

18 December 2018
[69-18]

Approval report – Application A1161

Potassium polyaspartate as a Food Additive

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Enartis Pacific Pty Ltd. to permit potassium polyaspartate as a food additive (stabiliser) in wine at a maximum permitted level of 100 mg/L.

On 13 September 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 5 submissions.

FSANZ approved the draft variation on 5 December 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 17 December 2018.

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 Food technology, hazard and dietary exposure assessment report

Executive summary

FSANZ has assessed an application from Enartis Pacific Pty Ltd. to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of potassium polyaspartate as a food additive in wine at a maximum permitted level of 100 mg/L. Potassium polyaspartate is a stabiliser that prevents growth of potassium bitartrate crystals.

Based on the FSANZ food technology assessment, the use of potassium polyaspartate 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 stabiliser.

Based on the FSANZ hazard and dietary exposure assessments, there are no public health and safety concerns relating to the use of potassium polyaspartate as a food additive in wine at the proposed levels.

Potassium polyaspartate has an accepted specification in a secondary source recognised by section S3—3(j) of the Code. There is no international Codex standard for wine, nor permission in the Codex general standard for food additives for potassium polyaspartate in wine. The European Union (EU) permits potassium polyaspartate for use as a stabiliser against tartrate crystallisation in wine at levels of no more than 100 mg/L (European Commission, 2017).

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

FSANZ has therefore approved a draft variation to permit the use of potassium polyaspartate as a food additive in wine, sparkling wine and fortified wine at a maximum permitted level of 100 mg/L.

1 Introduction

1.1 The applicant

Enartis Pacific Pty. Ltd. is part of the international Esseco Group S.r.l. (Italy) which develops, produces and sells food ingredients, food additives and processing aids for the wine industry. They also provide research, analytical and consulting services for the wine industry.

1.2 The application

The purpose of the application is to amend the Code to permit potassium polyaspartate as a food additive, with the technological purpose as a stabiliser in wine, at a maximum permitted level of 100 mg/L. Potassium polyaspartate prevents the growth of potassium bitartrate crystals.

Potassium bitartrate crystals, also known as “wine diamonds” can develop during storage. The presence of these crystals in the base of a wine bottle or around the cork is unacceptable in terms of wine quality. They can appear ‘glass like’ which affects the aesthetics and consumer acceptability of the wine. Physical and/or chemical processes can be used to remove the tartrate crystals.

Potassium polyaspartate is the potassium salt of polyaspartic acid. Potassium polyaspartate is superior to other permitted food additives used as stabilisers in wine. It has no negative effects on the sensory properties of wine.

1.3 The current Code requirements

Potassium polyaspartate is not currently permitted to be added to wine as a food additive. Australia and New Zealand food laws require that food for sale must comply with the Code requirements.

1.3.1 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 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 stabiliser is a permitted technological purpose.

Schedule 15 lists the specific food additive permissions for different classes of food products. Item 14.2.2 in the table to section S15—5 lists the permitted food additives for wine, sparkling wine and fortified wine. It also sets a maximum permitted level for each. Wine, sparkling wine and fortified wine meet the definition of ‘wine’ as defined in section 1.1.2—3.

Schedule 8 lists food additive names and code numbers for labelling purposes.

1.3.2 Labelling requirements

Paragraph 1.2.4—2(3)(b) of Standard 1.2.4 provides that a statement of ingredients is not required for a standardised alcoholic beverage.

1.3.3 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. Section S3—3 of Schedule 3 provides a list of specifications contained in secondary sources. These secondary sources include the resolutions of the International Organisation of Vine and Wine (OIV) – see paragraph S3—3(j). There is an OIV resolution for potassium polyaspartate; namely, OIV resolution OIV-OENO 572-2017 Monograph for potassium polyaspartate (OIV, 2017a). This means that if potassium polyaspartate is permitted, a new specification is not needed.

1.3.4 Australian production requirements

Wine manufactured in Australia must also comply with the requirements of Standard 4.5.1 – Wine Production Requirements, which is an Australia-only Standard. Only those food additives listed in the Table to clause 3 of Standard 4.5.1 are permitted to be used in the manufacture or production of wine in Australia. Those substances may be used subject to any limit imposed by clause 5 of Standard 4.5.1.

1.4 International requirements

There is no international Codex standard for wine, nor permission in the Codex general standard for food additives for potassium polyaspartate in wine. At the Codex Committee for Food Additives (CCFA), 50th session in 2018, potassium polyaspartate as a stabiliser in wine at a maximum permitted use level of 100 mg/L was added to the list of priority substances for evaluation by JECFA (Codex, 2018a).

Also at CCFA's 50th session, Class names and the international numbering system for food additives, CXG 36-1989 was updated and now includes the international numbering system (INS) for potassium polyaspartate as INS no. 456 (Codex, 2018b).

The EU permits potassium polyaspartate as a stabiliser against tartrate crystallisation in wine at levels of no more than 100 mg/L (European Commission, 2017). The EU requirement also references the OIV's International Code of Oenological Practices, and treatment with potassium polyaspartate that does not exceed 100 mg/L (OIV, 2017a and b). Although the OIV resolutions are non-regulatory, the EU requirement means that relevant OIV resolutions for potassium polyaspartate must be met.

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 FSANZ Act;
- 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.

1.7 Decision

The draft variation as proposed following assessment was approved with a minor change after consideration of submissions. This was inclusion of the international numbering system (INS) number for potassium polyaspartate which is '456'.

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

FSANZ called for submissions on the draft variation between 13 September 2018 and 25 October 2018.

5 submissions were received, with 4 supporting the application. Those supporting the application were;

- The Victorian Department of Health and Human Services and Victorian Department of Economic Development, Jobs, Transport and Resources
- Ministry for Primary Industries – New Zealand Food Safety
- New Zealand Winegrowers
- New Zealand Food and Grocery Council

The issues raised in submissions from Ministry for Primary Industries – New Zealand Food Safety and South Australia Health and FSANZ's responses are detailed in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Given FSANZ's risk assessment conclusion of an ADI 'not specified' why is a numerical maximum permitted level (MPL) of 100 mg/L proposed.</p>	<p>Ministry for Primary Industries – New Zealand Food Safety</p>	<p>In the absence of public health and safety concerns an MPL of 100 mg/L was set to:</p> <ul style="list-style-type: none"> • enable trade of New Zealand and Australian wines as the MPL is consistent with EU requirements and OIV non-regulatory resolutions. This benefit was identified in cost benefit considerations for this application • be consistent with the MPL requested for the proposed FAO/WHO Joint Expert Committee on Food Additives (JECFA) evaluation. • be consistent with the MPL of 100 mg/L requested by the applicant and information supporting the application.
<p>FSANZ to consider working with the Codex Committee on Food Additives (CCFA) to obtain an INS food additive code number.</p>	<p>Ministry for Primary Industries – New Zealand Food Safety</p>	<p>Following FSANZ's assessment, the INS number for potassium polyaspartate became available following the CCFA's 50th session meeting in 2018. The Codex guidelines CAC/GL 36-1989, Class names and the international numbering system for food additives has been updated to include an international numbering system (INS) number for potassium polyaspartate which is '456'. This will be included in the proposed draft variation.</p>
<p>The main premise for the limited toxicological assessment of potassium polyaspartate in application A1161 is because "Such studies are not considered to be necessary based on the in vitro findings indicating that gastrointestinal digestion and absorption of potassium polyaspartate is likely to be minimal".</p>	<p>South Australia Health</p>	<p>The toxicological database indicated that gastrointestinal degradation and absorption of potassium polyaspartate is likely to be minimal. Potassium polyaspartate was not genotoxic in vitro, and no adverse effects were observed in 14-day and 90-day repeated dose oral toxicity studies in rats at doses up to 1000 mg/kg bw/day, the highest dose tested.</p>

Alcohol use disorders are common in Australia. There is evidence in the literature that chronic alcohol abuse may lead to reduced gut integrity in affected individuals. It may be appropriate for FSANZ to be certain that intestinal absorption of potassium polyaspartate remains negligible in the presence of the positive control (ethanol) – which is the context in which the food will be made available to the community.

South Australia Health.

FSANZ concluded that additional studies on the chronic toxicity/carcinogenicity studies and reproductive/developmental toxicity of potassium polyaspartate were not required based on a weight of evidence approach taking into account that:

- minimal proteolytic digestion of potassium polyaspartate was observed *in vitro*, and an *in vitro* study found no evidence of absorption across a human intestinal cell monolayer
- potassium polyaspartate was not genotoxic
- there was no evidence from subchronic studies of lesions that could lead to neoplasia through non-genotoxic mechanisms, and
- there was no evidence of adverse effects on reproductive tissues or the oestrus cycle in the 90-day toxicity study.

In addition, the digestion product of potassium polyaspartate is aspartic acid, a macronutrient and normal component of protein. Even if it is assumed that all (100%) of potassium polyaspartate is converted into aspartic acid and absorbed, the dietary intake of aspartic acid from the use of potassium polyaspartate will be negligible compared to the intake in the normal diet and does not represent a safety concern.

The NOAEL in the 90-day repeated dose oral toxicity study in rats (1000 mg/kg bw/day) is more than 1200-fold higher than the highest 90th percentile exposure to potassium polyaspartate in the dietary exposure assessment (0.79 mg/kg bw/day) and provides a significant margin of safety for potassium polyaspartate according to its proposed uses. This exposure level is associated with the consumption of nearly a bottle of wine per day.

While the submitter has identified concerns that alcohol use disorders are common in Australia and that chronic alcohol abuse may lead to reduced gut integrity in affected

Issue	Raised by	FSANZ response (including any amendments to drafting)
		<p>individuals, they have not provided a pharmacokinetic basis for interactions between potassium polyaspartate and alcohol that may lead to significant safety concerns.</p> <p>FSANZ notes that alcohol abuse is associated with a range of other serious adverse health effects including liver damage, impaired absorption and bioavailability of nutrients, cancer of the liver and several other sites, birth defects and developmental disorders. Such injurious effects are likely to be far more significant than any theoretical safety concerns associated with ingestion of small amounts of potassium polyaspartate as a food additive in wine, such that additional studies involving co-exposure of potassium polyaspartate and alcohol does not merit further investigation as a part of this assessment.</p> <p>Many food additives are consumed by individuals who also consume alcohol, however introducing regulatory requirements to test the impact of alcohol and other dietary components on the toxicity of all food additives would not be practicable.</p> <p>FSANZ notes that the European Food Safety Authority (EFSA) reached the same conclusion on data requirements in its 2016 assessment of the Safety of potassium polyaspartate for use as a stabiliser in wine.</p>
<p>Also that given a statement of ingredients is not required for use of this food additive in wine, sparkling wine and fortified wine the assessment does not address potential allergenicity. FSANZ should confirm there is no allergenicity concerns.</p>	<p>South Australia Health.</p>	<p>No reports of allergy to potassium polyaspartate or sodium polyaspartate have been identified in the published scientific literature. Potassium polyaspartate was also found not to induce an immune response in a human monocytic cell line <i>in vitro</i>. Potassium hydroxide is not considered to be a food allergen, nor is aspartic acid. Based on the available evidence, potassium polyaspartate is unlikely to pose an allergenicity concern.</p>

2.2 Risk assessment

2.2.1 Food technology assessment conclusions

Potassium polyaspartate, in the amount and form proposed, is more effective than other food additives in preventing the growth of potassium bitartrate crystals.

It is suitable for its proposed use in wine, sparkling wine and fortified wine. Stability studies show it is stable for up to 12 months in wine.

The Code currently sets an identity and purity specification for potassium polyaspartate, which is an internationally accepted specification (refer to section 1.3.3).

2.2.2 Hazard and dietary exposure assessment conclusions

The submitted data, and information from other sources, were considered adequate to define the hazard of potassium polyaspartate.

Results of *in vitro* studies indicate that gastrointestinal degradation and absorption of potassium polyaspartate is likely to be minimal. Potassium polyaspartate was not genotoxic *in vitro*, and no adverse effects were observed in 14-day and 90-day repeated dose oral toxicity studies in rats at doses up to 1000 mg/kg bw/day, the highest dose tested.

A dietary exposure assessment was conducted for Australian and New Zealand population groups based on the proposed draft variation. The estimated mean and 90th percentile dietary exposures range from 0.031 mg/kg bw/day to 0.35 mg/kg bw/day and from 0.072 mg/kg bw/day to 0.79 mg/kg bw/day respectively across the population groups assessed.

The no observed adverse effect level (NOAEL) in the 90-day repeated dose oral toxicity study in rats (1000 mg/kg bw/day) is more than 1200-fold higher than the highest 90th percentile exposure to potassium polyaspartate in the dietary exposure assessment.

Based on the reviewed data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate for potassium polyaspartate.

There are no public health and safety concerns from the use of potassium polyaspartate as a food additive in wine at the proposed maximum permitted level of 100 mg/L.

2.3 Risk management decision

Based on the food technology, hazard and dietary exposure assessments, its use is technologically justified and there are no public health and safety concerns with using potassium polyaspartate as a food additive in the manner proposed in the application.

Based on the risk assessment, the decision was made to approve a draft variation to the Code. The draft variation proposed following assessment was approved with a minor change after considering submissions. This was inclusion of the international numbering system (INS) number for potassium polyaspartate which is '456'.

Permitting potassium polyaspartate as a food additive in wine at a maximum permitted level of 100 mg/L will require amending item 14.2.2 in the table to section S15—5 of Schedule 15 and of clauses 3 and 5 of Standard 4.5.1. A consequential amendment is required to section S8—2 to include potassium polyaspartate, INS 456. The approved draft variation will make these amendments.

2.3.1 Labelling

Standardised alcoholic beverages are generally not required to have a statement of ingredients (as per paragraph 1.2.4—2(3)(b) of Standard 1.2.4). Therefore, like most other food additives when used in standardised alcoholic beverages, the requirement to provide a statement of ingredients will not apply when potassium polyaspartate is used in wine, sparkling wine and fortified wine.

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 are 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.

2.4.2 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 is no Codex or equivalent international standard for potassium polyaspartate as a food additive in wine and amending the Code to allow permission is unlikely to have a significant effect on international trade. Potassium polyaspartate has been included on the list of priority substances for evaluation by JECFA at a maximum use level of 100 mg/L (Codex, 2018a). The EU already permits its use at the same maximum permitted level requested by the applicant (100 mg/L), so it would enable Australia to meet EU trade agreement obligations and also not competitively disadvantage Australia and Australian winemakers, and also New Zealand winemakers in meeting EU requirements. Its use in winemaking would also be voluntary. 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

2.5.1 Section 29

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 successfully 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 (see 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 approving the draft variation as opposed to maintaining the status quo by rejecting the draft variation. This analysis considers permitting potassium polyaspartate as a food additive. 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 potassium polyaspartate as a food additive.

Costs and benefits of permitting potassium polyaspartate as a food additive

Potassium polyaspartate, as a food additive, stabilises wine by preventing the growth of potassium bitartrate crystals. Although the presence of the crystals in wine does not pose a health risk, their presence affects the aesthetics and consumer acceptability of the wine. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists. Industry will benefit from having additional choice available to them. The additive may be a superior production method compared to costly physical processes like cold stabilisation and other permitted food additives.

The food additive is permitted in wine by the EU which may be a trade opportunity for Australia and New Zealand wine industries, although there may also be competing imports from these countries into the domestic market.

Benefits to consumers include wine with improved sensory quality attributes. There may be downward price pressure on wine as costs for physical processes like cold stabilisation are not needed.

Permitting potassium polyaspartate 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's assessment is that the direct and indirect benefits that would arise from permitting potassium polyaspartate as a food additive in wine 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 standards in question apply in both Australia and New Zealand (with the exception of Standard 4.5.1). 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 has completed a hazard and dietary exposure assessment (SD1) which is summarised in section 2.2.2. Based on the hazard and dietary exposure assessments, there are no public health and safety concerns from the use of potassium polyaspartate as a food additive in wine at the proposed levels.

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

As discussed in section 2.3.1, the existing labelling provisions for food additives will apply consistent with those for wine and other standardised alcoholic beverages.

2.5.2.3 The prevention of misleading or deceptive conduct

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

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, hazard and dietary exposure assessments (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant scientific 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**

The EU permits potassium polyaspartate at levels of no more than 100 mg/L (European Commission, 2017). There is no international Codex standard for wine or permission in the Codex general standard for food additives for potassium polyaspartate in wine. At the 50th session of CCFA, potassium polyaspartate as a stabiliser in wine at a maximum use level of 100 mg/L was added to the list of priority substances for evaluation by JECFA (Codex, 2018).

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

Permitting this food additive gives the applicant and winemakers the opportunity to improve wine quality and provides cost and time efficiencies (refer to section 2.6.1)

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

FSANZ did not identify any relevant issues relating to this consideration.

- **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](#)¹ 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 potassium polyaspartate as a food additive (stabiliser) in wine is consistent with the Ministerial Policy Guideline and the specific order principles for 'Technological Function' as a food additive.

3 References

Codex Alimentarius Commission, Codex committee on food additives 50th session. (2018a). [Agenda item 7, Proposals for additions and changes to the priority list of substances proposed for evaluation by JECFA](#). Accessed 30 July 2018.

Codex Alimentarius Commission. (2018b). [Class names and the international numbering system for food additives CXG 36-1989](#), Adopted in 1989. Revised in 2008, Amended in 2018. Accessed on 1 November 2018.

European Commission (2017). Official Journal of the European Union. Commission Delegated Regulation (EU) 2017/1961 of 2 August 2017 amending [Regulation \(EC\) No 606/2009 as regards certain oenological practices](#). Accessed 29 Jun 18.

International Organisation of Vine and Wine (OIV) (2017a). International Code of Oenological Practices. [Resolution OIV-OENO 572-2017. Monograph on potassium polyaspartate](#). Accessed 27 Jun 18.

International Organisation of Vine and Wine (OIV) (2017b). International Code of Oenological Practices. [Resolution OIV-OENO 543-2016. Treatment with potassium polyaspartate in wine](#). Accessed 27 Jun 18.

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)*

¹ <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 A1161 – Potassium polyaspartate as a Food Additive) 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 the variation.

Dated [To be completed by Delegate]

[Insert Delegate's details]

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 the above notice.

1 Name

This instrument is the *Food Standards (Application A1161 – Potassium polyaspartate as a Food Additive) 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] Standard 4.5.1 is varied by

[1.1] inserting in the table to clause 3, in alphabetical order

Potassium polyaspartate

[1.2] omitting paragraph 5(5)(h), substituting

(h) 200 mg/L of added dimethyl dicarbonate; and

(i) 100 mg/L of potassium polyaspartate.

[2] Schedule 8 is varied by

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

Potassium polyaspartate 456

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

456 Potassium polyaspartate

[3] Schedule 15 is varied by inserting in item 14.2.2 of the table to section S15—5, in numerical order

456 Potassium polyaspartate 100

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.

FSANZ accepted application A1161 which seeks to permit the use of potassium polyaspartate as a food additive - stabiliser in wine. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared 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 sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has prepared a draft variation to the Code to permit potassium polyaspartate as a food additive – stabiliser in wine at a maximum permitted level of 100 mg/L.

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 A1161 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 13 September 2018 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 15 and Standard 4.5.1 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

Item [1.1]

Item [1.1] of the draft variation amends Standard 4.5.1 by inserting a reference to 'Potassium polyaspartate' into the table to clause 3 in alphabetical order. The effect of this amendment will be to permit the use of this substance in the production of wine, sparkling wine and fortified wine in Australia.

Item [1.2]

Item [1.2] of the draft variation amends subclause 5(5) of Standard 4.5.1 by adding paragraph(i). The new paragraph sets a maximum permitted level for potassium polyaspartate of 100 mg/L. The effect of this amendment will be to impose a requirement that wine, sparkling wine and fortified wine produced in Australia must contain no more than 100 mg/L of potassium polyaspartate.

Item [2.1]

Item [2.1] of the draft variation amends the alphabetical listing in the table to section S8—2 by inserting the food additive name 'Potassium polyaspartate' and code number '456' into that listing in alphabetical order.

Item [2.2]

Item [2.2] of the draft variation amends the numerical listing in the table to section S8—2 by inserting the food additive code number '456 and name 'Potassium polyaspartate' into that listing in numerical order.

Item [3]

Item [3] of the draft variation amends item 14.2.2 of the table to section S15—5. Item 14.2.2 relates to wine, sparkling wine and fortified wine. The amendment inserts into item 14.2.2 an entry for potassium polyaspartate (INS number 456), with a maximum permitted level of 100 mg/L. The effect of this amendment will be to permit, for the purposes of Standard 1.3.1, that substance's use as a food additive in that category of food products subject to that maximum permitted level.

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



Food Standards (Application A1161– Potassium polyaspartate as a food additive) 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 Delegate's details
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 A1161 – Potassium polyaspartate as a food additive) 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] Standard 4.5.1 is varied by

[1.1] inserting in the table to clause 3, in alphabetical order

Potassium polyaspartate

[1.2] omitting paragraph 5(5)(h), substituting

- (h) 200 mg/L of added dimethyl dicarbonate; and
- (i) 100 mg/L of potassium polyaspartate.

[2] Schedule 8 is varied by

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

Potassium polyaspartate –

[2.2] omitting the following from the table to section S8—2 entitled ‘Food additive names—numerical listing’,

– Sodium hydrosulphite

substituting

– Potassium polyaspartate

– Sodium hydrosulphite

[3] Schedule 15 is varied by omitting from item 14.2.2 in the table to section S15—5,

150a	Caramel I – plain	GMP
substituting		
	Potassium polyaspartate	100
150a	Caramel I – plain	GMP