COMMISSION IMPLEMENTING REGULATION (EU) 2022/1375

of 5 August 2022

concerning the denial of authorisation of ethoxyquin as a feed additive belonging to the functional group of antioxidants and repealing Implementing Regulation (EU) 2017/962

(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 Articles 9(2) and 13(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 or denying such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Ethoxyquin was authorised without a time limit by Directive 70/524/EEC as a feed additive for use for all animal species. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of ethoxyquin as a feed additive for all animal species, requesting the additive to be classified in the category 'technological additives'. 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') noted in its opinion of 21 October 2015 ([3]) that it could not conclude on the efficacy and safety of the additive ethoxyquin for animals, consumers and the environment, due to an overall lack of data submitted by the applicant. In particular, no conclusion was possible on the absence of genotoxicity of the metabolite ethoxyquin quinone imine and concerns were raised as to the possible mutagenicity of the impurity *p*-phenetidine. Consequently, it had not been established that the additive ethoxyquin does not have an adverse effect on animal health, human health and the environment. Therefore, the existing authorisation of the additive ethoxyquin was suspended by Commission Implementing Regulation (EU) 2017/962 ([4]).

(5) 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 the necessary studies to be carried out. According to that time schedule, the outcome of the last of those studies had to be available by July 2018.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2015;13(11):4272.
([4]) 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).

(6) In accordance with Implementing Regulation (EU) 2017/962, the suspension measure is to be reviewed by 31 December 2022 and in any event after the adoption by the Authority of a non-favourable opinion on the safety and efficacy of the additive ethoxyquin.

(7) Since the adoption of the Authority's opinion of 21 October 2015, the applicant submitted to the Commission successive packages of supplementary data on 11 March 2016, 15 December 2017, 20 April 2018 and 23 June 2021, which were forwarded to the Authority. Further supplementary data was submitted by the applicant to the Authority in the course of the data assessment, as well as on 24 September 2020.

(8) On 27 January 2022, the Authority adopted an opinion ([5]) following the assessment of the supplementary data submitted by the applicant, taking into account in particular the modified specifications of the additive ethoxyquin, in which the content of the impurity *p*-phenetidine was reduced to a level lower than 2,5 ppm, and considering the proposed inclusion level of 50 mg of the additive per kg in complete feed. In its opinion, the Authority could not conclude on the safety of the additive ethoxyquin at any level for long-living and reproductive animals, considering that the additive contains *p*-phenetidine, a recognised possible mutagen which remains as an impurity in the additive, but in regards to which the applicant did not provide additional information addressing this safety concern. Concerning the safety of the use of ethoxyquin for the consumers, no conclusion could be drawn due to the presence of *p*-phenetidine and in the absence of data on the residues of *p*-phenetidine in tissues and products of animal origin. In addition, in the absence of residue data in milk, the Authority could not conclude on the consumers' safety of ethoxyquin, when used in feed for milk-producing animals. With regard to the safety for the user, the Authority concluded that users' exposure should be minimised in order to reduce the risk of exposure to *p*-phenetidine by inhalation. Regarding the safety for the environment, the Authority stated that supplementary data would be needed to conclude on the safety of ethoxyquin for the terrestrial compartment when fed to terrestrial animals. In addition, the Authority considered that a risk for the aquatic compartment could not be excluded when the additive is used in terrestrial animals and that a risk of secondary poisoning via the aquatic food chain could not be excluded either. Furthermore, the Authority concluded that a risk could not be excluded for ethoxyquin used in sea-cages for marine sediment-dwelling organisms.

(9) The Authority's opinion of 27 January 2022 shows, therefore, that it has not been established that ethoxyquin does not have an adverse effect on animal health, human health or the environment, when used as a feed additive in the functional group 'antioxidants'.

(10) The assessment of ethoxyquin thus shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are not satisfied and accordingly, the authorisation of ethoxyquin as a feed additive belonging to the functional group 'antioxidants' should be denied.

(11) It derives from the above review that Implementing Regulation (EU) 2017/962 should be repealed.

(12) 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

Denial of authorisation

The authorisation of ethoxyquin (E 324) as an additive in animal nutrition belonging to the additive category 'technological additives' and to the functional group 'antioxidants', is denied.

([5]) EFSA Journal 2022;20(3):7166.

Article 2

Repeal of Implementing Regulation (EU) 2017/962

Implementing Regulation (EU) 2017/962 is repealed.

Article 3

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, 5 August 2022.

For the Commission
The President
Ursula VON DER LEYEN