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Modification of the terms of authorisation of lecithins as a feed additive for all animal species

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

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the modification of the terms of authorisation of lecithins as a feed additive for all animal species. Lecithins are currently authorised for use in feed for all animal species (Commission Implementing Regulation (EU) 2017/2325). The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion of the additive lecithins in 2016. The Panel concluded that lecithins are safe for the target species, the consumer, the user and the environment, and that they are efficacious as emulsifier. The requested modification refers to the alignment of the specifications of the feed additive to the specifications set for lecithins when used as food additives, and the inclusion in the authorisation of rapeseed among the botanical sources of hydrolysed and de-oiled lecithins and of de-oiled hydrolysed soybean lecithins as an additional form of the additive. Based on the data available, all the lecithins of different botanical origin and their forms under application meet the specifications set for the use of lecithins as a food additive. The Panel therefore recommended applying the specifications set for food additive to the lecithins under application. In its previous opinion, the Panel concluded that lecithins are safe for the target species, the consumer, the user and the environment, and that they are efficacious as an emulsifier. The Panel is not aware of any information related to the use of rapeseed as an additional source of hydrolysed liquid lecithins and de-oiled lecithin powder that would modify the previous conclusions.

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1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from ELMA (Europe Lecithin Manufacturers Association)² for authorisation of the product 1c322i – lecithins liquid, 1c322ii – hydrolysed lecithins, 1c322iii – lecithins de-oiled when used as a feed additive for all animal species (category: technological additives; functional group: 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 13(3) (modification of the authorisation of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 28 May 2018.

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 1c322i – lecithins liquid, 1c322ii – hydrolysed lecithins, 1c322iii – lecithins de-oiled, when used under the proposed conditions of use (see Section 3.1.2).

1.2. Additional information

The additive under assessment is lecithins. The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion of the additive lecithins in 2016 (EFSA FEEDAP Panel, 2016). The Panel concluded that lecithins are safe for the target species, the consumer, the user and the environment, and that they are efficacious as emulsifier. Lecithins are currently authorised for use in feed for all animal species (Commission Implementing Regulation (EU) 2017/2325).³

The applicant is now requesting the modification of the specifications of the additive to align them with those of lecithins used as food additives, the inclusion of rapeseed among the botanical sources of hydrolysed lecithins and de-oiled lecithins and of de-oiled hydrolysed soybean lecithins as an additional form of the additive.

The additive 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 acceptable daily intake (ADI) 'not limited'. The Cosmetic Ingredient Review (CIR, 2015) has also evaluated the safety of lecithins when used in cosmetics.

The additive is authorised for use as a food additive by Regulation (EC) No 1333/2008⁴, 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 a food additive are laid down in Regulation (EU) No 231/2012.⁵

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 – Europe Lecithin Manufacturers Association. Avenue de Tervueren, 13A-b7, 1040, Brussels, Belgium.

³ Commission Implementing Regulation (EU) 2017/2325 of 14 December 2017 concerning the authorisation of preparations of lecithins liquid, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species and amending Implementing Regulation (EU) 2017/1007. OJ L 333, 15.12.2017, p. 17.

⁴ 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, p. 16.

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.

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁶ in support of the authorisation request for the use of 1c322i – lecithins liquid, 1c322ii – hydrolysed lecithins, 1c322iii – lecithins de-oiled as a feed additive. The technical dossier was prepared following the provisions of Article 13 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008⁷ 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, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁸

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of 1c322i – lecithins liquid, 1c322ii – hydrolysed lecithins, 1c322iii – lecithins de-oiled 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), Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC (EFSA, 2008) and Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012b).

3. Assessment

This application concerns a request for the modification of the terms of authorisation of lecithins as technological feed additives (functional group: (c) emulsifiers) for all animal species.

In the current authorisation as a feed additive,³ the three forms of lecithins (lecithins liquid, hydrolysed lecithin and lecithins de-oiled) are characterised based on their content of phospholipids and moisture, which differ from the specifications for lecithins used as food additive.

The applicant is now requesting the alignment of the specifications of the feed additive to the specifications set for lecithins when used as food additive. In addition, the applicant is seeking the inclusion in the authorisation of rapeseed among the botanical sources of hydrolysed lecithins and de-oiled lecithins and of an additional form of the additive (de-oiled hydrolysed soybean lecithins).

3.1. Characterisation

The additive under assessment consists predominantly of lecithins (synonyms: phosphatides, phospholipids, lysolecithins) and other extracted substances (glycolipids, neutral lipids and free fatty acids, and carbohydrates). Lecithins are usually phospholipids, composed of phosphoric acid with choline, glycerol and one (the lyso-forms) or two fatty acids.

The specifications for lecithins as a food additive are : < 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 O₂/kg as peroxide value.⁹

In the previous opinion (EFSA FEEDAP Panel, 2016), the three forms of lecithins ((i) regular liquid lecithins, derived from soybean, rapeseed and sunflower; (ii) hydrolysed liquid lecithins, derived from soybean and sunflower; (iii) de-oiled lecithins powder derived from soybean and sunflower) were fully characterised according to the specifications proposed by the applicant, which were in line with those for the use of lecithins as food additive.

Regular liquid lecithins are produced by either mechanical or solvent extraction. From regular liquid lecithins, the de-oiled lecithins powder (solvent extraction) and the hydrolysed lecithins powder

⁶ FEED dossier reference: FAD-2018-0018.

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/jrcsh/files/finrep-fad-2010-0364-lecithins.pdf>

⁹ Commission Regulation (EU) No 231/2012.

(enzymatic treatment) are derived. The newly proposed form, de-oiled hydrolysed lecithins from soybean, is produced by the concomitant application of solvent extraction and enzymatic treatment.

The results of the analysis of five batches of de-oiled hydrolysed lecithins from soybean were already included and summarised in the previous opinion, but they were included in the results presented for de-oiled lecithin powder. The characterisation of this newly proposed form of lecithins is now included in Table 1.

To support the inclusion of rapeseed as a source of hydrolysed liquid lecithins and de-oiled lecithins powder, data on five batches of each form were submitted.¹⁰

A summary of the characterisation of the four forms of lecithins (regular liquid lecithins, hydrolysed liquid lecithins, de-oiled lecithins powder and de-oiled hydrolysed lecithins), derived from the three botanical sources (soybean, sunflower and rapeseed) are summarised in Table 1.

Table 1: Summary of the results of the analysis of regular liquid lecithins, hydrolysed liquid lecithins (HLL), de-oiled lecithins powder and de-oiled hydrolysed lecithins

	Food specifications	Regular liquid lecithins (n = 21) ^(a)		Hydrolysed liquid lecithins (HLL) (n = 22) ^(b)		De-oiled lecithin powder (n = 17) ^(c)		De-oiled hydrolysed lecithins (n = 5) ^(d)	
		Min.	Max.	Min.	Max.	Min.	Max.	Min.	Max.
Loss on drying (%)	< 2	0.30	0.48	0.25	0.73	0.86	1.90	0.86	1.00
Acetone-insoluble matter (%)	> 60 (HLL > 56)	60.1	68.0	56.0	68.4	96.0	98.4	96.0	96.5
Toluene-insoluble matter (%)	< 0.3	0.04	0.20	0.04	0.2	0.01	< 0.3	0.03	< 0.3
Acid value (mg of potassium hydroxide per gram)	< 35 (HLL < 45)	15.9	32.0	26.7	44.9	23.0	29.2	24.7	29.1
Peroxide value (mmol O₂/kg)	< 10	< 0.5	< 3	< 0.1	3.1	0	< 1	< 1	< 1

(a): 5 batches from soybean, 8 batches from rapeseed and 8 batches from sunflower.

(b): 9 batches from soybean, 5 batches from rapeseed and 8 batches from sunflower.

(c): 6 batches from soybean, 5 batches from rapeseed and 6 batches from sunflower.

(d): 5 batches from soybean.

The specifications for lecithins as a food additive also include maximum level for arsenic (3 mg/kg), lead (2 mg/kg) and mercury (1 mg/kg).

The purity (concentrations of heavy metals and arsenic, dioxins and dioxin like polychlorinated biphenyls (PCBs), mycotoxins, pesticides and residual solvents and microbial contamination) of the four forms of lecithins derived from the three botanical sources (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 lecithins powder (7 batches from soybean and 5 batches from sunflower)) was already evaluated in the previous opinion (EFSA FEEDAP Panel, 2016). The Panel did not identify any impurity at concentrations of concern. The results obtained from the analysis of regular liquid lecithins from rapeseed are considered representative for the other two forms of the rapeseed derived lecithins (hydrolysed and de-oiled), that are obtained by further processing of the regular liquid lecithins. The results of the analysis of arsenic, lead and mercury in five new batches of rapeseed de-oiled lecithins powder showed concentrations of < 0.1, < 0.05 and < 0.005 mg/kg additive, respectively, confirming the absence of concern.

Considering all the above, the four forms of lecithins under assessment, independently from the botanical origin, meet the specifications set for food additive use.

¹⁰ Technical dossier/Section II/Annex_II_B_Rapeseed lecithins.

The Panel notes that in the powder forms, the acetone-insoluble matters content is substantially greater (i.e. > 95%) than that implied by the existing food specification due to the extraction of neutral lipids.

3.1.1. Stability and homogeneity

In the previous opinion (EFSA FEEDAP Panel, 2016), the Panel assessed the results of the analysis of four batches of regular liquid lecithins and three batches of de-oiled lecithins (stored for 36 months, at temperatures between 10 and 35°C), and of one batch of hydrolysed liquid lecithins (stored for 24 months at temperatures between 1 and 35°C) of different botanical origin. All the samples were analysed for moisture content, acetone-insoluble matter, acid value and peroxide value. The regular and hydrolysed liquid lecithins, in addition, were analysed for toluene-insoluble matter and aerobic bacteria and *Salmonella* spp. count: for the hydrolysed lecithins phospholipid composition was also analysed. No differences to the initial values were observed after storage. In the previous opinion the stability of lecithins in feeds (cookies for dog and cat pelleted feed) and their capacity to homogeneously distribute was also assessed. No additional information was submitted for the rapeseed hydrolysed and de-oiled lecithins. However, the Panel considers that the previous conclusions would apply to all forms and sources of lecithins under application.

3.1.2. Conditions of use

Lecithins are 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

In its previous opinion (EFSA FEEDAP Panel, 2016), the Panel concluded that (i) lecithins are safe for all target species, and that setting a maximum content for lecithins is not considered necessary, (ii) the use of lecithins in animal nutrition does not pose any risk to the consumer, (iii) lecithins are not irritant to the skin and eyes, not skin sensitiser and not harmful by inhalation, and (iv) no risk for the environment is expected from the use of lecithins in animal nutrition.

The Panel is not aware of any information related to the use of rapeseed as an additional source of hydrolysed liquid lecithins and de-oiled lecithin powder that would modify the previous conclusions.

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 concentrations.

4. Conclusions

Based on the data available, all the lecithins of different botanical origin and their forms under application meet the specifications set for the use of lecithins as a food additive. The Panel therefore recommends applying the specifications set for food additive to the lecithins under application.

In its previous opinion on the additive lecithins (EFSA FEEDAP Panel, 2016), the Panel concluded that lecithins are safe for the target species, the consumer, the user and the environment, and that they are efficacious as emulsifier. The Panel is not aware of any information related to the use of rapeseed as an additional source of hydrolysed liquid lecithins and de-oiled lecithin powder that would modify the previous conclusions.

Documentation provided to EFSA

- 1) 1c322i - lecithins liquid, 1c322ii - hydrolysed lecithins, 1c322iii - lecithins de-oiled. March 2018. Submitted by ELMA - Europe Lecithin Manufacturers Association.
- 2) Comments from Member States.

Chronology

Date	Event
11/04/2018	Dossier received by EFSA
17/04/2018	Reception mandate from the European Commission
28/05/2018	Application validated by EFSA – Start of the scientific assessment
08/06/2018	Comments received from Member States
12/06/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

ADI	acceptable daily intake
CAS	Chemical Abstracts Service
CIR	Cosmetic Ingredient Review
EEC	European Economic Community
ELMA	Europe Lecithin Manufacturers Association
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
HLL	hydrolysed liquid lecithins
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
PCB	polychlorinated biphenyl
SCF	Scientific Committee for Food
WHO	World Health Organization