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Safety and efficacy of VevoVitall® (benzoic acid) as feed additive for minor porcine species

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Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on VevoVitall® (benzoic acid) as a feed additive for minor porcine species, when used as zootechnical additive at a maximum level of 5,000 mg/kg complete feed. The safety and efficacy of the additive had been evaluated by the FEEDAP Panel on weaned piglets (at the maximum supplementation level of 5,000 mg/kg complete feed) and pigs for fattening and pigs for reproduction (at the maximum level of 10,000 mg/kg complete feed). Subsequent to EFSA's assessments, the additive has been authorised for use in feed of weaned piglets, pigs for fattening and sows. To the knowledge of the FEEDAP Panel, there was no new information that might modify its previous assessments on VevoVitall® concerning safety for consumers and the environment; therefore, this opinion focused only on the safety of the target animals and the efficacy of the product. The FEEDAP Panel concluded that VevoVitall® is safe at the supplementation level of 5,000 mg/kg complete feed for minor porcine species for fattening and for reproduction; the FEEDAP could not conclude on the safety of the additive for weaned minor porcine species. VevoVitall® does not represent a risk for the consumer and the environment. VevoVitall® does not pose a risk by inhalation to users and is not skin sensitiser, but is a skin irritant and a severe eye irritant. VevoVitall® has the potential to decrease the urinary pH in minor porcine species at the dose of 5,000 mg/kg complete feed. A remark on the relevance of the claim has been posted by the Panel.

Keywords: zootechnical additive, other zootechnical additives, VevoVitall®, benzoic acid, minor porcine species, urinary pH

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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 European Union (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 minor porcine species (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 8 February 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) and pigs for reproduction (EFSA FEEDAP Panel, 2012a, 2015).

The product from the applicant, either as VevoVitall® or as benzoic acid, is authorised in the EU as a zootechnical additive for weaned piglets[3] at the maximum content of 5,000 mg/kg complete feeding stuffs and for pigs for fattening[4] and sows[5] at maximum content of 10,000 mg/kg complete feeding stuffs.

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[6] in support of the authorisation request for the use of VevoVitall® (benzoic acid) as a feed additive. The technical dossier was prepared following the provisions of Article 7 of Regulation (EC) No 1831/2003, Regulation (EC) No 429/2008[7] and the applicable EFSA guidance documents.

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) 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.

[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 Mszczonów, Poland.
[3] Commission Regulation (EC) No 1730/2006 of 23 November 2006 concerning the authorisation of benzoic acid (VevoVitall) as a feed additive. OJ L 325, 24.11.2006, p. 9.
[4] Commission Regulation (EC) No 1138/2007 of 1 October 2007 concerning the authorisation of a new use of benzoic acid (VevoVitall) as a feed additive. OJ L 256, 2.10.2007, p. 8.
[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.
[6] FEED dossier reference: FAD-2016-0077.
[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.

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.[8]

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 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, 2008a), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012d) and the Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008b).

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).

In the current application, the applicant is seeking the use of VevoVitall® as a zootechnical additive (functional group: other zootechnical additives) in minor porcine species at the maximum dose of 5,000 mg/kg complete feed. The specific claim is the decrease in urinary pH.

3.1. Characterisation

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

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.[9,10] 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.[11] The stability of the additive in complete feed after pelleting (85°C) was demonstrated for 12 months.[12]

3.1.2. Conditions of use

VevoVitall® is intended to be used in minor porcine species at a maximum level of 5,000 mg/kg feed. 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 dose for minor porcine species (5,000 mg/kg feed) is the same as that authorised for weaned piglets and half of the dose authorised for pigs for fattening or sows. To the knowledge of the FEEDAP Panel, there is no new information that might modify its previous assessments on VevoVitall® concerning safety for consumers and the environment. The FEEDAP Panel confirms, therefore, its former opinion, expressed when firstly assessed VevoVitall® for piglets (EFSA, 2005), that benzoic acid does not represent a risk for the consumer and the environment.

[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/default/files/FinRep-FAD-2010-0029.pdf
[9] Technical Dossier/Section II/Annex 2-12.
[10] Technical Dossier/Section II/Annex 2-10.
[11] Technical Dossier/Section II/Annex 2-9.
[12] Technical Dossier/Section II/Annex 2-11.

3.2.1. Safety for the target species

A tolerance study was submitted to support tolerance of wild boars to VevoVitall®.[13] The study could not be considered because of some weaknesses in its design, namely, the low number of animals, the absence of pen replicates in the treatments and of the testing of an overdose and its short duration.

The FEEDAP Panel notes that VevoVitall® has been demonstrated to be safe for weaned piglets at a maximum of 5,000 mg/kg complete feed (EFSA, 2005) without a margin of safety. Due to the lack of margin of safety, the FEEDAP cannot conclude on the safety of VevoVitall® for weaned minor porcine species at 5,000 mg/kg.

VevoVitall® is safe for pigs for fattening, sows, gilts and boars at a maximum of 10,000 mg/kg complete feed (EFSA, 2007; EFSA FEEDAP Panel, 2015); this will ensure two- to threefold margin of safety considering the proposed dose level of 5000 mg VevoVitall/kg. Therefore, the FEEDAP Panel concludes that VevoVitall® at 5,000 mg/kg complete feed is safe for minor porcine species for fattening and for reproduction.

3.2.2. Safety for the users

VevoVitall® is unlikely to give rise to an appreciable inhalation exposure, since the particle fraction of inhalable size ($\leq$ 100 μm) represents about 0.6% and particles of the respirable fraction ($\leq$ 10 μm and below) are virtually absent; the dusting potential is very low (0.04 g/m^3).[14]

The Committee for Risk Assessment of the European Chemicals Agency (ECHA) concluded in 2012 that benzoic acid should be classified as Eye Damage 1 and Skin Irritant 2.[15] The hazard for the eyes was assigned on the basis of two guideline-based *in vivo* studies on rabbits which showed that benzoic acid powder to be moderately to severely irritating to the eye. Whereas two guideline-based *in vivo* studies on rabbits indicated absent or slight skin irritation, available human data show that benzoic acid is capable of inducing non-immunological contact urticaria; this lesion is regarded as an irritation reaction without requiring previous sensitisation. Accordingly, benzoic acid was not considered as a skin sensitiser. To the best knowledge of the FEEDAP Panel, there are no new data that may modify the conclusions of the ECHA assessment.

The FEEDAP Panel concludes that the use of VevoVitall® does not pose a risk by inhalation to users and is not a skin sensitiser; the new available data confirm that the additive is a skin irritant and a severe eye irritant.

3.3. Efficacy

Considering that the mode of action – decrease of urinary pH – is well known in the major porcine species and that it can be reasonable assumed that VevoVitall® produces the same effect in the minor porcine species as in the major species, a direct extrapolation of efficacy is accepted without further experimental evidence.

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[16] and Good Manufacturing Practice.

4. Conclusions

VevoVitall® is safe at the supplementation level of 5,000 mg/kg complete feed for minor porcine species for fattening and for reproduction. VevoVitall® does not pose a risk to users by inhalation and is not skin sensitiser; the new available data confirm that the additive is a skin irritant and a severe eye irritant.

[13] Technical Dossier/Section III/Annex 3-22.
[14] Technical Dossier/Section III/Appendix 3-32 (values reported represent the average of three lots for particle size and two lots for dusting potential).
[15] Technical Dossier/Section III/Appendix 3-9.
[16] 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.

The FEEDAP Panel confirms its former opinion that benzoic acid does not represent a risk for the consumer and the environment. VevoVitall® does not pose a risk to users by inhalation and is not skin sensitiser; the new available data confirm that the additive is a skin irritant and a severe eye irritant.

VevoVitall® has the potential to decrease the urinary pH in minor porcine species.

5. Remark

The FEEDAP Panel reiterates its view (already described in previous Opinions) that an effect on urinary pH alone is of little practical or biological relevance unless it is demonstrated to be linked to a clear beneficial effect on animal production, performance, welfare or on the environmental consequences of animal production.

Documentation provided to EFSA

1) VevoVitall® (benzoic acid) for minor porcine species. December 2016. Submitted by DSM Nutritional Products Ltd.
2) Comments from Member States.

References

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EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance for establishing the safety of additives for the consumer. EFSA Journal 2012;10(1):2537, 12 pp. https://doi.org/10.2903/j.efsa.2012.2537

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012d. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety and efficacy of VevoVitall® (benzoic acid) as a feed additive for pigs for reproduction (gestating and lactating sows, boars and gilts). EFSA Journal 2015;13(7):4157, 7 pp. https://doi.org/10.2903/j.efsa.2015.4157