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Safety of potassium diformate (Formi™ LHS) as a feed additive for sows, from ADDCON EUROPE GmbH

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Jaume Galobart and Maria Vittoria Vettori

Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the assessment of the application for renewal of authorisation of potassium diformate as a feed additive for sows (brand name Formi™ LHS). The additive was re-evaluated by the Panel in 2009. In its assessment on the renewal of the additive adopted by the FEEDAP Panel in 2020, the Panel concluded that the information provided by the applicant did not fulfil the minimum requirements to support that Formi™ LHS remained safe under the approved conditions for target species, consumers and users. In the same opinion, the Panel concluded that the use of Formi™ LHS under the approved conditions remained safe for the environment. In the present assessment, the applicant conducted a literature search to fulfil the data requirements for the renewal application and no relevant information regarding adverse effects in target animals (pigs, piglets and sows), consumers and users were identified. Based on this, and the fact that the manufacturing and composition of the additive have not been modified, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in the previous re-evaluation opinion adopted by the FEEDAP Panel in 2009. Therefore, the Panel concludes that the additive remains safe for sows and the consumer under the authorised conditions of use. Regarding user safety, the Panel reiterates that for the additive, 'except for ocular irritation potential, no effects requiring specific user protection measures were found'.

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Keywords: Formi™ LHS, zootechnical additive, potassium diformate, sows, safety, efficacy, renewal

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Correspondence: feedap@efsa.europa.eu

Panel members: Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference as provided by the European Commission	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Safety	5
4. Conclusions.....	5
5. Documentation as provided to EFSA/Chronology.....	6
References.....	6
Abbreviations.....	6

1. Introduction

1.1. Background and Terms of Reference as provided by the European Commission

Regulation (EC) No 1831/2003 establishes rules governing the Community authorization of additives for animal nutrition and, in particular, Article 9 defines the terms of the authorization by the Commission.

The applicant, ADDCON EUROPE GmbH, is seeking a Community authorization of potassium diformate as feed additive to be used as zootechnical additive for sows for reproduction (Table 1).

Table 1: Description of the substance

Category of additive	Zootechnical additives
Functional group of additive	Other zootechnical additives
Description	Potassium diformate
Target animal category	Sows for reproduction
Applicant	ADDCON EUROPE GmbH
Type of request	New opinion

On 29 January 2020, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety and efficacy of the product, could not conclude on the safety for animals, consumer and users. After discussion with Member States on the last Standing Committee, it was suggested to check for the possibility to demonstrate the safety.

The Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment and allow a revision of the Authority's opinion. The new data have been received on 1 July 2020 and were already transmitted to EFSA by the applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion on potassium diformate as a feed additive for sows for reproduction based on the additional information submitted by the applicant.

1.2. Additional information

The EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued four opinions on Formi™ LHS: one on the efficacy and safety for the sows, consumers, users and the environment (EFSA, 2004), one on the safety and efficacy for weaned piglets and pigs for fattening (EFSA, 2006), one on the re-evaluation of the product as feed additive for sows (EFSA, 2009) and another on the application for renewal of authorisation of Formi™ LHS (potassium diformate) for sows (EFSA FEEDAP Panel, 2020).

Potassium diformate was authorised by Commission Regulation (EC) No 184/2007 as a feed additive for piglets (weaned) and pigs for fattening.¹ Potassium diformate is currently authorised by Commission Regulation (EU) No 333/2012 as a preservative feed additive for all animal species.² The additive is also authorised by Commission Regulation (EU) No 104/2010³ as a zootechnical feed additive for sows.⁴

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information⁵ to a previous application of the same product.⁶

¹ Commission Regulation (EC) No 184/2007 of 20 February 2007 concerning the authorisation of potassium diformate (Formi LHS) as a feed additive, OJ L 291, 5.11.2005, p. 8.

² Commission 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 89, 28.3.2006, p. 6.

³ Commission Regulation (EU) No 104/2010 of 5 February 2010 concerning the authorization of potassium diformate as a feed additive for sows (holder of authorization BASF SE) and amending Regulation (EC) No 1200/2005, OJ L 35, 6.2.2010, p. 4.

⁴ The change of the holder of the authorisation was done by Commission Implementing Regulation (EU) No 2017/410 of 8 March 2017 amending Regulations (EC) No 184/2007 and (EU) No 104/2010, as regards the name of the holder of the authorisation of potassium diformate. OJ L 63, 9.3.2017, p. 93.

⁵ FAD-2020-0051.

⁶ FAD-2019-0007.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of Formi™ LHS (potassium diformate) is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

3. Assessment

The additive Formi™ LHS, consisting of potassium diformate, is authorised in feed for sows under the category of zootechnical additives (functional group of other zootechnical additives (improvement of zootechnical parameters)) in the range of 10,000–12,000 mg/kg complete feedingstuffs.

The product currently authorised contains a minimum of 98% potassium diformate, with a maximum of 1.5% silicate (as an anticaking agent) and a maximum of 0.5% water.

The FEEDAP Panel issued an opinion on the re-evaluation of Formi™ LHS (potassium diformate) for sows in 2009 (EFSA, 2009) and an opinion on the renewal of authorisation of the additive in 2020 (EFSA FEEDAP Panel, 2020). In the renewal opinion data on the characterisation of the active substance was described; the applicant provided evidence that the additive currently in the market complies with the specifications set in the authorisation and confirmed that there have been no changes in the manufacturing process since the additive was authorised. In the same opinion, the Panel could not reach a conclusion on the safety for the target species, consumer and user due the lack of appropriate evidence. For the current assessment, the applicant submitted new data to support the safety of the additive which are assessed below.

3.1. Safety

In the opinion adopted in 2020 (EFSA FEEDAP Panel, 2020), it was concluded that:

‘The Panel considers that the information provided by the applicant does not fulfil the minimum requirements to support that Formi™ LHS remains safe under the approved conditions for target species, consumers, and users.

The Panel concludes that the use of Formi™ LHS under the approved conditions remains safe for the environment’.

The applicant conducted a literature search covering the period 2000–2020 in the databases TOXCENTER, BIOSIS, AGRICOLA, HCAPLUS, PQSCITECH, MEDLINE, ESBIODBASE, EMBASE and CABA; a single concept search strategy (i.e. search for CAS number⁷ and the chemical names⁸) was applied. Studies in target animals (pigs, piglets and sows), consumers and users were considered for the scope of the present assessment. In total, 147 records were retrieved from bibliographic databases and were screened for relevance by expert reviewers. Based on the evaluation of the summary of the records (titles/abstracts), 144 publications were assessed and were considered not relevant; three full-text documents were assessed in detail and it was concluded that these publications did not report adverse effects in target animals (pigs, piglets and sows), consumers and users.

Based on the above and the fact that the manufacturing and composition of the additive have not been modified, the FEEDAP Panel considers that there is no evidence to reconsider the conclusions reached in the previous opinion (EFSA, 2009). Therefore, the Panel concludes that the additive remains safe for sows and the consumer under the authorised conditions of use. Regarding user safety, the Panel reiterates that for the additive, ‘except for ocular irritation potential, no effects requiring specific user protection measures were found’.

4. Conclusions

The additive currently in the market complies with the existing conditions of authorisation.

There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions in 2009.

⁷ 20642-05-1.

⁸ POTASSIUM BIFORMATE, POTASSIUM DIFORMATE, POTASSIUM FORMATE (1:2), POTASSIUM HYDROGEN, DIFORMATE, FORMI LHS.

The Panel concludes that the additive remains safe for sows, the consumer and the environment under the authorised conditions of use. Regarding user safety, the Panel reiterates that for the additive, 'except for ocular irritation potential, no effects requiring specific user protection measures were found.'

5. Documentation as provided to EFSA/Chronology

Date	Event
01/07/2020	Dossier received by EFSA. Formi LHS (potassium diformate) for sows for reproduction. Submitted by Addcon GmbH
14/07/2020	Reception mandate from the European Commission
29/08/2020	Application validated by EFSA – Start of the scientific assessment
18/11/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

EFSA FEEDAP Panel EFSA Panel on Additives and Products or Substances used in Animal Feed