APPLICATION A1048
CO-EXTRUDED POLYSTYRENE & PVPP AS A PROCESSING AID
EXPLANATORY STATEMENT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application from BASF on 3 June 2010. This Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new processing aid which is a co-extrudate of polystyrene and polyvinyl polypyrrolidone (PVPP) (the resin).

The resin (trade name Crosspure®) removes particulates including microorganisms, and haze material (polyphenols and polyphenol-protein complexes) from beverages. It is intended to be used primarily in beer manufacture as an alternative treatment to replace the filtration step, usually performed by diatomaceous earth, and the adsorption step, usually performed by permitted processing aids such as PVPP. The request is to assess the resin as a clarifying, filtration and adsorbent agent to improve clarity and stability of the treated beverage.

Prior to any approval being granted for a processing aid a pre-market assessment of its safety, as well as an assessment ofits technological function, is required.Processing aids used in food manufacture are regulated under Standard 1.3.3. The co-extrusion of polystyrene (70%) and PVPP (30%) to produce the resin does not result in any chemical cross-linking, that is, does not create a new polymer. Various cross-linked polystyrene- and styrene-based resins and PVPP are already permitted processing aids under Standard 1.3.3.

The resin itself has not been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, JECFA has assessed PVPP and has written a specification for it (Monograph 1 2006). Food Chemicals Codex (FCC) has also assessed and written a specification for PVPP. Specifications for polystyrene are included in the Code of Federal Regulations of the United States of America (§177.1640).

The Applicationwas assessed under the General Procedure.

Risk and Technical Assessment

Evidence presented in support of the Application provided adequate assurance that the resin is technologically justified and has been demonstrated to be effective in achieving its stated purpose. As the resin is not a novel polymer, and specifications for the individual constituents (polystyrene and PVPP) already exist, no amendment to the specifications is considered necessary.

The hazard assessment considered the chemistry and impurity profile of the resin, unpublished data on the acute toxicity and genotoxicity of the resin, and the migration of residual monomers into beverages. Results indicate that there is likely to be no migration of monomers from the resin and negligible carry-over of the resin in treated beverages. The history of safe use of polystyrene and PVPP was also taken into consideration. In the absence of any dietary hazard posed by the resin and the very limited potential for its migration into beverages, the resin is considered to pose a negligible risk to public health and safety.

The overall conclusion of this risk and technical assessment is that the use of co-extruded polystyrene and PVPP as a processing aid is technologically justified and raises no public health and safety issues.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the*Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether there are any other measures that would be more cost-effective than variations to Standard 1.3.3 and Standard 4.5.1 that could achieve the same end

- any relevant New Zealand standards

- any other relevant matters

Decision

To approve the draft variation to the Table to clause 6 of Standard 1.3.3 – Processing Aids, to permit the use of the resin co-extruded polystyrene andpolyvinyl polypyrrolidone, as a clarifying, filtration and adsorbent agent and draft variations to Standard 1.3.3and to clause 5 of Standard 4.5.1 – Wine Production Requirementsto replace the maximum permitted level for PVPP with GMP for consistency.

Reasons for Decision

An amendment to the Code approving the use of the resin as a processing aid in Australia and New Zealand is approved on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the resin does not raise any public health and safety concerns.

- Use of the resin to remove particulates including microorganisms and haze material (polyphenols and polyphenol-protein complexes), from beverages is technologically justified and would be expected to provide benefits to food manufacturers as an alternative to current treatments.

- Permitting use of the resin would not impose significant costs for government agencies, consumers or manufacturers.

- The amended draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

Consultation

Public submissions were invited on the Assessment Report between 5 November and 17 December 2010. Comments were specifically requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of the resin. A total of five submissions were received as a result of the public consultation. A summary of these is included at **Attachment 2**to this Report.

As this Application was assessed as a General Procedure, there was one round of public comment following the preparation of an Assessment Report. Responses to the Assessment Report were used to develop this Approval Report, with the main issues raised in submissions specifically discussed.

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1048coex4892.cfm

SD Risk and Technical Assessment Report

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from BASF on 3 June 2010. This Application sought to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include a new processing aid, which is an extrudate from polystyrene and polyvinyl polypyrrolidone (PVPP) (the resin).

1. The Issue / Problem

The Applicant proposes the use of the resin in beverages and liquid foods, particularly beer. The resin is proposed to be used as a filtration, clarification and adsorbent agent to clarify and improve the stability of the treated beverage, as an alternative to current treatments.

A pre-market assessment and approval is required before any new processing aid is permitted. A safety assessment of the resin, as well as an assessment of the technological suitability of the resin for its purported use, must be undertaken and considered before any permission may be granted.

2. Current Standard

2.1 Background

Processing aids used in food manufacture are regulated under Standard 1.3.3.

A processing aid is described in clause 1 of Standard 1.3.3 as:

> *A substance listed in clauses 3 to 18, where –*
>
> *(a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and*
> *(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.*

The Table to clause 6 contains a list of permitted decolourants, clarifying, filtration and adsorbent agents. The resin is not a currently permitted processing aid, although various cross-linked polystyrene- and styrene-based resins and PVPP are permitted as processing aids.However, while various cross-linked polystyrene- and styrene-based resins are currently permitted processing aids, polystyrene itself is not permitted as a processing aid.

2.2 International Regulations

To date, the resin itself has not been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). However, PVPP has been assessed under the synonym insoluble polyvinylpyrrolidone by JECFA (Monograph 1 2006). Food Chemicals Codex (FCC) has also assessed PVPP, although this monograph was renamed crospovidone as of February 2010. Specifications for polystyrene exist in the US Code of Federal Regulations (§177.1640).

The resin is approved for use in France, Russia and the US. Specific regulatory approval is not required in the European Union, China, India, the Philippines or South Africa and therefore the resin may be used in these jurisdictions.

2.3 Nature of the Resin

The resinis manufactured through the co-extrusion of polystyrene (70%) and PVPP (30%). This process does not create a new polymer, i.e. there is no chemical cross-linking of PVPP and polystyrene. The granules produced are further processed to obtain two different grades of the resin, being Crosspure® F and Crosspure® XF, each of different average particle diameters.

2.4 Technological Purpose

The resin is intended to be used primarily in beer manufacture to replace both the filtration step, usually performed by diatomaceous earth, as well as the stabilisation step, usually performed by permitted processing aids such as PVPP. The resin physically filters particulates including some microorganisms (yeasts and bacteria) comparable to the filtration performed by diatomaceous earth. The resin also stabilises the treated beverage by adsorbing precursor substances (polyphenols and polyphenol-protein complexes) that are known to form haze and particulates in the aged beverage. The resin is therefore able to be used as a single-step alternative to these two steps. Although the primary use for the resin is envisaged to be in beer manufacture, it is expected that it would also function to remove particulates and haze material from other beverages.

3. Objectives

The objective of the Assessment was to determine whether it is appropriate to amend Standard 1.3.3 to permit the use of the resin co-extruded polystyrene and PVPP as a processing aid.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

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

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

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

The Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals*includespolicy principles in regard to substances added to achieve a solely technological function such as food additives and processing aids. According to these guidelines, permissions 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.

The main objective which applies to this Application is the protection of public health and safety. This objective has been met through the completion of a Risk and Technical Assessment Report, which concluded that the use of co-extruded polystyrene and PVPP as a processing aid raises no public health and safety issues.In addition, the Risk and Technical Assessment Report addressed the technological justification of the use of the processing aid, in accordance with the Ministerial Council Policy Guideline: *Addition to Food of Substances other than Vitamins and Minerals.*

4. Questions to be answered

For this Application, FSANZ has considered the following key questions to address the objectives described in section 3:

- Does the resin product present any food safety issues?

- Does the resin achieve its stated technological purpose?

RISK ASSESSMENT

A detailed assessment of the safety and function of the resin has been undertaken for this Application. The summary and conclusions from this risk assessment are presented below. The full risk assessment is contained in the Supporting Document – the Risk and Technical Assessment Report.

In addition to information supplied by the Applicant, other available resource material, including published scientific literature and general technical information, was used in this assessment.

5. Risk and Technical Assessment Summary

5.1 Summary

The resin is a new filtration and absorbent agent proposed for use to remove particulates and haze material from beverages such as beer. Various cross-linked polystyrene- and styrene-based resins and PVPP are already permitted food processing aids in Australia and New Zealand.

Evidence presented in support of the Application provided adequate assurance that the resin is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

As the resin is not a novel polymer, and specifications for the individual constituents (polystyrene and PVPP) already exist, no amendment to the specifications is considered necessary.

The hazard assessment considered the chemistry and impurity profile of the resin, unpublished data on the acute toxicity and genotoxicity of the resin, and the migration of residual monomers into beverages. Results indicate that migration of monomers from the resin is unlikely to occur and there would be negligible carry-over of the resin in treated beverages. The history of safe use of polystyrene and PVPP was also taken into consideration. In the absence of any dietary hazard posed by the resin and the very limited potential for its migration into beverages, the resin is considered to pose a negligible risk to public health and safety.

5.2 Conclusions

The overall conclusion of this risk and technical assessment is that the use of co-extruded polystyrene and PVPP as a processing aid is technologically justified and raises no public health and safety issues.

Risk Management

6. Options

Processing aids require pre-market approval under Standard 1.3.3, therefore it is not appropriate to consider non-regulatory options in this case. Two regulatory options have consequently been identified:

Option 1: Reject the Applicationthus maintaining the *status quo*.

Option 2: To approvedraft variations to Standard 1.3.3 to permit the use of the resin as a processing aid.

7. Impact Analysis (RIS ID: 11840)

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts. The level of analysis is commensurate to the nature of the application and significance of the impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will seek further advice from the Office of Best Practice Regulation (OBPR) and estimate compliance costs of regulatory options.

FSANZ has conducted, with OBPR subsequently approving, a preliminary assessment of this Application(RIS ID 11840). This assessment concluded that there were no business compliance costs involved and/or minimal impact and consequently a Regulation Impact Statement (RIS) is not required.

7.1 Affected Parties

The affected parties to this Application include:

- those sectors of the food industry wishing to produce and market food products produced usingthe resinas a processing aid
- consumers of food products produced usingthe resin as a processing aid
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

7.2 Benefit Cost Analysis

7.2.1 Option 1: Reject the Application

This option is the *status quo*, with no changes to the Code.

Rejecting the Application would disadvantage relevant food industries where the resin could provide an alternative to currently available treatments.

7.2.2 Option 2: To approve draft variations to Standards 1.3.3to permit the use of the resin as a processing aid

This option will provide potential benefits to food manufacturers by making available a single-step alternative to current two-step treatments. No added costs to consumers are expected. The use of the resinas a processing aid is technologically justified and raises no public health and safety issues.

As a processing aid, the use of the resin will not need to be labelled; therefore significant compliance costs for government enforcement agencies in testing for the presence of the resin in the final food are not expected. In addition, there is likely to be no migration of monomers from the resin and negligible carry-over of the resin in treated beverages.

7.3 Comparison of Options

Given that the approval of this Application imposes no financial burden on any sector of the community, and given that the use of this resin raises no public health and safety issues, Option 2 is the preferred option.

7.4 Other Risk Management Matters

In the Table to clause 6 in Standard 1.3.3, which regulates the use of permitted decolourants, clarifying, filtration and adsorbent agents, no restriction is applied on the foods in which these products may be used. PVPP is currently permitted in this Table, and its use is therefore currently not restricted to beer or beverages. However, the maximum permitted level for PVPP is 100 mg/kg in foods. In the Risk and Technical Assessment Report, the analysis of the migration of the resin and residual monomers of the resin into treated beverages identified no public health and safety concerns. It is therefore deemed that setting a maximum permitted level for co-extruded polystyrene and PVPP is not necessary. It is appropriate to apply a good manufacturing practice (GMP) limit to this processing aid, as has been applied to other permitted decolourants, clarifying, filtration and adsorbent agents.

Based on the risk and technical assessment for this Application, it is also appropriate to amend the maximum permitted level for PVPP to GMP. This will prevent an inconsistency in the permitted levels between PVPP used in isolation and PVPP co-extruded with polystyrene, as noted in a submission to the Assessment Report (see section 9.2.2).

Communication and Consultation Strategy

8. Communication

FSANZ has applied a basic communication strategy to this Application.The strategy involvednotifying subscribers and any interested parties of the availability of the Assessment Report for public commentand placing the Report on the FSANZ website.

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options.
The issues raised in the public submissions are evaluated and addressed in FSANZ ApprovalReports.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If the FSANZ Board approves the amended draft variations to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code, if approved by the Ministerial Council, in the national press and on the FSANZ website.

9. Consultation

9.1 Public Consultation

The Assessment Report was notified for public comment between 5 November 2010 and 17 December 2010. Comments were specifically requested on the scientific aspects of the Application including the technological function and any safety considerations, as well as information relating to any potential costs or benefits associated with use of the resin as a processing aid.As this Application was assessed under a General Procedure, there was only one round of public comment.

Five submissions were received during the public consultation period. A summary of these is provided in **Attachment 2**.

All submitters (three government agencies and two professional organisations) supported the Application. One government agency noted inconsistencies and possible enforcement issues that the proposed drafting would cause.

FSANZhas taken these comments into account in preparing the Approval Report forthis Application.

9.2 Issues raised in submissions

9.2.1 Permission for polystyrene versus the co-extruded resin as a processing aid

South Australia Health noted that polystyrene is considered safe for use as a processing aid internationally, and that as PVPP is a currently permitted processing aid in the Code, permitting polystyrene as a processing aid would,in effect,permitthe use of the co-extruded resin as a processing aid.

This would also prevent the need for future separate permissions for other combinations of polystyrene and permitted processing aids. South Australia Health further stated that permitting the co-extruded resin rather than polystyrene could hinder innovation within the food industry and restrict trade.

9.2.1.1 Response

The current Application requests that the co-extruded resin be permitted as a processing aid, and the data provided in support of this Application relate specifically to the safety and technological function of this resin. FSANZ therefore needs to assess the technological function and safety of the resin rather than polystyrene itself. Although FSANZ notes the rationale provided by the submitter for their suggestion, a separate Application or Proposal, with appropriate supporting data, would be required to permit the use of polystyrene as a processing aid in Australia and New Zealand.

9.2.2 Inconsistency and possible enforcement issues which will arise from the proposed drafting

South Australia Health noted that permitting the co-extruded resin to be used according to GMP whilst PVPP when used alone is currently permitted to be used to a maximum permitted level of 100mg/kg will create an inconsistency and possible enforcement issues.

9.2.2.1 Response

FSANZ notes and supports the suggestion made by South Australia Health to replace the maximum permitted level for PVPP with GMP. Replacement of the maximum permitted level for PVPP with GMP is consistent with the outcomes of the risk and technical assessment of the Application for the co-extruded resin. Therefore, subsequent drafting changes to Standard 1.3.3 have been included in this Approval Report to permit PVPP to be used according to GMP. Consequential drafting changes to Standard 4.5.1 have also been included, as suggested by South Australia Health.

9.2.3 Errors in Risk and Technical Assessment Report

South Australia Health noted that there was an error in the CAS numbers in the Risk and Technical Assessment Report, and that the wording regarding current permissions for polystyrene was misleading as it suggested that polystyrene was an approved processing aid.

9.2.3.1 Response

The CAS numbers and incorrect wording have been corrected in the Risk and Technical Assessment Report. The wording has been corrected to state that while various cross-linked polystyrene- and styrene-based resins are permitted processing aids, polystyrene itself is not a permitted processing aid.

9.2.4 Request for advice on analytical methods

Queensland Health requested advice on whether other Australian laboratories currently have the capability to measure residual amounts of either polystyrene or PVPP, singly or in combination, in beverages.

9.2.4.1 Response

PVPP is currently permitted as a processing aid, and polystyrene is a component of permitted processing aids, therefore residues of these substances could already be present in foods. FSANZ is not aware of the capabilities of Australian laboratories to measure these residues.

9.2.5 Request for FSANZ to make enquiries on methodological details

Queensland Health requested that FSANZ make enquiries regarding the details of the study of the migration of the resin into aqueous simulants, which was performed in accordance with European Standard EN 1186-3.

9.2.5.1 Response

FSANZ considers that the level of reporting detail contained in the analytical report within the Application was adequate, particularly as the test method complied with a current European standard for the analysis of migration of food contact materials. A weblink to the relevant European legislation describing the test method is provided in the Risk and Technical Assessment Report. If any details important for the risk assessment were not provided in an Application, FSANZ would seek to establish these details independently or via contact with the Applicant, but this was not the case for this Application.

9.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to allow the resin as a permitted processing aid is unlikely to have a significant effect on international trade as the component polymer PVPP complies with relevant international specifications written by JECFA and FCC, and the component polymer polystyrene complies with relevant standards such as the US Code of Federal Regulations.

Notification to WTO under Australia and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements was not considered necessary.

Conclusion

10. Conclusion and Decision

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the amended draft variations to Standards 1.3.3 and 4.5.1.

The Approval Report concludes that use of the resinas a processing aid is technologically justified and does not pose a public health and safety risk, when used in beer and other beverages.

An amendment to the Code giving permission for the use of the resin as a processing aid in Australia and New Zealand is recommended on the basis of the available scientific information.

The Approved amended draft variations are provided at**Attachment 1A.**

Decision

To approve the draft variation to the Table to clause 6 of Standard 1.3.3 – Processing Aids, to permit the use of the resin co-extruded polystyrene andpolyvinyl polypyrrolidone, as a clarifying, filtration and adsorbent agentand draft variations to Standard 1.3.3 and to clause 5 of Standard 4.5.1 – Wine Production Requirements to replace the maximum permitted level for PVPP with GMP for consistency.

10.1 Reasons for Decision

An amendment to the Code approving the use of the resin as a processing aid in Australia and New Zealand is approved on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that the use of the resin does not raise any public health and safety concerns.
- Use of the resin to remove particulates including microorganisms, and haze material (polyphenols and polyphenol-protein complexes), from beverages is technologically justified and would be expected to provide benefits to food manufacturers as an alternative to current treatments.
- Permitting use of the resin would not impose significant costs for government agencies, consumers or manufacturers.
- The amended draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

11. Implementation and Review

If the amended draft variations are approved, the FSANZ Board's decision will then be notified to the Ministerial Council. If no review of the Board's decision is requested by the Ministerial Council, the amended draft variations to the Code are expected to come into effect on gazettal.

ATTACHMENTS

1A. Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)
1B. Draft variation to the *Australia New Zealand Food Standards Code* (at Assessment)
2. Summary of Public Submissions on the Assessment Report

Attachment 1A

Draft variations to the *Australia New Zealand Food Standards Code* (at Approval)

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from the* Table to clause 6 –

Polyvinyl polypyrrolidone	100

substituting –

Polyvinyl polypyrrolidone	GMP

[1.2] *inserting in the* Table to clause 6–

Co-extruded polystyrene and polyvinyl polypyrrolidone	GMP

[2] ***Standard 4.5.1*** *of the Australia New Zealand Food Standards Code is varied by omitting subclause 5(5), substituting –*

(5) Wine, sparkling wine and fortified wine must contain no more than –

(a) 250 mg/L in total of sulphur dioxide in the case of products containing less than 35 g/L of sugars, or 300 mg/L in total of sulphur dioxide in the case of other products; and
(b) 200 mg/L of sorbic acid or potassium sorbate expressed as sorbic acid; and
(c) 1 g/L of soluble chlorides expressed as sodium chloride; and
(d) 2 g/L of soluble sulphates expressed as potassium sulphate; and
(e) 400 mg/L of soluble phosphates expressed as phosphorus; and
(f) 1.5 g/L of volatile acidity excluding sulphur dioxide, expressed as acetic acid; and
(g) 0.1 mg/L of cyanides and complex cyanides expressed as hydrocyanic acid; and
(h) 200 mg/L of addeddimethyl dicarbonate.

Attachment 1B

Draft variation to the *Australia New Zealand Food Standards Code* (at Assessment)

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

To commence: on gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 6 –

Co-extruded polystyrene and polyvinyl polypyrrolidone	GMP

Attachment 2

Summary of Public Submissions on the Assessment Report

Five submissions were received during the public consultation period in response to the Assessment Report.

All submitters (three government agencies and two professional organisations) supported the Application. One government agency noted inconsistencies and possible enforcement issues that the proposed drafting would cause.

A summary of all submissions received is provided in Table 1 below.

Table 1: Summary of Submissions

Submitter	Group	Comments
Brewers Association of Australia & New Zealand	Professional Organisation	Supports the preferred approach identified by FSANZ.
Food Technology Association of Australia	Professional Organisation	Supports Agreed with Option 2, to prepare a draft variation to Standard 1.3.3 to permit the use of the resin,as a processing aid."
New Zealand Food Safety Authority	Government	Supports. Notes proposed use and international approvals. Satisfied the proposed use is technologically justified and that no public health and safety concerns were identified.
Food Policy and Programs Branch, South Australia Health	Government	Supports option 2 – to prepare a draft variation however: Notes that polystyrene is considered safe for use as a processing aid internationally, and that a permission for polystyrene would provide a permission for the co-extruded resin. Providing a permission for the co-extruded resin rather than polystyrene could hinder innovation within the food industry and restrict trade. Unclear why JECFA, FCC and USFDA have not assessed the resin – may be because they considered assessing the combination of the two processing aids redundant. Notes inconsistency and possible enforcement issues caused by setting a GMP limit for the co-extruded resin whilst PVPP alone has a limit of 100mg/kg. Permission for use of PVPP in wine standard may also need to be amended to GMP for consistency. Notes some errors in Assessment Report which may be misleading.

Submitter	Group	Comments
Queensland Health	Government	Supports option 2 – to prepare a draft variation to Standard 1.3.3. Acknowledges that a safety assessment has concluded that the use of the resin does not raise any public health and safety concerns, as it is just a physical combination of two polymers already approved as processing aids, apparently all but minor amounts are removed from treated foods, and toxicology studies are favourable. Notes that use of the resin is technologically justified, and use of the resin expected to provide benefits to food manufacturers and consumers. Requests advice as to whether another Australian laboratory has capability to measure residual amounts of either polystyrene or PVPP, singly or in combination, in beverages. Notes analytical techniques referred to in Risk and Technical Assessment Report are for assay of the monomers for purity and trace monomers in treated beverages. Requests FSANZ make enquires to establish details of test method of migration of the resin into aqueous simulants.