COMMISSION IMPLEMENTING REGULATION (EU) 2023/1698

of 6 September 2023

concerning the renewal of the authorisation of a preparation of potassium diformate as a feed additive for sows (holder of the authorisation: ADDCON Europe GmbH) and repealing Regulation (EU) No 104/2010

(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 and renewing such authorisation.

(2) A preparation of potassium diformate was authorised for 10 years as a feed additive for sows by Commission Regulation (EU) No 104/2010 ([2]).

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of potassium diformate as a feed additive for sows in the additive category 'zootechnical additives' and in the functional group 'other zootechnical additives (improvement of zootechnical parameters)'. The application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.

(4) The European Food Safety Authority ('the Authority') concluded in its opinions of 29 January 2020 ([3]) and 18 November 2020 ([4]) that the preparation of potassium diformate remains safe for sows, the consumers and the environment under the conditions of use currently authorised. It also reiterated that except for ocular irritation potential, no effects requiring specific user protection measures were found.

(5) In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ([5]), the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application. In addition, on 28 April 2023, the Reference Laboratory published an addendum to its evaluation report, updating its recommendations for the analytical methods for the determination of potassium diformate (as total formic acid) in the feed additive, premixtures and compound feed, and for the determination of total potassium in the feed additive.

(6) The Annex to Regulation (EU) No 104/2010 provides for the description of the functional group 'other zootechnical additives (improvement of zootechnical parameters)'. However, in order to ensure consistency with the current approach concerning the authorisation of additives belonging to the functional group of other zootechnical additives, it is appropriate to further specify the function performed by the additive, which is to improve the performance parameters of sows.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Regulation (EU) No 104/2010 of 5 February 2010 concerning the authorisation of potassium diformate as a feed additive for sows (holder of authorisation BASF SE) and amending Regulation (EC) No 1200/2005 (OJ L 35, 6.2.2010, p. 4.).
([3]) *EFSA Journal* 2020;18(2):6024.
([4]) *EFSA Journal* 2020;18(12):6339.
([5]) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

(7) The assessment of the preparation of potassium diformate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of this additive should be renewed.

(8) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Those protective measures should be without prejudice to other worker safety requirements under Union law.

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

(10) As a consequence of the renewal of the authorisation of the preparation of potassium diformate as a feed additive, Regulation (EU) No 104/2010 should be repealed.

(11) 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

Renewal of the authorisation

The authorisation of the preparation of potassium diformate, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives (improvement of performance parameters)', is renewed subject to the conditions laid down in the Annex.

Article 2

Repeal of Regulation (EU) No 104/2010

Regulation (EU) No 104/2010 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing this substance, which are produced and labelled before 27 March 2024 in accordance with the rules applicable before 27 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 27 September 2024 in accordance with the rules applicable before 27 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

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, 6 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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 active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of performance parameters)									
4d800	ADDCON Europe GmbH	Potassium diformate	*Additive composition* Preparation of potassium diformate, min. 98 % Silicate max. 1,5 % Water max. 0,5 % Solid form *Characterisation of active substance* Potassium diformate, solid $KH(COOH)_2$ CAS No 20642-05-1 *Analytical method* (1) For the determination of potassium diformate (as total formic acid) in the feed additive, premixtures and compound feeds: ion chromatography with conductivity detection (IC-CD) – EN 17294. For the determination of total potassium in the feed additive: — atomic absorption spectrometry (AAS) – EN ISO 6869; or	Sows	—	10 000 (2)	12 000 (3)	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated 2. The maximum content of potassium diformate shall be 12 000 mg/kg of complete feedingstuff with a moisture content of 12 % for sows, whether used alone as a zootechnical additive or used in combination with other sources of potassium diformate. 3. The mixture of different sources of formic acid shall not exceed the permitted maximum level of 10 000 mg formic acid/kg of complete feedingstuff with a moisture content of 12 %. 4. The additive shall be incorporated in feed in form of a premixture.	27 September 2033

			— inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN 15510.					5. In the directions for use of the additive, premixture and feedingstuff the following shall be indicated: 'The simultaneous use of different organic acids or their salts is contraindicated where one or more of them is used at or near the maximum permitted content'. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal eye protective equipment.	

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.
(2) 10 000 mg/kg potassium diformate equals 6993 mg/kg as formic acid.
(3) 12 000 mg/kg potassium diformate equals 8391 mg/kg as formic acid.