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Safety of use of oat lecithin as a food additive

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Abstract

The EFSA Panel on Food Additives and Flavourings (FAF) provides a scientific opinion on the safety of oat lecithin for use as a new food additive in the proposed food category (FC05.1) 'cocoa and chocolate products'. Oat lecithin is an oil, containing polar lipids (≥ 35% w/w) and non-polar lipids (55–65% w/w), obtained by ethanol extraction and subsequent fractionation (water/ethanol) from oat suitable for food consumption. This lecithin does not meet the specification parameter for the authorised food additive lecithins (E 322) of 'not less than 60% of substances insoluble in acetone' which represents the polar lipid content (phospholipids and glycolipids). Oat lecithin is expected to undergo hydrolysis in the gastrointestinal tract and this hydrolysis resembles that of other edible vegetable oils. Oat lecithin did not induce gene mutations or structural chromosomal aberrations in the absence or presence of metabolic activation. No treatment-related adverse effects were observed with oat lecithin in 28-day studies in rats and dogs at the highest dose tested. The toxicological database for oat lecithin was limited. Considering the composition of oat lecithin (similar components in different ratio) and the fact that it undergoes the same biotransformation, resulting in similar metabolites as those from lecithins (E 322) re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food (EFSA ANS) in 2017, the Panel considered the possibility to use the read-across approach from toxicological data on lecithins (E 322). Based on the toxicological data provided for oat lecithin along with read across from lecithins (E322) to oat lecithin no additional toxicological data were required. Therefore, the Panel considered that the previous conclusion for lecithins (E322) equally applies to oat lecithin to be used as food additive. Mean exposure ranged from < 0.01 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. The 95th percentile of exposure ranged from 0 mg/kg bw per day in infants to 22.5 mg/kg bw per day in children. The Panel concluded that there is no need for a numerical ADI and there is no safety concern for oat lecithin to be used as a food additive at the proposed use (FC 05.1) and use levels. The Panel recommended that the European Commission considers including specifications for oat lecithin as a new food additive.

Keywords: oat lecithin, E 322, food additive

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Summary

Following a request from the European Commission to the European Food Safety Authority (EFSA), the EFSA Panel on Food Additives and Flavourings (FAF) was asked to provide a scientific opinion on the safety of the proposed amendment of the specifications of the food additive lecithins (E 322) and in the proposed food category 05.1. 'Cocoa and chocolate products as covered by Directive 2000/36/EC', in accordance with Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

According to the applicant, oat lecithin is an oil, composed of polar lipids (≥ 35% w/w) and non-polar lipids (55–65% w/w), obtained by ethanol extraction and subsequent fractionation (water/ethanol) from oats suitable for food consumption. This lecithin does not meet the specification parameter for lecithins (E 322), as defined in the Commission Regulation (EU) No 231/2012, of 'not less than 60% of substances insoluble in acetone' which represents the polar lipid content (phospholipids and glycolipids). Therefore, the applicant has requested to have specifications for oat lecithin as an append to the current specifications for lecithins (E 322) as a food additive.

The Panel noted that according to the mandate received from the European Commission the scientific opinion of EFSA should address a proposed amendment to the current specifications of lecithins (E 322). On the other hand, the Panel noted that the applicant proposed to have specifications for oat lecithin as an append to the current specifications for lecithins (E 322). Since it is not clear what change in the EU legislation would be implied by an append to the current specifications, the FAF Panel considered that separate specifications could be needed for oat lecithin rather than to broaden the existing specifications for lecithins (E 322) to encompass the description of oat lecithin. Therefore, this assessment for oat lecithin is considered as for a new food additive.

Lecithins (E 322) was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) that concluded that there was no need for a numerical acceptable daily intake (ADI) for lecithins (E 322) and that there was no safety concern for the general population (from 12 weeks of age) at the refined exposure assessment for the reported uses of lecithins (E 322) as a food additive (EFSA ANS Panel, 2017).

Oat Lecithin is an oil composed of a polar lipid fraction of more than 35% being the percentage of phospholipids (including phosphatidyl choline) around 15–20% and glycolipids of 20–25%. The remaining consists of neutral lipids (55–65%). Lecithins (E 322) has a higher polar lipid fraction mainly consisting of phospholipids of more than 60% (being phosphatidyl choline 13–28%) and the remaining in the form of triglycerides, sterols and carbohydrate. Therefore, the Panel considered that the components of the lecithins (E322) and oat lecithin are similar but present in different proportions.

Oat lecithin is expected to undergo hydrolysis in the gastrointestinal tract and this hydrolysis resembles that of other edible vegetable oils and of lecithins (E 322).

The Panel was provided only with 28-day studies with oat lecithin in rats and dog. The Panel noted that no treatment-related adverse effects were observed in these studies and consequently identified the no observed adverse effect level (NOAEL) as the highest dose tested, i.e. 5,000 mg/kg bw per day in both studies. However, the Panel noted that these studies are not sufficient for concluding on the potential for subchronic toxicity.

Oat lecithin did not induce gene mutations in the absence or presence of metabolic activation and did not induce structural chromosomal aberrations in the absence or presence of S9 metabolic activation. The Panel noted that no *in vitro* micronucleus test was submitted that would have been required according to the Guidance on Food Additives (EFSA ANS Panel, 2012). The Panel also noted that, although the available chromosomal aberrations test did not show any indication of numerical aberrations, this test is not designed to detect aneugenicity and, accordingly, an *in vitro* micronucleus test would generally be warranted.

However, considering that:

- oat lecithin is obtained by ethanol extraction and subsequent fractionation (water/ethanol) from oat suitable for food consumption
- the main components of oat lecithin (phospholipids, glycolipids and triglycerides) are similar to those in lecithins (E 322) and are not expected to be aneugenic
- based on the method of production and on the proposed specifications for oat lecithin, the presence of genotoxic impurities at concentrations that could induce detectable increases of micronuclei in an *in vitro* micronucleus assay would not be expected

The Panel deemed the available information in this case sufficient to conclude that there is no concern with respect to genotoxicity for oat lecithin.

According to the applicant, as it is proposed to have specifications for oat lecithin as an append to the current specifications for lecithins (E 322) as a food additive (and both are chemically related), a read-across approach from toxicological data evaluation by the ANS Panel in the re-evaluation of lecithins (E 322) is proposed.

The Panel noted that the available toxicological data on oat lecithin submitted within the application dossier did not fulfil the requirements applicable to Guidance for the submission of food additive. Based on the composition of oat lecithin (similar components in different ratio) and the fact that it undergoes the same biotransformation, resulting in similar metabolites as those from lecithins (E 322), the applicant proposed a read-across approach from toxicological data evaluated by the ANS Panel in the re-evaluation of lecithins (E 322) The Panel agreed with the possibility to use read-across approach from toxicological data on lecithins (E 322).

Subchronic toxicity studies in rats and dogs, reviewed during the re-evaluation of lecithins (E 322), did not report any adverse effect, even at the highest dose tested (5,460 mg lecithins/kg bw per day in rats) (EFSA ANS Panel, 2017). The Panel noted that this NOAEL is consistent with the lack of treatment-related adverse effects up to 5,000 mg/kg bw per day, the highest dose tested, observed in the two 28-day studies provided for oat lecithin.

Furthermore, in the re-evaluation of lecithins (E 322), no adverse effects were observed in chronic/carcinogenicity and developmental toxicity studies (EFSA ANS Panel, 2017).

Based on the toxicological data provided for oat lecithin along with read across from lecithins (E 322) to oat lecithin no additional toxicological data were required. Therefore, the Panel considered that previous conclusion for lecithins (E 322) equally applies to oat lecithin to be used as food additive, i.e. there is no need for a numerical ADI.

To assess the dietary exposure to oat lecithin, the exposure was calculated based on the upper end of the normal use level of 10,000 mg/kg proposed by the applicant, while its request is for an authorisation of oat lecithin in the food category (FC 05.1) 'cocoa and chocolate products as covered by Directive 2000/36/EC' at *quantum* satis (QS).

Mean exposure to oat lecithin from its use as a food additive ranged from < 0.01 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. The 95th percentile of exposure ranged from 0 mg/kg bw per day in infants to 22.5 mg/kg bw per day in children.

Considering that the request is for an authorised use at *quantum satis*, if the use level would be higher than 10,000 mg/kg, then, the current exposure estimates would result in an underestimation of the exposure to oat lecithin as a food additive.

The Panel concluded that there is no need for a numerical ADI and there is no safety concern for lecithin obtained from oat suitable for human consumption, to be used as a food additive at the proposed use (FC 05.1) and use levels.

The Panel recommended that the European Commission considers including specifications for oat lecithin as a new food additive in Commission Regulation (EU) No 231/2012.

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1. Introduction

The present opinion deals with the evaluation of the safety oat lecithin when used as a food additive at the proposed use and use level.

According to the applicant, oat lecithin is an oil comprised of polar lipids (≥35% w/w) and non-polar lipids (55–65% w/w) that are natural constituents of oat grain seeds. This oil does not meet the specification parameter for lecithins (E 322) of 'not less than 60% of substances insoluble in acetone' which represents the polar lipid content (phospholipids and glycolipids). The applicant has requested to have specifications for oat lecithin as an append to the current specifications for lecithins (E 322) as a food additive.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

The use of food additives is regulated under the European Parliament and Council Regulation (EC) No. 1333/2008 on food additives.[1] Only food additives that are included in the Union List, in particular in Annex II to that Regulation, may be placed on the market and used in foods under the conditions of use specified therein. Moreover, food additives shall comply with the specifications as referred to in Article 14 of that Regulation and laid down in Commission Regulation (EU) No 231/2012.[2]

An application has been introduced for an amendment of the specifications of the food additive Lecithins (E 322) and the authorisation for its use as an emulsifier in the food category 5.1. 'cocoa and chocolate products as covered by Directive 2000/36/EC'.

According to the Applicant, oat lecithin is an oat oil derived from water and ethanol extraction of food-grade oat grain seeds. It is comprised of at least 35% polar lipids that are natural constituents of oat grain seeds and are unaltered during the production process. As regards the manufacturing process, the oat lecithin is obtained from food-grade oat kernels that are sieved and extracted using ethanol at elevated temperature to produce a crude lipid extract. This crude extract undergoes multistage evaporation and filtration, yielding crude oat oil, which is separated, evaporated and filtered to produce oat lecithin.

The applicant proposes the name 'oat lecithin' due to the similarity to lecithins, which are currently authorised as food additive (E 322), in terms of origin, composition and technological function. According to the applicant, there are some differences in the specifications between 'oat lecithin' and lecithins (E 322).

1.1.2. Terms of Reference

The European Commission requests the European Food Safety Authority to perform a risk assessment to provide a scientific opinion on the safety of the proposed amendment of the specifications of the food additive lecithins (E 322) and proposed use in the food category 5.1. 'cocoa and chocolate products as covered by Directive 2000/36/EC', in accordance with Regulation (EC) No. 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.[3]

1.1.3. Interpretation of Terms of Reference

The EFSA Panel on Food Additives and Flavourings (FAF) noted that according to the mandate received from the European Commission the scientific opinion of EFSA should address a proposed amendment to the current specifications of lecithins (E 322) as set in Regulation (EU) No 231/2012. On the other hand, the Panel noted that the applicant proposed to have specifications for oat lecithin as an append to the current specifications for lecithins (E 322). Since it is not clear what change in the EU legislation would be implied by an append to the current specifications, the FAF Panel considered that separate specifications could be needed for oat lecithin rather than to broaden the existing specification for lecithins (E 322) to encompass the description of oat lecithin. Therefore, this assessment for oat lecithin is considered as for a new food additive.

[1] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008.

[2] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) no 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012

[3] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

1.2. Information on existing authorisations and evaluations

Lecithins (E 322) is an authorised food additive in the EU according to Regulation (EC) No 1333/2008 on food additives and specifications have been defined in the Commission Regulation (EU) No 231/2012.

Lecithins (E 322) was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) that concluded that there was no need for a numerical acceptable daily intake (ADI) for lecithins (E 322) and that there was no safety concern for the general population (from 12 weeks of age) at the refined exposure assessment for the reported uses of lecithins (E 322) as a food additive (EFSA ANS Panel, 2017).

2. Data and methodologies

Data

The present evaluation is based on the data on oat lecithin in a newly submitted dossier by the applicant ('Documentation provided to EFSA' No1) and additional information submitted by the applicant during the assessment process following request by EFSA ('Documentation provided to EFSA' No 2).

Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012) was followed for the assessment.

Dietary exposure to oat lecithin from its proposed use as a food additive was estimated by combining the food consumption data available within the EFSA Comprehensive European Food Consumption Database with the proposed use level provided by the applicant using the Food Additives Intake Model 2.0 (FAIM) (https://dwh.efsa.europa.eu/bi/asp/Main.aspx?rwtrep=FAIM, accessed on October 2019).

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

Oat lecithin is an oat oil extracted from food-grade oat grain seeds from *Avena sativa* by ethanol which is further fractionated by addition of ethanol and water in order to achieve its high polar lipid content.

Oat lecithin is comprised largely of non-polar lipids (58% w/w) and polar lipids (> 35% w/w). The non-polar lipids largely comprise of triglycerides. The polar lipid fraction is comprised of a 20–25% glycolipids digalactosyl diacylglycerol and monogalactosyl monoacylglycerol; and 15–20% of phospholipids including phosphatidyl choline and N-acyl-phosphatidyl ethanolamine.

Information on the fatty acid profile of the neutral lipids was available, being saturated fatty acids 19.2% of the total fatty acids (mainly palmitic and stearic acids), monounsaturated fatty acids 38.7% (mainly oleic acid) and polyunsaturated fatty acids 39.9% (linoleic and alpha-linolenic acids).

Oat lecithin has a yellow–brown colour and a typical oat cereal taste. It has a moisture content of 2% or less and an acid value of 30 mg KOH/g or less.

Table 1 presents the composition of oat lecithin in comparison to the available information on lecithins (E 322) which is necessary considering the background and term of reference as provided by the European Commission.

Table 1: Composition of oat lecithin and lecithins (E322)

Oat lecithin (Documentation provided to EFSA No. 1 and 2)					Lecithins (E 322) (EFSA ANS Panel, 2017)			
Polar lipids	> 35%	Glycolipids	digalactosyl diacylglycerol and monogalactosyl monoacylglycerol	20–25%	Phospholipids/ glycolipids	> 60%	Phosphatidyl choline	13–28%
		Phospholipids	phosphatidyl choline and N-acyl-phosphatidyl ethanolamine	15–20%			Phosphatidyl ethanolamine	6–14%
							Phosphatidyl inositol	6–21%
							Phosphatidic acid	1–9%
Neutral lipids	55–65%	Triglycerides	Saturated fatty acids	17–20%[(a)]				
			Monounsaturated fatty acids	38–42%%[(a)]				
			Polyunsaturated fatty acids	38–42%%[(a)]				
		Undefined compounds		2%				
					Triglycerides, sterols and carbohydrates	40%		
Choline: analytical measurements show a maximum amount of 1.2% of choline can be released, and a maximum amount of 2% choline is proposed in the specifications					Theoretically calculated content of choline that can be released from E 322 ranges from 1.7 to 3.4%			

(a): Percentage refers to the total esterified fatty acids.

As mentioned in the re-evaluation of lecithins (E322), the content of choline that can theoretically be released from phosphatidylcholine containing two linoleated groups is 13.2% (EFSA ANS Panel, 2017); therefore, the calculated content of choline that can theoretically be released from E322 ranges from 1.7 to 3.4%.

For oat lecithin analytical measurement show a maximum amount of 1.2% of choline (in five analysed batches), and a maximum amount of 2% choline is proposed in the specifications.

3.1.2. Specifications

The proposed specifications for oat lecithin are listed in Table 2.

Table 2: Specifications for oat lecithin as proposed by the applicant (Documentation provided to EFSA No. 2)

	Oat lecithin (Documentation provided to EFSA No. 2)	Lecithins (E 322) (Commission Regulation (EU) No 231/2012)
Parameter	**Specification**	
Synonyms	Fractionated oat oil	Phosphatides; Phospholipids
Definition	Oat lecithin is an oat oil rich in polar lipids, mainly galactolipids and contains natural antioxidants.	Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity. The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithin phosphatides
EINICS	281-672-4	232-307-2

	Oat lecithin (Documentation provided to EFSA No. 2)	Lecithins (E 322) (Commission Regulation (EU) No 231/2012)
Assay	Not less than 30% of substances insoluble in acetone	Not less than 60% of substances insoluble in acetone
Description	Yellowish-brown viscous liquid	Brown liquid or viscous semi-liquid or powder
Identification		
Choline	Not more than 2 g/100 g	Passes test for choline
Phosphorous	Not less than 0.5%	Passes test for phosphorous
Polar lipids	Not less than 35% w/w	
Neutral lipids	55–65% w/w	
Fatty acids		Passes test for fatty acids
Saturated	17–20% w/w	
Monounsaturated	38–42% w/w	
Polyunsaturated	38–42% w/w	
Purity		
Loss of drying	Not more than 2%	Not more than 2% (105C, 1 h)
Toluene-insoluble matter	Not more than 1% w/w	Not more than 0.3%
Acid value	Not more than 30 mg KOH/g	Not more than 35 mg KOH/g
Peroxide value	Not more than 10 meq O_2/kg fat	Not more than 10
Residual ethanol	Not more than 300 mg/kg	
Arsenic	Not more than 0.1 mg/kg	Not more than 3 mg/kg
Lead	Not more than 0.05 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 0.01 mg/kg	Not more than 1 mg/kg
Cadmium	Not more than 0.05 mg/kg	
Microbiological criteria		
Aerobic plate count	Not more than 1,000 CFU/g	
Yeast	Not more than 100 CFU/g	
Moulds	Not more than 100 CFU/g	
Enterobacteriacease	Not more than 10 CFU/g	
Aerobic spores	Not more than 1 CFU/g	
Other		
Gluten	Not more than 20 mg/kg	
Pesticides residues	According to Regulation (EC) 396/2005	

The Panel noted that in the definition proposed by the applicant, it is indicated that oat lecithin contains natural antioxidants. Although these antioxidants are likely to be derived from oat, their nature is not specified. The indication of antioxidant content has no value as part of the definition of the food additive.

Furthermore, information on how oat lecithin is produced should be included in the definition. The Panel noted that in the definition of oat lecithin the source of oat should be specified as claimed by the applicant that is extracted using ethanol from oat grain/kernels suitable for human consumption.

The specific components of oat lecithin that are insoluble in acetone, as described in the assay, are most likely composed of polar lipids (phospholipids and glycolipids), as the acetone insoluble content is directly proportional to the polar lipid content.

The Panel noted that the parameters listed under identification would more properly be described as 'Composition'.

Analytical results for five non-consecutive batches have been provided to show that the oat lecithin complies with the proposed specifications; however, not all the parameters proposed in the specification were analysed for all the batches.

3.1.3. Manufacturing process

Oat lecithin is produced using oat kernels suitable for human consumption, which are sieved and the coarse, fibre-rich, bran fraction is partially extracted using ethanol at an elevated temperature (60–80°C) to isolate the oat lipid fraction composed of neutral and polar lipids. The extract is then separated from bran solids by centrifugation, and the extract is further concentrated by a series of evaporation steps that result in a final content of 90%. This crude product is subject to fractionation in a closed system by a succession of ethanol-water dilutions in order to fractionate the polar lipid-rich fraction, and this fraction is then filtered and subject to a final evaporation step, resulting in a final content of > 98% with less than 2% of water.

3.1.4. Methods of analysis in food

The applicant proposed the quantification of the food additive in food by measuring the content of digalactosyl-diacylglycerol. The presence of oat oil could be assessed based on the fatty acid profile and analysis of avenanthramides would also indicate the presence of oat oil.

However, the Panel noted that these are indirect methods that do not allow the differentiation and quantification of oat lecithin from other ingredients present in foods from food category (FC 05.1) for which the applicant has requested the authorisation of oat lecithin.

3.1.5. Stability of the substance, and reaction and fate in food

No information on the stability of the substance itself nor on reaction and fate in food was provided by the applicant.

The storage of lecithins in the presence of air leads to the development of an off-flavour and black colouration due to the autoxidation of the unsaturated fatty acids (Tanno, 2012).

3.2. Proposed uses and use levels

Through the current application, an authorisation is sought with regard to the food category of 'cocoa and chocolate products as covered by Directive 2000/36/EC' (FC 05.1) as shown in Table 3.

Table 3: Proposed use level of oat lecithin in foods (Documentation provided to EFSA No. 1)

Food category number	Food category name	Proposed use level(mg/kg)	
		Normal	Maximum
05.1	Cocoa and chocolate products as covered by Directive 2000/36/EC	2,000–10,000	*Quantum satis*

Lecithins (E 322) have a maximum permissible limit (MPL) of *quantum satis* for use in FC 05.1 'cocoa and chocolate products as covered by Directive 2000/36/EC' (Annex II to Regulation (EC) No 1333/2008); the applicant requests that the same MPL of *quantum satis* is granted for oat lecithin. However, use levels were proposed for use in cocoa and chocolate products (FC 05.1) at typical levels from 0.2% to 1% for oat lecithin (i.e. 2,000–10,000 mg/kg). The proposed level of 10,000 mg/kg was used in the exposure assessment below.

3.3. Exposure data

3.3.1. Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). Consumption surveys added in the Comprehensive Database in 2015 were also taken into account in this assessment.[3]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons may not be appropriate. Depending on the food

category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from infants, toddlers, children, adolescents, adults and the elderly were used in the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 4).

Table 4: Population groups considered for the exposure estimates of oat lecithin

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers[a]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children[b]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[b]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Netherlands, Sweden, UK Regulations

(a): The term 'toddlers' in the Comprehensive Database (EFSA, 2011a) corresponds to 'young children' in (EC) No 1333/2008 and (EU) No 609/2013.
(b): The terms 'children' and 'the elderly' correspond, respectively, to 'other children' and the merge of 'elderly' and 'very elderly' in the Comprehensive Database (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system was linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform the exposure assessments. In practice, the FoodEx food codes were matched to the FCS food categories.

Food category considered for the exposure assessment of oat lecithin

The food category of 'cocoa and chocolate products as covered by Directive 2000/36/EC' for which use level of oat lecithin is proposed was selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

3.4. Exposure estimates

3.4.1. Exposure to oat lecithin from its proposed use as a food additive

The Panel estimated the chronic dietary exposure to oat lecithin for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to oat lecithin was calculated by multiplying concentration of oat lecithin for the food category 'cocoa and chocolate products as covered by Directive 2000/36/EC' (FC 05.1) with its respective consumption amount per kilogram body weight for each individual in the Comprehensive Database. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

The exposure was estimated in this way for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). Based on these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with

a sufficiently large sample size (EFSA, 2011a). Therefore, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain was not estimated in the present assessment.

Estimate of exposure based on the Food Additives Intake Model (FAIM) template

The applicant has provided an estimate of the exposure to oat lecithin based on the output obtained using the FAIM model (version 1) ('Documentation provided to EFSA' No 1).

The Panel decided not to use the estimate exposure generated from the FAIM tool version 1 and provided by the applicant since a new version of the FAIM tool (version 2)[4] has been made available since the receipt of the current application.

The Panel noted that assessment provided by the applicant using the FAIM tool version 1 gave similar but higher estimates of exposure than the ones calculated by the Panel using FAIM tool version 2.

The Panel therefore decided to perform a new estimate exposure using the FAIM tool (version 2). The results of the estimate exposure are reported in Table 5. Detailed results per population group and survey are presented in Appendix A.

Table 5: Estimate exposure to oat lecithin (mg/kg bw per day) from its proposed use as a food additive (10,000 mg/kg) using FAIM 2

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
• Mean	0.0–1.2	0.2–6.6	1.1–7.1	0.9–4.2	0.3–1.4	0.2–0.9
• 95th percentile	0–4.5	1.7–14.7	5.2–22.5	3.8–14.3	1.8–6.3	0.9–3.9

Mean exposure to oat lecithin from its use as a food additive ranged from < 0.01 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. The 95th percentile of exposure ranged from 0 mg/kg bw per day in infants to 22.5 mg/kg bw per day in children.

Uncertainty analysis

Uncertainties in the exposure assessment of oat lecithin have been discussed above. In accordance with the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised in Table 6.

Table 6: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Correspondence of proposed use levels to the food items in the EFSA Comprehensive Database: uncertainties to which types of food the levels refer	+/–
Uncertainty in possible national differences in use levels of food categories	+/–
Concentration data: – proposed use levels considered applicable to all foods within the entire food category	+
Proposed use level exposure assessment scenario: – exposure calculations based on the highest normal proposed use level proposed by the applicant	+/–

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Oat lecithin is requested to be authorised in one food category. All foods belonging to this FC were assumed to contain oat lecithin at 10,000 mg/kg. In the re-evaluation of lecithin (E 322) (EFSA ANS Panel, 2017), it was noted that 80–85% of products under FC 05.1 were labelled to contain lecithins (E 322) according to Mintel, suggesting that this food additive is widely use in this FC. Currently,[5] lecithins (E 322) is used in 90–96% of products belonging to the FC 05.1. If oat lecithin would be used

[4] Available online: https://www.efsa.europa.eu/en/applications/foodingredients/tools
[5] Mintel GNPD: http://www.gnpd.com/sinatra/home/ accessed on 18/10/2019.

as an alternative to lecithins (E 322) in FC 05.1 and also taking into account brand-loyalty to these products, then the exposure estimate to oat lecithin is likely to be realistic.

Considering that the request is for an authorised use at *quantum satis*, if the use level would be higher than 10,000 mg/kg, then, the current exposure estimates would result in an underestimation of the exposure to oat lecithin as a food additive.

3.5. Biological and Toxicological data

3.5.1. Absorption, distribution, metabolism and excretion

According to the applicant, oat lecithin is a component of the oat grain seeds and is expected to exhibit similar metabolic fate to other edible vegetable oils and fatty acids. When ingested, dietary lipids are hydrolysed by buccal, gastric, pancreatic and intestinal lipases (reviewed in Institute of Medicine (IOM), 2005). These lipases catalyse the breakdown of triacylglycerides into a mixture of free fatty acids and acylglycerols followed by hydrolysis into free fatty acids in the presence of bile acids. These compounds may then be assembled together with cholesterol, phospholipid and apoproteins and absorbed in the small intestine.

Human

A human study on absorption, distribution, metabolism, excretion (ADME) of oat lecithin itself is not available. Yet the gastrointestinal digestibility of oat oil, specifically, a vegetable-oil emulsion of oat oil and palm oil ('Fabuless' or 'Olibra'[6]) in yoghurt was investigated in healthy humans (Knutson et al., 2010).The study, conducted in a randomised, double-blind, placebo-controlled crossover design in 16 healthy individuals (4 men, 12 women), compared digestion and absorption of lipids in 'Fabuless' with those of milk fat *via* a validated intestinal perfusion technique. Volunteers received an infusion of 300 g yoghurt containing either 8.5 g dairy fat (control) or 8.5 g of fat as an oat oil/palm oil emulsion (test yoghurt); then gastric and intestinal samples were drawn before the infusion of the yoghurt products and at regular 30-minute intervals at up to 180 minutes post-infusion.

Analyses of the samples demonstrated that hydrolysis of the lipids started in the stomach, with approximately 76.2% of the lipids in the test product remaining as triacylglycerides and small amounts of diacylglycerides and monoacylglycerides present. At up to 180 minutes, triacylglycerides continued to be the major component recovered in the stomach, whilst samples obtained in the proximal part of the jejunum demonstrated that the majority of lipids were almost fully hydrolysed to free fatty acids, with notably more free fatty acids detected from the test yoghurt compared to the control. The authors concluded that significant amounts of free fatty acids were observed in the proximal jejunum during the 180 minutes post-ingestion of the test yoghurt compared to the fatty acids from milk fat.

Overall, hydrolysis of oat lecithin in the gastrointestinal tract resembles that of other edible vegetable oils, starting in the stomach and with the lipids being hydrolysed to free fatty acids in the proximal part of the jejunum within 3 hours.

3.5.2. Short-term and subchronic toxicity

The applicant has provided subchronic toxicology studies which deviate in duration of the study from the EFSA guidance for submission for food additives evaluation (EFSA ANS Panel, 2012).

Rat

In a GLP 28-day oral toxicity study in Crl:CD(SD) IGS BR rats, oat lecithin was tested (Documentation provided to EFSA No. 3). Rats (10/sex per group) were administrated corn oil (control) or oat lecithin at doses of 1,250, 2,500, or 5,000 mg/kg bw per day by gavage (dose volumes were 5 mL/kg bw for control and high-dose groups, 1.25 mL/kg bw for the low-dose group and 2.5 mL/kg bw for the mid-dose group) for 28 days. Animals were observed daily for changes in clinical condition, with ophthalmoscopic examinations performed on control and high-dose animals. Body weights and food consumption were recorded weekly. Haematology, clinical biochemistry and urinalysis, macroscopic and microscopy examination were performed.

[6] Olibra or Fabuless is comprised of 31 to 35% fat, of which oat lecithin comprises 5 to 6% (i.e. represent 2% of finished product) (Documentation provided to EFSA n 1).

No test article-related deaths were observed during the study. Clinical observations (including some instances of staining in all male groups and for mid- and high-dose females in addition to infrequent occurrences of thinning fur among low-, mid-, and high-dose groups) were considered to be unrelated to the test article; there were also no test item-related ophthalmoscopic findings. No differences in body weight or food consumption were observed between test item-treated groups and controls. Some scattered statistically significant changes in haematological, clinical chemistry, urinalysis parameters or relative organ weights (kidney and liver) were observed. The Panel noted that the reported effects were not dose-related or were minor and considered them not adverse in the absence of related histopathologic or item-related macroscopic changes.

Microscopic findings were generally infrequent, of a minor nature and consistent with the usual pattern of findings in rats of this strain and age. Inflammatory cell foci/myofibre degeneration in the sternum and oesophagus were reported in some control and high-dose animals. The Panel noted that inflammatory cell foci were also observed in several organs (liver, pancreas, kidney, epididymis, prostate, lung and heart) in control and treated rats. This was considered as a general health problem in the rats rather than as a treatment-related effect.

The authors identified a NOAEL for oat lecithin of 5,000 mg/kg bw per day, the highest dose tested. The Panel agreed with this NOAEL.

Dog

In a GLP 28-day oral toxicity study in dog, oat lecithin was tested (Documentation provided to EFSA No. 4). Beagle dogs (3/sex per group) were administered with corn oil (control) or oat lecithin at 1,250, 2,500 or 5,000 mg/kg bw per day (dose volumes were 5 mL/kg bw for control and high-dose groups, 1.25 mL/kg bw for the low-dose group and 2.5 mL/kg bw for the mid-dose group) by oral gavage for 28 days. Animals were observed daily for changes in clinical condition, with ophthalmoscopic examinations performed on control and high-dose animals before the start of dosing and in Week 4. Body weights and food consumption were recorded weekly. Haematology, clinical biochemistry and urinalysis, macroscopic and microscopy examination were performed.

There were no deaths, no test item-related clinical signs and no ocular findings considered to be related to administration of the test item. No biologically relevant differences in body weight or food consumption were observed between test item-treated group and controls. There were no test item-related differences in haematological, clinical biochemistry or urinalysis parameters between controls and test item-treated groups. At necropsy, there were no differences in organ weights and no macroscopic or microscopic findings considered to be related to administration of the test item.

The authors identified a NOAEL for oat lecithin of 5,000 mg/kg bw per day, the highest dose tested. The Panel agreed with this NOAEL.

Overall the Panel noted that no adverse effects were observed in two 28-day studies on oat lecithin in rats and dogs and consequently the NOAEL was at the highest dose tested 5,000 mg/kg bw per day in both studies. No 90-day toxicity study in rats with oat lecithin was provided.

3.5.3. Genotoxicity

In vitro

A GLP-compliant bacterial reverse mutation assay was conducted in accordance with Organisation for Economic Co-operation and Development (OECD) Testing Guideline No. 471 (Documentation provided to EFSA No. 5). *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 and *Escherichia coli* strain WP2 *uvrA* were exposed to oat lecithin (dissolved in sterile anhydrous analytical-grade dimethyl sulphoxide [DMSO]) at concentrations of 1.6, 8, 40, 200, 1,000 or 5,000 μg/plate, in the absence and presence of S9 metabolic activation. Appropriate negative (solvent) and positive controls were included. Precipitation of the test article was observed at the highest treatment concentration both in the presence and absence of S9. Evidence of cytotoxicity was observed only at the highest concentration tested in strain TA102 in the presence of S9. No biologically relevant, dose-related or reproducible increases in revertant colonies were observed in any of the tester strains following exposure to oat lecithin at any concentration, either in the absence or presence of S9. The positive controls induced biologically relevant increases in revertant colony counts (with metabolic activation where required), which demonstrated the sensitivity of the assay and metabolic activity of the S9 preparations.

A GLP-compliant *in vitro* chromosomal aberration test was conducted in cultured human blood lymphocytes in accordance with OECD Testing Guideline No. 473 (Documentation provided to EFSA No. 6). Oat lecithin (dissolved in DMSO) was incubated with human lymphocyte cultures at concentrations ranging from 23.74 to 5,000 μg/mL in the presence and absence of S9 metabolic activation. In the short-term assay, lymphocytes were incubated with oat lecithin for 3 hours in the presence or absence of S9 and were harvested after a 17-hour recovery period. In the continuous assay, lymphocytes were incubated with oat lecithin for 20 hours and harvested following the treatment period. Cells were analysed for chromosomal aberrations and mitotic index. Appropriate negative (solvent) controls and positive controls were included. Concentrations of 2,109 μg/mL and higher resulted in precipitation of the test article in the short-term assay, and concentrations of 288.2 μg/mL and higher produced precipitates in the continuous assay. No statistically significant differences in the frequencies of cells with structural aberrations were observed between treated groups and the negative (solvent) control, and numbers fell within historical negative control range. Regarding numerical aberrations, the cultures treated with oat lecithin fell within the historical negative control range for polyploidy, endoreduplication and hyperploidy, with the exception of a marginal increase in polyploid cells observed after short-term treatment in the presence of metabolic activation at a concentration of 2,813 μg/mL in the first experiment and at 5,000 μg/mL in the in the second experiment. The Panel considers these findings of no biological relevance since the replicate cultures at these concentrations did not exhibit similar increases and all other treated cultures fell within historical control ranges for numerical aberrations. The positive controls induced biologically relevant increases in revertant colony counts (with metabolic activation where required), which demonstrated the sensitivity of the assay and metabolic activity of the S9 preparations.

Oat lecithin did not induce gene mutations in the absence or presence of metabolic activation and did not induce structural chromosomal aberrations in the absence or presence of S9 metabolic activation.

3.5.4. Chronic toxicity and carcinogenicity

No data were provided.

3.5.5. Reproductive and developmental toxicity

No data were provided.

3.5.6. Hypersensitivity, allergenicity and food intolerance

According to the applicant, due to the nature of oat lecithin, being a refined plant oil, it is not anticipated to be a risk of allergenicity or hypersensitivity beyond that of oats themselves and certainly of no higher allergenic risk than lecithins (E 322) produced from soya or egg. Reviews of the published literature have indicated that the refinement process involved in the manufacture of vegetable oils removes or considerably decreases the allergenicity of oils and, in general, vegetable-derived oils demonstrate very little allergenic risk (Crevel and Kerkhoff, 2000).

Analytical results from two batches showed the absence of gluten (< LOD of 7 mg/kg) and therefore below the value of 20 mg/kg proposed by the applicant for specifications (Table 2).

3.5.7. Other studies

Oat oil preparations have been investigated in rodent studies examining its potential protective effects against certain pathological states because of its antioxidant properties (Li et al., 1999; Ben Halima et al., 2014; Tong et al., 2014). These studies were not designed to investigate the safety of the proposed use of oat lecithin as food additive and were not considered for hazard characterisation.

3.5.8. Human studies

Olibra[6] has been investigated in several published human studies (Burns et al., 2000, 2001, 2002; Logan et al., 2006; Diepvens et al., 2007; Haenni et al., 2009; Smit et al., 2011; Chan et al., 2012; Rebello et al., 2012; Ohlsson et al., 2014). In these studies, the highest dose of Olibra provided to subjects was 6 g/day (equivalent to approximately 0.12 g oat lecithin) and the longest treatment period was 4 months. These studies were designed to investigate efficacy in promoting satiety and management of body weight. According to the applicant, Olibra was well-tolerated and was not

associated with any obvious adverse effects, however, the Panel noted that the doses of oat lecithin are lower than the estimated exposure from the proposed use as food additive (Table 5).

4. Discussion

According to the applicant, oat lecithin is an oil composed of polar lipids (≥35% w/w) and non-polar lipids (55–65% w/w). This oil does not meet the specification parameter for lecithins (E 322) of 'not less than 60% of substances insoluble in acetone' which represents the polar lipid content (phospholipids and glycolipids). The polar lipid fraction consists of 15–20% phospholipids (including phosphatidyl choline) and 20–25% glycolipids (Table 1).

In the re-evaluation of lecithins (E322), the main source of lecithins was identified as being soya bean but with other plant sources including cottonseeds, corn, sunflower seeds and rapeseed, together with animal sources such as egg yolk (EFSA ANS Panel, 2017). The Panel noted that lecithins (E 322) has a higher polar lipid fraction mainly consisting of phospholipids of more than 60% (being phosphatidyl choline 13–28%) and the remaining in form of triglycerides, sterols and carbohydrate. According to Wendel (1995), the phospholipid composition of soya bean lecithin on an oil-free basis, a source of lecithins (E 322), is 21% phosphatidylcholine, 22% phosphatidylethanolamine, 19% phosphatidylinositol, 10% phosphatidic acid, 1% phosphatidylserine and 12% glycolipids (Wendel, 1995 as reported in the EFSA ANS Panel, 2017). According to the proposed specifications, oat lecithin should contain no more than 2% choline while a range of 1.7–3.4% choline was reported for lecithins (E 322) (EFSA ANS Panel, 2017).

The Panel considered that the components of the lecithins (E322) and oat lecithin are similar but present in different proportions (Table 1). For these reasons, the Panel considered more appropriate to have separate specifications for oat lecithin rather than to broaden the existing specification for lecithins (E 322) to encompass the description of oat lecithin. Thus, oat lecithin was assessed as a new food additive.

The Panel considered that the specifications proposed by the applicant for oat lecithin (Table 2) should be taken into account for the EU specifications for oat lecithin as a food additive with the following modifications:

- delete the antioxidant content from the definition of the food additive
- information on how oat lecithin is produced should be included in the definition: the source of oat should be specified as suitable for human consumption, as well as ethanol indicated as extraction solvent
- the parameters listed under identification would more properly be described as 'Composition'.
- the parameter of 'Not less than 30% of substances insoluble in acetone' proposed for the assay should refer to polar lipids

Oat lecithin is expected to undergo hydrolysis by various lipases in the gastrointestinal tract, similar to other edible vegetable oils and esterified fatty acids. The gastrointestinal metabolic fate of oat lecithin itself has not been studied. Yet, a 'digestion' study in humans with an emulsion of palm oil and oat-oil (94:6 w/w) formulated in yoghurt, showed hydrolysis of lipids, starting in the stomach with the majority of lipids then hydrolysed to free fatty acids in the proximal part of the jejunum. The hydrolysis of oat lecithin in the gastrointestinal tract resembles that of other edible vegetable oils (e.g. the formation of fatty acids resulting from the hydrolysis of lecithins (E 322)).

The FAF Panel was provided only with 28-day studies with oat lecithin in rats and dogs. The Panel noted that no treatment-related adverse effects were observed in these studies and consequently identified the NOAEL as the highest dose tested, i.e. 5,000 mg/kg bw per day in both studies. However, the Panel noted that these studies are not sufficient for concluding on the potential for subchronic toxicity.

Oat lecithin was tested in a bacterial reverse mutation assay and did not induce gene mutations at concentrations up to 5000 μg/plate, in the absence or presence of metabolic activation. Oat lecithin did not induce structural chromosomal aberrations when tested up to its limit of cytotoxicity at concentrations of up to 5,000 μg/mL, in the absence or presence of S9 metabolic activation. In this study no biologically relevant increase in the frequency of cells with numerical aberrations (polyploidy, endoreduplication, hyperploidy) was reported.

The Panel noted that no *in vitro* micronucleus test was submitted that would have been required according to the Guidance on Food Additives (EFSA ANS Panel, 2012). The Panel also noted that, although the available chromosomal aberrations test did not show any indication of numerical

aberrations, this test is not designed to detect aneugenicity and, accordingly, an *in vitro* micronucleus test would generally be warranted.

However, considering that:

- oat lecithin is obtained by ethanol extraction and subsequent fractionation (water/ethanol) from oat suitable for food consumption
- the main components of oat lecithin (phospholipids, glycolipids and triglycerides) are similar to those in lecithins (E322) and are not expected to be aneugenic
- based on the method of production and on the proposed specifications for oat lecithin, the presence of genotoxic impurities at concentrations that could induce detectable increases of micronuclei in an *in vitro* micronucleus assay would not be expected.

The Panel deemed the available information in this case sufficient to conclude that there is no concern with respect to genotoxicity for oat lecithin.

The Panel noted that the available toxicological data on oat lecithin submitted within the application dossier did not fulfil the requirements applicable to Guidance for the submission of food additive (EFSA ANS Panel, 2012)

Based on the composition of oat lecithin (similar components in different ratio as presented in Table 1) and the fact that it undergoes the same biotransformation, resulting in similar metabolites as those from lecithins (E322), the applicant proposed a read-across approach from toxicological data evaluated by the ANS Panel in the re-evaluation of lecithins (E 322) (EFSA ANS Panel, 2017). An overview of the toxicological data available for lecithins (E 322) for the different endpoints is available in Appendix B. The Panel agreed with the possibility to use read-across approach from toxicological data on lecithins (E 322).

Subchronic toxicity studies in rats and dogs, reviewed during the re-evaluation of lecithins (E 322), did not report any adverse effect, even at the highest dose tested (5,460 mg lecithins/kg bw per day in rats) (EFSA ANS Panel, 2017). The Panel noted that this NOAEL is consistent with the lack of treatment-related adverse effects up to 5,000 mg/kg bw per day, the highest dose tested, observed in the two 28-day studies provided for oat lecithin.

Furthermore, in the re-evaluation of lecithins (E 322), no adverse effects were observed in chronic/carcinogenicity and developmental toxicity studies (EFSA ANS Panel, 2017).

Based on the toxicological data provided for oat lecithin along with read across from lecithins (E 322) to oat lecithin no additional toxicological data were required. Therefore, the Panel considered that the previous conclusion for lecithins (E 322) equally applies to oat lecithin to be used as food additive, i.e. there is no need for a numerical ADI.

To assess the dietary exposure to oat lecithin, the exposure was calculated based on the upper end of the normal use level of 10,000 mg/kg proposed by the applicant, while its request is for an authorisation of oat lecithin in the FC 05.1 'cocoa and chocolate products as covered by Directive 2000/36/EC' at *quantum satis*.

Considering that the request is for an authorised use at *quantum satis*, if the use level would be higher than 10,000 mg/kg, then, the current exposure estimates would result in an underestimation of the exposure to oat lecithin as a food additive.

Mean exposure to oat lecithin from its use as a food additive ranged from < 0.01 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. The 95th percentile of exposure ranged from 0 mg/kg bw per day in infants to 22.5 mg/kg bw per day in children.

In the re-evaluation of lecithins (E 322) (EFSA ANS Panel, 2017), it was noted that 80–85% of products under FC 05.1 were labelled to contain E 322 according to Mintel, suggesting that this food additive is widely use in this FC. Currently, lecithins (E 322) is used in 90–96% of products belonging to the FC 05.1. If oat lecithin would be used as an alternative to lecithin (E 322) in FC 05.1 and also taking into account brand-loyalty to these products, then the exposure estimate to oat lecithin is likely to be realistic.

Considering that according to the proposed specifications, oat lecithin should contain no more than 2% choline, the Panel noted that if oat lecithin were to be used as an alternative to lecithins E 322 (containing 1.7–3.4% choline) then exposure to choline would not be higher than previously estimated (EFSA ANS Panel, 2017).

5. Conclusions

The Panel concluded that there is no need for a numerical ADI and there is no safety concern for lecithin obtained from oat suitable for human consumption, to be used as a food additive at the proposed use (FC 05.1) and use levels.

The Panel recommended that the European Commission considers including specifications for oat lecithin as a new food additive in Commission Regulation (EU) No 231/2012.

6. Recommendations

The Panel recommended that the EC considers the following modifications to the specifications proposed by the applicant for oat lecithin (Table 2):

- To delete the antioxidant content from the definition of the food additive
- information on how oat lecithin is produced should be included in the definition: the source of oat should be specified as suitable for human consumption, as well as ethanol indicated as extraction solvent
- the parameters listed under identification would more properly be described as 'Composition'.
- The parameter of 'Not less than 30% of substances insoluble in acetone' proposed for the assay should refer to polar lipids as the insoluble part

Documentation provided to EFSA

1) Application to append oat lecithin to the specifications for lecithins (E 322) in the European Union. 4th December 2018. Submitted by Intertek Scientific & Regulatory Consultancy on behalf of Swedish Oat Fiber on 21st December 2018.
2) Additional information on 22 May 2919. Submitted by Intertek Scientific & Regulatory Consultancy in response to a request from EFSA.
3) Covance Laboratories Ltd, 2003a. Fractionated oat oil (FOO): 28-day oral (gavage) administration toxicity study in the rat. Covance Study Number 2213/005. Included in the application dossier submitted on 21st December 2018.
4) Covance Laboratories Ltd, 2004. Fractionated oat oil (FOO): 28-day oral (gavage) administration toxicity study in the dog. Covance Study Number 2213/006. Included in the application dossier submitted on 21st December 2018.
5) Covance Laboratories Ltd, 2003b. Fractionated oat oil (FOO): reverse mutation in five histidine-requiring strains of *Salmonella typhimurium*. Covance Study Report No 2213/7. Included in the application dossier submitted on 21st December 2018.
6) Covance Laboratories Ltd, 2003c. Fractionated oat oil (FOO): Induction of chromosome aberration in cultured human peripheral blood lymphocytes. Covance Study Report No 2213/8. Included in the application dossier submitted on 21st December 2018.

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Abbreviations

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism, excretion
ANS	EFSA Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CFU	colony forming units
DMSO	dimethyl sulphoxide
FAF	EFSA Panel on Food Additives and Flavourings
FAIM	Food Additives Intake Model
FAO	Food and Agriculture Organization of the United Nations
FC	food category

FCS	food categorisation system
FOO	fractionated oat oil
GLP	good laboratory practice
IOM	Institute of Medicine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OECD	Organisation for Economic Co-operation and Development
LOD	limit of detection
MPL	maximum permissible limit
NOAEL	no observed adverse effect level
QS	*quantum satis*
WHO	World Health Organisation

Appendix A – Summary of total estimated exposure of oat lecithin from its proposed use as food additive using FAIM 2 per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix A can be found in the online version of this output ('Supporting information' section)

Appendix B – Summary of toxicological data required for food additives evaluations as provided by the applicant (Documentation provided to EFSA No. 2)[(a)]

Specific Data Required by EFSA	Provided for oat lecithin	Provided for lecithins (E 322)
Toxicokinetics		
Tier 1 – *in vitro* absorption and metabolism information	No	No (*in vivo* studies provided instead)
Tier 2 – *in vivo* distribution, metabolism and excretion information	Yes – toxicokinetics of a lipid fraction containing 6% oat lecithin investigated in humans	Yes – several *in vivo* studies using radiolabelled lecithins are available in animals and humans
Tier 3 (if excretion is limited or slow) – toxicokinetic parameters following repeated administration		
Toxicity (subchronic, chronic toxicity and carcinogenicity)		
Tier 1– Repeated dose 90-day oral toxicity study in a rodent species (OECD TG 408)	No – but 28-day studies conducted in rats and dogs	Yes – subchronic studies conducted in rats and dogs
Tier 2 (if needed) – chronic toxicity study and carcinogenicity (OECD TG 452, 453)	No (not required)	Yes – 24 week, 48-week and 2-year rat studies conducted
Tier 3 (if needed) – alternative models (e.g. transgenic mouse models)	No (not required)	No (not required)
Reproductive and developmental toxicity		
Tier 1– data from repeated dose 90-day oral toxicity study in a rodent species (OECD TG 408)	No – but no test item-related adverse findings in reproductive organs in 28-day studies	Yes – no test item-related adverse findings in reproductive organs in the subchronic, chronic toxicity and carcinogenicity studies
Tier 2 (if needed based on Tier 1 and toxicokinetic data): • Prenatal developmental toxicity study (OECD TG 414) • Extended one-generation reproduction toxicity study (OECD TG 443)	No (not required)	Yes – developmental studies conducted in rats, mice and rabbits. Neurodevelopmental studies conducted in rats and mice.
Tier 3 (where results in Tier 2 trigger need)- case-by-case approach	No (not required)	No (not required)

(a): 'Genotoxicity' and 'Additional studies' were included in the Table as provided by the applicant but not reproduced here.