



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/11640/2017 Rev. 1 CIS  
(POOL/E5/2017/11640/11640R1-EN  
CIS.doc)  
[...](2017) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**concerning the authorisation of preparations of lecithins, lecithins hydrolysed and  
lecithins de-oiled as feed additives for all animal species and amending Regulation (EU)  
No 2017/1007**

(Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

## **concerning the authorisation of preparations of lecithins, lecithins hydrolysed and lecithins de-oiled as feed additives for all animal species and amending Regulation (EU) No 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<sup>1</sup>, 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<sup>2</sup>.
- (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 an existing product, 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<sup>3</sup> 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 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.

---

<sup>1</sup> OJ L 268, 18.10.2003, p. 29.

<sup>2</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>3</sup> EFSA Journal 2016;14(8):4561.

- (5) The assessment of lecithins, 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 to this Regulation.
- (6) It is considered appropriate to harmonise the characteristics of the lecithins, lecithins hydrolysed and lecithins de-oiled and the conditions of use to avoid the distortion of the market, Regulation (EC) 2017/1007<sup>4</sup> should be amended according.
- (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 additive specified in Annex I belonging to the additive category ‘technological additives’ and to the functional group ‘emulsifiers’, is authorised as additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*  
*Amendment to Regulation (EU) 2017/1007*

The Annex to Implementing Regulation (EU) No 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 [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [*24 months after the date of entry into force*

---

<sup>4</sup> Commission Implementing Regulation (EU) 2017/1007 of 15 June 2017 concerning the authorisation of a preparation of lecithins as feed additive for all animal species (OJ L 153, 16.6.2017, p. 13).

*of this Regulation – Date to be inserted by the Service responsible for the publication]* in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication]* 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.

Done at Brussels,

*For the Commission*

*The President*

*Jean-Claude JUNCKER*