



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

8-06

13 December 2006

INITIAL ASSESSMENT REPORT

APPLICATION A585

DIMETHYL DICARBONATE AS A PROCESSING AID

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 7 February 2007

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED**

(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

An Application (A585) was received on 17 May 2006 from Brooke-Taylor & Co Pty Ltd, on behalf of Lanxess Deutschland GmbH (formerly Bayer Chemicals AG) seeking to amend Schedule 1 of Standard 1.3.1 – Food Additives, of the *Australia New Zealand Food Standards Code* (the Code), to remove the entries for dimethyl dicarbonate (DMDC) and replace these with corresponding entries in Standard 1.3.3 – Processing Aids.

Schedule 1 of Standard 1.3.1 currently contains permissions for use of DMDC (INS 242) in fruit and vegetable juice and juice products, water based flavoured drinks and wine, including sparkling and fortified wines.

The Applicant requests that these permissions be relocated to Standard 1.3.3 - Processing Aids, Table to clause 14 - Permitted processing aids with miscellaneous functions. According to the Applicant, the mode of action of DMDC more appropriately aligns with the definition of a processing aid within Standard 1.3.3 than the definition of a food additive.

Standard 1.2.4 of the Code sets out specific requirements for the labelling and naming of food ingredients. It requires that food additives be included in the ingredient list and are identified by their appropriate technological function. However, processing aids are not required to be declared in the ingredient list. Therefore the amendments to the Code sought by the Applicant would remove the labelling requirements for products treated with DMDC.

A previous Application (A259) was received by the then ANZFA on June 1995 from Bayer Australia Limited, seeking to permit the use of DMDC as a cold sterilising agent in alcoholic and non-alcoholic, carbonated and non-carbonated beverages. In 1996 DMDC was approved for use as a food additive (preservative agent) in non-alcoholic, carbonated and non-carbonated beverages. In 2004 FSANZ approved the use of DMDC as a food additive (preservative agent) in wine as a result of the Assessment of Application A474 - Winemaking.

At that time, the use of DMDC was considered comparable to that of a food additive although it is not present in the final food. Classification of DMDC as a processing aid was not considered appropriate since such a classification would be inconsistent with the use of the terms 'pure' and 'fresh'. To promote consistency with other countries, DMDC was classified as a food additive.

FSANZ has identified two regulatory options for this Application: Option 1 – Maintain the *status quo* and do not change the regulation of DMDC as a food additive; and Option 2 – Remove the permission for the use of DMDC from Standard 1.3.1- Food Additives and insert permission for use of DMDC as a processing aid in Standard 1.3.3- Processing Aids.

This Initial Assessment Report is not an assessment of the merits of the Application but rather is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Purpose

The purpose of undertaking an assessment of this Application is to determine whether it is appropriate to amend the Code to remove the entries for DMDC in Standard 1.3.1 - Food Additives and replace these with corresponding entries in Standard 1.3.3 - Processing Aids.

Preferred Approach

That FSANZ accepts the Application and proceeds to Draft Assessment.

Reasons for Preferred Approach

After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks the approval of DMDC as a processing aid and removal of the existing permission for the use of DMDC as a food additive. Such an approval if accepted, would warrant variations to Standard 1.3.1-Food Additives and Standard 1.3.3-Processing Aids.
- There is currently no permission in the Code for DMDC as a processing aid.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than variations to Standards 1.3.1 and 1.3.3 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Consultation

FSANZ seeks comments on this Initial Assessment Report. These submissions will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report. Comments are requested particularly regarding the implications of labelling changes if this Application is approved.

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INVITATION FOR PUBLIC SUBMISSIONS

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 of this Application. 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 need to be received by FSANZ by 6pm (Canberra time) 7 February 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

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.

INTRODUCTION

This Application (A585) seeks amendments to the Code to remove the entries for dimethyl dicarbonate (DMDC) in Schedule 1 of Standard 1.3.1 – Food Additives and replace these with corresponding entries in Standard 1.3.3 – Processing Aids. As a consequence of DMDC being regulated as a processing aid rather than a food additive if approved, there would be no requirement to include DMDC in the ingredient list on the label of a food containing DMDC.

This Application is presented by Brooke-Taylor & Co Pty Ltd on behalf of Lanxess Deutschland GmbH (formerly Bayer Chemicals AG). Lanxess is the manufacturer of DMDC (brand name Velcorin®) and Victus International is the Australian distributor of Velcorin®.

DMDC is currently used in beverages in accordance with its permission for use as a food additive (as a preservative agent) in fruit and vegetable juice and juice products, water based flavoured drinks and wine, including sparkling and fortified wines.

DMDC is added to the beverage package (bottle or can) immediately before filling. It functions to inactivate micro-organisms by entering the cell and inactivating some of the key enzymes required for cell function. At a molecular level, DMDC causes methoxycarbonylation of imidazole groups in enzymes essential to normal cellular metabolism, resulting in cell death. Excess DMDC then completely hydrolyses in the presence of water to form methanol and carbon dioxide.

The Applicant states that there is no residual DMDC activity in the beverage based on its hydrolysis rate. The rate of the hydrolysis reaction to form methanol and carbon dioxide is dependent on the temperature of the beverage. At 10°C (50°F) it takes approximately 4 hours for DMDC to completely break down. At 21°C (70°F) the break down of DMDC occurs in about 2 hours. Accordingly, there is no residual antimicrobial activity in a product sold through a normal commercial beverage distribution system.

1. Background

1.1 Current Standard

Schedule 1 of Standard 1.3.1 currently contains the following permissions for DMDC (INS 242).

Cat No.	Food Category	Max level	Units	Qualifications
14.1.2.	Fruit and vegetable juices and fruit and vegetable juice products	250	mg/kg	
14.1.3	Water based flavoured drinks	250	mg/kg	
14.2.2	Wine, sparkling wine and fortified wine	200	mg/kg	

The Applicant requests that these permissions be relocated to Standard 1.3.3 - Processing Aids, Table to clause 14 - Permitted processing aids with miscellaneous functions, as the mode of action of DMDC more appropriately fits within the definition of a processing aid within Standard 1.3.3 than a food additive.

In support of this, the Applicant states that other substances such as ozone and hydrogen peroxide, that have similar modes of action to DMDC, are treated as processing aids in Standard 1.3.3 of the Code.

1.2 International Standards

1.2.1 Codex

DMDC has been included in the Codex General Standard for Food Additives (GSFA) on the basis of its listing within the European Union (EU) food additive directive (see below). The accompanying Note 18 indicates that residues are not to be detected in the final food.

Dimethyl Dicarbonate INS: 242

Function: Preservative

Food Cat.	No. Food Category	Max Level	Comments	Year Adopted
14.1.4	Water-based flavoured drinks, including 'sport,' 'energy,' or 'electrolyte' drinks and particulated drinks	250 mg/kg	Note 18	1999
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa	250 mg/kg	Note 18	2004
14.2.2	Cider and perry	250 mg/kg	Note 18	2004
14.2.3	Grape wines	200 mg/kg	Note 18	2004
14.2.4	Wines (other than grape)	250 mg/kg	Note 18	2004
14.2.5	Mead	200 mg/kg	Note 18	2004

Note 18 states 'Added level; residue not detected in ready-to-eat food.'

Codex does not have a separate standard for processing aids. It does however have an Inventory of Processing Aids (IPA). This IPA is not a standard but an advisory list that has not been approved or agreed through the formal Codex process. FSANZ notes that DMDC is listed in the IPA as a micro-organism control agent for wine, with a requirement of no residues in the final food.

1.2.2 Regulation in other countries

The EU and USA regulated processing aids differently to Australia and New Zealand. They both do not have independent standards for processing aids separate from food additives unlike the Code. How DMDC is regulated in those countries is indicated in the sections below. FSANZ is not aware that DMDC is considered or regulated as a processing aid in either of these two areas.

1.2.2.1 European Union

DMDC is permitted by EU directive 95/2/EC, as a food additive, in non-alcoholic flavoured drinks, alcohol-free wine and liquid-tea concentrate at an ingoing amount of 250 mg/L, with residues not detectable.

1.2.2.2 United States

The Food and Drug Administration (FDA) has permitted the use of DMDC, as a food additive (food preservative), to prevent the growth of yeast in wine and for the inhibition of yeasts in alcohol-free wine and low alcohol wines by the addition of up to 200 mg/L provided the initial yeast counts were reduced to less than 500 viable cells per mL after an initial filtration or pasteurisation. DMDC is used to stabilise slightly sweet white wines and unfiltered red wines.

1.3 Historical Background

A previous Application (A259) was received by the then ANZFA on June 1995 from Bayer Australia Limited, seeking to permit the use of DMDC as a cold sterilising agent in alcoholic and non-alcoholic, carbonated and non-carbonated beverages. In 1996 DMDC was approved as a food additive (preservative agent) in non-alcoholic, carbonated and non-carbonated beverages.

At that time, the use of DMDC was considered comparable to that of a food additive although it is not present in the final food. Classification of DMDC as a processing aid was not considered appropriate since such a classification would be inconsistent with the use of the terms 'pure' and 'fresh'. To promote consistency with other countries, DMDC was classified as a food additive.

The conclusion of Application A259 was that use of DMDC was technically justified in a range of beverages and poses no public health and safety risk at the proposed level of use, up to 250 mg/L. In 2004, FSANZ approved the use of DMDC as a food additive (preservative agent) in wine as a result of the Assessment of Application A474 - Winemaking.

2. The Issue

2.1 Standards definitions

The definitions for Food Additive and Processing Aid are included in Standards 1.3.1 and 1.3.3 of the Code respectively.

Food Additive

A food additive is any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5. It or its by-products may remain in the food.

Processing Aid

Processing aid means a substance listed in clauses 3 to 18, where –

- (a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and*
- (b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.*

2.2 Labelling of Food Additives

Standard 1.2.4 of the Code sets out specific requirements for the labelling and naming of food ingredients. It requires that food additives be included in the ingredient list and are identified by their appropriate technological function and specific name or code number. The most relevant technological function in Schedule 5 to Standard 1.3.1 in relation to DMDC is ‘preservative’.

According to the Applicant, the labelling of DMDC as a ‘preservative’ food additive in this way:

- presents the erroneous impression that the product contains an active preservative at the time of sale;
- requires manufacturers to label their product in a manner which contravenes Australian and New Zealand fair trading legislation with regard to the ‘preserved’ status of the product; and
- misleads consumers that the product contains a preservative and will be microbiologically stable once opened.

FSANZ will assess this issue in detail at Draft Assessment. FSANZ is seeking comments on this aspect of the Application to assist in completing the Draft Assessment.

2.3 Consistency with International Regulations

As was mentioned in section 1.2 (International Standards) of this Report, DMDC is regulated as a food additive by Codex, the EU and the FDA. If DMDC were to be regulated in Australia and New Zealand as a processing aid rather than as a food additive it would create an inconsistency with international regulation, and this may have trade implications. This issue will be further discussed at Draft Assessment Report.

3. Objectives

The objective of this assessment is to determine whether it would be appropriate to amend the Code to remove the entries for DMDC in Standard 1.3.1 and replace these with corresponding entries in Standard 1.3.3 in order to more accurately recognise the technological functions performed by this substance.

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. Key Assessment Questions

Does the function of DMDC more appropriately align with the definition for processing aid or food additive?

How would amendment of the Code to remove the entries for DMDC as a food additive and replace them with corresponding entries as a processing aid affect stakeholders, in particular consumers?

Are there any national or international regulations that consider DMDC to be a processing aid?

It is possible, that if DMDC were to be regulated as a processing aid, the food industry may market products containing DMDC as 'preservative free'. Are the words 'preservative free' truthful for products treated with DMDC?

5. Food Technology Considerations

DMDC is added to the beverage package (bottle or can) immediately before filling. It functions to inactivate micro-organisms by entering the cell and inactivating some of the key enzymes required for cell function. Residual DMDC activity in the beverage is based on its hydrolysis rate. DMDC hydrolyses on contact with water to form methanol and carbon dioxide. Accordingly, there is no residual antimicrobial activity in a product sold through a normal commercial beverage distribution system.

The Applicant claims that there is no residual presence of DMDC or residual antimicrobial activity in the finished beverage and any residual methanol and carbon dioxide resulting from the use of DMDC is at a similar or lower level than and cannot be distinguished analytically from that which occurs naturally in the beverages.

RISK ASSESSMENT

6. Safety Assessment

DMDC was evaluated by the European Scientific Committee on Food (SCF) in 1990 and considered acceptable for the cold sterilisation of soft drinks and fruit juices at levels of addition up to 250 mg/L.

DMDC was also evaluated in 1990 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) which considered it inappropriate to establish an Acceptable Daily Intake (ADI) taking into account that the compound hydrolyses in aqueous media and that residual levels are below analytical detection limits. DMDC was considered acceptable as a cold sterilising agent for beverages up to a level of addition of 250 mg/L.

As mentioned in Section 1.3, an Application (A259) to allow the use of DMDC in beverages was previously assessed by the then ANZFA in 1996. A safety Assessment of the use of DMDC and breakdown products was undertaken and no public health and safety concerns were identified at the proposed levels of use.

A re-evaluation of the available safety data will be undertaken prior to Draft Assessment. Microbiological issues arising will be also addressed prior to Draft Assessment.

7. Dietary Modelling

FSANZ will consider the dietary exposure aspects of the risk assessment for this application more fully at Draft Assessment. This would include assessing the dietary exposure to the breakdown products of DMDC.

RISK MANAGEMENT

8. 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 agencies in Australia and New Zealand.

There are no options other than a variation to Standard 1.3.1 (and Standard 1.3.3) for this Application. Therefore the regulatory options available for this application are:

Option 1: Maintain the *status quo* and do not change the regulation of DMDC as a food additive; and

Option 2: Remove permission for the use of DMDC from Standard 1.3.1- Food Additives and insert permission for use of DMDC as a processing aid in Standard 1.3.3- Processing Aids.

9. Impact Analysis

9.1 Affected Parties

The parties affected by this Application include the following:

- consumers, particularly those who have concerns about food additives;
- the manufacturing and retail sectors of the beverage industry; and
- Australian Government, State and Territory agencies and government agencies in New Zealand.

9.2 Benefit Cost Analysis

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To develop the analysis of the cost and benefits of the regulatory options proposed, FSANZ seeks comments on the following:

- potential cost and benefits to the beverage industry;
- which beverage products are likely to be affected;
- the effect on the beverage and wine export industry;
- concentrations of DMDC breakdown products in foods where DMDC is permitted to be used;
- consumer perceptions of potential marketing of products containing DMDC as ‘preservative free’ should the amendments to the Code sought by the Applicant be accepted;
- any cost that may occur if DMDC were to be regulated as a processing aid rather than as a food additive; and
- any costs or benefits to Australian Government, State and Territory agencies responsible for enforcement of the Code.

COMMUNICATION

10. Communication and Consultation Strategy

This Application seeks approval for DMDC as a processing aid within Standard 1.3.3 and the removal of DMDC from the Standard 1.3.1 - Food Additives. This is considered a routine classification matter. As a result, FSANZ has applied a basic communication strategy to Application A585. This involves advertising the availability of the Initial Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, FSANZ will notify the Ministerial Council. The Applicant and stakeholders, including the public, will be notified on the gazettal of changes to the Code in the national press and on the website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

11. Consultation

11.1 Public consultation

Public comment is sought on the Initial Assessment Report for this Application.

The purpose of the Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any matter of interest to them in relation to the Application.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FSANZ will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this Application. All stakeholders must observe the relevant due date for submissions.

Comments that would be useful could cover:

- technological justification for the amendment to the Code, that is should DMDC be regulated as a processing aid in preference to its regulation as a food additive;
- views in relation to the subsequent change to labelling requirements for DMDC, should the amendments sought by the Applicant be approved;
- arguments in support of, or opposition to, permitting the amendment to the Code;
- likely costs and benefits of the amendment to the Code;
- possible effects on international trade if DMDC were to be regulated in Australia and New Zealand as a processing aid rather than as a food additive; and
- parties that might be affected by having this Application approved or rejected.

11.2 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 Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (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.

CONCLUSION

12. Conclusion and Preferred Approach

Preferred Approach

That FSANZ accepts the Application and proceeds to Draft Assessment.

This Initial Assessment Report is based mainly on information provided by the Applicant, supplemented by data from the previous review of DMDC (Application 259). After considering the requirements for Initial Assessment as prescribed in section 13 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ has decided to accept the Application for the following reasons:

- The Application seeks the approval of DMDC as a processing aid and removal of the existing permission for the use of DMDC as a food additive. Such an approval if accepted, would warrant variations to Standard 1.3.1-Food Additives and Standard 1.3.3-Processing Aids.
- There is currently no permission in the Code for DMDC as a processing aid.
- The Application is not so similar to any previous application that it ought not be accepted.
- There are no other measures that would be more cost-effective than variations to Standards 1.3.1 and 1.3.3 that could achieve the same end.
- At this stage no other relevant matters are apparent.

Responses to this Initial Assessment Report will be used to develop the next stage of the Application and the preparation of a Draft Assessment Report.