SCIENTIFIC OPINION

EFSA Journal

ADOPTED: 13 July 2016

doi: 10.2903/j.efsa.2016.4560

Safety and efficacy of lecithins (Lipidol) 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 (Lipidol) for all animal species. The additive consists predominantly of lecithins and other extracted substances. 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, safety, efficacy, technological additive, emulsifier

Requestor: European Commission

Question number: EFSA-Q-2014-00464

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Acknowledgements: The Panel wishes to thank the members of the Working Group on Technological additives, including Anne-Katrine Lundebye, Carlo Nebbia and Derek Renshaw, for the preparatory work on this scientific opinion.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of lecithins (Lipidol) for all animal species. EFSA Journal 2016;14(8):4560, 12 pp. doi:10.2903/j.efsa.2016.4560

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

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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 Pathway Intermediates Limited[2] for re-evaluation of the product lecithins (Lipidol), when used as a feed additive for all animal species (category: technological; functional group: (c) emulsifiers).

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 15 January 2015.

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 (Lipidol), 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) have 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.[3] The additive is also authorised for use as food additive by Directive 95/2/EC,[4] 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[5].

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[6] in support of the authorisation request for the use of lecithins (Lipidol) as a feed additive. The

[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] Pathway Intermediates Ltd, Unit 46 Atcham Business Park, SY4 4UG Shrewsbury, United Kingdom.
[3] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs. OJ L 270, 14.12.1970, p. 1.
[4] 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.
[5] 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.
[6] FEED dossier reference: FAD-2010-0398.

technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[7] 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.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of lecithins (Lipidol) 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 a feed additive (category: technological; functional group: (c) emulsifiers) for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the product

Lecithins are extracted from crushed soybeans and pasteurised, can be partially hydrolysed, and then blended in order to obtain an additive with consistent emulsification properties. The additive consists predominantly of lecithins (CAS no. 8002-43-5, synonyms: phosphatides, phospholipids, lysolecithins) and other extracted substances (glycolipids, glycerides and free fatty acids, carbohydrates and fibre). The additive is a dark amber to brown viscous fluid (viscosity: maximum 10 Pa.s at 25°C) with a density of about 1.04 g/cm^3, a variable but generally low solubility in water and in cold oils, and high solubility in hot oils and in mineral oils.

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

The applicant reported the typical composition of the additive as follows: 18% phospholipids, 11% lysophospholipids, 6% other phospholipids, 14% glycolipids, 4% sterols, 38% glycerides and free fatty acids, 4% carbohydrates and fibre each, and 1% moisture. The typical composition is confirmed by a nuclear magnetic resonance (NMR) spectrometry analysis (^{1}H, ^{13}C and ^{31}P measured as active nucleus) of five batches of the additive.[9] The phospholipid fraction of the additive (five batches) were also identified as 1-lysophosphotidylcholine (0.4–0.6%), 2-lysophosphotidylcholine (4.3–5.5%), lysophosphotidylinositol (1.4–2.5%), lysophosphatidylethanolamine (2.06–3.49%), phosphotidylinositol (7.3–7.8%), lysophosphatidic acid (0.9–1.9%), phosphatidylcholine (5.4–3.9%), phosphatidic acid (0.9–1.8), *N*-acylphosphatidylethanolamine (0.7–1.1%), phosphatidylethanolamine (1.5–2.7%) and other minor phosphopilids (3.6–4.8%). The product contains about 1.6% phosphorus.[9]

[7] 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.

[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/finrep-fad-2010-0398-lipidol.pdf

[9] Supplementary Information August 2015/Composition of Lipidol full.

Linoleic and palmitic acids concentrations were also analysed in five additional batches of the additive.[10] They amounted on average to 3.99% and 0.80%, respectively. Free fatty acids amount to 17–20 molar % of the total fatty acids.[9]

The additive lecithins is further specified, for its use as a food additive, with: loss on drying: < 2%; acetone-insoluble matter: > 60% (hydrolysed lecithins: > 56.0%), toluene-insoluble matter: < 0.3%; acid value: < 35 mg of potassium hydroxide/g (hydrolysed lecithins: < 45 mg of potassium hydroxide/g), peroxide value: ≤ 10. Five batches of the additive were analysed for some of these parameters, resulting in the following ranges of values: loss on drying: 0.57–0.91%; acetone-insoluble matter: 51.29–54.95%; toluene-insoluble matter: 0.73–0.98%; peroxide value: 0. Acid value was not analysed.[11] The results showed that the specifications for acetone-insoluble matter and toluene-insoluble matter set for the food additive were not met.

3.1.2. Purity

Three batches of the additive were analysed for arsenic (< 0.06 mg/kg), lead (< 0.13 mg/kg) and mercury (< 0.01 mg/kg). Mycotoxin analysis showed concentrations of aflatoxin B1 < 0.01 μg/kg, ochratoxin A < 10 μg/kg and total fumonisin < 0.22 mg/kg; they all were of no concern. Total dioxins were ≤ 0.20 ng WHO-PCDD/F-TEQ per kg and dioxin-like polychlorinated biphenyls (dl-PCBs) ≤ 0.069 ng WHO-PCB-TEQ/kg and did not raise any concern.[12] Over 480 pesticides were tested and levels were below the respective limit of detection[13] and of no concern. No analysis was performed on the additive regarding microbiological contamination.

3.1.3. Stability and homogeneity

In order to demonstrate the stability of the additive, samples of the additive were stored in open tubes for 14 days at 55°C and 60% relative humidity, and then analysed by NMR.[14] No differences to control samples were observed in the concentration of lysophosphatidylcholine, lysophosphatidylinositol, lysophosphatidylethanolamine and lysophosphatidic acid.

No specific studies for the stability in feedingstuffs were submitted. 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.

3.1.4. 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 100–1,500 mg/kg complete feed.

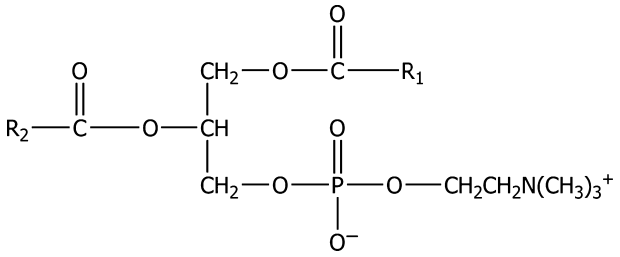

Figure 1: Molecular structure of phosphatidylcholine. Phosphatidylcholine harbours two fatty acids; lysophosphatidylcholine harbours one fatty acid

[10] Supplementary Information August 2015/EFSA Report FFA Analysis.
[11] Supplementary Information August 2015/ILS Reports_1.
[12] Supplementary Information August 2015/Sciantec reports.
[13] Supplementary Information August 2015/ILS Reports_2.
[14] Technical dossier/Section II/Annex_II_4_Accelerated_Storage _Test.

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).

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 available source of choline. However, milk fat was slightly reduced, whereas fatty acid pattern was not affected. It should be mentioned that the lecithins 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. 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 lecithin 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 day 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.

The applicant also provided a trial performed with 704 Ross 308 one-day-old chickens for fattening.[15] The animals were divided into four groups fed for 42 days a mash basal maize/wheat diet and soybean diet, supplemented with 0 or 500 mg lecithins/kg feed, or a negative control diet (basal diet characterised by reduced energy content: −75 kcal/kg AME (apparent metabolisable energy), and reduced crude protein and amino acid content (−2%), supplemented with 0 or 500 mg lecithins/kg feed. Each treatment consisted of eight pens with 22 chickens each. The animals were weighted (per pen) at the start of the trial, at day 21 and at day 42 and on the same days feed intake was measured. Weight gain and feed to gain ratio were calculated for the respective periods. At day 21, faecal samples were collected from each pen and apparent faecal digestibility of gross energy, crude protein and ether extract were determined. The data were analysed with a completely randomised design with ANOVA, the pen being the statistical unit. No differences in any of the parameters analysed were registered between the groups administered 500 mg lecithins/kg feed and the respective control group. Even if the study does not fulfil the criteria of a tolerance study, it was considered as a supporting evidence of the safety of lecithins for the target species.

3.2.3.1. Conclusions on the safety for target species

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 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.

[15] Technical dossier/Section III/Annex_III_1a_Broiler_feeding_trial and Annex_III_1B_Broiler_feeding_trial_raw_data.

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 (oily product) 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 a 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) Lipidol Lecithin. November 2010. Submitted by Pathway Intermediates Ltd.
2) Lipidol Lecithin. Supplementary information. August 2015. Submitted by Pathway Intermediates Ltd.
3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for lecithin (Lipidol).
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Abbreviations

ADI	average daily intake
AME	apparent metabolisable energy
ANOVA	analysis of variance
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 and Agriculture Organization of the United Nations
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
HLL	hydrolysed liquid lecithins
HSPC	hydrogenated soy phosphatidylcholine
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NMR	nuclear magnetic resonance
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 (Lipidol)

In the current applications authorisation is sought under article 10(2) for Lipidol under the 'category'/'functional groups' 1(c) 'technological additives'/'emulsifiers' 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.

Lipidol is a complex mixture of lipids containing phosphoric acid, choline, fatty acids, glycerol, glycolipids, triglycerides and phospholipids. It is obtained from oil-bearing seeds (e.g. soybeans, rapeseeds and sunflower seeds) and appears as dark amber to brown viscous liquid. The Applicant stated that the purity criteria/specification set in Directive 96/77/EC for the food additive are applicable also for the feed additive. The same requirements are also established in Commission Regulation (EU) No 231/2012 published after the application was submitted. The Applicant did not specify the minimum or maximum inclusion levels, but stated that they range from 0.01% to 0.15% of Lipidol in feedingstuffs.

The Applicant submitted single-laboratory validated and a further verified method based on 31P NMR spectroscopy to quantify the phospholipid fraction of lecithins in feed additive. However, due to the limited availability of the required instrumentation, the EURL does not consider NMR spectroscopy suitable for official control.

Instead, for the characterisation of the feed additive, the EURL considers the methods described in Regulation (EU) No 231/2012 and in the FAO JECFA ('lecithins' monograph) suitable for official control. 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.

As the accurate quantification of lecithins added to feedingstuffs is not achievable experimentally, the EURL cannot evaluate nor 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.