

September 3rd, 2020

Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604
Email: submissions@foodstandards.gov.au

Dear Sir/Madam

Re: A1175 – Rapeseed protein isolate as a novel food (**Application**)

Merit Functional Foods (**Merit**) refers to Food Standards Australia New Zealand's (**FSANZ**) Call for Submission dated 31 July 2020 (**Call for Submission**) and Supporting Document 1 dated 31 July 2020 (**SD1**), relating to the Application.

Merit welcomes the opportunity to comment on Application A1175 – Rapeseed protein isolate as a novel food (A1175) and supports the approval of Rapeseed protein isolate as a novel food in Australia and New Zealand.

This submission is approved by Merit Functional Foods' Board and Co-CEOs.

Merit submits that the following amendments should be made to the proposed specification:

- Increase the ash content limit to 5% (from 4% as currently proposed); and
- Increase the fat content limit to 5% (from 2% as currently proposed).

The reasons for these changes are discussed in further detail below.

INTRODUCTION

By way of background, in 2019, Merit Functional Foods Corporation was established in a joint venture with Burcon NutraScience Corporation who was a joint submitter of US FDA GRAS notice NO. GRN 000327 referenced in the Application by DSM Nutritional Asia Pacific (A1175). Merit Foods is building a state-of-the-art plant protein production facility in Manitoba, Canada, where it will produce, under licence from Burcon Nutrascience, novel pea and canola protein ingredients. Supertein®, Puratein® and Nutratein® canola proteins are currently under licence to Merit Functional Foods Corporation and marketed under the brand names, Puratein® HS,

Puratein® and Puratein®-C, respectively. Those rapeseed protein isolates were the subject of GRN 000327 (**GRN327**).

Materials used to support the GRN 000327 submission were subsequently cited in GRN 000386 (**GRN386**). The FDA issued a letter of no objection in relation to each GRN327 and GRN 386. These notices are both referred to in the Call for Submission and SD1.

ECONOMIC IMPACT OF PERMITTING RAPESEED PROTEIN ISOLATE

Merit agrees with FSANZ's conclusion in the Call for Submission that the direct and indirect benefits that would arise from permitting rapeseed protein isolate as a novel food are likely to outweigh the associated costs.

There is increasing demand globally, including in Australia, for products made with plant-based proteins. The approval of rapeseed protein isolate as a novel food would harmonise Australia's regulatory position with that in other key jurisdictions including the EU and the US.

Merit submits the scope of the approval of rapeseed protein isolate as a novel food should be adequately broad to provide flexibility to manufacturers, accommodate for variation in raw material inputs, and increase competition and innovation in the market. The approval should also ensure the interests of the public in terms of quality, health and safety are adequately guarded. Lastly, consistency with the regulatory position in other jurisdictions is important in fostering international trade.

Merit requests that FSANZ consider amendments (discussed below) to the proposed product specification for rapeseed protein isolates, specifically the Ash and Fat limits outlined in Attachment A to the Call for Submission (**Draft Variation**). Merit's proposed amendments to the Draft Variation accord with the position in other jurisdictions. The proposed amendments below are consistent with the Ministerial Council Policy Guidelines on Novel Foods, and would encourage industry growth, innovation and international trade of rapeseed protein isolate as a food.

SUGGESTED AMENDMENTS TO DRAFT VARIATION

For the foregoing reasons, we request FSANZ consider the following specific amendments to the proposed product specification for rapeseed protein isolate proposed to be included in Schedule 3 of the FSANZ Code, which are

consistent with the relevant parameters in the Codex standard (CODEX STAN 174-1989):

1. **Increase the ash limit to 5%.** S3-40(b) of the Draft Variation current provides that the rapeseed protein isolate can contain no more than 4% ash. This is an unnecessarily strict standard and is not consistent with the regulatory standard in the US and the EU.

According to section 3.2.3 of the CODEX STAN 174-1989, “the yield of ash on incineration shall not exceed 10% on a dry weight basis.”

GRN327 provides an ash content limit ash of ≤6%.

On page 34 of the Application, DSM confirms that its product is similar to those in GRN327:

“The composition of DSM and ADM/Burcon products is comparable, with protein contents oft at least 90%, and levels of moisture ash, carbohydrates, fats, and fibre in the same range for these products.”

The consumption of rapeseed protein isolate with 6% ash content has been demonstrated to be safe (see the original submission to GRN327 page 32 to 42, for discussion of the toxicological studies performed using rapeseed protein isolate (Supertein) containing 6% ash).

Accordingly, we submit an increase of the ash content limit to be no more than 5% does not present any material concerns and accords with the position taken overseas, including in the US.

2. **Increase the fat limit to 5%.** S3-40(b) of the Draft Variation current provides that the rapeseed protein isolate can contain no more than 2%. According to section 3.2.4 of the CODEX STAN 174-1989, “the residual fat content shall be compatible with Good Manufacturing Practice.” The European Union's approval of rapeseed protein isolate (2014/424/EU) referred to in the Call for Submission, does not specify a limit for fat.

Fat content of protein isolates can be manipulated for a desired functionality in the finished protein isolates that can impact the properties of foods utilizing those isolates. Additionally, modification of the cruciferin to napin ratio of a rapeseed protein isolate may also result in changes to finished fat content of a protein isolate. Changes in the ratios of these two proteins can be attributed to process, rapeseed varietal, growing region, or seasonality. As fat levels relate

to erucic acid content, using the values provided in the A1175, the requested increase of the fat content limit to 5% would require the consumption of approximately 60g protein isolate/kg bw/day to reach the tolerable intake level of 7.5 mg erucic acid/kg bw/day established by Food Standards Australia New Zealand. The exposure to erucic acid is therefore well below the provisional tolerable daily intake established by FSANZ. Further, increasing the fat content limit to a maximum of 5% will not affect compliance with CODEX STAN 210-1999, which provides that rapeseed oil must not contain more than 2% erucic acid.

There is no evidence indicating that consumption of rapeseed protein isolate containing 5% fat causes any harm or toxicity.

Accordingly, we submit an increase of the fat content limit to a maximum of 5% does not present any material concerns.

In conclusion, the adjustments to the values for ash and fat in the proposed specification fall well within the limits set forth in CODEX STAN 174-1989 and will provide flexibility to manufacturers, accommodation to unanticipated changes to raw material inputs, and increased competition and innovation in the marketplace.

We thank FSANZ for its consideration of these submissions and would be pleased to discuss our submission further. Please direct any correspondence to Alexandra Fontaine, Director of Quality Assurance at Merit Functional Foods.



Merit[™]
Functional Foods

[Redacted]
Director of Food Safety & Quality

Sincerely

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