SCIENTIFIC OPINION



Safety and efficacy of a feed additive consisting of benzoic acid (Kalama® Animal Feed Grade Benzoic acid) for weaned piglets and pigs for fattening (Emerald Kalama Chemical, B.V)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of benzoic acid (Kalama®) as a zootechnical feed additive for weaned piglets at a level of 5000 mg/kg complete feed and for pigs for fattening at a minimum content of 5000 mg/kg and a maximum content of 10,000 mg/kg complete feed. The FEEDAP Panel concluded that benzoic acid is safe for weaned piglets at 5000 mg/kg complete feed and for pigs for fattening at 10,000 mg/kg complete feed. The Panel considered the use of benzoic acid under the proposed conditions of use to be of no concern for consumer safety and the environment. Benzoic acid poses a risk by inhalation, it is irritant to skin and corrosive to eyes, but no conclusions can be drawn on dermal sensitisation. The additive, benzoic acid, is efficacious as a zootechnical feed additive for weaned piglets and for pigs for fattening at the proposed conditions of use.

KEYWORDS

benzoic acid, efficacy, Kalama®, other zootechnical additives, safety, zootechnical additives

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1 | INTRODUCTION

1.1 | Background and terms of reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Emerald Kalama Chemical, B.V.² for the authorisation of the additive consisting of benzoic acid (Kalama® Animal Feed Grade Benzoic acid), when used as a feed additive for weaned piglets and pigs for fattening (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 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 5 September 2022.

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 benzoic acid (Kalama® Animal Feed Grade Benzoic acid), when used under the proposed conditions of use (see **Section 3.1.4**).

1.2 | Additional information

The additive consists of benzoic acid. EFSA issued five opinions on the safety and efficacy of the benzoic acid when used in feed for weaned piglets (EFSA, 2005), pigs for fattening (EFSA, 2007), pigs for reproduction (EFSA FEEDAP Panel, 2012a), an opinion assessing benzyl alcohols, benzaldehydes and benzoic acid as food flavourings (EFSA FGE Panel, 2012)³ and another opinion on the safety and efficacy of benzoic acid as a technological feed additive for weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2019a). Benzoic acid as a food additive was re-evaluated by the EFSA Panel on Food Additives and Nutrient Sources Added to Food in 2016 (EFSA ANS Panel, 2016). In 2012, the European Chemical Agency performed a risk assessment and proposed a classification for benzoic acid (ECHA, 2012).

Benzoic acid is currently authorised as a sensory feed additive (flavouring compounds) for all animal species (2b08021)⁴ and as a zootechnical additive (other zootechnical additives) for weaned piglets,⁵ pigs for fattening,^{4,6} sows^{7,8} for minor porcine species for fattening and for reproduction⁹ (4d210), being the holder of the authorisation for the latter, different to the applicant from the current application.

Benzoic acid is authorised as a food additive in the EU (E210).

2 DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier¹⁰ in support of the authorisation request for the use of benzoic acid (Kalama® Animal Feed Grade Benzoic acid) as a feed additive. The dossier was received on 06 December 2021 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00740

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 5 September to 5 December 2022 for which the received comments were considered for the assessment.

¹Regulation (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. ²Emerald Kalama Chemical, B.V., Montrealweg 153,197 KH Rotterdam, The Netherlands.

³On request from the European Commission, Question No (EFSA-Q-2012-00621, EFSA-Q-2012-00620, EFSA-Q-2012-00619, EFSA-Q-2012-00618), adopted on 20 November 2012. ⁴Commission Implementing Regulation (EU) 2017/63 of 14 December 2016 concerning the authorisation of benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, 4-isopropylbenzaldehyde, p-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate and isobutyl benzoate as feed additives for all animal a species and of veratraldehyde and gallic acid as feed additives for certain animal species OJ L 13, 17.01.2017, p. 214.

⁵Commission Implementing Regulation (EU) 2018/1550 of 16 October 2018 concerning the renewal of the authorisation of benzoic acid as a feed additive for weaned piglets and pigs for fattening and repealing Regulations (EC) No 1730/2006 and (EC) No 1138/2007 (holder of authorisation DSM Nutritional Products Ltd) OJ L 260, 17.10.2018, p. 3. ⁶Commission Implementing Regulation (EU) 2020/1031 of 15 July 2020 concerning the authorisation of benzoic acid as a feed additive for pigs for fattening (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional Products Sp. Z o.o) OJ L 227, 16.7.2020, p. 21.

⁷Commission Implementing Regulation (EU) 2016/900 of 8 June 2016 concerning the authorisation of benzoic acid as a feed additive for sows (holder of authorization DSM Nutritional Product Sp. z o. o.) OJ L 152, 9.6.2016, p. 18.

⁸Corrigendum in OJ L 303, 10.11.2016, p. 26 Corrigendum to Commission Implementing Regulation (EU) 2016/900 of 8 June 2016 concerning the authorisation of benzoic acid as a feed additive for sows (holder of authorisation DSM Nutritional Product Sp. z o. o.) OJ L 303, 10.11.2016, p. 26.

⁹Commission Implementing Regulation (EU) 2018/983 of 11 July 2018 concerning the authorisation of benzoic acid as a feed additive for minor porcine species for fattening and for reproduction (holder of authorisation DSM Nutritional Products Sp. z o. o.) OJ L 176, 12.07.2018, p. 17.

¹⁰Dossier reference: FEED-2021-2111.

In accordance with Article 38 of the Regulation (EC) No 178/2002¹¹ and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,¹² a non-confidential version of the dossier has been published on Open.EFSA at https://open.efsa.europa.eu/questions/FEED-Q-2021-00740.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, ¹³ EFSA carried out a public consultation on the non-confidential version of the technical dossier from 23 April to 19 May 2023. The comments received have been carefully evaluated and one entry was registered but the comments submitted dimmed as not relevant to the scope of the public consultation, and therefore, were not considered further.

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, peer-reviewed scientific papers, other scientific reports and experts' (elicitation) knowledge, 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 benzoic acid in the feed additive, premixtures and animal feed are valid and applicable for the current application.¹⁴

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of benzoic acid (Kalama® Animal Feed Grade Benzoic acid) is in line with the principles laid down in Regulation (EC) No 429/2008¹⁵ and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019b).

3 | ASSESSMENT

The additive Kalama® Animal Feed Grade Benzoic acid (referred to in this opinion as Kalama®) consists of benzoic acid and is intended to be used as a zootechnical additive (functional group: other zootechnical additives) in feed for weaned piglets and pigs for fattening. The applicant claims an effect on improvement of performance parameters: weight gain or feed to gain ratio in weaned piglets and a urinary pH decrease in pigs for fattening.

3.1 | Characterisation

3.1.1 | Composition and manufacturing of the additive

The additive consists of benzoic acid and is obtained by chemical synthesis from toluene. The purification is achieved via crystallisation to obtain the benzoic acid in form of flakes.¹⁶ The full description of the manufacturing process of benzoic acid was provided in a previous opinion (EFSA, 2005) with no changes applied since the previous assessment.

Benzoic acid ($C_7H_6O_2$) has a molecular weight of 122.12 g/mol, Chemical Abstracts Service Number (CAS) No 65-85-0, European Inventory of Existing Commercial Chemical Substances (EINECS) No 200-168-2.¹⁷

The additive is specified to contain of benzoic acid with a moisture content had analysis of five batches of the product showed concentrations of benzoic acid of 99.9% in all batches. Moisture content in the five analysed batches averaged 0.02% (0.01%–0.03%), which is in agreement with specifications. 19

Four batches of the additive were analysed for impurities. Levels of lead, arsenic, cadmium and mercury were in all cases below the limit of quantification (LOQ) of the assay which were 0.05, 0.01, 0.01 and 0.0025 mg/kg, respectively.²⁰ The five

¹¹Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

 $^{{}^{12}} Decision\ available\ at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements$

 $^{^{13}} Decision\ available\ at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements$

 $^{^{14}} Evaluation \ report\ available\ on\ the\ EU\ Science\ Hub\ https://joint-research-centre.ec.europa.eu/publications/fad-2010-0029_en$

¹⁵Commission 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.

¹⁶Sect_II.1_II.2_Identity_rev1.

¹⁷Sect_II.1_II.2_Identity_rev1.

¹⁸Sect_II.1_II.2_Identity_rev1.

¹⁹Annex_II_1_CoAs.

²⁰Benzoic acid – elemental analysis 4 lots.

batches analysed for the batch-to-batch variation were also analysed for phthalic acid (average 24.4 mg/kg; range 8–45 mg/kg), chloride (all batches 0.07%) and biphenyls (average 40.4 mg/kg; range 38–50 mg/kg).²¹

Polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), and the sum of PCDD/F and coplanar dioxin-like polychlorinated biphenyls (Co-planar PCBs) were analysed in three batches and found below the corresponding limit of quantification (LOQ).²² The calculated (upper bound) levels of dioxins and the sum of dioxins and dioxin-like-PCBs were 0.18 ng WHO-PCDD/F-TEQ/kg and 0.32 ng WHO-PCDD/F-PCB-TEQ/kg, respectively (average of the three batches).

The detected amounts of the above-described impurities do not raise safety concerns.

3.1.2 | Physico-chemical properties of the additive

The additive appears as white solid flakes with a density of 1320 kg/m 3 . It has a solubility in water of 3.5 g/L at 25 $^{\circ}$ C and the octanol/water partition coefficient (LogK $_{ow}$) is 1.88.

The dusting potential of three batches of the additive was determined in triplicate using the Stauber-Heubach method and showed values of Laser diffraction analysis showed that of the particles had a diameter below and of the particles were

3.1.3 | Stability and homogeneity

The shelf-life of the additive (1 batch) was studied when stored on its original packaging under dry and dark conditions at room temperature for 5 years. No relevant losses were detected.²⁴

In another study, three batches were stored 24 months at $25-30^{\circ}$ C and 60% relative humidity. Recovery of benzoic acid remained > 99.9% at the end of the study.²⁵

In a previous opinion (EFSA, 2007), the stability of benzoic acid when incorporated to a pelleted feed for pigs for fattening at 0.1 or 2% was studied over a storage period of 9 months at room temperature. No losses of benzoic acid were observed after 3 months, while losses between 5% and 20% were observed after storage for 9 months.

The capacity of the additive to homogeneously distribute was previously demonstrated in a previous opinion (EFSA, 2007) in three batches of feed containing 1.0%, 1.1% and 1.3% benzoic acid.

3.1.4 | Conditions of use

The additive is intended for use in feed for weaned piglets at a level 5000 mg/kg complete feed and for pigs for fattening at a minimum content of 5000 mg/kg complete feed and a maximum content of 10,000 mg/kg complete feed.²⁶

The applicant suggested the following statements under other provisions for weaned piglets:

- 1. The mixture of different sources of benzoic acid must not exceed the permitted maximum level in complete feed of 5000 mg/kg of complete feed.
- 2. Recommended minimum dose: 5000 mg/kg of complete feed.
- 3. Complementary feed containing benzoic acid must not be fed directly to weaned piglets, unless thoroughly mixed with other feed materials of the daily ration.
- 4. For weaned piglets up to 25 kg.
- For safety, it is recommended to use breathing protection and gloves during handling.

Additionally, the applicant suggested the following under other provisions for pigs for fattening:

- 1. Complementary feedingstuffs containing benzoic acid shall not be fed to pigs for fattening as such.
- 2. Complementary feedingstuffs for pigs for fattening should be thoroughly mixed with other feed materials of the daily ration
- 3. For user safety: Measures should be taken to minimise the production of breathable dust from this additive. Material safety data sheets (MSDS) available.

²¹Annex_II_1_CoAs.pdf.

 $^{^{22}\}mbox{Annex_II}_2_\mbox{Dioxin test report.}$

 $^{^{23}} Sect_II.1_II.2_Identity_rev1.$

²⁴Annex_II_5.1_real_time_stability.

 $^{^{25}} Annex_II_5.2_accelerated_stability.$

 $^{^{26}} Sect_II.5_Conditions_of_use.$

3.2 | Safety

To support the safety of the additive for the target species, consumer, users and the environment, the applicant made reference to the studies submitted in the context of two previous applications for the same active substance and already assessed by the FEEDAP Panel (EFSA, 2005, 2007). The Panel notes that the composition and the conditions of use of the additive under assessment are the same as the one previously assessed and currently authorised for benzoic acid, and therefore, the studies assessed in the previous opinions can be used to support the safety in the present evaluation. In addition, the applicant referenced to the previous assessment on the safety of benzoic acid as a food additive (EFSA ANS Panel, 2016) or for the user (ECHA, 2012).

The safety of benzoic acid as a food additive was assessed by EFSA Panel on Food Additives and Nutrient Sources Added to Food in 2016 (EFSA ANS Panel, 2016). The ANS Panel concluded that benzoic acid does not raise a genotoxicity safety concern and proposed an acceptable daily intake (ADI) of 5 mg benzoic acid/kg body weight (bw) per day based on the no observed adverse effect level of 500 mg benzoic acid/kg bw per day (the highest dose tested) in a four-generation reproductive toxicity study with benzoic acid in rats.

3.2.1 | Safety for the target species

The FEEDAP Panel assessed the safety of benzoic acid in two separate studies with weaned piglets (EFSA, 2005) and in one study for pigs for fattening (EFSA, 2007) in which no adverse effects were found with benzoic acid levels up to 5000 mg/kg complete feed and 10,000 mg/kg complete feed for weaned piglets and pigs for fattening, respectively.

The applicant conducted a literature search²⁷ on the safety of benzoic acid for the target species covering the period 2003–2023 (literature search carried out in April 2023) across 19 electronic databases (Adis Clinical Trials Insight, AGRICOLA, AGRIS, Allied & Complimentary Medicine™, Aqualine, Aquatic Science & Fisheries Abstracts, BIOSIS® Toxicology, BIOSIS Previews®, CAB ABSTRACTS, EMBASE®, Environment Abstracts, Foodline®: SCIENCE, FSTA®, MEDLINE®, NTIS, Risk Abstracts, ToxFile®, Toxicology Abstracts, Zoological Record Plus). The search included terms relative to the safety of benzoic acid to pigs (all life stages). A detailed description of the iterations used, and the inclusion and exclusion criteria applied in the search, was fully described. From the literature search, a total of 49 papers were identified as potentially relevant. Of those, the FEEDAP Panel considered that only five papers provided relevant information on regard of the safety of benzoic acid for weaned piglets and pigs for fattening and are described below.

The five publications evaluated the effect of benzoic acid supplementation on the absorption of calcium and phosphorous and/or bone characteristics in weaned piglets (Gutzwiller, Schlegel, et al., 2011) and pigs for fattening (Bühler, Bucher, & Wenk, 2010; Bühler, Liesegang, et al., 2010; Gutzwiller, Hess, et al., 2011; Sauer et al., 2009). The results of these studies showed that benzoic acid, when supplemented at the proposed conditions of use (i.e. 5000 mg/kg in weaned piglets and 10,000 mg/kg in growing pigs) to diets with low phosphorus content, may interfere with phosphorus absorption and/or bone mineralisation. The FEEDAP Panel does not consider these effects to represent a hazard, provided that diets are adequate in available phosphorus content.

Overall, the FEEDAP Panel considers that there are no new data that would lead to the revision of the previous conclusions on the safety for weaned piglets and pigs for fattening.

Considering that:

- (i) no adverse effects were observed in weaned piglets fed diets with 5000 mg benzoic acid/kg complete feed and in pigs for fattening at 10,000 mg/kg complete feed (EFSA, 2005, 2007),
- (ii) that there are no new data that would lead to the revision of the conclusions on the safety for weaned piglets and pigs for fattening reached in the previous opinions,
- (iii) benzoic acid does not raise a genotoxicity safety concern (EFSA ANS Panel, 2016),
- (iv) the composition of the additive and the conditions of use are the same as those previously assessed and currently authorised,

the FEEDAP Panel concludes that Kalama® is safe for weaned piglets at the level of 5000 mg/kg complete feed and for pigs for fattening at a maximum recommended dose of 10,000 mg/kg complete feed.

3.2.2 | Safety for the consumer

The safety for the consumer derived from the use of 5000 and 10,000 mg benzoic acid/kg complete feed for weaned piglets and pigs for fattening was first assessed by the FEEDAP Panel in 2005 and 2007 (EFSA, 2005, 2007).

The FEEDAP Panel concluded that the use of benzoic acid in weaned piglets and pigs for fattening is of no concern for the consumer (EFSA, 2005, 2007). These conclusions were based on the results reported in published studies (Bridges et al., 1970;

²⁷Benzoic Acid Literature Search Report 8 June 2023.

Kristensen et al., 2009; Partanen et al., 2001) which demonstrated that benzoic acid supplemented at the maximum proposed concentration (i.e. 10,000 mg/kg feed) in pigs for fattening is rapidly absorbed and metabolised in the liver and its conjugation with glycine is followed by efficient excretion as hippuric acid. These physiological mechanisms prevent from the accumulation of benzoic acid and hippuric acid in body fluids and tissues at the dietary level tested.

The FEEDAP Panel confirms its previous conclusions that the use of benzoic acid in weaned piglets at 5000 mg/kg complete feed and pigs for fattening up to 10,000 mg/kg complete feed does not raise any concern for consumer safety.

3.2.3 | Safety for the user

The FEEDAP Panel noted that benzoic acid is classified under the Classification, Labelling and Packaging (CLP) Regulation²⁸ as STOT RE 1,²⁹ Eye Damage 1 and Skin Irritant 2. Therefore, the FEEDAP Panel concluded that benzoic acid poses a risk by inhalation. It is irritant to skin and corrosive to eyes. No conclusions can be drawn on dermal sensitisation due to the lack of data.

3.2.4 | Safety for the environment

The FEEDAP Panel reiterates the considerations previously expressed on benzoic acid as a feed additive that this compound is naturally present in plants (EFSA, 2005). Benzoic acid administered to farm animals will be mainly excreted as urinary hippuric acid, an endogenous metabolic by-product. Also, benzoate metabolites, which may occur in the excreta, have low potential for adverse effects in aquatic or terrestrial organisms. Therefore, no concerns for environment are expected.

3.3 | Efficacy

The additive Kalama® is intended to be used as a zootechnical additive (functional group: other zootechnical additives). The applicant claims an effect on improvement of performance parameters: weight gain or feed to gain ratio in weaned piglets and a urinary pH decrease in pigs for fattening.

To support the efficacy of the additive, the applicant made reference to the efficacy studies submitted in previous applications for the use of benzoic acid in weaned piglets and pigs for fattening, and already assessed by the FEEDAP Panel (EFSA, 2005, 2007). In those opinions, the FEEDAP Panel concluded that:

- based on the results of three performance trials, the inclusion of 0.5% benzoic acid in complete feed for weaned piglets improves performance parameters (weight gain or feed to gain ratio) in weaned piglets up to 25 kg.
- based on the results of five studies in pigs for fattening, the supplementation of pigs diets with benzoic acid at 5000 mg/kg compete feed significantly reduces urinary pH in pigs for fattening.

Therefore, the conclusions reached in the previous assessment fully apply to the current application. Therefore, the FEEDAP Panel concludes the additive is efficacious as a zootechnical additive in weaned piglets and for pigs for fattening at a minimum content of 5000 mg/kg complete feed.

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 Regulation³⁰ and good manufacturing practice.

4 | CONCLUSIONS

The FEEDAP Panel concludes that the additive is safe for weaned piglets up to 5000 mg/kg complete feed and for pigs for fattening at 10,000 mg/kg complete feed.

The FEEDAP Panel considers that the use of benzoic acid is safe for consumers and the environment.

The FEEDAP Panel concludes that benzoic acid poses a risk by inhalation. It is irritant to skin and corrosive to eyes. No conclusions can be drawn on dermal sensitisation due to the lack of data.

Benzoic acid is efficacious as a zootechnical feed additive for weaned piglets and for pigs for fattening at a minimum content of 5000 mg benzoic acid/kg complete feed.

²⁸Annex VI of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

²⁹Specific target organ toxicity (lung; inhalation). Toxic: danger of serious damage to health by prolonged exposure through inhalation.

³⁰Regulation (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.

ABBREVIATIONS

ANS EFSA Scientific Panel on Additives and Nutrient Sources added to Food

BW body weight

CAS Chemical Abstracts Service

CEF EFSA Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids

ECHA European Chemicals Agency

EINECS European Inventory of Existing Chemical Substances

EURL European Union Reference Laboratory

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

FGE food group evaluation LOQ limit of quantification

Log K_{ow} logarithm of octanol–water partition coefficient SCAN Scientific Committee on Animal Nutrition

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2021-00740

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REFERENCES

Bridges, J. W., French, M. R., Smith, R. L., & Williams, R. T. (1970). The fate of benzoic acid in various species. The Biochemical Journal, 118, 47–51.

Bühler, K., Bucher, B., & Wenk, C. (2010). Apparent nutrient and mineral digestibility in growing–finishing pigs fed phosphorus reduced diets supplemented with benzoic acid and phytase. *Livestock Science*, 134(1–3), 103–105.

Bühler, K., Liesegang, A., Bucher, B., Wenk, C., & Broz, J. (2010). Influence of benzoic acid and phytase in low-phosphorus diets on bone characteristics in growing-finishing pigs. *Journal of Animal Science*, 88(10), 3363–3371.

ECHA (European Chemical Agency). (2012). Opinion proposing harmonised classification and labelling at EU level of Benzoic Acid. https://echa.europa.eu/documents/10162/19cef803-4ba7-dc99-469c-c6f3a75e7b47

EFSA (European Food Safety Authority). (2005). Opinion of the scientific panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product VevoVitall® as a feed additive for weaned piglets in accordance with regulation (EC) No 1831/2003. EFSA Journal, 3(12), 290. https://doi.org/10.2903/j.efsa.2005.290

EFSA (European Food Safety Authority). (2007). Opinion of the panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of VevoVitall® (benzoic acid) as feed additive for pigs for fattening. EFSA Journal, 457. https://doi.org/10.2903/j.efsa.2007.457

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources Added to Food). (2016). Scientific opinion on the re-evaluation of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) as food additives. EFSA Journal, 14(3), 4433. https://doi.org/10.2903/j.efsa.2016.4433

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2012a). Scientific opinion on the safety and efficacy of VevoVitall® (benzoic acid) as feed additive for pigs for reproduction. EFSA Journal, 10(7), 2775. https://doi.org/10.2903/j.efsa.2012.2775

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2012b). Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal, 10(1), 2539. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz,

- Y., Villa, R. E., Woutersen, R., Aquilina, G., ... Gropp, J. (2019a). Scientific opinion on the safety and efficacy of benzoic acid as a technological feed additive for weaned piglets and pigs for fattening. *EFSA Journal*, *17*(1), 5527. https://doi.org/10.2903/j.efsa.2019.5527
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Bastos, M., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Brock, T., de Knecht, J., ... Azimonti, G. (2019b). Guidance on the assessment of the safety of feed additives for the environment. *EFSA Journal*, 17(4), 5648. https://doi.org/10.2903/j.efsa.2019.5648
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., ... Innocenti, M. L. (2017a). Guidance on the assessment of the safety of feed additives for the consumer. *EFSA Journal*, 15(10), 5022. https://doi.org/10.2903/j.efsa.2017.5022
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., ... Innocenti, M. L. (2017b). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, 15(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., ... Martino, L. (2017c). Guidance on the assessment of the safety of feed additives for the target species. *EFSA Journal*, 15(10), 5021. https://doi.org/10.2903/j.efsa.2017.5021
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., ... Martino, L. (2018). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, *16*(5), 5274. https://doi.org/10.2903/j.efsa.2018.5274
- EFSA FGE Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids). (2012). Scientific opinion on Flavouring group evaluation 20, revision 4 (FGE.20Rev4): Benzyl alcohols, benzaldehydes, a related acetal, benzoic acids, and related esters from chemical groups 23 and 30. EFSA Journal, 10(12), 2994. https://doi.org/10.2903/j.efsa.2012.2994
- Gutzwiller, A., Hess, H. D., Adam, A., Guggisberg, D., Liesegang, A., & Stoll, P. (2011). Effects of a reduced calcium, phosphorus and protein intake and of benzoic acid on calcium and phosphorus metabolism of growing pigs. *Animal Feed Science and Technology, 168*(1–2), 113–121.
- Gutzwiller, A., Schlegel, P., Guggisberg, D., & Stoll, P. (2011). Effects of benzoic acid and of the dietary Ca: P ratio on growth performance and bone breaking strength of weaned piglets. *Journées de la Recherche Porcine en France*, 43, 125–126.
- Kristensen, N. B., Nørgaard, J. V., Wamberg, S., Engbaek, M., Fernández, J. A., Zacho, H. D., & Poulsen, H. D. (2009). Absorption and metabolism of benzoic acid in growing pigs. *Journal of Animal Science*, 87(9), 2815–2822.
- Partanen, J. I., Juusola, P. M., & Minkkinen, P. O. (2001). Determination of stoichiometric dissociation constants of benzoic acid in aqueous sodium or potassium chloride solutions at 25°C. *Journal of Solution Chemistry.*, 30, 443–462.
- Sauer, W., Cervantes, M., Yanez, J., Araiza, B., Murdoch, G., Morales, A., & Zijlstra, R. T. (2009). Effect of dietary inclusion of benzoic acid on mineral balance in growing pigs. *Livestock Science*, 122(2–3), 162–168.

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