APPLICATION A1025
CLASSIFICATION OF DIMETHYL DICARBONATE
EXPLANATORY STATEMENT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application (A1025 - Classification of Dimethyl Dicarbonate) from Lanxess Deutschland GmbH (Germany, formerly Bayer Chemicals AG) and Victus International, on 3 June 2009. Lanxess is the manufacturer of Dimethyl Dicarbonate (DMDC) (brand name Velcorin®) and Victus International is the Australian distributor of Velcorin®. Application A1025 seeks a reassessment of the regulatory classification of DMDC. DMDC is currently listed as a food additive for use in some beverages in Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standards Code* (the Code).

The Application states that DMDC is currently regulated as a food additive despite having a mode of action which is more consistent with the definition of a processing aid under Standard 1.3.3 – Processing Aids. The Applicant asserts that DMDC is neither present nor technologically functional in the food as sold. Further, that by classifying DMDC as a food additive and therefore requiring it to be labelled as a preservative in the statement of ingredients, the Code does not reflect that DMDC has no ongoing antimicrobial function in the finished product.

This assessment has considered the technological function and the mode of action of DMDC and its appropriate classification in the Code. This Application was assessed under the General Procedure.

Risk and Technical Assessment

A safety assessment of DMDC and its breakdown products was undertaken by the then Australia New Zealand Food Authority (ANZFA) in 1996, with no public health and safety issues identified. Since this assessment, no new data has been generated to suggest that this conclusion should be amended. This Application does not include any changes to the currently permitted food categories or any increase in the usage level. Therefore, there are no health and safety issues associated with this Application.

The Code currently permits the use of DMDC as a microbial control agent in fruit and vegetable juice and juice products; water based flavoured drinks; formulated beverages; wine, including sparkling and fortified wine; and fruit wine, vegetable wine and mead (including cider and perry). It is used to inactivate residual spoilage organisms in these beverages when produced with good hygienic practice.

DMDC is added to the beverage stream during the processing stage before it is filled into packages. DMDC breaks down in the presence of water to form primarily methanol and carbon dioxide. This breakdown occurs within four hours in typical applications. There is no ongoing antimicrobial activity from DMDC, or the breakdown products, in a product sold through a normal commercial beverage distribution system.

Standard 1.3.3 provides the following description of a processing aid:

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.

The current classification of DMDC as a food additive was made in 1996 by the then ANZFA, partly to promote consistency with other countries at that time. In assessing this Application, FSANZ now considers this classification to be inappropriate, as it does not adequately capture the mode of action of DMDC. FSANZ affirms the mode of action of DMDC meets the description of a processing aid in the Code and therefore should be classified as such. Additionally, DMDC is already treated as a processing aid in a number of overseas jurisdictions (e.g. Germany, Austria).

There are other microbial control agents, such as ozone, hydrogen peroxide, lactoperoxidase, sodium thiocyanate and octanoic acid, which are regulated as processing aids in Standard 1.3.3.

Standard 1.2.4 – Labelling of Ingredients provides for a limited number of labelling exemptions under certain conditions. One of these exemptions permitted under clause 3 of this Standard relates to a substance used as a processing aid in accordance with Standard 1.3.3. Reclassifying DMDC as a processing aid would consequently exempt it from being declared in the statement of ingredients. This exemption is consistent with the treatment of all processing aids in the Code and is not specific to this substance only. This exemption also aligns with the regulatory approach used by some overseas jurisdictions.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from an amendment to the Code to reclassify DMDC for use as a processing aid would outweigh the direct and indirect benefits to the community, Government or industry

- whether other measures (available to the Authority or not) would be more cost-effective than variations to Standards 1.3.1 and 1.3.3 that could achieve the same end

- whether there are any relevant New Zealand standards
- any other relevant matters.

Decision

To approve the draft variations to Standard 1.3.1 – Food Additives and Standard 1.3.3 – Processing Aids, to reclassify dimethyl dicarbonate from a food additive to a processing aid.

Reasons for Decision

An amendment to the Code to permit the reclassification of DMDC for use as a processing aid in Australia and New Zealand is approved on the basis of the available evidence for the following reasons:

- The mode of action of DMDC meets the description of the processing aid in the Code. There are substances with similar technological function as DMDC currently classified as processing aids in the Code.
- The reclassification of DMDC does not raise any public health and safety risks.
- The amendments to the Code correct an inappropriate classification of DMDC in the Code.
- The consequent exemption from the requirement to declare DMDC in the statement of ingredients as a result of the reclassification aligns with the regulatory approach used by some jurisdictions internationally.
- The regulatory impact assessment has concluded that there are no to low additional business compliance costs involved and minimal impact associated with this reclassification.
- There are no other measures than variations to Standard 1.3.1 and 1.3.3 that could achieve the same end.
- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

Consultation

Public submissions were invited on the Assessment Report between 18 August and 29 September 2010. Comments were specifically requested on the scientific aspects of this Application, in particular information relevant to the technological justification of DMDC as a processing aid and other relevant scientific matters.

A total of eight submissions were received. Four submissions supported the reclassification of DMDC from a food additive to a processing aid. Two submissions opposed the reclassification. One did not provide a preference.

The remaining submission stated that there is a potential to classify DMDC as either an additive or a processing aid. This submission preferred to see the reclassification handled in a systematic manner along with any other similar substances requiring reclassification. A summary of the submissions is provided in **Attachment 2** to this Report.

FSANZ has taken the relevant submitters' comments into account in preparing the Approval Report. Specific issues raised in the submissions are addressed in Section 10.1.

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Introduction

Food Standards Australia New Zealand (FSANZ) received an Application (A1025-Classification of Dimethyl Dicarbonate) from Lanxess Deutschland GmbH (Germany, formerly Bayer Chemicals AG) and Victus International, on 3 June 2009. Lanxess is the manufacturer of Dimethyl Dicarbonate (brand name Velcorin®) and Victus International is the Australian distributor of Velcorin®. Application A1025 seeks a reassessment of the regulatory classification of Dimethyl Dicarbonate (DMDC). DMDC is currently listed as a food additive for use in some beverages in Schedule 1 of Standard 1.3.1 – Food additives in the *Australia New Zealand Food Standards Code* (the Code).

The Code permits the use of DMDC as a microbial control agent in fruit and vegetable juice and juice products, water based flavoured drinks, formulated beverages, wine, including sparkling and fortified wine, and fruit wine, vegetable wine and mead (including cider and perry). It is used to inactivate residual spoilage organisms in these beverages when produced in accordance with good hygienic practice. DMDC is added to the beverage stream before it is filled into packages. It acts as a microbial control agent by inhibiting enzymes of the microorganisms, resulting in cell inactivation. Excess DMDC breaks down in the presence of water to form primarily methanol and carbon dioxide. There is no residual DMDC in the beverage after four hours in typical applications. Accordingly, there is no ongoing antimicrobial activity in a product sold through a normal commercial beverage distribution system.

This assessment has considered the technological function and the mode of action of DMDC and its appropriate classification in the Code.

1 The Issue / Problem

1.1 Classification of DMDC

Application A1025 seeks a reassessment of the regulatory classification of DMDC. DMDC is currently regulated as a food additive.

The Application states that DMDC is currently regulated as a food additive in Standard 1.3.1 in the *Australia New Zealand Food Standards Code* (the Code) despite having a mode of action which is more consistent with the definition of a processing aid under Standard 1.3.3 – Processing Aids.

The Applicant asserts that DMDC is neither present nor technologically functional in the beverage as sold. Further, that by classifying DMDC as a food additive and therefore requiring it to be labelled as a preservative in the statement of ingredients, the Code does not reflect that DMDC has no ongoing antimicrobial function in the finished product.

The Applicant has indicated that these issues are considered as a barrier for DMDC usage by manufacturers. The Applicant has submitted letters from manufacturers supporting this Application.

Additives and processing aids are required to undergo a pre-market assessment before they are approved for use in food manufacture in Australia and New Zealand. As DMDC is already an approved food additive in Standard 1.3.1 this assessment has been limited to its appropriate classification.

1.2 Drafting clarification in the Code

The maximum permitted level in the Code means the maximum amount of additive which may be present in the final food as sold or consumed. The Applicant suggests that FSANZ may wish to consider amending the Code to clarify that the maximum permitted level for DMDC is the maximum level that may be added during the manufacturing process and that no residual DMDC is permitted in the food as sold. This approach is consistent with Codex and overseas jurisdictions.

2. Background

2.1 Historical Background

A previous Application (A259) was received by the then Australia New Zealand Food Authority (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 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 considered to be inconsistent with the use of certain claims such as 'fresh' and 'pure' since there would be no requirement to declare it on the label. In order to facilitate labelling when used, and promote consistency with some other countries, it was considered appropriate to classify DMDC 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 in wine as a result of the assessment of Application A474 – Winemaking.

An Application (A585) was received on 17 May 2006 from Brooke-Taylor & Co Pty Ltd, on behalf of Lanxess Deutschland GmbH seeking to amend Schedule 1 of Standard 1.3.1 – Food Additives, to remove the entries for dimethyl dicarbonate (DMDC) and replace these with corresponding entries in Standard 1.3.3 – Processing Aids. However, on 8 February 2010, subsequent to the acceptance of the current Application, Application A585 was withdrawn at the request of the Applicant.

2.2 Current Standards

2.2.1 Food Additives

DMDC (INS Number 242) is currently listed as a food additive in Schedule 1 of Standard 1.3.1. The list of food categories with the maximum permitted level of DMDC is summarised in Table 1.

The maximum permitted level specified in Standard 1.3.1 means the maximum amount of additive which may be present in the final food as sold. The Code currently permits the presence of DMDC in the final food as sold up to the maximum level specified in Table 1.

Table 1: Food categories with their maximum permitted level of DMDC in Code

Category No.	Food category	Max permitted level (mg/kg)
14.1.2	Fruit and vegetable juices and fruit and vegetable juice products	250
14.1.3	Water based flavoured drinks	250
14.1.4	Formulated beverages	250
14.2.2	Wine, sparkling wine and fortified wine	200
14.2.4	Fruit wine, vegetable wine and mead (including cider and perry)	200

2.2.2 Labelling of Ingredients

Standard 1.2.4 - Labelling of Ingredients sets out specific requirements for the labelling and naming of food ingredients. Under this Standard, food additives must be declared on the label using the prescribed additive class name, followed by its specific name or code number in brackets. As DMDC is a microbial control agent, the most suitable class name currently used to declare DMDC, in accordance with Schedule 1 of Standard 1.2.4 is 'preservative' and the code number is (242).

Standard 1.2.4 also provides for a limited number of labelling exemptions under certain conditions. One of these exemptions, permitted under clause 3 of this Standard, relates to a substance used as a processing aid in accordance with Standard 1.3.3. If DMDC is classified as a processing aid, there will be no requirement to declare it in the statement of ingredients.

2.3 International Regulatory Considerations

While in the Code processing aids have their own standard independent of food additives, internationally, there is variability in regulatory approaches for processing aids. Several overseas jurisdictions classify processing aids as a subset of additives and exempt processing aids from labelling.

Section 2.3.2 describes the regulatory status and use of DMDC in a number of countries.

2.3.1 Codex

DMDC was evaluated in 1990 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1991). It was considered acceptable as a cold sterilising agent for beverages when used in accordance with good manufacturing practice up to a maximum concentration of 250 mg/L.

DMDC has been included in the Codex General Standard for Food Additives (Table 2). The accompanying Note 18 indicates that DMDC residues are not to be detected in the final 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 for use in wine and beverages. The IPA states that DMDC is *acceptable for use as a cold sterilization agent in beverages when used according to good manufacturing practice up to a maximum concentration of 250mg/L*.

Table 2: Food categories with their maximum permitted level of DMDC in CODEX

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

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

2.3.2 Regulation in other countries

The EU and USA regulate processing aids differently to Australia and New Zealand. Neither of these jurisdictions have independent standards for processing aids separate from food additives. DMDC is regulated in these jurisdictions as indicated in the sub-sections below.

2.3.2.1 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 DMDC residues not detectable in the final food. DMDC is also permitted in wine at levels of no more than 200 mg/L with the requirement of 'no detectable DMDC residues in the wine placed on the market'.

In Germany, DMDC is regarded as meeting the definition of 'processing aid' in Art. 3 No. 2b of Regulation (EC) No. 1333/2008 on food additives. Consequently DMDC is not required to be labelled.

In Austria, in accordance with the Austrian Food Labelling Regulations of 1993, DMDC is classified as a processing aid and is not required to be labelled.

2.3.2.2 United States of America

The US Food and Drug Administration (USFDA), prior to 1997, permitted the use of DMDC as a food additive (microbial control agent) in the following beverages where the viable microbial load has been reduced to 500 microorganisms per mL, or less, by current good manufacturing practices prior to the addition of DMDC:

(1) in wine, dealcoholised wine, and low alcohol wine in an amount not exceeding 200 mg/L.
(2) in ready-to-drink teas in an amount not exceeding 250 mg/L.
(3) in carbonated or noncarbonated, non-juice containing (less than or equal to 1 percent juice), flavoured or unflavoured beverages containing added electrolytes in an amount not exceeding 250 mg/L.
(4) in carbonated, dilute beverages containing juice, fruit flavour, or both (juice content not exceeding 50 percent), in an amount not to exceed 250 mg/L.

Since 1997, DMDC has also been permitted for use as a food contact substance when used as a microbial control agent at levels not exceeding 250 mg/L in carbonated beverages containing up to and including 100 percent juice and flavoured water beverages (carbonated and non-carbonated) that contain low levels of juice or artificial or natural flavours.

The different approaches by FDA in regulating DMDC are due to legislative and regulatory changes to the definition of a food additive that occurred in 1997.

In accordance with Code of Federal Regulations (21 C.F.R §101.100 (a)(3)), DMDC is regarded as meeting the definition of 'incidental additive' and therefore exempt from labelling. Processing aids are listed as a type of 'incidental additive'.

2.3.2.3 Other Countries

The following information was also submitted by the Applicant.

Chile

Correspondence (with English translation) from the Ministry of Health stating that DMDC is not subject to ingredient labelling.

Colombia

Correspondence (with English translation) from the National Institute of Drug and Food Vigilance – INVIMA, Ministry of Social Protection stating that when DMDC is used at a maximum level of 250 mg/kg ingredient labelling of the finished food or beverage is not applicable.

Indonesia

Correspondence (with English translation) from the Drug and Food Control Agency of the Republic of Indonesia (BADAN POM RI) advising that DMDC is permitted as a processing aid up to a maximum level of 250 mg/kg provided that there shall be no residue left in the final product.

The Philippines

Correspondence in English from the Department of Health, Bureau of Food and Drugs, stating that if Velcorin® (i.e. DMDC) is used as a processing aid, then it may not be declared in the ingredient list.

2.4 Nature and use of the chemical compound

DMDC (Velcorin®) is a colourless liquid with an ester like pungent odour. DMDC is soluble in water (3.65% solubility), aqueous solutions (e.g. beverages) and alcohol, where it is hydrolysed. This hydrolysis is a quick process: 1 hour at 30°C and within 5 hours at 10°C (Delfini et al., 2002). DMDC solidifies below 17°C. It acts as a microbial control agent by inhibiting enzymes of the microorganisms, resulting in cell inactivation. DMDC undergoes hydrolysis in the presence of water to form primarily methanol and carbon dioxide, which are natural components of fruit and alcoholic drinks.

To enable a safe and precise addition of DMDC in beverages at the right temperature, Lanxess supplies a dosing machine to its customers with the purchase of Velcorin®. As a result, the Applicant claims that the use of DMDC is tightly controlled in a manner that is consistent with good manufacturing practice.

3. Objectives

An Application was received seeking a reassessment of the regulatory classification of Dimethyl Dicarbonate (DMDC). Therefore the assessment considered the technological function and the mode of action of DMDC and its appropriate classification in the Code.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- 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[1].

4. Questions to be answered

The key questions which FSANZ considered as part of the assessment were:

1. What is the technological function of DMDC?
2. Would there be a risk to public health and safety should there be a change in the classification of DMDC in the Code?
3. What is the appropriate classification of DMDC that would capture the mode of action of DMDC?
4. What are the labelling issues related to the reclassification of DMDC?

Risk and Technical Assessment

The risk assessment has considered the technological function and safety of DMDC in response to the questions posed in Section 4.

[1] In May 2008, the Australia and New Zealand Food Regulation Ministerial Council endorsed the Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals. This includes policy principles in regard to substances added for technological purposes such as food additives and processing aids.

5.1 Technological function of DMDC

DMDC is added to the beverage stream at the processing stage before it is filled into packages.

DMDC is used as a microbial control agent to inactivate residual spoilage organisms in the processing of permitted beverages produced with good hygienic practice. It breaks down in the presence of water to form primarily methanol and carbon dioxide. In typical beverage applications, there is no residual DMDC after approximately four hours (Labor Dr. Haase-Aschoff, 1991). Accordingly, there is no ongoing antimicrobial activity, as a result of using DMDC, in a product sold through a normal commercial beverage distribution system. The breakdown products of DMDC do not perform a technological function in the final beverage. In conclusion, DMDC is used in the processing of permitted beverages and functions as a microbial control agent. This treatment is time limited.

The maximum permitted level specified in Standard 1.3.1 means the maximum amount of additive which may be present in the final food as sold. The Code currently permits the presence of DMDC in the final food as sold.

5.2 Health and safety considerations

A search of the scientific literature covering the period since ANZFA's 1996 assessment of DMDC has found no new data to suggest that the previous conclusions on the public health and safety of DMDC should be amended. On this basis and given that there are no changes to the currently permitted food categories or any increase in the usage level of DMDC, the Code amendments do not raise any public health and safety issues, including those relating to possible intolerance reactions from exposure to DMDC or any of its breakdown products (e.g. methanol).

Various international regulatory bodies have evaluated DMDC and have concluded that there are no health and safety concerns when used in the permitted food categories at the prescribed usage levels.

The safety of DMDC was evaluated by USFDA in 1988 and approved for use in wines as a yeast inhibitor up to a concentration of 200 mg/L.

The European Scientific Committee on Food (SCF, 1992) evaluated DMDC in 1990 and concluded that it was suitable for the cold sterilisation of soft drinks and fruit juices at levels up to 250 mg/L. In 2001, this Committee set an upper limit of 200 mg/L for the use of DMDC in alcoholic beverages, which already contain methanol (SCF, 2001).

DMDC was also evaluated in 1990 by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1991). It was considered acceptable as a cold sterilising agent for beverages when used in accordance with good manufacturing practice up to a maximum concentration of 250 mg/L.

Risk Management

In response to the questions posed in Section 4, the risk management has considered the appropriate classification of DMDC and the labelling issues that may arise as a result of any labelling exemption for DMDC.

6.1 Appropriate classification of DMDC

As stated previously, DMDC, a microbial control agent, is added to the beverage stream during the processing stage before it is filled into packages. DMDC breaks down in the presence of water to form primarily methanol and carbon dioxide. This breakdown occurs within four hours in typical applications. There is no ongoing antimicrobial activity, from DMDC or the breakdown products, in a product sold through a normal commercial beverage distribution system.

The purpose of a food additive and the description of a processing aid are included in Standards 1.3.1 and 1.3.3 respectively.

6.1.1 Food Additive

A food additive is any substance not normally consumed as a food 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.

6.1.2 Processing Aid

Processing aid includes any substances 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.

Currently, DMDC is classified in Standard 1.3.1 as a food additive. This classification was made in 1996 by the then ANZFA partly to promote consistency with other countries. In assessing this Application, FSANZ now considers this classification to be inappropriate as it does not adequately capture the mode of action of DMDC. FSANZ affirms the mode of action of DMDC meets the description of a processing aid in the Code and therefore should be classified as such.

There are other microbial control agents such as ozone, hydrogen peroxide, lactoperoxidase, sodium thiocyanate and octanoic acid, which are regulated as processing aids in Standard 1.3.3.

The Code currently permits the presence of DMDC in the final beverage as sold. Removal of this permission would preclude the addition of DMDC to beverages that are available for sale within a short time after production. This change is likely to result in greater regulatory control of the use of DMDC.

6.2 Issues related to labelling and associated claims

Standard 1.2.4 - Labelling of Ingredients provides for a limited number of labelling exemptions under certain conditions. One of these exemptions permitted under clause 3 of this Standard relates to a substance used as a processing aid in accordance with Standard 1.3.3. Reclassifying DMDC as a processing aid would exempt it from being declared in the statement of ingredients.

FSANZ is aware of some consumer concern in relation to labelling exemptions. Specifically, that labelling exemptions prevent the provision of adequate information to enable informed choices.

One submission to the Assessment report stated that consumers have the right to know of all the ingredients used in making a food irrespective of the functionality, presence or absence in the final food.

Three submissions in favour of the reclassification stated that the current labelling requirement for DMDC does not reflect that it has no ongoing antimicrobial function in the finished product. One of these submissions stated that it is not technically correct to declare DMDC as a preservative as it does not have an ongoing technological function. This submission also stated that consumers normally expect a declared preservative to have an active preserving function in the finished product as sold.

DMDC is not present in the food as sold. The consequent exemption for DMDC from being declared in the statement of ingredients, as a result of the reclassification as a processing aid, is consistent with the treatment of all processing aids in the Code and is not specific to this substance only.

Currently, there are several other substances (e.g. hydrogen peroxide, octanoic acid) in the Code with the same function that are exempt from being declared in the statement of ingredients. Additionally, processing aids are exempt from being declared in the statement of ingredients in several jurisdictions internationally.

Therefore, FSANZ considers the concerns raised in relation to labelling exemptions relates to a wider issue which is beyond the scope of this Application.

There have also been some concerns that if DMDC was classified as a processing aid and therefore not declared in the statement of ingredients, the product could claim ‘preservative free’, ‘fresh’ or ‘pure’. Three out of the eight submissions highlighted this issue. One of these submissions, received from New Zealand Commerce Commission, states the following.

> *In our view, whether or not DMDC is present in the final product, claims such as 'preservative free' or 'natural' may be liable to mislead consumers where DMDC has been used in the manufacturing process of that product.*
>
> *We consider that consumers are likely to expect that products labelled as 'preservative free' or 'natural' are completely free from any exposure to DMDC at any time throughout the production process as well as containing no DMDC in the final product. We also consider that care should be taken when using the terms 'fresh' or 'pure' as, depending on the context in which such representations are made, they may also be liable to mislead consumers.*

The claims related matter cannot be explicitly considered within the Code. Claims in relation to labelling and representations about food made by manufacturers in Australia or New Zealand must not be misleading or deceptive. These should meet the requirements of the Commonwealth *Trade Practices Act 1974*, the New Zealand *Fair Trading Act 1986*, and the Australian State and Territory Food Acts and fair trading laws. Manufacturers may be liable for penalties where claims about a food are found to be misleading or deceptive.

6.3 Risk management strategy

This assessment has concluded that DMDC should be reclassified as a processing aid.

Additionally, FSANZ considers it appropriate to require DMDC to be absent in the final food as sold. This would preclude the addition of DMDC to beverages that are available for sale within a short time after production.

The reclassification of DMDC does not raise any public health and safety issues, including those relating to possible intolerance reactions from exposure to DMDC or any of its breakdown products (e.g. methanol). DMDC is an approved substance in the Code for use in permitted beverages at permitted levels for a technological purpose. There are no changes to the food categories in which DMDC is permitted to be used or any increase in the usage levels.

Two regulatory options have been identified for this Application.

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

As this assessment considered the appropriateness of the classification of DMDC in the Code it was not appropriate to consider non-regulatory options.

Two regulatory options have been identified for this Application:

Option 1: Reject the Application, thus maintaining the *status quo*.

Option 2: To approve draft variations to Standard 1.3.1 – Food Additives, and Standard 1.3.3 – Processing Aids, to reclassify dimethyl dicarbonate from a food additive to a processing aid.

8. Impact Analysis (RIS ID: 11589)

In developing food regulatory measures 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 relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts. The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. FSANZ has conducted the assessment of this Application and the Office of Best Practice Regulation has subsequently approved the assessment which has concluded that there are no to low additional business compliance costs involved and minimal impact and consequently a Regulation Impact Statement (RIS) is not required.

8.1 Affected Parties

The parties affected by this Application include the following:

- the manufacturer of DMDC
- consumers, particularly those who have concerns about labelling exemptions
- the manufacturing and retail sectors of the beverage industry

- Australian Government, State and Territory agencies and government agencies in New Zealand.

8.2 Benefit Cost Analysis

8.2.1 Option 1 – Reject the Application

This option is the *status quo*, with no changes to the Code.

By rejecting the Application, the current classification of DMDC as an additive in the Code will not capture its appropriate mode of action. This issue may continue to be considered as a barrier to use by manufacturers. Some imported beverages may require additional labelling to indicate the use of DMDC during their production.

8.2.2 Option 2 – To approve draft variations to Standards 1.3.1 and 1.3.3

This option would more appropriately classify DMDC in the Code. There could also be some potential benefits for the beverage manufacturing industry. Such benefits are most likely to include providing manufacturers with an added choice of an antimicrobial processing aid. The reclassification of DMDC does not raise any public health and safety concerns.

Currently, there is a requirement to declare DMDC in the statement of ingredients with the prescribed additive class name 'preservative'. As a result of the reclassification, there will not be a requirement to declare DMDC. This exemption would align with the regulatory approach used by some other jurisdictions internationally.

When a variation is made to the Code, subclause 1(2) of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions, provides that a food product is taken to comply with any variations to the Code for a period of 12 months after the commencement of the variation, if the food product otherwise complies with the Code before the variation commenced. Given the time allowance under clause 1 of Standard 1.1.1, FSANZ believes there should not be any additional labelling costs or any other costs imposed on the manufacturer. There should not be any additional labelling costs when DMDC is used in wines with long shelf life (i.e. shelf life of more than 12 months) because these beverages are exempt from ingredients labelling.

There may be a marginal increase in compliance costs for government enforcement agencies. For example, when investigating representations about foods, there may be an additional requirement to verify if DMDC has been used. FSANZ considers the increase in cost related to this additional requirement to be negligible. There should be no added costs to consumers.

8.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia and New Zealand.

For this Application, Option 1, the *status quo*, is considered less acceptable because DMDC will remain inappropriately classified in the Code. Additionally, the inappropriate classification of DMDC may continue to be considered as a barrier to use by manufacturers.

Option 2 is favoured since DMDC will be more appropriately classified in the Code. There could also be some potential benefits for the beverage manufacturing industry. No adverse costs have been identified with Option 2. Overall, the benefits outweigh the costs.

Communication and Consultation Strategy

9. Communication

FSANZ has applied a general communication strategy for Application A1025. This has involved advertising the availability of the assessment report for public comment in the national press and making the report available on the FSANZ website.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options. The issues raised in the public submissions are evaluated and addressed in FSANZ assessment reports.

The Applicant, individuals and organisations that made submissions on this Application will be notified at each stage of the Application. The decision of the FSANZ Board to approve the draft variations will be notified to the Ministerial Council. If a request to review the decision is not made by the Ministerial Council, the variation to the Code will be gazetted. Stakeholders (including the Applicant) and submitters will be advised of the notification and gazettal in the national press and on the FSANZ website. FSANZ also provides an advisory service to the jurisdictions on changes to the Code.

10. Consultation

10.1 Issues Raised in Public Consultation

The Assessment Report was advertised for public comment between 18 August and 29 September 2010. Comments were specifically requested on the scientific aspects of this Application, in particular information relevant to the technological justification of DMDC as a processing aid and other relevant scientific matters. As this Application is being assessed under a General Procedure, there was one round of public comment.

A total of eight submissions were received. Four submissions supported the reclassification of DMDC from a food additive to a processing aid. Two submissions opposed the reclassification. One did not provide a preference. The remaining submission stated that there is a potential to classify DMDC as either an additive or a processing aid. This submission preferred to see the reclassification handled in a systematic manner along with any other similar substances requiring reclassification. A summary of the submissions is provided in **Attachment 2** to this Report.

FSANZ has taken the relevant submitters' comments into account in preparing the Approval Report. Specific issues raised by submitters are further discussed below.

10.1.1 The amendment of Standard 1.3.3

One submission questioned if it would be more appropriate to place the permission to use DMDC as a processing aid in the Table to clause 14 (Permitted processing aids with miscellaneous functions) instead of the proposed approach of a new clause 19 (Dimethyl dicarbonate as a microbial control agent).

10.1.1.1 FSANZ Response

The maximum permitted level specified in the Table to clause 14 is the maximum amount of the relevant processing aid which may be present in the final food.

With DMDC, the new Table to clause 19 provides the maximum permitted addition level and not the maximum amount present in the final food. There is also an additional condition imposed that DMDC should not be present in the final food. As such, it does not fit well within the Table to clause 14.

10.1.2 Addressing issues related to the definition of additive and processing aid

One submission stated that the issues related to the definition of additive and processing aid identified as part of a review of the Code may lead to incorrect classification of substances and their functionalities. Therefore this submission sought the reclassification of DMDC to be done in a systematic manner along with any other similar substances in the Code that function as both additive and processing aid.

10.1.2.1 FSANZ Response

FSANZ is currently addressing the issues related to the definitions of additive and processing aid as a result of the legislative audit of the Code. For example, an additive is not defined in the Code. FSANZ is currently considering the options for an inclusion of an additive definition in the Code and other changes to address the issues.

The assessment related to DMDC is based on an Application submitted to FSANZ. FSANZ is required to process Applications within a set timeframe. Therefore, it is not possible to wait until the issues related to the definitions are addressed.

10.1.3 The classification of DMDC

One submission stated that there is a potential for classifying DMDC as either an additive or a processing aid. This submission also stated that DMDC fits with the description of an additive since its breakdown products methanol and carbon dioxide remain in the final food.

10.1.3.1 FSANZ Response

In accordance with Standard 1.3.3, a processing aid is not intended to, and does not, perform a technological function in the final food.

DMDC is added to the beverage stream at the processing stage before it is filled into packages. In typical beverage applications, there is no residual DMDC after approximately four hours. Accordingly, there is no technological function of DMDC in a product sold through a normal commercial beverage distribution system. The breakdown products of DMDC, even though present in the final beverage, do not perform a technological function. Therefore, FSANZ considers that the current classification of DMDC as an additive to be inappropriate.

10.1.4 Consumer issues

One submission considered the Application to be focussing on marketing of a product where DMDC is used as ‘additive free’ rather that the technological justifications. This submission stated that consumer issues have not been adequately addressed in the current assessment.

Another submission stated that consumers have the right to know of all the ingredients used in making a food.

10.1.4.1 FSANZ Response

The reclassification of DMDC as a processing aid is based on technological justification. Where possible, FSANZ has addressed the consumer related issues in section 6.2 of this report.

10.1.5 The use of claims on products treated with DMDC

Three submissions stated that the reclassification of DMDC may result in claims such as 'preservative free', 'fresh', 'additive free' and 'pure' on products where DMDC has been used.

10.1.5.1 FSANZ Response

This matter cannot be explicitly considered within the Code. Claims in relation to labelling and representations about food made by manufacturers in Australia or New Zealand must not be misleading or deceptive. FSANZ has included additional information in section 6.2 of this report in relation to claims. This information was provided by New Zealand Commerce Commission (NZCC) as part of their submission. NZCC considers that consumers are likely to expect products claiming 'preservative free' or 'natural' to be completely free from any exposure to DMDC.

10.1.6 Previous prosecution related to claims

One submission indicated that a manufacturer was prosecuted previously for failing to state the use of DMDC as a preservative. The manufacturer declared DMDC as a 'microbial control agent' rather than a 'preservative' in the statement of ingredients and made a 'preservative free' claim on that product.

10.1.6.1 FSANZ Response

FSANZ has been aware of this case. FSANZ considers the judgement made by the Magistrate reflected the current classification of DMDC in the Code. It does not preclude the reclassification of DMDC. The issues related to labelling and associated claims have been addressed in Section 6.2 of this report.

10.1.7 DMDC is a recognised food additive

The following were some of the reasons provided by a submission for not supporting the reclassification.

- The specified technological function of DMDC as a preservative is contrary to the definition of a processing aid.
- DMDC meets the definition of an ingredient in accordance with Standard 1.2.4 prior to any decomposition occurring.
- If DMDC is classified as a processing aid, the ingredient list of the product in which DMDC was used should include the presence of the breakdown products.
- DMDC is an internationally-recognised food additive with an INS number of 242.

10.1.7.1 FSANZ Response

As stated in section 5.1 of this report, DMDC performs a technological purpose in the processing of beverages as a microbial control agent, and does not perform a technological function in the final food. Therefore, DMDC meets the description of a processing aid.

FSANZ acknowledges that DMDC meets the definition of an ingredient in accordance with Standard 1.2.4[2]. However, clause 3 of Standard 1.2.4 exempts the declaration of processing aid in the statement of ingredients. There are no requirements in the Code for the declaration of breakdown products. Additionally, the breakdown products of DMDC are also naturally present in fruit and alcoholic drinks.

FSANZ also acknowledges that DMDC is an internationally recognised food additive. In 1996 the then ANZFA classified DMDC as an additive to promote consistency with other countries.

Several international jurisdictions classify processing aids as a subset of additives. These jurisdictions consider DMDC as an additive but treat it as a processing aid and exempt it from labelling. However, in Australia and New Zealand, additives and processing aids are treated separately with two independent standards in the Code. These independent standards reflect the differences between additives and processing aids. The assessment has indicated that the current classification of DMDC as an additive in the Code is inappropriate.

10.1.8 Labelling of additives

One submission raised technical issues related to labelling of additives. These were related to the difference between 'preservative' and other synonyms such as 'microbial control agent' and the requirements related to labelling of inactive versus active forms of additives. These were raised as arguments for not supporting the reclassification of DMDC.

10.1.8.1 FSANZ Response

FSANZ has considered these arguments in developing this Approval Report.

10.2 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.

Amending the Code to reclassify DMDC from a food additive to a processing aid is unlikely to have a significant effect on trade. DMDC is already treated as a processing aid in a number of jurisdictions internationally. Consequently, these jurisdictions exempt DMDC from labelling. For these reasons, it has been considered not necessary to notify the WTO under either the Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements.

[2] *Processing aid includes any substances 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.

Conclusion

11. Conclusion and Decision

This Application has been assessed against the requirements of Section 29 of the FSANZ Act.

The Assessment has concluded that the reclassification of DMDC from a permitted food additive to a processing aid is technologically appropriate and does not pose a public health and safety risk.

An amendment to the Code, for the approval of the reclassification of DMDC for use as a processing aid instead of a food additive in Australia and New Zealand is recommended on the basis of the available scientific information.

The approved draft variation is provided in **Attachment 1**.

Decision

To approve the draft variations to Standard 1.3.1 - Food Additives, and Standard 1.3.3 – Processing Aids, to reclassify dimethyl dicarbonate from a food additive to a processing aid.

11.1 Reasons for Decision

An amendment to the Code to permit the reclassification of DMDC for use as a processing aid in Australia and New Zealand is approved on the basis of the available evidence for the following reasons:

- The mode of action of DMDC meets the description of the processing aid in the Code. There are substances with similar technological function as DMDC currently classified as processing aids in the Code.
- The reclassification of DMDC does not raise any public health and safety risks.
- The amendments to the Code correct an inappropriate classification of DMDC in the Code.
- The consequent exemption from the requirement to declare DMDC in the statement of ingredients as a result of the reclassification aligns with the regulatory approach used by some jurisdictions internationally.
- The regulatory impact assessment has concluded that there are no to low additional business compliance costs involved and minimal impact associated with this reclassification.
- There are no other measures than variations to Standard 1.3.1 and 1.3.3 that could achieve the same end.
- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

12. Implementation and Review

The FSANZ Board's decision will be notified to the Ministerial Council. Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

13. References

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United States Food and Drug Administration (1988). Federal Register. 53 (204), 41325-41329

Joint FAO/WHO Expert Committee on Food Additives and Contaminants (JECFA) (1991) Thirty-seventh report of JECFA, WHO Technical Report Series No. 806, WHO, Geneva.

Labor Dr. Haase-Aschoff (1991). Hydrolysis of Velcorin® in iced tea and a water based flavoured drink. Unpublished analytical results.

Scientific Committee on Food (SCF) (1992) Report on a second series of food additives of various technological functions (opinion expressed on 19th October 1990). Twenty-sixth series of Reports of the SCF. Office of Official Publications of the European Communities, Luxembourg.

Scientific Committee on Food (SCF) (2001). Opinion of the Scientific Committee on Food on the use of dimethyl dicarbonate (DMDC) in wines, opinion expressed on 11 July 2001.

Attachments

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of submissions

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

[1] ***Standard 1.2.4*** *of the Australian New Zealand Food Standards Code is varied by –*

[1.1] *omitting from* Schedule 1, Part 1 –

Dimethyl dicarbonate	242

[1.2] *omitting from* Schedule 2, Part 2 –

Dimethyl dicarbonate	242

[2] ***Standard 1.3.1*** *is varied by –*

[2.1] *omitting from* Schedule 1 *under item* 14.1.2 Fruit and vegetable juices and fruit and vegetable juice products –

242	Dimethyl dicarbonate	250	mg/kg

[2.2] *omitting from* Schedule 1 *under item* 14.1.3 Water based flavoured drinks* –

242	Dimethyl dicarbonate	250	mg/kg

[2.3] *omitting from* Schedule 1 *under item* 14.1.4 Formulated Beverages* –

242	Dimethyl dicarbonate	250	mg/kg

[2.4] *omitting from* Schedule 1 *under item* 14.2.2 Wine, sparkling wine and fortified wine –

242	Dimethyl dicarbonate	200	mg/kg

[2.5] *omitting from* Schedule 1 *under item* 14.2.4 Fruit wine, vegetable wine and mead (including cider and perry) –

242	Dimethyl dicarbonate	200	mg/kg

[3] ***Standard 1.3.3*** *is varied by –*

[3.1] *omitting from* clause 1 –

processing aid means a substance listed in clause 3 to 18, where –

substituting –

processing aid means a substance listed in clause 3 to 19, where –

[3.2] *inserting after* clause 18 –

19 Dimethyl dicarbonate as a microbial control agent

(1) Dimethyl dicarbonate may be added in the manufacture of a food listed in Column 1 in the Table at a concentration no more than the maximum permitted addition level in Column 2 in the Table.

(2) Dimethyl dicarbonate must not be present in the food as sold.

Table to clause 19

Column 1	Column 2
Food	**Maximum permitted addition level (amount of dimethyl dicarbonate/ amount of food)**
Fruit and vegetable juices and fruit and vegetable juice product	250 mg/kg
Water-based flavoured drinks	250 mg/kg
Formulated beverages	250 mg/kg
Wine, sparkling wine and fortified wine; and fruit wine, vegetable wine and mead (including cider and perry)	200 mg/kg

Attachment 2

Summary of Submissions

Submitter	Comments
Australian Beverages Council Limited	Supports the reclassification of DMDC from a food additive to a processing aid. Agrees that DMDC is neither present nor technologically functional in the beverage as sold. Considers the current labelling requirement for DMDC does not reflect that it has no ongoing antimicrobial function in the finished product and causes a barrier for usage by manufacturers. States that the reclassification would bring closer alignment with Codex and approach taken by other international regulators.
Food Technology Association of Australia	Supports the reclassification of DMDC from a food additive to a processing aid.
New Zealand Food Safety Authority	Supports the reclassification of DMDC from a food additive to a processing aid. Agrees that the mode of action of DMDC in beverages is consistent with that of a processing aid rather than a food additive. Considers that it is not technically correct to declare DMDC as a preservative in the statement of ingredients as it readily breaks down in water with no ongoing antimicrobial function. Believes that consumers normally expect a declared preservative to have an active preserving function in the finished product as sold. Questions if it would be more appropriate to place the permission to use DMDC as a processing aid in the Table to clause 14 instead of the proposed approach of a new clause 19.
Queensland Health	Supports the reclassification of DMDC from a food additive to a processing aid. Agrees that the mode of action of DMDC meets the description of a processing aid. Considers the current requirement to declare DMDC in the statement of ingredients does not reflect that it has no ongoing antimicrobial function in the finished product.
New Zealand Commerce Commission	Provides comments on labelling issues. Considers the use of claims such as ‘preservative free’ and ‘natural’ on products where DMDC has been used may be liable to mislead consumers. Believes that consumers are likely to expect products with such claims to be free from any exposure to DMDC during the production process. Also considers that care should be taken when using terms such as ‘fresh’ or ‘pure’.
New South Wales Food Authority	Requests FSANZ to reconsider the classification of DMDC because it can be potentially classified as either an additive or processing aid. Concerned that the reclassification of DMDC may result in claims such as ‘preservative free’, ‘fresh’, and ‘pure’ on products where DMDC has been used. Indicates that a manufacturer was prosecuted previously for failing to state the use of DMDC as a preservative. The manufacturer declared DMDC as a ‘microbial control agent’ rather than a ‘preservative’ in the statement of ingredients and made a ‘preservative free’ claim on that product. Believes that since the breakdown products of DMDC such as methanol and carbon dioxide remains in the finished product it fits with the description of an additive. Understands that there are a number of issues in relation to the definition of food additive and processing aid in the Code. Seeks the current reclassification to be done in a systematic manner along with other similar substances that require reclassification.

Submitter	Comments
	Considers the Application to be focussing on marketing of a product where DMDC is used as 'additive free' rather that the technological justifications. States that the consumer issues have not been adequately addressed in the Assessment report.
Leo Adler	Does not support the reclassification of DMDC. Believes that as part of consumers' right to know, any additives used in the processing of foods should be declared in the statement of ingredients irrespective of its functionality or its presence or absence in the final food.
Professional Food & Pharmaceutical Services	Does not support the reclassification of DMDC. Believes that DMDC is internationally recognised as a food additive and has a technological function of a preservative which is contrary to the definition of a processing aid. Considers the reclassification of DMDC as a processing aid would result in 'no preservative added' claims on products which may be deceptive or misleading. Is not convinced by the reasons given for reclassification.