

**Application to amend the Australia New Zealand  
Food Standards Code to permit 2-methyloxolane  
as a processing aid**

**Pennakem Europa  
France**

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## EXECUTIVE SUMMARY

Pennakem Europa (Pennakem) is submitting this application to Food Standards Australia New Zealand to request amendment to the Australia New Zealand Food Standards Code (the Code) to permit the use of 2-methyloxolane (2-MeOx) as a processing aid. 2-MeOx functions as an extraction solvent. Extraction solvents are used during the manufacture of foods to extract and separate components of foods, including oil and protein from oilseeds and other plant-based food sources. Extraction solvents are also used to extract other components, such as flavours, fragrances, and colours. Permitted extraction solvents are listed in section S18—8 of the Code. 2-MeOx is not listed in section S18—8 and therefore requires a pre-market assessment and approval by FSANZ before it can be used as a processing aid in Australia and New Zealand.

Pennakem has developed 2-MeOx as a safe, renewable, biomass derived extraction solvent that is produced from agricultural by-products such as corn stover, sugarcane bagasse and rice straw. If approved, 2-MeOx will provide food manufacturers with a sustainably sourced extraction solvent alternative to many of the currently permitted extraction solvents sourced from petrochemicals, including hexane, which is the predominant extraction solvent currently used worldwide.

Pennakem has established a strong evidence base to support the safe use of 2-MeOx at the levels proposed in this application, including commissioning a series of toxicity studies. The European Food Safety Authority (EFSA) has recently assessed the same data package that has been supplied in this application. EFSA concluded that the use of 2-MeOx as a processing aid is safe and established a tolerable daily intake (TDI) of 1 milligram per kilogram of body weight per day. At the time of submitting this application, the European Commission is preparing to amend the European law (Directive 2009/32/CE) to permit 2-MeOx as a processing aid (expected to be finalised early in 2023). Feedback provided to Pennakem by the European Commission, indicates the maximum permitted levels (MPLs) for 2-MeOx are proposed to be the same as the European MPLs for hexane. This strategy will enable extraction plants to transition to the use of 2-MeOx as a substitute for hexane. Existing machinery will not need significant alterations to use 2-MeOx if 2-MeOx can be used at the same level as hexane.

Pennakem is proposing a similar approach be taken to approving the use of 2-MeOx as a processing aid in foods in Australia and New Zealand. The MPL for hexane in section S18—8 is higher than the European MPLs (20 milligrams per kilogram (mg/kg) compared to 10 mg/kg<sup>1</sup>). Permitting 2-MeOx to be present in foods at an MPL of 20 mg/kg will facilitate the process of extraction plants in Australia and New Zealand transitioning to the use of 2-MeOx as a substitute for hexane. In reality, MPLs are likely to be lower than 20 mg/kg due to a variety of reasons, but particularly due to organoleptic properties of certain foods (including oil) being more favourable at lower levels of 2-MeOx; and potential use of purpose-built machinery that can use lower levels of 2-MeOx (than machinery that has typically used hexane). Pennakem has conducted a dietary exposure assessment which concludes that at an MPL of 20 mg/kg for 2-MeOx dietary exposure to 2-MeOx is still below the TDI established by EFSA. Pennakem proposes a separate, lower MPL for infant formula products and infant foods (5 mg/kg), based on both the dietary exposure for this vulnerable population group being more protective at this level and this level also being achievable for these food groups.

2-MeOx is a safe, environmentally sustainable extraction solvent that will provide benefits for industry and consumers if permitted to be used as a processing aid in Australia and New Zealand.

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<sup>1</sup> 10 mg/kg defatted protein & flour, 30 mg/kg defatted soya products, 5 mg/kg defatted cereal germs