COMMISSION IMPLEMENTING REGULATION (EU) 2021/412

of 8 March 2021

amending Implementing Regulation (EU) 2017/962 as regards the review of the suspension of the authorisation of ethoxyquin as a feed additive

(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(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2017/962 ([2]) suspended the authorisation of the additive ethoxyquin on the basis of the opinion of the European Food Safety Authority ('the Authority') of 21 October 2015 ([3]), which could not conclude on the safety and efficacy of the additive due to an overall lack of data submitted by the applicant in the framework of the authorisation procedure.

(2) The authorisation of the additive ethoxyquin was suspended pending the submission and assessment of supplementary data to be produced by the applicant, in accordance with a time schedule listing in order of priority the studies to be carried out successively. According to that time schedule, the outcome of the last of those studies would be available by July 2018.

(3) In accordance with Implementing Regulation (EU) 2017/962, the suspension measure is to be reviewed by 31 December 2020 at the latest, after due assessment of the required supplementary data.

(4) While the applicant has submitted successive packages of supplementary data, major delays occurred in the generation of a series of data, in particular concerning the demonstration of the safety of the additive ethoxyquin for the environment. The reasons for those delays include the need to initiate further studies in order to comply with the specific data requirements set out in Commission Regulation (EC) No 429/2008 ([4]) and the related Authority's detailed guidance, and difficulties in finding appropriate laboratories or testing facilities for the conduction of certain studies.

(5) The applicant last submitted supplementary data on the environmental risk assessment in September 2020. Depending on the outcome of the assessment by the Authority of those supplementary data, it cannot be excluded that the applicant may still be requested to provide further information and data.

(6) In view of the above, the Authority should be granted sufficient time to complete the assessment process of all supplementary information and data submitted or still to be submitted by the applicant in order to demonstrate the safety and efficacy of the additive ethoxyquin. It is therefore appropriate to postpone the review of the suspension measure until the completion of the assessment process. The new timeframe for the review should be determined in consideration of an estimated maximum period needed for such completion. In any event, the suspension measure should be reviewed where, during the assessment process, the Authority adopts a non-favourable opinion on the safety or efficacy of the additive ethoxyquin.

(7) Implementing Regulation (EU) 2017/962 should therefore be amended accordingly.

([1]) OJ L 268, 18.10.2003, p. 29.

([2]) Commission Implementing Regulation (EU) 2017/962 of 7 June 2017 suspending the authorisation of ethoxyquin as a feed additive for all animal species and categories (OJ L 145, 8.6.2017, p. 13).

([3]) *EFSA Journal* 2015;13(11):4272.

([4]) 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) Taking into account that Implementing Regulation (EU) 2017/962 is to be reviewed by 31 December 2020 at the latest, this Regulation should enter into force as a matter of urgency in order to minimise any legal vacuum.

(9) 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

Amendment to Implementing Regulation (EU) 2017/962

Article 5 of Implementing Regulation (EU) 2017/962 is replaced by the following:

'*Article 5*

Review

This Regulation shall be reviewed by 31 December 2022 at the latest and in any event after the adoption by the Authority of a non-favourable opinion on the safety and efficacy of the additive ethoxyquin.'.

Article 2

Entry into force

This Regulation shall enter into force on the third 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, 8 March 2021.

For the Commission
The President
Ursula VON DER LEYEN