15 December 2020
[145-20]

Approval report – Application A1180

Natural Glycolipids as a preservative in non-alcoholic beverages

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by LANXESS Deutschland GmbH to permit the use of long-chain glycolipids from *Dacryopinax spathularia* ("jelly mushroom glycolipids") as a preservative in non-alcoholic beverages.

On 6 August 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

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

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from LANXESS Deutschland GmbH to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of a long-chain glycolipid mixture derived from *Dacryopinax spathularia* ('jelly mushroom glycolipids') for use as a food additive (preservative) in non-alcoholic beverages.

The application seeks permission for the following maximum permitted levels of jelly mushroom glycolipids to be permitted in the associated non-alcoholic beverages categories

1. 100 mg/kg for Fruit and vegetable juices and fruit and vegetable juice products
2. 50 mg/kg for Water based flavoured drinks;
3. 20 mg/kg for Formulated Beverages;
4. 10 mg/kg for Coffee, coffee substitutes, tea, herbal infusions and similar products;
5. 100 mg/kg for non-alcoholic beer.

Jelly mushroom glycolipids function as a preservative against common yeasts and moulds in non-alcoholic beverages.

Based on FSANZ's risk assessment, an acceptable daily intake (ADI) of 2.0 mg/kg body weight per day has been established. Dietary exposures estimated by FSANZ were below this ADI and therefore FSANZ has concluded that there are no public health and safety concerns from the use of jelly mushroom glycolipids at the proposed levels in the non-alcoholic beverage categories mentioned above.

Based on the FSANZ food technology assessment, the use of jelly mushroom glycolipids as a food additive in the quantity and form proposed is technologically justified. It is appropriately classified as a food additive since it provides a technological function as a preservative.

There is currently no specification for jelly mushroom glycolipids in the Code, nor are there any relevant international standards. As such, FSANZ has established a specification for jelly mushroom glycolipids to be included in Schedule 3 of the Code.

FSANZ has considered the potential impacts of approving a draft variation to the Code and has concluded that the direct and indirect benefits that would arise from permitting jelly mushroom glycolipids most likely outweighs the associated costs.

The draft variation proposed in call for submissions used the term "jelly mushroom glycolipids" for the purposes of the proposed permissions and specifications. However, based on a late submission from the applicant and the need to more clearly define the source of the glycolipids, FSANZ decided that 'sweet osmanthus ear glycolipids' was a more accurate and appropriate term or descriptor of jelly mushroom glycolipids for Code purposes. FSANZ therefore approved a draft variation to the Code to permit the use of 'sweet osmanthus ear glycolipids' as a food additive in the requested non-alcoholic beverage categories at the maximum permitted levels sought.

1 Introduction

1.1 The Applicant

LANXESS Deutschland GmbH is a company whose core business is the development, manufacture and marketing of chemical intermediates, additives, specialty chemicals and plastics.

1.2 The Application

The purpose of the application is to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (known as 'jelly mushroom glycolipids' or 'sweet osmanthus ear glycolipids') as a food additive for the purposes of preserving non-alcoholic beverages. The application sought permission for jelly mushroom glycolipids at specific maximum permitted levels ranging between 2 to 100 mg/kg for different non-alcoholic beverage categories[1].

Jelly mushroom glycolipids are considered by the applicant to have antifungal effects against common yeasts, moulds as well as antimicrobial effects against bacteria, and can be used to prolong the shelf life of non-alcoholic beverages. They may be used as an alternative in some instances to existing preservatives, as well as being used alongside existing production practices (e.g. heat treatment) to preserve beverages.

1.3 The current Standards

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

1.3.1 Permitted use

Jelly mushroom glycolipids are not currently permitted to be added to non-alcoholic beverages as a food additive – preservative.

1.3.2 Food additive permissions

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a food additive' unless that substance's use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is 'used as a food additive' if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is one of a number of substances listed in that section. These include a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table to section S14—2 provides that use as a preservative is a permitted technological purpose.

[1] Non-alcoholic beverage categories: Fruit and vegetable juices and fruit and vegetable juice products, Water based flavoured drinks, Formulated Beverages, Coffee, coffee substitutes, tea, herbal infusions and similar products, and non-alcoholic beer.

Schedules 15 and 16 list the specific food additive permissions for different categories of food products.

For the purposes of this application, the following items in the table to section S15—5 are relevant. Item 14.1.2 lists the permitted food additives for Fruit and vegetable juices and fruit and vegetable juice products. Item 14.1.3 lists the permitted food additives for Water based flavoured drinks. Item 14.1.4 lists the permitted food additives for Formulated Beverages. Item 14.1.5 lists the permitted food additives for Coffee, coffee substitutes, tea, herbal infusions and similar products. Item 14.2.1 lists the permitted food additives for Beer and related products (including alcoholic beverages that have had the alcohol reduced or removed).

1.3.3 Labelling

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

Standard 1.2.4 of the Code generally requires packaged food to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) of that Standard requires food additives to be declared in the statement of ingredients by one of the following ways:

- if the food additive can be classified into a class of additives listed in Schedule 7—by referring to the relevant class name, followed in brackets by the name or code number of the food additive indicated in Schedule 8;
- otherwise—by referring to the name of the food additive as indicated in Schedule 8.

Schedule 7 lists prescribed and optional food additive class names for use in the statement of ingredients. ‘Preservative’ is a prescribed class name.

Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes.

Schedule 8 does not refer to glycolipids from *Dacryopinax spathularia* as this substance is not currently permitted in the Code to be added to food as a food additive.

1.3.4 Identity and purity requirements

Food additives permitted by section 1.3.1 and Schedule 15 must also meet any relevant identity and purity specifications set out in Schedule 3.

1.3.5 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (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). Standards set by Codex provide a benchmark against which national food measures and regulations can be assessed. In certain situations however, FSANZ might receive an application to amend the Code for permission to use a new food additive before an international standard exists.

In this circumstance there are no international standards concerning the use of jelly mushroom glycolipids as a food additive. However, the substance is currently permitted for use in the USA where it has been determined as Generally Recognized as Safe (GRAS).

1.4 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 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous Application for the variation of a food regulatory measure that it ought to be rejected.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment and in the call for submissions was approved with one amendment. The amendment was to change the references in the draft variation to jelly mushroom glycolipids" to 'sweet osmanthus ear glycolipids'. This change was made as the term 'sweet osmanthus ear glycolipids' was considered a more accurate and appropriate term or descriptor of jelly mushroom glycolipids for Code purposes.

The approved draft variation is at Attachment A. The variation takes effect on gazettal.

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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Four submissions were received in relation to this application (Table 1). All four submissions were supportive of the current variation and no issues were raised in any submission.

Table 1: Summary of submissions

Submitter	Comments	FSANZ response
New Zealand Food and Grocery Council	Supportive	Noted
New Zealand Ministry for Primary Industries	Supportive	Noted
Tailored Beverage Company Pty Ltd	Supportive	Noted
Victorian Department of Health and Human Services.	Supportive	Noted

The applicant provided a late submission and three supporting letters from industry requesting FSANZ reconsider the use in the draft variation of the term 'jelly mushroom

glycolipids' . The applicant did not support the use of the term "jelly mushroom" as it would not be known to most consumers. The applicant and industry proposed alternative descriptive terms that could be used instead to describe the nature and type of product more precisely. The two alternatives were:

- Mushroom glycolipids or
- Sweet osmanthus ear glycolipids

FSANZ considered that "mushroom glycolipids" is too broad a term and would have the effect of granting a permission for glycolipids from all species of mushrooms. "Sweet osmanthis ear glycolipids" provides a more precise description of the source organism and, for that reason, FSANZ amended the draft variation accordingly.

2.2 Risk assessment

2.2.1 Food technology assessment

FSANZ concluded that the use of jelly mushroom glycolipids when used as a food additive for preservative purposes is justified. It may serve as an alternative to existing permitted preservatives, or be used in addition to beverage production methods used to reduce spoilage from yeasts, moulds and bacteria. There is no specification for jelly mushroom glycolipids in the Code. The approved draft variation includes a specification for jelly mushroom glycolipids based on the identification and purity data reviewed.

2.2.2 Microbiological assessment

The exact mechanism for the mode of action for the jelly mushroom glycolipids has not been established. However, the results of *in vitro* studies suggest that the surfactant properties of these glycolipids alter the cytoplasmic membrane leading to increased permeability. The metabolism of the cells is affected leading to cell death. Results of *in vitro* studies suggest that there are important differences in the response of microorganisms to jelly mushroom glycolipids. Gram-negative bacteria are the most resistant, followed by Gram-positive bacteria. Challenge studies using defined mixtures of yeasts and moulds highlighted differences between non-alcoholic beverage types. FSANZ concludes that the addition of jelly mushroom glycolipids at the proposed use levels is effective as a preservative against yeasts and moulds in non-alcoholic beverages.

2.2.3 Safety assessment

The submitted data, together with information located from other sources, are considered suitable to assess the safety of jelly mushroom glycolipids. The Supporting Document alongside this Approval Report has further detail regarding the safety assessment.

Pharmacokinetic data indicate that both the parent mixture and the hydrolysis products are likely to be poorly absorbed by the oral route. There was no evidence of persistence or bioaccumulation in any particular tissue. Acute oral toxicity in rats was greater than 2000 mg/kg bodyweight,

Short-term repeat-dose Good Laboratory Practice (GLP)-compliant studies in rats and dogs were submitted. In a 90-day drinking water study in Sprague Dawley rats, no adverse effects were found at the highest dose administered, equivalent to 1201 and 1423 mg/kg body weight (bw)/day in male and female rats, respectively. In a 90-day oral capsule study in Beagle dogs, a significant reduction, relative to that of controls, in group mean cumulative bodyweight gain in female dogs, with a corresponding but non-significant reduction in group mean food consumption, at 1000 mg/kg bw/day, is considered to be adverse by FSANZ. FSANZ considers that the No Observed Adverse Effect Level (NOAEL) for this study is 500

mg/kg bw/day.

No chronic or carcinogenicity studies of jelly mushroom glycolipids were submitted in the application or located from other sources. Jelly mushroom glycolipids were not genotoxic in GLP-compliant genotoxicity studies that included bacterial reverse mutation assay, micronucleus test in human lymphocytes, and cell gene mutation test (TK mutation test) in L5178Y mouse lymphoma cells. There was an absence of test article related lesions in the repeat-dose studies, and therefore there was no evidence of neoplastic potential by a non-genotoxic mechanism.

Potential for developmental and/or reproductive toxicity was assessed in two GLP-compliant studies in Sprague Dawley rats, a developmental toxicity study and a two-generation reproductive toxicity study. The NOAEL for parental toxicity, embryo/fetal developmental toxicity and toxicity to offspring was the highest dose tested in the two studies, 1000 mg/kg bw/day.

No human tolerance studies of jelly mushroom glycolipids were submitted or located from other sources. It is relevant that the source organism, *Dacryopinax spathularia*, is listed in the FAO compendium on edible mushrooms and is described as edible in peer-reviewed publications from a range of countries in multiple continents. There are no case reports of allergic reactions to the source organism, or evidence of allergenic potential of jelly mushroom glycolipids. There is a lack of evidence that glycolipids act as food allergens.

The Acceptable Daily Intake (ADI) is derived from the lowest NOAEL identified in animals, 500 mg/kg bw/day in Beagle dogs. FSANZ has applied an uncertainty factor of 10 for extrapolation from animals to humans, an uncertainty factor of 10 for variability between humans, and an uncertainty factor of 3 allowing for extrapolation from a subchronic study to chronic exposure, for a total uncertainty factor of 300. An uncertainty factor of 3, rather than 10, has been selected because there is a clear NOAEL at 500 mg/kg bw/day, and the effect is minimal at twice that value, although the dogs were at an age when growth is rapid and energy requirement is high. The ADI is established by division of the lowest NOAEL (500 mg/kg bw/day) by the total UF (300), approximately equalling 1.6, and rounded to 2.0 mg/kg bw/day.

In conclusion, FSANZ has established an ADI of 2.0 mg/kg bw/day, based on decreased bodyweight gain in growing dogs.

2.2.4 Dietary exposure assessment

The dietary exposure assessment for jelly mushroom glycolipids assessed additive uses across three scenarios; *General MPL*[2], *Specific MPL* and *Usual Use* levels across three population groups; Australians aged 2 years and above, New Zealanders aged 15 years and above and New Zealand children aged 5-14 years. The assessment showed that mean and 90th percentile (P90) estimated dietary exposures for all scenarios and population groups assessed was below the ADI of 2.0 mg/kg bw/day. The mean dietary exposures ranged between 10-35% of the ADI and P90 dietary exposures ranged between 20-75% of the ADI.

Across all population groups assessed and all scenarios, the two major contributing food categories to jelly mushroom glycolipids dietary exposures were: 1) Water based flavoured drinks, excluding powders, iced teas, brewed soft drinks; and 2) Fruit and vegetable juices.

Dietary exposures to jelly mushroom glycolipids for Australians aged 2 years and above (mean: 0.46 mg/kg bw/day; P90: 1.0 mg/kg bw/day) and New Zealander aged 15 years and

[2] Maximum Permitted Level.

above (mean: 0.38 mg/kg bw/day; P90: 0.87 mg/kg bw/day) are similar to those estimated for American consumers (mean: 0.51 mg/kg bw/day; P90: 1.09 mg/kg bw/day) in the US GRAS notification (US FDA, 2017)[3].

2.3 Risk management

Given the findings of the safety assessment, FSANZ considers an ADI of 2.0 mg/kg bw/day appropriate. It is noted the dietary exposure assessment indicates the requested levels of jelly mushroom glycolipids in different categories of non-alcoholic beverages would not exceed the proposed ADI. Furthermore, while the mode of action that allows the jelly glycolipids to inhibit mould and yeasts in beverages is not completely understood, it none the less shows a degree of efficacy in extending non-alcoholic beverage shelf life at the proposed levels of addition (2-100 mg/kg), with no public health and safety concerns being identified.

The risk management options available to FSANZ after assessment were to: reject the application; or prepare a draft variation to amend the Code to permit jelly mushroom glycolipids as a food additive in non-alcoholic beverages at the requested levels for different non-alcoholic beverage categories.

Since the risk assessment did not identify any public health and safety concerns, the decision was made to prepare a draft variation to the Code (Attachment A).

2.3.1 Labelling

In general, food additives in packaged food for sale must be listed in the statement of ingredients for the food concerned in accordance with requirements set out in section 1.2.4—7 of the Code.

This application seeks permission to use glycoplipids from jelly mushroom fungus as a preservative in non-alcoholic beverages. Glycolipids from *Dacryopinax spathularia* (a jelly mushroom fungus) does not yet have a number in the Codex Alimentarius International Numbering System (INS) for food additives.

The applicant had proposed ‘natural glycolipids’ as a possible name for glycolipids from jelly mushroom fungus for labelling purposes. FSANZ considers ‘natural glycolipids’ is not sufficiently specific given the three main glycolipids in the glycolipid mixture from jelly mushroom fungus are not found in other foods (SD1). Nor does the Code does define, prescribe or regulate the use of the word ‘natural’. Such a descriptor can be used voluntarily by food businesses and is subject to food laws, consumer protection laws and fair trading laws in Australia and New Zealand which prohibit representations about food that are, or are likely to be, false, misleading or deceptive.

Therefore, the name ‘sweet osmanthus ear glycolipids’ was approved to ensure that the glycolipid source is clearly identified. This name is one of four names listed in the GRAS notification[4] that can be used for labelling purposes in the USA.

Accordingly, based on current Code requirements for additive labelling and the absence of an INS number, the presence of glycolipids from jelly mushroom fungus in a food would need

[3] US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. https://www.fda.gov/media/113331/download

[4] The four names listed in the GRAS notification are: jelly mushroom glycolipids, sweet osmanthus ear glycolipids, *Cantharellus spathularius* ferment extract, mushroom ferment extract (*Dacryopinax spathularia*).

to be declared in the statement of ingredients using the class name ‘preservative’ followed by ‘sweet osmanthus ear glycolipids’ in brackets. Should an INS number be assigned in the future, this could be added to Schedule 8.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ’s social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

FSANZ took into account all public comments received following call for submissions before deciding to approve the draft variation.

2.4.2 World Trade Organization

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 Codex standards concerning the use of jelly mushroom glycolipids as a food additive in non-alcoholic beverages. Other than having GRAS status[5] in the U.S.A, there are currently no other national standards or regulations approving the use of jelly mushroom glycolipids, although dossiers for approval in the EU and Canada are in preparation by the applicant.

Amending the Code to permit jelly mushroom glycolipids as a food additive in non-alcoholic beverages is unlikely to have a significant effect on international trade given its use as a food additive is voluntary and the proposed amendment to the Code would not conflict with existing or standards. Therefore, a notification to the WTO under Australia’s and New Zealand’s obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 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.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new food additives

[5] https://www.fda.gov/media/113331/download

(OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting food additives is machinery in nature as they are part of implementing a regulatory framework where the use of the new additive is voluntary once the application has been approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to 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 is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considers permitting jelly mushroom glycolipids as a food additive in non-alcoholic beverages. FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting use of jelly mushroom glycolipids as a food additive in non-alcoholic beverages.

Costs and benefits of permitting jelly mushroom glycolipids as a food additive

Jelly mushroom glycolipids are considered in FSANZ's assessment to have antifungal effects against common yeasts and moulds and can be used to prolong the shelf life of non-alcoholic beverages. They may be used as an alternative in some instances to existing preservatives, as well as being used alongside existing production practices (e.g. heat treatment) to preserve beverages.

Jelly mushroom glycolipids are permitted for use as a preservative in the USA. Permission to use jelly mushroom glycolipids as a food additive, will enable Australian and New Zealand food manufacturers to access and use a product assessed as safe that is available to their overseas competitors. This will improve their capacity to compete in overseas markets, although there may also be competing imports from the USA into the domestic market.

Permitting jelly mushroom glycolipids may result in a small cost to government in terms of adding it to the current range of food additives that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ concluded that the direct and indirect benefits that would arise from permitting jelly mushroom glycolipids to be used as a food additive in non-alcoholic drinks most likely outweigh the associated costs.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant Standards apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ concluded from its risk assessment that there are no safety concerns associated with using jelly mushroom glycolipids as a preservative in non-alcoholic drinks at the specified maximum permitted levels. For more detail, see SD1.

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

FSANZ considers that existing labelling requirements which would apply to jelly mushroom glycolipids, as discussed in section 2.3.1, would provide sufficient information to enable consumers to make informed food choices.

2.5.2.3 The prevention of misleading or deceptive conduct

See the discussion at section 2.3.1.

2.5.3 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 food technology, risk and dietary exposure assessment (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also considered other information relevant to the application (referenced in the document and reference list).

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

Jelly mushroom glycolipids are GRAS in the USA for the preservative purpose proposed (GRN 740)[6]. The Applicant is reportedly in the process of seeking permissions for the use of jelly mushroom glycolipids in the European Union.

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

[6] US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. https://www.fda.gov/media/113331/download

Permission to use jelly mushroom glycolipids as a preservative in non-alcoholic beverages will enable Australian and New Zealand manufacturers to access and use a product assessed as safe that is available to some overseas competitors. This will improve the capacity of those manufacturers to compete in overseas markets. See discussion at section 2.5.1.1 above.

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

FSANZ's assessment based on the best available scientific evidence is that jelly mushroom glycolipids is safe for its proposed use as a food additive. It is permitted for use elsewhere and is therefore appropriate that Australian and New Zealand food industries can also benefit by gaining permission to use it.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline for Addition to Food of Substances other than Vitamins and Minerals[7] includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. 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, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting jelly mushroom glycolipids to be used as a preservative in non-alcoholic beverages at the specified permitted levels is consistent with the Ministerial Policy Guideline.

3 References

US FDA (2017) GRAS Notice (GRN) No. 740: GRAS Notification for Long-Chain Glycolipids from *Dacryopinax spathularia*. Accessed 3 June 2020. https://www.fda.gov/media/113331/download

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

[7] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

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

Food Standards (Application A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) Variation

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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 Delegate]

[Name 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 A1180 – Natural Glycolipids as a preservative in non-alcoholic beverages) 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

[1] **Schedule 2** is varied by inserting in the table to section S2—2 in alphabetical order

MPN	most probable number

[2] **Schedule 3** is varied by

[2.1] inserting in the table to subsection S3—2(2) in alphabetical order

Sweet osmanthus ear glycolipids	section S3—43

[2.2] inserting after section S3—42

S3—43 Specification for sweet osmanthus ear glycolipids

For sweet osmanthus ear glycolipids, the specifications are the following:

(a) CAS number—2205009-17-0;

(b) chemical structure—a mixture of long-chain glycolipids obtained from the fermentation and filtration of the non-GMO *Dacryopinax spathularia* strain MUCL 53181;

(c) description—off-white to ivory powder;

(d) pH—between 5.0 and 7.0 (1% aqueous solution);

(e) water—less than 5%;

(f) protein—less than 3%;

(g) fat—less than 2%;

(h) total glycolipid content on a dry weight basis for the powder—no less than 93%;

(i) lead—not more than 2 mg/kg;

(j) arsenic—not more than 1 mg/kg;

(k) cadmium— not more than 1 mg/kg;

(l) mercury— not more than 1 mg/kg;

(m) microbial limits:

  (i) total aerobic microbial count—not more than 100 cfu/g;

  (ii) total yeast and mould count—not more than 10 cfu/g;

  (iii) coliforms—not more than 3 MPN/g;

  (iv) *Escherichia coli*—not more than 3 MPN/g.

[3] **Schedule 8** is varied by

[3.1] inserting in the table to section S8—2 entitled ‘Food additive names—alphabetical listing’, in alphabetical order

Sweet osmanthus ear glycolipids	–

[3.2] inserting in the table to section S8—2 entitled ‘Food additive names—numerical listing’, after the entry for **‘**Sodium hydrosulphite**’**

–	Sweet osmanthus ear glycolipids

[4] **Schedule 15** is varied by

[4.1] inserting in item 14.1.2 of the table to section S15–5, after the heading ‘Fruit and vegetable juices and fruit and vegetable juice products’

Sweet osmanthus ear glycolipids	100	

[4.2] inserting in item 14.1.3 of the table to section S15–5, after the entry for ‘Quinine’

Sweet osmanthus ear glycolipids	50	

[4.3] inserting in item 14.1.4 of the table to section S15–5, after the entry for ‘Monk fruit extract (luo han guo extract)’

Sweet osmanthus ear glycolipids	20	

[4.4] inserting in item 14.1.5 of the table to section S15–5, after the entry for ‘Additives permitted at GMP’

Sweet osmanthus ear glycolipids	10	

[4.5] inserting in item 14.2.1 of the table to section S15–5, after the heading ‘Beer and related products’

Sweet osmanthus ear glycolipids	100	Only beer where the alcohol has been removed

Attachment B – 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.

The Authority accepted Application A1180 which seeks to permit the use of long-chain glycolipids from *Dacryopinax spathularia* (sweet osmanthus ear glycolipids) to be used as a food additive in non-alcoholic beverages. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose

The Authority has approved a draft variation to the Code to permit sweet osmanthus ear glycolipids as a food additive in non-alcoholic beverages at a maximum permitted level specified in Schedule 15 (depending on the beverage category). The technological purpose of sweet osmanthus ear glycolipids is use as a preservative in non-alcoholic beverages.

3. Documents incorporated by reference

The variations to food regulatory measures do 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 A1180 included one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new food additives (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting food additives is machinery in nature as they are part of implementing a regulatory framework where the use of the new additive is voluntary once the application has been approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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. Variation

Item [1] amends the table to section S2—2 in Schedule 2 by alphabetically inserting into the table:

- 'MPN' as a new unit of measurement; and
- 'most probable number' as the meaning of MPN.

'MPN' is a unit of measurement referred to in the new specification for sweet osmanthus ear glycolipids (see subitem [2.2] below).

Item [2] amends Schedule 3 by including a specification for sweet osmanthus ear glycolipids.

Subitem [2.1] inserts 'sweet osmanthus ear glycolipids' and 'section S3—43' in the table to subsection S3—2(2), in alphabetical order. This table sets out the relevant provisions where specifications for the listed substances are set out in Schedule 3.

Subitem [2.2] inserts the actual specification for sweet osmanthus ear glycolipids in Schedule 3.

Item [3] amends Schedule 8 by inserting 'sweet osmanthus ear glycolipids' into each of the following tables to section S8—2:

- the table to section S8—2 entitled 'Food additive names—alphabetical listing' (alphabetically) (see subitem [3.1]); and
- the table to section S8—2 entitled 'Food additive names—numerical listing' (above the entry for 'Sodium hydrosulphite') (see subitem [3.2]).

No INS number is prescribed as there is no current INS number for sweet osmanthus ear glycolipids.

The effect of this amendment is that, for the purposes of subsection 1.2.4—7(1) of the Code, 'Sweet osmanthus ear glycolipids' must be listed in the statement of ingredients for a food in which sweet osmanthus ear glycolipids is used as a food additive.

Item [4] amends the table to section S15–5 by inserting 'sweet osmanthus ear glycolipids' and specified maximum permitted levels into the table for the following categories of beverages:

- subitem [4.1] - 100 mg/kg for Fruit and vegetable juices and fruit and vegetable juice products;
- subitem [4.2] - 50 mg/kg for Water based flavoured drinks;
- subitem [4.3] - 20 mg/kg for Formulated Beverages;
- subitem [4.4] - 10 mg/kg for Coffee, coffee substitutes, tea, herbal infusions and similar products;
- subitem [4.5] - 100 mg/kg for beer where the alcohol has been removed.

The effect of this amendment is to permit, for the purposes of Standard 1.3.1, the use of sweet osmanthus ear glycolipids as a food additive in those categories of beverages at the specified maximum permitted levels.