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

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Abstract

Following a request from the European Commission, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) was asked to deliver an opinion on whole seeds of oilseed rape as a novel food (NF) pursuant to Regulation (EU) 2015/2283. The NF consists of seeds of oilseed rape, in particular double low white flowering varieties of Brassica napus (oilseed rape Brassica napus L. emend. Metzg). The NF's oilseed rape is produced following drying, cleaning and storage procedures traditionally used for oilseed rape in oil production. The NF is proposed to be used as an ingredient in 'Bread and rolls with special ingredients added' and 'Gluten free bread'. The target population is the general population. The highest daily intake of the NF was estimated for young children as 92.6 mg/kg body weight (bw) per day. The Panel notes that intakes of the NF can result in considerably increased levels of glucosinolates consumption as compared to intakes of glucosinolates from background diets. The Panel asked the applicant for additional studies to support the safety of the NF, but these were not provided. The Panel concludes that the safety of whole seeds of oilseed rape under the proposed conditions of use has not been established.

Keywords: novel foods, oilseed rape, rapeseed, Brassica, safety

Requestor: European Commission

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1. Introduction

1.1. Background and terms of reference as provided by the requestor

On 14 September 2018, the applicant "Erik Tybirk" submitted a request to the European Commission in accordance with Article 10 of Regulation (EU) 2015/2283[1] to place on the EU market whole seeds from double low varieties of oilseed rape (*Brassica napus* L emend. Metzg.) as a novel food.

The novel food (whole seeds from double low varieties of oilseed rape) is intended to be used as an ingredient in a number of foods.

In accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Commission asks the European Food Safety Authority to provide a scientific opinion by carrying out the assessment of whole seeds from double low varieties of oilseed rape (*Brassica napus* L emend. Metzg) as a novel food.

2. Data and methodologies

2.1. Data

The safety assessment of this novel food (NF) is based on data supplied in the application and information submitted by the applicant following EFSA's requests for supplementary information.

Administrative and scientific requirements for NF applications referred to in Article 10 of Regulation (EU) 2015/2283 are listed in the Commission Implementing Regulation (EU) 2017/2469[2].

A common and structured format on the presentation of NF applications is described in the EFSA guidance on the preparation and presentation of an NF application (EFSA NDA Panel, 2016). As indicated in this guidance, it is the duty of the applicant to provide all of the available (proprietary, confidential and published) scientific data (both in favour and not in favour) that are pertinent to the safety of the NF.

This NF application does not include a request for the protection of proprietary data.

2.2. Methodologies

The assessment follows the methodology set out in the EFSA guidance on NF applications (EFSA NDA Panel, 2016) and the principles described in the relevant existing guidance documents from the EFSA Scientific Committee. The legal provisions for the assessment are laid down in Article 11 of Regulation (EU) 2015/2283 and in Article 7 of Commission Implementing Regulation (EU) 2017/2469. The legal provisions for the assessment of food for special medical purposes are laid down in Regulation (EU) No 609/2013 and in Commission Delegated Regulation (EU) 2016/128[3].

This assessment concerns only the risks that might be associated with consumption of the NF under the proposed conditions of use and is not an assessment of the efficacy of the NF with regard to any claimed benefit. Furthermore, this assessment is not an assessment on whether the NF is suitable as stipulated by Regulation (EU) No 609/2013.

3. Assessment

3.1. Introduction

The NF which is the subject of the application falls under the food category 'food produced from plants', as described in Article 3 of Regulation (EU) 2015/2283. This NF consists of whole seeds of oilseed rape, in particular double low white flowering varieties of *Brassica napus* (oilseed rape_ *Brassica napus* L emend. Metzg). The NF is intended to be used as an ingredient in 'Bread and rolls with special ingredients added' and 'Gluten free bread'. The target population is the general population.

[1] Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) N0 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001. OJ L 327, 11.12.2015, pp. 1–22.

[2] Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. OJ L 351, 30.12.2017, pp. 64–71.

[3] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes. OJ L 25, 2.2.2016, p. 30–43.

3.2. Identity of the NF

The NF is whole seeds of oilseed rape (*Brassica napus* L emend. Metzg.) from cultivars, which according to the applicant fulfil the following specifications in the UPOV[4] variety descriptions: content of erucic acid less than 2% by mass in the oil; content of glucosinolates, low (maximum of 15 μmol/g seed at 9% moisture); colour of petals, white or crème; and no seeds from genetically modified organisms (GMOs). The NF mainly consists of fats (~ 48%), carbohydrates (~ 25%) and proteins (~ 18%).

The scientific name of the plant is *Brassica napus* L. The botanical family is *Brassicaceae*. The common names are raps, oilseed rape, rapeseed, canola, colza. The part of the plant to be used for food are the seeds (referred here in the application as 'whole seeds').

3.3. Production process

According to the applicant, the NF is produced according to good agricultural practice (GAP) and good manufacturing practice (GMP), and in compliance with Hazard Analysis Critical Control Points (HACCP) principles.

The production of oilseed rape for food use in the EU has mainly been directed towards edible oil. The novelty of this application is the use of whole seeds as food. The production of rapeseed for this NF is very similar to that of traditional production of rapeseed for oil in terms of cultivation, harvesting, drying, cleaning and storage. According to the applicant, the full production system is not yet in place and for example, the NF producer will invest in a magnetic device for the removal of iron pieces and a packaging machine when the application is approved.

Two types of oilseed rape are grown in Europe, spring oilseed rape and winter oilseed rape, the latter being the most cultivated variety. Seeds from these two types of varieties are very similar and are both used for the NF. The production of certified seed for sowing is routine for European farming that guarantees high quality of the seed used with regard to weed contaminations and purity of the variety used.

The applicant considered potential hazards for each of the steps from sowing to end user. Cultivation, harvest and drying of seeds should comply with current procedures and regulations as for whole seed rape for oil production.

The NF is only to be used as an ingredient in foods that will undergo a heat treatment during baking, which according to the applicant, contributes to reduce the microbiological content, to inactivate the myrosinase enzyme involved in the cleavage of glucosinolates and to improve the organoleptic properties.

The content of glucosinolates can vary between different seed lots. According to the applicant, seed lots with more than 15 μmol glucosinolates/g seed will not be used.

The Panel considers that the production process is sufficiently described.

3.4. Compositional data

In order to confirm that the manufacturing process is reproducible and adequate to produce on a commercial scale a product with the required characteristics, the applicant provided a batch-to-batch analysis of four independent batches (Table 1) for the NF, where physico-chemical parameters were measured, as well as the occurrence of microbiological and chemical contaminants. All analyses were conducted following internationally recognised standard methods or otherwise, validated internal methods. Information was provided on the accreditation of the laboratories that conducted the analyses presented in the application.

[4] The International Union for the Protection of New Varieties of Plants, https://www.upov.int.

Table 1: Batch to batch analysis of the NF

Parameter (per 100 g)	Batch number				Method of analysis
	#1	#2	#3	#4	
Energy (kJ)	2,294	2,276	2,162	2,323	
Energy (kcal)	557	553	525	564	
Total fat (g)	49.4	48.9	44.2	47.7	ISO 11085:2015/Gravimetry
Saturated fat	4.2	4.2	3.4	3.0	AOCS 1f-96 (2009)/GC-FID
Monounsaturated	27.9	27.6	25.9	30.3	AOCS 1f-96 (2009)/GC-FID
Polyunsaturated	15.0	14.8	12.7	12.2	AOCS 1f-96 (2009)/GC-FID
Total carbohydrate* (g)	23.9	25.4	26.9	22.7	Calculation
Sugars (g)	3.8	3.5	3.9	3.2	AOAC 982.14, mod/HPAEC-PAD
Dietary fibre (g)	24.1	25.9	25.8	27.6	AOAC 985.292003/Enzymatic-gravimetry
Protein (N*6.25) (g)	17.1	15.0	18.3	19.3	NMKL 6:2003 mod./Kjeldahl (titrimetry)
Ash (g)	3.9	3.6	3.0	3.8	NMKL 173:2005/Gravimetry
Water (g)	5.7	7.1	7.6	6.5	NMKL 23:1991 mod./Gravimetry
Peroxide value (meq/kg fat)	1.7	< 0.4	< 0.4	< 0.4	ISO27107:2009/Titrimetry
Arsenic (mg/kg)	< 0.1	< 0.1	< 0.1	< 0.1	EN ISO 17294m:2016/ICP-MS
Cadmium (mg/kg)	0.052	0.054	0.020	0.086	
Mercury (mg/kg)	< 0.005	< 0.005	< 0.005	< 0.005	
Lead (mg/kg)	< 0.05	< 0.05	< 0.05	< 0.05	
Coliforms (cfu/g)	< 10	< 10	< 10	< 10	AOAC 991.14/E-Cultural technique (media film)
E. coli (cfu/g)	< 10	< 10	< 10	< 10	AOAC 991.14/E-Cultural technique (media film)
Salmonella (in 25 g)	ND	ND	ND	ND	NMKL 71/D-Cultural technique (non-chromogenic media)
Aerobic plate count (cfu/g)	99,000	< 1,000	18,000	< 1,000	NMKL 86/D-Cultural technique (non-chromogenic media)
Moulds (cfu/g)	< 100	< 100	1700	100	NMKL98/E-Cultural technique (non-Chromogenic media)
Yeast (cfu/g)	< 100	< 100	< 100	100	NMKL98/E-Cultural technique (non-Chromogenic media)

AOAC: Association of Official Analytical Collaboration; AOCS: American Oil Chemist Society; cfu: colony forming units; GC-FID: Gas Chromatography with Frame Ionisation Detection; HPAEC-PAD: High-performance anion exchange chromatography–pulsed amperometric detection; ICP-MS: inductively coupled plasma-mass spectrometry; ISO: International Organisation for Standardisation; ND: not detected; NMKL: Nordic Committee on Food Analysis.
*: By difference: 100%–[protein % + moisture % + fat % + ash %].

Upon request of EFSA, the applicant also provided microbiological tests on additional batches at different storage times (Table 2). The Panel noted the high variability in total plate count between the batches, with two exceeding the specifications proposed by the applicant. This parameter is considered a process hygiene indicator and could affect the safety of the NF.

Table 2: Microbiological quality of the NF

Parameter (unit)	Batch number					Method
	#5 (67 months storage)	#6 (55 months storage)	#7 (45 months storage)	#8 (21 months storage)	#9 (9 months storage)	
Coliforms (cfu/g)	< 10	< 10	< 10	< 10	< 10	AOAC 991.14/E-Cultural technique (media film)
E. coli (cfu/g)	< 10	< 10	< 10	< 10	< 10	AOAC 991.14/E-Cultural technique (media film)
Salmonella (in 25 g)	ND	ND	ND	ND	ND	NMKL 71/D-Cultural technique (non-chromogenic media)
Aerobic plate count (cfu/g)	400	400	2,700	62,000	130,000	NMKL 86/D-Cultural technique (non-chromogenic media)
Moulds (cfu/g)	< 10	< 10	< 10	< 10	260	NMKL98/E-Cultural technique (non-chromogenic media)
Yeast (cfu/g)	< 10	< 10	190	< 10	64	NMKL98/E-Cultural technique (non-chromogenic media)
Bacillus cereus (cfu/g)	< 10	< 10	< 10	< 10	< 10	Mannitol-Egg-Yolk-Polymyxin Agar-S ISO 7932
Aerobic spores (cfu/g)	< 100	< 100	< 100	100	< 100	Blood Agar-S NMKL 189

AOAC: Association of Official Analytical Collaboration; cfu: colony forming units; ISO: International Organisation for Standardisation; NMKL: Nordic Committee on Food Analysis.

This NF includes varieties of the type Standard Double Low (Standard 00) where oil is the most abundant compound, ranging from ~45 to 52% (Table 1; OECD, 2011). According to the applicant, all new potential varieties are analysed for the most important constituents before being authorised for cultivation. The seed oil composition was tested. To this end, the applicant analysed several batches as described in Table 3.

Table 3: Batch analysis of fatty acid in oilseed rape seeds

Fatty acid (%)	Batch number					Method of analysis
	#10	#11	#12	#13	#14	
Oleic acid (C18:1)	60.7	62.4	56.3	54.5	61.5	ISO 5508
Linoleic acid (C18:2)	20.6	20.9	24.2	25.4	21.7	ISO 5508
Linolenic acid (C18:3)	10.5	9.8	11.1	11.5	10.4	ISO 5508
Erucic acid	0.3	0	0	0	0	ISO 5508

ISO: International Organisation for Standardisation.

Total and individual glucosinolates were analysed (method ISO 9167) by the applicant (see Table 4).

Table 4: Total and individual glucosinolates in the NF (method ISO 9167)

Glucosinolate (μmol/g)	Batch number						
	#15	#16	#17	#18	#19	#20	#21
Total glucosinolates	10.1	7.0	7.2	16.1	15.2	8.1	7.7
Epiprogoitrin	< 0.10	< 0.10	< 0.10	0.18	0.16	< 0.10	< 0.10
Glucobrassicanapin	0.44	< 0.10	0.35	1.71	1.15	0.74	0.38
Glucobrassicin	0.29	0.11	< 0.10	0.20	0.13	0.11	< 0.10
Gluconapin	1.84	0.66	1.38	3.31	3.47	1.79	1.89
Gluconapoleiferin	0.23	< 0.10	0.19	0.64	0.48	0.27	0.19
Gluconasturtiin	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10	< 0.10
Progoitrin	4.37	2.50	3.41	7.08	7.45	3.5	3.71
4-hydroxyglucobrassicin	2.9	3.75	1.88	3	2.31	1.65	1.56

The Panel notes that the content of total glucosinolates in two batches is above the values suggested in the specifications (Section 3.5).

Tannins, phytic acid and isothiocyanate assessed by the applicant can be found in Table 5.

Table 5: Tannins, phytic acid and isothiocyanates in the NF

Parameter	Batch number				Method
	#22	#23	#24	#25	
Tannins as tannic acid (%)	0.440	0.940	0.780	0.940	ISO 9648 UV/VIS
Phytic acid (%)	1.93	2.16	0.96	2.14	Anal. Biochemistry Vol 77:536–539 (1977) /ICP-OES
Isothiocyanates mg/kg	17.00	75.00	43.00	34.00	Titrimetry (ANA-07.1672)

ICP-OES: inductively coupled plasma-optical emission spectrometry; ISO: International Organisation for Standardisation; UV/VIS: ultraviolet visible spectrophotometry.

Phenolic compounds (sinapine and sinapic acid) were analysed in seven batches (Table 6).

Table 6: Sinapine and sinapic acid in the NF

Parameter	Batch number							Method
	#26	#27	#28	#29	#30	#31	#32	
Sinapine (mg/g)	11.4	12.5	12.2	11	12.7	10.1	10.3	HPLC-DAD
Sinapic acid (mg/g)	0.24	0.48	0.32	0.56	0.59	0.48	0.36	HPLC-DAD

HPLC-DAD: High-performance liquid chromatography with diode array detection.

Phytate was also analysed and the average content was 1.8% of the seed weight (Table 5).

Pesticides and aflatoxins were analysed and found to be below the applicable legal limits[5,6] for this type of food or for similar foods. Pesticides were not detected in four batches of the NF determined by pesticide screening (Methods DIN EN 15662 2018-6mod/LC-MS/MS[7]; ASU L 00.00-34:2010-09/GC-FPD; ASU L 00.00-34:2010-09/GC-EDC; ASU L 00.00-34:2010-09/GC-MS[8]). Aflatoxins B1, B2, G1 and G2 were below detection limits in all the batches analysed (total aflatoxins < 0.4 μg/kg, by method EN 14123/IAC-LC-FLD[9]).

The Panel considers that the information provided on the composition of the NF is sufficient for characterising the NF.

[5] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
[7] LC-MS/MS: liquid chromatography with tandem mass spectrometry.
[8] GC–MS: gas chromatography–mass spectrometry.
[9] IAC-LC-FLD: Immunoaffinity column-liquid chromatography-fluorescens detection.

3.4.1. Stability

The applicant initially provided data on composition after a storage of 9, 31, 68 and 81 months (Table 1). Upon request of EFSA, the applicant also provided microbiological tests on additional samples stored for longer than 40 months (see Table 2). Seeds are dried after harvest and stored at less than 8% water content. Considering that whole seeds are stored intact, chemical degradation due to lipid oxidation is considerably reduced.

The applicant proposes 3 years shelf-life from harvest, which, according to the applicant, is similar to other seeds used in baked products (e.g. sunflower, linseed, chia seeds, sesame seeds). The Panel notes the high total plate count in some of the batches of this application. Total plate count is considered a process hygiene indicator and could affect the safety of the NF. Therefore, the Panel could not conclude on the stability of the NF.

3.4.1.1. Stability in food products

The applicant performed microbiological tests of baked bread with rapeseeds in five batches and no issues of concern were identified in the batches provided.

Acrylamide data (method LC-MS/MS) were provided by the applicant in seven batches of seeds that underwent a thermal treatment to simulate baking conditions (reaching temperatures up to 165°C). The values were of < 30 (LOQ) μg/kg for all samples apart from 2 that were 44 μg/kg and 35 μg/kg. The values are below the benchmark levels for the presence of acrylamide[10] in wheat-based bread and soft bread other than wheat-based, defined as 50 and 100 μg/kg, respectively.

3.5. Specifications

The specifications of the NF are indicated in Table 7.

Table 7: Specifications of the NF

Parameter g/100 g (%)	Specifications
Dry matter	92–94%
Protein	15–22%
Fat	45–52%
Carbohydrate	21–28%
Dietary fibre	23–29%
Ash	2.8–4.4%
Water content	Max 8%
Glucosinolates	≤ 15.0 μmol/g seed at 9% moisture(a)
Cadmium	≤ 0.20 mg/kg
Lead	≤ 0.20 mg/kg
Purity of the seed lot	≥ 98% of seed lot is rapeseed Max 0.3% seed of other species Max 10 seeds of *Raphanus raphanistrum* per 100 g Max. 5 seeds of Rumex per 100 g seeds Max. 10 pieces of *Sclerotinia sclerotiorum* per 100 g
Aflatoxin B1	≤ 2 μg/kg
Total aerobic plate count	≤ 5,000 cfu/g
Yeasts and moulds	< 1,000 cfu/g
Coliforms	< 100 cfu/g
E. coli	< 10 cfu/g
Salmonella	Not detected in 25 g
Bacillus cereus	< 100 cfu/g

cfu: colony forming units.
(a): These are values reported by the applicant in the dossier.

[10] Commission regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food.

The applicant proposed a specification for total plate count as ≤ 100,000 cfu/g and for *Bacillus cereus* as < 1,000 cfu/g. As mentioned in Section 3.4.1, the Panel noted a high total plate count in some of the batches of this application. Total plate count is considered a process hygiene indicator and could affect the safety of the NF. A lower specification should be met, and the Panel proposes a specification limit of ≤ 5,000 cfu/g for total plate count. Similarly, a lower specification should be met for *B. cereus* and the Panel proposes a specification limit of < 100 cfu/g.

3.6. History of use of the NF and/or of its source

3.6.1. History of use of the source

Whole seeds of rapeseed are mainly used for the production of oil, which is widely consumed in Europe and worldwide. Rapeseed double low (00) varieties are bred to obtain a low erucic acid and glucosinolate content (OECD, 2011). Standards for oils have been described (Codex Alimentarius, 1999 (2017)). Key constituents having antinutritional and toxic effects have been already described (OECD, 2011). Furthermore, rapeseed protein isolates as well as rapeseed powder have been assessed by EFSA (EFSA NDA Panel, 2013, 2020).

By-products of rapeseed oil production, such as rapeseed meal, are used for feed. The Panel notes that inclusion rates of rapeseed meal are restricted because of glucosinolates (EFSA CONTAM Panel, 2008; OECD, 2011).

3.6.2. History of use of the NF

The use of whole seeds of rapeseed for human consumption has been reported anecdotally (Miller-Cebert et al., 2009; OECD, 2011).

3.7. Proposed uses and use levels and anticipated intake

3.7.1. Target population

The target population proposed by the applicant is the general population.

3.7.2. Proposed uses and use levels

The NF is intended to be used as an ingredient in 'Bread and rolls with special ingredients added' and 'Gluten free bread'. These food products defined using the FoodEx2[11] hierarchy, and the maximum proposed use levels are reported in Table 8.

Table 8: Food categories according to FoodEx2 hierarchy and maximum use levels intended by the applicant

FoodEx2 level	FoodEx2 code	Food category	Max use level (g NF/100 g)
A005K	L4	Bread and rolls with special ingredients added	4
A005R	L4	Gluten free bread	4

The seeds must be heated before they are consumed. Therefore, the seeds are not intended to be used as raw seeds.

3.7.3. Anticipated intake of the NF

EFSA performed an intake assessment of the anticipated daily intake of the NF based on the applicant's proposed uses and maximum proposed use levels (Table 8), using individual data from the EFSA Comprehensive European Food Consumption Database (EFSA, 2011). The lowest and highest mean and 95th percentile anticipated daily intake of the NF (on a mg/kg body weight (bw) basis), among the EU dietary surveys, are presented in Table 9.

The estimated daily intake of the NF for each population group from each EU dietary survey is available in the Excel file annexed to this scientific opinion (under supporting information).

[11] FoodEx2 is an EFSA standardised food classification and description system https://www.efsa.europa.eu/en/data/data-standardisation

Table 9: Intake estimate for the NF resulting from the use of the NF as an ingredient in the intended food categories at the maximum proposed use levels

Population group	Age (years)	Mean intake (mg/kg bw per day)		P95 intake (mg/kg bw per day)	
		Lowest[a]	Highest[a]	Lowest[b]	Highest[b]
Infants	< 1	0.18	8.7	0.0	72.9
Young children[d]	1 to < 3	0.56	26.8	0.0	92.6
Other children	3 to < 10	0.09	23.6	0.0	92.2
Adolescents	10 to < 18	0.05	12.8	0.0	70.6
Adults[c]	≥ 18	2.0	9.3	16.7	46.2

(a): Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 01/02/2022. The lowest and the highest averages observed among all EU surveys are reported in these columns.
(b): Intakes are assessed for all EU dietary surveys available in the food comprehensive database on 01/02/2022. The lowest and the highest P95th observed among all EU surveys are reported in these columns.
(c): Includes elderly, very elderly, pregnant and lactating women.
(d): Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

3.7.4. Estimate of exposure to undesirable substances

The applicant provided exposure calculations for glucosinolates, phytic acid and sinapine/sinapic acid.

Glucosinolates are considered undesirable substances in animal feed because of their anti-nutritional effects and potential to cause reduction in animal growth. Consequently, recommendations to restrict the use of rapeseed and rapeseed meal in farm animals have been set (EFSA CONTAM Panel, 2008). Progoitrin (and its cleavage products) is one of the main glucosinolates in *B. napus* known to have adverse effects in animals. Regarding humans, no health-based guidance values currently exist for glucosinolates, but its degradation products interfere with iodine uptake into the thyroid and subsequent synthesis of thyroid hormones and thereby may be involved in the development of goitre and hypothyroidism (Vanderpas, 2003; Bischoff, 2016; Di Dalmazi and Giuliani, 2021). Considering a maximum concentration of total glucosinolates of 15 μmol/g and of the individual glucosinolates progoitrin (7.45 μmol/g), glucobrassicin (0.29 μmol/g), 4-hydroxyglucobarassicin (3.75 μmol/g), gluconapin (3.47 μmol/g) and epigoitrin (0.18 μmol/g) in the NF, exposure to total and individual glucosinolates in the different population groups can be found in Table 10. These estimates are considered further in the nutrition and toxicological assessment (Sections 3.9 and 3.10).

Table 10: Anticipated highest P95 of daily intake of total and individual glucosinolates from the NF as ingredient in foods described in Table 9

Population group	Age (years)	Total glucosinol-ates (μmol/day)	Progoitrin (μmol/day)	Glucobrassicin (μmol/day)	4-hydroxyglu-cobrassicin (μmol/day)	Gluconapin (μmol/day)	Epigoitrin (μmol/day)
Infants	< 1	5.4	2.7	0.1	1.4	1.3	0.07
Young children[b]	1 to < 3	16.7	8.3	0.3	4.2	3.8	0.2
Other children	3 to < 10	31.9	15.8	0.6	8	7.3	0.4
Adolescents	10 to < 18	42.3	21	0.8	10.5	9.8	0.5
Adults[a]	≥ 18	48.5	23.9	0.9	12	11.1	0.6

(a): Includes elderly, very elderly, pregnant and lactating women.
(b): Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).

The maximum concentration of phytic acid in the NF was 2.2 g/100 g. Considering an exposure of the NF of 3.2 g per day for adults, it will result in 0.07 g of phytic acid.

Sinapine and sinapic acid concentrations are comparable to those in other foods such as mustard, onion, broccoli, cabbage, strawberry (EFSA NDA Panel, 2013, 2020; Nićiforović and Abramovič, 2014).

3.8. Absorption, distribution, metabolism and excretion (ADME)

No ADME data with the NF were submitted. Information on ADME provided is mainly based on studies published in the literature and previous EFSA opinions on rapeseed protein (EFSA NDA Panel, 2013, 2020). In those cases, the ADME analysis focused on protein, fibre as well as other constituents such as glucosinolates, sinapine and phytates because they were considered relevant compounds for a focused toxicological and/or nutritional assessment (EFSA NDA Panel, 2013, 2020).

3.9. Nutritional information

The major components of the NF are fat, protein, carbohydrate and dietary fibre.

In relation to the fat of the NF, the fatty acid composition is typical for the food grade rapeseed oil (Codex Alimentairus, 1999, 2017) and it does not raise concern.

Considering intake levels of the NF (Section 3.7.3) with a maximum content of protein of 19.3% reported in the batch-to-batch analysis, the highest mean and highest 95th percentiles daily protein intake from the NF have been estimated to reach maximum levels of 0.01 g/kg bw per day in adults. The Panel notes that the protein intake from the NF remains well below the population reference intakes (PRIs) for protein for all age groups. Similarly, the contribution of dietary fibre is rather small when considering anticipated intake of the NF and the exposure to the analysed minerals does not raise concern.

With regard to antinutritional factors, the assessment of this NF focused on glucosinolates, phytate and sinapine.

Potential adverse effects of the NF are primarily related to glucosinolates present in the whole seeds. These compounds are found in plants of the family *Brassicaceae*, e.g. cabbage, cauliflower, turnip, broccoli, mustard seed. Rapeseed oil, which is the main product from rapeseeds for current human consumption, does not significantly contribute to the dietary intake of glucosinolates.

Glucosinolates are broken down by myrosinase, a plant enzyme that is released from specific cell compartments as a result of cell disruption, e.g. by mechanical steps during food preparation or by chewing. It releases bioactive products including isothiocyanates, goitrin, nitriles and thiocyanates. Inactivation of the myrosinase enzyme prevents the formation of the cleavage products, but not entirely, as enzymatic activity of the gut microbiota can also break down glucosinolates. Furthermore, uncooked vegetables in the diet might also retain the myrosinase enzyme activity. The applicant provided an exposure assessment to total and individual glucosinolates progoitrin, glucobrassicin, 4-hydroxyglucobrassicin, gluconapin and epigoitrin from the NF (see Section 3.7.4). The applicant also provided glucosinolate intakes from background diet, mainly from cruciferous plants such as the *Brassicaceae* family. The applicant considered average occurrence levels of glucosinolates in plants based on information in the public literature (Verkerk and Dekker, 2004; Song and Thornalley, 2007; Felker et al., 2016; Lafarga et al., 2018) resulting in intakes of total glucosinolates from the background diet in adults and adolescents as follows: 117.8 and 45.8 μmol/day for total glucosinolates respectively, 16.1 and 5.7 μmol/day for progoitrin, respectively, and 53.8 and 14.6 μmol/day for glucobrassicin (see Annex B). The Panel notes that uncertainties remain in this calculation of glucosinolate intake from background diet because of the lack of a comprehensive database on total and individual glucosinolates content from commonly consumed foods. Furthermore, there were insufficient data available to estimate background dietary intake of 4-hydroxyglucobrassicin, gluconapin and epigoitrin. According to the data provided by the applicant, the intake of total glucosinolates from the NF could increase glucosinolate consumption by > 90% or > 40% as compared to the highest background mean intake of glucosinolate estimates for adolescents and adults, respectively. The intake of progoitrin from the NF could increase progoitrin by > 300% or > 100% as compared to the highest mean background intake of progoitrin estimates for adolescents and adults, respectively. This scenario may increase the risk of goitre or aggravate iodine deficiency (see Section 3.7.4) when iodine supply is low. In this context, the Panel notes that in specific European countries, iodine deficiency is an issue that in particular concerns pregnant and lactating women, children and adolescents (Ittermann et al., 2020; Remer et al., 2022; Woodside and Mullan, 2021; Henjum et al., 2019; Robert Koch Institute, 2015; Gärtner, 2016).

In relation to phytate, its content in the NF is < 2.2% and similar to concentrations in other foods (Schlemmer et al., 2009). Likewise, the content of sinapine is comparable to those in other foods (EFSA NDA Panel, 2013).

Considering the composition of the NF and the proposed conditions of use, the Panel cannot conclude on the nutritional assessment of the NF because of the high levels of glucosinolates in the NF and the lack of a relevant health-based guidance value.

3.10. Toxicological information

The applicant did not provide any toxicological studies with the NF. The toxicological assessment was performed following a tiered approach. Considering the knowledge on the product ADME (see Section 3.8), most parts of the NF will be absorbed in the gastrointestinal tract (protein, fat and minor constituents). For the assessment, additional information was taken into account using the safety data available on rapeseed protein (EFSA NDA Panel, 2013, 2020) and the history of consumption of rapeseed oil.

In relation to undesirable compounds in the NF, it is noted that the NF is whole seed of rapeseed double low (00) cultivars of *Brassica napus*. Double low cultivars in this NF are varieties of low content of erucic acid and of reduced content of glucosinolates.

Considering the NF origin and the batch test results (see Section 3.4), the Panel considers that the concentration of erucic acid in the NF does not raise concerns.

The biological effects of plant glucosinolates in mammalian species are predominantly related to the glucosinolate-derived compounds (isothiocyanates, goitrin, nitriles and thiocyanate). They have been shown to interfere with iodine uptake (thiocyanate ion) and the synthesis of thyroid hormones triiodothyronine (T3) and plasma thyroxine (T4) (5-vinyloxazolidine-2 thione), leading to hypothyroidism and enlargement of the thyroid gland (goitre). Because of the changes in thyroid function, clinical signs of toxicity described in farm animals include growth retardation, reduction in performance (milk and egg production), impaired reproductive activity and impairment of liver and kidney functions (EFSA CONTAM Panel, 2008). Comprehensive feeding trials in farm animals fed rapeseed meal or press cakes have been conducted, resulting in the recommendation to restrict the total glucosinolate content to 1–1.5 mmol per kg feed for monogastric animals, and even lower in feeds for young animals (EFSA CONTAM Panel, 2008). However, data on the toxicity of individual glucosinolates for food-producing animal species are very limited. The common practice combines the selection of low-glucosinolate plant varieties as forage plants and of maximum inclusion rates in animal diets. The applicant also referred to additional animal studies where toxicity of glucosinolates was investigated (Bille et al., 1983; Vermorel et al., 1986; Bjerg et al., 1989; Martins et al., 2022). However, none of these studies are suitable for establishing a health-based guidance value.

In addition, the applicant assessed potential adverse effects of tannins, sinapine, sinapic acid and phytic acid. The concentrations of these compounds in rapeseeds are comparable to other foods and have been previously assessed by EFSA (EFSA NDA Panel, 2013, 2020). Finally, the applicant also provided data on the formation of acrylamide in rapeseed when baked (see Section 3.4). The values reported in this application are in line with similar other products as previously described (EFSA CONTAM Panel, 2015).

3.10.1. Genotoxicity

No genotoxicity studies with the NF were provided. Given the nature of the NF, the Panel considered such test not necessary for the safety assessment.

3.10.2. Subchronic toxicity

No subchronic toxicity study with the NF was provided.

3.10.3. Human studies

No human studies with the NF were provided by the applicant.

The applicant addressed concerns related to glucosinolates by providing intakes of glucosinolates from the background diet and from the NF, and by referring to the scientific publications that reported on effects of glucosinolate intakes in various clinical trials (Langer et al., 1971; McMillan et al., 1986; Kensler et al., 2005; Shapiro et al., 2006). The applicant argues that based on these studies, so-called 'safe levels' for total and/or individual glucosinolates can be assumed.

Langer et al. (1971) investigated, in a total of 34 adult volunteers aged 19–46 years, radioiodine (131I) uptake into the thyroid following single administration of various doses of crystalline goitrin (isolated from rape seeds *Brassica napus oleifera*) in starch capsules. While the administration of 50

and 25 mg doses of goitrin resulted in significant decreases of the radioiodine uptake (at 50 mg in two out of six subjects an almost complete block of the uptake was found), in subjects receiving two doses of 10 mg goitrin (given 12 and 1 h before the radioiodine test), the mean individual change was non-significant. Based on this study, the applicant suggests that the administration of 10 mg goitrin (corresponding to 77 μmol) can be considered as a safe level of goitrin. The Panel notes, however, that diets may contain also other antithyroid compounds (e.g. thiocyanate and isothiocyanates), which may add to the effect of goitrin on the iodine uptake.

McMillan et al. (1986) examined the effect of 150 g cooked Brussels sprouts, given as part of a normal diet to 10 healthy volunteers over a period of 4 weeks, on thyroid function. The consumption of cooked Brussels sprouts had no effect on thyroid function as determined by measurement of TSH, thyroxine and triiodothyronine. The lack of antithyroid effects of 5-vinyloxazolidine-2-thione in this study has been attributed to inactivation of glucosinolate degrading enzyme myrosinase during cooking. The Panel notes that the composition of glucosinolates in Brussels sprouts is not representative for the NF.

In the study by Kensler et al. (2005), a randomised, placebo-controlled chemoprevention trial in 200 healthy adults aged between 25 and 65 years and living in Qidong, China, was conducted testing the effects of consuming hot water infusions of 3-day-old broccoli sprouts. The Panel notes that possible effects on thyroid function were not addressed and broccoli sprouts is not representative for the NF.

In a randomised, placebo-controlled, double-blind clinical phase I study, Shapiro et al. (2006) investigated the safety of repeated oral administration of aqueous extracts of broccoli sprouts containing either glucosinolates (mainly glucoraphanin) or isothiocyanates (produced from glucosinolates by deliberate myrosinase hydrolysis) in 12 healthy volunteers aged 21–57 years for 7 days. Three groups of subjects (each n = 4) received a controlled diet that was devoid of crucifers and other sources of inducers of phase 2 enzymes and the following doses divided each in three portions per day: group A, 75 μmol of glucosinolates; group B, 300 μmol of glucosinolates; and group C, 75 μmol of isothiocyanates. All subjects were questioned daily about symptoms possibly related to administration of the test substances or placebo. The reports revealed no significant or persistent symptomatic abnormalities at any time point. Routine blood and urine analyses as well as tests on thyroid (TSH, T3, T4) and liver function (ALT, AST) were obtained. Values outside normal limits were found both prior and after initiation of treatment in both placebo and treatment recipients. The Panel notes that the distribution of glucosinolates in broccoli sprouts differs from that in the NF and that the impact of additional intake of glucosinolates from other sources was not investigated.

In addition to the limitations of the studies mentioned above, the Panel notes that the studies on effects of glucosinolates on thyroid function were all of short duration, conducted in a small number of adult healthy volunteers and thus provide no information on effects in vulnerable population groups such as children, pregnant and lactating women or people with a marginal iodine status.

The NDA Panel considers that the information provided does not eliminate concerns related to potential effects of intakes of glucosinolates from this NF because the contribution of the NF as compared to the background diet will increase considerably for some segments of the population. To remove these concerns, the applicant was requested to provide a human study to determine the impact on iodine status resulting from the consumption of the NF at the proposed use levels, in addition to intakes of glucosinolates from background diets. However, the information was not provided by the applicant.

3.11. Allergenicity

The applicant did not carry out any specific study to determine the potential allergenicity of this NF.

Food allergy to rapeseed (*Brassica rapa* L.) and oilseed rape (*Brassica napus* L.) has been reported to occur (Poikonen et al., 2006, 2008; Puumalainen et al., 2006, 2015). Indications of cross-reactivity between rapeseed proteins and other food proteins, particularly seed storage proteins of mustard have been described (Monsalve et al., 1997; Poikonen et al., 2009). EFSA opinions on the allergenicity of rapeseed protein isolates or rapeseed powder were published and the NDA Panel considered that there is a possible risk of sensitisation to rapeseed and that it is likely that rapeseed can trigger allergic reactions in mustard allergic subjects (EFSA NDA Panel, 2013, 2020).

4. Discussion

This NF consists of whole seeds of oilseed rape, in particular double low white flowering varieties of *Brassica napus* L emend. Metzg. The production of oilseed rape for this NF is similar to that of traditional production of oilseed rape for oil in terms of harvesting, drying, cleaning and storage. The applicant intends to market the NF as an ingredient in 'Bread and rolls with special ingredients added' and 'Gluten free bread'. The target population is the general population.

Intake estimates for the NF consumed via foods in which it would be added as an ingredient were performed for the general population, based on the EFSA Comprehensive European Food Consumption Database. The highest daily intake of the NF was estimated for young children at 92.6 mg/kg body weight (bw) per day at the 95th percentile.

The major components of the NF are fat, carbohydrate, fibre and protein. Considering the low amount of the NF intake and of its protein content, the contribution of the NF to the overall dietary protein intake is small. Similarly, the contribution of fibre is also rather small when considering the anticipated NF intake. The exposure to the analysed minerals does not raise concerns.

The Panel notes that consumption of the NF can result in considerably increased intake of glucosinolates as compared to intakes of glucosinolates from background diets. This may increase the risk of developing goitre or aggravate iodine deficiency in humans when iodine supply is low.

5. Conclusions

The Panel concludes that the safety of the NF, whole seeds of oilseed rape, under the proposed conditions of use has not been established.

Steps taken by EFSA

1) On 29 May 2019 EFSA received a letter from the European Commission with the request for a scientific opinion on the safety of whole seeds of oilseed rape as a NF pursuant to Regulation (EU) 2015/2283. Ref. Ares(2019)3513377–29 May 2019.
2) On 29 May 2019, a valid application on whole seeds of oilseed rape, which was submitted by 'Erik Tybirk', was made available to EFSA by the European Commission through the Commission e-submission portal (NF 2018/0590) and the scientific evaluation procedure was initiated.
3) On 15 November 2019, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
4) On 18 October 2020, a complete package of additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
5) On 20 November 2020, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
6) On 5 June 2021, a complete package of additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
7) On 25 June 2021, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
8) On 25 April 2022, a complete package of additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
9) On 29 April 2022, EFSA requested the applicant to provide additional information to accompany the application and the scientific evaluation was suspended.
10) On 24 October 2022, a complete package of additional information was provided by the applicant through the Commission e-submission portal and the scientific evaluation was restarted.
11) During its meeting on 24 November 2022, the NDA Panel, having evaluated the data, adopted a scientific opinion on the safety of whole seeds of oilseed rape as a NF pursuant to Regulation (EU) 2015/2283.

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Abbreviations

ADME	Absorption, distribution, metabolism and excretion
AOAC	Association of Official Analytical Collaboration
AOCS	American Oil Chemist Society
bw	body weight
CFU	Colony forming unit
DIN	Deutsches Institut für Normung
FAIM	Food Additive Intake Model
GAP	Good Agricultural Practice
GC-FID	Gas Chromatography with Frame Ionisation Detection

GC-MS	Gas chromatography-mass spectrometry
GMP	Good Manufacturing Practice
GMO	Genetically Modified Organisms
HACCP	Hazard Analysis Critical Control Points
HPAEC-PAD	High-performance anion exchange chromatography-pulsed amperometry detection
HPLC-DAD	High-performance liquid chromatography with diode array detection
IAC-LC-FLD	Immunoaffinity column-liquid chromatography-fluorescence detection
ICP-MS	Inductively coupled plasma-mass spectrometry
ICP-OES	Inductively coupled plasma-optical emission spectrometry
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid chromatography with tandem mass spectrometry
LOQ	Limit of quantification
ND	Not detected
NDA	EFSA Panel on Nutrition, Novel Foods and Food Allergens
NF	Novel Food
NMKL	Nordic Committee on Food Analysis
NOAEL	no observed adverse effect level
OECD	Organisation for economic co-operation and development
PRI	Population reference intakes
UPOV	The International Union for the Protection of New Varieties of Plants
UV/VIS	Ultraviolet visible spectrophotometry

Annex A – Dietary exposure estimates to the Novel Food for each population group from each EU dietary survey

Information provided in this Annex is shown in an Excel file (downloadable at https://doi.org/10.2903/j.efsa.2023.7706).

Annex B – Intake estimate of total and individual glucosinolates from background diet*

Population group	Age (years)	Total glucosinolates (μmol/day)	Progoitrin (μmol/day)	Glucobrassicin (μmol/day)
Infants	< 1	45.5	6	14.3
Young children(b)	1 to < 3	50.8	6.9	15.9
Other children	3 to < 10	38.3	5.2	12
Adolescents	10 to < 18	45.8	5.7	14.6
Adults(a)	≥ 18	117.8	16.1	53.8

*: Estimates provided by the applicant considering average occurrence levels of glucosinolates in plants based on information in the public literature (Verkerk and Dekker, 2004; Song and Thornalley, 2007; Felker et al., 2016; Lafarga et al., 2018) and making use of the EFSA Dietary Exposure (DietEx) tool (https://www.efsa.europa.eu/it/science/tools-and-resources/dietex).
(a): Includes elderly, very elderly, pregnant and lactating women.
(b): Referred to as 'toddlers' in the EFSA food consumption comprehensive database (EFSA, 2011).