

5 November 2010

[22-10]

## **APPLICATION A1048 CO-EXTRUDED POLYSTYRENE & PVPP AS A PROCESSING AID ASSESSMENT REPORT**

---

### **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 an extrudate from polystyrene and polyvinyl pyrrolidone (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 of its 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 styrene-based resins, cross-linked polystyrene, 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 Application is being 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 beverage. 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 a variation to Standard 1.3.3 that could achieve the same end.
- any relevant New Zealand standards
- any other relevant matters

### **Preferred Approach**

**To prepare a 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 and polyvinyl pyrrolidone, as a clarifying, filtration and adsorbent agent.**

## **Reasons for Preferred Approach**

- An amendment to the Code approving the use of the resin as a processing aid in Australia and New Zealand is proposed 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 and consumers.
- 
- Permitting use of the resin would not impose significant costs for government agencies, consumers or manufacturers.
- 
- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.
- 
- There are no relevant New Zealand standards.

## Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, including the technological function and any information relevant to the safety assessment of the resin to be used as a processing aid.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be used to develop the Approval Report for this Application.

## Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 17 December 2010**

**SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED**

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the Application process can be directed to the Standards Management Officer at [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand  
PO Box 7186  
Canberra BC ACT 2610  
AUSTRALIA  
Tel (02) 6271 2222**

**Food Standards Australia New Zealand  
PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Tel (04) 978 5636**

# CONTENTS

|   |           |
|---|-----------|
| <b>INTRODUCTION.....</b>  | <b>9</b>  |
| 1. THE ISSUE / PROBLEM .....  | 9         |
| 2. CURRENT STANDARD.....  | 9         |
| 2.1 Background.....   | 9         |
| 2.2 International Regulations.....                                    | 10        |
| 2.3 Nature of the Resin.....  | 10        |
| 2.4 Technological Purpose.....  | 11        |
| 3. OBJECTIVES.....  | 11        |
| 4. QUESTIONS TO BE ANSWERED.....                                      | 13        |
| <b>RISK ASSESSMENT.....</b>   | <b>13</b> |
| 5. RISK AND TECHNICAL ASSESSMENT SUMMARY.....                         | 14        |
| 5.1 Summary.....  | 14        |
| 5.2 Conclusions.....  | 15        |
| <b>RISK MANAGEMENT.....</b>   | <b>15</b> |
| 6. OPTIONS .....  | 15        |
| 7. IMPACT ANALYSIS (RIS ID: 11840).....                               | 15        |
| 7.1 Affected Parties.....   | 16        |
| 7.2 Benefit Cost Analysis.....  | 16        |
| 7.3 Comparison of Options.....  | 17        |
| 7.4 Other Risk Management Matters.....                                | 17        |
| <b>COMMUNICATION AND CONSULTATION STRATEGY.....</b>                   | <b>17</b> |
| 8. COMMUNICATION.....   | 17        |
| 9. CONSULTATION.....  | 17        |
| 9.1 World Trade Organization (WTO).....                               | 18        |
| <b>CONCLUSION.....</b>  | <b>19</b> |
| 10. CONCLUSION AND PREFERRED OPTION.....                              | 19        |
| 10.1 Reasons for Preferred Approach .....                             | 19        |
| 11. IMPLEMENTATION AND REVIEW.....                                    | 21        |
| ATTACHMENT 1.....   | 22        |
| DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE..... | 22        |

## **SUPPORTING DOCUMENT**

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

SD1 Risk and Technical Assessment Report

## **Introduction**

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 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 styrene-based resins, cross-linked polystyrene, and PVPP are permitted as processing aids.

#### **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 resin is 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 this Assessment is 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* includes policy 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; and
- no nutrition, health or related claims are to be made in regard to the substance.

#### **4. Questions to be answered**

For this Application, FSANZ has considered the following key questions:

- 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. Cross-linked polystyrene, various 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 beverage. 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.

## 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 Application thus maintaining the *status quo*.

**Option 2:** To prepare a draft variation 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 using the resin as a processing aid
- consumers of food products utilising the resin as a processing aid
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations.

#### 7.2 Benefit Cost Analysis

OBPR has deemed that a cost benefit analysis for this Application is not required.

### **7.3 Comparison of Options**

Given that the acceptance 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, which regulates the use of permitted decolourants, clarifying and filtration 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 even only beverages. However, the maximum permitted level for PVPP is 100 mg/kg in foods. In the risk and technical assessment, 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.

## **Communication and Consultation Strategy**

### **8. Communication**

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the assessment report for public comment and placing the report on the FSANZ website.

The process by which FSANZ considers standard 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 approval reports.

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 draft variation 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**

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to 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.

#### **9.1 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 standards 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 is not considered necessary.

## **Conclusion**

### **10. Conclusion and Preferred Option**

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variation to Standard 1.3.3.

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

Therefore the preferred option, based on the available scientific information, is to prepare a draft variation to the Code giving permission for the use of the resin as a processing aid in Australia and New Zealand.

The proposed draft variation is provided in **Attachment 1**.

#### **Preferred Approach**

**To prepare a 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 and polyvinyl polypyrrolidone, as a clarifying, filtration and adsorbent agent.**

#### **10.1 Reasons for Preferred Approach**

- An amendment to the Code approving the use of the resin as a processing aid in Australia and New Zealand is proposed 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 and consumers.
  - Permitting use of the resin would not impose significant costs for government agencies, consumers or manufacturers.
  - The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

## **11. Implementation and Review**

Following the consultation period for this document, an Approval Report will be completed and the draft variation will be considered for approval by the FSANZ Board. If the draft variation is 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 proposed draft variation to the Code is expected to come into effect on gazettal.

### **ATTACHMENT**

1. Draft variation to the *Australia New Zealand Food Standards Code*

## Attachment 1

### Draft variation to the *Australia New Zealand Food Standards Code*

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

**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 |
|---|-----|