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## Safety and efficacy of benzoic acid as a technological feed additive for weaned piglets and pigs for fattening

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### Abstract

The additive under assessment is pure benzoic acid (> 99.8%), manufactured in the form of flakes. It is intended to be used as a technological feed additive (acidity regulator) in feedingstuffs for weaned piglets and pigs for fattening, with maximum contents of 5,000 and 10,000 mg/kg complete feed, respectively. Benzoic acid is safe for weaned piglets at 5,000 mg/kg complete feed, and at 10,000 mg/kg complete feed for pigs for fattening. The use of benzoic acid in feedingstuffs for piglets and pigs for fattening at the maximum application rate will not affect exposure of consumers to residues or metabolites of concern via food from treated animals. Therefore, the use of benzoic acid as technological additive in feeds for pigs to a maximum inclusion level of 10,000 mg/kg is considered safe for consumers. Benzoic acid is a skin and eye irritant but is not considered to be a skin sensitiser. Exposure via inhalation is unlikely. The use of benzoic acid in feedingstuffs for piglets and pigs for fattening will not pose a risk for the environment. Benzoic acid is efficacious as an acidity regulator in feedingstuffs for weaned piglets and pigs for fattening.

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## 1. Introduction

### 1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003<sup>1</sup> 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 two requests from Eastman Chemical B.V.<sup>2</sup> for authorisation of benzoic acid, when used as a feed additive for piglets and for pigs for fattening (category: technological additives; functional group: acidity regulator).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the applications 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 applications were considered valid by EFSA as 28/4/2017 (EFSA-Q-2017-00103) and 30/4/2018 (EFSA-Q-2017-00103).

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

### 1.2. Additional information

Benzoic acid (E 210) is authorised as a zootechnical additive for weaned piglets<sup>3</sup> and pigs for fattening<sup>4</sup> and as a chemically defined flavouring for all animal species.<sup>5</sup> Benzoic acid is also authorised as a food additive<sup>6</sup> and registered as a flavouring substance used in or on foodstuffs.<sup>7</sup>

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) has delivered five opinions on the safety and efficacy of benzoic acid itself as a zootechnical additive (EFSA, 2005, 2007; EFSA FEEDAP Panel, 2011a, 2012a, 2015, 2017a,b) and one as a technological additive for pigs for fattening and flavouring in feed for all animal species (EFSA FEEDAP Panel, 2016). The FEEDAP Panel also delivered an opinion in 2012 on the safety and efficacy of Crina<sup>®</sup> Poultry Plus (a feed additive containing benzoic acid) for chickens for fattening (EFSA FEEDAP Panel, 2012b). The EFSA Panel on Food Additives and Nutrient Sources (ANS) has also delivered an 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 ANS Panel, 2016).

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of two technical dossiers<sup>8</sup> in support of the authorisation request for the use of 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 and other scientific reports to deliver the present output.

<sup>1</sup> 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.

<sup>2</sup> Eastman Chemical B.V. Watermanweg 70, 3067 GG, Rotterdam, the Netherlands.

<sup>3</sup> Commission Regulation (EC) No 1730/2006 of 23 November 2006 concerning the authorisation of benzoic acid (VevoVital) as a feed additive. OJ L 325, 24.11.2006, p. 9.

<sup>4</sup> Commission Regulation (EC) No 1138/2007 of 1 October 2007 concerning the authorisation of a new use of benzoic acid (VevoVital) as a feed additive. OJ L 256, 2.10.2007, p. 8.

<sup>5</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedstuffs. OJ L 270, 14.12.1970, p. 1.

<sup>6</sup> 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.

<sup>7</sup> Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996. OJ L 084, 27.3.1999, p. 1.

<sup>8</sup> FEED dossier reference: FAD-2017-0009 and FAD-2018-0011.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the active substance in animal feed. The Executive Summary of the EURL report can be found in Annex A.<sup>9</sup>

## 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of benzoic acid is in line with the principles laid down in Regulation (EC) No 429/2008<sup>10</sup> and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012c), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011a,b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012d) and Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012e).

## 3. Assessment

The additive under assessment is benzoic acid, when used as a feed additive for weaned piglets and for pigs for fattening (category: technological additives; functional group: acidity regulators). The additive is intended to be used in premixtures and feedingstuffs for piglets and pigs for fattening, with a maximum content of 5,000 and 10,000 mg/kg feed, respectively.

### 3.1. Characterisation

The additive consists of benzoic acid (Chemical Abstracts Service (CAS) No 65-85-0; chemical formula: C<sub>6</sub>H<sub>5</sub>COOH; molecular weight: 122.12). The additive is manufactured [REDACTED]

The applicant specified content for benzoic acid of  $\geq 99.8\%$ . Five batches of the additive were analysed for benzoic acid content; [REDACTED]

Three batches were analysed for impurities,<sup>12</sup> showing concentrations of lead, cadmium and mercury in all cases below the limit of quantification (LOQ) (0.2, 0.2 and 0.1 mg/kg additive, respectively) while arsenic concentration was 0.1 mg/kg additive in the three batches. Fluorine was  $< 1.5$  mg/kg. The maximum contents of dioxins, of the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) and of non-dioxin-like PCBs were 0.13 ng WHO-PCDD/F-TEQ per kg, 0.19 ng WHO-PCDD/F-DL-PCB-TEQ per kg and 0.24 ng/kg, respectively.

The additive is in the form of flakes, 99.75% of which are retained by a 700- $\mu$ m sieve; only 0.05% of the additive passes a 300- $\mu$ m sieve.<sup>13</sup>

#### 3.1.1. Stability and homogeneity

The analysis of three batches of the additive sampled immediately after manufacturing and after storing in closed bags and ambient temperature for 24 months, showed no losses of benzoic acid.<sup>14</sup>

The stability of the additive was assessed measuring benzoic acid concentrations in premixture<sup>14</sup> and in feed for both piglets<sup>15</sup> (benzoic acid inclusion level: 5,000 mg/kg feed) and pigs for fattening<sup>16</sup> (benzoic acid inclusion level: 10,000 mg/kg feed). The two typical commercial vitamin/mineral premixtures for piglets and pigs for fattening were supplemented with benzoic acid at the relevant concentrations, and then stored in closed containers for 6 months at ambient temperature. Essentially, no differences in benzoic acid concentration were observed. Two mash feeds (one for piglets and one for pigs for fattening) were mixed with benzoic acid to reach the intended concentration; two different

<sup>9</sup> The full report is available on the EURL website: [https://ec.europa.eu/jrc/sites/jrcsh/files/finrep\\_fad-2017-0009\\_benzoic\\_acid.pdf](https://ec.europa.eu/jrc/sites/jrcsh/files/finrep_fad-2017-0009_benzoic_acid.pdf)

<sup>10</sup> 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.

<sup>12</sup> Technical dossier FAD-2018-0011/Section II/Annex\_II\_2 to 4 and Technical dossier FAD-2017-0009/Section II/Annex\_II\_2 to 4.

<sup>13</sup> Technical dossier FAD-2018-0011/Section II/Annex\_II\_5 and Technical dossier FAD-2017-0009/Section II/Annex\_II\_5.

<sup>14</sup> Technical dossier FAD-2018-0011/Section II/Annex\_II\_6 and Technical dossier FAD-2017-0009/Section II/Annex\_II\_6.

<sup>15</sup> Technical dossier FAD-2018-0011/Section II/Annex\_II\_7 and 8.

<sup>16</sup> Technical dossier FAD-2017-0009/Section II/Annex\_II\_7 and 8.

feeds for piglets and for pigs for fattening were mixed with benzoic acid and pelleted. The four feeds were then stored in closed containers for 3 months under ambient conditions. No losses of benzoic acid were observed in any of the analysed feeds.

To assess the capacity of the additive to homogeneously distribute in feed, 10 subsamples each of the four feeds (mash and pelleted, for piglets and pigs for fattening)<sup>17</sup> were analysed after manufacturing for benzoic acid concentration. The coefficients of variation (CVs) in the mash feeds were 1.4% and 1.9%, respectively. The CVs measured in the pelleted feeds were 8.2 and 5.2%, respectively.

### 3.1.2. Conditions of use

The additive is intended to be used in premixtures and feedingstuffs for piglets and pigs for fattening, with a maximum content of 5,000 and 10,000 mg/kg feed, respectively.

## 3.2. Safety

### 3.2.1. Safety for weaned piglets

A total of 144 castrated male and 144 female piglets (Topigs 20 × Belgian Piétrain, 26 days of age, body weight 5.7 kg) were fed diets supplemented with 0, 5,000 (1× the maximum recommended dose) or 10,000 (2× the maximum recommended dose) mg benzoic acid/kg feed. Group size was 8 replicates with 12 piglets each (representing 4 pens with castrated males and 4 pens with females per treatment). The diets (prestarter, from day 1 to 14; starter, from day 15 to day 42), consisting mainly of wheat, barley, soybean and soybean meal. The concentrations of the benzoic acid were analytically confirmed. Feeds (pelleted form) and water were offered *ad libitum* for 42 days. Health status and mortality were monitored daily. Feed intake and body weight were recorded at the beginning and at day 42 of the experiment, and average daily body weight gain and feed to gain ratio were calculated. At the end of the experiment, one piglet per pen (representing four castrated males and four females per treatment) was randomly selected, blood samples were taken for haematology<sup>19</sup> and biochemistry<sup>20</sup> and piglets killed for necropsy. A non-inferiority test was performed with the data for performance parameters, considering the pen as the experimental unit.<sup>21</sup>

Mortality and culling of piglets were low (< 4%) and not different between treatments. The zootechnical parameters of the two groups administered benzoic acid were not different from those of the control group (control group results: average daily gain 0.32 kg/day; average daily feed intake 0.44 kg/day; feed to gain ratio 1.37), as well as the haematological and blood biochemical parameters. Gross pathology did not reveal any abnormalities of the observed organs.

### 3.2.2. Safety for pigs for fattening

Two tolerance studies were submitted. The first tolerance study was not further considered, due to a not treatment related high mortality of pigs (up to 21% in the 1× the maximum recommended use level group), caused by pneumonia (infection caused by *Actinobacillus pleuropneumonia* confirmed in all dead animals).<sup>22</sup>

In the second tolerance trial,<sup>23</sup> a total of 54 castrated male and 54 female pigs (Topigs 20 × Belgian Piétrain, 84 days of age, body weight 24.0 kg) was fed diets supplemented with 0, 10,000 (1× the maximum recommended dose) or 15,000 (1.5× the maximum recommended dose) mg benzoic acid/kg feed. Group size was six replicates with six pigs each (representing three pens with castrated males and three pens with females per treatment). The diets, consisting mainly of wheat, barley, maize, and soybean meal, were isonitrogenous (16.3% crude protein (CP)). The concentrations of the benzoic acid were analytically confirmed. Feeds (pelleted form) and water were offered *ad libitum* for

<sup>17</sup> Technical dossier FAD-2018-0011/Section II/Annex\_II\_7 and 8, and Technical dossier FAD-2017-0009/Section II/Annex\_II\_7 and 8.

<sup>19</sup> Red blood cell count (RBC), haemoglobin, white blood cell count (WBC).

<sup>20</sup> Total protein, albumin, cholesterol, triglycerides, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyltranspeptidase (GGT), alkaline phosphatase (ALP), urea, creatinine.

<sup>21</sup> The  $\delta$  equivalence margins were set at 12% for final body weight, average daily gain and average daily feed intake, at 5% for feed to gain ratio and at 25% for haematology and blood biochemistry.

<sup>22</sup> Technical dossier FAD-2017-0009/Section III/Annexes 2–14.

<sup>23</sup> Technical dossier FAD-2017-0009/Supplementary information April 2018/Annexes 21–40.

42 days. Health status and mortality were monitored daily. Feed intake and body weight were recorded at the beginning and day 42 of the experiment, and average daily body weight gain and feed to gain ratio were calculated. At the end of the experiment, two pigs per pen (representing six castrated males and six females per treatment) were randomly selected, blood samples were taken for haematology<sup>24</sup> and biochemistry<sup>25</sup> and pigs were killed for necropsy.<sup>26</sup> A non-inferiority test was performed with the data for performance parameters, considering the pen as the experimental unit.<sup>21</sup>

No animals died during the study; a female pig was removed from the control group, because of signs of anorexia. The zootechnical parameters of the two groups administered benzoic acid were not different from those of the control group were (control group results: average daily gain 0.67 kg/day; average daily feed intake 1.36 kg/day; feed to gain ratio 2.03), as well as the haematological and blood biochemical parameters. Gross pathology did not reveal any abnormalities of the observed organs.

### 3.2.2.1. Conclusions on the safety for the target species

Benzoic acid is safe for weaned piglets at 5,000 mg/kg complete feed with a margin of safety of two, and at 10,000 mg/kg complete feed for pigs for fattening, with a margin of safety of 1.5.

### 3.2.3. Safety for the consumer

No specific studies were provided by the applicant. The toxicokinetics of benzoic acid has been evaluated in its general aspects by the Scientific Committee for Food (European Commission, 2002). The toxicological profile of benzoic acid was assessed by the EFSA Panel on Food Additives and Nutrient Sources Added to Food (EFSA ANS Panel) in 2016. The EFSA ANS Panel identified a no-observed-adverse-effect-level (NOAEL) of 500 mg benzoic acid/kg body weight (bw) per day as the highest dose tested in a four-generation reproductive study in rats; from this study, the Panel derived an acceptable daily intake (ADI) of 5 mg/kg bw using an uncertainty factor of 100 (EFSA ANS Panel, 2016).

Benzoic acid is rapidly metabolised and excreted mainly as urinary hippuric acid and deposition in edible tissues is negligible. Consequently, foods of animal origin are likely to provide only a very minor contribution, if any, to the overall dietary intake of benzoic acid, which is mostly provided by foods of vegetable origin and food additives (EFSA ANS Panel, 2016).

The FEEDAP Panel considers that the use of benzoic acid in animal nutrition at the maximum application rate will not affect exposure of consumers to residues or metabolites of concern via food from treated animals. Therefore, the use of benzoic acid as technological additive in feeds for pigs to a maximum inclusion level of 10,000 mg/kg is safe for consumers.

### 3.2.4. Safety for the user

No specific studies were provided by the applicant.

The applicant makes reference to an existing European regulation describing risks for users following exposure to benzoic acid (Regulation No 1272/2008).<sup>27</sup> This classifies benzoic acid as a skin irritant category 2 and eye damage category 1. It is also classified as 'significantly toxic to pulmonary (lung) tissue after repeated exposure'. The additive is manufactured in the form of flakes, with only 0.05% of the particles with diameter < 300 µm. Exposure via inhalation is unlikely.

The Committee for Risk Assessment of the European Chemicals Agency (ECHA) in 2012 assessed benzoic acid, and also concluded that benzoic acid should be classified as Eye Damage 1 and Skin Irritant 2.1. In addition, 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

<sup>24</sup> Red blood cell count (RBC), haematocrit, haemoglobin, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, red cell distribution width, platelets, white blood cell count (WBC), white blood cell differentials (neutrophils, lymphocytes, monocytes, eosinophils, basophils).

<sup>25</sup> Total protein, albumin, cholesterol, bilirubin, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyltranspeptidase (GGT), alkaline phosphatase (ALP), lactate dehydrogenase (LDH), amylase, creatine kinase, glucose, urea, creatinine, sodium, potassium, chloride, calcium, phosphorus, magnesium.

<sup>26</sup> Liver, kidneys, spleen, adrenal gland, lungs, stomach, pancreas, small intestine, colon, caecum, thymus, thyroid gland, heart, mesenterium including lymph nodes.

<sup>27</sup> 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. OJ L 353, 31.12.2008, p. 1.

previous sensitisation. Based on the studies described in the ECHA report, benzoic acid is not considered as a skin sensitiser.

Benzoic acid is a skin and eye irritant but is not considered to be a skin sensitiser. Exposure via inhalation is unlikely.

### 3.2.5. Safety for the environment

Benzoic acid is naturally present in plants. Benzoic acid administered to pigs will be mainly excreted as urinary hippuric acid, a metabolic by-product, which do not possess a biological activity of environmental concern. Consequently, the FEEDAP Panel concludes that the use of benzoic acid in animal nutrition will not pose a risk for the environment.

## 3.3. Efficacy

Two *in vitro* studies were provided to support the efficacy of benzoic acid as an acidity regulator in feedingstuffs for weaned piglets and pigs for fattening.<sup>28</sup>

Three commercial feeds for weaned piglets and three for pigs for fattening were supplemented with benzoic acid (feeds composition described in Appendix A) at concentrations of 0, 1,250, 2,500, 3,750 or 5,000 mg benzoic acid/kg feed in weaned piglets and with 0, 2,500, 5,000, 7,500 or 10,000 mg benzoic acid/kg feed in pigs for fattening. Four subsamples for each concentration were taken from each feedingstuffs. After the supplementation, each feedingstuffs subsample was ground, and a sample of 10 g of the mash feed was added to 100 mL of distilled deionised water. The solution was stirred for 2 min and then set for sedimentation for another 5 min. Subsequently, a sample of 25 mL of the supernatant was transferred to a clean recipient where the pH was measured. The results were statistically analysed using the linear mixed model.

In the six feedingstuffs, the increasing levels of benzoic acid decreased the pH in a linear and statistically significant manner. The effect of benzoic acid on the pH is related to the buffering capacity of the feedingstuffs, and was different in the three feedingstuffs. The average pH values of the 12 samples measured for each benzoic acid concentrations in the feeds for weaned piglets decreased from 5.69 (control) to 5.09 (10,000 mg benzoic acid/kg feed). The corresponding pH values measured in the feed for weaned piglets were 5.34 (control) and 5.08 (10,000 mg benzoic acid/kg feed).

The results of the study showed that benzoic acid is efficacious as an acidity regulator in feedingstuffs for weaned piglets and pigs for fattening.

## 4. Conclusions

Benzoic acid is safe for weaned piglets at 5,000 mg/kg complete feed with a margin of safety of 2, and at 10,000 mg/kg complete feed for pigs for fattening, with a margin of safety of 1.5.

The use of benzoic acid as a technological additive in feeds for pigs to a maximum inclusion level of 10,000 mg/kg is safe for consumers.

Benzoic acid is a skin and eye irritant but is not considered to be a skin sensitiser. Exposure via inhalation is unlikely.

The use of benzoic acid in animal nutrition will not pose a risk for the environment.

Benzoic acid is efficacious as an acidity regulator in feedingstuffs for weaned piglets and pigs for fattening.

## Documentation provided to EFSA

- 1) Benzoic acid for pigs for fattening. February 2017. Submitted by Eastman Chemical B.V.
- 2) Benzoic acid for piglets (weaned). March 2018. Submitted by Eastman Chemical B.V.
- 3) Benzoic acid for pigs for fattening. Supplementary information. August 2018. Submitted by Eastman Chemical B.V.
- 4) Benzoic acid for piglets (weaned). Supplementary information. August 2018. Submitted by Eastman Chemical B.V.
- 5) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for benzoic acid.
- 6) Comments from Member States.

<sup>28</sup> Technical dossier FAD-2017-0009/Section IV/Annex\_IV\_I and Technical dossier FAD-2018-0011/Section IV/Annex\_IV\_I.



## Chronology

Date	Event
20/2/2017	Dossier FAD-2017-0009 received by EFSA
9/11/2017	Dossier FAD-2017-0009 Supplementary information requested by EFSA
28/3/2018	Dossier FAD-2018-0011 received by EFSA
9/7/2018	Dossier FAD-2018-0011 Supplementary information requested by EFSA
1/8/2018	Dossier FAD-2017-0009 Supplementary information received
1/8/2018	Dossier FAD-2018-0011 Supplementary information received
27/11/2018	Dossier FAD-2017-0009 Opinion adopted by the FEEDAP Panel. End of the Scientific assessment
27/11/2018	Dossier FAD-2018-0011 Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

## References

- EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product VevoVital<sup>®</sup> as feed additive for weaned piglets in accordance with Regulation (EC) 1831/2003. EFSA Journal 2005;3(12):290, 13 pp. <https://doi.org/10.2903/j.efsa.2005.290>
- EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of VevoVital<sup>®</sup> (benzoic acid) as feed additive for pigs for fattening. EFSA Journal 2007;5(3):457, 14 pp. <https://doi.org/10.2903/j.efsa.2007.457>
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- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011a. Technical guidance: tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
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## Abbreviations

ADI	acceptable daily intake
ALP	alkaline phosphatase
ALT	alanine aminotransferase
ANS	EFSA Panel on Food Additives and Nutrient Sources
AST	aspartate aminotransferase
CAS	Chemical Abstracts Service
CP	crude protein
CV	coefficient of variation
DDGS	Distillers Dried Grains with Solubles
DL-PCB	dioxin-like polychlorinated biphenyl
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
GGT	gamma-glutamyltranspeptidase
IPCS/INCHEM	International Programme on Chemical Safety
LDH	lactate dehydrogenase
LOD	limit of detection
LOQ	limit of quantification
NOAEL	no-observed-adverse-effect-level
PCDD/F	polychlorinated dibenzo- <i>p</i> -dioxin/dibenzofuran
RBC	red blood cell count
RP-HPLC	reversed-phase high-performance liquid chromatography
SCAN	Scientific Committee on Animal Nutrition
TEQ	toxic equivalent
UV	Ultraviolet
WBC	white blood cell count
WHO	World Health Organization

## Appendix A – Composition of the feeds used in the efficacy studies

**Table A.1:** Composition of the feeds for pigs for fattening used for the efficacy trial<sup>(a)</sup>

Ingredient	Feed A	Feed B	Feed C
	%	%	%
Wheat and wheat derived products	55.0	41.4	47.0
Barley	15.0	21.9	12.5
Maize	5.1	8.9	11.8
Soybean meal	7.6	6.4	11.0
Palm kernel flakes	–	3.9	5.0
Rapeseed meal	1.8	–	4.1
Fat and oil	1.1	0.1	3.1
Soybean fibre	–	0.9	2.5
Vitamin and mineral premix including enzymes and amino acids	3.3	2.7	3.0
Bakery by products	7.5	7.4	–
Molasses	2.1	2.0	–
DDGS	–	4.4	–
Sugar beet pulp	1.5	–	–

DDGS: Distillers Dried Grains with Solubles.

(a): Technical dossier FAD-2017-0009/Section IV/Annexes IV\_3.

**Table A.2:** Composition of the feeds for weaned piglets used for the efficacy trial<sup>(a)</sup>

Ingredient	Feed A	Feed B	Feed C
	%	%	%
Wheat and wheat derived products	18.3	31.5	25.8
Barley and barley derived products	–	25.0	25.0
Soya and soya derived products	6.9	20.7	18.3
Oat and oat derived products	10.9	–	7.5
Maize and maize derived products	6.5	10.0	2.5
Fat and oils	10.5	1.0	0.6
Beet pulp	–	1.5	–
Vitamin and mineral premix	10.0	10.0	20.0
Short chain fatty acid blend	3.6	0.3	0.2
Dextrose	6.1	–	–
Brewer's yeast	3.9	–	–
Potato protein	5.8	–	–
Whey powder	17.3	–	–

(a): Technical dossier FAD-2018-0011/Section IV/Annexes IV\_3.

## **Annex A – Evaluation Report on the Analytical Methods submitted in connection with the Application for Authorisation of a Feed Additive according to Regulation (EC) No 1831/2003**

In the current application authorisation is sought under article 4(1) for benzoic acid under the 'category'/functional group' 1(j) 'technological additives'/acidity regulator' according to the classification system of Annex I of Regulation (EC) No 1831/2003 for pigs for fattening. Benzoic acid is a feed additive currently authorised as a chemically defined flavouring for all animal species and as zootechnical additive for porcine and poultry species. The feed additive consists of benzoic acid white crystalline flakes with a minimum purity of 99.8%. It is intended to be incorporated directly in feedingstuffs or through premixtures at maximum inclusion levels of 10 g/kg of complete feedingstuffs. For the characterisation quantification of benzoic acid in the feed additive, premixtures and feedingstuffs the Applicant submitted an analytical method based on reversed-phase high-performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV) similar to the one described in the ISO 9231:2008 standard. The EURL evaluated several dossiers related to feed additives containing benzoic acid, and recommended for official control the European Pharmacopoeia method (01/2008.0066) for the characterisation of benzoic acid (feed additive), and the ISO 9231:2008 method for the quantification of benzoic acid in premixtures and feedingstuffs leading to relative precisions (repeatability and intermediate precision) ranging from 0.4% to 1.9% for feedingstuffs and premixtures containing 3–5 and 50–100 g/kg, respectively, and a limit of quantification (LOQ) of 0.5 g/kg feedingstuffs. The Applicant applied the above mentioned HPLC-UV method in the frame of the stability confirming thus its suitability. Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.