APPLICATION TO AMEND THE AUSTRALIA AND NEW ZEALAND FOOD STANDARDS CODE FOR THE INCLUSION OF MOLECULARLY-IMPRINTED ADSORBENT RESINS (MOLECULARLY-IMPRINTED POLYMERS OR MIPS), AS A PROCESSING AID FOR WINE

Contents

EXECUTIVE SUMMARY

This application seeks to amend the Australia and New Zealand Food Standards Code for the inclusion of molecularly-imprinted adsorbent resins (molecularly-imprinted polymers or MIPs), as a processing aid for wine. It seeks to amend Standard 4.5.1 – Wine production requirements (Australia only), to remove a restriction in that Standard.

Molecularly-imprinted polymers are a type of cross-linked polyester resin. Polyester resins, cross-linked, as a broad category, are currently approved under Standard 1.3.3-5. They are listed in Schedule 18-3 as a processing aid permitted for use in food for certain purposes, such technological purposes being as decolourant, clarifying, filtration and/or adsorbent agents. They are therefore a permitted processing aid in food in both Australia and New Zealand (Clause 3 of Standard 1.3.3). They are also therefore a permitted processing aid for wine produced in New Zealand and wine produced in other countries and sold in Australia (subject to the production laws of such countries permitting same).

Standard 4.5.1 does not identify particular uses for permitted processing aids for the production of wine in Australia, but it is anticipated that molecularly-imprinted polymers would be used as an adsorbent agent. This would allow them to be used in the same manner, and for the same technological purposes in Australian wine, for which they are currently permitted by FSANZ as polyester resins, cross-linked, in the production of New Zealand wine, other imported wines, and in the production of food generally.

The applicant, amaea Limited, is a commercial producer of a cross-linked polyester resin product which is molecularly imprinted to provide precise and selective adsorption of specific molecules from fluids. The applicant currently markets this product to wine producers in the United States, Canada and New Zealand. Similarly to approval under Standard 1.3.3 of the Australia New Zealand Food Standards Code, polyester resins, cross-linked, are also permitted for use in the United States (by way of section 21 CFR §177.2420 of the United States Federal Food, Drug and Cosmetic Act) and molecularly-imprinted polymers are specifically approved for use in wine production in the United States by the TTB.

The applicant's product is a molecularly-imprinted polymer intended to be used for repeated use in the removal of target molecules such as off-flavours and aromas from beverages including wine. It is particularly beneficial in targeting molecules associated with smoke taint from exposure of grapes to bushfires.

The applicant's product may be washed of target molecules removed from wine and reused in a repeated and sustainable manner.

The processing aid is insoluble and macroscopic and losses of a molecularly imprinted polymer into wine are prevented using standard filtration techniques already commonly used for wine production in Australia. In the case of the applicant's product, molecularly-imprinted polymers are applied within a packed column, and wine is treated by passing it through the column. The molecularly-imprinted polymers remain packed within the column, and standard filters are used at column outlets to mitigate the risk of them ever remaining in the treated wine.

The applicant submits that there is no safety or dietary risk associated with the use of molecularly-imprinted polymers in the production of wine in Australia, which would not already be present in the permitted use under FSANZ of the broader category of polyester resins, cross-linked, including molecularly-imprinted polymers, as a processing aid for the production of wines in New Zealand and other countries.

GENERAL REQUIREMENTS

B. APPLICANT DETAILS

amaea Limited
NZBN: 9429051405915

Contact Person:

[redacted]

Address:

[redacted]

Nature of applicant's business:
www.amaea.com

amaea is a molecular filtration solutions provider located in New Zealand. amaea's core technology is molecularly imprinted polymers (MIPs), which are crosslinked polyester resins that are designed to selectively adsorb and remove specific molecules or groups of molecules from fluids.

amaea's technology has the potential to be used to: 1) remediate unwanted flavour and/or aroma compounds; or 2) balance flavour profiles.

amaea's current focus is on developing a portfolio of molecular filtration solutions targeted to current wine quality and wine production challenges, including:

- products targeted to event-based wine quality challenges such as smoke impact and Brettanomyces impact;
- regenerable alternatives to single-use fining agents, for balancing bitterness and improving wine sensory profile;
- alternatives to existing high-impact winemaking practices, for example heat stabilisation and cold stabilisation of wine, which are energy-intensive and have an undesirable environmental impact.

Its polyester resins are designed to help wine producers tailor the sensory profile of their products, using a more sustainable, low-impact production solution.

amaea's first product to market in the United States and Canada is amaea VPx, a molecularly imprinted cross-linked polyester resin for smoke impact remediation of wine. Due to the effects of climate change, wildfires are increasingly prevalent in many major winemaking geographies. Smoke damage to grapes caused by these wildfires results in wine with a distinct smoky flavour and aroma, which is often not saleable. amaea VPx is designed to selectively remove the volatile phenol molecules that are responsible for smoke characteristics. Its application significantly reduces the sensory impact of smoke, without undesirably affecting the positive flavour/aroma profile and quality of the wine; thus restoring smoke impacted wines to saleable quality. amaea VPx is in use in North America with over 1 million L of smoke impacted wine treated in the first 6 months of commercial use.

C. PURPOSE OF THE APPLICATION

The intention of this application is to allow molecularly-imprinted polymers as a processing aid for wine, *via* amendment of Standard 4.5.1. The proposed variation partially removes a restriction imposed by Standard 4.5.1, by allowing a substance to be used as a processing aid for production of wine in Australia, which is from a category of substances already approved for production of wine in New Zealand and elsewhere.

Molecularly-imprinted polymers are a type of cross-linked polyester resin. Polyester resins, cross-linked, as a broad category, are currently approved under Standard 1.3.3-5 and listed in Schedule 18-3 as a processing aid permitted for use in food for certain purposes, such technological purposes being as decolourant, clarifying, filtration and/or adsorbent agents. Schedule 18-3 permits the use of polyester resins, cross-linked, at levels of good manufacturing practice, which limits the amount of the substance that is added to food to the lowest possible level necessary to accomplish its desired effect.

Polyester resins, cross-linked are already therefore a permitted processing aid for use in the production of food in both Australia and New Zealand (Clause 3 of Standard 1.3.3). They are also therefore a permitted processing aid for the production of wine in New Zealand and the production of wine produced in other countries and sold in Australia. The application is related to a proposed change within Standard 4.5.1 – Wine production requirements (Australia only), for the inclusion therein of molecularly-imprinted polymers, a type of polyester resin, cross-linked, and is to address the information requirements for Section 3.1 (General Requirements) and Sub section 3.3.2 (Processing Aids) in the Application Handbook. This application proposes the same usage levels for molecularly-imprinted polymers for use in wine produced in Australia, under Standard 4.5.1, as currently set forth in Schedule 18-3 for polyester resins, cross-linked, that of good manufacturing practice.

D. JUSTIFICATION FOR THE APPLICATION

(a) Need for the Proposed Change.

This proposal provides an opportunity to enable Australian wine producers to access the latest resin technology, giving them access to the same type of technology as food producers and other wine producers selling wine in Australia.

(b) Advantages of the Proposed Change Over the Status Quo

Current resins permitted as processing aids for the production of wine by Standard 4.5.1, including ion exchange resins, do not have the selective adsorbent benefits of molecularly imprinted polymers.

The polymerisation of molecularly imprinted polymers in the presence of a template molecule enables a producer to remove undesired molecules with accuracy and selectivity. In the case of the applicant's product, the polymerisation of molecularly imprinted polymers is carried out in the presence of a template molecule that is analogous to the molecular shape, size and structure of the compound(s) that are intended to be adsorbed by that molecularly imprinted polymer. This approach enables molecularly imprinted polymers to capture target molecules with a high degree of accuracy and selectivity.

Scale applications of the applicant's molecularly imprinted polymers on wine damaged by smoke in the United States and Canada have shown successful remediation, while retaining the quality, fruit character and body of the wine, using both analytical and sensory assessment of the treated wines.

The proposed change offers a much more selective filtration process to wine producers in Australia, which in turn has the potential to maximise the quality of their wine.

Molecularly-imprinted polymers may be targeted for repeated use in the removal of molecules such as off flavours or aromas, including but not limited to phenolic compounds.

As an example of use, when the applicant's molecularly imprinted polymers are used in processing, juice or wine is passed through a column containing the polymer (typically after fermentation, but the polymer can also be used to process juice and wine at other points during the wine making process). The molecularly-imprinted polymer captures the target molecules in the wine/juice until it is saturated with the target molecule. At that point, the polymer can be flushed to remove the target compound, and is then ready to process more wine/juice. This process can be repeated, such that the molecularly imprinted polymers can process high volumes of wine/juice over their useful life.

The ability for repeat use of a molecularly-imprinted polymer offers a number of advantages over the status quo, including: displacement of single-use additives, minimised waste generation from additive use, and reduced labour requirement during wine production.

See below evidence that the industry generally or other specific companies have an interest in, or support, the proposed change:

- The applicant recently agreed and commenced, a project with Wine Australia that focuses on go-to-market for smoke remediation.
- The applicant was a collaborator on an Australian Cooperative Research Centres Project (CRC-P) on smoke remediation, spanning from about 2021-2023, where it supplied its resin for use in smoke remediation trials (see e.g. *Amelioration of Smoke Taint in Wine via Addition of Molecularly Imprinted Polymers during or after Fermentation*, Wilkinson & Ors, J. Agric. Food Chem. 2024, 72, 32, 18121–18131 (Attachment A), *Adsorption properties of molecularly imprinted polymers designed for removal of smoke taint compounds from wine*, Huo & Ors, Food Research International, Volume 206, 2025, 116048, ISSN 0963-9969 (Attachment B)).
- The applicant recently agreed a licence with VAF Memstar to use its molecularly imprinted polymers if and when this application is approved.
- The Wine Industry Technical Advisory Committee of Australian Grape & Wine recently indicated its general support for this application, noting that the technological application and potential industry benefit that may be derived from such a product, in support of mitigating impacts of smoke impacted wines, are an area of ongoing industry priority.

(c) Status of Similar Application made in other Countries

<u>United States:</u>
In the United States, under 21 CFR §177.2420 (annexed in full in Attachment C, as at the date of this application), regulated by the FDA, crosslinked polyester resins may be used repeatedly for applications in food in accordance with three basic requirements: (1) the resin meets certain compositional requirements; (2) finished food-contact articles derived from the crosslinked polyester meet certain extractables limits; and (3) finished food-contact articles are cleansed prior to first use.

As an example of implementation of this regulation, the applicant sought pre-notification consultation in connection with its own polymer from the FDA in 2022. On 3/01/2023, the applicant received formal confirmation from the FDA's Centre for Food Safety and Applied Nutrition that it had 'no objection to the use of [the applicant's] MIP in the treatment of wine', based on compliance with 21 CFR §177.2420 (Attachment D).

The applicant obtained a preliminary conclusion from the TTB, on 28/02/24, permitting the use of such polymers generally as a wine and juice treating material and process. The TTB holds the authority to approve such processes under 27 CFR §24.250 (Title 27 – Alcohol, Tobacco and Other Excise Taxes, Part 24 – Wine, Section 250 – Application for use of new treating material or process). TTB maintains a

current list at its website of authorised materials and processes.[1] The applicant's application resulted in subsequent approval for: "Molecularly-imprinted adsorbent resins (molecularly-imprinted polymers or MIPs): For repeated use in the removal of target molecules such as off flavors or aromas, including but not limited to phenolic compounds associated with smoke taint/impact due to exposure from wildfire smoke." Such approval is conditioned on a requirement that: "*The molecularly imprinted adsorbent resins must comply with 21 CFR §177.2420 paragraphs a, b, and d.*" (noting that *"extractives testing under §177.2420 paragraph c is not required because MIP that achieves the intended technical effect will have a high food-contact surface to mass ratio implying the extractives specifications will be met").* A printout of this TTB webpage as at the date of this application is included at Attachment E.

D.1. REGULATORY IMPACT INFORMATION

D.1.1 Costs and benefits

In the face of worsening bushfires, and more widespread affected areas across more of the year, winemakers in Australia are increasingly being forced to manage smoke taint in their wines. In 2020, Australian Grape and Wine Incorporated estimated that bushfires and smoke taint would cost the wine industry about AU$40 million.

Exposure to smoke can result in wines with undesirable sensory characters, and consumers have been shown to respond negatively to smoke tainted wines.[2] Offering an additional solution to winemakers, molecularly-imprinted polymers can be used repeatedly in the treatment of undesirable smoke characters as well as other phenolic concerns. The use of molecularly-imprinted polymers is a low cost, sustainable way of dealing with problem molecules through highly selective adsorption, with minimal impact on the fruit character and body of treated wines.

Commercial treatments using the applicant's product in the United States and Canada have demonstrated high success rates in returning smoke impacted wines to their intended price category, therefore maximising value recovery from damaged wine.

The use of molecularly-imprinted polymers as a processing aid will be entirely voluntary. Individual wineries will consider the benefits in wine quality, wine value recovery, sustainability, process efficiencies, and waste decrease against the additional cost of these polymers in comparison to alternative treatments for the relevant technological purposes. It is consistent with the increasing consumer expectations of achieving more sustainable industry practices.

There will be no increased regulatory or enforcement costs for the government.

D.1.2 Impact on International Trade

There will be no impact on imported wines, including New Zealand-produced wines, as polyester resins, cross-linked, are already permitted as a processing aid in general for food (under Standard 1.3.3)(see part 3.1.3), and molecularly-imprinted polymers are a type of cross-linked polyester resin.

[1] https://www.ttb.gov/regulated-commodities/beverage-alcohol/wine/treating-materials

[2] See e.g. AWRI Fact Sheet – Case study: consumer acceptance of smoke-affected wines (https://www.awri.com.au/wp-content/uploads/2020/04/Consumer-acceptance-of-smoke-affected-wines.pdf); *Consumer response to wine made from smoke-affected grapes*, Bilogrevic & Ors, Vol. 57 No. 2 (2023): OENO One, 16 June 2023 (https://oeno-one.eu/article/view/7261)

E. INFORMATION TO SUPPORT THE APPLICATION

A. Technical Information on the Processing Aid

A.1 Information on the type of processing aid

More broadly, polyester resins, cross-linked, are designed to be technologically used as decolourants, clarifying, filtration and adsorbent agents. They are permitted for these uses in food by Standard 1.3.3, via Schedule 18-3, at levels consistent with GMP. Their use in wine production is permitted in New Zealand under the Food Standards Code already. The use of molecularly-imprinted polymers can act as a decolourant, but operates more particularly as a physical process, for adsorbent and nanofiltration purposes.

A.2 Information on the identity of the processing aid

Polyester resins, cross-linked, are the result of the condensation of one or more acids with one or more alcohols or epoxides, followed by copolymerisation with one or more crosslinking agents. There is no common chemical name for polyester resins or molecularly-imprinted polymers, as they can be produced from a range of base elements. The structure inherently depends on the acids and alcohols or epoxides used to produce it. The nature of the processing aid is such that it can be produced using different formulas.

The inclusion of polyester resins, cross-linked as a processing aid in Schedule 18-3 provides little information on the permitted structure of the permitted polyester resins and permitted cross-linking. It is instructional to view the detail in the definition of polyester resins, cross-linked, for use in the United States in food, in 21 CFR §177.2420 (which is included in full in Attachment C – it is our understanding that this regulation was once referenced directly in the Food Standards Code[3]). For the purposes of this application, the applicant submits that the definition within the CFR can be used to address and limit the relevant identity of polyester resins, cross-linked.

Molecularly-imprinted polymers are crossed-linked polyester polymer beads that have been synthesised using a molecular imprinting technique that creates cavities in the polymer matrix with a binding affinity for chosen "template" molecules, such as phenolic smoke taint molecules.

A.3 Information on the chemical and physical properties of the processing aid

Physical and chemical properties:
Polyester resins, cross-linked, are produced by the condensation reaction of one or more acids and one or more alcohols, followed by copolymerisation with one or more cross-linking agents. The United States CFR, in Attachment C, sets out permitted acids, alcohol and agents for the purposes of such production.

A molecularly imprinted polymer, such as the applicant's, is a highly cross-linked polyester resin bead, manufactured to a physical size of 0.3-3 mm; the molecularly imprinted polymer has high porosity and high surface area, which contribute to its functionality as an adsorbent material.

A molecularly imprinted polymer is chemically inert in the matrix they are designed for use in, with high mechanical strength and stability over a wide pH (pH of 2-8) and temperature range (0-50 degrees Celsius). The chemical and physical properties of the processing aid enable it to be used repeatedly in wine, in particular, as an adsorbent agent to capture and remove target molecules.

[3] See e.g. NSW Regulation 1991 – No. 116 – *Food Act 1989*, adopting amendments to the National Food Standards Code set out in Schedule 1 to the Food Standards Code (Adoption) Regulation 1989, such amendments inserting polyester resins cross linked, and citing CFR Title 21 Part 177.2420.

Potential for migration of the resin or substances used to manufacture the resin:
A molecularly imprinted polymer such as the applicant's is thoroughly cleansed following manufacture and prior to first use in contact with food. The molecularly imprinted polymer by necessity meets the extractives limits set out in 21 CFR §177.2420 (c), which require that the extractives do not exceed 0.1 mg/in^2 of food contact surface when extracted with solvent(s) characterising the type of food the material will be in contact with.

It has been independently determined that the applicant's molecularly imprinted polymer meets the extractives limitations as a result of the high surface area-to-mass ratio of the finished polymer particles, which has been experimentally calculated to be 307.2 m^2/g. Specifically, if it is assumed that the applicant's molecularly imprinted polymer completely dissolves when extracted for end testing, it is calculated that the end test requirement of 21 CFR §177.2420 (c) will be met as follows:

$$1 \text{ g resin} / 307.2 \text{ m}^2 \times 1 \text{ m}^2 / 1550 \text{ in}^2 = 2.1 \times 10^{-6} \text{ g/in}^2 \text{ (or } 0.002 \text{ mg/in}^2\text{)}$$

It should be noted that this worst-case assumption materially exaggerates the actual extractives since the applicant's molecularly imprinted polymer is highly stable and does not dissolve during use (as evidenced in the following section) but it serves to demonstrate that the total extractives will be well below the 0.1 mg/in^2 limit. As a result of both the thorough cleansing of the applicant's molecularly imprinted polymer following manufacture and adherence to the extractives limits by way of the high surface area-to-mass ratio, the polymer will not migrate substances that exceed limits that are safe for human consumption.

Also, as noted above, this position has been independently reviewed by the US FDA's Centre for Food Safety and Applied Nutrition, which has confirmed in writing that the applicant's resin complies with 21 CFR §177.2420, including the extractives limits set out in (c), and that it has no objection to the use of molecularly imprinted polymers such as the applicant's resin in wine in the United States. It has also been validated by the US TTB, who have included a confirmatory statement on their website to this effect to accompany the approval for molecularly imprinted adsorbent resins (as referenced in section D (c) above).

Further to the above, molecularly imprinted polymers are insoluble and macroscopic, and losses of the polymers into wine are prevented by straightforward and efficient filtration techniques already commonly used in wine production (see further detail in A.6 below). In the case of the applicant's product, the molecularly imprinted polymers are applied commercially in adsorption columns. The polymer is retained in the columns by specially designed wedge wire flow distribution nozzles/screens. This type of equipment set up is typical of adsorbents such as ion exchange regularly used in food and beverage processing. Molecularly imprinted polymer use is eminently suitable for targeted use by wine producers whilst having minimal if any impact on the core characteristics of the producer's wine.

Stability of the resin in wine:
As noted above, a molecularly imprinted polymer has high mechanical strength and high stability over a wide pH (pH of 2-8) and temperature range (0-50 degrees Celsius). Together these properties mitigate the risk of physical breakdown and/or degradation of molecularly imprinted polyester resins in wine. As defined and limited by the United States definition in 21 CFR §177.420 (in Attachment C), the resin must meet extractives limits in the course of food contact.

To evidence this for its own product, the applicant has completed extended stability testing by storing its resin at a pH 2.8 (noting that the pH of wine can range from 2.8-3.8, so pH 2.8 represents the more acidic end of this range) for a period of 2 years (see Attachment F). The results of this testing confirmed that there is no change to the physical form of the resin and adsorption efficiency is maintained at the same level as the control resin.

Regeneration and efficiency of the resin:
The applicant's molecularly imprinted polymer is regenerated by way of an elution process, which involves passing a food grade solvent over the polymers – this process releases the target compounds that were adsorbed by the molecularly imprinted polymer through a change in polarity and regenerates the polymer for repeat use to adsorb the given target compounds from wine. Provided that standard operating processes for regeneration are followed, there is no loss in adsorption efficacy over the useful life of the molecularly imprinted polymer.

A.4 Manufacturing process

Cross-linked polyester resins, including molecularly-imprinted polymers, are produced by the condensation of one or more acids with one or more alcohols or epoxides, followed by copolymerisation with one or more crosslinking agents. The full standard manufacturing process for these resins is set out within the scope of 21 CFR §177.2420 (referred to above and set out in Attachment C). The specific manufacturing process for molecularly imprinted polymers involves selecting reactants from a) (1), (2) and (3) of 21 CFR §177.2420 and polymerising in the presence of a template molecule that is analogous to the molecular shape, size and structure of the compound(s) that are intended to be adsorbed by the resin – this process produces a molecularly imprinted cross-linked polyester resin. The template molecule is removed from the manufactured resin, which then undergoes a number of cleaning and drying steps, as required by 21 CFR §177.2420 (d), to prepare it for use as a food contact material. The process does not involve or result in carry-over of allergens, or pose any food safety issues in the production of wine not already identified in the assessment and inclusion of polyester resins, cross-linked, in Standard 1.3.3-5, Schedule 18-3.

By way of the molecular imprints that are formed during the manufacturing process, the applicant's molecularly imprinted polymer is selective for phenolic compounds. When put into contact with smoke-impacted wine, the molecularly imprinted polymer selectively binds free phenol molecules (including syringol, guaiacol and cresol compounds) that are responsible for smoke flavour and aroma. In practice, this is done by packing the molecularly imprinted polymers into stainless steel columns – the smoke-impacted wine passes through the column, which facilitates capture and removal of the smoke marker compounds, after which the wine passes out of the column having been remediated of smoke damage.

A.5 Specification for identity and purity

Polyester resins, cross-linked, including molecularly imprinted polymers, may present different specifications for identity and purity, given the different combination of acids, alcohols, and cross-linking agents which may be used to produce them. In the case of the applicant's product, as an example, safety data and technical data sheets are annexed in Attachment G.

A.6 Analytical method for detection

Molecularly imprinted polymers are not likely to be present in the final food, as losses of the resin into wine are prevented using standard filtration techniques. As noted in A.4, in the case of the applicant's molecularly imprinted polymer , the polymer is packed into stainless steel columns, through which wine is pumped. To prevent losses of the polymer into wine, the applicant specifies the use of 1 micron filters at the outlet of each column that is used to treat wine. Given that the particle size of the molecularly imprinted polymer is 0.3-3 mm (as described in A.3 above), a 1 micron (0.001 mm) filter is effective in preventing migration of the polymer into wine. Note that as part of the standard commercial manufacturing process for the applicant's molecularly imprinted polymer, a combination of 0.3 mm sieve and a continuous washing process are used to ensure consistency of polymer particle sizes to greater than 0.3 mm.

The vast majority of wine produced in Australia is filtered for the removal of microorganisms, via a range of standard filtration techniques other than the type of column filtration described above. A methodical description of available techniques is produced by the Australian Wine Research Institute and made available at its website.[4] A broad selection of these techniques are capable of filtering out molecularly-imprinted polymers.

Given the physical methods used to prevent losses of the polymer into wine, an analytical method is not provided here.

B. Information related to the safety of the processing aid

Polyester resins, cross-linked, are already deemed safe under FSANZ for the production of wine in New Zealand, and for the production of wine from other countries which is sold in Australia. It is the applicant's submission that there is no additional safety consideration needed for the extension of that permission to the production of wine in Australia, through the granting of this application. Polyester resins, cross-linked, including molecularly-imprinted polymers, have also long been recognised as safe for use in repeated contact with food in the United States, through such inclusion in 21 CFR §1772420.

B.1 General information on the industrial use of the chemical

Molecularly-imprinted polymers are also commercially available for sorbent extraction for analytical scale sample preparation and cleanup. An example of a producer making such products is Affinisep.[5]

B.2 General information on the use of the chemical as a food processing aid in other countries

Please see section J below on International and Other Standards. The applicant, as noted above, markets its molecularly-imprinted polymers in the United States, Canada and New Zealand currently, and has a range of wine-producing customers using its product in such countries.

B.3 Data on the toxicokinetics and metabolism of the chemical processing aid and, if necessary, its major metabolites

B.4 Information on the toxicity of the chemical processing aid and, if necessary, its major metabolites

Polyester resins, cross-linked, including molecularly-imprinted polymers, are already a permitted processing aid for use in food in Australia and New Zealand and use in wines produced other than in Australia. It is the applicant's submission that there are no potential negative toxicokinetic, metabolic, or toxic impacts in the production of wine in Australia which would not already be present in permitted use under the Food Standards Code.

The processing aid is further insoluble and macroscopic and is designed to be substantively removed from wine through filtration processes. To the extent that negligible residues of the processing aid may remain in wine, in use of a molecularly-imprinted polymer meeting the requirements of 21 CFR §177.2420, no negative impact pertaining to toxicokinetics, metabolism and toxicity of the chemical processing aid are expected.

B.5 Safety assessment reports prepared by international agencies or other national government agencies, if available

As set forth extensively in this application, polyester resins, cross-linked, which category includes molecularly-imprinted polymers, have been assessed in the United States of America as safe for use as

[4] See e.g. https://www.awri.com.au/industry_support/winemaking_resources/storage-and-packaging/pre-packaging-preparation/filtration-physical-removal-of-microorganisms/

[5] https://www.affinisep.com/products/ready-to-use-kits-spe-and-mips/

articles or components of articles for repeated use in contact with food, subject to the conditions set out in 21 CFR §177.2420 (in Attachment C).

Molecularly-imprinted polymers have specifically been assessed by the TTB as safely permitted for use in the production of wine (see D (c) above and Attachment C).

F. Information related to the dietary exposure to the processing aid.

F.1 A list of foods or food groups likely to contain the processing aid or its metabolites.

Molecularly-imprinted polymers are proposed to be used as a processing aid for wine, in particular, Australian produced wine (as they may already be used in production of New Zealand wine and other imported wines sold in Australia).

F.2 The levels of residues of the processing aid or its metabolites for each food group.

The losses of molecularly-imprinted polymers as a processing aid into wine are substantively prevented by standard wine filtration processes (see A.6 above).

The applicant's molecularly-imprinted polymers is administered within a column that is packed with the resin; wine is in contact with the polymer by passing it through the column, whereby contact with the polymer enables capture of the target molecules and molecular filtration of the wine. As noted in section E A.6 above, specifically sized filters at the outlet of the column allow the treated wine to exit the column and prevent the molecularly imprinted polymers from being retained in the treated wine.

It is not anticipated that there would be any more than negligible residue of the processing aid remaining in Australian produced wine, and no level of residue of the processing aid in Australian produced wine any different to that which might be found in New Zealand produced wine using the processing aid under the Food Standards Code as it currently stands.

F.3 For food or food groups not currently listed in the most recent Australian or New Zealand national Nutrition Surveys (NNSs), information on the likely consumption.

Due to filtration, the processing aid is expected to be present in the finished wine at insignificant levels and is not expected to have any technical or functional effect in the wine. In the case of the applicant's product, molecularly imprinted polymrs are applied within a packed column, and wine is treated by passing it through the column. The molecularly imprinted polymers remain packed within the column, and this mitigates the risk of them ever remaining in the wine.

A molecularly-imprinted polymer by necessity meets the extractives limitations for polyester resins, cross-linked, set out in 21 CFR §177.2420 (c), as a result of the high surface area-to-mass ratio of the finished molecularly imprinted polymer particles. This further evidences the position that a molecularly-imprinted polymer used as a processing aid will not be present in wine at levels that are significant for human consumption.

F.4 The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid.

The use of molecularly-imprinted polymers in the production of wine in Australia is difficult to predict. The applicant anticipates that its products may be used as a sustainable, long-term alternative for smoke taint treatment by producers regularly affected by such issues, or for the purposes of fining applications for wines, but this would remain an extremely small percentage of Australian wines available in the market.

F.5 Information relating to the levels of residues in foods in other countries.

There is no level of residue identified in the Food Standards Code currently for polyester resins, cross-linked as a processing aid. It is not anticipated that there would be any level of residue of molecularly-imprinted polymers as a processing aid in Australian produced wine any different to that which might be found in New Zealand produced wine using a polyester resin, cross-linked, as a processing aid under the Food Standards Code as it currently stands.

As noted in earlier sections, in the United States, polyester resins, cross-linked, including molecularly-imprinted polymers, must comply with extractives limits set out in 21 CFR §177.2420 (c). Molecularly-imprinted polymers comply with these limits.

F.6 For foods where consumption has changed in recent years, information on likely food consumption.

n/a

E.1 DATA REQUIREMENTS

The applicant has undertaken a literature search to determine if any new data is available for the use of cross-linked polyester resins in wine, which is attached at Attachment H.

F. ASSESSMENT PROCEDURE

This application seeks the appropriate assessment procedure is **General Procedure Level 1.** The application extends the use of a permitted food processing aid to Australian produced wine.

G. CONFIDENTIAL COMMERCIAL INFORMATION

No confidential or commercial information is incorporated in this application.

I. EXCLUSIVE CAPTURABLE BENEFIT.

Although the applicant would benefit from the proposed change, by being able to market its products to Australian wine producers, it is one of a number of worldwide commercial producers of molecularly-imprinted polymers, and the proposed change is broad enough to capture many different products other than the applicant's product. It is the applicant's submission that there is no exclusive capturable benefit to the applicant.

J. INTERNATIONAL AND OTHER STANDARDS

A. Codex Alimentarius Commission (Codex) Standards

Codex Alimentarius does not have specific standards for processing aids, and many countries do not regulate processing aids in the same manner as the Food Standards Code. There is no Codex Alimentarius standard for wine.

B. OIV Standards

The adsorbent agent application of molecularly-imprinted polymers as a membrane for the extraction of target molecules is addressed under OIV Standards.

The use of membranes is permitted by the Code as a physical process for:

- the treatment of musts using membrane techniques enabling the selective holding back or passing of some compounds in musts (at paragraph 2.0.1. of the International Code of Oenological Practices (the "OIV Code"), under OIV Resolution 373A of 2010, provided in Attachment I); and
- the treatment of wine using membrane techniques enabling the selective holding back or passing of some compounds in wine (at paragraph 3.0.1. of the OIV Code, under OIV Resolution 373B of 2010, provided in Attachment J).

In each case, the treatment is recognised as a permitted treatment with separative techniques, for three generally stated objectives:

a) to elaborate more balanced wine in terms of organoleptic characteristics,
b) to compensate effects of adverse weather conditions and climate change, and to resolve certain organoleptic issues,
c) to expand the techniques available for development of products more adapted to consumer expectations.

C. Other National Standards

Information in connection with the approval for use of polyester resins, cross-linked in the production of food in the United States has been extensively provided above.

In Canada, the Canadian Food and Drugs Act and the Food and Drugs regulations issued by Health Canada permit processing aids to be marketed without prior approval from HPFB based on a company making a safety determination pursuant to Section 4(1) of the Food and Drugs Act, meaning a determination that use of the processing aid does not render the food injurious to health (see more detail in Attcahment K in connection with the applicant's assessment). Health Canada also provides strong deference to the safety assessments of the United States FDA, including in this circumstance 21 CFR §177.2420. Polyester resins, cross-linked, including molecularly-imprinted polymers, are permitted on this basis.

In New Zealand, as noted in sections above, polyester resins, cross-linked, including molecularly-imprinted polymers, are approved under Standard 1.3.3-5 of the Australia New Zealand Food Standards Code, and are listed in Schedule 18-3 as a processing aid permitted for use in food for certain purposes, such technological purposes being as decolourant, clarifying, filtration and/or adsorbent agents. They are therefore a permitted processing aid for use in the production of food in both Australia and New Zealand (Clause 3 of Standard 1.3.3). They are also therefore a permitted processing aid for the production of wine in New Zealand.

In Japan, there is a positive list for permitted plastic base polymers in the *Food Sanitation Act*, which includes a listing for "cross-linking polyester" for use in food production, including, specifically, alcoholic beverage production; an extract from the ASDEAN datatabase for Japan and the relevant extract from Table 1(1) is included in Attachment L. The listing requires that a cross-linking polyester copolymer consist of one or more acids (listed under section A) and one or more alcohols (listed under section B) and/or epoxides (listed under section C), cured with cross-linking agents (listed under section D).[6]

K. STATUTORY DECLARATION

Attached (Attachment M).

J. CHECKLIST

Attached (Attachment N).

[6] *Food Sanitation Act*, Japan: Table 1 (1) in Appended table 1 of Specifications and Standards Notification; Base polymers (Plastics). Listed in the ASEAN-Japan Chemical Safety Database: https://www.ajcsd.org/chrip_search/cmpInfDsp?cid=C005-388-89A&bcPtn=5. See Japan's positive list for base polymers (plastic) at Appended Table 1 (1), listing 2- for "Cross-linking polyester" at Ministry for Health, Labour & Welfare website https://www.mhlw.go.jp/content/11130500/000872915.xlsx

Attachments

Abbreviations

AWRI	The Australian Wine Research Institute
CFR	Code of Federal Regulations
FDA	US Food & Drug Administration
GMP	Good Manufacturing Practice
MIP	Molecularly imprinted polymer
OIV	The International Organisation of Vine and Wine
TTB	US Alcohol and Tobacco Tax & Trade Bureau