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Safety and efficacy of lecithins for all animal species

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of lecithins for all animal species. The additive consists predominantly of lecithins derived from rapeseed, sunflower and soybean, with other plant extracts. Three different forms of the additive are produced: regular liquid lecithins, hydrolysed liquid lecithins and de-oiled lecithin powder. Lecithins are usually phospholipids, composed of phosphoric acid with choline (or ethanolamine, inositol, serine or hydrogen, in phosphatidic acid), glycerol and one or two fatty acids. Lecithins are safe for all target species. Setting a maximum content for lecithins is not considered necessary. The use of lecithins in animal nutrition does not pose any risk to the consumer. Lecithins are not irritant to the skin and eyes, not skin sensitisers and not harmful by inhalation. No risk for the environment is expected from the use of lecithins in animal nutrition. Lecithins are considered efficacious as emulsifiers at the recommended use levels.

Keywords: lecithins, hydrolysed lecithins, de-oiled lecithins, safety, efficacy, technological additive, emulsifier

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest 1 year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of 7 years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from ELMA (Europe Lecithins Manufacturers' Association)[2] for re-evaluation of the product lecithins, when used as a feed additive for all animal species category: technological; functional groups: (c) emulsifiers, (d) stabilisers, (e) thickeners and (f) gelling agents. During the assessment, the applicant requested limiting the application for authorisation to the functional group (c) emulsifier.[3]

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 1 December 2014.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product lecithins, when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

The additive under assessment is composed of lecithins (phospholipids).

The additive lecithins (including hydrolysed lecithins) has been assessed by the European Commission Scientific Committee for Food (SCF) (European Commission, 1982, 1997) and were considered safe for use in food. The Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974) has evaluated lecithins, proposing an ADI 'not limited'. The Cosmetic Ingredient Review (CIR, 2015) has also evaluated the safety of lecithins when used in cosmetics.

The additive lecithins is currently authorised for use as feed additive in feedingstuffs for all animal species with no minimum and maximum content by the Council Directive 70/524/EEC.[4] The additive is also authorised for use as food additive by Directive 95/2/EC,[5] following the *quantum satis* principle, with the exception of (i) 'non emulsified oils and fats of animal or vegetable origin (except virgin oils and olive oils) and non emulsified oils and fats of animal or vegetable origin (except virgin oils and olive oils) specifically intended for cooking and/or frying purposes or for the preparation of gravy (maximum content 30 g/L)'; (ii) 'infant formulae for infants in good health (maximum content 1 g/L)'; (iii) 'follow-on formulae for infants in good health (maximum content 1 g/L)'; and (iv) 'weaning foods for infants and young children in good health (maximum content 10 g/kg in biscuits and rusks cereal-based foods baby foods)'. The specifications for lecithins when used as food additive are laid down in Regulation (EU) No 231/2012[6].

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] ELMA (European Lecithins Manufacturers Association), Avenue de Tervueren 13 A – Bte 7, 1040 Brussels, Belgium. Companies: ADM Specialty Ingredients (Europe-BV) – The Netherlands; Koninklijke Bunge BV – The Netherlands; Cargill Texturizing Solutions Deutschland GmbH & Co. KG – Germany; LECICO GmbH/Chemi SpA – Germany; IMCOPA Food Ingredients – The Netherlands; Lasenor Emul SL – Spain; Solae Europe SA/DuPont – Switzerland; Sternchemie/Berg + Schmidt GmbH & Co. KG – Germany; Sime Darby Unimills BV – The Netherlands.

[3] Supplementary Information April 2015.

[4] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs. OJ L 270, 14.12.1970, p. 1.

[5] European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. OJ L 61, 18.3.1995, p. 1.

[6] 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, p. 1.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[7] in support of the authorisation request for the use of lecithins as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[8] and the applicable EFSA guidance documents.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers and other scientific reports to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of lecithins in animal feed. The Executive Summary of the EURL report can be found in Annex A.[9]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lecithins is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008a), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008b), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d).

3. Assessment

This application concerns the re-evaluation of lecithins as technological feed additives when used as a feed additive (category: technological; functional group: (c) emulsifiers) for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the product

The additive consists predominantly of lecithins (CAS No 8002-43-5, synonyms: phosphatides, phospholipids, lysolecithins) and other extracted substances (glycolipids, neutral lipids and free fatty acids, and carbohydrates) (Table 1).

Lecithins are usually phospholipids, composed of phosphoric acid with choline, glycerol and one (the lyso- forms) or two fatty acids (Figure 1). The choline moiety can be replaced by ethanolamine, inositol or serine or hydrogen (phosphatidic acid).

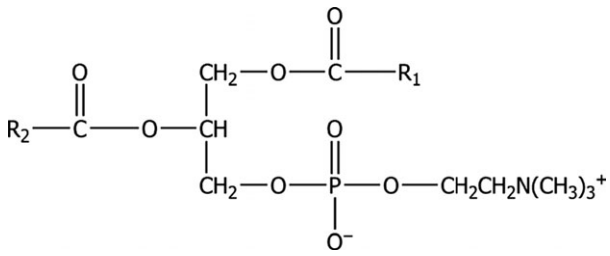

Figure 1: Molecular structure of phosphatidylcholine. Phosphatidylcholine harbours two fatty acids; lysophosphatidylcholine harbours one fatty acid

[7] FEED dossier reference: FAD-2010-0364.

[8] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/finrep-fad-2010-0364-lecithins.pdf

The lecithins under assessment derive from rapeseed, sunflower and soybean. Three different forms of the additive are produced: regular liquid lecithins, hydrolysed liquid lecithins and de-oiled lecithin powder. Regardless of their botanical origin, the regular liquid lecithins are produced by either mechanical or solvent extraction. The regular liquid lecithins may be further processed by additional solvent extraction steps to remove neutral lipids and thus, to produce de-oiled lecithin powder, or by enzyme treatment to produce the hydrolysed liquid lecithins. From rapeseed only the regular liquid lecithins are produced, while from sunflower and soybean hydrolysed and de-oiled lecithins are also available.

The typical composition of the three forms of lecithins is reported in Table 1. The phospholipid concentration in the regular and in the hydrolysed liquid lecithins is similar. The ratio of specific phospholipids would differ (higher level of the lyso- form, as indicated by the increase in free fatty acids).

Table 1: Typical qualitative composition of regular liquid lecithins, hydrolysed liquid lecithins and de-oiled lecithin powder, as proposed by the applicant

	Lecithin form		
	Regular liquid lecithins	**Hydrolysed liquid lecithins**	**De-oiled lecithin powder**
Phospholipids (%)	48–50	44–46	75–76
Glycolipids (%)	6–7	6–7	12–14
Carbohydrates (%)	5–6	5–6	7–9
Neutral lipids (%)	36–38	36–38	1–2
Free fatty acids (%)	1	5	1
Moisture (%)	1	1	1

The typical fatty acid profile of lecithins is dependent on the botanical origin (Table 2).

Table 2: Typical qualitative fatty acid profile of lecithins from rapeseed, sunflower and soybean, as proposed by the applicant

	Botanical origin		
	Rapeseed	**Sunflower**	**Soybean**
Palmitic (C 16:0) (%)	12–24	10–20	18–24
Stearic (C 18:0) (%)	1	1–5	3–5
Oleic (C 18:1) (%)	30–38	23–43	9–15
Linoleic (C 18:2) (%)	35–45	36–58	52–60
Linolenic (C 18:3) (%)	4–8	1	4–8
Others (%)	1	1	1

For lecithins used as food additive, Commission Regulation (EU) No 231/2012 sets the following specification: < 2% loss on drying, > 60% acetone-insoluble matter (> 56% for hydrolysed lecithins), < 0.3% toluene-insoluble matter, < 35 mg of potassium hydroxide(KOH)/g as acid value (< 45 mg KOH/g for hydrolysed lecithins) and ≤ 10 mmol O_2/kg as peroxide value.

Analysis of multiple batches of each form of the additive (including each relevant botanical origin) were provided (Table 3).

Table 3: Summary of the results of the analysis of regular liquid lecithins, hydrolysed liquid lecithins (HLL) and de-oiled lecithin powder

	Food specifications	**Regular liquid lecithins (HLL) (n = 21)[a]**		**Hydrolysed liquid lecithins (n = 17)[b]**		**De-oiled lecithin powder (n = 17)[c]**	
		Min.	**Max.**	**Min.**	**Max.**	**Min.**	**Max.**
Loss on drying (%)	< 2	0.30	0.48	0.26	0.73	0.86	1.90
Acetone-insoluble matter (%)	> 60 (HLL > 56)	60.1	68.0	56.1	68.4	96.0	98.4
Toluene-insoluble matter (%)	< 0.3	0.04	0.20	0.04	0.2	0.01	< 0.3

	Food specifications	Regular liquid lecithins (HLL) (n = 21)[a]		Hydrolysed liquid lecithins (n = 17)[b]		De-oiled lecithin powder (n = 17)[c]	
		Min.	Max.	Min.	Max.	Min.	Max.
Acid value (mg of potassium hydroxide/gram)	< 35 (HLL < 45)	15.9	32.0	26.7	44.9	24.7	29.2
Peroxide value (mmol O_2/kg)	< 10	< 0.5	< 3	< 0.1	3.1	0.02	< 1

(a): Five batches from soybean, eight batches from rapeseed and eight batches from sunflower.
(b): Nine batches from soybean and eight batches from sunflower.
(c): Eleven batches from soybean and six batches from sunflower.

The three forms of lecithins under assessment meet the specifications set for food additive use. In the powder form, the acetone-insoluble matter content is substantially greater (i.e. > 95%) than that implied by the existing food specification due to the extraction of neutral lipids.

3.1.2. Physico-chemical characteristics

Regular and hydrolysed liquid lecithins are brown viscous fluids (viscosity: 10 Pa.s at 25°C) with a density of about 1.04 g/cm^3, dispersible in water and with a high solubility in fats.[10] The de-oiled lecithins are in the form of a brown powder, with a relative density of 0.41. Three batches of the de-oiled lecithin powder with different physical characteristics were analysed for particle size distribution (by laser diffraction), showing variable results.[11] The coarser powders had < 0.3% of the particles with a diameter ≤ 200 μm; the finest powder had < 13.9% and < 1.6% of the particles with diameters < 100 μm and 50 μm, respectively. One batch (triplicate analysis) of a de-oiled lecithin powder showed a dusting potential (analysed by the Stauber–Heubach method) of < 4 g/m^3.[12]

3.1.3. Purity

The applicant has provided analysis of multiple batches of each form of the additive and for each relevant botanical origin.

A total of 25 batches of regular liquid lecithins (10 batches from soybean, 9 batches from rapeseed and 6 batches from sunflower), of 7 batches of hydrolysed liquid lecithins (2 batches from soybean and 5 batches from sunflower) and of 12 batches of de-oiled lecithin powder (7 batches from soybean and 5 batches from sunflower) were analysed for impurities.[13] The results showed the following maximum concentrations: arsenic < 0.05 mg/kg; lead < 0.17 mg/kg; mercury < 0.08 mg/kg. Dioxins were ≤ 0.24 ng WHO-PCDD/F-TEQ per kg and dioxin like polychlorinated biphenyls (PCBs) ≤ 0.075 ng WHO-PCB-TEQ/kg and did not raise any concern (22 batches total, 11 from soybean, 3 from rapeseed and 8 from sunflower).[14] Mycotoxin analysis showed concentrations of aflatoxin B1 < 0.03 μg/kg (27 batches total, 12 from soybean, 8 from rapeseed and 7 from sunflower) and of ochratoxin A < 10 μg/kg (20 batches total, 3 from soybean, 10 from rapeseed and 7 from sunflower).[15] These concentrations are of no concern. No microbial contamination (Total plate count: < 3,000 UFC/g; Coliforms: absent in 1 g; *Salmonella* spp.: absent in 25 g; yeast and moulds < 100 UFC/g) was detected in 48 batches of the different forms of lecithins (30 from soybean, 3 from rapeseed and 15 from sunflower).[16] A wide range of pesticides (up to over 400) were tested (22 batches total, 11 from soybean, 3 from rapeseed and 8 from sunflower)[17] and levels were below the respective limit of detection and of no concern. Six batches of lecithins from soybean were analysed for residual solvent

[10] Technical dossier/Section II/Annex_II_6_SDS_Lecithins.
[11] Supplementary Information April 2016/Annex 100- Particle size report_2001.
[12] Supplementary Information April 2016/Annex 101-Analytical data for de-oiled lecithin by Stauber–Heubach method April 2016.
[13] Technical dossier/Section II/Annex_II_1_Chemical purity_Lecithins and Supplementary Information April 2016/Annexes 4–8, 12–14, 18–20, 26–30, 36, 37, 41, 42, 48–54, 71–75, 85–87.
[14] Technical dossier/Section II/Annex_II_4_Tox purity_Lecithins and Supplementary Information April 2016/Annexes 7, 12, 14, 18–20, 55, 56, 60–63, 65, 66, 69, 70, 95.
[15] Technical dossier/Section II/Annex_II_4_Tox purity_Lecithins and Supplementary Information April 2016/Annexes 4–7, 12, 14, 18–20, 56–61, 64–68, 95.
[16] Technical dossier/Section II/Annex_II_2_Microb purity_Lecithins and Supplementary Information April 2016/Annexes 1–3, 9–11, 22–25, 31–35, 38–40, 43–47, 76–84, 88–94.
[17] Technical dossier/Section II/Annex_II_3a_Pesticide purity_data and Supplementary Information April 2016/Annexes 7, 12, 18–20, 55–56, 60–63, 65, 66, 69, 70, 95.

concentration, with the following results: hexane < 1 mg/kg, ethanol < 3.8 mg/kg and acetone < 2.5 mg/kg.[18] These concentrations are considered of no concern.

3.1.4. Stability and homogeneity

To determine the shelf-life of lecithins in ambient conditions, four batches of regular liquid lecithins[19] and three batches of de-oiled lecithins[20] were stored for 36 months, and one batch of hydrolysed liquid lecithins[21] stored for 24 months. All samples were analysed for moisture, acetone-insoluble matter, acid value and peroxide value; the regular and hydrolysed liquid lecithins, in addition, for toluene-insoluble matter and aerobic bacteria and *Salmonella* spp. count; the hydrolysed one also for phospholipid composition. No differences from the initial values were observed after storage.

For technological additives, stability in feedingstuffs can be demonstrated by persistence of the effect, and no demonstration of homogeneous distribution is considered necessary if the efficacy of the additive as emulsifier is demonstrated. Lecithins are authorised as food additives, and the emulsifying effect seen when used in food could reasonably be expected to be seen when used in feed. Therefore, it is assumed that the additive under assessment is sufficiently stable for the purpose of use.

Additional evidence of stability in feedingstuffs was provided in a study in which lecithin presence was analytically measured in two feedingstuffs dog cookies[22] (two batches) and cat pelleted feed[22] (one batch). The feedingstuffs (lipid content 18–22%) were supplemented with regular liquid lecithins at levels of 0.55% in dog cookies and 0.2% in cat feed, and then stored for 3 months at 25 or 40°C. The two feedingstuffs were monitored for lipid, and total lecithins, phosphatidylcholine, lysophosphatidylcholine and phosphorus content. No changes indicative of a loss of stability over the 3-month storage were observed in the two feedingstuffs and either temperature, considering that the supplement amounted only to 30% (dog cookies) and 20%(cat feed) of total lecithins.

As long as lecithins serve their technological function as emulsifier, a further demonstration of homogeneous mixing is not considered essential.

3.1.5. Conditions of use

The additive lecithins is intended to be used in feedingstuffs for all animal species with no minimum or maximum content. However, the applicant proposed use levels of 1,000–10,000 mg/kg complete feedingstuffs for all animal species. Only for shrimps the highest proposed inclusion level corresponds to 20,000 mg/kg complete feed.

3.2. Safety

No specific studies with the product under assessment have been provided. The safety assessment of lecithins has been based on published literature. Lecithins are normal constituents of feed materials and animal tissues and products. Hydrolysed lecithins are produced in the gut as a result of normal digestion (European Commission, 1982).

The lecithins used in the toxicological studies were extracted from different sources. Taking into account that the phospholipid fraction is essentially similar, the FEEDAP Panel considered that the differences would not affect the toxicological profile of lecithins and, therefore, regarded the studies relevant for the risk assessment of the product under assessment.

3.2.1. Absorption, distribution, metabolism and excretion

Lecithins are essentially hydrolysed by pancreatic phospholipase A2 to lysolecithins and fatty acids in the lumen of the small intestine, a small portion being absorbed intact. Both moieties are taken up by intestinal mucosal cells. After mucosal uptake, lysolecithins are preferentially re-esterified with fatty acids (acylation in rat liver microsomes (Lands, 1960)) to produce lecithins *de novo* which are incorporated into the surface coat of chylomicrons or become part of cell membranes and undergo complete lipolysis with release of fatty acids, which in turn are incorporated into triglycerides (Grundy, 1987).

[18] Technical dossier/Section II/Annex_II_5_Residual solvents_Lecithins.
[19] Technical dossier/Section II/Annex II_8a_Shelf life stability.
[20] Supplementary Information April 2016/Annex 97-Shelf Stability Study De-oiled Powder Lecithin ADM 2011.
[21] Supplementary Information April 2016/Annex 96-Shelf life of hydrolyzed lecithin.
[22] Technical dossier/Section II/Annex_II_8c_Stability in feed_Lecithins (final).

In ruminants, the slow disappearance of phospholipids in ruminal contents of sheep suggests that a fraction of dietary phospholipids could escape fermentation and reach the small intestine (Jenkins et al., 1989), where a similar fate as in monogastrics would likely occur.

3.2.2. Toxicological studies

The most recent review of lecithin toxicity was published by the Cosmetic Ingredient Review (CIR, 2015). The available toxicological studies are briefly summarised below.

Toxicological studies of a variety of lecithins of different origin showed them to be of low toxicity. Acute oral toxicity of phospholipids from bovine cerebral cortex (BC-PS) was low in mice: median lethal dose (LD_{50}) > 5,000 mg/kg bw. Gavage doses of up to 1,000 mg/kg bw per day of BC-PS produced no adverse effects in rats when given for 26 weeks or in dogs when given for 1 year. A 2-year chronic toxicity study in rats given 4% soya lecithins in their diet (1,479 and 2,280 mg/kg bw per day for males and females, respectively) showed increased parathyroid gland hyperplasia and associated myocardial fibrosis, which were attributed to increased phosphate in the diet. Lecithins were not carcinogenic in an oral carcinogenicity study in mice. No adverse effects were seen in a rat developmental toxicity study which used gavage doses of up to 200 mg/kg bw per day of phosphatidylserine. A rabbit developmental toxicity study showed no fetal abnormalities but there was reduced fetal weight at a gavage dose level of 450 mg/kg bw per day of phosphatidylserine, with a no observed adverse effect level (NOAEL) of 150 mg/kg bw per day.

Mutagenicity studies done with different phospholipids (bacterial reverse mutation test, *in vitro* chromosome aberration assay in human lymphocytes, a gene mutation assay in mouse lymphoma cells, an *in vitro* UDS (Unscheduled DNA Synthesis) assay in HELA S3 cells and an *in vivo* oral micronucleus assay in mice) showed no evidence of genotoxicity (Heywood et al., 1987).

The toxicological data on lecithins showed no effects of concern and no indication of genotoxicity and carcinogenicity.

3.2.3. Safety for the target species

Lecithins are normal constituents of feed materials and animal products, as nutritional reserve of phospholipids (eggs, milk). As examples: (i) the lecithin content of soybean is given by Wood and Allison (1982) as 1.48%. When feeding a diet with 20% full fat soybeans, the diet would contain about 0.3% crude lecithins. (ii) Soybean oil is reported to contain 3.7% phospholipids (Hammond et al., 2005); feeding a diet with 10% soybean oil would result in a crude lecithin content of about 0.37%. Thus, lecithins are not expected to produce signs of intolerance under normal feeding conditions when carefully balanced diets are provided.

The above expectations are confirmed by a number of publications in several animal species. For example, Cantor et al. (1997) fed chickens for fattening diets supplemented with 0%, 2.5% and 5% soy lecithins at the expense of a fat blend for 6 weeks. Dietary treatment did not affect broiler performance. Baynen and Van Gils (1983) fed groups of veal calves (a total of 175 Holstein-Friesian bull calves, 40.9 kg bw on average) with skim milk-based milk replacer containing 0%, 2% and 4% added native soybean lecithins for 20 weeks. The overall daily gain was 1,243 g/day; no differences between the groups were reported. De Nardi et al. (2012) concluded from a study with a total of 12 mid-lactating dairy cows comparing total mixed rations (TMR) with 6% of dry matter (DM) soy lecithins (a by-product of biodiesel production) or another choline source that soy lecithins can be used as an available source of choline. However, milk fat was slightly reduced, whereas fatty acid pattern was not affected. It should be mentioned that the lecithin diet provided about 14 g choline per cow and day, but the choline diet 25 g. From a study with sheep (a total of 12 Hampshire wethers), Jenkins et al. (1989) concluded that phospholipids are degraded in the rumen and inhibit ruminal digestion in a manner similar to that of commercial fats and oils. Somewhat in contrast, Wettstein et al. (2000) concluded that lecithins might be preferred to oils when used as energy source in diets of dairy cows. The lecithins levels tested was 1.2–1.5% (DM) of the TMR.

Brown et al. (1997) stated in a review that 'fish and crustaceans are apparently the only animal groups that require phophatidylcholine in their diet'. The same authors fed Atlantic salmon (*Salmo salar*) and Coho salmon (*Oncorhynchus kisutch*) fingerlings (3–4 g bw) for 56 days diets containing 3% different soybean-derived lecithin products. All products appeared beneficial in the study with Coho salmon, but not with Atlantic salmon. The authors discussed the possibility that the lecithin concentration used did not cover the requirements of Atlantic salmon. Poston (1991) fed triplicate groups of 150 rainbow trout fry (0.12 g bw) soyprotein/amino acid mixture-based diets with

0%, 4% and 8% added soy lecithins for 16 weeks. Both lecithin concentrations improved growth significantly and reduced mortality without substantial differences between the two levels. Azarm et al. (2013) fed triplicate groups of 165 rainbow trout (*Oncorhynchus mykiss*) fry (0.12 g bw) diets supplemented with 0%, 2%, 3% and 6% soybean or egg lecithins at the expense of soybean oil for 40 days, with no adverse effects observed. The authors concluded that both lecithin sources improved growth, with the egg lecithins appearing somewhat superior to soybean lecithins.

3.2.3.1. Conclusion

Lecithins are normal constituents of feed materials commonly used in feed formulation. A number of studies in several target species showed that no adverse effects at normal inclusion level are to be expected. The FEEDAP Panel considers that lecithins are safe for all target species, and that setting a maximum content for lecithins is not considered necessary. It is noteworthy that fish and crustaceans may have a nutrient requirement for phospholipids.

3.2.4. Safety for the consumer

Lecithins are authorised as food additive with no maximum content and with ADI not specified. Lecithins are natural constituents of plants and animal products, as components of biological components and as a nutritional reserve of phospholipids (eggs, milk). Lecithins in animal products result from dietary sources and *de novo* synthesis. The metabolic fate of lecithins is common to all animal species, including humans, lysolecithins being intermediate metabolites. An accumulation in animal tissues and products is not expected.

Therefore, the FEEDAP Panel concludes that the use of lecithins in animal nutrition does not pose any risk to the consumer.

3.2.5. Safety for the user

No specific studies to support the safety for users were submitted in the dossier. The report on lecithins of the CIR (2015) summarises the available studies, which are briefly reported below.

The subacute inhalation toxicity of aerosols of liposomes of hydrogenated soy phosphatidylcholine (HSPC) was tested in mice by nose-only exposure for 1 h/day for 5 days/week over 4 weeks. The liposomes contained 50 mg HSPC/mL and a total volume of 20 mL of liposomes was administered daily. It was demonstrated that the test material was taken up by alveolar macrophages. The phagocytic function of the macrophages was not affected. Transmission microscopy and morphometry showed no effects on lung histology. The FEEDAP Panel notes that this study does not meet the current requirements for subacute inhalation toxicity (OECD Guideline 412). However, inhalation exposure to the additive under assessment would be minimal.

In a single-insult occlusive patch test in rabbits, a 65% solution of lecithins was minimally irritating. Hydrogenated lecithins were not a primary irritant in rabbits.

A 65% solution of lecithins and products containing 2.25% or 3% of this solution were non-irritating to minimally irritating to unrinsed rabbit eyes.

A 15% solution of hydrogenated lecithins in petroleum and products containing low concentrations of lecithins (0.1–0.3% of a 65% solution) did not produce skin sensitisation in humans. No information was available on the sensitising potential of undiluted lecithins.

3.2.5.1. Conclusion on the safety for the user

Lecithins are not irritant to the skin and eyes, not skin sensitisers and not harmful by inhalation.

3.2.6. Safety for the environment

Lecithins are normal constituents of plants and animals. Once ingested, lecithins are extensively metabolised. Therefore, the use of lecithins in animal nutrition does not increase their concentration in the environment. No risk for the environment is expected.

3.3. Efficacy

Lecithins are authorised for use as food additive with the function of emulsifier. The effect seen when used in food could reasonably be expected to be seen when used in feed at the recommended concentration.

4. Conclusions

Lecithins are safe for all target species. Setting a maximum content for lecithins is not considered necessary.

The use of lecithins in animal nutrition does not pose any risk to the consumer.

Lecithins are not irritant to the skin and eyes, not a skin sensitiser and not harmful by inhalation.

No risk for the environment is expected from the use of lecithins in animal nutrition.

Lecithins are considered efficacious as emulsifiers at the recommended use levels.

Documentation provided to EFSA

1) Lecithins for all animal species. November 2010. Submitted by ELMA (European Lecithin Manufacturers Association).
2) Lecithins for all animal species. Supplementary information. April 2016. Submitted by ELMA (European Lecithin Manufacturers Association).
3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Lecithins for all animal species.
4) Comments from Member States.

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Abbreviations

ADI	average daily intake
AME	apparent metabolisable energy
BW	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
CIR	Cosmetic Ingredient Review
DM	dry matter
EC	European Commission
EEC	European Economic Community
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
HSPC	hydrogenated soy phosphatidylcholine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyls
PCDD/F	polychlorinated dibenzodioxins/furans
SCF	Scientific Committee for Food
TEQ	toxic equivalent
TMR	total mixed ration
UDS	Unscheduled DNA Synthesis
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for lecithins E322

In the current applications authorisation is sought under article 10(2) for Lecithins under the 'category'/'functional groups' 1(c), 1(d), 1(e) and 1(f) 'technological additives'/'emulsifiers', 'stabilisers', 'thickeners' and 'gelling agents' according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additive for all animal species. Lecithins are mixtures or fractions of phosphatides obtained from animal or vegetable foodstuffs, including hydrolysed products produced by enzymatic reaction with suitable phospholipase. Lecithins are extracted from eggs and oil-bearing seeds, and they appear as a brownish viscous liquid, paste or powder. The Applicant stated that the purity criteria/specification set in Directive 2008/84/EC for the food additive are applicable also for the feed additive. Lecithins are used as emulsifying agents to homogenize feed matrixes consisting of oily and aqueous phases. The Applicant did not specify the minimum or maximum inclusion levels, but stated that lecithins are used *quantum satis* in feed corresponding to concentrations up to 5% w/w.

For the characterisation of lecithins, the Applicant submitted the internationally recognised monograph 'Lecitin' from the FAO JECFA Compendium, cited in Commission Regulation (EU) 231/2012. Identification is based on the qualitative tests for acetone-insoluble matter; solubility in water; choline; phosphorus; fatty acid; and hydrolysed lecithins. The feed additive is further characterised using the following quantitative assays: loss on drying; acid value; peroxide value; and toluene-insoluble matter.

For the quantification of lecithins in feedingstuffs, the Applicant submitted a two-step indirect method based on (1) lipid extraction from the feedingstuffs followed by (2) phosphorus quantification in the lipid fraction by the colorimetric determination of the formed phosphomolybdate complex. According to the Applicant, the results correlate with the content of lecithins in feedingstuffs. The Applicant provided few experimental results obtained in the frame of the stability study of the additive in feedingstuffs. However, the EURL considers that these results are not sufficient to demonstrate the accurate and unambiguous quantification of lecithins in feedingstuffs. Therefore, the EURL cannot recommend any method for official control to quantify lecithins in feedingstuffs.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.