

APPLICATION EXECUTIVE SUMMARY

December 2024

TO:

Food Standards Australia New Zealand

IN RELATION TO:

Application to amend Schedule 15 – *Substances that may be used as food additives* of the Australia New Zealand Food Standards Code

Extension of use to permit polyglycerol esters of interesterified ricinoleic acid (PGPR) (476) in sauces and toppings (including mayonnaises and salad dressings)

This Application is to amend Schedule 15 – *Substances that may be used as food additives* of the Australia New Zealand Food Standards Code (hereafter, the Code) to extend the permitted use of polyglycerol esters of interesterified ricinoleic acid (PGPR) (476) in sauces and toppings (including mayonnaises and salad dressings).

PGPR is already approved for food use within Australia and New Zealand for other food categories.

The inclusion of PGPR as a permitted emulsifier in schedule 15 -20.2.0.4 - Sauces and toppings (including mayonnaises and salad dressings) will enable these products to be formulated with reduced oil whilst maintaining a pleasant mouth feel, therefore reducing the contribution of fat to the diet, and delivering superior product characteristics.

Whilst fat is an essential component of the diet that provides energy, essential fatty acids, and fat-soluble vitamins, excessive intake of fat, especially saturated and trans fats, can increase the risk of cardiovascular diseases, diabetes, and some cancers. The WHO recommends the total fat intake of an individual should be limited to less than 30% of the total energy intake, and the intake of saturated fats should be less than 10% of the total energy intake, and trans fats less than 1%¹. The WHO also advises consumers to replace saturated and trans fats with unsaturated fats, such as those found in fish, nuts, seeds, and vegetable oils². Reducing the oil levels in products such as mayonnaise and dressings whilst keeping preferred sensory characteristics will therefore help consumers meet the WHO targets for a healthy diet.

The technological purpose of PGPR will be as an emulsifier to facilitate the formation or maintenance of an emulsion between two or more immiscible phases. The request for permission to add up 8,000 mg/kg of PGPR to emulsified sauces would allow lowering their oil content without modifying the organoleptic properties and appeal of the products.

PGPR is known to be an excellent W/O emulsifier that allows the emulsification of high amounts of water in oil and is the most effective way to achieve this outcome. The level proposed is consistent with the technological function.

The function of the emulsifier remains the same over the shelf life of the food: it is there to stabilise the emulsion over the entire shelf life and hence ensure constant food quality over the entire shelf life, without any phase separation.

The Applicant has not identified any public health and safety issues in relation to the request for the addition of PGPR to Sauces and toppings. PGPR has a long history of regulatory approval and was first evaluated in 1969. The 1973 JECFA reevaluation ([published 1974](#)) has later been expanded with newly available additional data to support the metabolic fate.

¹ [Diet, nutrition, and the prevention of chronic diseases: report of a joint WHO/FAO expert consultation, Geneva, 28 January - 1 February 2002](#)

² [Healthy diet \(who.int\)](#)

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The safety of PGPR (E476) as a food additive has been re-evaluated in 2017 by the EFSA Panel on Food Additives and Nutrient Sources added to Food ([EFSA, 2017](#)). EFSA considered a combined 2-year chronic toxicity/carcinogenicity study in rats as the critical study for determining a reference point. Based on the absence of adverse effects, a no observed adverse effect level (NOAEL) of 2500 mg/kg bw per day, the only dose tested, was identified. By applying a safety factor of 100, the acceptable daily intake (ADI) for PGPR was set at 25 mg/kg bw per day.

JECFA has been asked to re-evaluate the safety of INS 476, considering the new EFSA 2017 ADI. Consequently, INS 476 has been added to the JECFA priority, however it is not included in the JECFA 2025 work program.

The Codex Alimentarius *General Standard For Food Additives* ([Codex Stan 192-1995](#)) allows the addition of INS 476 to several food categories (FC) where it serves the technological function of an emulsifier. For FC 12.6.1 Emulsified sauces and dips, INS 476 is permitted at a maximum level of 5,000 mg/kg. An application for amending the conditions of use of INS 476 for FC 12.6.1 to allow up to 8,000 mg/kg in products with more than 20% oil content has been approved by CCFA54 and was due for endorsement by CAC47 (meeting ended 30.11.2024).

Almost all jurisdictions allow the addition of PGPR to emulsified sauces, mostly at levels of max 5,000 mg/kg, in line with Codex GSFA. However, the European Union, USA, Canada, and the United Kingdom already allow max 8,000 mg/kg.

The requested amendment is voluntary so manufacturers will be able to choose whether they take up the opportunity to provide sauces and toppings containing PGPR for their consumers.

Under existing labelling requirements in the Code (unless the food is exempt from the requirement for a statement of ingredients) PGPR will require declaration as a food additive in the statement of ingredients on the label of foods.

Consumers will be able to identify products that contain PGPR and make an informed choice to purchase these products.

To: Food Standards Australia New Zealand
In relation to extension of use to permit additive 476 (PGPR) in sauces and toppings

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