

Consultation request to determine the status of three ingredients derived from seeds of oilseed rape (*Brassica napus*), pursuant to Article 4(2) of Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods

Recipient Member State: The Netherlands

Assessment by the Novel Food Unit of the Medicines Evaluation Board Agency, 28 June 2024

Name of the foods: three ingredients derived from seeds of oilseed rape.

Description of the foods: The foods in question are three ingredients produced from dehulled seeds of oilseed rape (*Brassica napus*), using a fractionation process that involves a combination of physical and chemical treatments in an aqueous environment. According to the dossier, the resulting products are a powder with approximately 56% protein, a creamy semi-solid product with approximately 20% lipids, and a coarse grain dry fiber with approximately 45% fiber. The applicant proposes to use these preparations as an ingredient in several food products.

Status: When used as a food ingredient these products have to be regarded as novel foods, since no evidence was presented to demonstrate previous consumption to a significant degree of the applicant's products derived from seeds of oilseed rape. The Novel Food Unit notes that some potential uses, which are briefly mentioned in the dossier, may be subject to separate EU legislation on food additives.

Novel food category: The applicant has suggested that the appropriate category from the Novel Food Regulation for these foods would be:

- (iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union and is consisting of, isolated from or produced from a plant or a variety of the same species obtained by:
- traditional propagating practices which have been used for food production within the Union before 15 May 1997; or
 - non-traditional propagating practices which have not been used for food production within the Union before 15 May 1997, where those practices do not give rise to significant changes in the composition or structure of the food affecting its nutritional value, metabolism or level of undesirable substances;

We agree with this suggestion.

Reasons statement: The applicant has not demonstrated a history of consumption for any of the three ingredients derived from seeds of oilseed rape. Convincing information regarding a previous consumption presented in the dossier concerns only rapeseed oil, rather than the actual preparations in the request.

The starting material are whole seeds of oilseed rape (*Brassica napus*). No human consumption to a significant degree within the Union before 15 May 1997 has been established for the whole seeds. For that reason, a novel food application has been assessed by the European Food Safety Authority regarding the safety of whole seeds of oilseed rape (*Brassica napus* L emend. Metzg.) (EFSA NDA Panel, 2023). In practice, these seeds have mainly been used for the production of oil, and standards

for rapeseed oils have been described (Codex Alimentarius, 2023). Such rapeseed oil was widely consumed worldwide, and is not considered to be a novel food in Europe. For other food ingredients derived from the seeds, a human consumption to a significant degree within the Union before 15 May 1997 has not been demonstrated. Therefore, rapeseed protein, partially defatted rapeseed powder, as well as rapeseed oil high in unsaponifiable matter, have been assessed and authorized as novel foods (EC 2006; EC 2014; EC 2021)

The applicant has mentioned similarities of their products with authorized novel foods. However, the present authorizations do not cover the newly developed products. The fact that somewhat similar preparations from rapeseed have already been assessed as novel foods has no impact on the novelty of these preparations.

References:

Codex Alimentarius, 2023. Codex standard for named vegetable oils. Codex Standard 210-1999/2023. https://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

EC 2006: Commission Decision of 24 October 2006 authorising the placing on the market of rapeseed oil high in unsaponifiable matter as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

[Decision - 2006/722 - EN - EUR-Lex \(europa.eu\)](#)

EC 2014: Commission Implementing Decision of 1 July 2014 authorising the placing on the market of rapeseed protein as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (notified under document C(2014) 4256)

[Implementing decision - 2014/424 - EN - EUR-Lex \(europa.eu\)](#)

EC 2021: Commission Implementing Regulation (EU) 2021/120 of 2 February 2021 authorising the placing on the market of partially defatted rapeseed powder from Brassica rapa L. and Brassica napus L. as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

[Implementing regulation - 2021/120 - EN - EUR-Lex \(europa.eu\)](#)

EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods, and Food Allergens), 2023. Safety of whole seeds of oilseed rape (Brassica napus L emend. Metzg.) as novel food pursuant to Regulation (EU) 2015/2283. EFSA Journal 2023;21(1):7706, 20 pp.

[Safety of whole seeds of oilseed rape \(Brassica napus L emend. Metzg.\) as a novel food pursuant to Regulation \(EU\) 2015/2283 \(wiley.com\)](#)