Assessment of the feed additive consisting of potassium diformate for all animal species for the renewal of its authorisation (Addcon GmbH)

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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 potassium diformate for all animal species. The additive was initially evaluated in 2004 and re-evaluated by the Panel in 2012, with the conclusion that the additive (i) was safe for the target species, the consumer and the environment when used under the proposed conditions; (ii) was an eye irritant and (iii) had the potential to increase the storage time of raw fish and fish by-products for feed use in a dose-dependent manner at low temperature. The FEEDAP Panel considered that the use of potassium diformate under the approved conditions of use remains safe for consumers and the environment, and that it is an eye irritant. Due to the absence of data, the FEEDAP Panel could not conclude on the potential of the additive to be a skin irritant or a respiratory or dermal sensitiser. Regarding the safety for the target species, the FEEDAP Panel considered that the mixture of different sources of potassium diformate remains safe for use in sows’ feed under the approved conditions of use (12,000 mg/kg complete feed). However, based on a tolerance trial, the Panel concluded that the maximum safe level of potassium diformate in weaned piglets should be reduced to 6,000 mg/kg complete feed and the same conclusion was extended to pigs for fattening. Owing to the lack of information provided, the Panel could not conclude on the safety of the additive for species other than pigs under the approved conditions. The present application 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.

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Keywords: potassium diformate, all animal species, safety, efficacy, renewal

Requestor: European Commission
Question number: EFSA-Q-2021-00102
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Declarations of interest: The declarations of interest of all scientific experts active in EFSA’s work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Fašmon Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Anguita M, Galobart J and Ortuño J, 2022. Scientific Opinion on the assessment of the feed additive consisting of potassium diformate for all animal species for the renewal of its authorisation (Addcon GmbH). EFSA Journal 2022;20(3):7167, 8 pp. https://doi.org/10.2903/j.efsa.2022.7167

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
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1. Introduction

1.1. Background and Terms of Reference

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 GmbH\(^2\) for renewal of the authorisation of the product potassium diformate when used as a feed additive for all animal species (category: technological additive; functional group: preservative).

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 15 July 2021.

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 feed additive consisting of potassium diformate, when used under the proposed conditions of use (see Section 3.1.2).

1.2. Additional information

EFSA issued two opinions on the safety and efficacy of this product when used as a preservative in raw fish and fish by-products for feed uses for all animal species (EFSA, 2004; EFSA FEEDAP Panel, 2012).

Potassium diformate is currently authorised by Commission Regulation (EU) No 333/2012 as a technological feed additive (functional group: preservative) for all animal species (1a237a).\(^3\) The active substance potassium diformate is also authorised as azootechnical feed additive (functional group: acidity regulator) for sows (4d800).\(^4\)

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\(^5\) in support of the authorisation request for the use of 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 or other expert bodies and peer-reviewed scientific papers, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the active substance in animal feed are valid and applicable for the current application.\(^6\)

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\(^1\) Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the 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 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.

\(^4\) COMMISSION IMPLEMENTING REGULATION (EU) No 104/2010 of 05 February 2010 concerning the authorisation 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. 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.98.

\(^5\) FEED dossier reference: FAD-2021-0003.

\(^6\) The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-018803030312
2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of potassium diformate is in line with the principles laid down in Regulation (EC) No 429/20087 and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b) and Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013).

3. Assessment

The additive potassium diformate in liquid form (50:50 diluted in water) is authorised as a technological additive (functional group: preservatives) for use 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 of raw fish.

The applicant has applied for the renewal of this authorisation under the same conditions of use currently authorised.

3.1. Characterisation

3.1.1. Characterisation of the additive

The additive is an aqueous solution (specific weight at 20°C: 1,225–1,325 kg/m³, pH 4.0–4.5) containing 45–55% of potassium diformate (potassium hydrogen diformate, CAS No 20642-05-1, EINECS number 243-934-6, molecular weight 130.12, molecular formula C₂H₃O₄K). At pH > 4, the product dissociates to formate and potassium ions.

The applicant stated that there have been no changes in the manufacturing process since the additive was authorised.

The applicant provided data on the batch-to-batch variation of eleven recent batches of the additive,8 showing an average value of potassium diformate of 49.7 (47.8–51.5)% (w/w).

Five batches of the additive were analysed for chemical impurities.9 Heavy metals (cadmium, lead and mercury), fluorine and arsenic levels were below the limit of quantification (LOQ) of the analytical methods.10 Polychlorinated dibenzodioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and coplanar dioxin-like polychlorinated biphenyls (co-planar PCBs) were analysed in three batches and found below the corresponding LOQ.11 The calculated (upper bound) levels of dioxins and the sum of dioxins and dioxin-like-PCBs were 0.15 ng WHO-PCDD/F-TEQ/kg and 0.096 ng WHO-PCDD/F-PCB-TEQ/kg, respectively (in all three batches).

No new data have been provided regarding the physico-chemical properties or stability of the additive. Since no changes have been introduced in the additive or its manufacturing process, the data described in the previous opinions still apply (EFSA, 2004; EFSA FEEDAP Panel, 2012).

3.1.2. Conditions of use

Potassium diformate is authorised as a preservative for raw fish and fish by-products for feed use for all animal species.

The authorising regulation under other provisions states that:

- 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 of 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 feedingstuffs of 18,000 mg/kg complete feedingstuffs for weaned piglets and 12,000 mg/kg complete feedingstuffs for sows and pigs for fattening.

7 Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
8 Technical dossier/Section II/Annex II_1 to 6 and SIn_041121/Annexes 1 to 5.
9 Technical dossier/SIn_041121/Annexes 1 to 5.
10 LOQ (mg/kg): As=0.1; Cd=0.1; F=5; Hg=0.01; Pb=0.1.
11 Technical dossier/Section II/Annex II_10.
Indicate in the instructions for use: ‘The simultaneous use of other organic acids at the maximum permitted doses is contraindicated’.

‘For safety: breathing protection, eye protection and gloves shall be used during handling’.

The applicant has not requested to modify the current conditions of use.

3.2. Safety

The safety of the additive for the target species, the consumers, the users and the environment has already been assessed by the FEEDAP Panel (EFSA, 2004; EFSA FEEDAP Panel, 2012). The FEEDAP Panel concluded that the additive is safe for the target species, the consumers and the environment when used under the proposed conditions, and is an eye irritant.

In the current application, the applicant submitted a tolerance study to support the safety for weaned piglets, which had already been assessed in a previous opinion (EFSA FEEDAP Panel, 2021). Based on the results from that tolerance trial, the Panel concluded that potassium diformate as the active substance is safe for weaned piglets at the level of 6,000 mg/kg complete feed with no margin of safety and the same conclusion was extended to pigs for fattening.

3.2.1. Extensive literature search

The applicant conducted a literature search covering the period 2000–2020 in the databases TOXCENTER, BIOSIS, AGRICOLA, HCAPLUS, PQSCITECH, MEDLINE, ESBIOBASE, EMBASE and CABA; a single concept search strategy (i.e. search for CAS number and the chemical names) was applied. Studies in certain target species (restricted to 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 provide relevant information regarding adverse effects in target animals (pigs, piglets and sows), consumers and users. The Panel notes that this literature search was limited to pigs as target species and did not address any other target species covered by the current authorisation.

Owing to the nature of the active substance and its metabolism, the FEEDAP Panel considers that there is no need for additional information on the safety for the environment in the context of the renewal of authorisation of this additive.

3.2.2. Conclusions on safety

Based on the information provided by the applicant 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. Therefore, the additive is regarded safe under the approved conditions for consumers and the environment, and it is an eye irritant. Due to the absence of data, the FEEDAP Panel cannot conclude on the potential of the additive to be a skin irritant or a respiratory or dermal sensitisier.

With regard to the target species, the Panel concludes that potassium diformate remains safe for sows at a maximum level of 12,000 mg/kg complete feed. For weaned piglets, potassium diformate is safe at a maximum level of 6,000 mg/kg complete feed with no margin of safety and the same conclusion is extended to pigs for fattening. The FEEDAP Panel notes that the maximum safe level in piglets and pigs for fattening is not aligned with the current authorisation, which indicates that the mixture of different sources of potassium diformate shall not exceed the permitted maximum level in complete feedingstuffs of 18,000 mg/kg complete feedingstuffs for weaned piglets and 12,000 mg/kg complete feedingstuffs for sows and pigs for fattening.

Considering that no new information was provided, the Panel cannot conclude whether the additive remains safe under the approved conditions for species other than pigs.

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 as a preservative in raw fish and fish by-products for feed use. Therefore, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.
4. Conclusions

The FEEDAP Panel considers that the use of potassium diformate under the approved conditions of use is safe for consumers and the environment. The additive is an eye irritant. The FEEDAP Panel cannot conclude on the potential of the additive to be irritant to the skin or a respiratory or skin sensitisier.

Regarding the safety for the target species, the FEEDAP Panel considers that the maximum potassium diformate level in feed for sows (12,000 mg/kg) remains safe under the approved conditions of use. However, the Panel considers that the maximum safe level for weaned piglets and pigs for fattening is 6,000 mg/kg complete feed, which is lower than the one included in the current authorisation. Owing to the lack of information, the Panel cannot conclude on whether the additive remains safe under the approved conditions for the other species for which it is authorised.

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 as a preservative in raw fish and fish by-products for feed use.

5. Documentation provided to EFSA/Chronology

| Date       | Event                                                                 |
|------------|-----------------------------------------------------------------------|
| 26/01/2021 | Reception mandate from the European Commission                        |
| 19/02/2021 | Dossier received by EFSA. FAD-2021-0003. Potassium diformate (KDF preservative) for all animal species. Submitted by Addcon GmbH |
| 15/07/2021 | Application validated by EFSA – Start of the scientific assessment     |
| 29/09/2021 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. Issues: general/purity/safety |
| 18/10/2021 | Comments received from Member States                                  |
| 04/11/2021 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 27/01/2022 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment  |

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### Abbreviations

| Abbreviation | Full Form |
|--------------|-----------|
| CAS          | Chemical Abstracts Service |
| EINECS       | European Inventory of Existing Chemical Substances |
| EUROL        | European Union Reference Laboratory |
| FAO          | Food Agricultural Organization |
| FEEDAP       | EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed |
| LOD          | limit of detection |
| LOQ          | limit of quantification |
| OECD         | Organisation for Economic Co-operation and Development |
| PCB          | polychlorinated biphenyl |
| PCDD         | polychlorinated dibenzodioxin |
| PCDF         | polychlorinated dibenzofurans |
| SCAN         | Scientific Committee on Animal Nutrition |
| TEQ          | toxic equivalent |
| WHO          | World Health Organization |