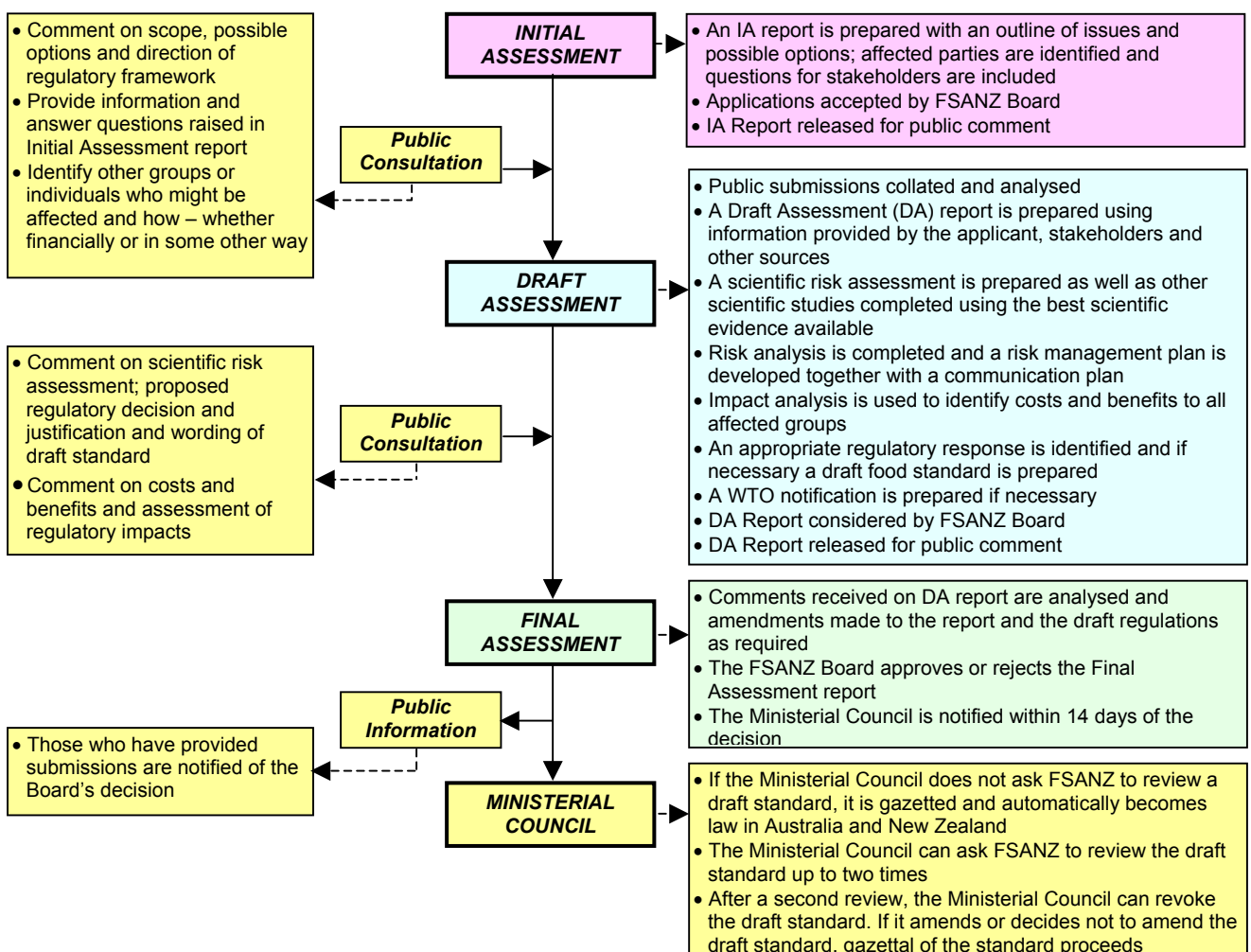
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P287, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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

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

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

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 1 December 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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

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

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Executive Summary and Statement of Reasons

Proposal P287 has been prepared to review the use of the intense sweetener cyclamate across the whole food supply. This is in light of a recent survey conducted on behalf of FSANZ on the consumption of intense sweeteners in Australia and New Zealand, which concluded that some consumers of cyclamate products currently for retail sale on the market exceeded the acceptable daily intake (ADI¹) for cyclamate.

This Initial Assessment Report is not a detailed assessment of Proposal P287 but rather an assessment of whether the Proposal should undergo further consideration. The Report is based mainly on information provided by the recent intense sweetener survey, published in 2004 and has been written to assist in identifying the affected parties and to outline expected relevant issues required to complete the assessment. The information needed to complete the assessment will include information received from public submissions.

- Proposal P287 has been assessed against the matters in section 13 (2) of the FSANZ Act. FSANZ is preparing this Proposal to address a potential public health and safety concern based on information arising from the recent intense sweetener survey, which concluded that some consumers of cyclamate-containing products exceed the ADI.

Accordingly, FSANZ now seeks public comment in order to proceed to the Draft Assessment Report.

¹ The current ADI for cyclamate is 11 mg/kg bw/day

1. Introduction

A recent FSANZ survey found that some consumers of cyclamate products currently for retail sale on the market exceeded the acceptable daily intake (ADI) for cyclamate².

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

2. Regulatory Problem

2.1 Current Standard

Current permissions in the *Australia New Zealand Food Standards Code* (the Code) under Standard 1.3.1 – Food Additives for cyclamate are as follows:

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

2.2 Problem identified by the 2003 survey.

In 2001, FSANZ undertook an evaluation of Standard 1.3.1 Food Additives as part of its Evaluation Strategy, to assess if the change from a prescriptive food additive standard in the former Australian *Food Standards Code* to a more generic one in the *Australia New Zealand Food Standards Code*, had resulted in an impact on public health and safety. Changes in the use of intense sweeteners in the food supply and resultant consumer exposure were evaluated, using baseline data from a 1994 sweetener survey (Australian population only). This group of additives were selected due to a high consumer interest in low joule products, widespread use in the food supply and the fact that several sweeteners were subject to further monitoring following the review process.

The evaluation indicated no public health and safety concerns for most sweeteners including aspartame and sucralose, which now have permissions for use at Good Manufacturing Practice (GMP) levels as well as a few specific permissions where maximum limits apply for use in specific foods. The exception was cyclamate, where permissions had actually been made more restrictive.

² Consumption of Intense Sweeteners in Australia and New Zealand. Prepared by Roy Morgan Research. 2004.

Despite the permissions for cyclamate in soft drinks being reduced in the Code following the review (based on findings of the 1994 survey that some consumers were exceeding the cyclamate ADI), a group of high consumers of products containing cyclamate in the 2002-2003 survey still exceeded the ADI. The evaluation indicates this is due to an increase in intense sweetened products available, continuing high levels of cyclamate in cordials and home brand soft drinks at the time of the survey and the relatively low sucrose equivalent of cyclamate compared to other sweeteners.

2.3 Potential public health risks

In summary, the intense sweetener survey identified subgroups of the Australian and New Zealand populations that were high consumers of cyclamate-containing foods and at possible risk from exceeding the ADI. Studies in animals have shown effects on some reproductive parameters in male rats following administration of high doses of cyclamate in the diet of rats (**refer to Section 5.1**). Therefore, the potential long-term effects on health in humans of consumption over the ADI may need to be considered, although it is questionable whether high consumers of cyclamate products would exceed the ADI on a regular basis and whether effects in animals at much higher doses would cause similar adverse effects in humans.

A more detailed dietary exposure assessment and assessment of any new safety data on cyclamate may assist FSANZ in determining whether exceeding the ADI may pose a real risk to public health and safety.

3. Objective

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

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

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

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

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and

- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Key overall findings of the intense sweetener survey

As part of the FSANZ Evaluation Strategy 2001-2003, a survey of the use of intense sweetened foods by Australians and New Zealanders aged 12 years and above was undertaken, using the services of Roy Morgan Research, between August 2002 and February 2003. The survey was conducted in three phases:

1. a computer assisted telephone interviewing (CATI) survey of 3,529 people (2,514 in Australia and 1,015 in New Zealand) weighted to represent the population distribution of each country. This survey phase aimed to record consumption patterns of intense sweetened foods and to identify users of these foods to participate in subsequent survey phases;
2. a seven-day, brand specific, self-completed diary of consumption amounts of intense sweetened foods among 400 respondents (263 in Australia and 137 in New Zealand), who were identified as consumers of these foods. Food consumption data reported in the diary were matched with sweetener concentration data supplied by industry; and
3. a separate diary survey of 298 people (223 in Australia and 75 in New Zealand) with either diabetes or impaired glucose tolerance.

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

A review of products available in Australia that contain intense sweeteners, conducted as a preliminary step in this survey, indicated that the number of foods containing intense sweeteners available in 2002 has approximately doubled since 1994. There now appear to be more product categories containing intense sweeteners, and more individual products within these categories.

From this survey the key findings were:

- mean consumer exposure to all intense sweeteners surveyed was below the relevant Acceptable Daily Intake (ADI);
- exposure in relation to each ADI was highest for cyclamate with some high consumers exceeding the cyclamate ADI³;
- cordials, fruit drinks and carbonated soft drinks were the major contributors to cyclamate exposure;
- women, people with diabetes and those on weight control diets were more likely to use foods containing intense sweeteners;

³ The current ADI for cyclamate is 11 mg/kg bw/day

- those with diabetes or impaired glucose tolerance who consume foods containing intense sweeteners were not exposed to higher amounts of intense sweeteners than consumers who have neither of these medical conditions.

Compared to a similar survey of Australians aged 12-39 years conducted in 1994:

- consumption amounts of carbonated soft drinks and yoghurts/mousses containing intense sweeteners had increased;
- dietary exposure to acesulphame K had increased;
- dietary exposure to aspartame, saccharin and cyclamate had remained constant.

4.2 Exposure to cyclamate as measured in the survey

Some high consumers of foods containing cyclamate were found in this survey to have cyclamate exposures that exceeded the ADI. Soft drinks and cordials were the major contributors to cyclamate exposure in both countries, with tabletop sweeteners also contributing to cyclamate exposure among New Zealanders, particularly older New Zealanders⁴.

Across the 71% of diary survey participants who consumed foods containing cyclamate during the seven-day diary survey, 95th percentile dietary exposure to cyclamate represented 85% of the ADI. However exposure varied with age and country. In Australia, 25-39 year old consumers and the small number of 12-17 year old consumers exceeded the cyclamate ADI at the 95th percentile (151% and 245% respectively), while in New Zealand the small base of 25-39 year old consumers, as well as those consumers aged 60 years and over, also exceeded the cyclamate ADI at the 95th percentile (104% and 112% respectively).

Exposure to cyclamates, expressed as a proportion of the ADI, has not decreased since the 1994 survey.

4.3 Exposure to cyclamate assuming Code limits are fully adopted

The survey was conducted during the transition period to the Code so that products were still available for sale, and were consumed by survey participants, that conformed to the requirements of the former Australian *Food Standards Code* and the New Zealand Food Regulations. These requirements were substantially different in relation to the amounts of cyclamate permitted in some foods. Following consideration of the results of a similar survey conducted in 1994 during the review of the former Australian *Food Standards Code*, permitted levels of cyclamate in low joule beverages were substantially reduced (from 20 to 0.6 g/kg), as were levels in other low joule products, and cyclamates were no longer permitted in table top sweeteners in New Zealand.

⁴ The Code does not permit the use of cyclamate in tabletop sweeteners nor did the former Australian Food Standards Code. The 1984 New Zealand Food Regulations did permit the use of cyclamate in tabletop sweeteners prior to February 2003, when the Code became the only legal Food Standards in force for manufacturers.

Additional exposure estimates were therefore prepared assuming that all foods consumed in the survey contained levels of cyclamate now permitted under Standard 1.3.1 of the Code. Estimated exposures for high consumers (95th percentile) remained at or above the ADI for New Zealanders aged 25-39 years (103%) and Australians aged 12-39 years (110%). Exposure of the total survey population (all ages) at the 95th percentile was estimated at 73% of the ADI.

4.4 Exposure to cyclamate in children

Children under 12 years of age were not included in the survey, for methodological and cost reasons. Exposure of Australian children aged 2-11 years to cyclamate was therefore estimated using the food consumption data measured in the 1995 National Nutrition Survey and weighted mean cyclamate levels collected in the 2002-2003 survey. Exposure of Australians aged 12+ years was also estimated using the 1995 consumption figures for comparison with the survey results. Consumption data for New Zealand children is not yet available.

Using this approach, mean and 95th percentile exposure to cyclamate among Australian children aged 2-11 years who were consumers of cyclamate-containing foods was estimated to be approximately 50% and 200% of the ADI respectively. The estimates of mean and 95th percentile cyclamate exposure among those aged 12+ years were approximately half those reported from the survey; this difference in estimated exposure is likely to reflect the observed increase in soft drink consumption since the 1995 National Nutrition Survey and several other factors. This suggests that estimates of children's exposure are also likely to be lower than would have been observed had young children been included in the 2002-2003 survey population.

4.5 Work Plan Classification

This proposal has been provisionally rated as Category of Assessment 4 (level of complexity) and placed in Group 1 on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Safety of cyclamate-containing foods

In 1982 the World Health Organisation's Joint Expert Committee on Food Additives (JECFA) allocated an acceptable daily intake (ADI) of 11 mg/kg body weight based on the results of male rats fed diets containing cyclohexylamine⁵ at daily doses of 50, 100, 200, or 300 mg/kg/day for 90 days. This ADI was calculated using a safety factor of 100-fold (based on a NOAEL⁶ of 100 mg/kg/day) below the level of cyclohexylamine found to produce testicular effects in rats (namely; testicular atrophy, decreased organ weight, decreased spermatogenesis and degeneration of the tubular epithelium) and allowed for the approximate human conversion rate of 30% of ingested cyclamate to cyclohexylamine by intestinal bacteria.

⁵ Cyclohexylamine is a metabolite (breakdown product) of cyclamate

⁶ No Observed Adverse Effect Level (NOAEL). This is the highest dose administered to rats where no adverse effects were observed.

On 9 March 2000, the European Commission's Scientific Committee on Food expressed an opinion on the safety of cyclamate based on further studies conducted and considered that an ADI of 7 mg/kg bw/day was more appropriate, compared to the current ADI of 11 mg/kg bw/day.

FSANZ will re-examine the toxicological data in relation to cyclamate at Draft Assessment and in particular, examine the following issues in relation to the safety of cyclamate:

What are the possible public health and safety consequences of exceeding the ADI for specific consumers (e.g. children and other potentially at risk population subgroups who are high consumers of cyclamate-containing products)?

What is an appropriate strategy for ensuring the safe use of cyclamates in foods?

5.2 Dietary exposure

FSANZ will undertake a dietary exposure assessment to determine overall exposure to cyclamate for a range of populations using either existing permissions detailed above or more recent data on manufacturers' use levels.

FSANZ is seeking data from manufacturers of cyclamate-containing foods in order to determine the precise levels used in foods currently marketed in Australia and New Zealand, where the amount of cyclamate used in a given food product has changed significantly from that used in 2002-2003 (as reflected in the data submitted by manufacturers to FSANZ for use in the 2002-3003 survey).

5.3 Views of major interest groups/stakeholders

All major stakeholder groups have been previously involved in the intense sweetener survey and implementation of this evaluation activity, either by membership of the project team or as a representative on the Stakeholder Advisory Group on Evaluation. The stakeholder groups were very supportive of all the evaluation research projects and the decision to make the research results publicly available, regardless of the content of each report.

The full report of the intense sweetener survey was made available on the FSANZ website as well as in hard copy for a limited distribution to interested parties. Copies of the final report were also forwarded formally to members of the Board, the FSANZ Data and Evaluation Steering Committee, the stakeholder Advisory Group on Evaluation, the TAG Committee, the Maori Reference Group and the Implementation Sub-Committee (ISC) of the Australian Government Department of Health and Ageing for their information.

Articles were also placed in *Food Surveillance News* and other relevant newsletters, for example the Dietitians Association of Australia newsletter.

FSANZ has also recently (June 2004) contacted key industry associations in regard to this Proposal, and has invited them to participate in providing comment throughout the stages of this Proposal. These industry members have expressed a willingness to contribute to the assessment process.

5.4 International regulations on cyclamate

Cyclamate is currently approved for use in more than 50 countries. However, it is still not permitted for use in the USA and Canada only permits cyclamate use in tabletop sweeteners.

What effects, if any, on international trade would occur if FSANZ decreased the cyclamate permissions in selected foods?

6. Risk Management

In developing a meaningful and realistic risk management strategy to protect any groups considered at risk of excess exposure to cyclamate from the food supply, FSANZ will raise the awareness of and seek input from key stakeholders in industry, government agencies and consumers.

This may involve consideration of the following:

- reviewing maximum limit permission for cyclamate in foods;
- identifying appropriate options to manage the risk of high dietary exposure to cyclamate;
- consideration of a public education campaign to alert specific consumers to the possibility of over-consumption of cyclamate-containing products; and
- consider specific targeted options for groups considered particularly susceptible to exceeding the ADI or develop community wide options to assist in decreasing exposure for high consumers.

7. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles.

The possible regulatory options available for this Proposal have been identified in the Risk Management section.

To further develop the impact analysis in terms of the costs and benefits of the regulatory options proposed, FSANZ seeks comment on the following:

Scientific aspects of the Proposal in particular any information relevant to the safety assessment and/or dietary exposure assessment.

What are the potential costs or benefits of the proposed risk management options to you as a stakeholder? Do the benefits outweigh the costs?

What are the costs or benefits for consumers of the proposed risk management options in terms of public health and safety, consumer information and labelling? Do any identified health benefits for the targeted group of consumers (e.g. people with diabetes and other high consumers) outweigh any costs to non-target groups?

What are the costs or benefits for business of the proposed risk management options – increased market opportunities both domestically and overseas, production costs, marketing costs including providing advice to consumers, additional labelling requirements?

What are the costs and benefits for government of the proposed risk management options – administrative, public health and safety?

In particular, can food manufacturers specifically indicate the effect of reducing the permitted levels of cyclamate as an ingredient in foods; including: effects of continued use of cyclamate as an ingredient, use of other sweeteners in low joule products, impact on the product range and magnitude of any change in costs and final prices to consumers?

Additionally, can consumers, particularly those with diabetes or on weight control diets, and health professionals, comment on the effect of any measurable increase in prices of low joule food products, or reduction in the range of these products?

8. Impact Analysis

Parties likely to be affected by the possible options as listed above are consumers, manufacturers and State/Territory and New Zealand Health Departments.

8.1 Affected Parties

- those sectors of the food industry wishing to retain the manufacturing of cyclamate and/or the marketing of cyclamate-containing food products and in particular the effects on small business (if any);
- consumers, in particular those who seek cyclamate-containing products who may be disadvantaged if regulatory measures were required that decreased availability of some products on the market;
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

9. Consultation

9.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this Proposal. There will also be a further round of public comment after the Draft Assessment Report is completed.

9.2 World Trade Organization (WTO)

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

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

10. Conclusion and Recommendation

- Proposal P287 has been assessed against the matters in section 13 (2) of the FSANZ Act. FSANZ is preparing this Proposal to address a potential public health and safety concern based on information arising from the recent intense sweetener survey, which concluded that some consumers of cyclamate-containing products exceed the ADI.

Accordingly, FSANZ now seeks public comment in order to proceed to the Draft Assessment stage.