

28 February 2012

[5-12]

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

Executive Summary

Purpose

The Application sought permission to use dimethyl ether as an extraction solvent processing aid, to treat all dairy ingredients and dairy products¹.

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 sought 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.

Two other ethers, dibutyl and diethyl ether, are currently 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 assessment supported its use and released a scientific opinion in 2009.

Risk Assessment

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

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

Dimethyl ether is proposed for use as an extraction solvent for separating 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. The 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 indicates 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 after 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 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 limited risk management aspects to the assessment.

FSANZ concluded after assessment that dimethyl ether is safe as an extraction solvent processing aid to use on any foods. The Applicant proposed, and FSANZ supported, a maximum permitted level for all dairy ingredients and dairy products of 2 mg/kg for treated food², which is the same limit in the Code as for two other currently permitted ether extraction solvents, dibutyl and diethyl ether. This limit applies to the residual amount of the solvent remaining in food after dimethyl ether processing. Dimethyl ether is added 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 added a specification for dimethyl ether to the Schedule in Standard 1.3.4.

FSANZ has also approved amendments to the Code arising from 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 considered these two Applications concurrently.

Assessing the Application

The Application was assessed under the General Procedure which included one round of public comment.

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 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 arise from the development or variation of the food regulatory measure.

² This is the same maximum permitted level requested for Application A1062

- There are no other measures that are more cost-effective than the variations to Standards 1.3.3 and 1.3.4 that would achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

Decision

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

Reasons for Decision

An amendment to the Code allowing the use of dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products was approved because:

- A detailed safety assessment 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 was 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.
- The 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 25 October 2011 and 6 December 2011. Comments were 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. Three submissions were received as a result of this public consultation that all supported the proposed variations. Issues raised in the submissions have been addressed by FSANZ, and the report amended to reflect any changes. The summary of the submissions is contained in Table 1 in Section 10.1 of the Report.

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this 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 sought 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 began assessing the Application on 1 September 2011.

FSANZ has also approved amendments to the Code arising from 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 considered these two Applications concurrently.

1. The Issue / Problem

A pre-market assessment and approval is required before any new processing aid can 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 was required.

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.

There was no permission to use dimethyl ether as an extraction solvent processing aid to treat food.

Two ethers (dibutyl ether and diethyl ether) 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. 2000 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 preparing 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) undertook 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. The EC Directive was implemented in the UK in September 2011.

The Applicant and FSANZ were not aware of any other permissions to use dimethyl ether as an extraction solvent to treat food in other countries, such as the United States 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 proposed using dimethyl ether as an extraction solvent processing aid to extract both polar and non-polar lipids from both liquid and dry foods. Dimethyl ether has been identified as a very powerful extraction solvent when used as a pressurised liquid.

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

3. Objectives

The objective of FSANZ's assessment was to determine whether it was 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 COAG Legislative and Governance Forum on Food Regulation (the Forum)³ Policy Guideline, *Addition to Food of Substances other than Vitamins and Minerals*, includes specific order policy principles for adding 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 given 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?

³ Formerly called the Australia and New Zealand Food Regulation Ministerial Council

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 indicates 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 was 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 lipids from solid and aqueous foods when it is used as a near critical liquid⁴ produced by compressing the gas and slightly heating it. The analysis concluded that, as proposed by the Applicant, dimethyl ether performed 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 concluded that use of dimethyl ether as an extraction solvent processing aid for treating food did not raise any public health and safety risks, and its use was technologically justified for the stated purpose. Therefore, there were no specific safety risks to manage.

6.1 Limitations on permitted food types

The Applicant requested dimethyl ether be permitted as an extraction solvent processing aid to treat all dairy ingredients and dairy products. FSANZ concluded that there were no reasons to restrict the foods further than as requested.

6.2 Residue limits for treated food

There was no justification on safety grounds to require a maximum permitted level. Regardless of the use of a maximum permitted level, there is a general requirement to ensure residues of extraction solvents for processed foods are kept as low as is practicable. The Applicant requested 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) currently permitted as extraction processing aids in the Standard i.e. 2 mg/kg of treated food.

⁴ 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.

This level is also the limit of determination of the analytical method used by the Applicant to check for residues.

FSANZ decided to require a maximum permitted level rather than use the general limit of Good Manufacturing Practice (GMP). The reasons for requiring a maximum permitted level of 2 mg/kg were the lack of health and safety concerns when used as proposed by the Applicant, ensuring consistency with other similar ether extraction solvents and the limit of determination of the analytical method.

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.

The very low residue limit for dimethyl ether adopted in the EU was suggested by the European petitioner. Their application was for extraction of proteins which were subsequently vacuum processed and used in other foods. There is no justification for adopting such a low level on safety grounds. Furthermore, the Applicant has indicated that their analytical method used to determine residues is not sensitive enough to measure such low concentrations (see Section 6.3). Therefore FSANZ has recommended a higher level of 2 mg/kg.

6.3 Methods of analysis

The Applicant 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 was required in the Schedule to Standard 1.3.4. The development of a specification for dimethyl ether is discussed in section 2.1.4 in SD1.

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

Table 1: 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.

7. Options

Processing aids require pre-market approval under Standard 1.3.3. Therefore, it was not appropriate to consider any non-regulatory options for this Application. Two regulatory options were considered:

Option 1: Approve the variation to Standard 1.3.3 to permit the use of dimethyl ether as an extraction solvent processing aid to treat dairy ingredients and products.

Option21: Reject the draft variation to the Code on which submissions were sought

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 costs and benefits associated with the proposed amendments to the Code were analysed using regulatory impact principles. The level of analysis was 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 (OBPR) provides a standing exemption from the need to assess if a Regulation Impact Statement (RIS) was required for applications relating to processing aids as they are minor or machinery in nature and the permission would be voluntary.

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 Cost Benefit Analysis

8.2.1 *Approve a variation to Standard 1.3.3*

This option provides positive benefits to food manufacturers, as well as food consumers. That is, food processors 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.

8.2.2 Reject the draft variation

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 would disadvantage those members of the food industry who wish 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.

8.3 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, the decision was made to approve the variation to the Code.

Communication and Consultation Strategy

9. Communication

FSANZ developed and applied a basic communication strategy to this Application. The strategy involved notifying subscribers and any interested parties of the availability of the reports for public comment and placing the reports on the FSANZ website. A media release was also prepared to announce a call for submissions.

The process by which FSANZ considers Standard matters is open, accountable, consultative and transparent. Public submissions are sought to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options.

The Applicant, individuals, and organisations making submissions on this Application, are notified at each stage of the assessment of the Application. FSANZ has notified the decision to the Forum. 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

10.1 Issues raised in submissions

Public comments were sought on the Assessment Report on the scientific aspects of the Application, which included any safety aspects of using dimethyl ether as an extraction solvent processing aid to process food and its technological function. Comments were also sought on the proposed draft variations to the Code, including the proposed specification for dimethyl ether to be added to Standard 1.3.4.

Three submissions were received, with the summary of any issues, the name of the submitter and FSANZ's response provided in Table 2.

Table 2: Summary of issues raised in submissions and FSANZ’s response

Issue	Submitter	FSANZ’s response
The variation in section 7 should refer to the category of food (dairy ingredients and products) the Applicant is seeking permission for not all food as this is presumptuous.	Food Technology Association of Australia	The comment is noted and supported. Amendment has been made to the wording of option 2 in Section 7 of the Report. A similar amendment has also been made to the A1062 Approval Report for consistency (though the same submitter did not note this in their A1062 submission)
Requests that the Applicant provides further information explaining why their analytical method for the presence of dimethyl ether is less sensitive compared to the reported EFSA method.	New Zealand Ministry of Agriculture and Forestry	The methodology used by the applicant may differ from that referred to by EFSA. However a method with a greater level of sensitivity is not necessary if a maximum permitted level of 2 mg/kg is permitted. This is addressed in the Approval Report (see Section 6.2 and 6.3).
Supports the Application and the variation to the Code	Queensland Health	No issues raised

Primary Legislative Objectives

11. Addressing the Primary Objectives of Section 18 of the FSANZ Act

FSANZ is required by its legislation to meet the subsection 18(1) 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 was the protection of public health and safety. The other two had less direct relevance although they were also taken into consideration.

11.1 Protection of public health and safety

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

11.2 Provision of adequate information relating to food to enable consumers to make informed choices

This objective was taken to relate to labelling of processed foods.

As noted in Section 6.5, processing aids (including other extraction solvent processing aids) are not subject to ingredient labelling so there are no labelling requirements for using dimethyl ether as an extraction solvent processing aid.

11.3 Prevention of misleading and deceptive conduct

FSANZ concluded that there were no misleading or deceptive conduct aspects.

11.4 Subsection 18(2) considerations

FSANZ must also have regard to the matters set out in subsection 18(2) of the FSANZ Act (as copied in Section 3 of this Report). FSANZ considered these matters as follows:

- FSANZ's risk analysis was based on the best available scientific evidence.
- There is no international (Codex) standard for processing aids. However, dimethyl ether is permitted as an extraction solvent in the EU for a restricted use.
- Permitting the use of dimethyl ether as an extraction solvent processing aid assists the Australian and New Zealand food industry as it provides an alternative extraction solvent that may have advantages over currently approved solvents.
- There are no fair trading issues.

11.4.1 Consistency with Forum Policy Guidelines

FSANZ is required to have regard to the Forum Policy Guidelines relevant to the Application. For this Application the Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals* was considered. Since the purpose for use of dimethyl ether is as an extraction solvent processing aid, consideration falls under 'Technological Function'. FSANZ therefore considered the Application under the five specific policy principles noted in Section 3.

The Applicant clearly articulated the technological function (the stated purpose), as being an extraction solvent processing aid to treat food. FSANZ's assessment concluded that at the amounts and in a form proposed by the Applicant, dimethyl ether is able to achieve the technological function. The assessment confirmed the use of dimethyl ether to treat food is safe. The Applicant makes no nutrition, health or related claims in relation to the substance. It is possible, though not explicitly stated in the Application, that food manufacturers could use dimethyl ether to extract fat from food products to produce low fat versions of the food that might then be eligible for low fat content claims.

Conclusion

12. Conclusion and Decision

This Application was assessed against the requirements of section 29 of the FSANZ Act and the applicable Forum Policy Guideline.

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

Therefore, based on the available scientific information, the decision has been made to approve the variation to Standard 1.3.3 allowing dimethyl ether as an extraction solvent processing aid to treat all dairy ingredients and dairy products sold in Australia and New Zealand. A specification for dimethyl ether to be added to the Schedule of Standard 1.3.4 has also been approved.

FSANZ was required to consider the requests to vary the Code for the two concurrent dimethyl ether Applications (this Application and A1062) separately and independently. This is because FSANZ cannot assume that both Applications will be approved as requested. Therefore, individual variations to the Code, specific to the requests of the individual Applicants, have been written. It is possible that the variations could be combined at a later stage as part of some mechanism (e.g. a future Code maintenance proposal) so that the permission in the Code to use dimethyl ether as an extraction solvent processing aid would be simplified to read 'all foods'.

Decision

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

Reasons for Decision

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

- A detailed safety assessment 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 was 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.
- The variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

13. Implementation

The variations will come in to effect on gazettal.

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)

ATTACHMENTS

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

Variation to the *Australia New Zealand Food Standards Code*



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

Specification for dimethyl ether

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

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 sought approval to use 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 approved a draft Standard.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation, 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 sunseting 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. The variation approves the use of dimethyl ether 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, a specification for dimethyl ether has been 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 included one round of public consultation following an assessment and the preparation of draft variation. An Assessment Report (which included the draft Standard) was released for consultation on 25 October 2011 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. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

Item [1] provides 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. This item also provides a definition for dairy ingredient.

Item [2] inserts a specification for dimethyl ether in the Schedule to Standard 1.3.4.