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Assessment of the application for renewal of authorisation of Formi™ LHS (potassium diformate) for sows

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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 Formi™ LHS (potassium diformate) for sows. 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 present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive.

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

Requestor: European Commission

Question number: EFSA-Q-2019-00112

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Addcon[2] for renewal of the authorisation of the product Formi™ LHS (potassium diformate), when used as a feed additive for sows (category: zootechnical additives; functional group: other zootechnical additives).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 14(1) (renewal of the authorisation). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 5 June 2019.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Formi™ LHS, when used as a feed additive for sows, when used under the proposed conditions of use (see Section 3.1.3).

1.2. Additional information

The EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued three 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) and another one on the re-evaluation of the product as feed additive for sows (EFSA FEEDAP Panel, 2009).

Potassium diformate was authorised by Commission Regulation (EC) No 184/2007 as feed additive for piglets (weaned) and pigs for fattening.[3] Potassium diformate is currently authorised by Commission Regulation (EU) No 333/2012 as a preservative feed additive for all animal species.[4] The additive is also authorised by Commission Regulation (EU) No 104/2010[5] as feed additive for sows.[6]

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier in support of the authorisation request for the use of Formi™ LHS (potassium diformate) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.[7]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Addcon GmbH, Parsevalstrasse 6, 06749, Bitterfeld-Wolfen, Germany.
[3] 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.
[4] 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.
[5] Commission Regulation (EU) No 104/2010 of 5 February 2010 concerning the authorization 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.
[6] 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.
[7] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0044

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy 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 and the functional group of other zootechnical additives (improvement of zootechnical parameters) in the range of 10,000–12,000 mg/kg complete feedingstuffs. The applicant has applied for the renewal of this authorisation.

3.1. Characterisation

3.1.1. Characterisation of the active substance

The active substance is potassium diformate (KCOOH*HCOOH), which is an association of potassium formate and formic acid. It has the chemical formula $C_2H_3O_4K$, molecular weight of 130.1 Da, CAS number 20642-05-1 and EINECS number 243-934-6. The applicant confirmed that there have been no changes in the manufacturing process since the additive was authorised.[8]

The product currently authorised contains a minimum of 98% potassium diformate, with a maximum of 1.5% silicate (as anticaking agent) and a maximum of 0.5% water. The analysis of ten recent batches of the additive, produced in 2017, showed that Formi™ LHS meets those specifications: average potassium diformate 98.34% (range 98.2–98.5%) and average water 0.19% (range 0.1–0.3%).[9]

Analytical data of heavy metals (cadmium (Cd), lead (Pb) and mercury (Hg)) and arsenic (As) content in three recent batches of the additive were provided;[10] values reported were all below the limit of detection (LOD) and are considered of no concern.

Dioxins (polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F)) measured in three batches amounted to < 0.09 ng BEQ/kg, and the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) was < 0.2 ng Bioanalytical Equivalents (BEQ)/kg. Non-dioxin-like PCBs were 1.2 ng/g. The values are of no concern.[11]

Due to its chemical nature, it is not expected that the additive supports microbiological growth.

The additive is described as a dry, white and free flowing crystalline product, with a bulk density of 900–1,000 kg/m^3. It has a pH of 4.5 in a 60% aqueous solution. The dusting potential of the additive was measured in three batches and ranged from 0.254 to 0.415 g/m^3).[12]

3.1.2. Stability and homogeneity

The shelf-life of the product has been tested in three batches of Formi™ LHS stored in polyethylene bags at room temperature for 24 months; the average recovery of potassium diformate was 96.5%.

The capacity of Formi™ LHS to homogeneously distribute in feed was studied in mash and pelleted pig feed at two different inclusion levels (0.5% and 1.8%). Ten subsamples were analysed per feed and inclusion level. The coefficients of variation (CVs) in mash feed were 6.1% and 10.4% for the 0.5 and 1.8% inclusion levels, respectively. The CVs in pelleted feed (n = 10) were 7.7% and 15.5% for the 0.5 and 1.8% inclusion levels, respectively.

3.1.3. Conditions of use

Formi™ LHS is authorised to be used in feed for sows at a minimum and maximum content of 10,000 and 12,000 mg/kg complete feed, respectively.

The authorisation contains the following 'Other provisions': (i) the mixture of different sources of potassium diformate must not exceed the permitted maximum level in complete feedingstuff of

[8] Technical dossier/ Supplementary information October 2019/Annex_4.
[9] Technical dossier/Section II/Annex II_2.
[10] Technical dossier/ Supplementary information October 2019/2019_10_15 FAD 2019 0007, Annex_1. LOD in mg/kg were 0.01 for Hg, 0.02 for Cd and 0.03 for As; LOQ was 0.06 for Pb.
[11] Technical dossier/Supplementary information October 2019/Annex_2.
[12] Technical dossier/Supplementary information October 2019/2019_10_15 FAD 2019 0007, Annex_3.

12,000 mg/kg of complete feedingstuff, (ii) the additive shall be incorporated in the feed in form of a premixture, (iii) the product can produce risk of serious damage to the eye, (iv) measures to protect the workers shall be adopted.

The applicant proposes to maintain the same conditions of use as the current authorisation.

3.2. Safety

3.2.1. Safety

In its opinion on the safety and efficacy of Formi™ LHS (EFSA FEEDAP Panel, 2009) the FEEDAP Panel concluded as follows regarding the safety for the target animals, consumer, and user:

> 'The additive Formi™ LHS appears to be tolerated at the level of 5.0% (analysed value). Therefore, the FEEDAP Panel considers Formi™ LHS to be safe for use in sows at a maximum dose of 1.2%, with a margin of safety of approximately four. Although Formi™ LHS has a potential antimicrobial effect in the gastrointestinal tract, the nature of the product makes selection for bacteria resistant to clinically relevant antibiotics unlikely.'

> 'Considering the absence of genotoxicity, the low toxicity of potassium diformate and the lack of an increased consumer exposure to formate, the FEEDAP Panel considers that the use of Formi™ LHS as a feed additive in sows under the proposed conditions of use is safe for the consumer.'

> 'The data submitted in the dossier to assess user safety was previously assessed by SCAN (EC, 2001) on the basis of skin and eye irritation studies, skin sensitisation test (Magnusson-Kligman test with Guinea pigs) and an acute inhalation toxicity test (rat). The FEEDAP Panel has reviewed the data and reached the same conclusions as SCAN. Except for ocular irritation potential, no effects requiring specific user protection measures were found'

Regulation (EC) No 429/2008 and the FEEDAP Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013) foresees the need for submission of evidence that, in the light of the current knowledge, the additive remains safe under the approved conditions for target species, consumers, users/workers and the environment. The applicant did not provide any new information in the current application, but only a review of the toxicological studies already assessed in previous FEEDAP opinions.[13] Despite the request from EFSA to provide information to support the safety of the additive, the applicant only submitted a generic statement in which declared that no reports on adverse effects on target animals, consumers, and user and environment were reported in the EU on the company's complaint system since 2012. The FEEDAP Panel notes, however, that such a complaint system is not designed to identify adverse effects linked to the active substance reported elsewhere in the world and does not cover cases/scientific reports from, e.g. literature studies. Therefore, the Panel considers that the information provided by the applicant does not fulfil the minimum requirements to support that the additive remains safe under the approved conditions for target species, consumers, and user.

3.2.2. Safety for the environment

In its opinion on the safety and efficacy of Formi™ LHS (EFSA FEEDAP Panel, 2009), the FEEDAP Panel concluded as follows regarding the safety for the environment:

> 'The FEEDAP Panel concludes, [...], that since the excretion products formic acid and formate are naturally occurring metabolites, and the use of potassium diformate would not substantially increase excretion of formate (and potassium ions) in the environment, no further environmental assessment is necessary'.

The FEEDAP Panel reiterates its previous conclusion on the safety for the environment.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.

[13] Technical dossier/Section III/Annex III_27.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[14] and Good Manufacturing Practice.

4. Conclusions

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 present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive.

Documentation as provided to EFSA/Chronology

Date	Event
29/02/2019	Dossier received by EFSA. Formi LHS (potassium diformate) for sows for reproduction. Submitted by Addcon GmbH.
21/02/2019	Reception mandate from the European Commission
05/06/2019	Application validated by EFSA – Start of the scientific assessment
08/08/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterization of the additive, studies concerning the safety of the additive*
24/10/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
05/09/2019	Comments received from Member States
29/01/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EC (European Commission), 2001. Report of the Scientific Committee on Animal Nutrition on the use of potassium diformate (FormiTM LHS) as feed additive. http://ec.europa.eu/food/fs/sc/scan/out83bis_en.pdf

EFSA (European Food Safety Authority), 2004. Scientific Opinion of the Panel on Additives and Products or Substances used in Animal feed on the safety and efficacy of Formi LHS for sows. EFSA Journal 2004;2 (12):139, 9 pp. https://doi.org/10.2903/j.efsa.2004.139

EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product "Formi™ LHS" as a feed additive for weaned piglets and pigs for fattening in accordance with Regulation (EC) No 1831/2003. EFSA Journal 2006;4 (2):325, 16 pp. https://doi.org/10.2903/j.efsa.2006.325

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2009. Scientific Opinion on the safety and efficacy of Formi™ LHS (potassium diformate) as a feed additive for sows on request from the European Commission. EFSA Journal 2009;7(9):1315, 17 pp. https://doi.org/10.2903/j.efsa.2009.1315

EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2013. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. https://doi.org/10.2903/j.efsa.2013.3431

Abbreviations

BEQ	Bioanalytical Equivalents
CAS	Chemical Abstracts Service
CV	coefficient of variation
DL-PCB	dioxin-like polychlorinated biphenyl
EINECS	European Inventory of Existing Commercial Chemical Substances

[14] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans