

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/1374****of 5 August 2022****concerning the authorisation of potassium diformate as a feed additive for weaned piglets, pigs for fattening and sows, and repealing Implementing Regulation (EU) No 333/2012****(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 and renewing such authorisation.
- (2) Potassium diformate was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 333/2012 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of potassium diformate as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation. The applicant has later withdrawn the application for all animal species except for weaned piglets, pigs for fattening and sows.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 January 2022 <sup>(3)</sup> that the applicant had provided evidence that the additive complies with the conditions of authorisation. The Authority further concluded that potassium diformate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additive is an eye irritant, but it could not conclude on the potential of the additive to be an irritant to the skin or a respiratory or skin sensitiser. Therefore, 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. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment 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 that additive should be renewed.
- (6) As a consequence of the renewal of the authorisation of potassium diformate as a feed additive, Implementing Regulation (EU) No 333/2012 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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

<sup>(2)</sup> Commission Implementing Regulation (EU) No 333/2012 of 19 April 2012 concerning the authorisation of a preparation of potassium diformate as a feed additive for all animal species and amending Regulation (EC) No 492/2006 (OJ L 108, 20.4.2012, p. 3).

<sup>(3)</sup> EFSA Journal 2022;20(3):7167.

HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the substance specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'preservatives', is renewed subject to the conditions laid down in that Annex.

*Article 2*

Implementing Regulation (EU) No 333/2012 is repealed.

*Article 3*

**Transitional measures**

1. The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 28 February 2023 in accordance with the rules applicable before 28 August 2022 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 28 August 2023 in accordance with the rules applicable before 28 August 2022 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 substance as specified in the Annex which are produced and labelled before 28 August 2024 in accordance with the rules applicable before 28 August 2022 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*

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

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## ANNEX

Identification number of the additive	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 active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives.								
1a237a	Potassium diformate	Additive composition:	Sows		-	12 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Only permitted in raw fish and fish by-products for feed use with a maximum content of 9 000 mg potassium diformate as active substance per kg raw fish. 3. The maximum content of potassium diformate shall be 6 000 mg/kg of complete feedingstuff with a moisture content of 12 % for weaned piglets and pigs for fattening and 12 000 mg/kg of complete feedingstuff with a moisture content of 12 % for sows, whether used alone as a preservative or used in combination with other sources of potassium diformate. 4. The mixture of different sources of formic acid shall not exceed the permitted maximum level in complete feedingstuffs of 10 000 mg/kg complete feedingstuffs for weaned piglets, pigs for fattening and sows.	28.8.2032
		Potassium diformate: 50 ± 5 % Liquid form (50:50 diluted in water) Characterisation of the active substance: Potassium diformate C <sub>2</sub> H <sub>3</sub> O <sub>4</sub> K CAS number: 20642-05-1 Einecs number: 243-934-6 Produced by chemical synthesis Analytical method <sup>(1)</sup> : For the determination of potassium diformate (as total formic acid) in the feed additive, premixture, feedingstuffs: — Ion chromatography with conductivity detection (IC-CD) – EN 17294; For the determination of potassium in the feed additive: — Atomic absorption spectrometry (AAS) – EN ISO 6869; or	Weaned piglets and pigs for fattening		-	6 000		

		— Inductively coupled plasma-atomic emission spectrometry (ICP-AES) – EN15510.					<p>5. Indicate in the instructions of use of the additive, premixture and related feedingstuffs for food-producing animals: ‘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’.</p> <p>6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eyes, skin and breathing protection.</p>	
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(<sup>1</sup>) 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](https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en)