

09/03
21 May 2003

INITIAL ASSESSMENT REPORT

APPLICATION A469

TO AMEND PERMISSIONS FOR SACCHARIN AND CYCLAMATE IN WATER BASED FLAVOURED DRINKS.

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
2 JULY 2003

(See “Invitation for Public Submissions” for details)

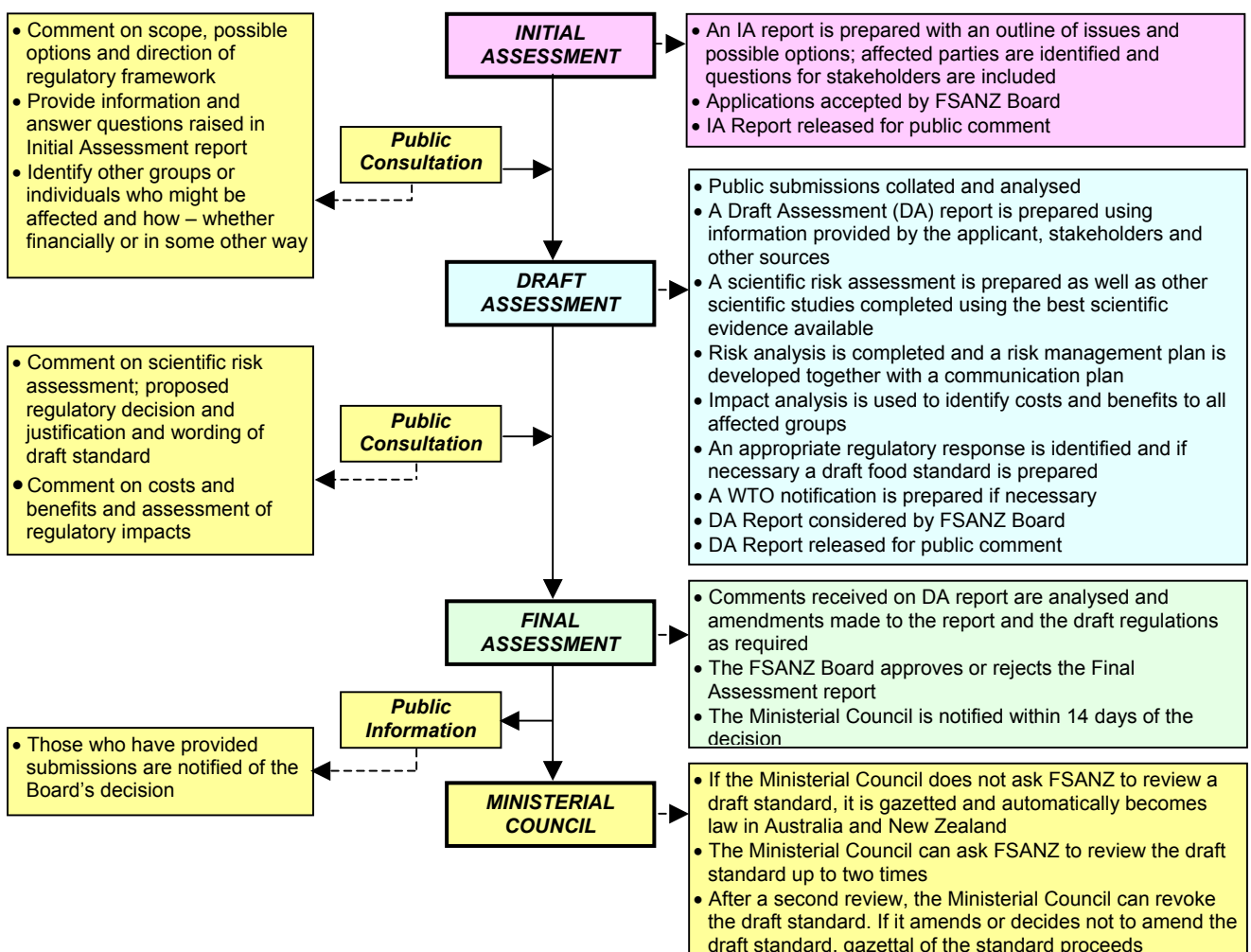
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 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 *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 Assessment Report of Application A469, which includes the identification and discussion of the key issues.

The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the *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 assessment for this application. Submissions should, where possible, address the objectives of the Authority as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the *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. 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.

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 the Authority by: **2 July 2003**. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent 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 .

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 including other general enquiries and requests for information.

Further Information

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

Food Standards Australia New Zealand
PO Box 7186
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APPLICATION A469 – TO AMEND PERMISSIONS FOR SACCHARIN AND CYCLAMATE IN WATER BASED FLAVOURED DRINKS

Executive Summary

This is an initial assessment report only and based on available information provided by the applicant. Public submissions are invited on this initial assessment report and will be used as part of the draft assessment stage.

The Australasian Soft Drinks Association (ASDA) submitted an application on 6 June 2002 to amend Schedule 1 subitem 14.1.3 in Standard 1.3.1. of the *Food Standards Code* to increase the maximum permitted levels of saccharin and cyclamate in water-based flavoured drinks.

The applicant requests amendment to the current permissions for the levels of saccharin (150 mg/kg) and cyclamate (1200 mg/kg) for inclusion in diet cordials and diet soft drinks. The applicant claims that the requested levels are considerably lower than those permitted for use in the old *Food Standards Code* and were permitted for use during the transition period until December 2002 (saccharin 1.5g/kg and cyclamate 20g/kg). However they are higher than those adopted in the current Food Standards Code (saccharin 80 mg/kg and cyclamate 600 mg/kg). The applicant claims that current permitted levels will force some beverage manufacturers to either withdraw their products from the market place or to reformulate to the legally permitted levels.

1. Introduction

The Australasian Soft Drinks Association (ASDA) submitted an application on 6 June 2002 to amend schedule 1 of subsection 14.1.3 of Standard 1.3.1. of the *Australia New Zealand Food Standards Code (Food Standards Code)* to increase the maximum permitted levels of saccharin and cyclamate in water-based flavoured drinks.

2. Regulatory Problem

The applicant requests permission for levels of saccharin (150 mg/kg) and cyclamate (1200 mg/kg) for inclusion in diet cordials and diet soft drinks. The applicant claims that the requested levels are considerably lower than those permitted for use in the former *Food Standards Code* and were permitted for use during the transition period until December 2002 (saccharin 1.5g/kg and cyclamate 20g/kg). However they are higher than those adopted in the current *Food Standards Code* (saccharin 80 mg/kg and cyclamate 600 mg/kg). The applicant claims that current permitted levels will force some beverage manufacturers to either withdraw their products from the market place or to reformulate to the legally permitted levels.

2.1 Current Regulations

Food Standards Code

In subitem 14.1.3 Schedule 1 of Standard 1.3.1 - Food additives, permits levels of saccharin (80 mg/kg) and cyclamate (600 mg/kg) in water-based flavoured drinks.

2.2 Overseas Regulatory status

International

United States - Code of Federal Regulations

21CFR189.135 Food containing any added or detectable level of cyclamate is deemed to be adulterated in violation of the act based upon an order published in the Federal Register of October 21, 1969 (34 FR 17063).

21CFR180.37 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. The food additives meet the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 22, 62, 266-267, 297-299. 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.

(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.

3. Objective

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 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

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

4.2 Workplan Classification

This Application had been provisionally rated as complexity Category 3 and placed in Group 2 on the FSANZ standards development Workplan. This Initial Assessment confirms these ratings. Further details about the Workplan and its classification system are given in Information for Applicants at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Safety issue as limits were lowered in the *Food Standards Code* review following dietary exposure assessment

During the review of the *Food Standards Code*, the permitted levels for cyclamates and saccharin were determined for the broad category of water-based flavour drinks and safety concerns were raised for the use of levels higher than those currently permitted.

5.2 Industry inability to meet revised intense sweetener levels without reformulation

The levels of 600 mg/kg for cyclamates, and 80 mg/kg for saccharin may force some manufacturers of soft drinks and cordials to reformulate or withdraw their products from the marketplace. The industry considers that both actions are unnecessary given that these products have had a history of safe consumption in the market place for a number of years.

According to the applicant, 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 soft drinks, which use 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, which would have the right synergistic properties.

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.

Saccharin is approved in the US as a special dietary sweetener. It is commercially available in three forms: acid saccharin, sodium saccharin and calcium saccharin. Sodium saccharin is the most commonly used form because of its high solubility and stability. In aqueous solutions, saccharin demonstrates high stability over a wide pH range.

Cyclamate is available for use in more than 50 countries but not currently in the USA. It is almost always used in combination with other sweeteners. It has a favourable flavour profile and is better able to mask bitterness than sugar. It is extremely stable at both high and low temperatures, over a wide pH range, as well as in the presence of light, oxygen and other ingredients.

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.

5.3 FSANZ currently examining intense sweetener exposure in Australia and New Zealand

FSANZ is currently conducting a detailed survey of use of intense sweetened foods in Australia and New Zealand, which will include revised estimates of exposure to intense sweeteners, including saccharin and cyclamate. Information from the detailed survey will assist in the assessment of this application.

6. Regulatory Options

Options available are:

- Option 1. Reject the application;
- Option 2. Accept the application and prepare a draft assessment report to consider amending Standard 1.3.1 - Food additives, to permit levels of saccharin (150 mg/kg) and cyclamate (1200 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 cyclamate and saccharin as a sweetener.
2. Consumers of water-based flavoured drinks containing cyclamate and saccharin as a sweetener.
3. Government agencies enforcing the food regulations.

8. Consultation

8.1 Public consultation

This Initial Assessment Report will be made available for public submissions. This allows interested parties (food industry groups, food companies, consumers and consumer groups and government agencies) to make submissions including any technical matters that may be relevant.

Areas that FSANZ is seeking public comment on in order to assess this application include:

- The need for an amendment to permit levels of saccharin (150 mg/kg) and cyclamate (1200 mg/kg) in water-based flavoured drinks.
- Any public health and safety implications arising from amendment of the permitted levels.
- Cost implications of amendment of the permitted levels.

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.

Amending the Code is unlikely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment (formerly Full Assessment) and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusion and Recommendation

The above application fulfils the requirements for Initial Assessment as prescribed in section 13 of the *FSANZ Act 1991*.

In making an initial assessment of the application, the Authority must have regard to the following matters:

- (a) whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires;
- (b) whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
- (c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
- (d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
- (e) any other relevant matters.

The Application relates to a matter that may warrant a variation of a food regulatory measure.

It is recommended that the application A489 be accepted and public submissions be sought in order for FSANZ to make a draft assessment of this application.

If subsequently agreed by the Authority and supported by the Australia and New Zealand Food Regulation Ministerial Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would provide increased permitted levels of cyclamate and saccharin in water-based flavoured drinks.