

**15 December 2020**  
**[145-20]**

Approval report – Application A1175

Rapeseed protein isolate as a novel food

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by DSM Nutritional Products Asia Pacific to permit the use of rapeseed protein isolate as a novel food.

On 31 July 2020, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 12 submissions.

FSANZ approved the draft variation on 1 December 2020. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 15 December 2020.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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## Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

- SD1 Food technology, microbiological, nutrition, toxicology and dietary exposure assessment report (at Approval)

# Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from DSM Nutritional Products Asia Pacific to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of rapeseed protein isolate as a novel food.

Rapeseed protein isolate can be used as a protein source in a range of foods and use levels. It is used as a replacement for proteins sourced from animal (e.g. whey) or other plants (e.g. soy, pea), including for use in new product development. Given the protein content of at least 90% it can also provide a range of technological functions in food.

Food technology, microbiological, nutrition, toxicology and dietary exposure assessments were undertaken by FSANZ to evaluate potential risks associated with the addition of rapeseed protein isolate as a novel food.

The food technology assessment concluded that rapeseed protein isolate when used as a replacement protein source, including for use in new product development, is technologically justified in the quantities and form proposed. It is suitable for addition at typical use levels up to 10% in a range of foods. Modern cultivars of *Brassica* species that rapeseed protein isolate is sourced from are naturally low in the anti-nutritional factors erucic acid and glucosinolates. For this reason the source, as well as limits for erucic acid and glucosinolates, are included in the proposed draft variation.

Rapeseed protein isolate contains mustard proteins, and proteins which may cross-react with related mustard species due to the high amino acid sequence similarity between the proteins. This means that rapeseed protein isolate may cause an allergic response in individuals with mustard allergy. Because of this risk, FSANZ will delay the commencement date for the draft variation and work with the Australasian Society of Clinical Immunology and Allergy (ASCIA), allergy support organisations and other expert bodies to raise awareness with consumers who have a mustard allergy of the potential for an allergic response to rapeseed protein isolate.

The microbiological assessment identified that there are adequate production control measures in place and concluded that there is a low risk in relation to the potential for microbiological contamination by *Salmonella* species (*Salmonella* spp.) and *Bacillus cereus* (*B. cereus*) within the rapeseed protein isolate. The proposed draft variation includes microbiological controls, including those for *Salmonella* spp. to ensure the risk remains low.

Rapeseed protein isolate, when used as a protein source in foods at the proposed typical or maximum use levels, does not raise nutritional concerns. The protein quality of rapeseed protein isolate, as determined from its amino acid profile and digestibility, is comparable to that of the milk protein casein and is slightly higher than that of soy protein isolates.

FSANZ has considered the potential impact of approving a draft variation to the Code and has concluded that the direct and indirect benefits that would arise from permitting rapeseed protein isolate most likely outweighs the associated costs. The Office of Best Practice Regulation (OBPR) advised FSANZ that no Regulation Impact Statement is needed in relation to the regulatory change proposed (OBPR correspondence dated 16 October 2020 and OBPR ID 42490).

FSANZ has therefore approved a draft variation to the Code with a delayed commencement date of 30 June 2021 to permit the use of rapeseed protein isolate as a novel food, subject to specified conditions of use. Permission was not requested or given for use in infant formula products (includes infant formula, follow-on formula and infant formula products for special

dietary uses) or infant foods.

# 1 Introduction

## 1.1 The Applicant

DSM Nutritional Products Asia Pacific (DSM) are a global company specialising in health, nutrition and materials. Nutritional Products are part of the nutrition group of the company and produce essential nutrients and other ingredients for the feed, food, pharmaceutical and personal care industries.

## 1.2 The Application

The purpose of the application is to amend the *Australia New Zealand Food Standards Code* (the Code) to permit rapeseed protein isolate as a novel food. Rapeseed protein isolate is intended for use as a protein source in a range of food classes as a direct protein replacement for other proteins derived from animal (e.g. whey) or plant (e.g. soy, pea) proteins. The applicant did not seek permission for use of rapeseed protein isolate in infant formula products (includes infant formula, follow-on formula and infant formula products for special dietary uses) and infant foods.

Rapeseed protein isolate is derived via extraction from rapeseed press cake, which is retained after oil pressing from the seeds of one of more of *Brassica napus*, *Brassica rapa* or *Brassica juncea*. DSM's rapeseed protein isolate is sourced from modern cultivars of *Brassica* species lower in the anti-nutritional factors erucic acid and glucosinolates than in traditional *Brassica* varieties. These anti-nutritional factors are components present in a food that can exert a negative impact on the nutritional quality of the protein. The manufacturing process is also designed to minimise these anti-nutritional factors. Although the common name for these low erucic acid and glucosinolate *Brassica* species in North America and Australasia is canola, the term rapeseed protein isolate is referred to throughout this document.

The application stated that rapeseed protein isolate has similar nutritional quality to dairy proteins, being slightly higher than that of soy protein isolates. It provides a desirable sensory profile when added to foods. Rapeseed isolate's high protein content of at least 90% provides broad functionality in a range of foods, with typical use levels from 2% to 10%.

The proposed typical use levels include bakery products ( $\leq 5\%$ ), beverages, such as fruit juice and blends, soft drinks, formulated beverages, dairy and plant based milks, energy drinks and various dairy products ( $\leq 5\%$ ). It is also suited to use in mixed foods such as ready to eat meals, soup, pasta and extruded snacks including cookies, meat analogues ( $\leq 5\%$ ) and protein based products such as energy bars, pasta, protein powders and beverages ( $\leq 10\%$ ).

Rapeseed protein isolate has not yet been produced commercially for use in food as at 2016 (Campbell, 2016). To FSANZ's knowledge this is still the case despite international regulatory permissions for its use in food being approved since 2010. Therefore there was no information available for the purpose of this assessment on its actual use and levels in food, market uptake or market share, or on any changes in mustard allergy prevalence.

## 1.3 The current Code requirements

Rapeseed protein isolate is not currently permitted as a novel food. FSANZ's Advisory Committee on Novel Foods provided a view in May 2017 that rapeseed protein isolate was a non-traditional and novel food (FSANZ, 2017).

Australia and New Zealand food laws require that food for sale must comply with the Code requirements listed in sections 1.3.1 to 1.3.4 of this report.

### **1.3.1 Novel food permission**

Section 1.5.1—2 of the Code provides a definition for novel food and matters that the assessment process must give regard to.

Section 1.5.1—3 permits a food offered for retail sale to consist of, or have as an ingredient, a novel food, if the novel food is listed in the table to section S25—2 and any conditions of use specified in the table are complied with.

The table to section S25—2 (sale of novel foods) lists permitted novel foods together with their conditions for use including use levels, restrictions on use and labelling requirements.

### **1.3.2 Identity and purity requirements**

Novel foods permitted by sections 1.5.1—3 and S25—2 must also meet any relevant identity and purity specifications set out in section S3—2 and section 1.1.1—15. Section S3—2(1)(a) and the table to section S3—2 includes a list of substances and provisions.

### **1.3.3 Contaminant and natural toxicant requirements**

The table to subsection S19—6(2) details requirements for maximum levels of natural toxicants in classes of food.

### **1.3.4 Labelling requirements**

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

Subsection 1.2.3—4(1) requires certain foods and substances to be declared when present as ingredients in a food for sale.

Standard 1.2.4 generally requires food products to be labelled with a statement of ingredients.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made about food.

Standard 1.2.8 generally requires food products to be labelled with nutrition information.

## **1.4 International requirements**

The European Union (EU) permits the use of rapeseed protein isolate as a novel food by EU standard 2014/424/EU (European Commission, 2014). This permission is based on the European Food Safety Authority's (EFSA's) assessment for a similar rapeseed protein isolate product (EFSA, 2013). More recently, the applicant's rapeseed protein isolate has been considered as substantially equivalent to the EU permission for rapeseed protein isolate (FSAI, 2017). The Food Safety Authority of Ireland (FSAI) also approved a similar rapeseed protein isolate product as a novel food in 2012 (FSAI, 2012).

In the United States of America, the US Food and Drug Administration has provided “no

questions” letters to generally recognised as safe (GRAS) notifications for similar rapeseed protein isolate products in the notices, GRN327 and GRN386 (US FDA, 2010 and 2011). The US FDA also responded with a no questions asked letter for GRAS notification GRN000683 from the applicant for their rapeseed protein isolate (US FDA, 2017).

The Codex General Standard for Vegetable Protein Products, CXS 174-1989 includes rapeseed protein isolate as described in this application (Codex, 2019). The Codex General Principles of Food Hygiene, CXC 1-1969 (2003) and Code of Hygienic Practice for Low Moisture Foods, CXC 75-2015 apply to the manufacture and production of rapeseed protein isolate (Codex, 2018).

There is also a Codex standard for named vegetable oils, CXC 210 – 1999 that includes a definition for rapeseed oil and further details; low – erucic acid rapeseed oil must not contain more than 2% erucic acid (as % of fatty acids) (Codex, 2019b). EFSA’s assessment also includes this value (EFSA, 2013). DSM’s rapeseed protein isolate is sourced from varieties that are lower in erucic acid than traditional varieties. Together with the manufacturing process, which further reduces levels, the isolate contains no more than 0.005% erucic acid and is consistent with the Codex standard (Codex, 2019b).

Following EFSA’s assessment a specification of not more than 1 µmol/g was established for glucosinolates (EFSA, 2013). This is also consistent with the specified level in GRAS notifications 386 and 683 for which US FDA provided no questions asked letters (US FDA 2011 and 2017).

Codex standards and guidance apply internationally although they are not a requirement in Australia and New Zealand unless incorporated in and given effect through relevant national legislation and standards.

## **1.5 Reasons for accepting Application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure
- it was not so similar to a previous application for the variation of a food regulatory measure that it ought to be rejected.

## **1.6 Procedure for assessment**

The Application was assessed under the General Procedure.

## **1.7 Decision**

The draft variation was approved with the following amendments following consideration of submissions.

For the rapeseed protein isolate specification;

- removal of appearance as a tan powder
- an increase in ash content to not more than 5%
- an increase in fat content to not more than 5%.

The approved draft variation is at Attachment A. The variation will have a delayed commencement date and take effect on 30 June 2021.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on the draft variation between 31 July 2020 and 4 September 2020.

Twelve submissions were received, with four supporting the application. Of those supportive submissions, three also raised issues. Those supporting the application were;

- New Zealand Food and Grocery Council
- The Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions
- South Australia Health
- Merit Functional Foods.

There were eight submissions that raised issues and FSANZ’s responses to these are included in Table 1.

**Table 1: Summary of issues raised in submissions**

Issue	Raised by	FSANZ response (including any amendments to drafting)
<b>Allergen and dietary exposure assessment</b>		
<p>In response to FSANZ’s allergenicity assessment, Allergy and Anaphylaxis Australia’s (A &amp; AA’s) website does note mustard as a potential allergen capable of causing anaphylaxis. ASCIA’s website also mentions almost any food can cause an allergic reaction, mustard is not specifically mentioned. EFSA’s assessment also concluded rapeseed protein isolate can trigger allergic reactions.</p>	<p>Allergy and Anaphylaxis Australia (A &amp; AA), Australasian Society of Clinical Immunology and Allergy (ASCIA)</p>	<p>The allergenicity assessment (see section 5.2.3 in SD1) concluded that rapeseed protein isolate has the potential to induce allergenic responses in individuals who are allergic to mustard.</p> <p>The risk management approach will include the development and implementation of a communication strategy and supporting materials to inform mustard allergic individuals of the potential risk of an allergic reaction from consuming foods with rapeseed protein isolate.</p>



Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>FSANZ to provide evidence that permitting rapeseed protein isolate as a novel food and allergen into the diet in a wide variety of core foods (in larger amounts than mustard) will not increase allergic reactions and affect Australian's food allergy prevalence.</p>	<p>A &amp; AA, ASCIA</p>	<p>FSANZ has consulted with the Food Allergy and Intolerance Scientific Advisory Group (FAISAG<sup>1</sup>) regarding the prevalence of mustard allergy in Australian and New Zealand populations. The FAISAG indicated that mustard allergy is rare in their patient populations, but cases of anaphylaxis have occurred. Although the addition of rapeseed protein isolate to the food supply could result in increased population exposure to mustard, the development of a risk communication strategy and supporting materials (sections 2.4.1 and 2.4.2) will be used to help manage the risk of the potential for an allergic response to rapeseed protein isolate for mustard-allergic individuals. Rapeseed protein isolate has not been produced commercially for use in food as at 2016 (Campbell, 2016). To FSANZ's knowledge this is still the case despite international regulatory permissions being approved since 2010. Therefore consumption and rapeseed protein isolate allergy prevalence data are not available from other jurisdictions.</p>
<p>An allergen risk assessment should be conducted before another call for submissions is made.</p>	<p>Australasian Society of Clinical Immunology and Allergy (ASCIA)</p>	<p>An allergenicity assessment was undertaken (see section 5.2.3 in SD1). As this application was assessed under the general procedure, there is one call for submissions.</p>

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<sup>1</sup> The Food Allergy and Intolerance Scientific Advisory Group (FAISAG) is an advisory group that has been established to assist FSANZ on matters relating to food allergy and intolerance for the purposes of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act). Members include the General Manager for Science and Risk Assessment within FSANZ and members selected by FSANZ on the basis of FSANZ's assessment of their relevant experience and expertise in food allergy and intolerance. The FAISAG provide non-binding advice to FSANZ on matters relating to food allergy and intolerance.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>There appears to be a risk for latex allergy which has not been considered.</p> <p>How significant rapeseed protein isolate would be in relation to those with mustard and/or latex allergy. Or potentially as a new allergy.</p> <p>Useful to have EU data on the introduction of rapeseed protein, cross-reactivity in those with mustard and/or latex allergy and consumer feedback on warning statement.</p>	<p>Allergy New Zealand</p> <p>NSW FA</p>	<p>Clinically relevant cross-reactivity between natural rubber latex allergens and proteins in some fruits has previously been described (Blanco, 2003). The submitter provided one study that described in vitro cross-reactivity between latex allergens and turnip (<i>Brassica rapa</i>) proteins (Hänninen et al., 1999). However not all cross-reactivities are of clinical significance. FSANZ conducted a search in Pubmed using the search terms 'latex', 'allergy' and 'Brassica napus or Brassica rapa or Brassica juncea'. One relevant publication was identified that described clinical cross-reactivity between turnip and a single latex allergen in one individual (Pereira et al., 2007). ASCIA notes that some foods may cause allergic symptoms in people with latex allergy, most commonly caused by banana, kiwi and passion fruit, plums, strawberry and tomato. Further studies would be required to establish the clinical significance of consuming rapeseed protein isolate for latex-allergic individuals.</p> <p>To FSANZ's knowledge rapeseed protein isolate has not been commercially produced for use in food, including in Australia and New Zealand. There is no EU data on the introduction of rapeseed protein, cross-reactivity in those with mustard and/or latex allergy or consumer feedback on warning statement.</p>
<p>EU regulation should be considered by those manufacturers exporting to EU countries.</p>	<p>Allergy New Zealand</p>	<p>Meeting EU requirements, including any export requirements is not in the scope of FSANZ's regulatory responsibility. It is the responsibility of manufacturers who choose to use rapeseed protein isolate and export to EU countries.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<b>Microbiological risk assessment</b>		
<p>DSM want to clarify controls for the risk of <i>Salmonella</i> in CanolaPRO for FSANZ to conclude that <i>Salmonella</i> does not pose a microbiological risk. There are further controls for activities before production, raw material checks, temperature checks including in process checks including log reductions for <i>Salmonella</i> and end product microbiological specifications.</p>	<p>Applicant, DSM Nutritional Products Asia Pacific</p>	<p>New information provided in the submission was used to update the microbiological risk assessment for convenience foods. It was concluded that controls for microbiological risk for <i>Salmonella</i> from raw materials through to the end product showed a low level of risk. The risk management approach of including <i>Salmonella</i> in the specification for rapeseed protein isolate remains appropriate based on the further production controls assessed to ensure the risk remains low.</p>
<p>Providing a microbiological specification for which the microbiological risk assessment showed a low level of risk when use will be mostly in cooked products seems unnecessary, better to follow good manufacturing practice. Other protein isolates from soy or whey do not have a specification in S27.</p>	<p>SA Health</p>	<p>The microbiological assessment (see section 3.4 in SD1) identified that rapeseed protein isolate may be used in foods that do not have further processing steps e.g. a heating step like cooking. Protein isolates from whey and soy differ in the production process from rapeseed protein isolate in that they have additional microbiological controls. For example whey protein isolate would be made using pasteurised milk. Soy protein isolates are likely to be a low moisture food and named in the Codex Code of Hygienic Practice for Low Moisture Foods CXC 75-2015. These controls mean they inherently have a lower level of risk.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<b>Food technology</b>		
Sodium bisulfite may be used in production and there is no permission in Schedule 18 of the Code.	A & AA	The applicant has clarified that sodium bisulfite will be used in production. The scope of this application and assessment was permission for rapeseed protein isolate as a novel food and not permission for sodium bisulfite as a processing aid. Meeting requirements in the Code such as those in Schedule 18 for processing aids is the responsibility of the manufacturer(s).
As noted in the paper, the collective term for <i>Brassica</i> species low in erucic acid and glucosinolates is Canola. This can be used in place of the name Rapeseed. The variation for Schedules 3 and 25 should include the common name used in America and Australasia, Canola alongside rapeseed protein isolate.	New Zealand Ministry for Primary Industries, New Zealand Food Safety (NZ MPI NZFS)	Modern cultivars of <i>Brassica</i> species that are low in anti-nutrients; erucic acid and glucosinolates can be referred to as canola. We also note this name is used in America and Australasia.
<b>Food technology and legal</b>		
The specification stipulates the appearance. This is prescriptive and does not serve to protect public health and safety.	SA Health	Although the applicant included information for the appearance of their rapeseed protein isolate as a 'tan powder', the EU specifies a 'white to off white' colour and the US FDA a 'brown to yellow' colour. FSANZ is also aware there can be variation in the colour depending on the raw material and manufacturing process. As specifications for colour differ, the specification in the Code will not include appearance or colour so as not to be prescriptive and restrict trade.
A prescriptive regulation of the composition is restrictive to manufacturing variations. Quality is better controlled by a manufacturer.	SA Health	The food technology assessment reviewed international standards, including compositional requirements for protein, carbohydrate, fat and ash. The applicant also provided analytical results for batches of rapeseed protein isolate (see section 2.7 in SD1). The specification included in the draft variation is intended to allow for variations in raw material and manufacturing processes and not be restrictive to trade. The Code provides for specifications for novel foods to be set out in Schedule 3 (also see section 1.1.1—15). It is usual to include compositional requirements in a product specification.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The maximum levels (in mg/kg) for a food should be used, rather than a % level as not consistent drafting.</p>	<p>SA Health</p>	<p>It is appropriate to use the unit as a percentage (%) in the rapeseed protein isolate specification, which is consistent with other specifications for novel foods listed in Schedule 3. The unit milligrams per kilogram (mg/kg) is typically used for small concentrations in a specification. For example limits for metals.</p>
<p>Creating a vertical regulation for a food product including specifications does not seem appropriate and prescriptive. Doing this will proliferate standards making the Code difficult to read and interpret.</p>	<p>SA Health</p>	<p>The draft variation is consistent with the Code's intent and structure which provides for specific and separate regulation of food products that are novel foods. The Code expressly authorises and provides for specifications for novel foods to be set out in Schedule 3 of the Code, also see section 1.1.1-15. Where there is not a relevant specification in a primary or secondary source, a specification for a novel food can be included in Schedule 3.</p> <p>FSANZ is not aware of any evidence that the draft variation listing novel food permissions in Schedule 25 and novel food specification in Schedule 3 has or will result in proliferation of individual standards.</p> <p>FSANZ is not aware of any evidence from stakeholders that the specific novel food permission and specification will be difficult to read and interpret. Matters relating to the Code's approach and structure for novel food regulation is out of scope for Application A1175.</p>
<p>Instead of providing an individual specification in S3—40 for rapeseed protein isolate there are other relevant Schedules in the Code that could be used i.e. S19 could include a limit for erucic acid, S19—4 could include a limit for lead, S27 could include microbiological limits.</p>	<p>SA Health</p>	<p>See response above</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The proposed draft variation provides a definition for rapeseed protein isolate. If a definition is needed, it should be placed in preliminary provisions in the Code.</p>	<p>SA Health</p>	<p>The amendment in the draft variation does not provide a definition for rapeseed protein isolate. Instead, it provides permission and conditions for use as a novel food. That is, the proposed entry provides that rapeseed protein isolate is a permitted novel food subject to three conditions of use that apply to that permitted novel food. The conditions listed are based on information in the assessment report (see SD1) and the risk management approach in this approval report.</p>
<p><b>Food technology and cost/benefit assessment</b></p>		
<p>It is unclear whether the varieties of Canola low in erucic acid and glucosinolates can be grown in parts of Australia and the economic impact of this.</p>	<p>Victorian Dept. of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>The viability of crops being grown in Australia and their economic impact is not within the scope of this application and assessment.</p>
<p>For other varieties of Canola that can be grown in States and Territories in Australia, whether they would meet the proposed specification for rapeseed protein isolate.</p>	<p>Victorian Dept. of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>FSANZ has assessed the safety of specific varieties of rapeseed that are modern cultivars and low in anti-nutrients erucic acid and glucosinolates, <i>B. napus</i>, <i>B. rapa</i> and <i>B. juncea</i> only. Based on the evidence assessed in this application FSANZ is not aware of whether there are other varieties that would meet the proposed product specification. Permitting the use of other varieties as a source of rapeseed protein isolate for use in food may need to be considered in the form of an application to FSANZ.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<b>Food technology and toxicological assessment</b>		
<p>Amend the product specification proposed in the draft variation as follows;</p> <p>Increase ash content limit to 5%, currently 4%.</p> <p>Increase fat content limit to 5%, currently 2%.</p> <p>Consistency with US FDA GRAS GRN 327 and Codex Standard 174-1989.</p>	<p>Merit Functional Foods (MFF)</p>	<p>A further comparison with international standards, including Codex Standard 174-1989 for vegetable protein products including for the applicant's product and their analytical results for batch's (see Tables 2.4 and 2.5 in SD1) was mostly consistent with 5% limits for ash and fat.</p> <p>The composition limits for fat and ash of 5% now in the draft variation would allow for raw material and manufacturing process variations as well as not restricting trade. It is also intended that this would allow manufacturers of similar rapeseed protein isolates to meet these specifications.</p>
<p>The 6% ash content has been demonstrated to be safe as per US FDA GRAS GRN 327.</p>	<p>MFF</p>	<p>Although FSANZ does not recognize a GRAS Notification to the US FDA as a safety assessment, there are no safety or nutritional concerns with the requested increase in ash content.</p>
<p>Changing the fat content limit to 5% and given the consumption of approx. 60g/kg bodyweight/day (bw/day), the exposure to erucic acid would be well below the TDI.</p> <p>No evidence there is harm or toxicity.</p>	<p>MFF</p>	<p>Providing the erucic acid exposure remains below the FSANZ tolerable intake (TDI) of 7.5 mg erucic acid/kg bw/day, there would not be toxicity concerns in increasing the fat content limit to 5%.</p>
<p>The amendment would be consistent with Ministerial Policy Council Guidelines on Novel Foods and encourage industry growth, innovation and international trade.</p>	<p>MFF</p>	<p>The Ministerial Policy Council Guidelines on Novel Foods has been considered and would be met in granting permission for rapeseed protein isolate (see section 2.5.3). Although these Guidelines do not include aspects of market growth and trade, broader FSANZ Act objectives do and have been considered in this application (see section 2.5.3).</p>
<p>The change would also not affect compliance with Codex Standard 210-1999 for vegetable oils and the erucic acid limit of 2%.</p>	<p>MFF</p>	<p>Codex Standard 210-1999 is for vegetable oils, including rapeseed oil so is not directly relevant to the erucic acid content in rapeseed protein isolate. The food technology assessment noted that following manufacturing, the erucic acid content will be substantially lower in rapeseed protein isolate (see section 2.2.1.1 in SD1).</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<b>Overall risk assessment and toxicological assessment. Manufacturing process</b>		
Concerns for physical and mental health effects from pesticides and insecticides used for growing rapeseed crops including glyphosate. Also has the potential to increase the world's crop production.	Allergy/Intolerance to Rapeseed Oil Group	The purpose and scope of this application is for rapeseed protein isolate as a novel food and ingredient. FSANZ does not regulate rapeseed crop production or the approval for the domestic use of agricultural chemicals (such as insecticides and herbicides), which are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA).
Build-up of erucic acid and absorption of neonicotinoids used in pesticides and insecticides on crops has health effects, including glyphosate in urine.	Allergy/Intolerance to Rapeseed Oil Group	Erucic acid is not bioaccumulative but is rapidly metabolised in the liver. Studies in rats indicate that the half-life of a single dose of erucic acid is less than 24 hours. Pesticides, including neonicotinoids and glyphosate, are regulated by the APVMA, not by FSANZ so these concerns are outside the scope of this application.
Concerns that rapeseed is used in approx. 95% of processed food, baby formula, cosmetics, toiletries and vitamin supplements and fed to animals making it difficult to avoid consumption.	Allergy/Intolerance to Rapeseed Oil Group	FSANZ does not regulate cosmetics, toiletries, vitamin supplements, or animal feed. These concerns are outside the scope of this application. The applicant is not requesting permission for the use of rapeseed protein isolate in infant formula products. In the draft variation a condition is listed that it must not be added to infant formula products and food for infants.
The manufacturing process means it is almost worthless in terms of nutrients. The marketing is misleading.	Allergy/Intolerance to Rapeseed Oil Group	The nutrition assessment findings show rapeseed protein isolate can be used as a protein source without raising concerns in relation to the protein adequacy of the diet, when used at the proposed maximum or typical use levels.  Foods are subject to Australian and New Zealand consumer laws. These laws prohibit foods from being represented in a way that is false or misleading, and protect consumers from misleading marketing practices..



Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>We oppose permitting rapeseed as rapeseed protein isolate to meet protein needs and request documentation showing findings that support the use for human consumption.</p>	<p>Allergy/Intolerance to Rapeseed Oil Group</p>	<p>Rapeseed protein isolate is intended to be used as a protein source and ingredient, as a replacement for existing protein sources. The nutrition assessment together with risk management approach support the use for permission as a novel food and ingredient (see sections 2.2.4 and 2.3.3). In brief, rapeseed protein isolate can be used in a range of foods and use levels. A thorough risk analysis process, including risk assessment, risk management and risk communication, has been followed to determine there is not a negative impact on public health and safety.</p>
<p><b>Labelling</b></p>		
<p>Both Canada and the EU require the declaration of mustard. Also, the EU requires for food containing rapeseed protein a statement that it may cause reactions for consumers allergic to mustard. The statement needs to appear in close proximity to the list of ingredients.</p>	<p>Allergy NZ NSW Food Authority</p>	<p>FSANZ recognises there are countries that identify mustard as an allergen to be declared when present in a food. As noted above, the FAISAG have indicated the prevalence of mustard allergy in Australia and New Zealand populations is rare but cases of anaphylaxis do occur. To manage the potential risk of an allergic reaction, FSANZ will develop and implement a communication strategy to inform mustard allergic individuals of the potential risk (see section 2.4.2).</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>No requirement for labelling</p> <ul style="list-style-type: none"> <li>- If added as a compound ingredient at less than 5%.</li> <li>- At food service, including in restaurant menus as requirement is only for allergens that require labelling.</li> <li>- As a novel food there is no basis for consumers making an informed choice.</li> </ul>	A & AA	<p>The existing generic labelling requirements will apply to rapeseed protein isolate to enable consumers to make informed choice (see section 2.3.5).</p> <p>Under these existing requirements, the provision of information on rapeseed protein isolate will be similar to that available for other permitted novel ingredients as well as for mustard.</p>
<b>Risk management</b>		
<p>Consult with FSANZ allergy expert working group, Food Allergy and Intolerance Scientific Advisory Group, Other expert bodies e.g. Royal Prince Alfred Hospital Allergy Unit)</p>	A & AA - National Allergy Strategy, NSW Food Authority	<p>Further discussion with ASICA, allergy support organisations and other expert bodies has been initiated and will continue with the development of a communication strategy to assist in informing and creating awareness for mustard allergic individuals.</p>
<p>Risk management approach does not explain actions expected of other organisations, including pro-active measures for these organisations to take in addressing the risk of cross-reactivity. Information after an allergic reaction does not equate to risk management.</p>	A & AA	<p>Further discussion with ASCIA, allergy support organisations and other expert bodies has been initiated and will continue in development of a communication strategy. This will assist in providing a pro-active approach in providing information to stakeholders and mustard allergic individuals.</p>
<p>Messaging through websites and social media may not reach all persons with mustard allergy.</p>	A & AA – National Allergy Strategy	<p>Given the potential for rapeseed protein isolate to cause reactions for mustard allergic individuals, the risk management approach includes the development of a communication strategy. FSANZ intends to work with ASICA, allergy support organisations and other expert bodies to assist in informing and creating awareness for mustard allergic individuals.</p>
<p>A &amp; AA does not consider the proposed risk management approach is similar to overseas.</p>	A & AA	<p>Noted. The intent of the statement that the risk management approach is similar to overseas is that Canada has a precautionary approach for the use of rapeseed protein isolate.</p>
<p>Consumer awareness through labelling is not sufficient to address public health and safety concerns, especially in food service.</p>	A & AA	<p>A risk communication strategy (sections 2.4.1 and 2.4.2 ) is being developed with ASICA, allergy support organisations and other expert bodies to ensure mustard allergic individuals are informed and aware of the potential for an allergic reaction to rapeseed protein isolate.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Following consultation with allergy groups, in the case there are acute anaphylactic responses in the Aust/NZ population consider listing rapeseed protein isolate in Standard 1.2.3 (of the Code). This would allow for informed purchase decisions and also allow for labelling in all packaged food, including as a compound ingredient less than 5%. The current proposed risk management approach of informing A &amp; AA and ASCIA does not help sensitive consumers as there are no details on guiding concerned consumers. Could result in reduced confidence for individuals with mustard allergy.</p>	<p>NSW Food Authority, A &amp; AA – National Allergy Strategy</p>	<p>FSANZ’s revised risk management strategy is to develop and implement a communication strategy to inform mustard allergic individuals of the potential risk from rapeseed protein isolate (see section 2.4.2).</p> <p>Generic ingredient labelling requirements will apply to the use of rapeseed protein isolate in food to enable informed choice. In the case of compound ingredients, the existing labelling requirements will also apply. This is the same approach which currently applies to the use of mustard in food.</p>
<p>Given the risk assessment for allergenicity, and prevalence of mustard allergy in New Zealand/Australian populations is not well understood, further consideration for allergen labelling or steps to alert sensitive consumers of risks posed by this new food ingredient is needed.</p>	<p>MPI NZFS</p>	<p>FSANZ intends to develop and implement a communication strategy to inform mustard allergic individuals of the potential risk from rapeseed protein isolate (see section 2.4.2).</p>
<p>Consider a broader communication strategy should rapeseed protein isolate be permitted for use.</p>	<p>National Allergy Strategy</p>	<p>A risk communication strategy is being developed to ensure that mustard allergic individuals are informed and aware that rapeseed protein isolate when used as an ingredient in food has the potential to cause allergic reactions.</p>

## 2.2 Risk assessment

The risk assessment has been completed and included in Supporting Document 1 (refer to SD1). Sections 2.2.1 to 2.2.6 in this report provides a summary of these assessments.

### 2.2.1 Food technology assessment

The food technology assessment concluded that rapeseed protein isolate, when used as a novel food ingredient and as a protein replacement, including for use in new product development in a range of foods is technologically justified at the levels and form proposed. The proposed typical use level in a range of foods is up to 10%. For use in food, rapeseed protein needs to be sourced from the following modern cultivars of these *Brassica* species: *B. napus*, *B. rapa* and *B. juncea* that are low in the anti-nutritional factors erucic acid and glucosinolates.

Rapeseed protein isolate also provides various technological functions in foods, including thickening, water binding, emulsifying, gelling, foaming and providing texture.

### **2.2.2 Allergenicity**

The risk assessment (refer to SD1 section 5.2.3) has identified that rapeseed plants contain mustard proteins and proteins, which may cross-react with related mustard species due to the high amino acid sequence similarity between the proteins. FSANZ considers that rapeseed protein isolate has the potential to induce allergic responses in individuals who are allergic to mustard. In response to submissions received, FSANZ consulted with the Food Allergy and Intolerance Scientific Advisory Group (FAISAG) for advice regarding the use of rapeseed protein isolate in the food supply.

FAISAG members indicated that:

- The prevalence of mustard allergy in Australia and New Zealand is very low, however cases of anaphylaxis do occur
- There was a general concern of a risk to mustard-allergic consumers from the presence of mustard (as rapeseed protein isolate) in a food that does not have mustard labelled.
- One member raised concern with the avoidance of a product without evidence of clinical allergy
- One member noted a concern similar for all compound ingredients that are not common allergens, the labelling of rapeseed protein would not be required if present as part of a compound ingredient that was less than 5% of the final food.

### **2.2.3 Microbiological assessment**

FSANZ concludes that rapeseed protein isolate does not pose a microbiological risk for *Salmonella* spp. in some types of manufactured convenience foods that do not undergo a final microbiocidal step. Rapeseed protein isolate may be a low moisture food (as defined by the Codex Alimentarius Commission) and the water activity of the product inhibits the growth of pathogens including *Salmonella* spp. and *B. cereus*, provided suitable storage conditions are maintained. The applicant has certification in relevant food safety management systems to control foodborne hazards. A screening method was used to assess the risk for *Salmonella* spp. and *B. cereus* when the product is used in manufactured convenience foods. The risk levels determined were low for both *Salmonella* spp. and *B. cereus*. For cooked foods, such as bakery products, where rapeseed protein isolate is used as an ingredient, the risk will also be low for both *Salmonella* spp. and *B. cereus*.

### **2.2.4 Nutrition assessment**

Rapeseed protein isolate, when used as a protein source in foods at the proposed maximum or typical use levels, does not raise nutritional concerns.

The protein quality of rapeseed protein isolate, as determined from its amino acid profile and digestibility, is comparable to that of the milk protein casein and is slightly higher than that of soy protein isolates.

At the highest typical use level of 10% in foods, the maximum phytate level in rapeseed protein isolate proposed in the application (1.5% w/w) equates to maximum levels in foods of

0.15%, which is close to the lower end of the range reported for commonly consumed foods such as cereals, beans and nuts. Also, the maximum phytate level of 1.5% is similar to the maximum levels reported for soy protein isolates (1.5–1.7%) which are the most widely used plant protein isolates. Therefore, phytate levels of up to 1.5% in rapeseed protein isolate do not raise concerns regarding mineral bioavailability.

As rapeseed protein isolate will be used as an ingredient in foods as a replacement for other protein sources, including for use in new product development, usual protein intakes are not expected to change if rapeseed protein isolate is approved as a protein source.

### **2.2.5 Dietary exposure assessment**

FSANZ estimated dietary exposure to rapeseed protein isolate based on the most recent consumption data from national nutrition surveys for Australians and New Zealanders, and information on proposed foods and maximum and typical use levels. The dietary exposure to the two anti-nutritional factors evaluated in the hazard assessment, erucic acid and glucosinolates, were also estimated from the rapeseed protein isolate and compared to exposures that might occur from the normal diet from *Brassica* vegetables (e.g. broccoli, cauliflower and cabbage). The dietary exposure assessment also fed into parts of the toxicology assessment such as that for the metal contaminant lead. Results based on typical use levels better reflect longer term or chronic risk, and therefore these were used by FSANZ for risk characterisation purposes.

The estimated mean and 90th percentile dietary exposures to rapeseed protein isolate across the population groups assessed based on typical use levels were 0.55-1.25 g/kg bw/day and 1.09-2.28 g/kg bw/day, respectively. These values assume rapeseed protein isolate is the only form of protein used in all foods included in all food classes proposed by the applicant.

For erucic acid, estimated dietary exposures from rapeseed protein isolate were higher than the dietary exposures from *Brassica* vegetables for all population groups assessed for Australia and New Zealand. For glucosinolates, Australians were exposed to more glucosinolates from rapeseed protein isolate than from the *Brassica* vegetables, however, for New Zealand, dietary exposures to glucosinolates from *Brassica* vegetables were higher than exposures from rapeseed protein isolate. The additional exposure to glucosinolates from rapeseed protein isolate of around 20 mg/day is equivalent to the consumption of around 30 g/day of *Brassica* vegetables (one large broccoli floret or one medium cauliflower floret).

### **2.2.6 Toxicological assessment**

Of the plant metabolites in rapeseed protein isolate that are considered to have anti-nutritional potential, two are considered to have toxic effects, erucic acid and glucosinolates.

Erucic acid is not considered to represent a risk because the dietary exposure assessment demonstrated that the addition of rapeseed protein isolate to the diet at both proposed maximum and typical use levels does not result in an exceedance of the Provisional Tolerable Daily Intake (PTDI) of 7.5 mg/kg bw/day for erucic acid established by FSANZ in 2003. No new information was located to suggest that the PTDI established in 2003 should be revised.

There is no health-based guidance value (HBGV) for glucosinolates, but the dietary exposure assessment has shown that the addition of rapeseed protein isolate to the diet is comparable to the addition of amounts of *Brassica* vegetables that are within normal daily consumption.

Glucosinolates in rapeseed protein isolate are not considered to represent a health concern.

Increased dietary exposures to certain elemental contaminants (arsenic, lead, cadmium, zinc, copper and chromium) from the addition of rapeseed protein isolate to the diet are estimated to be low based on typical use levels and the small market update estimated by the applicant, and are not of toxicological concern.

## **2.3 Risk management decision**

The risk management options available to FSANZ after the assessment were to:

- Reject the application, or
- Prepare a draft variation to amend the Code to permit rapeseed protein isolate as a novel food and protein source in a range of foods and use levels.

The risk assessment identified public health and safety concerns associated with the potential allergenicity of rapeseed protein isolate in mustard-allergic individuals, the potential for microbiological contamination with *Salmonella spp.* the *Brassica* species it is sourced from and the need to maintain the levels of some metal contaminants to be as low as reasonably achievable. These are discussed in sections 2.2.1 to 2.2.4.

### **2.3.1 Allergenicity**

Mustard-allergic individuals may be unaware of the potential risk of allergy posed by consuming rapeseed protein isolate. Therefore in permitting rapeseed protein isolate as a novel food, FSANZ proposes to work with the Australasian Society of Clinical Immunology and Allergy (ASCIA) and allergy support organisations (e.g. Allergy New Zealand, Allergy & Anaphylaxis Australia) and other expert bodies in developing and implementing risk communication. This would be for the purpose of informing and ensuring mustard-allergic individuals are aware of the potential risk from consuming rapeseed protein isolate as an ingredient.

### **2.3.2 Microbiological risk**

The most appropriate risk management option is to include microbiological testing specification parameters, including for *Salmonella spp.* as verification of process control.

This is in addition to the applicant's Food Safety System Certification FSSC 22000 food safety management system to control foodborne hazards and the use of Good Hygienic Practices and Good Manufacturing Practices.

### **2.3.3 Nutrition**

Including a 1.5% maximum limit for phytates in the proposed specification for rapeseed protein isolate, and as proposed by the applicant, does not raise nutritional concerns. This is consistent with the maximum limit of 1.5% for phytates applied in the nutrition assessment and with EFSA's assessment, and the US FDA's "no questions" letters to GRAS notifications for rapeseed protein isolate (EFSA, 2013 and US FDA 2010, 2011 and 2017).

### **2.3.4 Food technology**

Rapeseed protein isolate for use in food is sourced from modern cultivars of *Brassica* species low in the anti-nutritional factors erucic acid and glucosinolates. For this reason the following *Brassica* species: *B. napus*, *B. rapa* and *B. juncea*, from which rapeseed protein isolate can be obtained, are included in the proposed draft variation to the Code.

Although there are some international standards and guidance for what may be considered 'low' for erucic acid and glucosinolates in rapeseed oils, these are not directly applicable as rapeseed protein isolate is extracted from rapeseed press cake, a by-product of the oil production. Instead, it is more appropriate to include maximum limits (MLs) for erucic acid of 0.005% and for glucosinolates of 1 µmol/g in the specification included in the proposed draft variation to the Code. The ML for erucic acid is lower than the 2% set for rapeseed oil in international standards and guidance. The ML for glucosinolates is consistent with EFSA's assessment and product specification for rapeseed protein isolate and also the US FDA's no questions asked letters to GRAS notifications (EFSA, 2013 and US FDA 2011 and 2017). The proposed MLs were also used for the dietary exposure and toxicological risk assessments for which public health and safety concerns were not identified.

Compositional requirements have also been included in the specification for protein, carbohydrate, fat, ash and moisture. These are consistent with aspects of the risk assessment, development of a specification for a novel food and some international requirements. The compositional requirements also allow scope for variation in raw material and manufacturing processes.

Although the toxicology assessment did not raise public health and safety concerns regarding metal contaminants, there are ML's in S3—4 of the Code for arsenic, cadmium and lead, so rapeseed protein isolate would need to meet these. Subsequent assessment by FSANZ where a mean value of 0.013 mg/kg from 8 batches was used for the toxicology and dietary assessment for lead, confirmed there are no public health and safety issues.

However, for consistency with some international limits and to allow for variation in raw materials and manufacturing processes, a limit for lead of 0.5 mg/kg as also proposed by the applicant has been included in the proposed draft variation to the Code.

### **2.3.5 Labelling of foods containing rapeseed protein isolate**

The existing generic labelling requirements in the Code will apply to the use of rapeseed protein isolate in food to provide information to enable consumers to make informed choices.

#### **2.3.5.1 Statement of ingredients**

Generic labelling provisions in *Standard 1.2.4 – Information requirements – statement of ingredients* require food for sale to be labelled with a statement of ingredients unless exempt. Ingredients must be included in the statement of ingredients using either a name by which the ingredient is commonly known; a name that describes the true nature of the ingredient; or a generic name if one is specified in Schedule 10. In the case of rapeseed protein isolate there is no generic name that is applicable. Therefore the manufacturer will need to use a name by which the ingredient is commonly known or that describes the true nature of the ingredient.

Standard 1.2.4 requires a statement of ingredients to list all of the ingredients in a food in descending order of ingoing weight (except where exempt). This includes compound ingredients (i.e. an ingredient made from two or more ingredients), unless the compound ingredient makes up less than 5% of the final food. In this case, the compound ingredient must be listed and any food additives and allergens declared. The generic requirement for a statement of ingredients will apply to rapeseed protein isolate similar to other permitted novel ingredients. In the case of compound ingredients, the existing requirements will also apply to rapeseed protein isolate. This is the same approach which currently applies to compound ingredients containing mustard.

### **2.3.5.2 Mandatory declarations**

*Standard 1.2.3 - Information requirements – warning statements, advisory statements and declarations* requires added sulphites to be declared when they are present in a food in amounts of 10 mg/kg or more. This allows consumers sensitive to sulphites to make informed, safe food choices. The applicant has stated sodium bisulphite will be used during the manufacture of rapeseed protein isolate, and if used, then it is in amounts less than 10 mg/kg (refer to section 2.5 in SD1). In the case where rapeseed protein isolate is used as an ingredient in a food, a sulphite declaration would not be required, unless other sources of sulphites are added in combination to bring the total concentration in a food above 10 mg/kg.

### **2.3.5.3 Nutrition Information**

*Standard 1.2.8 – Nutrition information requirements* requires a nutrition information panel (NIP) be provided on the label of a food unless exempt. The use of rapeseed protein isolate as an ingredient in a food will contribute to the protein content of the food. As the NIP is required to include the average quantity of protein in a serving of food and per 100 g or per 100 mL, this will assist consumers to make informed choice about foods containing rapeseed protein isolate.

### **2.3.5.4 Nutrition content and health claims**

*Standard 1.2.7 – Nutrition, health and related claims* in conjunction with Schedule 4 sets out the requirements for the use of voluntary nutrition content and health claims on foods, including the criteria that must be met for claims to be made. Manufacturers choosing to make nutrition content or health claims about foods containing rapeseed protein isolate would need to meet these requirements.

## **2.3.6 Preferred Risk management approach**

Based on the risk assessment and identified public health and safety issues, the preferred approach is to prepare a draft variation to the Code, including a product specification for rapeseed protein isolate.

Based on the allergenicity assessment and risk for mustard allergic individuals, a delayed commencement date of 30 June 2021 would provide additional time for FSANZ to work with ASCIA, allergy support organisation and other expert bodies to raise awareness of the potential risk.

Providing permission for rapeseed protein isolate as a novel food will require amendment of the table to subsection S25—2 and the table to subsection S3—2; and the insertion of a product specification for rapeseed protein isolate in Schedule 3.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called on to obtain the views of the public, including interested parties on issues raised by the application and the



impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on an application or proposal was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

## **2.4.2 Implementation**

FSANZ is working with ASCIA, allergy support organisations and other expert bodies to develop a risk communication strategy and relevant materials to raise awareness with, and inform mustard allergic individuals of the potential risk.

Communication materials to be developed include a consumer information page on our website, a downloadable fact sheet and social media.

## **2.4.3 World Trade Organisation (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 international Codex standards and guidance that are relevant to rapeseed protein isolate (refer to section 1.4 International requirements). The EU and USA both allow for the use of various rapeseed protein isolates, including the applicant's rapeseed protein isolate. For these reasons, amending the Code to permit rapeseed protein isolate is consistent with existing international and national standards. The proposed regulatory measure would also not competitively disadvantage Australian and New Zealand food businesses in allowing them to add rapeseed protein isolate to foods to replace protein sources from animal (e.g. whey) and other plant derived proteins (e.g. soy, pea), including for use in new product development. The use of rapeseed protein isolate is also voluntary. It is unlikely there would be a significant effect on international trade.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### **2.5.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR) advised FSANZ that no Regulation Impact Statement is needed in relation to the regulatory change proposed (OBPR correspondence dated 16 October 2020 and OBPR ID 42490).

FSANZ has, however, considered the costs and benefits that may arise from the proposed measure. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status

quo is rejecting the application). This analysis considers permitting rapeseed protein isolate as a novel food.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting rapeseed protein isolate. FSANZ is of the view that no other realistic food regulatory measures exist.

### **Costs and benefits of permitting rapeseed protein isolate as a novel food**

Foods containing rapeseed protein isolate would provide a replacement and/or new protein source for food manufacturers.

Due to the voluntary nature of the permission, food manufacturers and retailers would only use the new rapeseed protein isolate, where they believe a net benefit exists for them. That is, it either reduces costs of production or increases the quality of food, potentially increasing their market share. Consumers may benefit from this to some extent either through lower costs or higher quality food relative to the present food supply.

There may be small and likely inconsequential costs of monitoring an additional food ingredient for regulators to ensure compliance with labelling requirements.

Approval would appear consistent with Australian and New Zealand obligations under WTO agreements and Free Trade Agreements given the previously outlined public health and safety concerns in permitting rapeseed protein isolate would be managed.

### **Conclusions from cost benefit considerations**

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting rapeseed protein isolate as a novel food most likely outweigh the associated costs.

#### ***2.5.1.2 Other measures***

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

#### ***2.5.1.3 Any relevant New Zealand standards***

The proposed regulatory measures apply in both Australia and New Zealand. There are no other relevant New Zealand only Standards.

#### ***2.5.1.4 Any other relevant matters***

Other relevant matters are considered below.

### **2.5.2 Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### **2.5.2.1 Protection of public health and safety**

FSANZ has completed nutrition, microbiological, toxicology and dietary exposure assessments, which are summarised in section 2.2. The risks identified were in relation to the potential for microbiological contamination, potential for allergic reaction in consumers with mustard allergy and the need to ensure levels of substances such as phytates and certain metal contaminants are retained as low as reasonably achievable. Existing requirements and risk management measures will minimise these risks.

### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The application of existing generic labelling requirements will provide information to enable consumers to make informed choices about the presence of rapeseed protein isolate in a food.

### **2.5.2.3 The prevention of misleading or deceptive conduct**

There are no issues identified with this application relevant to this objective.

## **2.5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the food technology, microbiological, nutrition, toxicological and dietary exposure assessments (SD1). The applicant submitted supporting information, including scientific studies, product information and relevant literature, as part of their application. FSANZ also considered other information relevant to the application (referenced in the document and reference list).

- **the promotion of consistency between domestic and international food standards**

The permission the applicant is seeking is consistent with some international food standards for the applicant's product and similar rapeseed protein isolates in Codex standard and guidelines, and also in the EU and USA (refer to section 1.4 – International requirements).

- **the desirability of an efficient and internationally competitive food industry**

Permitting this food ingredient gives the applicant and food businesses the opportunity to replace proteins sourced from animal (e.g. whey) or other plants (e.g. soy, pea), including for use in new product development. As there are permissions for use internationally this may assist in making prices competitive internationally for food businesses who choose to use rapeseed protein isolate. Despite international permissions since 2010, rapeseed protein isolate has not yet been produced commercially for use in food as at 2016 (Campbell, 2016). It is FSANZ's understanding that this is still the case.

- **the promotion of fair trading in food**

FSANZ did not identify any issues relating to this consideration.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline [Addition to Food of Substances other than Vitamins and Minerals](#)<sup>2</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as an ingredient. These specific order policy principles state that permission 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.

FSANZ has determined that permitting rapeseed protein isolate as a novel food for use in a range of foods is consistent with the Ministerial Policy Guideline and the specific order principles for 'Technological Function' for use as a replacement protein source. The principles for 'any other purpose' could also be considered and are met in relation to the functionality associated with protein.

The Ministerial Policy Guideline on [Novel Foods](#)<sup>3</sup> includes specific order policy principles on novel foods. These specific order policy principles state that permission should be granted where:

- public and industry confidence in the food system is maintained.  
The risk assessment and risk management, including labelling requirements and a communication plan will provide confidence for the food industry and consumers. Input from stakeholders including the public and industry (though the call for submissions and extended consultation) has assisted in building confidence for the public and industry in that by granting the permission, subject to specified conditions of use there are no public health and safety concerns.
- the assessment process aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.  
FSANZ has processes in place to ensure access to confidential commercial information and confidential information can be considered and restricted as appropriate.
- consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function.  
Existing labelling requirements in the Code will require that rapeseed protein isolate is clearly identified in the statement of ingredients, in the same manner as for other food ingredient.

### 3 Implementation

The communications plan will be further developed and implemented with ASCIA, allergy support organisations and other expert bodies before the delayed commencement date (refer to 2.4.2).

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<sup>2</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

<sup>3</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Novel-Foods>

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## Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

## **Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code***



### **Food Standards (Application A1175 – Rapeseed protein isolate as a novel food) Variation**

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and title of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

## 1 Name

This instrument is the *Food Standards (Application A1175 – Rapeseed protein isolate as a novel food) Variation*.

## 2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

## 3 Commencement

The variation commences on 30 June 2021.

### Schedule

[1] **Schedule 3** is varied by

[1.1] inserting the following row into the table to S3—2(2), in alphabetical order –

rapeseed protein isolate section S3—40

[1.2] inserting after section S3—39

### S3—40 Specification for rapeseed protein isolate

For rapeseed protein isolate, the specifications are the following:

- (a) Composition:
  - (i) Total protein (%) – no less than 90; and
  - (ii) Carbohydrates (%) – no more than 7; and
  - (iii) Fat (%) – no more than 5; and
  - (iv) Ash (%) – no more than 5; and
  - (v) Moisture (%) – no more than 7;
- (b) Purity:
  - (i) Glucosinolates ( $\mu\text{mol/g}$ ) – no more than 1;
  - (ii) Erucic acid (%) – no more than 0.005;
  - (iii) Phytates (% w/w) – no more than 1.5;
- (c) Metals:
  - (i) Lead (mg/kg) – no more than 0.5;
- (d) Microbiological:
  - (i) Total plate count (cfu/g) no more than 10,000; and
  - (ii) *E. coli* (cfu/10g) absent; and
  - (iii) *Salmonella* spp. (cfu/25g) absent; and
  - (iv) Yeasts and moulds (cfu/g) less than 100.

[2] **Schedule 25** is varied by inserting into the table to section S25—2, in alphabetical order

Rapeseed protein isolate	<ol style="list-style-type: none"><li>1. Must be derived from rapeseed press cake retained after oil pressing from the seeds of one or more of:<ul style="list-style-type: none"><li>(a) <i>Brassica napus</i>;</li><li>(b) <i>Brassica rapa</i>; or</li><li>(c) <i>Brassica juncea</i>.</li></ul></li><li>2. Must not be added to:<ul style="list-style-type: none"><li>(a) infant formula products; and</li><li>(b) food for infants.</li></ul></li><li>3. Must comply with the specifications for rapeseed protein isolate listed in section S3—40.</li></ol>
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## **Attachment B – Draft Explanatory Statement**

### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (FSANZ, the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted application A1175 which seeks to permit rapeseed protein isolate as a novel food. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation.

### **2. Purpose**

The Authority has prepared a draft variation to the Code to permit the sale of rapeseed protein isolate as a novel food, subject to specified conditions of use.

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1175 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

### **6. Variation**

Item [1] amends Schedule 3 of the Code. Sub item [1.1] inserts a reference to rapeseed protein isolate into the table to S3—2(2), linking rapeseed protein isolate to a new specification located at section S3—40. Sub item [1.2] inserts a product specification for rapeseed protein isolate at section S3—40. The specification includes required composition, purity, metal content and microbiological limits.

Item [2] amends Schedule 25 by inserting a permission for the sale of the novel food rapeseed protein isolate into the table to section S25—2, and specifying conditions for its use.

These conditions include a requirement specifying how the substance can be derived; a requirement not to add the substance to infant formula products or food for infants; and a requirement that the substance comply with the specifications listed in section S3—40.



## Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



### Food Standards (Application A1175 – Rapeseed protein isolate as a novel food) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name and title of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

