

**08/03**  
**19 March 2003**

## **INITIAL/DRAFT ASSESSMENT REPORT s.36**

### **PROPOSAL P273**

### **INTENSE SWEETENERS IN JELLY**

**DEADLINE FOR PUBLIC SUBMISSIONS** to the Authority in relation to this matter:

**16 April 2003**

*(See 'Invitation for Public Submissions' for details)*

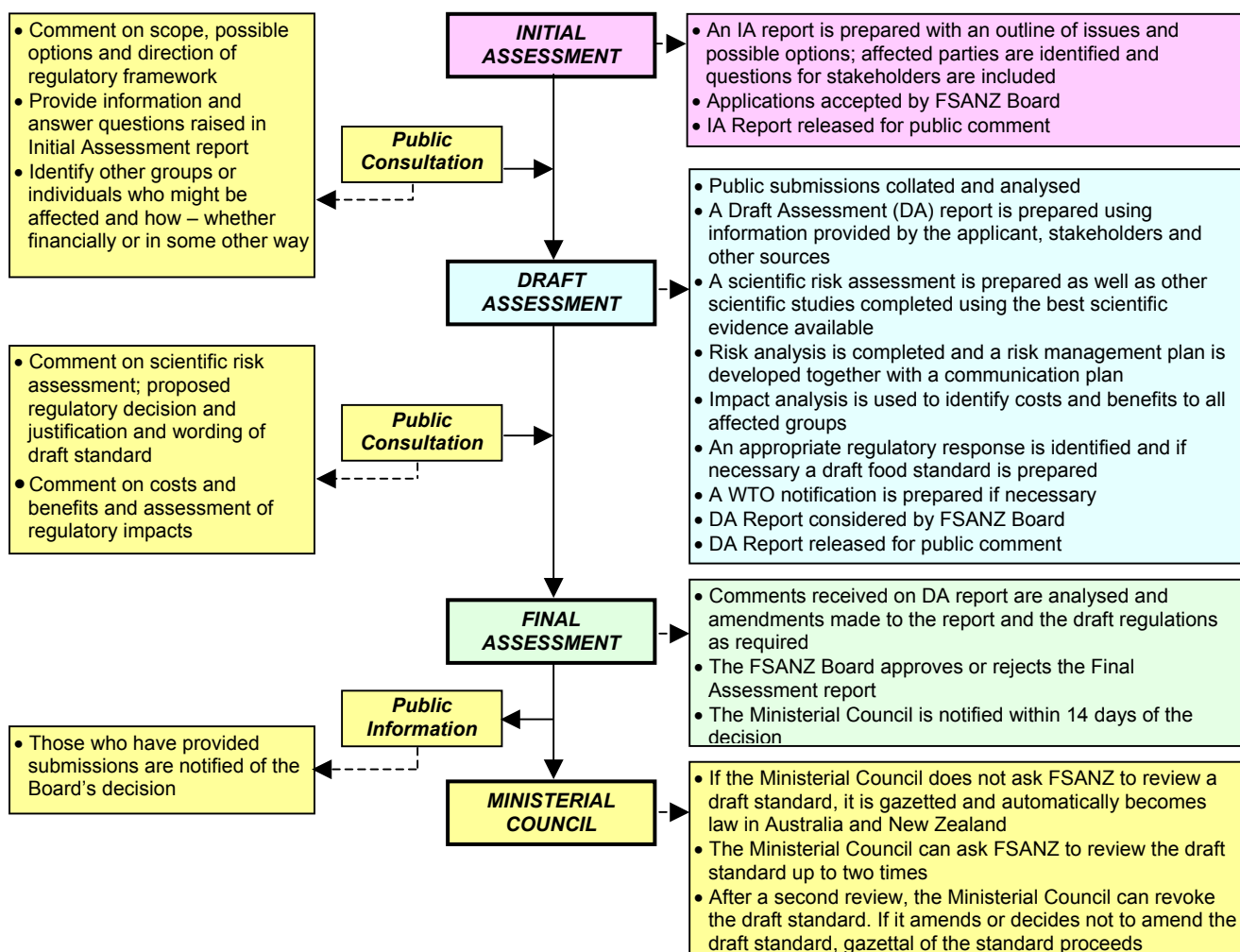
## FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

The Authority has prepared an Initial/Draft Assessment Report of Proposal P273 and prepared a draft variation to the *Australia New Zealand Food Standards Code*.

The Authority invites public comment on this Initial/Draft Assessment Report based on regulation impact principles and the draft variation to the *Australia New Zealand Food Standards Code* for the purpose of preparing an amendment to the *Australia New Zealand Food Standards Code* for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Final Assessment for this proposal. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). Information providing details of potential costs and benefits of the proposed change to the *Australia New Zealand Food Standards 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires the Authority to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Under section 36 of the FSANZ Act, the Authority opted to omit one round of public consultation as it was satisfied that the Proposal raises issues of minor significance and complexity only. Furthermore, the Authority considered that omitting to invite public submissions prior to making a draft assessment, would not significantly adversely affect the interests of any person or body. Subject to the *Administrative Appeals Tribunal Act 1975*, application may be made to the Administrative Appeals Tribunal, for review of the decision (under section 36) by a person whose interests are affected by the decision.

The Authority will conduct a single round of public consultation and now invites submissions on this Initial/Draft Assessment Report based on regulation impact principles and the draft variation to Volume 2 of the *Food Standards Code* for the purpose of preparing an amendment to the *Food Standards Code* for approval by the FSANZ Board.

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](http://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](http://www.foodstandards.govt.nz)

Submissions should be received by the Authority **by 16 April 2003**. 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 Liaison Officer at the above address or by emailing [slo@foodstandards.gov.au](mailto:slo@foodstandards.gov.au).

Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority's Information Officer at either of the above addresses or by emailing [info@foodstandards.gov.au](mailto:info@foodstandards.gov.au).

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## Executive Summary and Statement of Reasons

Until their repeal in December 2002, the *New Zealand Food Regulations, 1984* (NZFR) and the then Volume 1 of the *Food Standards Code* permitted the use of cyclamates and saccharin in low joule jelly. Currently the *Australia New Zealand Food Standards Code* (the Code) does not permit the use of cyclamates and saccharin in jelly.

The regulatory problem is that industry in both Australia and New Zealand has an established history of the use of cyclamates and saccharin in low joule jellies. During the recent review of food standards, neither industry or government submissions from New Zealand or Australia ever remarked the omission from the Code of the permissions for the use of cyclamate and saccharin in low joule jelly. Only late in the transition period, shortly before repeal of the then Volume 1 of the *Food Standards Code* and the NZFR, was the issue of the omissions raised as a problem for the manufacturers of these products. Although other intense sweeteners are permitted in the Code, it seems that almost all low joule jellies produced in Australia and New Zealand use only cyclamates and saccharin.

Without permission in the Code for the use of cyclamates and saccharin in jelly, consumers of these specialty products will be disadvantaged. Consumers of these products include people with type 1 or type 2 diabetes, obesity, hypertension, or other conditions calling for weight loss and/or dietary sugar restriction.

Because of the anomaly between industry use and permissions in the Code, there is a strong public interest relating to the effective administration in the food regulatory system that justifies this proposal being placed in Work Plan Group 1. This Proposal does not significantly adversely affect the interests of any person or body and so it is intended to progress this matter under section 36 of the *Food Standards Australia New Zealand Act, 1991*, omitting one round of public comment.

After consideration of the issues associated with technological justification for the use of the intense sweeteners in low joule jelly, and with the dietary modelling that assessed the likely exposure to cyclamates and saccharin from low joule jelly, FSANZ recommends that Item 20.2 Mixed Foods, sub-item jelly in Schedule 1 of Standard 1.3.1 – Food Additives be amended to include permissions for the use of cyclamates and saccharin in jelly at the maximum permitted levels of 1600 mg/kg and 150 mg/kg respectively in the final food.

Reasons for these recommendations are that the proposed amendment:

- will resolve the unforeseen anomalies between the use of cyclamates and saccharin by jelly manufacturers and current Code permissions;
- is technologically justified because manufacturers will be permitted to use low cost and highly stable intense sweeteners with favourable taste profiles in low joule jellies;
- presents no significant increase in risk to public health and safety because the contribution of low joule jelly to the overall intake of cyclamates and saccharin is likely to be insignificant even for high consumers of these sweeteners;

- is unlikely to have a significant effect on international trade because the proposed amendment broadens intense sweetener permissions rather than restricts them, which would have the effect of a slight increase in international trade in jelly, although the volume and value of international trade in low joule jelly is not high; and
- will result in significant benefits to consumers (including people with type 1 and type 2 diabetes, obesity, hypertension, or other conditions calling for weight loss and/or dietary sugar restriction) and manufacturers, which will outweigh the significant costs associated with the unavailability of locally made low joule jelly.

## 1. Introduction

Until their repeal in December 2002, the *New Zealand Food Regulations, 1984* (NZFR) and the then Volume 1 of the *Food Standards Code* permitted the use of cyclamates and saccharin in low joule jelly. Currently the *Australia New Zealand Food Standards Code* (the Code) does not permit the use of cyclamates and saccharin in jelly.

Late in 2002, shortly before the repeal of the NZFR and Volume 1, industry representatives contacted FSANZ requesting that the permissions be continued in Volume 2 of the *Food Standards Code* (now the *Australia New Zealand Food Standards Code* (the Code)). Without permission in the Code for the use of cyclamates and saccharin in jelly, their products would no longer be compliant, and consumers of these specialty products would be disadvantaged. Consumers of these products include people with type 1 or type 2 diabetes, obesity, hypertension, or other conditions calling for weight loss or dietary sugar restriction.

## 2. Regulatory problem

The regulatory problem is that industry in both Australia and New Zealand has an established history of the use of cyclamates and saccharin in low joule jellies. During the recent review of food standards, neither industry or government submissions from New Zealand or Australia ever remarked the omission from the Code of the permissions for the use of cyclamate and saccharin in low joule jelly. Only late in the transition period, shortly before repeal of the then Volume 1 of the *Food Standards Code* and the NZFR, was the issue of the omissions raised as a problem for the manufacturers of these products. Although other intense sweeteners are permitted in the Code, it seems that almost all low joule jellies produced in Australia and New Zealand use only cyclamates and saccharin.

## 3. Objective

The main objective of this proposal is to determine if it is appropriate to permit the use of saccharin and cyclamates in jelly and to evaluate any impacts on public health and safety from such permission.

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 *Food Standards Australia New Zealand Act 1991*. 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**

The review for the development of the joint food additives standard (P150) proposed that permissions for cyclamates and saccharin be reduced and/or deleted for many foods. This decision was based on the outcome of dietary modelling that showed a high intake of cyclamates and saccharin in some consumers, where intake levels were approaching or exceeding the Acceptable Daily Intakes (ADIs) for these intense sweeteners as determined by the Joint WHO/FAO Expert Committee on Food Additives (JECFA).

The P150 review was finalised in June 1999 and at no time before its finalisation did industry or government submissions, from either Australia or New Zealand, request that permission for cyclamates and saccharin use in jelly be included in the Code. The joint Australia New Zealand standard regulating food additives was gazetted in June 2000 and again, with amendments, in December 2000, along with the rest of the Code.

### **4.2 Work Plan Classification**

Permissions for cyclamates and saccharin are urgently needed in the Code to allow the manufacture of low joule jelly for consumers of these products. The lack of permission in the Code was overlooked until late in 2002 just before the repeal of the NZFR and the then Volume 1 of the Code.

Although other intense sweeteners are permitted in the Code, it seems that almost all low joule jellies produced in Australia and New Zealand use only cyclamates and saccharin. Because of the anomaly between industry use and permission in the Code, there is a strong public interest relating to the effective administration in the food regulatory system that justifies this proposal being placed in Work Plan Group 1.

## **5. Relevant Issues**

### **5.1 Technological justification**

Cyclamates are one of the most economical non-caloric sweeteners. Saccharin also is low in cost compared with other intense sweeteners. The two sweeteners when combined have a synergistic effect – that is the sweetness of the combination is greater than the sum of the individual parts. Cyclamates have a more favourable taste profile than saccharin in most food applications and do not leave an unpleasant aftertaste at normal use concentrations.

The primary advantage of the sweetener blend is that saccharin (300 times sweeter than sucrose) boosts the sweetening power of cyclamates (30 times sweeter than sucrose), whereas cyclamates mask the aftertaste that some people associate with saccharin. Both saccharin and cyclamates are also more stable than most other intense sweeteners. In dry form both are stable for several years. They also are highly soluble and remain stable over a wide pH range and temperature range.<sup>1</sup>

In summary, continued use of the blend of cyclamates and saccharin is technologically justified on the basis of the low cost, extreme stability and favourable taste profile of the two sweeteners used in combination.

Alitame and acesulfame potassium are currently permitted in the Code for use in jelly. Aspartame and sucralose are also permitted in a wide range of foods, including jelly. From industry use data provided commercial-in-confidence for FSANZ's intense sweetener survey, it seems that these permitted sweeteners are rarely used by jelly manufacturers in Australia or New Zealand. The technological feasibility of using these sweeteners in place of cyclamates and saccharin is therefore not well known.

Information from manufacturers about the feasibility of reformulating low joule jelly products with the currently permitted intense sweeteners (aspartame, sucralose, acesulphame potassium and alitame) would be helpful in preparing the Final Assessment Report.

### **5.2 Dietary modelling**

The dietary assessment report for cyclamates and saccharin (at Attachment 2) found that jelly was not identified as being a significant source of exposure to either saccharin or cyclamates. Therefore there is unlikely to be any adverse effect to public health and safety if the proposed amendment to the Code were to be approved.

### **5.3 Other applications to extend use of cyclamates and saccharin**

FSANZ is currently preparing an Initial Assessment report for Application A469 – Artificial sweetener levels in flavoured drinks. The outcome of the assessment of this application may significantly affect the intake of cyclamates and saccharin. Dietary modelling has not yet been done for A469. However, whatever the outcome of A469, the additional contribution for low joule jelly to the overall intake of these intense sweeteners is likely to be negligible (see dietary assessment report at Attachment 2).

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<sup>1</sup> *Alternative Sweeteners (3<sup>rd</sup> Edition, Revised and Expanded)* Nabors L O'B (ed) Marcel Dekker Inc 2001 New York, Basel.

## 5.4 FSANZ Intense Sweetener Survey

Following the development of the *Food Standards Code*, FSANZ put in place a program to monitor the levels and use of some food additives, including both cyclamates and saccharin. As part of this program, FSANZ has commissioned a survey of the use of intense sweetened products by Australians and New Zealanders aged 12 years and above.

This survey is expected to provide refined estimates of exposure to cyclamates, saccharin and other permitted intense sweeteners. Results of the survey are expected later in 2003. These results may have some bearing on cyclamates and saccharin permissions in the Code.

## 6. Regulatory options

Possible options are:

1. include permission for the use of cyclamates and saccharin in jelly in Schedule 1 of Standard 1.3.1 – Food Additives; or
2. do not include permission for the use of cyclamates and saccharin in jelly in Schedule 1 of Standard 1.3.1 – Food Additives.

## 7. Impact analysis

### 7.1 Groups affected by proposal

#### 7.1.1 Option 1 – If the proposed permission is approved:

##### Food industry

- Jelly manufacturers in New Zealand and Australia will be able to manufacture products that were permitted until the NZFR and the then Volume 1 of the Code were repealed in December 2002.
- Jelly manufacturers will have permission in the Code to use low cost, stable and reliable intense sweeteners.

##### Consumers

- Low joule jelly products will continue to be available to consumers who need to reduce caloric intake for weight loss purposes, including people with type 1 or type 2 diabetes, obesity, hypertension, or other conditions calling for weight loss and/or dietary sugar restriction.
- The low cost of cyclamates and saccharin compared with other intense sweeteners will help keep the retail cost of these products down.
- Food additive labelling requirements in the Code will inform consumers of the presence of these intense sweeteners.

### Government and enforcement agencies

- There would be no significant change to the current regulatory framework.
- Potential enforcement requirements needed.

#### 7.1.2 *Option 2 –If the proposed permission is not approved:*

### Food industry

- Jelly manufacturers will need to reformulate low joule jelly products using alternative intense sweeteners. Consequent labelling and packaging changes will also be required.

### Consumers

- Once product packaged on or before 20 December 2002 runs out, there will be no locally made low joule jelly products available until reformulation and repackaging processes have been undertaken and completed satisfactorily.

### Government and enforcement agencies

- There would be no significant change to the current regulatory framework.
- Increased active enforcement of this requirement needed.

## 7.2 **Data collection**

FSANZ has conducted two major dietary exposure assessments for saccharin and cyclamates 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 food standard on food additives (P150 – Review of food additives).

The dietary modelling for this report is based on these surveys. See dietary assessment report at Attachment 2.

Following the development of the Code, FSANZ put in place a program to monitor the levels and use of some food additives, including both cyclamates and saccharin. As part of this program, FSANZ has commissioned a survey of the use of intense sweetened products by Australians and New Zealanders aged 12 years and above. This survey is expected to provide refined estimates of exposure to cyclamates, saccharin and other permitted intense sweeteners. Results from this latest survey are expected later in 2003.

### **7.3 Impact analysis**

Based on the issues detailed above, the preferred option is Option 1. That is, to amend the Code to include permission for cyclamates and saccharin in low joule jelly. The proposal is technologically justified and dietary modelling indicates that there will be no significant increase in risk to public health and safety if the amendment were to be approved.

## **8. Consultation**

Submissions are sought from jelly producers in Australia and New Zealand on the issues raised in this proposal. Information about the feasibility of reformulating low joule jelly products with the currently permitted intense sweeteners (aspartame, sucralose, acesulphame potassium and alitame) would be helpful in preparing the Final Assessment report.

Submissions are also sought from consumers of low joule jellies or their representatives.

### **8.1 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.

Amending the *Food Standards Code* to allow cyclamates and saccharin in low joule jelly is unlikely to have a significant effect on international trade because:

- low joule jellies are low value products that are not traded in large volumes; and
- broadening these food additive permissions is likely to slightly increase rather than restrict trade in low joule jelly products.

WTO notification is considered therefore unnecessary.

## **9. Conclusion and recommendation**

FSANZ recommends that Item 20.2 Mixed Foods, sub-item jelly in Schedule 1 of Standard 1.3.1 – Food Additives be amended to include permissions for the use of cyclamates and saccharin in jelly at the maximum permitted levels of 1600 mg/kg and 150 mg/kg in the final food respectively.

Reasons for these recommendations are that the proposed amendment:

- will resolve the unforeseen anomalies between the use of cyclamates and saccharin by jelly manufacturers and current Code permissions;
- is technologically justified because manufacturers will be permitted to use low cost and highly stable intense sweeteners with favourable taste profiles in low joule jellies;
- presents no significant increase in risk to public health and safety because the contribution of low joule jelly to the overall intake of cyclamates and saccharin is likely to be insignificant even in high consumers of these sweeteners;

- is unlikely to have a significant effect on international trade because the proposed amendment broadens intense sweetener permissions rather than restricts them, which would have the effect of increasing international trade in jelly, although the volume of international trade in low joule jelly is not high; and
- will result in significant benefits to consumers (including people with type 1 and type 2 diabetes, obesity, hypertension, or other conditions calling for weight loss and/or dietary sugar restriction) and manufacturers, which will outweigh the significant costs associated with the unavailability of locally made low joule jelly.

## **10. Implementation and review**

FSANZ has commissioned a survey of the use of intense sweetened products by Australians and New Zealanders aged 12 years and above. This survey is expected to provide refined estimates of exposure to cyclamates, saccharin and other permitted intense sweeteners. Results from this latest survey are expected later in 2003 and may have a bearing on permissions for the use of intense sweeteners.

FSANZ recommends that the effective date for the proposed amendments be from the date of gazettal.

### **Attachments**

1. Draft variations to the *Australia New Zealand Food Standards Code*.
2. Dietary Assessment report: Estimated dietary exposure to saccharin and cyclamates through consumption of intense-sweetened jelly in Australia and New Zealand.

**Draft Variations to the Food Standards Code**

**To commence: On gazettal**

[1] *Standard 1.3.1 of the Australia New Zealand Food Standards Code is varied by inserting in Schedule 1, under item 20.2, sub-item jelly –*

952	Cyclamates	1600	mg/kg
954	Saccharin	150	mg/kg

## Dietary Assessment Report

### Estimated dietary exposure to saccharin and cyclamate through consumption of intense-sweetened jelly in Australia and New Zealand

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 food standard on food additives (P150 – Review of food additives).

In both these assessments, the Acceptable Daily Intakes (ADIs) used were 11 mg/kg bw for cyclamate and 5 mg/kg bw for saccharin.

#### 1994 study

This study focussed on those people identified in a preliminary study as being ‘high consumers’ of intense sweetened foods. Among those in this group who consumed foods containing either cyclamate or saccharin, mean exposure to cyclamate and saccharin represented 23% and 9% respectively of the relevant ADI. At the 90<sup>th</sup> percentile of exposure, cyclamate exposure marginally exceeded the ADI (107%), with saccharin exposure at 56% of the ADI. While the sample size in this study was too small to allow a precise estimate of exposure at the 90<sup>th</sup> percentile, the study findings suggest there may be a small but significant proportion of the population at risk of exceeding the ADI for cyclamate. For example Aboriginal and Torres Strait Islander consumers reported mean daily consumption of cordial of 1275 mL/day, resulting in the ADI for cyclamate being exceeded from this product alone.

The 1994 study found that intense sweetened jelly was not a major contributor to dietary exposure to either saccharin or cyclamate. Jelly contributed only 4% to the mean cyclamate exposure and 1% to the mean saccharin exposure. Cordial was the major dietary exposure source for cyclamate (86%) and cordials and table top sweeteners the main sources for saccharin.

Only 1% of the total survey population (not only those identified as high consumers) ate intense sweetened jelly during the survey period, with females and those on weight control or low sugar diets or with a medical condition requiring restricted sugar intake being more likely to consume it. Among those who consumed intense sweetened jelly, mean daily consumption was 74±14 g. 90<sup>th</sup> percentile consumption of intense sweetened jelly was 229 g per day.

## **Review of food additives (P150)**

The dietary modelling conducted for the development of the joint food additives standard found dietary exposure to cyclamates and saccharin to be at similar levels to those found in the 1994 survey. For cyclamates, there was found to be potential for a high consumer of soft drinks containing cyclamates to exceed the ADI. For saccharin, it was found that some individual consumers of saccharin based table top sweeteners may exceed the ADI.

Jelly was not identified as being a significant source of exposure to either saccharin or cyclamate.

## **Current activity**

Following the development of the *Food Standards Code*, FSANZ put in place a program to monitor the levels and use of some food additives, including both cyclamate and saccharin. As part of this program, FSANZ has commissioned a survey of the use of intense sweetened products by Australians and New Zealanders aged 12 years and above. This survey is expected to provide refined estimates of exposure to cyclamate, saccharin and other permitted intense sweeteners.