

SUBSTANTIAL EQUIVALENCE OPINION

Rapeseed protein

The Food Safety Authority of Ireland (FSAI) received an application in November 2016 from DSM Food Specialities B.V. of the Netherlands for an opinion on the substantial equivalence of its rapeseed protein to the same ingredient already authorised as a novel food on the EU market. The comparator rapeseed protein was authorised by Commission Implementing Decision 2014/424/EU.

The novel ingredient is derived from pressed non-GM rapeseed material (press cake) from which the oil has been removed. It is composed primarily of soluble protein ($\geq 90\%$ w/w) with relatively minor amounts of carbohydrate, fat and ash also present. The protein ingredient is extracted from non-GM seed material using an aqueous salt solution and further processed using physical separation and concentration techniques. The applicant asserts that enzymes or solvents are not used in the production process and that the protein source is intended to be used as a food ingredient similar to the EU-authorised comparator. The applicant considers the ingredient to be novel and fall within the category of “*foods and food ingredients consisting of or isolated from plants*” as set out in *Article 1.2(e)* of the novel food Regulation EC No. 258/97.

Composition

The applicant has provided data demonstrating the compositional similarity of DSM’s rapeseed protein with the comparator in terms of protein, carbohydrate, fat, ash and moisture. The novel ingredient falls within all of the compositional criteria of the comparator as set out in the Annex of Commission Implementing Decision 2014/424/EU.

Total protein	$\geq 90\%$	Ash	$\leq 4\%$
Soluble protein	$\geq 85\%$	Fibre	$\leq 0.5\%$
Moisture	$\leq 7\%$	Total glucosinolates	≤ 1 mmol/l
Carbohydrate	$\leq 7\%$	Total phytate	$\leq 1.5\%$
Fat	$\leq 2\%$	Lead	≤ 0.5 mg/kg

Nutritional Value and Metabolism

The overall composition of the novel ingredient and its authorised counterpart are similar and therefore the nutritional value and metabolism would not be expected to differ.

Intended Uses

Similar to the EU-authorised comparator, the applicant intends to include the novel ingredient as a vegetable protein source in general foods, with the exception of infant formula and follow-on formula.

Level of Undesirable Substances

Batch analysis data relating to microbial contaminants (yeasts/moulds, *Salmonella*, *Escherichia coli*, aerobic bacteria and coliforms), heavy metals (arsenic, cadmium, mercury and lead) and pesticides are provided and do not identify any cause for concern.

Conclusions

The FSAI is satisfied from the information provided by the applicant that rapeseed protein marketed by DSM Food Specialities B.V. is substantially equivalent to rapeseed protein authorised for the EU market by Commission Implementing Decision 2014/424/EU to Siebte PMI Verwaltungs GmbH of Germany. The novel ingredient will be used as a vegetable protein source in foods, with the exception of infant formula and follow-on formula. The designation of the novel ingredient in foods containing it will be “rapeseed protein” in accordance with *Article 2* of the Commission Implementing Decision. In line with *Article 3* of that Decision, a foodstuff containing the novel ingredient shall carry an easily visible and legible statement (in close proximity to the list of ingredients where relevant) that it may cause a reaction in consumers who are allergic to mustard and products thereof.