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Efficacy of calcium formate as a technological feed additive (preservative) for all animal species

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Abstract

In 2014, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of calcium formate when used as a technological additive (preservative) for all animal species. Calcium formate was considered safe for all animal species at a maximum concentration of 10,000 mg formic acid equivalents/kg complete. Calcium formate was also considered safe for the consumer and the environment. The Panel also concluded that calcium formate is non-irritant to skin but causes severe adverse effects in eyes. It is likely that handling the additive could result in skin reactions and in the production of respirable dust that could present a risk to unprotected workers. The Panel also concluded that 'Data submitted do not provide convincing evidence of the efficacy of the additive when used as a preservative for compound feed or feed materials'. In the current opinion, additional data to demonstrate the efficacy of calcium formate as a preservative in feed for all animal species were assessed. The Panel concluded that calcium formate has the potential to be efficacious as a preservative in feedingstuffs for all animal species at the proposed use level.

Keywords: technological additive, preservative, calcium formate, efficacy

Requestor: European Commission

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1. Introduction

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

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

The applicant, LANXESS Deutschland GmbH, is seeking a Community authorisation for calcium formate as a feed additive to be used as a preservative for all animal species (Table 1).

Table 1: Description of the substances

Category of additive	Technological additives
Functional group of additive	Preservative
Description	Calcium formate
Target animal category	All animal species
Applicant	LANXESS Deutschland GmbH
Type of request	New opinion

On 28 October 2014, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on opinion on the safety and efficacy of calcium formate when used as a technological additive for all animal species as preservative for compound feed or feed materials. After the discussion with the Member States on the Standing Committee, it was suggested to check for the possibility to demonstrate the efficacy.

The Commission (EC) gave the possibility to the applicant to submit complementary information in order to complete the assessment and to allow a revision of the Authority's opinion. The new data have been received on 13 January 2020.

In view of the above, the Commission asks the Authority to deliver a new opinion on calcium formate as a feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

Calcium formate is currently listed in the EU Register of Feed Additives as a technological additive (functional group: preservative) for use in feed for all animal species. The re-evaluation of calcium formate as a technological additive (functional group: preservative) for use in feed for all animal species is the subject of the current application.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered in 2014 and opinion on the safety and efficacy of calcium formate when used as a technological additive for all animal species (EFSA FEEDAP Panel, 2014). In this opinion, the FEEDAP Panel concluded that 'Calcium formate had no discernible effects on microbial numbers in the feed materials examined'.

The applicant has now submitted additional data to demonstrate the efficacy of calcium formate as a preservative in feed for all animal species.

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information[1] following a previous application on the same product.[2]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of calcium formate is in line with the principles laid down in Regulation (EC) No 429/2008[3] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

[1] Dossier reference: FAD-2020-0020.
[2] Dossier reference: FAD-2010-0303.
[3] 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.

3. Assessment

The additive under assessment is calcium formate. The additive is intended to be used as a technological additive, functional group preservative in feedingstuffs and water for drinking for all animal species. The proposed maximum contents in feed are of 10,000 mg/kg complete feed.

For all animal species, all expressed as formic acid/kg complete feed. The additive was fully characterised in the previous opinion entitled 'the safety and efficacy of calcium formate when used as a technological additive for all animal species' (EFSA FEEDAP Panel, 2014). Calcium formate was considered safe for all animal species at a maximum concentration of 10,000 mg formic acid equivalents/kg complete feed. Calcium formate was also considered safe for the consumer and the environment. The Panel also concluded that calcium formate is non-irritant to skin but causes severe adverse effects in eyes. It is likely that handling the additive could result in skin reactions and in the production of respirable dust that could present a risk to unprotected workers.

Regarding the use of the additive as preservative in feedingstuffs, based on the available data the Panel concluded that 'calcium formate had no discernible effects on microbial numbers in the feed materials examined'.

The applicant has now provided additional data to support the efficacy of calcium formate as a preservative in feedingstuffs for all animal species.

3.1. Efficacy

The endpoints to demonstrate the efficacy of an additive in the functional group preservative is 'inhibition of microbial growth, particularly that of biotic and spoilage organisms'.[3] The period for which a preserving effect is claimed shall be demonstrated.

To support the efficacy of calcium formate as preservative in feedingstuffs for all animal species, three *in vitro* studies were provided.

3.1.1. Study 1 – Totally mixed ration

In the first study, a totally mixed ration (TMR) was prepared with 52% grass silage, 37% corn silage, 7.6% crimped wheat, 2.9% protein feed, 0.3% minerals and 0.25% salt. The dry matter (DM) content was approx. 43%. Three representative samples of the TMR were collected at study start to determine DM content, pH, and yeasts, moulds and total aerobic counts. The TMR was either left untreated (control, six replicates (350 g fresh matter (FM) each, in test tubes of 1,300 mL)) or treated with 3.0 g calcium formate/kg fresh TMR (six replicates). These samples were exposed to an aerobic environment (20 ± 1°C ambient temperature and 60–70% relative humidity) while their core temperatures were monitored. The lower end of the tubes was covered with an autoclaved, woven fabric to allow air to pass through. Sample temperatures were recorded every 2 h for a period of 5.3 days. Three replicates each were removed and analysed for pH, yeasts, moulds and total aerobic counts when the control samples went 5°C above the ambient temperature (T1). The remaining samples were analysed when the treated TMR reached the same temperature difference (T2).

The data were analysed statistically using a one-way ANOVA. Significance was set a $p < 0.05$.

At T1, treated samples, compared to the control, showed a significantly lower pH values (4.34 vs. 4.45), significantly lower counts for yeasts (6.35 vs. 7.50 log CFU/g) and total aerobic counts (6.63 vs. 7.59 log CFU/g). At T2, the differences in pH became more marked (4.59 vs. 6.12) and remained significant for yeast count (7.97 vs. 8.43 log CFU/g) and total aerobic counts (7.91 vs. 8.66 log CFU/g). T2 was reached 1.8 days after the T1.

3.1.2. Study 2 – Beet pulp

In the second study, that followed the same protocol described for Study 1, beet pulp (DM 27.5%) samples (660 g fresh matter (FM) each, in test tubes of 1,300 mL) were analysed for aerobic stability and DM content, pH, and yeast, moulds and total aerobic counts.

At T1, treated samples, compared to the control, showed a significantly lower pH values (3.66 vs. 3.95), significantly lower counts for yeasts (5.06 vs. 7.26 log CFU/g) and total aerobic bacteria (6.73 vs. 8.53 log CFU/g). At T2, that was reached 1.9 days after the T1, only yeasts counts were different between the treated and the control samples (6.79 vs. 7.88 log CFU/g, respectively).

3.1.3. Study 3 – Distiller's grains

Distiller's grains as a high moisture feed ingredient (8.2% DM), was taken for the third study. Distiller's grains were mixed with Ca-formate at 0 or 3.0 g/kg fresh matter. Twelve test tubes (500 mL volume, filled with 250 mL distiller's grains) for each treatment were stored at ambient temperature (20 ± 2°C). Once a day, samples were mixed manually for approximately 10 min to homogenize and to increase the aeration intensity. Sample temperatures were recorded every 2 h. Three tubes per treatment were removed and analysed for pH, yeast, mould and total aerobic count after 17, 24, 33 and 40 days (T1, T2, T3 and T4).

No differences were observed along the study in aerobic stability and in pH between the control and the Ca-formate treated distiller's grains. At all the sampling times the treated samples, compared to the control, showed a significantly lower counts for yeasts (T1: < 1.70 vs. 7.11 log CFU/g, T2: 2.87 vs. 6.61 log CFU/g, T3: 4.45 vs. 7.19 log CFU/g, T4: 2.39 vs. 6.97 log CFU/g). Total aerobic bacteria count was affected only at T4 (9.38 vs. 9.04 log CFU/g in treated and control, respectively), as well as moulds count (4.16 vs. < 1.70 log CFU/g in treated and control, respectively).

4. Conclusions

The results of three *in vitro* studies with compound feedingstuffs and feed materials showed that calcium formate has the potential to be efficacious as a preservative in feedingstuffs for all animal species at the proposed use level.

Documentation as provided to EFSA/Chronology

Date	Event
13/01/2020	Dossier received by EFSA - Calcium formate. Submitted by LANXESS Deutschland GmbH
13/01/2020	Mandate received by EFSA
18/03/2020	Application validated by EFSA – Start of the scientific assessment
07/05/2020	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2014. Scientific Opinion on the safety and efficacy of calcium formate when used as a technological additive for all animal species. EFSA Journal 2014;12(11):3898, 18 pp. https://doi.org/10.2903/j.efsa.2014.3898

EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2018. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

Abbreviations

CFU	Colony forming Unit
DM	dry matter
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FM	fresh matter
TMR	totally mixed ration