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 (Text with EEA relevance)

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

(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 9(2) 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Lecithins were authorised without a time limit in accordance with Directive 70/524/EEC as feed additive for all animal species. These additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 an application was submitted for the re-evaluation of preparations of lecithins as feed additives for all animal species. The applicant requested those additives to be classified in the additive category ‘technological additives’ and in the functional group ‘emulsifiers’. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 13 July 2016[(3)] that, under the proposed conditions of use, the preparations of lecithins, lecithins hydrolysed and lecithins de-oiled do not have an adverse effect on animal health, human health or the environment. The Authority also concluded that the preparations are considered efficacious for use in feed as emulsifiers. The Authority does not consider that there is a need for specific requirements of post-market

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2325. (See end of Document for details)*

monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of lecithins liquid, lecithins hydrolysed and lecithins de-oiled shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparations should be authorised as specified in the Annex I to this Regulation.

(6) It is considered appropriate to harmonise the characteristics of the lecithins, lecithins liquid, lecithins hydrolysed and lecithins de-oiled and the conditions of use to avoid the distortion of the market, Commission Implementing Regulation (EU) 2017/1007[(4)] should be amended accordingly.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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

Authorisation

The additives specified in Annex I belonging to the additive category ‘technological additives’ and to the functional group ‘emulsifiers’, are authorised as additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2017/1007

The Annex to Implementing Regulation (EU) 2017/1007 is replaced by the text in Annex II to this Regulation.

Article 3

Transitional measures

1 The additives specified in Annex I and premixtures containing those additives which are produced and labelled before 4 July 2018 in accordance with the rules applicable before 4 January 2018 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the additives as specified in Annex I which are produced and labelled before 4 January 2019 in accordance with the rules applicable before 4 January 2018 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 4 January 2020 in accordance with the rules applicable before 4 January 2018 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 4

Entry into force

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2325. (See end of Document for details)*

[F1 ANNEX I

Textual Amendments

F1 Substituted by 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).

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	*Additive composition* Preparations of: — lecithins and hydrolysed lecithins in liquid (plastic to fluid) form; — de-oiled lecithins and de-oiled hydrolysed	All animal species	—	—	—	In the label of feed additive and premixures the form(s) used shall be indicated	6 July 2027

a 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

b 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).

c 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

d 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]

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2017/2325. (See end of Document for details)*

				lecithins in solid form. *Characterisation of the active substance* Lecithins, hydrolysed lecithins, de-oiled lecithins and de-oiled hydrolysed lecithins derived from soybean, sunflower or rapeseed: CAS no. 8002-43-5; Assay: — Lecithins, de-oiled lecithins: not less than 60,0 % of substances insoluble in acetone;				

a 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

b 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).

c 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

d 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**]**