Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of VevoVitall® (benzoic acid) as feed additive for pigs for fattening

(Question No EFSA-Q-2006-056)

Adopted on 7 March 2007

SUMMARY
The European Food Safety Authority (EFSA) received a request from the European Commission for authorisation of the product VevoVitall®, consisting of 99.9% benzoic acid in flaked form, to be used as a feed additive for pigs for fattening (category: zootechnical additives). EFSA was asked to deliver an opinion on the safety of VevoVitall® for the target animal, consumer, user and the environment, and on the efficacy of the product. Benzoic acid is proposed by the applicant to be used in pigs for fattening in order to decrease the urinary pH and to reduce ammonia emission in a dose range of 5000 to 10000 mg kg\(^{-1}\) complete feed.

Benzoic acid has been previously authorized at Community level as ‘acidity regulator’ for pigs for fattening at levels 5000 to 10000 mg kg\(^{-1}\) complete feed. In a previous opinion of the SCAN (EC, 2002) it was concluded that there was insufficient evidence for a noticeable decrease in ammonia production.

Five studies submitted provide evidence that both the lowest and the highest applied dietary levels of benzoic acid (5000 and 10000 mg kg\(^{-1}\)) are effective in reducing urinary pH in pigs for fattening. Two of four feeding studies submitted provide evidence for a significant reduction of ammonia emission at the highest level of 10000 mg benzoic acid kg\(^{-1}\) diet, the lowest level being not effective in all studies.

A reduction in urinary pH is not a recognised attribute of a feed additive and, in the view of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), has no direct benefit \textit{per se}. Since the relation between urinary pH and reduced ammonia emission is not adequately established, the FEEDAP Panel cannot conclude on the efficacy of benzoic acid to reduce the ammonia emission.

On the basis of two tolerance studies the FEEDAP Panel concludes that 10000 mg benzoic acid kg\(^{-1}\) complete feed (the highest dose recommended by the applicant) is safe for pigs for fattening with a narrow margin of safety (less than 1.5).

No new data were provided on the safety for the consumer, the user and the environment. The FEEDAP Panel confirms its former opinion, expressed when assessing benzoic acid for piglets (EFSA, 2005), that benzoic acid does not represent a risk for the consumer and the environment, and recommends appropriate labelling due to the potential to induce skin and eye irritation.
The FEEDAP Panel does not see a need for specific requirements of post-market monitoring.

**Key words:** benzoic acid, pig for fattening, efficacy, ammonia emission, safety for the target animal, hippuric acid, VevoVitall®
BACKGROUND

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 lies down that any person seeking an 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 the company DSM Special Products\(^2\) for authorisation of the product VevoVitall\(^\circledR\), consisting on benzoic acid, to be used as a feed additive for pigs for fattening (category: zootechnical additives; functional groups: “substances which favourably affect the environment” and “other zootechnical additives”) under the conditions mentioned under Table 1.

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. According to Article 8 of that Regulation, 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. The particulars and documents in support of the application were considered valid by EFSA as of 24 of August of 2006.

Benzoic acid (E 210) has been previously authorised at Community level until 25 of May 2007, under Directive 70/524/EEC, as “acidity regulator” for pigs for fattening at levels of 5 to 10 g kg\(^{-1}\) complete feedingstuffs.\(^3\) The product VevoVitall\(^\circledR\) is authorised for use in weaned piglets.\(^4\)

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion (EC, 2002) on the efficacy of this product, the impact on products of animal origin, and the safety for pigs for fattening, consumer and user and the environment. EFSA issued an opinion on the safety and efficacy of VevoVitall\(^\circledR\) for weaned piglets (EFSA, 2005).

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003 EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. Therefore, 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\(^\circledR\), based on benzoic acid, when used under the conditions described in Table 1.

---

\(^1\) OJ L 268, 18.10.2003, p.29
\(^2\) DSM Special Products. Poststraat 1. 6135 KR Sittard. The Netherlands
\(^3\) OJ L 126, 22.5.2003, p.24
\(^4\) OJ L 325, 24.11.2006, p.9
### Table 1. Register entry as proposed by the applicant

<table>
<thead>
<tr>
<th>Additive</th>
<th>Benzoic Acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Registration number/EC No/No (if appropriate)</td>
<td>E 210</td>
</tr>
<tr>
<td>Category of additive</td>
<td>Zootechnical</td>
</tr>
<tr>
<td>Functional group of additive</td>
<td>Other zootechnical additives (pH decrease) Substances which favourably affect the environment (ammonia decrease)</td>
</tr>
</tbody>
</table>

#### Description

<table>
<thead>
<tr>
<th>Composition, description</th>
<th>Chemical formula</th>
<th>Purity criteria (if appropriate)</th>
<th>Method of analysis (if appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid</td>
<td>C_7H_6O_2</td>
<td>Benzoic acid: ≥99.9 % * Water: ≤0.5% Phtalic acid: ≤100 mg kg⁻¹ Biphenyls: ≤100 mg kg⁻¹ Heavy metals: ≤10 mg kg⁻¹ Arsenic: ≤2 mg kg⁻¹</td>
<td>At pH 11-12 the sample will be extracted (1h, 100ºC) after acidification the pH &lt; 1 and filtration analysis by HPLC, standard addition method</td>
</tr>
</tbody>
</table>

#### Trade name (if appropriate)

VevoVitall®

#### Name of the holder of authorisation (if appropriate)

DSM Special Products

#### Conditions of use

<table>
<thead>
<tr>
<th>Species or category of animal</th>
<th>Maximum Age</th>
<th>Minimum content of complete feedingstuffs</th>
<th>Maximum content of complete feedingstuffs</th>
<th>Withdrawal period (if appropriate)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigs for fattening</td>
<td>slaughtering</td>
<td>5000</td>
<td>10000</td>
<td></td>
</tr>
</tbody>
</table>

#### Other provisions and additional requirements for the labelling

**Specific conditions or restrictions for use (if appropriate)**

VevoVitall® shall be incorporated directly in compound feeds

**Specific conditions or restrictions for handling (if appropriate)**

MSDS available

**Post market monitoring (if appropriate)**

Post market monitoring is not appropriate No additional requirements further to the need for traceability and recall procedures established by Regulation No 178/2002.

**Specific conditions for use in complementary feedingstuffs (if appropriate)**

In complementary feedingstuffs, the concentration of VevoVitall® shall be calculated in order to achieve a concentration of 5000 – 10000 mg kg⁻¹ daily ration.

#### Maximum Residue Limit (MRL) (if appropriate)

<table>
<thead>
<tr>
<th>Marker residue</th>
<th>Species or category of animal</th>
<th>Target tissue(s) or food products</th>
<th>Maximum content in tissues</th>
</tr>
</thead>
</table>
ASSESSMENT

1. Introduction

Benzoic acid (VevoVitall®) has already a provisional authorisation as a feed additive within the group of acidity regulators for pigs for fattening (see Commission Regulation 877/2003/EC on the use of the acidity regulator "Benzoic acid in feedingstuffs"). The provisional authorisation is granted by the EC until 25 May 2007. The product was entered in the Community Register of Feed Additives pursuant to Regulation (EC) No 1831/2003 on the 7th November 2005.

In 2002, the Scientific Committee on Animal Nutrition (SCAN) adopted an opinion on the use of benzoic acid in feedingstuffs for pigs for fattening (EC, 2002). The overall conclusion of the SCAN was that the addition of benzoic acid to pig feed has a dose-related effect on lowering the pH of urine, which, in turn, is supposed to decrease the ammonia emission from slurry. However, insufficient evidence was provided to demonstrate that the recommended dietary incorporation levels of 5000 to 10000 mg kg\(^{-1}\) would reduce the pH sufficiently to produce a noticeable decrease in ammonia production.

Benzoic acid (VevoVitall®) has been recently evaluated by the European Food Safety Authority (EFSA) and an opinion in favour of the authorisation of 5000 mg VevoVitall® kg\(^{-1}\) complete feedingstuff for piglets (functional group: other zootechnical additives) was published (EFSA, 2005).

The applicant applies now for authorization for benzoic acid (VevoVitall®) for pigs for fattening at a dose of 5000 to 10000 mg kg\(^{-1}\) complete feedingstuff under the functional groups of other zootechnical additives and substances that favourably affect the environment.

2. Characterisation of the product

VevoVitall® consists at least of 99.9 % benzoic acid (benzenecarboxylic acid, phenylcarboxylic acid, C.A.S. number 65-85-10, E-210) as active substance. The product is marketed in form of flakes. Particle size is reported to be typically between 0.5 and 4.5 mm indicating also very low dustiness.

Benzoic acid from VevoVitall® meets the EU specifications requirements as regards purity and heavy metals. Although the overall impurities are stated not to exceed 0.1 %, no specific information is provided on the concentration of chlorinated organic compounds.

A 4-years shelf-life was observed by re-analysing samples. VevoVitall® is not intended to be incorporated in the feed via premixtures. The storage stability of benzoic acid flakes in complete feeds for pigs for fattening was assessed in pelleted feedingstuffs containing 0.1 and 2 % VevoVitall®. Benzoic acid was stable during three months at room conditions, while between 80 and 95 % of the benzoic acid was still determined after nine months of storage.

Homogeneity was tested in three batches containing from 0 to 1.0, 1.1 and 1.3 % VevoVitall®. Samples were collected at different intervals from the mixture. Six analyses from each batch confirmed intended concentration of benzoic acid and demonstrated good homogeneity (SD 0.1 %).

---

5 O.J. L 126, 22.5.03, p. 24
No relevant incompatibilities or interactions with feedingstuffs, carrier and other additives are known.

2.1. Evaluation of the analytical methods by the Community Reference Laboratory (CRL)

EFSA has verified the report submitted by the Community Reference Laboratory (CRL), the Executive Summary of which is attached as Appendix.

3. Efficacy

In order to meet the requirement for the approval of the dietary use of benzoic acid as zootechnical additive for pigs, a number of additional studies with growing/finishing pigs were conducted by using the minimal and maximal recommended dietary levels (5000-10000 mg kg$^{-1}$) of benzoic acid. The evaluation involved five studies which were carried out recently. The studies were mainly focused on determining the effect of this organic acid on urinary pH in growing/finishing pigs and ammonia emission from the slurry. The studies consisted of one balance and four feeding trials.

3.1. Balance study

This study$^6$ includes two balance trials aimed at testing the effect of benzoic acid at two dietary levels, 5000 mg kg$^{-1}$ (Trial 1) and 10000 mg kg$^{-1}$ (Trial 2) on urinary pH and excretion of hippuric acid. In addition, the effect on nitrogen balance was examined. In total, 12 crossbred female pigs were used in each trial with an average initial body weight of 25 kg. After a pre-test period of four weeks, four pigs per group of treatment were selected, inserted with a urinary catheter and housed in metabolism cages. The balance period lasted six days. Faeces and urine were quantitatively collected daily in order to estimate the nitrogen retention. The basal diet was based on barley, wheat and soybean meal. The addition of benzoic acid was verified by analysis.

<table>
<thead>
<tr>
<th></th>
<th>Trial 1</th>
<th>Trial 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzoic acid (%)</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>Number of animals</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Urinary pH</td>
<td>7.26</td>
<td>6.63*</td>
</tr>
<tr>
<td>Benzoic acid intake (mmol d$^{-1}$)</td>
<td>0</td>
<td>69.6</td>
</tr>
<tr>
<td>Hippuric acid excretion via urine (mmol d$^{-1}$)</td>
<td>5.3</td>
<td>87.4</td>
</tr>
<tr>
<td>N-retention (% of intake)</td>
<td>55.7</td>
<td>58.1</td>
</tr>
</tbody>
</table>

* Significantly different from the corresponding control (P<0.05)

Data (Table 2) were analysed by the Mixed Model Procedure throughout the whole balance period. On a mean basis, the reduction in urinary pH after supplementation of benzoic acid (5000 to 10000 mg kg$^{-1}$) resulted in a dose-dependent significant decrease of urinary pH. The intake of benzoic acid appeared to be excreted nearly completely as hippuric acid via the urine. Nitrogen retention was not affected significantly by including benzoic acid in the diet.

---

$^6$ Technical Dossier. Annex 7.3.4
3.2. Feeding trials

Study 1

The effect of a dietary level of 5000 mg benzoic acid kg⁻¹ on urinary pH and the excretion of hippuric acid was examined in comparison to non-supplemented controls. Each of the two treatment groups consisted of eight crossbred female pigs. On the day of urine collection, the animals were inserted with a urinary catheter and temporarily moved to metabolism cages. The trial lasted 89 days and involved the live weight period of 33 to 110 kg. Urine samples were taken at day 0 and day 5 and further at intervals of 14 days. In total eight urine collections were carried out. Performance data was also determined at intervals of 14 days. All data was submitted to statistical analysis. The basal diet was based on barley, wheat and soybean meal and fed on an ad libitum basis. The addition of benzoic acid was verified by analysis. Overall, the health of the pigs was good, no mortality was recorded.

There were no significant differences in weight gain, feed intake and feed conversion efficiency between the two treatments. Urinary concentration of hippuric acid significantly increased throughout the experimental period by including 5000 mg benzoic acid kg⁻¹ diet. Urinary pH was significantly lower in six out of seven collection periods during treatment. 5000 mg benzoic acid kg⁻¹ did not influence the urinary concentration of total N, urea and creatinine.

Study 2

The effect of two dietary levels (5000 and 10000 mg kg⁻¹) of benzoic acid on performance, urinary pH and ammonia emission in growing/finishing pigs were examined. The trial covered the live weight period of 29 to 105 kg. Cross bred pigs were housed in a practical barn with concrete slatted floors. Each treatment group (control, 5000 and 10000 mg benzoic acid kg⁻¹ complete feed) consisted of 40 pigs, sub-divided into eight replicates (pens), four pens with each five barrows and four pens with each five females. The basal diet was based on wheat, barley, peas and soybean meal. The addition of benzoic acid was verified by analysis. Feed was available ad libitum during the growing period (up to 60-65 kg body weight) and fed on a restricted basis (near the ad libitum level) during the finishing period. Samples of urine were collected six times for pH measurements (days 15, 28, 44, 58, 71 and 83) during the trial. Once a week, the degree of pen dirtiness was assessed by visual score in all the rooms. In the three rooms, ammonia concentration and emission were measured from the beginning of the study until the day of slaughtering. Ammonia concentration was measured using colorimetric gas detector tubes (Draeger) in the ambient air at 0.3 and 1 meter above the floor. Each week ammonia concentration in emitted air was measured by bubbling method. For pig performance, data were submitted to analysis of variance (general linear model procedure) including the effect of the treatment (room), pen and sex. The period (growing and finishing) was added to the model for the comparison of pig performance. For ammonia in the ambient and in the emitted air, effects of the treatment and times of presence (from start to slaughter) were included in the statistical analysis. For urinary pH, only the effect of the treatment was included.

During the experimental period only one pig of the control group and one of the 10000 mg benzoic acid kg⁻¹ group died. Performance data were determined at the end of the growing and finishing period and no differences could be noted for the different groups. Carcass

---

7 Technical Dossier. Annex 7.3.6
6 Technical Dossier. Annex 7.3.3
9 Complementary information. Annex IV. December 2006
composition was not affected by including 5000 mg benzoic acid kg\(^{-1}\) in the diet. However, at an inclusion level of 10000 mg benzoic acid kg\(^{-1}\) in the diet, percentage of meat was reduced significantly, whereas fat layer was increased significantly. Dirtiness of pigs and pens were not significantly affected by the treatments. Urinary pH was significantly decreased by adding benzoic acid to the diet at 5000 and 10000 mg kg\(^{-1}\). The reduction in ammonia emission from pigs was found to be significant when the diet was supplemented with 10000 mg benzoic acid kg\(^{-1}\) but not with the minimum recommended dose.

**Study 3**

The effect of 5000 mg benzoic acid kg\(^{-1}\) on performance, urinary pH and ammonia emission in growing/finishing pigs was examined in comparison to non-supplemented controls.\(^{10}\) A total of 144 pigs (males and females) was used. The study lasted from 30 kg live weight until slaughter. The cross bred pigs were allocated to two identical rooms with totally slatted floors. Each group consisted of 72 pigs, sub-divided into six replicates (pens). The basal diet was based on wheat, barley, peas and soybean meal. The addition of benzoic acid was verified by analysis. Feed was available *ad libitum* during the growing period (up to 60-65 kg body weight) and fed on a restricted basis (near the *ad libitum* level) during the finishing period. The animals were weighed at the beginning of the study, at the feed change, and just before departure for the slaughterhouse. Feed consumption was recorded per pig by an Electronic Feed Dispenser. Every two weeks, urinary pH was measured in ten pigs per room. Ammonia concentration in the ambient air was monitored every week using diffuse passive tubes. Measurements were made at four areas and two heights (0.3 and 1 meters above the floor). Ammonia in the exhaust air was measured every week by using the bubbling method. For pig performance, data were submitted to analysis of variance (general linear model procedure) including the effect of the treatment (room), pen and sex. The period (growing and finishing) was added to the model for the comparison of pig performance. For ammonia in the ambient and in the emitted air, effects of the treatment and times of presence (from start to slaughter) were included in the statistical analysis. For urinary pH, only the effect of the treatment was included.

Dietary addition of benzoic acid significantly improved the zootechnical parameters (average daily gain, 830 vs. 878 g d\(^{-1}\); feed conversion, 2.86 vs. 2.78 g feed g\(^{-1}\) gain). Mean urinary pH was significantly reduced by benzoic acid from 7.06 to 6.61. Concerning ammonia in the ambient and ammonia emission, no effect of the treatment was observed.

**Study 4**

In this study\(^{11}\) the effect of a dietary level of 10000 mg benzoic acid kg\(^{-1}\) on urinary pH and ammonia emission was examined in comparison to non-supplemented controls. The trial was carried out at a swine production farm composed by eight rooms ventilated with a fan of 50 cm diameter with a capacity for about 80 pigs (26 to 90 kg). Each room was sub-divided into eight pens (10 pigs/pen) of which 60 % of the pen area had a concrete slatted floor. Pigs of four rooms got the diet supplemented with 10000 mg benzoic acid kg\(^{-1}\) and those of the other four rooms the control diet. The basal diet was based on wheat, barley and soybean meal. The addition of benzoic acid was verified by analysis. Feed (as pellets) and water were available *ad libitum*. Urinary pH and ammonia emission were measured six times throughout the experimental period. Urine samples were collected from three or four pigs within each room and taken by catching the urine in a pan with long steel when the animals were urinating. The pH was measured with a Sentron 2001 pH analyzer. Ammonia emission was measured by sampling the air in the fan shaft with a constant air flow

\(^{10}\) Complementary information. Annex III. December 2006  
\(^{11}\) Technical Dossier. Annex 7.3.5
through heated and insulated Teflon tubes and the concentration of ammonia was determined. Means of ammonia emissions and pH of urine were calculated for both groups and for each measuring period. Furthermore, means of live weight of animals, ventilation rate, temperature and relative humidity were calculated. The effect of VevoVitall® on ammonia emission was determined by using the REML (Restricted Maximum Likelihood) procedure of Genstat. Within the model, corrections were made for differences in number of animals, live weight and differences in temperature.

Lower values for urinary pH and ammonia emission were found in pigs fed the benzoic acid diet at all measuring times (Table 3). Benzoic acid supplementation significantly reduced ammonia emission calculated on the basis of statistically adjusted mean values. The urinary pH directly measured at the location was found to be significantly reduced in the benzoic acid group.

Table 3. Effect of a dietary level of 10000 mg benzoic acid kg⁻¹ on urinary pH and ammonia emission

<table>
<thead>
<tr>
<th>Benzoic acid (mg kg⁻¹)</th>
<th>0</th>
<th>10000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary pH measured directly on location</td>
<td>6.1ᵃ</td>
<td>5.2ᵇ</td>
</tr>
<tr>
<td>Ammonia emission (g h⁻¹) *</td>
<td>29.1ᵃ</td>
<td>21.1ᵇ</td>
</tr>
</tbody>
</table>

ᵃ,ᵇ: Means within a row with no common superscript differ significantly (P<0.001 for urinary pH, P<0.05 for ammonia emission)

*Values adjusted by statistical procedures for number of pigs, live weight and temperature

3.3. Meat quality and sensory properties

In its opinion on benzoic acid for pigs for fattening the SCAN (EC, 2002) concluded that some minor changes to texture, pH and flavour occurred in benzoic acid-treated animals and that ‘it was not clear whether consumers would judge the changes to be favourable or unfavourable.’ Since this data was all obtained with over doses of benzoic acid, a conclusion on the potential influence of benzoic acid at recommended doses cannot be reached.

No new data was provided on the effects of VevoVitall® on meat quality and sensory properties.

3.4. Conclusion on efficacy

The five studies submitted provide evidence that both the lowest and the highest applied dietary levels of benzoic acid (5000 and 10000 mg kg⁻¹) will significantly reduce urinary pH in pigs for fattening. The applicant consequently applied for an approval of VevoVitall® as zootechnical additive and proposed a new functional group ‘pH regulation of urine.’ However an effect of this nature is not foreseen in Article 5(3) of Regulation (EC) No 1831/2003.

The applicant introduced a study of Canh et al. (1998) which intended to demonstrate the relation of a lower urinary pH and reduced ammonia emission. The FEEDAP Panel considered the presented linear regression equation [Log (ammonia emission)=3.76 (± 0.11) + 0.22 (±0.02) x urinary pH, R²= 0.84] and found that the regression equation could be applied for a very limited range of urinary pH.

The applicant also proposed to list VevoVitall® under the functional group ‘substances which favourably affect the environment.’ The suitability of VevoVitall® for this functional group can be evaluated by measuring ammonia emission. Only two of the four feeding studies submitted provide evidence for a significant reduction of ammonia emission at the
highest level of 10000 mg benzoic acid kg\(^{-1}\) diet, the lowest level being not effective in all studies. The FEEDAP Panel notes that there were no benefits to the addition of VevoVitall\(^\circledR\) at the minimum recommended dose. Although there was some evidence of a reduction in ammonia at 10000 mg benzoic acid kg\(^{-1}\), this was insufficient to conclude on the efficacy of VevoVitall\(^\circledR\).

The effect of benzoic acid at the recommended dose level on meat quality and sensory properties could not be assessed due to the lack of new data.

4. Safety

4.1. Safety for target species

4.1.1. Studies on target animals

In the previous SCAN opinion (EC, 2002) a dose-related adverse effect on pigs for fattening was observed in one study (Lenis et al., 1998) down to the lowest dose tested of 15000 mg benzoic acid kg\(^{-1}\). The SCAN considered this finding as probably being ‘fortuitous’ and concluded that 10000 mg kg\(^{-1}\) feed is well tolerated.

In order to obtain additional information on the safety of VevoVitall\(^\circledR\) as feed additive for growing pigs, a new tolerance study was performed.\(^{12}\) Special attention was given to the effects of the additive on feed intake, water consumption and morphological alterations of the stomach mucosa. The trial involved three experimental groups (control, 10000 and 20000 mg benzoic acid kg\(^{-1}\) complete feed). Twenty four animals (individually housed) were allocated to each of the experimental treatments taking into account body weight, gender, litter and health status. The diet was based on barley, wheat and soybean meal. A grower diet was provided during the period of 28-86 kg body weight and a finisher diet during the period of 86-119 kg body weight. The diets did not contain any medication and the addition of benzoic acid was verified by analysis. The trial involved a pre-experimental period of 15 days and an experimental period of 71-84 days. After 42 days of the experimental period, eight pigs per treatment were slaughtered at a mean body weight of about 86 kg. The remaining animals were slaughtered after an experimental period of 71 days (34 pigs) or 84 days (14 pigs) at a mean body weight of 119 kg.

Studied parameters included: body weight (start of the experiment, six weeks, 10 to 12 weeks), feed intake and water consumption (growing period, finishing period), faecal consistency (daily), state of health (daily), carcass (meat percentage, backfat thickness), liver and kidneys weight, macroscopic evaluation of the pars oesophagea and the fundus of the stomach.

The effects of the experimental treatments were tested for significance by analysis of variance (treatments block/litter). Results for water intake and water to feed ratio were also analysed for significance by analysis of variance (treatments, sex within experimental unit). Contrasts between means of treatments were evaluated using the Student’s t-test (P<0.05).

Body weight gain and feed conversion ratio were not statistically different between the treatments. Water intake was significantly higher in the growing period for both benzoic acid groups (P<0.05) when compared to control animals. Over the complete experimental period, no significant differences in water intake or water to feed ratio were observed. Carcass weight and meat percentage at slaughter were not affected by the treatments. Liver weight appeared not to be affected by the treatments, unlike kidney weight which was

\(^{12}\) Complementary information. Annex VI. December 2006
found significantly increased by the 20000 mg benzoic acid kg\(^{-1}\) level when, compared to the two other groups. Concerning the morphological status of the mucosa of the stomach, no significant differences could be noticed for the different treatments; two animals in the 20000 mg benzoic acid kg\(^{-1}\) group had ulcers in the fundus region compared to only one in the other groups. However, time dependent effects could not be assessed, as individual data were not submitted. The other parameters were not influenced by the addition of benzoic acid.

Overall, this study demonstrated that benzoic acid can be considered as safe at the maximum recommended dose, with a margin of safety of 1.5 taking into account the previous study.

4.1.2. **Microbiological safety**

No new data were submitted by the applicant.

Previous opinions (EC, 2002; EFSA, 2005) concluded that benzoic acid has an effect on a number of bacterial species along the piglet and pig intestine. The recommended use of benzoic acid for piglets (maximum 5000 mg kg\(^{-1}\) feed) appears to reduce a number of lactic acid bacteria in the stomach and *Enterobacteriaceae* in the caecum, without otherwise adversely affecting the gut microbiota (EFSA, 2005).

SCAN concluded that supplementation of diet with benzoic acid (15000 mg kg\(^{-1}\) feed, a concentration greater than the recommended range) reduced the number of some bacterial groups in the faeces of pigs for fattening. Data for the highest recommended dose were not submitted.

4.1.3 Conclusion on the safety for the target species

A recently submitted study, considered together with the previous one, confirms that 10000 mg benzoic acid kg\(^{-1}\) complete feed (the highest dose recommended by the applicant) can be considered safe with a narrow margin of safety (less than 1.5, taking into account previous study).

4.2. **Safety for consumers, users and the environment**

No new data has been submitted. However, the FEEDAP Panel considers that its opinion formerly expressed when assessing the use of VevoVitall\textsuperscript{®} in piglets (EFSA, 2005) applies equally to the use of VevoVitall\textsuperscript{®} in pigs for fattening.

‘Pharmacokinetic studies in laboratory animals and sows indicate that, owing to rapid metabolism and excretion, an accumulation of benzoic acid and its metabolites is not to be expected in piglets.

Both the SCF and the SCAN have evaluated benzoic acid in 2002, concluding that the compound does not present any significant risk for consumers, either from direct intake as food additive or from exposure to residues in pig tissues. No new data are available that would require a modification of the SCAN position. According to EU legislation, benzoic acid is considered a substance not subject to MRLs.

For user safety no new data are available that would require a modification of the SCAN position. The SCAN recommended appropriate labelling due to the potential of benzoic acid to induce skin and eye irritation. SCAN further recommended that measures should be taken in order to minimize the production of respirable dust from this product. The FEEDAP Panel supports these recommendations.
The use of benzoic acid as feed additive does not pose any significant concern for the environment.

5. Post-market monitoring

The FEEDAP Panel does not see a need for specific requirements of post market monitoring, in addition to the need for traceability and recall procedures established by Regulation (EC) No 183/2005.\(^{13}\)

CONCLUSIONS

The five studies submitted provide evidence that both the lowest and the highest applied dietary levels of benzoic acid (5000 and 10000 mg kg\(^{-1}\)) are effective in reducing urinary pH in pigs for fattening. Two of four feeding studies submitted provide evidence for a significant reduction of ammonia emission at the highest level of 10000 mg benzoic acid kg\(^{-1}\) diet, the lowest level being not effective in all studies.

A reduction in urinary pH is not a recognised attribute of a feed additive and, in the view of the FEEDAP Panel, has no direct benefit per se. Since the relation between urinary pH and reduced ammonia emission is not adequately established, the FEEDAP Panel cannot conclude on the efficacy of benzoic acid to reduce the ammonia emission.

The FEEDAP Panel concludes that 10000 mg benzoic acid kg\(^{-1}\) complete feed (the highest dose recommended by the applicant) is safe with a margin of safety of less than 1.5.

No new data were provided on the safety for the consumer, the user and the environment. The FEEDAP Panel confirms its former opinion, expressed when assessing benzoic acid for piglets (EFSA, 2005), that benzoic acid does not represent a risk for the consumer and the environment, and recommends appropriate labelling due to the potential to induce skin and eye irritation.

The FEEDAP Panel does not see a need for specific requirements of post-market monitoring.

REFERENCES


DOCUMENTATION PROVIDED TO EFSA
2. Supplementary information on VevoVitall® (Benzoic acid) used as zootechnical additive in feed for fattening pigs. December 2006.
4. Comments from the Member States received through the EFSAnet.

SCIENTIFIC PANEL MEMBERS
Georges Bories, Paul Brantom, Joaquim Brubau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debsky, Noël Dierick, Anders Franklin, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Anne-Katrine Lundbye Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Nebbia, Walter Rambeck, Guido Rychen, Atte von Wright and Pieter Wester

ACKNOWLEDGEMENT
The Scientific Panel on Additives and Products or Substances used in Animal Feed wishes to thank Prof. Pascal Sanders for his contribution to this opinion.

APPENDIX
Executive Summary of the Evaluation Report of the Community Reference Laboratory Feed Additives Authorisation on the Method(s) of Analysis of VevoVitall® (Benzoic acid) for pigs for fattening.

VevoVitall® is a feed additive for which authorisation is sought under the category "zootechnical additives", functional groups "other zootechnical additives" and "substances which favourably affect the environment", according to the classification system of Annex I of Regulation (EC) No 1831/2003. VevoVitall® contains high purity benzoic acid (≥ 99.9 % on anhydrous basis) as active substance.

In the current application authorisation is sought for use of VevoVitall® for pigs for fattening. The feed additive is intended to be mixed into compound feedingstuffs at a concentration of 5000 mg to 10000 mg/kg feedingstuffs.

For the determination of the benzoic acid in the feed additive the CRL recommends a titrimetric assay as specified by the corresponding monograph of the European Pharmacopoeia.

For the determination of the active substance in feedingstuffs a Reversed Phase High Performance Liquid Chromatography (RP HPLC) method with diode array detection (DAD) is submitted. The method’s performance characteristics include a recovery rate between 94 % and 113 %, a relative repeatability standard deviation (RSDr) of 2 % and a relative within-laboratory reproducibility standard deviation (RSDR) of 5 %. The limit of detection of the
method is 500 mg/kg and the limit of quantification is 2000 mg/kg. These performance characteristics are considered acceptable and the method is therefore considered suitable for official control purposes, if the analysis aims at the quantification of the target analyte in feedingstuffs samples in the frame of the sought authorisation, i.e. in target feed samples (feedingstuffs for pigs for fattening) at the target concentration range of benzoic acid (5000 to 10000 mg/kg).

Control methods are submitted for determination of possible contaminants and impurities (heavy metals, arsenic, organic impurities) in the feed additive which are considered suitable for the intended purposes. For official controls of heavy metals various standard methods, based on the same analytical technique and routinely applied by official control authorities are available and recommended by the CRL.

Further testing or validation by the CRL is not considered necessary.