

**31 July 2020**

**[130–20]**

**Call for submissions – Application A1175**

Rapeseed protein isolate as a novel food

FSANZ has assessed an Application made by DSM Nutritional Products Asia Pacific to amend the Code to permit the use of rapeseed protein isolate as a novel food and has prepared a draft food regulatory measure. Pursuant to section 31 of the Food Standards Australia New Zealand Act 1991 (FSANZ Act), FSANZ now calls for submissions to assist in consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](http://www.foodstandards.gov.au/code/changes/submission/Pages/default.aspx).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](http://www.foodstandards.gov.au/code/changes/submission/Pages/default.aspx).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct application number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](http://www.foodstandards.gov.au/code/changes/Pages/Documents-for-public-comment.aspx). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 4 September 2020**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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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

# Executive summary

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. The rapeseed protein isolate is obtained from *Brassica* species which is low in the anti-nutritional factors, erucic acid and glucosinolates[[1]](#footnote-2) which is important for its addition to food. The collective term for *Brassica* species low in erucic acid and glucosinolates is Canola, which is the common name in North America and Australasia and can be used in place of the term rapeseed.

Food technology, microbiological, nutrition, toxicology and dietary exposure assessments were undertaken by FSANZ to evaluate any potential risks associated with the permission for 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. The *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 plants contain proteins which show an allergenic cross-reactivity with the proteins found in *Brassica* species (such as mustard). Individuals with an allergy to mustard may therefore be at risk of reacting to foods containing rapeseed or rapeseed products. However, FSANZ is not aware of any cases in the Australian or New Zealand population. FSANZ proposes to alert Australasian Society of Clinical Immunology and Allergy and allergy consumer support organisations as to the potential for cross reactivity with mustard allergy.

The microbiological assessment identified a risk in relation to the potential for microbiological contamination within the rapeseed protein isolate. FSANZ concluded that there is a low-medium risk for *Salmonella spp*. and low risk for *Bacillus cereus*. The risk management option is to include microbiological testing parameters for *Salmonella spp*. in the proposed draft variation, which is in addition to the applicant’s current Food Safety System Certification.

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.

Rapeseed protein isolate contains anti-nutritional components such as phytic acid, erucic acid, glucosinolates, and other substances such as heavy metals. Phytate levels of up to 1.5% in rapeseed protein isolate do not raise concerns regarding mineral bioavailability. Erucic acid is not considered to represent a risk because the estimated dietary exposures at both proposed maximum and typical use levels do not exceed the Provisional Tolerable Daily Intake (established by FSANZ). The amount of glucosinolates from rapeseed protein isolate are comparable to the addition of amounts of *Brassica* vegetables (such as broccoli, cauliflower and cabbage) that are within normal daily consumption and are therefore not considered to represent a risk.

Metal contaminants from rapeseed protein isolate did not represent a risk, however amounts of arsenic, cadmium and lead in the diet, including from rapeseed protein isolate, should be kept as low as reasonably achievable.

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 outweigh the associated costs. FSANZ would welcome any more information about costs, benefits or market data.

FSANZ has therefore prepared a draft variation 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) and infant foods.

# 1 Introduction

## 1.1 The applicant

DSM Nutritional Products Asia Pacific 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 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 as 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.

The generic term for edible varieties of rapeseed oil in North America and Australasia is Canola (Can" from Canada and "OLA " meaning "Oil, low (erucic) acid"), bred from rapeseed cultivars of *B. napus* and *B. rapa* to produce oil with less than 2% erucic acid and a meal with less than 30 µm/g glucosinolates (Gunstone, 2004). The term rapeseed protein isolate is referred to throughout this document.

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 *Brassica* species lower in the anti-nutritional factors; erucic acid and glucosinolates than traditional *Brassica* varieties. Anti-nutritional factors such as erucic acid and glucosinolates, 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.

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%.

Table 2.2 in SD1 lists the food classes and examples of foods together with the proposed typical and maximum use levels that could utilise rapeseed protein isolate as a protein source. The proposed typical use levels include bakery products (≤ 5%), beverages, such as fruit juice and blends, soft drinks, formulated beverages, dairy and plant based milks, energy drinks and various dairy products (≤ 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 (≤ 5%) and protein based products such as energy bars, pasta, protein powders, beverages (≤ 10%).

## 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 - 1.3.4 of this report.

### 1.3.1 Novel food permission

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

Section 1.5.1-3 details requirements for foods offered for retail sale can consist of, or have as ingredient, a novel food listed in the table to section S25-2.

The table to Schedule 25-2 (sale of novel foods) lists permitted novel foods together with conditions for use including use levels, restrictions for use and labelling.

### 1.3.2 Identity and purity requirements

Novel foods permitted by section 1.5.1-3 and S25-2 must also meet any relevant identity and purity specifications set out in section S3-2. 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 in the 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 asked 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.

## 1.6 Procedure for assessment

The application is being assessed under the general procedure.

# 2 Summary of the assessment

The risk assessment has been completed and is included in Supporting Document 1 (SD1). Section 2.1 provides a summary of these assessments.

## 2.1 Risk assessment

### 2.1.1 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 *Brassica* species 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.

### 2.1.2 Cross-reactivity with mustard allergy

The risk assessment (refer to SD1 section 5.2.3) has identified that rapeseed plants contain proteins which show an allergenic cross-reactivity with the proteins found in some *Brassica* species (such as mustard). Also one of the *Brassica* species that rapeseed protein isolate can be derived from is brown mustard. Individuals with an allergy to mustard may therefore be at risk of reacting to foods containing rapeseed or rapeseed products. However, FSANZ is not aware of any case studies of mustard allergy in the Australian or New Zealand population, and notes the Australasian Society of Clinical Immunology and Allergy (ASCIA) website does not discuss mustard allergy.

### 2.1.3 Microbiological assessment

FSANZ concludes that as rapeseed protein isolate is a low moisture food it may pose a microbiological risk for *Salmonella* spp. if used in some types of manufactured convenience foods with no subsequent microbiocidal step. The applicant has in place certification in relevant food safety management systems (refer to section 3.3 in SD1) to control foodborne hazards, however there are no microbial reduction steps in the manufacturing process of the rapeseed protein isolate. A screening method was used to assess the risk for *Salmonella* spp. and *B*. *cereus* through consuming the product when used in manufactured convenience foods. The risk assessment concluded that the risk levels were low-medium for *Salmonella* spp. and low for *B*. *cereus*. For cooked foods, such as bakery products, where rapeseed protein isolate is used as an ingredient, the risk level will be low for both *Salmonella* spp. and *B*. *cereus.*

### 2.1.4 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.

### 2.1.5 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 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).

### 2.1.6 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 dietary exposure assessment shows 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 downward.

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 therefore not considered to represent a risk.

Rapeseed proteins show high cross-reactivity with allergenic proteins in mustard, and have the potential to induce allergic responses, including cross-reactivity responses in individuals who are allergic to mustard.

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

## 2.2 Risk management

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 cross-reactivity with allergenic proteins in mustard, the potential for microbiological contamination within the rapeseed protein isolate 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 the sections 2.2.1 to 2.2.4.

### 2.2.1 Cross-reactivity with mustard allergy

Based on the potential for cross-reactivity, individuals who are allergic to mustard may be unaware of the risk posed by rapeseed protein isolate. Therefore in permitting rapeseed protein isolate as a novel food, FSANZ proposes to alert ASCIA and allergy consumer support organisations (e.g. Allergy New Zealand, Allergy & Anaphylaxis Australia) to the potential for cross reactivity with mustard allergy. We note similar approaches have been taken overseas in regard to managing the risk of cross-reactivity between rapeseed/canola products and for individuals with mustard allergy (Health Canada 2019).

### 2.2.2 Microbiological risk

Risks were assessed for *Salmonella* spp. and *Bacillus* *cereus* (refer to SD1 section 3.1) for ready-to-eat protein based foods e.g. protein-enriched powders that may not be heated and used up to levels of 10%. A screening method determined a low-medium risk for *Salmonella* spp. and low risk for *B*. *cereus*. The risk for other foods (e.g. bakery products) which have a pathogen reduction step such as cooking, would be low risk for both pathogens.

The most appropriate risk management option is to include microbiological testing parameters for *Salmonella spp.* (refer to Attachment A, 1.2 Specification for rapeseed protein isolate). This is in addition to the applicants 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.

### 2.2.3 Nutrition

The protein quality of rapeseed protein isolate is comparable with the milk protein casein as measured by PDCAAS[[2]](#footnote-3) and is slightly better than soy protein isolates (see SD1). The nutrition assessment did not identify concerns regarding mineral bioavailability due to phytate levels of up to 1.5% in the rapeseed protein isolate which compare to those found in soy protein isolate. Including a 1.5% maximum limit 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 the EFSA’s assessment, and the US FDA’s no questions asked letters to GRAS notifications for rapeseed protein isolate (EFSA, 2013 and US FDA 2010, 2011 and 2017).

### 2.2.4 Food technology

The food technology assessment considered the source for rapeseed protein isolate, manufacturing processes and composition including anti-nutritional factors and metal contaminants.

Rapeseed protein isolate for use in food is sourced from *Brassica* species low in the anti-nutritional factors erucic acid and glucosinolates. For this reason the *Brassica* species 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.

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. However, the Applicant proposed a limit for lead of 0.5 mg/kg. 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 international limits and to allow for variation in raw materials and manufacturing processes a limit for lead of 0.5 mg/kg has been included in the proposed draft variation to the Code.

### 2.2.5 Labelling of foods containing rapeseed protein isolate

The addition of rapeseed protein isolate to food will be subject to existing generic labelling requirements in the Code which will provide information to enable consumers to make informed choices.

#### 2.2.5.1 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.

#### 2.2.5.2 Mandatory declarations

The applicant has stated sodium bisulphite may be used during the manufacture of rapeseed protein isolate, and if used, then it is in amounts less than 10 mg/kg (see section 2.5 of SD1). *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. 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 were added in combination to bring the total concentration in a food above 10 mg/kg.

#### 2.2.5.3 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 protein content of the food. As the NIP is required to include the average quantity of protein, this will assist consumers to make informed choice about foods containing rapeseed protein isolate.

#### 2.2.5.4 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 before claims can be made. Manufacturers choosing to make nutrition content or health claims about foods containing rapeseed protein isolate would need to meet these requirements.

### 2.2.6 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.

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

## 2.3 Risk communication

### 2.3.1 Consultation

Consultation is a key part of FSANZ’s standards development process. FSANZ developed and applied a basic 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 are called to obtain the views of the public, including interested parties on issues raised by the application and the impacts of regulatory options

### 2.3.2 World Trade Organization (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 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.

## 2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

### 2.4.1 Section 29

#### 2.4.1.1 Consideration of costs and benefits

FSANZ is currently establishing whether or not a formal Regulation Impact Statement is needed in relation to the regulatory change proposed. The Office of Best Practice Regulation (OBPR) advised that FSANZ can commence consultation on this code variation and seek further information on likely economic impacts and provide this to OBPR for assessment of RIS requirements (OBPR correspondence dated 18 May 2020 and OBPR ID 42490). Further information is sought using the “Questions for submitters” later in this section.

FSANZ has also given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. 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, however information received through the consultation process may result in FSANZ arriving at a different conclusion.

##### 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 there are no public health and safety concerns in permitting rapeseed protein isolate.

##### Conclusions from cost benefit considerations

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

| **Questions for submitters** |
| --- |
| ***Do you anticipate any other costs or benefits of permitting rapeseed protein isolate besides what we have outlined in this section?******If not already answered, do you anticipate any specific economic or market impacts of permitting this new ingredient?******Please provide any evidence that you may have to support your views.*** |

#### 2.4.1.2 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.

#### 2.4.1.3 Any relevant New Zealand standards

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

#### 2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

### 2.4.2. Subsection 18(1)

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

#### 2.4.2.1 Protection of public health and safety

FSANZ has completed nutrition, microbiological, toxicology and dietary exposure assessments, which are summarised in sections 2.1.2 to 2.1.5. The risks identified were in relation to the potential for microbiological contamination, cross reactivity for consumers with mustard allergy and the need to maintain exposure to some metal contaminants as low as reasonably achievable. Existing requirements and risk management measures will be considered to minimise these risks.

#### 2.4.2.2 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.

#### 2.4.2.3 The prevention of misleading or deceptive conduct

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

### 2.4.3 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 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 other 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 more competitive internationally for food businesses who choose to use rapeseed protein isolate.

* **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 for [Addition to Food of Substances other than Vitamins and Minerals](http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals)*[[3]](#footnote-4)* 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](https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Novel-Foods)[[4]](#footnote-5) 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 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) will assist in building confidence for the public and industry in that by granting the permission, subject to specified conditions of use there are not 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. The condition to use ‘rapeseed protein isolate’ as an ingredient name will make the nature and identity of the ingredient clear to a consumer.*

# 3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

# 4 References

Codex Alimentarius Commission (2019) [General Standard for Vegetable Protein Products (VPP) CXS174-1989](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B174-1989%252FCXS_174e.pdf). Accessed 22 April 20.

Codex Alimentarius Commission (2019b) [Standard for Named Vegetable Oils CXC 210 – 1999.](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B210-1999%252FCXS_210e.pdf) Accessed 23 April 20.

Codex Alimentarius Commission (2018) [Code of Hygienic Practice for Low-Moisture Foods CXC 75-2015](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B75-2015%252FCXC_075e.pdf). Accessed 22 April 20.

Codex Alimentarius Commission (2003) [General Principles of Food Hygiene CXC 1-1969](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXP_001e.pdf). Accessed 22 April 2020.

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Food Safety Authority of Ireland (FSAI) [Safety Assessment on Novel Food Application for Rapeseed Protein.](https://www.fsai.ie/uploadedFiles/Science_and_Health/Novel_Foods/Applications/2012%20Rapeseed%20protein.pdf) Accessed 22 April 2020.

FSANZ (2017). Record of views from the Advisory Committee on Novel Foods (ACNF) or Novel Foods Reference Group (NFRG) to inquiries on Standard 1.5.1 Novel Foods. <https://www.foodstandards.gov.au/industry/novel/novelrecs/pages/default.aspx>. Accessed April 2020.

Gunstone (2004). Rapeseed and Canola Oil: Production, Processing, Properties and Uses, CRC Press, ISBN 1-4051-1625-0.

Health Canada (2019). Update: Information for Canadians with Mustard Allergy. <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-allergies-intolerances/food-allergies/update-mustard.html>. Accessed 25 May 2020.

US Food and Drug Administration (US FDA) (2010). [GRN327 Cruciferin-rich canola/rapeseed protein isolate and napin-rich canola/rapeseed protein isolate.](https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=327) Accessed 22 April 2020.

US Food and Drug Administration (US FDA) (2011) GRN386 [Canola protein isolate and hydrolysed canola protein isolate.](https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=386&sort=GRN_No&order=DESC&startrow=1&type=basic&search=386) Accessed 22 April 2020.

US Food and Drug Administration (US FDA) (2017) [Canola Protein Isolate from DSM Innovation Company (DSM).](https://www.fda.gov/media/106478/download) Accessed 22 April 2020.

**Attachments**

A. Draft variation to the *Australia New Zealand Food Standards Code*

B. Draft Explanatory Statement

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



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

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.

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 the date of gazettal.

**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) Appearance – tan powder;

 (b) Composition:

 (i) Total protein (%) – no less than 90; and

 (ii) Carbohydrates (%) – no more than 7; and

 (iii) Fat (%) – no more than 2; and

 (iv) Ash (%) – no more than 4; and

 (v) Moisture (%) – no more than 7;

 (c) Purity:

 (i) Glucosinolates (μmol/g) – no more than 1;

 (ii) Erucic acid (%) – no more than 0.005;

 (iii) Phytates (% w/w) – no more than 1.5;

 (d) Metals:

 (i) Lead (mg/kg) – no more than 0.5;

 (e) 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 | 1. Must be derived from rapeseed press cake retained after oil pressing from the seeds of one or more of: (a) *Brassica napus*; (b) *Brassica rapa*; or(c) *Brassica juncea.*2. Must not be added to:(a) infant formula products; and(b) food for infants.3. Must comply with the specifications for rapeseed protein isolate listed in section S3—40. |
|  |  |

## 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 (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. 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 appearance, 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.

1. Anti-nutritional factors such as erucic acid and glucosinolates, are components present in a food that can exert a negative impact on the nutritional quality of the protein. [↑](#footnote-ref-2)
2. Protein digestibility-corrected amino acid score. [↑](#footnote-ref-3)
3. <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals> [↑](#footnote-ref-4)
4. <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-Novel-Foods> [↑](#footnote-ref-5)