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

25 October 2011
[20-11]

APPLICATION A1056
DIMETHYL ETHER AS A PROCESSING AID FOR DAIRY INGREDIENTS & PRODUCTS ASSESSMENT REPORT

Executive Summary

Purpose

The purpose of the Application is to seek permission to use dimethyl ether as an extraction solvent processing aid, to treat all dairy ingredients and dairy products[1].

Background

Food Standards Australia New Zealand (FSANZ) received an Application from Fonterra Co-operative Group Limited on 24 November 2010 to amend the *Australia New Zealand Food Standards Code* (the Code) to approve the use of dimethyl ether as an extraction solvent processing aid for all dairy ingredients and dairy products. The Application seeks an amendment to the Table to clause 13 (Permitted extraction solvents) of Standard 1.3.3 – Processing Aids.

Dimethyl ether is a colourless gas at room temperature and pressure, which can be readily liquefied when compressed to produce a powerful extraction solvent. Liquefied dimethyl ether has advantages as an extraction solvent over a number of other currently permitted extraction solvents. It is proposed to extract both polar and non-polar lipids from liquid and dry foods.

There are currently two other ethers, dibutyl and diethyl ether, permitted as extraction solvent processing aids, in the Table to clause 13 of Standard 1.3.3, to treat all foods.

Dimethyl ether is permitted as an extraction solvent in Europe to extract fat from animal proteins under the Commission Directive 2010/59/EU. This approval occurred after the European Food Safety Authority made an assessment supporting this use and released a scientific opinion in 2009.

[1] Permission to use dimethyl ether as an extraction solvent for all non-dairy ingredients and products is being sought concurrently in Application A1062.

Risk Assessment

A risk and technical assessment was performed for this Application with the findings detailed in the Risk and Technical Assessment Report (Supporting Document 1).

Dimethyl ether is proposed for use as an extraction solvent for the separation of lipids from a range of dairy ingredients and dairy products. Dimethyl ether is compressed under high pressure for use as a liquid extraction solvent in the course of food processing. Evidence assessed provided adequate assurance that the proposed use of dimethyl ether is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

Animal and human data on inhalational exposure to dimethyl ether indicate a very low degree of toxicity. Adverse effects have been reported only at atmospheric concentrations greater than 20,000 ppm for acute exposure and 2,000 ppm for chronic exposure. Dietary exposure to dimethyl ether will be negligible due to rapid evaporation of any residual dimethyl ether present in food following processing, because of its low boiling point. Dimethyl ether is considered to pose no public health and safety issues associated with its proposed use.

The overall conclusion of the risk and technical assessment is that the use of dimethyl ether as a processing aid is technologically justified and raises no public health and safety issues.

Risk Management

Since the risk assessment concludes that there are no risks to manage and the use of dimethyl ether is technologically justified for use as an extraction solvent processing aid there are no specific risk management aspects to the assessment.

The conclusion from the assessment is that dimethyl ether is safe as an extraction solvent processing aid to use on any foods. The Applicant proposed and FSANZ supports a maximum permitted level for all dairy ingredients and dairy products of 2 mg/kg for treated food, which is the same limit currently in the Code for two other ether extraction solvents, dibutyl and diethyl ether. This limit applies to the residual amount of the solvent remaining in food after dimethyl ether processing. It is proposed to add dimethyl ether as an approved extraction solvent to clause 13 (Permitted extraction solvents) of Standard 1.3.3.

There are no specifications for dimethyl ether in the relevant monographs referenced in Standard 1.3.4 – Identity and Purity. Therefore, FSANZ has drafted a specification for dimethyl ether to be added to the Schedule for Standard 1.3.4.

Assessing the Application

The Application is being assessed under the General Procedure which includes one round of public comment.

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has 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 a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

- There are no other measures that would be more cost-effective than a variation to Standards 1.3.3 and 1.3.4 that could achieve the same end.

- Any relevant New Zealand standards.

- Any other relevant matters.

Preferred Approach

To prepare a draft variation to the Table to clause 13 of Standard 1.3.3 – Processing Aids to permit the use of dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity, to include a specification for dimethyl ether in the Schedule.

Reasons for Preferred Approach

An amendment to the Code approving the use of dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products is proposed for the following reasons:

- A detailed safety assessment has concluded that the use of dimethyl ether as an extraction solvent processing aid to treat all food does not raise any public health and safety concerns.

- The use of dimethyl ether as an extraction solvent processing aid to treat dairy ingredients and dairy products is technologically justified as an alternative to currently approved extraction solvents.

- Permitting the use of dimethyl ether as an extraction solvent processing aid would not impose significant costs to government agencies, consumers or manufacturers and the costs are not expected to outweigh the benefits.

- 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 are now invited to this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, including the safety assessment and technological function of using dimethyl ether as an extraction solvent to treat dairy ingredients and dairy products.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles 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 further considering this Application. Submissions should, where possible, address the objectives of

FSANZ as set out in section 18 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, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 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. 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 Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 6 December 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if 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.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy 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

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel (04) 978 5630

CONTENTS

SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1056dime5034.cfm.

SD1 Risk and Technical Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Fonterra Co-operative Group Limited on 24 November 2010 to amend the *Australia New Zealand Food Standards Code* (the Code) to approve the use of dimethyl ether as an extraction solvent processing aid for all dairy ingredients and dairy products. The Application seeks an amendment to the Table to clause 13 (Permitted extraction solvents) of Standard 1.3.3 – Processing Aids.

FSANZ accepted the Application after completing an administrative assessment on 14 December 2010. FSANZ commenced consideration of the Application on 1 September 2011.

FSANZ is also assessing another dimethyl ether Application, A1062 received from Industrial Research Limited (IRL), seeking permission to use dimethyl ether as an extraction solvent processing aid for all non-dairy ingredients and products. FSANZ is assessing these two Applications concurrently.

1. The Issue / Problem

A pre-market assessment and approval is required before any new processing aid is permitted to be used to treat or process food sold in Australia and New Zealand. Extraction solvents are considered and regulated as processing aids in the Code.

A safety assessment and an assessment of the technological function of using dimethyl ether as an extraction solvent for treating food is required before any permission may be granted.

2. Background

2.1 Current Standard

Processing aids used in food manufacture are regulated under Standard 1.3.3.

A processing aid is described in clause 1 of Standard 1.3.3.

> **processing aid** means a substance listed in clauses 3 to 19, 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.

Permitted extraction solvent processing aids are regulated under clause 13 (Permitted extraction solvents) within Standard 1.3.3. The Table to clause 13 contains a list of approved extraction solvents, the food which can be treated by the solvent and the maximum permitted level remaining in the final treated food.

Currently there is no permission to use dimethyl ether as an extraction solvent processing aid to treat food.

There are currently two ethers (dibutyl ether and diethyl ether) that are permitted as extraction solvents for all foods, both with maximum permitted levels of 2 mg/kg in the final treated food.

2.2 International regulations

Dimethyl ether is not listed or permitted in any Codex Standards, nor is there an entry for a specification in any monograph of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Food Chemicals Codex, since these publications deal with food additives while extraction solvents are considered processing aids.

The European Food Safety Authority (EFSA) produced a scientific opinion on the safety of using dimethyl ether as an extraction solvent (EFSA, 2009). EFSA concluded that it was safe to use dimethyl ether as an extraction solvent, as the petitioner proposed, to extract fat from animal protein products, in particular collagen, with a residue limit of 9 µg/kg of treated product. It is noted that this dimethyl ether residue limit is well below the Applicant's requested limit (and current residue limits for dibutyl ether and diethyl ether in the Code) of 2 mg/kg (i.e. 2,000 µg/kg). Subsequently, the Commission Directive 2010/59/EU dated 26 August 2010, amending the Commission Directive 2009/32/EC, incorporated a permission to use dimethyl ether as an extraction solvent in the preparation of defatted animal protein products. This Directive included a maximum permitted limit of 0.009 mg/kg dimethyl ether in the defatted protein product, reflecting the EFSA opinion. FSANZ proposes a different residue limit (called maximum permitted level in the Code), which is discussed in Section 6.2.

The UK Food Standards Agency (UK FSA) has recently undertaken consultation (between 18 May 2011 and 17 June 2011) on whether the national regulation should be amended to implement the European Commission Directive 2010/59/EU. A decision had not been published by the UK FSA at the time of completing this Report.

The Applicant and FSANZ are not aware of any other permissions to use dimethyl ether as an extraction solvent to treat food in other countries, such as the USA or Canada.

2.3 Nature of the processing aid

Dimethyl ether is a colourless gas with characteristic sweet ether like odour at room temperature and pressure. It can be readily liquefied when compressed to produce a colourless liquid which has advantages as an extraction solvent over a number of currently permitted extraction solvents.

2.4 Technological function

The Applicant proposes to use dimethyl ether as an extraction solvent processing aid to process food. Dimethyl ether has been identified as a very powerful extraction solvent when used as a pressurised liquid. It is proposed to extract both polar and non-polar lipids from both liquid and dry foods.

More detail on the technological function of dimethyl ether is provided in the Risk and Technical Assessment Report (SD1).

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Standard 1.3.3 to permit the use of dimethyl ether as an extraction solvent processing aid.

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.

The Ministerial Council Policy Guideline, *Addition to Food of Substances other than Vitamins and Minerals,* includes specific order policy principles for addition of substances such as processing aids where the purpose of the addition is to achieve a solely technological function. These specific order policy principles state that permission should be permitted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose'); and
- the addition of the substance to food is safe for human consumption; and
- the amounts added are consistent with achieving the technological function; and
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
- no nutrition, health or related claims are to be made in regard to the substance.

4. Questions to be answered

- Does the use of dimethyl ether as an extraction solvent processing aid to process food present any food safety issues?
- Does the use of dimethyl ether achieve its stated technological purpose?

The answers to these questions are provided in the Risk Assessment Summary below that has been extracted from the more detailed assessment in SD1.

RISK ASSESSMENT

5. Risk Assessment Summary

5.1 Hazard assessment conclusions

5.1.1 Does the use of dimethyl ether as an extraction solvent processing aid to process food present any food safety issues?

Data on inhalation exposure to dimethyl ether indicate a very low degree of toxicity and dietary exposure to the compound will be negligible.

The use of dimethyl ether as an extraction solvent processing aid raises no public health and safety issues.

5.2 Technological function

5.2.1 Does the use of dimethyl ether achieve its stated technological purpose?

Dimethyl ether has been shown to function and have technological advantages as an extraction solvent for treating various food matrices. The technological function as an extraction solvent processing aid is to extract both polar and non-polar polar lipids from solid and aqueous foods when it is used as a near critical liquid[2] produced by compressing the gas and slightly heating it. The analysis concludes that, as proposed by the Applicant, dimethyl ether performs the technological function as an extraction solvent processing aid for all dairy ingredients and dairy products..

Risk Management

6. Risk Management Issues

The risk assessment concludes that use of dimethyl ether as an extraction solvent processing aid for treating food does not raise any public health and safety risks, and its use is technologically justified for the stated purpose. Therefore, there are no specific safety risks to manage. A discussion on applying a maximum permitted limit for products processed with dimethyl ether is contained in Section 6.2.

6.1 Limitations on permitted food types

The Applicant has requested dimethyl ether be permitted as an extraction solvent processing aid to treat all dairy ingredients and dairy products. FSANZ concludes that there are no reasons to restrict the foods further than as requested. The Risk and Technical Assessment Report (SD1) concludes that dimethyl is both safe and technologically justified to treat dairy ingredients and dairy products as an extraction solvent processing aid.

[2] A critical point for a substance is when the liquid and vapour state becomes identical. A near critical liquid is close to the critical point, where the substance is in a liquid state that has properties of both liquids and gases.

6.2 Residue limits for treated food

The Applicant has requested and FSANZ supports that the maximum permitted (residue) level for food processed with dimethyl ether be the same as for the two other ethers (dibutyl and diethyl ether) permitted as extraction processing aids in the Standard i.e. 2 mg/kg of treated food. This level is also the limit of determination of the analytical method used by the Applicant to check for residues. There is no justification for reasons of safety for requiring a maximum permitted level but it is appropriate to ensure residues of extraction solvents for processed foods are kept as low as is practicable and technically justified.

This maximum permitted level (2 mg/kg) is higher than that permitted in Europe which has a limit of 0.009 mg/kg for the use of dimethyl ether as an extraction solvent to extract fat from animal protein products.

It is not clear why such a very low residue limit for dimethyl ether was initially suggested by the European petitioner and then supported by EFSA since there is no justification on safety grounds. Furthermore, the Applicant has indicated that their analytical method used to determine residues is not sensitive enough to measure to such extremely low concentrations (see Section 6.3).

6.3 Methods of analysis

The Application has provided details of an analytical method that can be used to determine residues of dimethyl ether in treated food. This analytical method was used for the testing of treated food provided in the Application.

The analytical method uses gas chromatography with detection via flame ionisation (FID) or mass spectroscopy. Sample injections are made using gas-tight syringes. The Applicant's estimated limit of quantitation is 5 mg/kg, with the limit of detection being 2 mg/kg.

The methods for analysing for residues of dimethyl ether are likely to be similar to analysing for residues of two currently permitted ether extraction solvents so potentially the same analytical method could be used for all three ether solvents.

6.4 Specification

There are no specifications for dimethyl ether in the relevant monographs referred to in clause 2 and 3 of Standard 1.3.4, so a new specific specification is required in the Schedule of Standard 1.3.4. The development of a specification for dimethyl ether is discussed in section 2.1.4 in SD1.

The proposed specification to be added to Standard 1.3.4 is provided below in Table 1.

Table 1: Proposed specification for dimethyl ether

Characteristic	Specification
Purity	Minimum of 99.8%
Methanol	Not greater than 200 mg/kg

6.5 Labelling

Substances used as processing aids in accordance with Standard 1.3.3 are not subject to ingredient labelling in the final food, under clause 3 of Standard 1.2.4 – Labelling of Ingredients.

6.6 Consistency with Ministerial Council Policy Guidelines

As noted in Section 3, FSANZ is required to have regard to the relevant Ministerial Council Policy Guidelines when developing or varying food standards. For this Application FSANZ needs to have regard to the Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals*, which for processing aids are the Special Order Policy Principles – Technological Function, listed in Section 3 of the Report.

The Applicant has clearly articulated the technological function (the stated purpose), as being an extraction solvent processing aid to treat food. FSANZ's assessment has concluded that at the amounts and in a form proposed by the Applicant dimethyl ether is able to achieve the technological function. The assessment has confirmed the use of dimethyl ether to treat food is safe. The Applicant makes no nutrition, health or related claims in regard to the substance itself. However, the Applicant and other dairy food producers may use dimethyl ether to extract fat from dairy ingredients or dairy products to therefore produce low fat versions, which may then be eligible for low fat content claims.

7. Options

Processing aids require pre-market approval under Standard 1.3.3. Therefore it is not appropriate to consider any non-regulatory options for this Application. There were two regulatory options available for this Application:

Option 1: Reject the Application
Option 2: Prepare draft variations to Standard 1.3.3 and 1.3.4 to permit the use of dimethyl ether as an extraction solvent processing aid to treat food.

8. Impact Analysis (RIS ID: 12065)

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact. The Office of Best Practice Regulation has advised that as the Application appears to be of a minor or machinery nature and any approval to use dimethyl ether would be as an alternative to other permitted extraction solvents, its use would be voluntary therefore a Regulation Impact Statement (RIS) is not required.

8.1 Affected Parties

The affected parties for this Application may include:

- those sectors of the food manufacturing industry who wish to use dimethyl ether as an extraction solvent processing aid to treat food
- consumers of food produced using dimethyl ether as an extraction solvent processing aid
- Government agencies with responsibility for ensuring compliance with the Code.

8.2 Benefit Cost Analysis

8.2.1 Reject the Application

This option would maintain the status quo, where no changes are made to the Code.

There were no advantages to any stakeholders with this option.

However, this option would disadvantage those members of the food industry who wished to use dimethyl ether as an extraction solvent to process food and food ingredients. In particular it would limit food processors from using an extraction solvent that has potential technological advantages over other solvents to extract polar and non-polar lipids from both solid and liquid foods.

8.2.2 Prepare a draft variation to Standard 1.3.3

This option potentially provides positive benefits to food manufacturers, as well as food consumers. That is, food processers could use a new extraction solvent that has technological advantages over other currently permitted and used extraction solvents. Dimethyl ether is claimed to have the ability to extract polar and non-polar lipids from both solid and liquid foods. These extraction processes could produce valued added ingredients or remove fat to produce novel lower fat products that could have consumer benefits. Since dimethyl ether is a gas at room temperature and pressure, any solvent residues are easily evaporated from treated food and therefore residue levels are likely to be lower where food has been processed with dimethyl ether compared to other extraction solvents. Also dimethyl ether is inert so it does not react with food components and no by-products of treatment are formed.

There may be a small compliance cost to government compliance agencies to develop analytical capacity to determine solvent residues in treated food. However, there are analytical methods available and they are likely to be similar to those already required to analyse for similar approved ether extraction solvents. Also since dimethyl ether is so volatile it is not expected that there will be any residues left in treated food to analyse.

8.3 Comparison of Options

Permitting the use of dimethyl ether as an extraction solvent processing aid would not impose any financial burden on any sector of the community, there may be economic benefits to the food industry and there are no public health and safety issues. Therefore option 2 was the preferred option.

Communication and Consultation Strategy

9. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the Assessment Reports for public comment and placing the reports 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 will be evaluated and addressed in the subsequent Approval Report.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If the FSANZ Board subsequently approves the draft variations to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press in Australia and New Zealand and on the FSANZ website.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in further considering this Application. Once the public comment period has closed there will be no further opportunity for public comment.

Comments are sought on the proposed draft variations (**Attachment 1**) to the Code, including the proposed specification for dimethyl ether to be added to Standard 1.3.4. Comments are also sought in relation to the scientific aspects of the Application, including any safety aspects of using dimethyl ether as an extraction solvent processing aid to process food and its technological function.

10.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for processing aids used to process food. Amending the Code to allow dimethyl ether as an extraction solvent processing aid is unlikely to have a significant effect on international trade. Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements was not considered necessary.

Primary Legislative Objectives

11. Addressing the primary objectives of section 18 of the FSANZ Act

FSANZ is required by its legislation to meet the section 18 objectives of the FSANZ Act when it is developing or varying a food standard as noted in Section 3 of this Report.

The primary objective relevant to consideration of this Application is the protection of public health and safety. The other two have less direct relevance although they are also taken into consideration.

11.1 Risk to public health and safety

FSANZ's risk assessment concluded that the use of dimethyl ether as an extraction solvent to treat all foods does not pose any public health and safety concerns.

11.2 Providing adequate information to enable informed consumer choice

For this Application this objective is taken to relate to labelling of processed foods.

As noted in Section 6.5, processing aids are not subject to ingredient labelling so there are no labelling requirements for using dimethyl ether as an extraction solvent processing aid. This is the same situation as for other extraction solvent processing aids.

11.3 Prevention of misleading and deceptive conduct

FSANZ has considered this objective and concluded that there are no misleading or deceptive conduct aspects to this Application.

Conclusion

12. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act and the Ministerial Council Policy Guideline relevant to this Application.

FSANZ concludes that the use of dimethyl ether as an extraction solvent processing aid does not pose any public health and safety risk and is technologically justified.

Therefore the decision, based on the available scientific information, is to prepare a draft variation to Standard 1.3.3 giving permission to use dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products sold in Australia and New Zealand. A specification has been drafted for dimethyl ether to be added to the Schedule of Standard 1.3.4.

The proposed draft variations are provided in **Attachment 1**.

Preferred Approach

To prepare a draft variation to the Table to clause 13 of Standard 1.3.3 – Processing Aids to permit the use of dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products.

To prepare a draft variation to Standard 1.3.4 – Identity and Purity to include a specification for dimethyl ether in the Schedule.

Reasons for Preferred Approach

An amendment to the Code approving the use of dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products is proposed for the following reasons:

- A detailed safety assessment has concluded that the use of dimethyl ether as an extraction solvent processing aid to treat all food does not raise any public health and safety concerns.

- The use of dimethyl ether as an extraction solvent processing aid to treat dairy ingredients and dairy products is technologically justified as an alternative to currently approved extraction solvents.

- Permitting the use of dimethyl ether as an extraction solvent processing aid would not impose significant costs to government agencies, consumers or manufacturers and the costs are not expected to outweigh the benefits.

- 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.

13. Implementation and Review

The draft variation will come in to effect on gazettal.

FSANZ is also concurrently assessing another dimethyl ether Application, A1062, for which the proposed drafting is to permit dimethyl ether to treat all non-dairy ingredients and products. How the variations for both Applications will be incorporated or combined in the Code will be decided at a later date.

References

Commission Directive 2010/59/EU from the Official Journal of the European Union http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:225:0010:0012:EN:PDF (accessed 17 August 2011)

EFSA 2009, Scientific Opinion of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing aids (CEF) on dimethyl ether as an extraction solvent. *The EFSA Journal* (2009) 984, 1-13. http://www.efsa.europa.eu/fr/scdocs/doc/984.pdf (accessed 17 August 2011)

ATTACHMENT

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

Attachment 1

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

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

Food Standards (Application A1056 – Dimethyl Ether as a Processing Aid for Dairy Ingredients & Products) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated XXXX

[Signature to be inserted]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1056 – Dimethyl Ether as a Processing Aid for Dairy Ingredients & Products) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

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

[1.1] *inserting in alphabetical order in clause 1 –*

dairy ingredient means an ingredient that is derived from a dairy source.

[1.2] *inserting in alphabetical order in the* Table to clause 13 –

Dimethyl ether	Dairy ingredients and dairy products	2

[2] ***Standard 1.3.4*** *is varied by inserting in the* Schedule –

Specification for dimethyl ether

Characteristic	Specification
Purity	Minimum of 99.8%
Methanol	Not greater than 200 mg/kg

Attachment 2

Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).`

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1056 which seeks to approve the use of dimethyl ether as an extraction solvent processing aid for dairy ingredients and dairy products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

Following consideration by Ministerial Council, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

Currently there is no permission for using dimethyl ether as an extraction solvent processing aid to treat any food, including dairy ingredients and dairy products. The draft variation is proposed to address this. Dimethyl ether is proposed as an extraction solvent processing aid to treat all dairy ingredients and dairy products with a maximum permitted level of 2 mg/kg in the final treated food.

There is currently no specification for dimethyl ether in the Code. Therefore, FSANZ is proposing to include a specification for dimethyl ether to be incorporated into the Schedule of Standard 1.3.4.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1056 will include one round of public consultation following an assessment and the preparation of draft variation. A Report (which includes the draft Standard) will be released for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to Standards 1.3.3 and 1.3.4 are likely to have a minor impact on business and individuals.

5. Variations

5.1 Item [1]

This item provides a definition for dairy ingredient in clause 1 of Standard 1.3.3 as well as inserts a permission in the Table to clause 13 of Standard 1.3.3 to permit the use of dimethyl ether to treat all dairy ingredients and dairy products as an extraction solvent processing aid.

5.2 Item [2]

This item inserts a specification for dimethyl ether in the Schedule of Standard 1.3.4.