

SCIENTIFIC OPINION

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Efficacy of sodium formate as a technological feed additive (hygiene condition enhancer) for all animal species

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Abstract

In 2015, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as feed hygiene agents for all animal species. In this opinion, two forms of the additive sodium formate, a solid form (specified to contain $\geq 98\%$ sodium formate (w/w)) and a liquid form (specified to contain a minimum of 15% sodium formate, a maximum of 75% free formic acid and a maximum of 25% water), were assessed. Sodium formate was considered safe for all animal species at a maximum concentration of 10,000 mg formic acid equivalents/kg complete feed (with the exception of pigs, for which a maximum concentration of 12,000 mg formic acid equivalents/kg complete feed was considered safe). Sodium formate was also considered safe for the consumer and the environment. The Panel also concluded that sodium formate is corrosive. The Panel also concluded that 'for sodium formate, limited data are available to demonstrate their effects in feed'. In the current opinion, additional data to demonstrate the efficacy of sodium formate liquid as a hygiene condition enhancer in feed for all animal species were assessed. The Panel concluded that sodium formate liquid has the potential to be efficacious as hygiene condition enhancer in feedingstuffs for all animal species at the proposed use level.

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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, FEFANA asbl, is seeking a Community authorisation of Sodium formate (E 237) as a feed additive to be used as a hygiene condition enhancer: substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination for all animal species (Table 1).

Table 1: Description of the substances

Category of additive	Technological additives
Functional group of additive	Hygiene condition enhancer
Description	Sodium formate (E 237)
Target animal category	All animal species
Applicant	FEFANA ASBL
Type of request	New opinion

On 30 April 2015, 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 efficacy of sodium formate in all animal species under the condition of use proposed by the applicant. Moreover, the FEEDAP Panel noted that decreasing the number of viable microbial cells in contaminated feed does not eliminate the potential hazards associated with bacterial toxins and endotoxins that may be present in feed.

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 29 October 2018.

In view of the above, the Commission asks the Authority to deliver a new opinion on sodium formate (E 237) as a feed additive for all animal species based on the additional data submitted by the applicant.

1.2. Additional information

The additive sodium formate (E 237) is currently authorised in the European Union (EU) as a feed additive (category: technological additives; functional group: silage additive).¹ The use of sodium formate as a technological additive (functional group: preservative) for use in feed for all animal species is currently subject of re-evaluation, according to Article 10 of Regulation (EC) No 1831/2003. The current application is for the authorisation of a new use of sodium formate as a technological additive (functional group: hygiene condition enhancer) in feed for all animal species.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered in 2015 an opinion on the safety and efficacy of ammonium formate, calcium formate and sodium formate when used as a technological additive (preservative) for all animal species (EFSA FEEDAP Panel, 2015a).

The FEEDAP Panel issued in 2015 an opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as feed hygiene agents for all animal species (EFSA FEEDAP Panel, 2015b). In this opinion, the Panel assessed the efficacy of sodium formate under the newly proposed (not existing when the assessment was performed) functional group 'feed hygiene agents', and used the criteria and the endpoints defined for the functional group 'preservative', since 'the differences between the functional group "preservatives" and the newly proposed functional group "feed hygiene agents/substances" appear to be marginal'. In this opinion, the FEEDAP Panel concluded that 'for sodium formate, limited data are available to demonstrate their effects in feed'. In 2015, the European Commission amended Regulation (EC) No 1831/2003 to include, in the category: technological additives, the functional group n) hygiene condition enhancer. The applicant has now submitted additional data to demonstrate the efficacy of sodium formate liquid as a hygiene condition enhancer in feed for all animal species.

¹ Commission Implementing Regulation (EU) 2016/2023 of 18 November 2016 concerning the authorisation of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species (OJ L 313, 19.11.2016, p. 14–20).

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information² following a previous application on the same product.³

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of sodium formate is in line with the principles laid down in Regulation (EC) No 429/2008⁴ and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive under assessment is sodium formate. The additive is intended to be used in feedingstuffs for all animal species, at the proposed use levels of 10,000 mg/kg complete feed for pigs (maximum content 12,000 mg/kg) and 5,000 mg/kg feed for all other species (maximum content 10,000 mg/kg feed), all expressed as formic acid/kg complete feed. Concentrations between 10,000 and 40,000 mg/kg feed (expressed as formic acid/kg complete feed) may be used for individual feed materials. The additive was fully characterised in the previous Scientific Opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as feed hygiene agents for all animal species (EFSA FEEDAP Panel, 2015b), in which the Panel described two forms of the additive: a solid form (specified to contain $\geq 98\%$ sodium formate (w/w)) and a liquid form (specified to contain a minimum of 15% sodium formate, a maximum of 75% free formic acid and a maximum of 25% water). Sodium formate was considered safe for all animal species at a maximum concentration of 10,000 mg formic acid equivalents/kg complete feed (with the exception of pigs, for which a maximum concentration of 12,000 mg formic acid equivalents/kg complete feed was considered safe). Sodium formate was also considered safe for the consumer and the environment. The Panel also concluded that sodium formate is corrosive.

Regarding the use of the additive as hygiene condition enhancers, owing the lack of studies done with sodium formate, the Panel concluded that limited data are available to demonstrate sodium formate effects in feed. The Panel also noted that: 'decreasing the number of viable microbial cells in contaminated feed does not eliminate the potential hazards associated with bacterial toxins and endotoxins that may be present in feed'.

The applicant has now provided additional data to support the efficacy of sodium formate liquid as a hygiene condition enhancer in feedingstuffs for all animal species. No data aimed to address the concern of the Panel on the potential hazard associated with (endo)toxins presence in feed were provided. Therefore, the present opinion focuses only on the assessment of the efficacy of sodium formate.

3.1. Efficacy

The functional group hygiene condition enhancer is defined as 'substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination'. To support the efficacy of sodium formate as hygiene condition enhancer in feedingstuffs for all animal species, five *in vitro* studies were provided. One study was done with pure cultures of pathogenic microorganisms (minimum inhibition concentration (MIC) test).⁵ This study was not considered further for the assessment since it is not possible, to extrapolate the results to an effect in feed.

Four *in vitro* studies were done with feed naturally or artificially contaminated with pathogenic microorganisms. In all the studies, only the liquid form of sodium formate (about 61% formic acid, 21% sodium formate and 18% water) was tested.

² Dossier reference: FAD-2018-0083.

³ Dossier reference: FAD-2013-0036.

⁴ 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.

3.1.1. Study 1

Koyuncu et al. (2013) performed a study comparing the antimicrobial activity of different organic acids against two serovars of *Salmonella* (Typhimurium 98/1991 and Infantis 167/2007) in compound mash feed for pigs for fattening and in soybean meal. The feed and the soybean meal were mixed with sodium formate liquid at concentrations of 0 (control), 9,000 and 15,000 mg sodium formate liquid/kg complete feed (confirmation of the concentration not reported in the publication). Duplicate samples of 4 g each of the feed and soybean meal were mixed with 0.1 mL of inoculum (10^8 to 10^9 colony forming units (CFU)/mL). The inoculated feed samples were then stored at room temperature ($20^\circ\text{C} \pm 2^\circ\text{C}$) for 0, 1, 4, 7, 14 and 28 days. Samples were collected and analysed for *Salmonella* content at each time point.

Differences in *Salmonella* counts reduction were observed between the feed types. In the mash feed, either of the concentrations of sodium formate tested reduced *Salmonella* (both serovars) concentration, compared to the control, in the samples collected after inoculation. The result shows a reduction of *Salmonella* over the experimental period in all groups, including the control group; the reduction in the control amounted to approximately 1–2 \log_{10} in the feedingstuffs and approximately 1 log in the soybean. The addition of sodium formate resulted in a reduction in *Salmonella* counts, compared to the control, of approximately 1–2 \log_{10} for the 9,000 mg sodium formate liquid/kg complete feed and 2–3 \log_{10} for the 15,000 mg sodium formate liquid/kg complete feed concentrations, at most time points. In soybean meal, the reduction of *Salmonella* (both serovars) counts was less marked, being approximately 0.5–1 \log_{10} compared to the control, irrespectively, from the sodium formate concentration.

3.1.2. Study 2



3.1.3. Study 3



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3.1.4. Study 4

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4. Conclusions

The results of four *in vitro* studies, in which complete feeds and feed materials were artificially contaminated with pathogen and spoilage microorganisms, showed that sodium formate liquid has the potential to be efficacious as hygiene condition enhancer in feedingstuffs for all animal species at the proposed use level.

Documentation provided to EFSA

- 1) Sodium formate. January 2019. Submitted by FEFANA asbl.

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Chronology

Date	Event
3/12/2018	Dossier received by EFSA
18/12/2018	Mandate received by EFSA
26/2/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015b. Scientific Opinion on the safety and efficacy of formic acid, ammonium formate and sodium formate as feed hygiene agents for all animal species. EFSA Journal 2015;13(5):4113, 24 pp. <https://doi.org/10.2903/j.efsa.2015.4113>
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- Koyuncu S, Andersson MG, Löfström C, Skandamis PN, Gounadaki A, Zentek J and Häggblom P, 2013. Organic acids for control of *Salmonella* in different feed materials. BMC Veterinary Research, 9, 81.

Abbreviations

- CFU colony forming unit
FEEDAP Panel on Additives and Products or Substances used in Animal Feed
MIC minimum inhibitory concentration