



09/02
8 May 2002

INITIAL ASSESSMENT REPORT
(PRELIMINARY ASSESSMENT – SECTION 13)

APPLICATION A438

GAMMA CYCLODEXTRIN AS A
NOVEL FOOD INGREDIENT / FOOD ADDITIVE

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

19 June 2002

(See “Invitation for Public Submissions” for details)

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FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFS) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australian New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australian New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australian New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.
- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

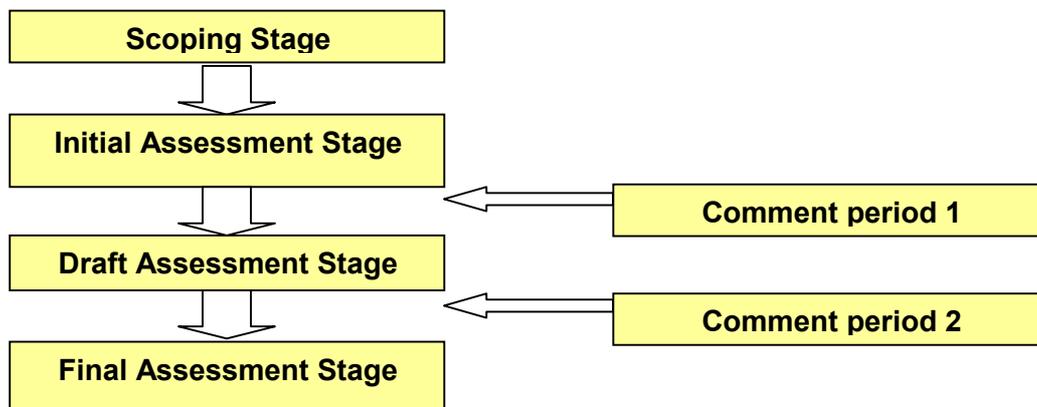
INVITATION FOR PUBLIC SUBMISSIONS

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an ‘application’ to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a ‘proposal’. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority may then undertake a draft assessment including preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

Comment opportunities in the usual assessment process to change the Australia New Zealand Food Standards Code (Note: this process may vary for matters that are urgent or minor)



Content of Submissions

Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. 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 presented should be in sufficient detail to allow independent scientific assessment.

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991 sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

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

In developing food regulatory measures and variations of food regulatory measures The Authority must also have regard to the following:

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

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.

Transparency

The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA 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 reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines

The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment periods of around 6 weeks, the periods allowed for comment may vary and may be limited to

ensure critical deadlines for projects can be met. Unless the Project Manager has given specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions

Submissions must be made in writing and should be clearly marked with the word **‘Submission’** and **quote the correct project number and title**. Submissions may be sent by mail to the Standards Liaison Officer at one of the following addresses:

Australia New Zealand Food Authority PO Box 7186 Canberra BC ACT 2610 AUSTRALIA Tel (02) 6271 2258 email: slo@anzfa.gov.au	Australia New Zealand Food Authority PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 email: anzfa.nz@anzfa.gov.au
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Submissions should be received by the Authority by: 19 JUNE 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

FURTHER INFORMATION

Further information on the application and submission process should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

INTRODUCTION

The Australia New Zealand Food Authority (ANZFA) is a bi-national statutory body responsible for developing draft food standards and draft variations of standards, to make recommendations to the Australia New Zealand Food Standards Council (ANZFSC) in relation to those drafts, and to review standards. ANZFSC may then decide to adopt the draft standards or draft variations of standards, which results in their incorporation into food laws of the Australian States and Territories, and New Zealand.

On 24 November 2000, ANZFSC adopted the *Australia New Zealand Food Standards Code* (known as Volume 2 of the *Food Standards Code*) that will apply in both Australia and New Zealand. A two-year transitional period has been implemented at the conclusion of which Volume 2 of the *Food Standards Code* will be the sole code for both countries. In the interim, for the majority of the food standards, there is a system of dual standards operating in both Australia and New Zealand.

An application has been received from Wacker Chemie GmbH on 12 April 2001 seeking to amend Standards A19/1.5.1 of the *Food Standards Code* to permit the use of gamma-cyclodextrin (γ -cyclodextrin) as a novel food ingredient. This application is at the preliminary assessment stage as detailed in the section 13 of the *Australia New Zealand Food Authority Act 1991*.

REGULATORY PROBLEM

The application is seeking approval of γ -cyclodextrin as a novel food. Under the current food regulations, novel foods are required to undergo a pre-market safety assessment, as per Standard A19/1.5.1 – Novel Foods. The purpose of Standard A19/1.5.1 is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail for consumption in Australia or New Zealand.

Novel Foods is defined in the Standard as:

A non-traditional food or food ingredient for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account-

- (a) the composition or structure of the product;
- (b) levels of undesirable substances in the product;
- (c) the potential for adverse effects in humans;
- (d) traditional preparation and cooking methods; or
- (d) patterns and levels of consumption of the product;

γ -Cyclodextrin could be considered a novel food ingredient (for some of the uses proposed) because it is a non-traditional food for which there is insufficient knowledge in the broad community to ensure safe use in the form in which it is presented. Its safety needs to be assessed before it can be marketed.

γ -Cyclodextrin also has properties consistent with its consideration as a food additive (see later discussion). Food additives also require pre-market assessment under Standard 1.3.1-Food Additives.

OBJECTIVE

The initial application received from Wacker Chemie GmbH on 12 April 2001 was seeking to amend Standards A19/1.5.1 of the *Food Standards Code* to permit the use of γ -cyclodextrin as a novel food ingredient. After consultations with ANZFA regarding its use as food additive, the applicant has agreed to amend the application title to include 'food additive'. The objective of this application is to determine whether the food standards can be amended to approve the use of γ -cyclodextrin as a novel food ingredient/food additive in a wide range of foods. Such an amendment to the *FSC* will need to be consistent with the section 10 objectives of ANZFA Act. The three primary objectives of the Authority 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, ANZFA 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; and
- the promotion of fair trading in food.

BACKGROUND

Properties of γ -cyclodextrin

γ -Cyclodextrin is a cyclic polymer consisting of eight glucose units linked by γ -1,4 bonds. It is produced enzymatically from liquefied starch. Due to the steric arrangement of the glucose units, the torus-shaped molecule has a hydrophobic inner surface cavity, and a hydrophilic outer surface, which allows it to form inclusion complexes with various organic compounds. This property forms the basis of numerous applications of γ -cyclodextrin in foods.

The applicant claims that γ -Cyclodextrin can form complexes with natural colours, flavours and vitamins allowing its use as a carrier and stabilizer for these additives. With polyunsaturated fatty acids (PUFA's), it is also claimed that it can be used to protect them from oxidation. In baked foods it is claimed to act as a dough conditioner and as a stabilizer

in oil/water emulsions in desserts. It is also claimed to act as a flavour modifier by suppressing undesirable characteristics.

Proposed uses

The substance is proposed to be used in the following foods for different applications:

1. Complexant for flavours, colours and sweeteners
 - Dry mixes for soups and beverages;
 - Dry mixes for dressings, gravies, and sauces;
 - Dry mixes for puddings, desserts, jellies and fillings
 - Instant coffees and teas;
 - Beverage whiteners;
 - Sugar confectionery, chewing gum, savoury snacks and biscuits;
 - Breakfast foods; and
 - Spices and seasonings
2. Complexant for vitamins- appropriate food uses
3. Complexant for PUFA's - appropriate food uses
4. Flavour modifier
 - Soy milk products
5. Stabilizer
 - Table spreads (reduced fat);
 - Frozen dairy desserts;
 - Dairy desserts;
 - Baked foods;
 - Breads;
 - Fruit based fillings;
 - Fat based fillings; and
 - Processed cheese

Approval in other countries

γ -Cyclodextrin is available in the USA as a Generally Recognised As Safe (GRAS) dietary ingredient (GRAS Notice No. GRN 000046). γ -Cyclodextrin is being considered for approval under EU regulations. It is considered to be a food in Japan and hence explicit approval is not required.

There are no Codex standards in relation to γ -cyclodextrin addition to foodstuff.

ISSUES TO BE ADDRESSED DURING ASSESSMENT

Is γ -cyclodextrin a novel food or a food additive?

The applicant has requested that γ -cyclodextrin be assessed as a novel food ingredient because of its use in table spreads at levels of up to 20%. While γ -cyclodextrin can be compared to other food ingredients such as starch and maltodextrin, and is nutritionally equivalent to these carbohydrates, the majority of its uses are based on its functionality. The evaluation of γ -cyclodextrin carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was based on its use as a food additive. Therefore it may be more appropriate to assess γ -cyclodextrin both as a food additive and as a novel food ingredient, depending on its use in particular foods.

Dietary considerations

Based on the US Food consumption data (1989-1991) the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has estimated that the mean estimated intake for γ -cyclodextrin from its use in food was approximately 4 grams per day. The estimated daily intake for the 90th percentile group was about 7.5 grams per day. These estimates are based on the use of γ -cyclodextrin in all foods and at the highest levels. The realistic dietary intake would be much lower.

During the Draft Assessment dietary modelling will be conducted by ANZFA to estimate the potential dietary intake of γ -cyclodextrin in Australia and New Zealand that may result from permitting its use in the foods specified in the application.

Nutritional considerations

γ -Cyclodextrin is hydrolysed by salivary and pancreatic amylases to glucose which is readily absorbed. Because starch and maltose are also converted to glucose after ingestion, γ -cyclodextrin can be considered to be nutritionally equivalent to these carbohydrates. Studies undertaken to assess the impact of γ -cyclodextrin consumption on the bioavailability of certain essential nutrients such as vitamins and essential fatty acids will be considered during the Draft Assessment.

Safety issues

The safety of γ -cyclodextrin for certain specified uses in food has been evaluated by JECFA. Based on their assessment, γ -cyclodextrin was considered to be a substance of low toxicity which did not represent a hazard to human health and subsequently a 'not specified' ADI was allocated. All of the studies considered by JECFA together with a gastrointestinal tolerance study in humans, a chronic 1-year toxicity study in rats and a carcinogenicity study in rats have been submitted to ANZFA. The available studies on the safety of γ -cyclodextrin will be evaluated during the Draft Assessment.

DRAFT REGULATORY OPTIONS

ANZFA is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, the food industry and

governments in both Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Food Standards Code will be analysed in a Regulatory Impact Assessment.

The regulatory options currently under consideration are:

Option 1. Not permit the use of γ -cyclodextrin.

Option 2. Permit the use of γ -cyclodextrin.

IMPACT ANALYSIS

Parties possibly affected by the options outlined include:

1. Food industry wishing to promote food products with γ -cyclodextrin.
2. Consumers who may benefit from the use of γ -cyclodextrin-containing products.
3. Government agencies enforcing the food regulations.

The draft regulatory options are as follows:

Option 1. Not permit the use of γ -cyclodextrin.

On the basis of this Initial Assessment, there are no perceived benefits to government, consumers or industry by maintaining the *status quo* and not giving specific permission in the *Food Standards Code* for the use of this ingredient.

On the basis of this Initial Assessment, there is no perceived cost for the government, however lack of approval in Australia or New Zealand may be construed as a non-tariff barrier to trade. Industry may also suffer from the non-availability of this ingredient.

Parties potentially disadvantaged by not permitting this substance, are the manufacturers of γ -cyclodextrin and producers who wish to use it in the manufacture of their final food products.

Option 2. Permit the use of γ -cyclodextrin.

On the basis of this Initial Assessment, industry and possibly consumers would benefit from this option. This option would result in no cost to government, industry or consumers, if its safety can be ensured.

Approval of γ -cyclodextrin would promote international trade in food products.

A more detailed analysis of the benefits and costs associated with the proposed amendment to the *Food Standards Code* will be considered at the Draft Assessment.

CONSULTATION

Public consultation

ANZFA is seeking public comment in order to assist in assessing this application. Public submissions will also be sought when the Draft Assessment (Full Assessment – section 15) is released. Comments that would be useful could cover:

- Technological properties of γ -cyclodextrin;
- Safety of γ -cyclodextrin; and
- Labelling of foods and food products containing γ -cyclodextrin.

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* to approve the addition of γ -cyclodextrin to foodstuff 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.

OTHER RELEVANT MATTERS

Workplan Classification

ANZFA's preliminary assessment of this application for placement on the Workplan was Group 2, Category 3 (see ANZFA website for further information about the workplan and the different groups and categories). Following Initial Assessment it is recommended that this is an appropriate grouping.

CONCLUSIONS

The above application fulfils the requirements for Preliminary Assessment as prescribed in section 13 of the *Australia New Zealand Food Authority Act 1991*.

Accordingly the Authority has decided to accept the application and will now proceed to the Draft Assessment Report (Full Assessment- section 15).

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to the *Food Standards Code*, as suggested by the applicant, would permit the use of γ -cyclodextrin as a novel food ingredient and/or the addition of γ -cyclodextrin as a food additive to food.