

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****(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 such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC⁽²⁾.

(2) Potassium diformate, solid form, was provisionally authorised in accordance with Directive 70/524/EEC as a feed additive for use on sows by Commission Regulation (EC) No 1200/2005 of 26 July 2005 concerning the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs⁽³⁾. That additive was subsequently entered into the Community 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 of that Regulation, an application was submitted for the re-evaluation of that additive, requesting that additive to be classified in the additive category 'zootechnical 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') concluded in its opinion of 15 September 2009⁽⁴⁾ that the additive does not have an adverse effect on animal health, consumer health or the environment and that the use of that additive can improve the performance of the animals. The Authority recommends appropriate measures for user safety. It does not consider that there is a need for specific requirements of post market monitoring. The Authority also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that additive shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) As a consequence, the provisions on that preparation in Regulation (EC) No 1200/2005 should be deleted.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Regulation (EC) No 1200/2005, Article 1 and Annex I are deleted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 195, 27.7.2005, p. 6.

⁽⁴⁾ EFSA Journal 2009; 7(9): 1315.

Article 3

This Regulation shall enter into force on the 20th day following 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 February 2010.

For the Commission

The President

José Manuel BARROSO

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/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical parameters)									
4d800	BASF SE	Potassium diformate	Additive composition: Potassium diformate, solid, min. 98 %, Silicate max. 1,5 %, Water max. 0,5 % Characterisation of the active substance: Potassium diformate, solid KH(COOH)₂ CAS No 20642-05-1 Analytical method ⁽¹⁾ Ion chromatography method equipped with electrical conductivity detection (IC/ECD)	Sows	—	10 000	12 000	The mixture of different sources of potassium diformate must not exceed the permitted maximum level in complete feedingstuff of 12 000 mg/kg of complete feedingstuff. The additive shall be incorporated in feed in form of a premixture. This product can produce risk of serious damage to the eye. Measures to protect workers shall be adopted.	26.2.2020

⁽¹⁾ Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives