8 November 2024
315-24

Approval report – Application A1260

2-Methyloxolane as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application submitted by Pennakem Europa[1] to permit the use of 2-methyloxolane as an extraction solvent processing aid in the processing and manufacture of food.

On 26 August 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission and one late comment.

FSANZ approved the draft variation on 30 October 2024. The Food Ministers' Meeting[2] was notified of FSANZ's decision on 8 November 2024.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] EcoXtract acquired Pennakem Europa following acceptance of the application by FSANZ. The applicant is now EcoXtract.
[2] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[3].

Supporting document 1 (SD1) Risk and technical assessment report (at approval)

[3] https://www.foodstandards.gov.au/food-standards-code/applications/Application-A1260-2-methyloxolane-as-a-processing-aid

Executive summary

EcoXtract (previously ‘Pennakem Europa’) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of 2-methyloxolane (2-MeOx) as an extraction solvent processing aid in the processing and manufacture of food.

2-MeOx can be used to extract and separate oils and proteins from plant-based products, including oilseeds. It can also be used to extract other components including flavours, fragrances and colours from plant-based sources.

2-MeOx performs its technological purpose during the production of food and is not performing its technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

No public health and safety concerns were identified in the assessment of 2-MeOx as an extraction solvent at the following maximum permitted levels (MPLs) for residual 2-MeOx:

- 3 mg/kg for Infant formula products;
- 5 mg/kg in Foods for infants and Formulated supplementary foods for young children; and
- 20 mg/kg for other foods.

Following assessment, FSANZ called for submissions regarding a draft variation to the Code on 26 August 2024 for a four-week consultation period. FSANZ received one submission and one late comment, both from government agencies in support of the draft variation.

Based on the information above and other relevant considerations set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions with a minor amendment to clause 1 of the approved draft variation to correct a formatting error. The approved draft variation will amend Schedule 3 and the table to section S18—8 of the Code, to permit the use of 2-MeOx as an extraction solvent processing aid in relation to food.

The permission will be subject to the condition that 2-MeOx must not be present in the food at a level greater than the corresponding MPL indicated in the table to section S18—8.

Additionally, the approved draft variation will add specifications to Schedule 3 of the Code that set out the identity and purity requirements specifically for 2-MeOx. The processing aid must meet these specifications, as well as the limits for arsenic and heavy metals set out in section S3—4, when added to food in accordance with the Code, or sold for use in food.

The effect of the approved draft variation will be to permit the proposed use of this extraction solvent processing aid in accordance with the Code.

1 Introduction

1.1 The applicant

The application was originally submitted by Pennakem Europa, a subsidiary of the Minafin Group. On 26 April 2024, EcoXtract acquired Pennakem Europa. Food Standards Australia New Zealand (FSANZ) received notification that EcoXtract was now the applicant for A1260 on 31 July 2024.

From their website[4], EcoXtract is a company that develops and produces renewable, bio-sourced extraction solvents.

1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of 2-methyloxolane (2-MeOx) as an extraction solvent processing aid in the processing and manufacture of food.

2-MeOx can be used to extract and separate oils and proteins from plant-based products, including oilseeds. It can also be used to extract other components including flavours, fragrances and colours from plant-based sources.

2-MeOx performs its technological purpose during the production of food and not in the food for sale, therefore functioning as a processing aid for the purposes of the Code.

2-MeOx is produced from agricultural by-products including corn cobs, sugarcane bagasse and rice straw. The applicant proposed that 2-MeOx can be used as an alternative to hexane, which is a permitted extraction solvent worldwide.

The application initially requested the following maximum permitted levels (MPLs) for residual 2-MeOx in foods.

- 5 mg/kg in infant formula products;
- 5 mg/kg in foods for infants; and
- 20 mg/kg in other foods.

During the assessment, the MPL for infant formula products proposed by the applicant was reduced to 3 mg/kg. This is because, at the requested MPL of 5 mg/kg, the estimated 90th percentile exposure to 2-MeOx was found to exceed the acceptable daily intake (ADI) of 1 mg/kg bw/day for infants aged 3 months and exclusively formula-fed. In addition, the applicant confirmed the MPL of 5 mg/kg for formulated supplementary foods for young children.

1.3 The current Standards

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

[4] https://ecoxtract.com/

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance *used as a processing aid* unless the use of that substance as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance *used as a processing aid* in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 list the permitted processing aids. Section 1.3.3—10 permits substances listed in the table to section S18—8 to be used as processing aids to perform the technological purpose of an extraction solvent if the substance concerned is used in relation to a food listed in the corresponding row of the table, and is not present in the food at a level greater than the MPL specified in the corresponding row of the table. 2-MeOx is not listed in the table to S18—8. Therefore, its use as an extraction solvent processing aid is currently not permitted by the Code.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code, or sold for use in food.

Schedule 3 includes a number of primary and secondary sources of specifications at S3—2 and S3—3 respectively. Where a substance does not have a relevant identity and purity specification within these sources, as is the case for 2-MeOx, then a new specification must be included in this Schedule.

In addition, S3—4 contains supplementary requirements relating to limits for arsenic and heavy metals for certain substances. 2-MeOx will also be required to comply with these requirements.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.4 International and overseas standards

1.4.1 International

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

In contrast to food additives, there is no Codex ‘general standard’ for processing aids. However, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as

processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.4.2 European regulations

Commission Directive (EU) 2023/175[5], dated 26 January 2023, authorised the use of 2-MeOx as an extraction solvent in the production or fractionation of fats, oils or cocoa butter; preparation of defatted protein products and defatted flours; and preparation of defatted cereal germs (Table 1).

Table 1 **Commission Directive (EU) 2023/175 – conditions of use for 2-MeOx**

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
2-methyloxolane	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs

The Directive also established specific purity criteria for 2-MeOx (Table 2).

Table 2 **Commission Directive (EU) 2023/175 – purity criteria for 2-MeOx**

CAS number	96-47-9
Assay	Content not less than 99,9 % expressed on dry basis
Purity	
Furan	Not more than 50 mg/kg (expressed on dry basis)
2-methylfuran	Not more than 500 mg/kg (expressed on dry basis)
Ethanol	Not more than 450 mg/kg (expressed on dry basis)

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of 2-MeOx as an extraction solvent processing aid in relation to food.

After FSANZ had regard to the only submission and late comment received during the call for submissions, the draft variation proposed following assessment was approved with a minor

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023L0175

amendment to clause 1 of the approved draft variation to correct a formatting error. The approved draft variation takes effect on gazettal and is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 26 August 2024 to 20 September 2024. One submission and one late comment were received.

In response to submissions, additional data was incorporated into section 5 (Discussion and risk characterisation) of SD1, and the reference was added to the reference list at section 7 of that report (see Table 3). In addition, a correction was made to one of the FSANZ references listed.

Table 3 **Summary of issues**

Issue	Raised by	FSANZ response
Supportive. The submitter suggested FSANZ include estimated food consumption data from the 2016 New Zealand Total Diet Study and use this to compare against the estimated amounts of foods that could be consumed without exceeding the acceptable daily intake (ADI), particularly for the older infant and young child age group.	New Zealand Food Safety	These data were incorporated into section 5 of the SD1 at approval. As noted in SD1, a comparison of these data was made against the estimated amounts of foods that could be consumed without exceeding the ADI (for infants and toddlers). It proved similar to the comparison made against 25th ATDS data and data from the Infant Feeding, Activity and Nutrition Trial (InFANT) program.
Supportive. The submitter supported the lower MPL proposed for infant formula products. The dietary exposure assessment identified exposure at 100% of the ADI for children up to 18 years of age for 'other FSMP' (food for special medical purposes other than very low energy diet or VLED). Although a conservative estimate, NSWFA recommended FSANZ inform medical professionals of the potential high intake of 2-MeOx from FSMP so that they can educate their patients on FSMP diets to avoid consuming other foods	New South Wales Food Authority (NSWFA) (Late comment)	In FSANZ's tiered approach to the dietary exposure assessment for consumers of 'other FSMP' (up to 18 years of age), it was assumed that 'other FSMP' are a sole source of nutrition and that all 'other FSMP' contain 2-MeOx at the proposed MPL (20 mg/ kg) (see section 4.2.3.2 of the SD1). As this approach assumes that 'other FSMP' consumers would not consume foods in addition to 'other FSMP', these consumers would not be exposed to 2-MeOx from other foods (e.g. general-purpose foods). The SD1 also outlines other worst case assumptions used for the assessment.

Issue	Raised by	FSANZ response
containing 2-MeOx. Noted section 1.3.3 indicates that processing aids be used at no more than the maximum level necessary to achieve the technological purpose under conditions of GMP. It is industry's responsibility to ensure the use of processing aids is at the lowest level necessary irrespective of any MPLs specified.		If despite the above, 'other FSMP' are not consumed as a sole source of nutrition, estimated dietary exposure from 'other FSMP' would be lower. The ADI being for lifetime exposure means that it is conservative and highly protective during shorter exposures. A small or transient dietary exposure above an ADI does not necessarily mean the exposed population is at significant additional health risk as a result of that exposure. Individuals consuming 'other FSMP' will be under medical supervision, including for use over extended periods of time. In light of the above, FSANZ is of the view medical professionals do not need to educate their patients about exposure to 2-MeOx from FSMP diets. FSANZ agrees with the submitter's final comment, which is reflected in section 2.4.3 of this report.

2.2 Food technology assessment

FSANZ has undertaken a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD1).

From the food technology assessment, FSANZ concludes 2-MeOx is technologically justified for use as an extraction solvent in food. It will be used to separate and extract oils and proteins from plant sources including corn and oilseeds. It will also be used to extract natural aroma, flavours and colourants, particularly those that are lipophilic (e.g. hops, annatto, carotenoids and chlorophyl).

The use of 2-MeOx as an extraction solvent is consistent with its typical function as a processing aid. That is, 2-MeOx performs its technological purpose during the production of food and is not performing a technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

Relevant identity and purity specifications for 2-MeOx will be included in the Code with which this processing aid will need to comply (in addition to the specifications in section S3—4) when added to food in accordance with this Code, or sold for use in food.

2.3 Risk assessment

FSANZ has assessed the public health and safety risks associated with 2-MeOx and its use as an extraction processing aid in the processing and manufacture of food (see SD1). A summary of this risk assessment is provided below.

Some residual 2-MeOx (1 mg/kg in liquid food and 10 mg/kg in solid food) is still present in the extracted products: refined oils, plant proteins or natural extracts (hop extract, carotenoid from algae, chlorophyll). However, toxicokinetic studies in rats and mice show that 2-MeOx is rapidly absorbed and excreted in these species and does not accumulate in any organ. In addition, its presence at residual levels can be managed through the setting of appropriate MPLs in the Code for different categories of food.

A range of *in vitro* and *in vivo* genotoxicity assays, including bacterial reverse mutation assays, mammalian gene mutation tests, micronucleus tests and a chromosomal aberration test, have been conducted. Collectively, these support the conclusion that 2-MeOx does not show genotoxic potential.

Long-term carcinogenicity studies are not required because 2-MeOx is not genotoxic and no lesions likely to lead to neoplasia by a nongenotoxic mechanism were observed in the three-month repeat-dose study conducted in rats. No case reports of allergy or intolerance attributable to oral exposure to 2-MeOx were located. From the lowest No Observed Adverse Effect Level (NOAEL) identified in animal studies, 100 mg/kg bw/day, FSANZ derived an acceptable daily intake (ADI) of 1.0 mg/kg bw/day.

Dietary exposure assessments (DEA) were conducted to capture all the foods/food groups requested and the different MPLs requested. The DEA covered populations in Australia and New Zealand including infants under 12 months and assessed residual 2-MeOx in foods at the following MPLs[6]:

Table 4 **2-MeOx MPLs for different food categories**

Food Category	Age	2-MeOx (mg/kg)
Infant formula products (includes infant formula, follow on formula and infant formula products for special dietary use)	under 12 months	3
Foods for infants	under 12 months	5
Formulated supplementary foods for young children	1 to 3 years	5
Other food	N/A	20

The dietary exposure to residual 2-MeOx from general purpose foods (including formulated meal replacements and formulated supplementary foods) at the requested MPL of 20 mg/kg of 2-MeOx was estimated to be approximately 65% of the ADI.

For infants aged 3 months, the estimated mean and 90th percentile (P90) dietary exposures to residual 2-MeOx from only infant formula at an MPL of 3 mg/kg of 2-MeOx were 40% and 80% of the ADI respectively. It was estimated that infants aged 9 months could consume up to 1447 g of food for infants (at 5 mg/kg of 2-MeOx), or up to 2894 g of general purpose foods (at 20 mg/kg of 2-MeOx), in addition to 555 g of follow on formula (at 3 mg/kg of 2-MeOx) per day before exceeding the ADI. It was estimated infants aged 12 months could

[6] During the assessment, the MPL requested by the applicant for infant formula products was revised to 3 mg/kg. In addition, the applicant confirmed the MPL of 5 mg/kg for formulated supplementary foods for young children.

consume up to 1500 g of food for infants (at 5 mg/kg of 2-MeOx), or up to 3000 g of general purpose foods (at 20 mg/kg of 2-MeOx), in addition to 420 g of formulated supplementary food for young children per day (at 5 mg/kg of 2-MeOx) before exceeding the ADI. These amounts were well above estimated or actual food consumption amounts reported.

For food for special medical purposes (FSMP) that are not very low energy foods and are referred to as 'other FSMP', estimated dietary exposures to residual 2-MeOx at an MPL of 20 mg/kg for adults and children were 60% and 100% of the ADI respectively. These estimates are, however, overestimates given the conservative assumptions used in the calculation. For instance, it was assumed that all other FSMP contain 2-MeOx at the proposed MPL (20 mg/ kg) to be representative of the worst-case scenario.

Based on the safety and dietary exposure assessments, there are no safety concerns associated with use of 2-MeOx as an extraction solvent (including residual levels) at the proposed MPLs in Table 4.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of four weeks.

The risk management options available to FSANZ after the assessment were to:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

The conclusions from the technical and risk assessment were that the proposed use of 2-MeOx is technologically justified and there were no safety concerns associated with its proposed use.

Having regard to the submission and late comment received, and for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment with a minor amendment to correct a formatting error (Attachment A).

Risk management considerations for this application relating to the regulatory approval, nomenclature, MPLs, specifications and labelling are discussed below.

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ has approved a draft variation to permit the use of 2-MeOx as a processing aid – to be used as an extraction solvent in food. The express permission also provides the permission for residual amounts to be present in the food for sale at levels no greater than the MPLs set out in the approved draft variation (Attachment A).

2.4.2 Nomenclature

For the purposes of the Code, FSANZ proposed the name 2-methyloxolane. This is consistent with the applicants' request and its IUPAC[7] identifiers of either 2-methyloxolane or 2-methyltetrahydrofuran (see Table 1 of SD1).

[7] International Union of Pure and Applied Chemistry

2.4.3 Maximum permitted levels

As described in section 2.3 of this report, FSANZ has concluded 2-MeOx can be used as a processing aid in all foods with the following residual levels set in the approved draft variation: at an MPL of 20 mg/kg, with the exception of Infant formula products, which will have an MPL of 3 mg/kg, Foods for infants, which will have an MPL of 5 mg/kg, and Formulated supplementary foods for young children, which will have an MPL of 5 mg/kg.

FSANZ's DEA identified no exceedances of the ADI for infant groups considered at the proposed MPLs. No other dietary exposure exceedances were identified for the foods/food groups requested (including for all categories of FSMP, which includes VLED products) at the proposed MPLs using conservative assumptions (refer section 4 of SD1).

General requirements for a substance to be used as a processing aid in relation to food set out in section 1.3.3. Paragraph 1.3.3—3(b) of the Code requires that the proportion of the substance to be used is 'no more than the maximum level necessary to achieve the technological purpose under conditions of GMP'. Ultimately it is industry's responsibility to ensure the use of this processing aid is:

- not present in the food at a level greater than the MPL specified for that substance; and
- used at no more than the maximum level necessary to achieve its technological purpose under conditions of GMP.

2.4.4 Specifications

Section 1.1.1—15 requires a substance that is *used as a processing aid* must comply with any relevant specification set out in Schedule 3 of the Code when added to food in accordance with the Code, or sold for use in food.

There is no relevant specification that would apply to 2-MeOx in Schedule 3 of the Code (other than the specifications for arsenic and heavy metals in section S3—4). Therefore, the approved draft variation will insert specifications setting out specific identity and purity requirements for 2-MeOx in Schedule 3, with which the processing aid will need to comply (in addition to those in section S3—4) when added to food in accordance with the Code, or sold for use in food.

Limits have been established for furan, 2-methylfuran and ethanol based on the potential for these substances to be present due to the manufacturing process and that among the impurities present in 2-MeOx preparations, furan and 2-methylfuran are those of the highest hazard.

The specifications for these impurities are consistent with those listed in Commission Directive (EU) 2023/175 (see Table 2 of this report).

The individual specification for 2-MeOx for inclusion in Schedule 3 is shown in Table 5.

Table 5 Specification for 2-MeOx proposed by FSANZ

Physical and chemical parameters	Specification
Chemical name	2-Methyloxolane
Chemical formula	$C_5H_{10}O$
CAS Number	96-47-9
Purity (on a dry weight basis)	not less than 99.9%
Ethanol (on a dry weight basis)	not more than 450 mg/kg
Furan (on a dry weight basis)	not more than 50 mg/kg
2-methylfuran (on a dry weight basis)	not more than 500 mg/kg

As mentioned above, section S3—4 contains additional MPLs for arsenic and metals for any substance, including 2-MeOx, for which there is no relevant specification under section S3—2 or S3—3, or if the monographs referred to in those sections do not contain a specification for identity and purity of the substance relating to arsenic or heavy metals. Section S3—4 provides that the substance must not contain on a dry weight basis more than:

- 2 mg/kg of lead; or
- 1 mg/kg of arsenic; or
- 1 mg/kg of cadmium; or
- 1 mg/kg of mercury.

The above specifications will apply to the applicant's 2-MeOx and to 2-MeOx produced by other manufacturers. That is, other parties will be able to manufacture 2-MeOx and can develop processes to use 2-MeOx in the manufacture and processing of food products. In doing so, those manufacturers/suppliers will be required to comply with the relevant specifications for 2-MeOx in Schedule 3.

2.4.5 Labelling

The generic exemption from listing processing aids in the statement of ingredients would apply to foods produced using this processing aid (see Section 1.3.3 above).

2.4.6 Risk management conclusion

The risk management conclusion is to permit this extraction solvent, with the listed name '2-methyloxolane', as a processing aid in the processing and manufacture of food, to extract and separate oils and proteins from plant-based products, including oilseeds. It can also be used to extract other components including flavours, fragrances and colours from plant-based sources. The extraction solvent will be listed in the table to section S18—8 of the Code, which includes processing aids permitted to perform the technological purpose of an extraction solvent in relation to food.

The express permission for the extraction solvent to be used as a processing aid in Schedule 18 of the Code will also provide the permission for residual amounts to be present in the food for sale at levels no greater than the corresponding MPLs specified in the table to section S18—8 as follows:

- 3 mg/kg (Infant formula products)
- 5 mg/kg (Foods for infants)
- 5 mg/kg (Formulated supplementary foods for young children) and
- 20 mg/kg (All other foods).

An individual specification for 2-MeOx will be included in Schedule 3 to ensure that there are relevant specifications for 2-MeOx in the Schedule (in addition to specifications in section S3—4), with which the substance will have to comply when added to food in accordance with this Code, or sold for use in food.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions

are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by the government submitters who made submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to the submission and late comment made during the call for submissions period.

2.5.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

As noted in section 1.4 of this report, the relevant international standard setting body is Codex. However, there is no Codex 'general standard' for processing aids. 2-MeOx has been authorised for use in the EU under Commission Directive (EU) 2023/175, dated 26 January 2023. In addition, the applicant has advised they are planning to seek approval for the use of 2-MeOx from the United States Food and Drug Administration.

The approved draft variation prescribes MPLs for 2-MeOx in several categories of food, but these are generally higher (i.e. less restrictive) or comparable with limits permitted in the EU (with the exception of defatted soya products as sold to the final consumer (see Table 1 of this report)). Therefore, FSANZ is of the view that amending the Code to permit the use of 2-MeOx as an extraction solvent processing aid in relation to food is unlikely to have a significant effect on international trade.

Regardless, FSANZ made a notification to the WTO for this application in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement. No WTO member nation has provided comment on this application.

2.6 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

Changes to Office of Impact Analysis requirements

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[8]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation

[8] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

concerned is approved. Under this approach, FSANZ's assessment is that a RIS was not needed for this application.

Consideration of costs and benefits to meet FSANZ Act requirements

FSANZ, however, considered the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry is likely to benefit, on balance, from a move from the *status quo* (where the status quo is rejecting the application). This analysis considered permitting the proposed use of 2-MeOx as an extraction solvent processing aid in relation to food.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting 2-MeOx to be used as an extraction solvent processing aid.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. No further information was received during the call for submissions that changed that assessment.

Costs and benefits of permitting the proposed use of 2-MeOx

In FSANZ's view, the likely benefits of making the amendments to the Code will outweigh the likely costs.

The food industry may benefit from the approval of the draft variation. 2-MeOx as a processing aid for the purpose of solvent extraction has different properties to other extraction solvents, some of which may be advantageous to food manufacturers under certain circumstances. The permission will be voluntary, therefore manufacturers will only use 2-MeOx where a commercial net benefit exists for them.

Consumers may benefit from the approval of the draft variation, where improvements in manufacturing processes result in products that better meet consumer demand, or where cost savings from manufacturers are passed on to consumers.

Permitting the proposed use of this extraction solvent may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting 2-MeOx to be used as a processing aid for the purpose of solvent extraction would most likely outweigh any costs. No further information has been received during the consultation process that changed that assessment.

2.6.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-

effective than a food regulatory measure developed or varied as a result of the application.

2.6.1.3 Any relevant New Zealand standards

The standards in the Code that are relevant to the permitted use of processing aids apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

FSANZ undertook a risk and technical assessment (see SD1) and concluded there were no public health and safety concerns associated with permitting the proposed use of 2-MeOx as a processing aid for the purpose of solvent extraction.

2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Existing labelling requirements will apply to 2-MeOx in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.4.5 of this report).

2.6.2.3 The prevention of misleading or deceptive conduct

There are no issues identified for this application relevant to this objective.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

Permitting the use of 2-MeOx as an extraction solvent processing aid in the Code is consistent with a similar permission to use this substance in Europe (Directive 2009/32/EC) (Commission Directive (EU) 2023).

- **the desirability of an efficient and internationally competitive food industry**

Australia and New Zealand will remain competitive with other international markets, where authorisation for the use of the 2-MeOx as an extraction solvent in food is already in place

(Europe) or occurs in the future. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of 2-MeOx as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of 2-MeOx for the applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, considering the costs and benefits of using the new processing aid, to determine if it is of benefit to their business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this consideration.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[9] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted 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')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of 2-MeOx as an extraction solvent processing aid in food would be consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

Commission Directive (EU) 2023/175 of 26 January 2023 amending Directive 2009/32/EC of the European Parliament and of the Council as regards 2-methyloxolane. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023L0175

Attachments

A. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

[9] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name and position title of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, before the table item dealing with 'Nicotinamide riboside chloride')

Insert:

2-Methyloxolane	section S3—52

[2] After section S3—51

Insert:

S3—52 Specification for 2-Methyloxolane

For 2-Methyloxolane, the specifications are the following:

(a) chemical name—2-Methyloxolane;
(b) chemical formula—$C_5H_{10}O$;
(c) CAS Number—96-47-9;
(d) purity (on a dry weight basis)—not less than 99.9%;
(e) ethanol (on a dry weight basis)—not more than 450 mg/kg;
(f) furan (on a dry weight basis)—not more than 50 mg/kg;
(g) 2-methylfuran (on a dry weight basis)—not more than 500 mg/kg.

Schedule 18—Processing aids

[3] Section S18—8 (table, before the table item dealing with 'Propane')

Insert:

2-Methyloxolane	Infant formula products	3
	Foods for infants	5
	Formulated supplementary foods for young children	5
	All other foods	20

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation

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.

The Authority accepted Application A1260 which sought to amend the Code to permit 2-methyloxolane (2-MeOx) as a processing aid for the purpose of an extraction solvent in relation to food. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation: the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State

and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending Schedule 3 and the table to section S18—8 of the Code to permit the use of 2-MeOx as a processing aid for the purpose of being an extraction solvent in relation to food. 2-MeOx can be used to extract and separate oils and proteins from plant-based products, including oilseeds. It can also be used to extract other components including flavours, fragrances and colours from plant-based sources. This permission is subject to the condition that 2-MeOx must not be present in the food at a level greater than the maximum permitted level indicated in the corresponding row of the table (3 mg/kg in Infant formula products; 5 mg/kg in Foods for infants and Formulated supplementary foods for young children; 20 mg/kg in all other foods). As a substance used as a processing aid, 2-MeOx will also have to comply with relevant specifications set out in Schedule 3 of the Code when added to food in accordance with the Code, or sold for use in food.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1260 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on the draft variation from 26 August to 20 September 2024.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA) [10]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS was not required for this application.

6. 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 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation*.

[10] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Schedule to the variation

Items [1] and **[2]** of the Schedule to the variation amends Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as processing aids, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food.

Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)). This table lists entries consisting of substances for which there are specifications in Schedule 3 (column 1); and their associated provisions (column 2).

Item [1] amends the table to subsection S3—2(2) by inserting a new entry into the table before the table item dealing with 'Nicotinamide riboside chloride'. The new entry consists of '2-Methyloxolane' in column 1 of the table and 'section S3—52' in column 2 of the table.

This amendment is consequential to the amendment in **item [2]** (see below).

Item [2] inserts new section S3—52 into Schedule 3, which sets out identity and purity specifications specifically for 2-MeOx.

Amendments in **items [1]** and **[2]** are related to the amendment in **item [3]** below, which will permit the use of 2-MeOx as a processing aid for certain technological purposes in accordance with the Code.

The effect of amendments in **items [1]** and **[2]** will be that when 2-MeOx is added to food in accordance with the Code, or sold for use in food, 2-MeOx will have to comply with the new specification in section S3—52, in addition to any other relevant specification in Schedule 3.

Item [3] of the Schedule to the variation amends Schedule 18 of the Code.

Schedule 18 lists substances that are permitted to be used as processing aids for the purposes of the Code.

In particular, **item [3]** inserts a new entry into the table to subsection S18—8 of the Code. This table lists substances that are permitted to function as extraction solvents in relation to food for the purposes of section 1.3.3—10 of the Code.

According to section 1.3.3—10, a substance listed in section S18—8 may be used as a processing aid to perform the technological purpose of an extraction solvent if the substance satisfies both of the following conditions – the substance:

- is used in relation to a food listed in the corresponding row of the table; and
- is not present in the food at a level greater than the maximum permitted level specified in the corresponding row of the table.

The term 'used as a processing aid' is defined in section 1.1.2—13 of the Code.

Th new entry will be inserted into the table to subsection S18—8 before the table item dealing with ‘Propane’; and consist of the following:

‘2-Methyloxolane’ is the substance listed in column 1 of the table.

The associated foods for this substance are listed in column 2 of the table as ‘Infant formula products’, ‘Foods for infants’, ‘Formulated supplementary foods for young children’ and ‘All other foods’.

The maximum permitted level corresponding to each food is set out in column 3 of the table as follows:

- 3 mg/kg (Infant formula products);
- 5 mg/kg (Foods for infants);
- 5 mg/kg (Formulated supplementary foods for young children); and
- 20 mg/kg (All other foods).

The amendment in **item [3]** will permit the proposed use of 2-MeOx as a processing aid in accordance with the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation

---

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Dated [To be completed by the Delegate]

[Insert name and position title of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

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[2] After section S3—51

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S3—52 Specification for 2-Methyloxolane

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