

8-04
20 October 2004

INITIAL ASSESSMENT REPORT

APPLICATION A527

DIMETHYL ETHER AS A PROCESSING AID

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

1 December 2004

(See 'Invitation for Public Submissions' for details)

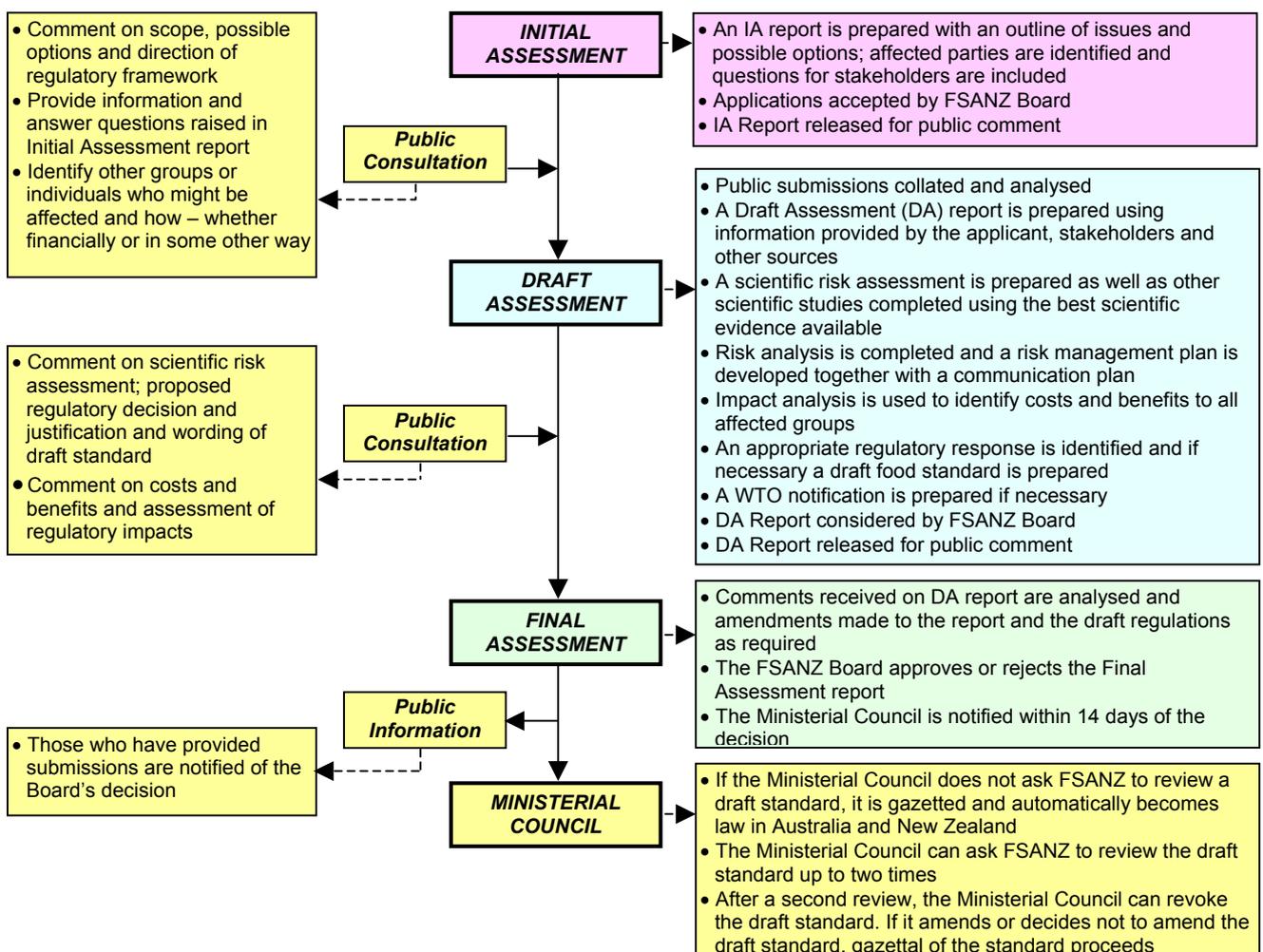
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A527, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 1 December 2004**

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

FSANZ received an Application on 14 January 2004 from Bio Extracts Holdings P/L, to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to approve the use of dimethyl ether as a new extraction solvent. Processing aids must not be added to food unless expressly permitted under Standard 1.3.3. In deciding whether to approve a processing aid FSANZ conducts a pre-market safety assessment. Work on the Application commenced on 6 February 2004. It is a Group 3 (cost-recovered) Application.

The Applicant wishes to use dimethyl ether as an extraction solvent. Dimethyl ether has advantages over similar and already approved solvents such as diethyl ether and hexane, since it is a gas at room temperature and pressure, so volatilises more readily from extracts leaving very low levels in the final extracts.

The primary aim of using dimethyl ether as an extraction solvent is to remove fats and oils from certain foods to produce reduced fat products and products that contain less oil.

This Initial Assessment Report is an assessment of whether the Application should be accepted for further consideration, according to criteria laid down in the FSANZ Act).

The purpose of this Report is to provide a summary of information supplied by the Applicant, outlining the relevant issues and to assist in identifying affected parties necessary to complete assessment of the Application.

Approved extraction solvents as processing aids are listed in the Table to clause 13 of Standard 1.3.3. Currently, there is no approval for dimethyl ether in this table though both diethyl ether and dibutyl ether are approved.

The Applicant is not aware of other national standards relating to the use of dimethyl ether as a processing aid (used as an extraction solvent) for food.

This Application has been assessed against the criteria set out in section 13 of the Act and accepted for the following reasons:

- The Application relates to a matter that warrants a variation to Standard 1.3.3 of the Code, since extraction solvents are listed in the Table to clause 13 of that Standard. Currently there is no approval for dimethyl ether in this Table.
- This Application is not so similar to a previous application that it ought not be accepted.
- There is no basis for considering, at this early stage of the assessment, that the costs that would arise from a variation to Standard 1.3.3 to approve the use of dimethyl ether as an extraction solvent would outweigh the direct and indirect benefits to the community, Government or industry.
- There are no other measures available to permit the use of dimethyl ether as a processing aid.

It has been concluded, in having regard to the criteria for an initial assessment in section 13 of the Act, that the Application be accepted for further consideration. Submissions are now invited to assist in assessing the Application at Draft Assessment.

1. Introduction

FSANZ received an Application on 14 January 2004 from Bio Extracts Holdings P/L, to amend Standard 1.3.3 – Processing Aids of the Code to approve the use of dimethyl ether as a new extraction solvent. Processing aids must not be added to food unless expressly permitted under Standard 1.3.3. In deciding whether to approve a processing aid FSANZ conducts a pre-market safety assessment. Work on the Application commenced on 6 February 2004. It is a Group 3 (cost-recovered) Application.

The Applicant wishes to use dimethyl ether as an extraction solvent as an alternative to the chemically similar, approved solvent, diethyl ether. Dimethyl ether has advantages over similar solvents such as diethyl ether and hexane since it is a gas at room temperature and pressure, so volatilises off more readily from extracts leaving very low levels in the final extracts.

The primary aim, as stated by the Applicant, of using dimethyl ether as a extraction solvent is to remove fats and oils from certain foods to produce reduced fat products and products that contain less oil. Reduced oil products have advantages of improved quality and shelf life since excess oil can oxidise or become rancid so cause deleterious effects with storage.

2. Regulatory Problem

Under Standard 1.3.3, processing aids, unless expressly permitted, must not be added to food. A processing aid is defined as:

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.

There is currently no approval for the use of dimethyl ether as a processing aid in the Code. The Applicant has applied to have dimethyl ether listed as an extraction solvent in the Table to clause 13 of Standard 1.3.3. The processing aids listed in this Table may be used as extraction solvents in the course of manufacture of the corresponding foods specified in the Table provided the final food contains no more than the corresponding maximum permitted level specified in the Table. Examples of approved extraction solvents include diethyl ether and dibutyl ether.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of dimethyl ether as a permitted extraction solvent in Standard 1.3.3 - Processing Aids.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The main section 10 objectives that assessment of this Application will meet are to ensure the protection of public health and safety and that the risk assessment for the approval of dimethyl ether as a processing aid in Standard 1.3.3 of the Code is based on the best available scientific evidence.

4. Background

4.1 Background

Extraction solvents are used in the food industry to remove compounds from foods or to produce concentrated food extracts such as natural flavours or colours. An example of removing compounds from foods is the use of extraction solvents such as methylene chloride to remove caffeine from coffee or tea. An example of using extraction solvents to produce concentrates is using carbon dioxide to extract, concentrate and remove unwanted components from hops to produce hop extracts containing the required bittering compounds which are used in beer manufacture.

Flavour and colour extracts are valued and used in the food manufacturing industries since they are produced to a standard and known concentration of active ingredients. The advantage is they can be accurately added to foods giving the desired attributes in a more consistent manner than using raw materials that may vary in composition with age, quality, the season and where produced.

4.2 Work Plan Classification

This Application had been provisionally rated as Category of Assessment 2 (level of complexity) and placed in Group 3 (cost-recovered) on the FSANZ standards development Work Plan. This Initial Assessment confirms these ratings. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

5. Relevant Issues

5.1 Nature of the processing aid

Dimethyl ether has the Chemical Abstracts System (CAS) number [115-10-6].

Its chemical structure is CH₃-O-CH₃, C₂H₆O, Molecular Weight 46.07.

Dimethyl ether is also called methyl ether, oxybismethane, wood ether and dimethyl oxide.

It is a colourless, flammable gas with a slight ethereal odour. It exists as a gas at room temperature and pressure and has a vapour pressure that is heavier than air.

Physical properties¹:

melting point: -141.50 °C

boiling point: -24.82 °C

flash point: -41 °C

Its general use is listed as an aerosol propellant, solvent, refrigerant and alternative diesel fuel.

Dimethyl ether is produced by the catalytic dehydration of methanol under high temperature and pressure.



5.2 Proposed use

The Application states that they wish to use dimethyl ether as an extraction solvent for a broad range of food products. They are seeking to use the solvent to remove fats and oils from food products to produce reduced fat and reduced oil products. A benefit of low oil products is an improved shelf life with reduced rancidity due to oxidation of oils. The aim may also be to use dimethyl ether to produce extracts from foods, such as oils and essential oils. The Applicant has successfully used this solvent on seed and nut meals, animal and fish tissue and herbs and spices.

The Applicant believes there will be no dietary implications for the processing aid since there are claimed to be very low if not negligible residues in the final food products.

¹ Merck Index, 13th Edition, Merck and Co. Ltd Whitehouse Station, N.J. (2001)

Safety Assessment

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand.

The Application contains a summary of toxicology studies performed with dimethyl ether. These include acute inhalation studies in rats and humans, acute cardiac sensitisation study in dogs, long-term inhalation study in rats, developmental study in rats, *in vitro* bacterial mutation study, *in vitro* chromosome aberration study and *in vivo* sex-linked recessive lethal assay. Because dimethyl ether is a gas at room temperature its main route for possible toxicity is by inhalation. The Applicant states that very low levels of residues will be in the final food. Residue data on food (mainly nut meal) treated with dimethyl ether to remove oils and fats were submitted by the Applicant, as requested by FSANZ, have indicated low levels. This residue information will be further evaluated as part of the safety assessment at Draft Assessment.

Dimethyl ether has not been assessed for use in food products in other countries, however international occupational health limits have been set by the American Industrial Hygiene Association (AIHA), and by Germany. For humans the 8 hour daily lifetime exposure limit for dimethyl ether is based on the rat NOAEL of 2,000 ppm and has been set at 1,000 ppm as an 8 hour Time Weighted Average (AIHA) or Maximum Exposure Level (Germany).

FSANZ requested and has received further information from the Applicant in order to complete the Draft Assessment, in particular the safety assessment. The requested information is:

- Residue levels including details of extraction method, analytical method and limit of detection for food and food extracts that have been extracted with dimethyl ether.
- Independent review of the toxicology data on dimethyl ether.
- Any other use of dimethyl ether as an extraction solvent in food industries (or if not food then pharmaceutical, medical or cosmetic industries).

The safety of dimethyl ether will be more fully considered at Draft Assessment.

5.4 International or other national regulatory standards

The Applicant is not aware of any international or other national standards relating to the use of dimethyl ether as a processing aid (use as an extraction solvent) for food. This includes the Codex Alimentarius, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), or the United States Pharmacopoeia.

FSANZ has also undertaken a preliminary search of various national regulations and standards and has also been unable to find any mention of approvals or likewise of dimethyl ether as a processing aid. It is not currently listed in the Codex Inventory of Processing Aids or the General Standard for Food Additives. It also does not appear to be listed in the USA Code of Federal Regulations.

The Applicant is aware that DuPont has submitted an application to the United States Environmental Protection Agency for registration of the chemical as an Inert Food-Use Conventional Pesticide Candidate.

The United Kingdom Food Safety Authority has a food regulation relevant for extraction solvents (The Extraction Solvents in Food Regulations 1993, plus subsequent 1995 and 1998 amendments) but again there is no mention of dimethyl ether. This regulation contains a list of permitted extraction solvents.

6. Regulatory Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand. The benefits and costs associated with the proposed amendment to the Code will be analysed using regulatory impact principles at Draft Assessment.

There are no options other than a variation to the Code for this Application. Therefore, the two regulatory options available for this Application are:

Option 1. Not approve the use of dimethyl ether as a processing aid.

Option 2. Approve the use of dimethyl ether as a processing aid.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include the following:

1. those sectors of the food industry wishing to produce and market food extracts produced using this extraction solvent, specifically companies who wish to manufacture low fat or low oil content products;
2. consumers; and
3. Australian, State, Territory and New Zealand Government agencies that enforce food regulations.

7.2 Impact Analysis

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

The regulatory impact of the proposed variation to the Code will be assessed at Draft Assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment in order to assist it in assessing this Application at Draft Assessment.

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

FSANZ is seeking public comment to assist it in assessing the Application. Comments on, but not limited to, the following would be useful:

- technological justification for the use of dimethyl ether as an extraction solvent;
- if there are any safety considerations with its proposed use;
- likely costs and benefits of using the extraction solvent; and
- affected parties to this Application.

8.2 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.

There are no relevant international standards and amending the Code to allow dimethyl ether to be used as an extraction solvent is unlikely to have a significant effect on international trade as most other national regulatory agencies do not regulate processing aids.. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

Having regard to the criteria in section 13 of the Act FSANZ recommends that the Application be accepted for the following reasons:

- The Application relates to a matter that warrants a variation to Standard 1.3.3 of the Code, since extraction solvents are listed in the Table to clause 13 of that Standard. Currently there is no approval for dimethyl ether in this Table.
- This Application is not so similar to a previous application that it ought not be accepted.

- There is no basis for considering, at this early stage of the assessment, that the costs that would arise from a variation to Standard 1.3.3 to approve the use of dimethyl ether as an extraction solvent would outweigh the direct and indirect benefits to the community, Government or industry.
- There are no other measures available to permit the use of dimethyl ether as a processing aid.

It is recommended that this Application now be progressed to Draft Assessment.