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# Safety and efficacy of VevoVitall® (benzoic acid) as feed additive for pigs for fattening

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## Abstract

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of VevoVitall® (benzoic acid) as a zootechnical feed additive for pigs for fattening. The additive is currently authorised for pigs for fattening with the effect of 'urinary pH decrease' at the minimum and maximum use of 5,000 and 10,000 mg/kg complete feed, respectively. The current application intends to support the use of the additive with the specific effect of 'improvement of performance parameters' at the minimum dose of 3,000 mg additive/kg complete feed, and keeping the same other conditions as for the use already authorised. The FEEDAP Panel assessed already the safety of the product when used in pigs for fattening in 2007 and 2017. The Panel confirms its former assessments that VevoVitall® used as a feed additive in pigs for fattening at the maximum level of 10,000 mg/kg is considered as safe for pigs for fattening, consumers of food derived from pigs fed the additive and the environment. VevoVitall® does not pose a risk by inhalation to users and is not a skin sensitiser but is a skin irritant and a severe eye irritant. Based on the results of three efficacy studies, the FEEDAP Panel concluded that VevoVitall® has the potential to increase the performance in pigs for fattening at the level of 3,000 mg/kg complete feed.



**Keywords:** zootechnical additive, other zootechnical additives, VevoVitall®, benzoic acid, pigs for fattening, performance improvement, efficacy

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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 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from DSM Nutritional Products AG represented in the EU by DSM Nutritional Products Sp. Z.o.o. Poland[2] for authorisation of the product VevoVitall® (benzoic acid), when used as a feed additive for 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). 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 17 October 2017.

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 VevoVitall® (benzoic acid), when used under the proposed conditions of use (see Section 3.1.2).

## 1.2. Additional information

The additive VevoVitall® (benzoic acid) consists of 99.9% benzoic acid.

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the efficacy of this additive, the impact on products of animal origin, and the safety for pigs for fattening, consumer and user and the environment (EC, 2002).

EFSA has issued five opinions on the safety and efficacy of VevoVitall® for weaned piglets (EFSA, 2005; EFSA FEEDAP Panel, 2011a), pigs for fattening (EFSA, 2007) pigs for reproduction (EFSA FEEDAP Panel, 2012a, 2015) and minor porcine species (EFSA FEEDAP Panel, 2017a). Furthermore, an opinion on VevoVitall® for the renewal of the authorisation for weaned piglets and pigs for fattening has also been issued (EFSA FEEDAP Panel, 2017b).

The product from the applicant, either as VevoVitall® or as benzoic acid, is authorised in the European Union as a zootechnical additive:

- for weaned piglets[3] and minor porcine species for fattening and for reproduction[4] at the maximum content of 5,000 mg/kg complete feedingstuffs, and
- for pigs for fattening[3] and sows[5] at the minimum and maximum content of 5,000 and 10,000 mg/kg complete feedingstuffs, respectively.

The safety and efficacy of VevoVitall® as a zootechnical additive for pigs for fattening has been assessed by the FEEDAP Panel (EFSA, 2007; EFSA FEEDAP Panel, 2017b); regarding efficacy, the claim of 'urinary pH decrease' was positively established at the minimum and maximum dose of 5,000 and 10,000 mg VevoVitall®/kg complete feed, respectively.

[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] DSM Nutritional Products Sp. z o.o., Tarczynska 113, 96-320 Mszczonow, Poland.
[3] Commission 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.
[4] Commission 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, 12.7.2018, p.17.
[5] 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 152, 9.6.2016, p.18.

Benzoic acid (E 210) as a food additive has been evaluated by EFSA (EFSA ANS Panel, 2016). Benzoic acid is authorised for use in several categories of food (Regulation (EU) No 1129/2011,[6] Regulation (EU) No 570/2012,[7] and Regulation (EU) 2015/538[8])

# 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[9] in support of the authorisation request for the use of VevoVitall® (benzoic acid) 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 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.[10]

## 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of VevoVitall® (benzoic acid) is in line with the principles laid down in Regulation (EC) No 429/2008[11] and the relevant guidance documents: Guidance on zootechnical additives (EFSA FEEDAP Panel, 2012b), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011b), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d).

# 3. Assessment

VevoVitall® is a feed additive consisting of 99.9% benzoic acid; it is the same product as that already evaluated by the FEEDAP Panel in previous opinions (EFSA, 2005, 2007; EFSA FEEDAP Panel, 2011a, 2012a, 2015, 2017a,b).

In the current application, the applicant is seeking the use of VevoVitall® as a zootechnical additive (functional group: other zootechnical additives) for pigs for fattening, with the specific effect of *improvement of performance parameters: weight gain or feed to gain ratio* at the minimum dose of 3,000 mg additive/kg complete feed.

## 3.1. Characterisation

The additive which is the subject of the present application has the same formulation and method of manufacture as those considered in the previous opinions (EFSA 2005, EFSA 2007, EFSA FEEDAP Panel, 2011a, 2012a, 2015, 2017a,b). Thus, data pertaining to composition, impurities, physical properties, shelf life and stability in feed still apply.

[redacted] The applicant provided analytical data of six batches of toluene[12] and three batches for the impurities specified in the latest authorisation[13] (phthalic acid, biphenyls). The results showed an average for phthalic acid of

[6] Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives. OJ L 295, 12.11.2011, p. 1.
[7] Commission Regulation (EU) No 570/2012 of 28 June 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of benzoic acid — benzoates (E 210–213) in alcohol-free counterparts of wine. OJ L 169, 26.9.2012, p. 43.
[8] Commission Regulation (EU) No 2015/538 of 31 March 2015 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of benzoic acid — benzoates (E 210–213) in cooked shrimps in brine. OJ L 88, 1.4.2014, p. 4.
[9] FEED dossier reference: FAD-2017-0049.
[10] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0029.pdf
[11] 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.
[12] Technical Dossier/Supplementary Information/Appendix 5.
[13] Technical Dossier/Section II/Annex 2-5.

30.3 mg/kg additive and for the sum of biphenyls 64.7 mg/kg, while toluene was not detected.[14] Thus, the product complied with the specifications provided by the applicant for impurities, which coincide with the limits foreseen in the product authorisation for phthalic acid (≤ 100 mg/kg) and biphenyls (≤ 100 mg/kg), and for toluene with the limits proposed by the VICH (Veterinary International Cooperation on Harmonisation of technical requirements for registration of medicinal products) on residual solvents in products for veterinary use.[15]

#### 3.1.1. Stability and homogeneity

The stability and homogeneity of VevoVitall® have been already evaluated in previous EFSA opinions. The applicant submitted copies of these studies in the new dossier.[16,17] Only the studies that were updated are described below.

A continuation of two studies submitted in the dossier of 2011 was provided. A shelf-life of the additive of 24 months under controlled conditions at 25 or 30°C was confirmed.[18] The stability of the additive in complete feed after pelleting (85°C) was demonstrated for 12 months.[19]

#### 3.1.2. Conditions of use

VevoVitall® is intended to be used in feed for pigs for fattening at a minimum and a maximum level of 3,000 and 10,000 mg/kg feed, respectively. The applicant also indicated that complementary feed containing benzoic acid may not be fed to animals as such and should be thoroughly mixed with other feed materials of the daily ration.

### 3.2. Safety

The recommended maximum dose (10,000 mg/kg feed) is the same as that authorised already for pigs for fattening. The applicant has submitted data to support the safety for the additive for target species, consumer, user/worker and the environment.

#### 3.2.1. Safety for target animals

The safety of the additive from the same additive for pigs for fattening was first assessed by the FEEDAP Panel in 2007 based on a tolerance study, and subsequently confirmed with the renewal application in 2017 (EFSA, 2007; EFSA FEEDAP Panel, 2017b). The safety of VevoVitall® for pigs for fattening was established at 10,000 mg/kg feed, with a margin of safety of less than 1.5.

#### 3.2.2. Safety for the consumer

The safety for the consumer derived from the use of 10,000 mg VevoVitall®/kg feed for pigs for fattening was first assessed by the FEEDAP Panel in 2007 and subsequently confirmed in 2017 (EFSA, 2007; EFSA FEEDAP Panel, 2017b).

The applicant made reference to a study not previously assessed by the FEEDAP Panel (Kristensen et al., 2009)[20] which showed that benzoic acid (at concentration 10,000 mg/kg feed) is rapidly absorbed and metabolised by the liver of pigs for fattening. Its conjugation with glycine is followed by efficient excretion as hippuric acid. These physiological mechanisms prevent accumulation of benzoic acid and hippuric acid in body fluids and tissues at the dietary level tested. These data support the previous conclusion of the FEEDAP Panel that the use of benzoic acid in pigs for fattening up to 10,000 mg/kg feed does not raise any concern for consumer safety.

#### 3.2.3. Safety for the user

The safety of the additive for the user was first assessed in 2007 and subsequently reviewed in 2017. The FEEDAP Panel concluded that VevoVitall® is a skin irritant and a severe eye irritant but is

[14] Limit of detection of the analytical method: 2 mg/kg.
[15] VICH GL18(R) (IMPURITIES SOLVENTS). June 2011. Available online: http://www.vichsec.org/component/attachments/attachments/154.html?task=download
[16] Technical Dossier/Section II/Annex 2-12.
[17] Technical Dossier/Section II/Annex 2-10.
[18] Technical Dossier/Section II/Annex 2-9.
[19] Technical Dossier/Section II/Annex 2-11.
[20] Technical Dossier/Section III/Annex 3-29.

not a skin sensitiser. The Panel also concluded that handling the additive does not pose a risk by inhalation to users considering the low dustiness of the additive and the minimal fraction of respirable and inhalable dust; thus inhalation exposure is considered as very low.

### 3.2.4. Safety for the environment

The safety of the additive for the environment was first assessed in 2007 and subsequently confirmed in 2017. No concerns for the environment resulting from the use of the additive at 10,000 mg/kg feed are expected.

The applicant provided the results of three literature searches, examining the databases Scopus and PubMed. The first search[21] covered the period from January 2012 until August 2015 and the following keywords were used: 'benzoic', 'benzoate', 'hippuric', 'air', 'soil', 'water' and 'environment'. The second search[22] covered the period from January 2012 until July 2016; the following keywords were used: 'benzoic', 'benzoate', 'hippuric', 'environmental toxicity' and 'ecotoxicity'. The third search[23] covered the period from June 2016 until July 2017; the following keywords were used: 'benzoate', 'benzoic', 'hippuric', 'environment', 'air', 'water', 'soil' and 'ecotoxicity'. These searches did not return any relevant hit, and thus the previous conclusion on the safety for the environment is retained.

## 3.3. Efficacy for pigs for fattening

In the current application, the applicant claims the specific effect of *improvement of performance parameters: weight gain or feed to gain ratio* in pigs for fattening at the minimum dose of 3,000 mg VevoVitall®/kg complete feed.

To support efficacy of the additive, four efficacy studies with pigs for fattening were submitted; three of the studies were performed in two EU Member States and another one outside the EU. One of the studies could not be considered because of a failure in the feed delivery recording system during the trial which did not allow the measurement of the feed intake.[24]

The design of the three assessed studies was very similar, with a control group given the basal diet compared to a treated group given the basal diet supplemented with VevoVitall® at the minimum recommended level of 3,000 mg/kg complete feed. Pigs were initially fed a starter diet and, subsequently, a finisher diet, both offered on an *ad libitum* basis. The benzoic acid concentration in the diets was analytically confirmed. Details on the study designs are given in Table 1.

**Table 1:** Details of the designs of the three studies conducted with VevoVitall® with pigs for fattening

| Study | Total number of animals Replicates per treatment/Pigs per replicate | Average initial body weight (kg) | Genotype Sex | Basal diet composition | Study Duration (days) |
|---|---|---|---|---|---|
| 1(5) | 288(1) 16/6 | 36.1 | PIC L1050 castrated ♂ | Corn–soybean | 70(2) |
| 2(6) | 480 12/20 | 32 | Ratterow Landroc × PIC337 sire ♂♀ | Wheat–barley–soybean–rapeseed | 82(3) |
| 3(7) | 192 48/2 | 27.5 | Topigs×Pietrain ♂♀ | Wheat–barley–soybean–rapeseed | 119(4) |

(1): Besides control and treatment at 3,000 mg VevoVitall®/kg complete feed, a treatment of 5,000 mg/kg complete feed was included in the study.
(2): The animals received a grower feed until day 35 and then a finisher feed until day 70.
(3): The animals received a grower feed until day 43 or 44, and then a finisher feed until day 82.
(4): The animals received a grower feed until day 42 and then a finisher feed until day 119.
(5): Technical Dossier/Section IV/Annex 4-2.
(6): Technical Dossier/Section IV/Annex 4-5 and Technical Dossier/Supplementary Information/Appendix 6,
(7): Technical Dossier/Supplementary Information/Appendix 7,

[21] Technical Dossier/Section II/Annex 3-49.
[22] Technical Dossier/Section II/Annex 3-50.
[23] Technical Dossier/Section II/Annex 3-51.
[24] Technical Dossier/Section IV/Annex 4-4.

Health status, mortality and culling were monitored throughout the studies. Body weight was measured individually at the beginning, at transfer from grower to finisher feed (day 35 for study 1, day 43 or 44 for study 2 and day 44 for study 3) and at the end of each study. Feed intake per pen was monitored. Average daily gain (ADG) and feed conversion rate (Feed:Gain) were calculated.

Regarding statistical analysis, for Study 1 an analysis of variance (ANOVA) was done with the data considering the effect of the diet and the block; mean groups were compared with Tukey test. For Study 2, an ANOVA was done with the data considering sex, treatment and block as fixed effects. For Study 3 an ANOVA was done with the data considering the effect of the diet, sex and the barn. In all cases, the experimental unit was the pen and the significance level was set at 0.05.

The summary of the performance data from the three efficacy studies conducted with VevoVitall® are shown in Table 2. Mortality/culling was low in all studies and no related to treatments. The results showed that the addition of 3,000 mg VevoVitall®/kg complete feed led to a significant improvement of average daily gain (in the three studies evaluated) and feed to gain ratio (in studies 1 and 2).

**Table 2:** Summary of the results of three efficacy studies performed with the additive VevoVitall® in diets of pigs for fattening

| Study No (Duration) | mg VevoVitall®/kg feed | Average daily feed intake (kg) | Final body weight (kg) | Average daily gain (kg/d) | Feed: Gain | Mortality and culls (%) |
|---|---|---|---|---|---|---|
| 1 (70 days) | 0 | 2,787 | 109.0[a] | 1.048[a] | 2.66[a] | 2.1 |
| | 3,000 | 2,860 | 113.8[b] | 1.110[b] | 2.58[b] | 3.1 |
| | 5,000 | 2,844 | 113.5[b] | 1.103[b] | 2.58[b] | 0 |
| 2 (82 days) | 0 | 2,200 | 103.8[a] | 0.872[a] | 2.53[a] | 1.7 |
| | 3,000 | 2,262 | 107.7[b] | 0.909[b] | 2.50[b] | 1.3 |
| 3 (119 days) | 0 | 2,212 | 128.7 | 0.852[a] | 2.60 | 2.1 |
| | 3,000 | 2,275 | 132.7 | 0.884[b] | 2.57 | 2.1 |

a,b: Within a study and a given parameter, means with different superscripts are significantly different ($p < 0.05$).

### 3.3.1. Conclusions on efficacy for pigs for fattening

The FEEDAP Panel concludes that VevoVitall® has the potential to increase the performance in pigs for fattening at the dose of 3,000 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 Regulation[25] and Good Manufacturing Practice.

# 4. Conclusions

The FEEDAP Panel confirms its former assessments that VevoVitall® used as a feed additive in pigs for fattening at the maximum level of 10,000 mg/kg is considered as safe for pigs for fattening, consumers of food derived from pigs fed the additive and the environment.

VevoVitall® does not pose a risk by inhalation to users and is not a skin sensitiser but is a skin irritant and a severe eye irritant.

VevoVitall® has the potential to increase the performance in pigs for fattening at the level of 3,000 mg/kg complete feed.

[25] 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.

## Documentation provided to EFSA/Chronology

| Date | Event |
|---|---|
| 31/08/2017 | Reception mandate from the European Commission |
| 05/09/2017 | Dossier received by EFSA. VevoVitall® (benzoic acid) for pigs for fattening. September 2017. Submitted by DSM Nutritional Products Ltd. |
| 17/10/2017 | Application validated by EFSA – Start of the scientific assessment |
| 17/01/2018 | Comments received from Member States |
| 08/05/2018 | Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation and efficacy* |
| 27/03/2019 | Reception of supplementary information from the applicant - Scientific assessment re-started |
| 15/05/2019 | Opinion adopted by the FEEDAP Panel. End of the Scientific assessment |

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## Abbreviations

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|---|---|
| ANOVA | analysis of variance |
| ADG | average daily gain |
| EURL | European Union Reference Laboratory |
| FEEDAP | EFSA Panel on Additives and Products or Substances used in Animal Feed |
| SCAN | Scientific Committee on Animal Nutrition |
| VICH | Veterinary International Cooperation on Harmonisation |