

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1980**of 13 December 2018****amending Implementing Regulation (EU) 2017/2325 as regards the terms of authorisation of preparations of lecithins liquid, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) The uses of the preparations of lecithins liquid, lecithins hydrolysed and lecithins de-oiled as feed additives were authorised as feed additives for all animal species by Commission Implementing Regulation (EU) 2017/2325 ⁽²⁾.
- (3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the applicant proposed changing the terms of authorisation of the preparations by submitting an application to align the specifications of lecithins as feed additives to the specifications set for lecithins when used as food additives and to extend the authorisation to the use of rapeseed as an additional source of lecithins hydrolysed and lecithins de-oiled. The application was accompanied by the relevant supporting data. The Commission forwarded the application to the European Food Safety Authority (hereinafter 'the Authority').
- (4) The Authority concluded in its opinion of 12 June 2018 ⁽³⁾ that all the lecithins of different botanical origin and their forms used as feed additive meet the specifications set for the use of lecithins as food additive and that the use of rapeseed as an additional source of lecithins does not modify the previous conclusions that the lecithins do not have an adverse effect on animal health, human health or the environment and that they are efficacious as emulsifier. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the proposed modifications to the authorisation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (6) Implementing Regulation (EU) 2017/2325 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Implementing Regulation (EU) 2017/2325 is replaced by the Annex to this Regulation.

*Article 2***Transitional measures**

1. The additives 1c322i, 1c322ii and 1c322iii and premixtures containing those additives which are produced and labelled before 2 July 2019 in accordance with the rules applicable before 2 January 2019 may continue to be placed on the market and used until the existing stocks are exhausted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ 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).

⁽³⁾ EFSA Journal 2018; 16(6):5334.

2. Compound feed and feed materials containing the additives as specified in Annex I which are produced and labelled before 2 January 2020 in accordance with the rules applicable before 2 January 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the additives as specified in Annex I which are produced and labelled before 2 January 2021 in accordance with the rules applicable before 2 January 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 December 2018.

For the Commission
The President
Jean-Claude JUNCKER

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of lecithins/kg of complete feedingstuff with a moisture content of 12 %			

Category of technological additives. Functional group: emulsifiers

1c322i	—	Lecithins	<i>Additive composition</i> Preparations of: — lecithins and hydrolysed lecithins in liquid (plastic to fluid) form; — de-oiled lecithins and de-oiled hydrolysed lecithins in solid form. <i>Characterisation of the active substance</i> Lecithins, hydrolysed lecithins, de-oiled lecithins and de-oiled hydrolysed lecithins derived from soybean, sunflower or rapeseed: CAS no. 8002-43-5; <u>Assay:</u> — Lecithins, de-oiled lecithins: not less than 60,0 % of substances insoluble in acetone; — hydrolysed lecithins and de-oiled hydrolysed lecithins: not less than 56,0 % substances insoluble in acetone. Loss on drying: not more than 2 % (105 °C, 1 hour) Toluene-insoluble matter: not more than 0,3 %	All animal species	—	—	—	In the label of feed additive and premixtures the form(s) used shall be indicated	6 July 2027
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Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of lecithins/kg of complete feedingstuff with a moisture content of 12 %			
			<u>Acid value:</u> — Lecithins, de-oiled lecithins not more than 35 mg of potassium hydroxide per gram; — hydrolysed lecithins and de-oiled hydrolysed lecithins: not more than 45 mg of potassium hydroxide per gram Peroxide value: equal to or less than 10 <i>Analytical method</i> ⁽¹⁾ For the characterisation of feed additive: Commission Regulation (EU) No 231/2012 ⁽²⁾ and the corresponding tests in the FAO JECFA monograph 'Lecithin' ⁽³⁾ ⁽⁴⁾						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽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, p. 1).

⁽³⁾ FAO JECFA Combined Compendium of Food Additive Specifications, 'Lecithin', Monograph No 4 (2007), http://www.fao.org/fileadmin/user_upload/jecfa_additives/docs/monograph4/additive-250-m4.pdf

⁽⁴⁾ FAO JECFA Combined Compendium for Food Additive Specifications — Analytical methods, test procedures and laboratory solutions used by and referenced in the food additive specifications, Vol. 4, <http://www.fao.org/docrep/009/a0691e/a0691e00.htm>