

Brussels, 14 December 2018¹

LECITHINS USED AS A FEED ADDITIVE ON THE EU MARKET

ELMA welcomes the publication of Commission Implementing Regulation (EU) 2018/1980 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.²

ELMA appreciates that Regulation (EU) 2018/1980 re-instates the harmonisation of requirements for the use of lecithins derived from soy, rapeseed and sunflower as feed additives with the requirements in the food additive specification for lecithins³ which was used in feed sector under the Directive 70/524/EEC concerning additives in feedingstuff.

Regulation (EU) 2018/1980 sets compositional criteria for lecithins derived from soy, rapeseed and sunflower which are in accordance with the specification for lecithins used as food additive. All lecithins derived from soy, rapeseed and sunflower complying with the feed additive specification in Annex to Regulation (EU) 2018/1980 are assigned with number **1c322i** according to the new numbering system for feed additives. In addition to the name 'lecithins', the Regulation requires indicating in the label of feed additive and premixtures the form(s) used.

For the purposes of GMP+ Feed Safety Standards, the following labelling is recommended:

1c322i – Lecithins	1c322i – Lecithins hydrolysed
1c322i – Lecithins de-oiled	1c322i – Lecithins hydrolysed de-oiled

Context

Lecithins have been authorised as a feed additive in the European Union under Directive 70/524/EEC concerning additives in feedingstuff. Under this Directive lecithins were assigned with number E 322 which is the E-number for lecithins used as a food additive. As Directive 70/524/EEC did not provide for specifications of feed additives, the food additive specification for lecithins (E 322) was used also for specifying lecithins used as feed additives.

Directive 70/524/EEC was repealed by Regulation (EC) No 1831/2003 on additives for use in animal nutrition which has introduced a new numbering system, provides for specifications and lays down an authorisation procedure for feed additives. The authorisation is granted in accordance with the procedure for a period of 10 years.

In accordance with Regulation (EC) No 1831/2003 ELMA submitted an application for authorisation for a renewal of the authorisation of lecithins, when used as a feed additive (category: emulsifier) for all

¹ Updated May 2019

² https://eur-lex.europa.eu/eli/reg_impl/2018/1980/oj

³ <https://eur-lex.europa.eu/eli/reg/2012/231/oj>



animal species. Consequently, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) in its opinion concluded that lecithins are safe for the target species, the consumer, the user and the environment, and that they are efficacious as emulsifier. ⁴

At the same time, EFSA also published a scientific opinion on another application for authorisation of a specific lecithin-based product that had been submitted for use as a feed additive. Unfortunately, the European Commission overlooked the opinion concerning ELMA's application and did not take it into account in its Implementing Regulation (EU) 2017/1007 concerning the authorisation of a preparation of lecithins as feed additive for all animal species, which laid down a specification for all lecithins.⁵

In attempt to correct this omission, the Commission published 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) 2017/1007.⁶ Unfortunately, the Implementing Regulation (EU) 2017/2325 had set unrealistic requirements in the feed additive specification based on literature data and in contradiction with the food additive specification despite referring to this specification as well as to the corresponding tests in the FAO JECFA monograph 'Lecithins' for characterisation of the feed additive. Thus, the specification and the different numbers for various forms of lecithins set in Regulation (EU) 2017/2325 could not be used.

Therefore, further to publication of Regulation (EU) 2017/2325, ELMA met with the European Commission and agreed to submit an application for modification of the terms of authorisation of lecithins in order to allow all lecithins within the scope of the favourable EFSA Opinion to remain on the market. Consequently, the EFSA FEEDAP Panel in its opinion on the ELMA application for modification of the terms of authorisation of lecithins as a feed additive recommended applying the specifications set for food additive to the lecithins under application. ⁷

Finally, Regulation (EU) 2018/1980 published following the EFSA opinion re-instates the harmonisation of requirements for the use of lecithins derived from soy, rapeseed and sunflower as feed additives with the requirements in the food additive specification for lecithins.

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4561>

⁵ https://eur-lex.europa.eu/eli/reg_impl/2017/1007/oj

⁶ https://eur-lex.europa.eu/eli/reg_impl/2017/2325/oj

⁷ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5334>