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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European

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).
- Potassium diformate, CAS number 20642-05-1, was (2) authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for use on all animal species by Commission Regulation (EC) No 492/2006 (3). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- In accordance with Article 10(2) of Regulation (EC) No (3) 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of potassium diformate as a feed additive for all animal species, requesting that additive to be classified in the additive category 'technological additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- The European Food Safety Authority ('the Authority') (4) concluded in its opinion of 13 December 2011 (4) that, under the proposed conditions of use, potassium diformate does not have an adverse effect on animal health, consumer health or the environment, and that it is effective in increasing the storage time of raw fish and fish by-products. It concluded that no safety concerns would arise for users provided that appropriate

protective measures are taken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- 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 use of that substance should be authorised as specified in the Annex to this Regulation.
- As a consequence of a new authorisation being granted by this Regulation, Article 3 of Regulation (EC) No 492/2006 and Annex III thereto should be deleted.
- Since the modifications to the conditions of authorisation of the feed additive are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of pre-mixtures and compound feed containing this preparation, as authorised by Regulation (EC) No 492/2006.
- 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 'technological additives' and to the functional group 'preservatives' is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

Article 3 of Regulation (EC) No 492/2006 and Annex III thereto are deleted.

Article 3

Premixtures and compound feed labelled in accordance with Directive 70/524/EEC before the entry into force of this Regulation and containing potassium diformate, as authorised by Regulation (EC) No 492/2006, may continue to be placed on the market and used until the existing stocks are exhausted.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ OJ L 270, 14.12.1970, p. 1.

⁽³⁾ OJ L 89, 28.3.2006, p. 6. (4) EFSA Journal 2012; 10(1):2530.

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, 19 April 2012.

For the Commission The President José Manuel BARROSO

				ANNEX					
						Minimum content	Maximum content		
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	mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			End of period of authorisation
Category of	technological	additives. Fu	unctional group: preservatives						
1a237a		Potassium diformate	Additive composition Potassium diformate: 50 ± 5 %, Water: 50 ± 5 %. Characterisation of the active substance Potassium diformate CAS No 20642-05-1 C ₂ H ₃ O ₄ K Produced by chemical synthesis Method of Analysis (¹)	All animal species				 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. For use in feed for pigs, the mixture of different sources of potassium diformate shall not exceed the permitted maximum level in complete feedingstuff of 18 000 mg per kg complete feedingstuff for weaned piglets and 12 000 mg per kg complete feed- 	11 May 2022

For the determination of total formate in premixtures and feedingstuffs:

Ion-exclusion high performance liquid chromatography with UV or refractive index detection (HPLC-UV/RI) or ion chromatography method equipped with electrical conductivity detection (IC-ECD).

Determination of potassium in the feed

EN ISO 6869: atomic absorption spectrometry (AAS) or EN 15510: inductively coupled plasma atomic emission

Determination of total formate in the

feed additive: EN 15909: reverse

spectrometry (ICP-AES)

phase HPLC-UV

additive:

cated'.

4. 'For safety: breathing protection, eye protection and gloves shall be used during handling'.

ingstuff for sows and pigs for

3. Indicate in the instructions for

'The simultaneous use of other

organic acids at the maximum permitted doses is contraindi-

fattening.

 $^{(^1) \ \} Details \ \ of the \ analytical \ methods \ are \ available \ at the \ following \ address \ \ of the \ Reference \ Laboratory: \\ http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx$