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Safety and efficacy of benzoic acid for pigs and poultry

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Abstract

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked by the European Commission to deliver a scientific opinion on the safety and efficacy of benzoic acid as feed flavouring for piglets (suckling, weaned), pigs for fattening, sows (for reproduction, in order to have benefit in piglets), minor porcine species, chickens (for fattening, reared for laying), hens (laying, breeding), turkeys (for fattening, for breeding purposes, reared for breeding) and minor poultry species. Benzoic acid is safe for weaned piglets at 2,500 mg/kg feed, and for laying hens, turkeys and chickens for fattening at 500 mg/kg feed; no conclusions could be drawn for suckling piglets and sows. The conclusions on weaned piglets can be extended to pigs for fattening and extrapolated to growing minor porcine species. The conclusions on chickens/turkeys for fattening can be extended to chickens reared for laying and turkeys reared for breeding and extrapolated to minor poultry species up to the point of lay. In the absence of safety margin in laying hens, no conclusions can be reached for minor poultry species for laying/breeding. The use of the additive is not expected to pose a risk to consumer, considering that the additive is rapidly metabolised with very low deposition, if any, in edible tissues of pigs and poultry and that foods of animal origin provide a very minor contribution, if any, to the overall dietary intake of benzoic acid. Owing to the unlikelihood of exposure, no risk to users upon inhalation of the additive is expected; the additive is not a skin sensitiser, but is a skin/ eye irritant. The proposed use of the additive does not pose environmental risks. Benzoic acid is authorised as food flavouring and its function in feed is essentially the same; no further demonstration of efficacy is necessary.

Keywords: sensory additives, flavouring compounds, benzoic acid, safety, efficacy, pigs, poultry

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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 Novus Europe S.A./N.V.[2] for authorisation of the product benzoic acid, when used as a feed additive for pigs (piglets (suckling and weaned), pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species) and poultry (chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species) (category: sensory additives; functional group: flavouring compounds).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 7 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 additive benzoic acid), when used under the proposed conditions of use (see Section 3.1.5).

1.2. Additional information

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the efficacy, the impact on products of animal origin, and the safety for pigs for fattening, consumer and user and the environment of benzoic acid (EC, 2002a). The Scientific Committee on Food (SCF) delivered an opinion on benzoic acid (EC, 2002b).

The FEEDAP Panel has delivered several scientific opinions on the safety and efficacy of benzoic acid as a zootechnical additive (EFSA, 2005, 2007; EFSA FEEDAP Panel, 2011a, 2012a,b, 2014, 2015). Benzoic acid as feed flavouring has been assessed by the EFSA FEEDAP Panel (2012c). More recently, the FEEDAP Panel has issued a scientific opinion on the safety and efficacy of benzoic acid as a feed additive for pigs for fattening when used as a technological additive and for all animal species when used as a sensory additive (EFSA FEEDAP Panel, 2016).

In the context of re-evaluation of food additives, the EFSA Panel on Food Additives and Nutrient Sources Added to Food has recently assessed benzoic acid and its salts (EFSA ANS Panel, 2016).

The safety of benzoic acid has been assessed by the International Programme for Chemical Safety (IPCS, 2000) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1996).

Benzoic acid has been recently authorised as flavouring compound for all animal species at the maximum content of 125 mg/kg complete feed.[3]

[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] Novus Europe S.A./N.V, Woluwe Atrium, 5th floor, Rue Nerveldstraat 101-103, B-1200, Brussels, Belgium.

[3] Commission Implementing Regulation (EU) 2017/63 of 14 December 2016 concerning the authorisation of benzyl alcohol, 4-isopropylbenzyl alcohol, benzaldehyde, 4-isopropylbenzaldehyde, salicylaldehyde, *p*-tolualdehyde, 2-methoxybenzaldehyde, benzoic acid, benzyl acetate, benzyl butyrate, benzyl formate, benzyl propionate, benzyl hexanoate, benzyl isobutyrate, benzyl isovalerate, hexyl salicylate, benzyl phenylacetate, methyl benzoate, ethyl benzoate, isopentyl benzoate, pentyl salicylate and isobutyl benzoate as feed additives for all animal a species and of veratraldehyde and gallic acid as feed additives for certain animal species. OJ L 13, 17.1.2017, p. 214.

Benzoic acid, either as such or under a specific brand name, is also approved for use as a zootechnical additive (other zootechnical additives) in weaned piglets[4] at a maximum dose of 5,000 mg/kg; in pigs for fattening[5] and sows[6] at a maximum dose of 10,000 mg/kg.

A preparation containing 80–83% benzoic acid is authorised a zootechnical additive (improvement of zootechnical parameters) in chickens for fattening, chickens reared for laying and minor poultry species for fattening and reared for laying[7]; the maximum dose of the additive is 300 mg/kg.

Benzoic acid (E 210) is also authorised as a food additive,[8] and is registered as a flavouring substance used in or on foodstuffs.[9] Benzoic acid is authorised to be used as monomer and additive to manufacture plastics with no particular restriction on its migration.[10]

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[11] in support of the authorisation request for the use of 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[12] and the applicable EFSA guidance documents.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, and other scientific reports to deliver the present output.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of the benzoic acid in animal feed. The Executive Summary of the EURL report can be found in Annex A.[13]

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 and the relevant guidance documents: Guidance for the preparation of dossiers for sensory additives (EFSA FEEDAP Panel, 2012d), Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011b), Guidance for establishing the safety of additives for the consumer (EFSA FEEDAP Panel, 2012e), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012f), Technical Guidance for assessing the safety of feed additives for the environment (EFSA, 2008a), Guidance for the preparation of dossiers for additives already authorised for use in food (EFSA FEEDAP Panel, 2012g) and Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition (EFSA, 2008b).

[4] 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. Commission Implementing Regulation (EU) No 226/2012 of 15 March 2012 amending Regulation (EC) No 1730/2006 as regards the conditions of use of benzoic acid (holder of authorisation Emerald Kalama Chemical BV). OJ L 77, 16.3.2012, p. 6.

[5] Commission Regulation (EC) No 1138/2007 of 1 October 2007 concerning the authorisation of benzoic acid (VevoVitall) as a feed additive. OJ L 265, 2.10.2007, p. 8.

[6] 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.

[7] Commission Implementing Regulation (EU) 2015/1426 of 25 August 2015 concerning the authorisation of the preparation of benzoic acid, thymol, eugenol and piperine as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and reared for laying (holder of the authorisation DSM Nutritional Product). OJ L 223, 26.8.2015, p. 6.

[8] 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.

[9] Commission Decision 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 84, 27.3.1999, p. 1.

[10] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

[11] FEED dossier reference: FAD-2016-0078.

[12] 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.

[13] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/updated_finrep_fad-2016-0078_benzoic_acid.pdf

3. Assessment

The applicant seeks the authorisation of benzoic acid as a sensory feed additive (flavouring compound) for pigs (piglets (suckling and weaned), pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species) and poultry (chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species).

3.1. Characterisation

3.1.1. Characterisation of the additive

'Benzoic acid' has the Chemical Abstracts Service (CAS) No 65–85–0. Its corresponding International Union of Pure and Applied Chemistry (IUPAC) name is 'Benzene carboxylic acid'. Its chemical formula is C_6H_5COOH and it has a molecular weight of 122.12 Da.

The additive is specified to content benzoic acid at a concentration ≥ 99%. The analysis of eight batches provided an average of 99.6% content of benzoic acid (range of 99.54–99.84%),[14] thus meeting the specification.

Undesirable substances analyses were provided.[15] Levels of lead, cadmium and mercury (results of three batches) were in all cases below the limit of quantification (LOQ) which was 0.5, 0.2 and 0.02 mg/kg, respectively. The analysis of arsenic (six batches) ranged from < 0.5 mg/kg (LOQ) to 2 mg As/kg additive. The results confirm that the additive meets the specifications described for heavy metals for benzoic acid as a food additive (Commission Directive 96/77/EC).[16] The content of dioxins and the sum of dioxins and dioxin-like PCBs (analysed in three batches) was 0.35–0.39 ng WHO-PCDD/F-TEQ/kg and 0.462–0.540 ng WHO-PCDD/F-PCB-TEQ/kg, respectively. The content of phthalic acid (three batches) ranged from 20 to 70 mg/kg (specification: ≤ 100 mg/kg) and that of total biphenyls (three batches) was ≤ 100 mg/kg (specification: ≤ 100 mg/kg) content.

The applicant provided analytical data in order to evaluate the possible presence of residual solvents in the additive.[17] Nine batches were analysed for residual toluene: results ranged from below 0.01 mg/kg (LOQ) to 0.039 mg/kg additive; these values are far below the VICH guideline limit for toluene residues (890 mg/kg; VICH, 2011). Six additional batches were analysed for the content of biphenyls: the content ranged from 34 to 60 mg/kg additive.

3.1.2. Physical state of the product

Benzoic acid is a white, free-flowing crystalline powder. The bulk and tap density of the additive is 0.55 g/mL and 0.66 g/mL, respectively (average values of three batches).[18]

The analysis on particle size distribution by laser diffraction (three batches) provided the following average results: 3.9, 31.6 and 63 % of particles below 10, 50 and 100 μm, respectively.[18] The dusting potential analysed in the same batches by the Stauber–Heubach method was virtually absent.[19]

3.1.3. Production process

Benzoic acid is an aromatic carboxylic acid produced by partial oxidation of toluene with oxygen. The applicant provided a flowchart of the production process.[20]

[14] Technical Dossier/Section II/Annex II_1_3 and II_1_4_2_1.
[15] Technical Dossier/Section II/Annex II_1_4_2_1.
[16] Commission Directive 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners. OJ L 339, 30.12.1996, p. 1.
[17] Technical Dossier/Supplementary information.
[18] Technical dossier/Section II/Annex II_1_5_1.
[19] Technical dossier/Section II/Annex II_1_5_2.
[20] Technical Dossier/Section II/Annex II_3_2.

3.1.4. Stability and homogeneity

The applicant stated that benzoic acid is stable for 42 months when stored in the original commercial packaging. However, a direct demonstration of stability of the additive or homogeneity was not provided.[21]

3.1.5. Conditions of use

The additive is intended to be used in pigs (piglets (suckling and weaned), pigs for fattening, sows for reproduction, sows in order to have benefit in piglets, minor porcine species) at a maximum dose of 2500 mg/kg complete feed; the use in poultry (chickens for fattening, chickens reared for laying, laying hens, breeding hens, turkeys for fattening, turkeys for breeding purposes, turkeys reared for breeding, minor poultry species) is proposed at a maximum of 500 mg/kg. In both cases (pigs and poultry), no minimum dose is proposed.

3.2. Safety

3.2.1. Safety for the target species

The applicant provided several tolerance studies and a literature search to support the safety of the additive for the target animal species and categories.

3.2.1.1. Tolerance studies

Study in piglets

To assess the tolerance of the additive in piglets, the applicant submitted a study on 128 weaned piglets (28 days old) [Pietrain × (Duroc × Landrace and LW × Landrace)].[22] The animals were penned in groups of four considering sex and body weight (2 ♂ and 2 ♀) and allocated to four experimental groups, representing eight replicates per treatment. Diets (based on maize and soybean meal) were fed *ad libitum* in pelleted form as a 14-day prestarted feed (28–42 days of age) and a 28-day starter feed (42–70 days of age). The experimental treatments included 0, 1,000, 2,500 (the maximum recommended dose) and 5,000 mg (2 × maximum recommended dose) benzoic acid/kg feed; benzoic acid content in diets was analytically confirmed. The study lasted 42 days. Mortality and health condition were monitored daily. Body weight (bw) and feed intake was measured at 14 and 42 days. At the end of the study, one piglet per pen (close to average pen weight) was selected for blood haematology[23] and blood biochemical[24] sampling, a complete necropsy was performed (including examination for gross abnormalities, relative weight of liver, spleen and kidneys) and tissue samples (liver, kidney and upper gut) were taken for histological examination. Relevantly, during necropsy, parakeratosis in the pars oesophagea and the histopathology were examined. The pen was the experimental unit for statistical purposes and the basic statistical model use was analysis of variance (ANOVA); means were compared among treatments with Tukey adjustment; significant differences were declared at $p \leq 0.05$. No statistical analysis was done for the gross pathology or the histopathology observations.

Mortality was low amounting overall to 1.6 % and was not treatment-related. No adverse effects were observed in any of the performance parameters tested (average values: body weight = 23.63 kg, average daily feed intake = 563 g, feed/gain ratio = 1.505), or in the biochemical and haematological parameters tested. The relative weights of the organs examined were not different among treatments. The observations of parakeratosis in the pars oesophagea and the histopathology showed some numerical differences but no treatment-related.

The results of this study support that benzoic acid can be tolerated in weaned piglets at a concentration in feed equal to 5,000 mg/kg, corresponding to twofold the maximum intended level proposed for use.

[21] The applicant submitted a study performed with Avimatrix®, an additive composed by ≥ 42.5 % benzoic acid, ≥ 2.5 % calcium formate, ≥ 0.8 % fumaric acid, and ≥ 45 % palm stearin. Technical Dossier/Section II/Annex II_4_1_1.

[22] Technical Dossier/Supplementary Information/Tolerance Piglets.

[23] Mean corpuscular haemoglobin concentration, mean corpuscular haemoglobin, mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, leucocytes, eosinophils, basophils, lymphocytes, monocytes, segmented.

[24] Alkaline phosphatase, glutamic pyruvate transaminase, aspartate aminotransferase, γ-glutamyl transpeptidase, lactate dehydrogenase, creatinine kinase, glucose, total proteins, albumin, uric acid.

Studies in chickens for fattening

Study 1

To assess the safety of the additive for poultry, the applicant initially proposed to use a tolerance study performed with chickens for fattening with the test item AviMatrix® (composed by ≥ 42.5 % benzoic acid, ≥ 2.5 % calcium formate, ≥ 0.8 % fumaric acid and ≥ 45 % palm stearin).[25] The study was conducted on 1,800 day-old male broiler chickens (Ross 308 strain) randomly assigned to the following treatments: basal diet only based on wheat, maize and soybean meal (negative control); basal diet plus 250 mg AviMatrix® (corresponding to approximately 120 mg benzoic acid)/kg feed; basal diet plus 500 mg AviMatrix® (approximately 240 mg benzoic acid)/kg feed; basal diet plus 1,000 mg AviMatrix® (approximately 480 mg benzoic acid)/kg feed; basal diet plus 3,000 mg AviMatrix® (approximately 1,440 mg benzoic acid)/kg feed. Each treatment comprised nine pens with 40 chickens each. Diets were fed in mash form during 35 days (starter: from day 1 to 21; grower: from day 22 to 35). Benzoic acid content was analytically confirmed in all treatments. Body weight and feed intake were recorded on days 0, 21 and 35 days. Mortality was checked daily. At the end of the study, one bird was randomly sampled from each pen in order to perform blood analyses for biochemical and haematological parameters and necropsy, with special attention to the presence of macroscopic changes of the oral cavity, crop and intestinal tract.

No adverse effects of treatment were detected, with the exception of significantly reduced total leucocyte and heterophil counts in birds supplemented with 3,000 mg AviMatrix®/kg feed compared to control, but not with 1,000 mg AviMatrix® or lower. The FEEDAP Panel considers that these changes may indicate an initial adverse effect, occurring at a supplementation level of 1,440 mg benzoic acid/kg feed, which is 2.9-fold higher than the intended maximum supplementation level in the current application; no adverse effects were observed at a supplementation level of 480 mg/kg feed, which is close to the intended maximum supplementation level of 500 mg/kg.

The FEEDAP Panel notes that the study concerns a different product, containing as well other substances; possible interactions cannot be ruled out altogether. Thus, the Panel considers that this study provides only supportive evidence to assess the tolerance of the additive under assessment in chickens for fattening.

Study 2

Another specific-to-the-additive study with 1,312 one-day-old Ross 308 male chickens was provided.[26] The birds were penned in groups of 41 and allocated to four experimental groups, representing eight replicates per treatment. Diets (based on maize and soybean meal) were fed *ad libitum* in crumble (starter)/pelleted (grower) form as a 21-day starter feed (0–21 days of age) and a 14-day grower feed (22–36 days of age). The experimental treatments included 0 (T1), 200 (T2), 500 (T3; the maximum recommended dose) and 1,500 (T4; 3 × maximum recommended dose) mg benzoic acid/kg feed; benzoic acid content in diets was analytically confirmed. The study lasted 36 days. Mortality and health condition were monitored daily. Body weight and feed consumption was measured at 21 and 35 days. At the end of the study, one bird per pen was randomly selected for blood sampling, including haematological[27] and biochemical[24] analyses. The same bird was submitted to a complete necropsy to assess gross abnormalities, relative weight of liver, spleen and kidneys; tissue samples (liver, kidney and upper gut) were taken for histological examination. The pen was the experimental unit for statistical purposes and the basic statistical model use was ANOVA; means were compared among treatments with Tukey adjustment; significant differences were declared at $p \leq 0.05$. No statistical analysis was done for the gross pathology or the histopathology observations.

Mortality was very low (0.8%) and not related to treatments. Considering the whole feeding period (0–35 days), no adverse effects were observed in any of the performance parameters tested (average values: body weight = 2,178 g, feed/gain ratio = 1.498), or in the biochemical and haematological parameters tested. No significant differences were detected in body weight and/or organs/tissue relative weight among treatment groups following gross pathology observation. Most of the animals did not present apparent macroscopic pathologies (6/8, 5/8, 5/8 and 6/8 from groups T4, T3, T2 and

[25] Technical Dossier/Section III/Annex III_1_1_1. This is the same study submitted by the applicant in the context of a previous application of another additive, and already evaluated by the FEEDAP Panel: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5025/epdf

[26] Technical Dossier/Supplementary Information/Tolerance Broiler.

[27] Mean corpuscular haemoglobin concentration, mean corpuscular haemoglobin, mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, leucocytes, eosinophils, basophils, lymphocytes, monocytes, heterophils.

T1, respectively). Few animals presented liver paleness discoloration or friability, with no great incidence in any group. The distribution of animals with these findings in all experimental groups suggests that no relationship with the treatment did exist.

The study indicates that benzoic acid is tolerated by chicken for fattening up to 1500 mg/kg.

Study in turkeys

To assess the additive tolerance in turkeys, a study with 815 one-day-old BUT10 female turkeys was provided.[28] The birds were penned in groups of 24–27 animals and allocated to four experimental groups, representing eight replicates per treatment. Diets (based on maize and soybean meal) were fed *ad libitum* in crumble/pelleted form as a 28-day starter feed (1–28 days of age) and a 14-day grower feed (29–42 days of age). The experimental treatments included 0, 200, 500 (the maximum recommended dose) and 1,500 (3 × maximum recommended dose) mg benzoic acid /kg feed; benzoic acid content in diets was analytically confirmed. The study lasted 42 days. Mortality and health condition were monitored daily. Body weight and feed consumption was measured at 28 and 42 days. At the end of the study, one bird per pen was randomly selected for blood sampling, including haematological[29] and biochemical[24] analyses. The same bird was submitted to a complete necropsy to assess gross abnormalities, relative weight of liver, spleen and kidneys; tissue samples (liver, kidney and upper gut) were taken for histological examination. The pen was the experimental unit for statistical purposes and the basic statistical model use was ANOVA; means were compared among treatments with Tukey adjustment; significant differences were declared at $p \leq 0.05$. No statistical analysis was done for the gross pathology or the histopathology observations.

Mortality was very low (0.5% and 0.9% in T3 and T4, respectively). Considering the whole feeding period (0–42 days), no adverse effects were observed in any of the performance parameters tested (average values: body weight = 2.199 kg, average feed intake = 78.62 g, feed/gain ratio = 1.537), or in the biochemical and haematological parameters tested.

In conclusion, the data from this study suggest that diets containing 1,500 mg/kg benzoic acid (3-fold maximum recommended dose) are well tolerated by turkeys for fattening.

Study in laying hens

To evaluate the tolerance of benzoic acid in laying hens, a study performed with 258 25-week old HyLine Brown pullets was submitted.[30] The birds were penned in groups of 8–9 birds and allocated to four experimental groups, representing eight replicates per treatment. Diets (based on maize and soybean meal) were fed *ad libitum* in mash form. The animals were fed a diet with a supplementation of four benzoic acid concentrations: 0, 200, 500 (the maximum recommended dose) and 1,500 (3 × maximum recommended dose) mg/kg feed; benzoic acid content in diets was analytically confirmed. The study duration was 57 days. Mortality, health condition and laying performance (laying intensity and unsaleable eggs) were monitored daily. Body weight, feed consumption and egg quality parameters[31] were measured at 28 and 56 days. At the end of the study, one bird per pen was randomly selected for blood sampling, including haematological[27] and biochemical[24] analyses. The same bird was submitted to a complete necropsy (including examination for gross abnormalities, relative weight of liver, spleen and kidneys); tissue samples (liver, kidney and upper gut) were taken for histological examination. The pen was the experimental unit for statistical purposes and the basic statistical model use was ANOVA; means were compared among treatments with Tukey adjustment; significant differences were declared at $p \leq 0.05$. No statistical analysis was done for the gross pathology or the histopathology observations.

Lymphocyte and monocyte counts were significantly different in the threefold group compared to the control. A significant decrease was also observed in the laying rate in the threefold group compared to the control (88.3% vs 93.3% in the unsupplemented group). No significant body weight and/or organs/tissue weight differences were detected between treatment groups following gross pathology observation. Several animals had liver discoloration and friability, corresponding to vacuolisation of hepatocytes; however, the distribution of animals with these lesions within all experimental groups suggests that no relationship with the treatment did exist. Egg quality parameters

[28] Technical Dossier/Supplementary Information/Tolerance Turkey.

[29] Mean corpuscular haemoglobin concentration, mean corpuscular haemoglobin, mean corpuscular volume, haematocrit, haemoglobin, erythrocytes, platelets, leucocytes, eosinophils, basophils, lymphocytes, monocytes, heterophils.

[30] Technical Dossier/Supplementary Information/Tolerance Hens.

[31] Egg yolk colour expressed on the Roche Yolk Color Fan scale; Haugh Units; Shell % (shell weight/egg weight); Shell Index (g shell/100 cm^2).

at the end of each period did not show any differences among the treatments, nor did the percentage of eggs classified into each size category.

No negative effects were observed at the recommended supplementation level of 500 mg/kg.

3.2.1.2. Literature search

The applicant provided two sets of literature search to further support the safety of the additive for the target animals. From the first literature search (databases examined: CAB Abstract and Medline; period covered: 2005–2016),[32] the applicant finally extracted five studies considered as relevant: two for piglets, two for chickens for fattening and one for turkeys. In the second literature search (databases examined: Medline (timespan: 2005–2016), Web of Science (timespan: 1900–2017); EFSA website),[33] the applicant identified three studies relevant to the assessment of safety in sows.

The studies reported in these scientific papers are summarised below.

Studies in piglets

Gheler et al. (2009) performed a study in piglets to investigate the effects of high benzoic acid supplementation (up to 7,500 (3 × maximum recommended dose) mg/kg complete feed) on the performance of animals. The lack of an appropriate negative control (experiment designed with a control diet with fumaric acid, levels used not found), makes the study not useful for the purposes of this assessment.

Gräber et al. (2012) investigated the effects of benzoic acid on the performance of piglets. A total of 120 hybrid piglets (3 weeks of age) [(German Landrace × German Edelschwein) × Pietrain] were used. Piglets were fed prestarter and starter diets (based on wheat, barley, maize and soybean) containing benzoic acid at 0, 3,500 (about 1.5 × maximum recommended dose) and 5,000 (2 × maximum recommended dose) mg/kg; a fourth group was fed with 4,000 mg sodium benzoate/kg complete feed. Benzoic acid in the diets was analytically determined. Piglets were therefore divided in four groups of 15 replicates, with two piglets each. The study lasted 42 days. Body weight and feed intake were measured at day 14 and 42. Data were treated by one-way ANOVA. In the overall results, piglets receiving 3,500 and 5,000 mg benzoic acid/kg feed had significantly improved weight gain and feed intake compared to the control. Thus, the results from this study indicate that a dose of 5,000 mg/kg benzoic acid (2 × the proposed maximum dose for pigs) has no adverse effects in performance parameters in weaned piglets.

Studies in sows

From the studies extracted by the applicant, the FEEDAP Panel noted that only two studies could be used to assess safety of the additive for sows.

Lovatto et al. (2009) performed a study with 15 gestating-lactating sows (Large White × Landrace, first to eighth parity) during 23 days (from day 2 preparturition to day 21 lactation). The animals were used in a randomised complete block with three treatments (control diet containing high moisture maize, control diet with benzoic acid at 5,000 mg/kg (2 × maximum recommended dose) and control diet with 5,000 mg fumaric acid/kg feed) with five sows each. The results of this study showed that supplementation of corn diets with benzoic acid did not affect sow's backfat thickness or feed intake or average daily intake; the average daily weight gain and average weaning live weight were neither influenced by the treatments.

Kluge et al. (2010) conducted two experiments to examine the effect of benzoic acid in the diet of lactating sows on the urinary pH and nutrient digestibility. In the first experiment, conducted with 28 crossbred sows [(Large White×Landrace)×Hermitage], three levels of benzoic acid in the diet were tested (5,000 mg/kg (2 × maximum recommended dose), 10,000 mg/kg (4 × maximum recommended dose) and 20,000 mg/kg (8 × maximum recommended dose)). In the second experiment, conducted with 14 sows of the same breed, only one dietary level of benzoic acid (5,000 mg/kg) was used. In both experiments the sows were fed a wheat-soybean meal-based diet. Feed intake was monitored over the lactation period. Animals were not reported to have any adverse effect on this zootechnical parameter.

The FEEDAP Panel considers that these studies can be taken as supportive evidence only: the sample size was in general low and in two out of the three experiments examined only one dose was tested. In addition, in the experiments of Kluge et al. (2010) only a limited investigation of some zootechnical parameters was performed. Therefore no direct conclusions can be drawn from them.

[32] Technical Dossier/Section III/RCVS 2016.
[33] Technical Dossier/Supplementary Information/Tolerance Sow.

Studies in chickens for fattening

The effect of benzoic acid on the performance of chickens for fattening was evaluated at 0, 2,500 (5 × maximum recommended dose), 5,000 (10 × maximum recommended dose) and 7,500 (15 × maximum recommended dose) mg/kg complete feed (Józefiak et al., 2007). A total of 400 one-day-old male Cobb 500 chickens for fattening were allocated to 40 replicate floor pens (ten birds per replicate) and were offered experimental diets for 42 days. Diets (based on maize, wheat and soybean meal) were fed in mash form *ad libitum.* Feed intake and body weight were registered at weekly intervals, and the body weight gain and feed/gain ratio were calculated. There were no significant differences in weight gain or performance between the control group and the group that received 2,500 mg/kg benzoic acid. Significantly decreased body weight gain and increased feed/gain ratio were observed in the treatment groups receiving 5,000 and 7,500 mg/kg benzoic acid.

In a further study, the effects of supplementation of benzoic acid (included at 0, 1,000 (2 × maximum recommended dose) and 2,000 (4 × maximum recommended dose) mg/kg complete feed) in 240 one-day-old male Ross 308 chickens for a total of 42 days were studied (Józefiak et al., 2010). Birds were kept in floor pens (10 replicate pens per treatment, with eight birds per pen) and were offered *ad libitum* experimental diets (containing maize, wheat and soybean meal) in mash form. Feed intake and body weight were registered at weekly intervals, and the body weight gain and feed/gain ratio were calculated. The overall study results indicated that there were no significant differences in feed/gain ratio among the treatments, but a significantly decreased body weight gain was observed in the group receiving 2,000 mg benzoic acid/kg diet.

Taken together, the results of these two studies indicate that the dose of 1,000 mg/kg (twofold the proposed maximum dose of benzoic acid in poultry) has no adverse effects on performance parameters in chickens for fattening.

Studies in turkeys for fattening

A total of 180-day-old male Nicholas 300 birds were fed basal diets (based on maize and soybean) supplemented with benzoic acid at 0, 300 and 1,000 (2 × maximum recommended dose) mg/kg feed for 56 days (Giannenas et al., 2014). The birds were randomly allocated into three groups of 10 birds each with six replicates. At the end of the experiment, body weight gain and feed to gain ratio were similar between the control group and the group receiving 1,000 mg/kg; a significantly improved growth and feed/gain ratio was observed in the group receiving 300 mg/kg benzoic acid. The results from this study indicate that a dose of 1,000 mg/kg benzoic acid (2 × the proposed maximum dose for poultry) has no adverse effects on performance parameters in turkeys for fattening.

3.2.1.3. Conclusions on safety for the target species

The studies provided demonstrate that the use of the additive is safe for weaned piglets at the maximum supplementation level of 2,500 mg/kg feed, and for laying hens, turkeys and chickens for fattening at the level of 500 mg/kg feed. No conclusions could be drawn for suckling piglets and sows. Taking all the evidence together and the related uncertainties, the FEEDAP Panel identified a margin of safety of 3 for piglets, and, at least, 2 for turkeys and chickens for fattening; no margin of safety could be identified for laying hens. Therefore, the conclusions on the safety of the additive for weaned piglets can be extended to pigs for fattening and extrapolated to growing minor porcine species. The conclusions on the safety for chickens for fattening and turkeys for fattening can be extended to chickens reared for laying and turkeys reared for breeding and extrapolated to minor poultry species up to the point of lay. In the absence of a margin of safety in laying hens, no conclusions can be reached for minor poultry species for laying/breeding.

3.2.2. Safety for the consumer

Benzoic acid was assessed by 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/kg benzoic acid/kg bw per day as the high dose tested in a four-generation reproductive study; from this study, the Panel derived an acceptable daily intake (ADI) of 5 mg/kg bw per day (expressed as benzoic acid) using an uncertainty factor of 100 (EFSA ANS Panel, 2016).

The toxicokinetic of benzoic acid has been evaluated in its general aspects by the SCF (EC, 2002b), and by the FEEDAP Panel in several instances: its use as zootechnical additive, either *as is* in piglets (EFSA, 2005) or as component of a preparation in avian species for fattening and reared for laying (EFSA FEEDAP Panel, 2012b). More recently, the EFSA ANS Panel has evaluated benzoic acid and its

sodium and potassium salts as food additives (EFSA ANS Panel, 2016). Based on all available evidence, benzoic acid is rapidly metabolised and excreted and deposition in edible tissues is negligible.

The FEEDAP Panel notes that only few data exist on the potential of benzoic acid for deposition in eggs. However, due to the general knowledge on the chemical and toxicokinetics properties of the substance and of its metabolism in food-producing animals, including birds, the FEEDAP Panel considers it unlikely that deposition in eggs would occur to any significant extent.

The FEEDAP Panel reiterates its previous considerations that benzoic acid is proven to be rapidly metabolised with very low deposition, if any, in edible tissues of mammalian and avian farm species. 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).

3.2.2.1. Conclusions on safety for the consumer

Considering the body of evidence available, the use of benzoic acid in animal nutrition at the maximum proposed levels will not affect exposure of consumers to residues or metabolites of concern via food from treated animals. Therefore, the use of benzoic acid as a flavouring agent in feeds for pigs and poultry at the proposed maximum inclusion levels in feeds is safe for consumers.

3.2.3. Safety for the user

No specific studies were provided by the applicant.

In its assessment of 2002, the SCAN (EC, 2002b) concluded that benzoic acid is an irritant for the skin and eyes and is hazardous by inhalation. The FEEDAP Panel supports the overall SCAN position and recommendations.

The FEEDAP Panel considers that the additive under assessment is virtually devoid of any dusting potential; therefore, since no inhalation exposure is expected to occur, no risk by inhalation is foreseen.

The Scientific Committee on Consumer Products (SCCP) in its opinion on benzoic acid as cosmetic preservative reviewed the available evidence on animal and human studies on the benzoic acid potential for skin irritation and sensitisation (EC, 2005). According to the SCCP conclusions, 'Benzoic acid is a mild skin irritant' whereas it did not give 'indication of a sensitizing effect in animals, but occasionally very low positive reactions were recorded with humans in patch tests with benzoic acid. It has been suggested that these positive reactions are a non-immunologic contact urticarial'.

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 2.1. 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 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. Therefore, the FEEDAP considers that the additive is a skin and eye irritant; it may pose a risk of contact allergy reactions in sensitised individuals.

3.2.3.1. Conclusions on safety for the user

Owing to the unlikelihood of exposure, no risk to users upon inhalation of the additive is expected. The additive is not a skin sensitiser, but is a skin and eye irritant.

3.2.4. Safety for the environment

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

3.3. Efficacy

As benzoic acid is authorised in food as a flavouring compound (Flavis No 08.021), and its function in feed is essentially the same as that in food, no further demonstration of efficacy of benzoic acid as flavouring in feed is considered necessary.

4. Conclusions

The additive is safe for weaned piglets at the maximum supplementation level of 2,500 mg/kg feed, and for laying hens, turkeys and chickens for fattening at the level of 500 mg/kg feed. No conclusions could be drawn for suckling piglets and sows. A margin of safety of 3 for piglets, and, at least, 2 for turkeys and chickens for fattening could be calculated; no margin of safety could be identified for laying hens. Therefore, the conclusions on the safety of the additive for weaned piglets can be extended to pigs for fattening and extrapolated to growing minor porcine species. The conclusions on the safety for chickens for fattening and turkeys for fattening can be extended to chickens reared for laying and turkeys reared for breeding and extrapolated to minor poultry species up to the point of lay. In the absence of a margin of safety in laying hens, no conclusions can be reached for minor poultry species for laying/breeding.

Considering that benzoic acid is rapidly metabolised with very low deposition, if any, in edible tissues of mammalian and avian farm species and that foods of animal origin provide a very minor contribution if any to the overall dietary intake of benzoic acid, the use of benzoic acid as feed flavouring is not expected to pose a risk to consumer safety

Owing to the unlikelihood of exposure, no risk to users upon inhalation of the additive is expected. The additive is not a skin sensitiser, but is a skin and eye irritant.

The use of benzoic acid under the conditions proposed does not pose a risk to the environment.

As benzoic acid is authorised in food as a flavouring compound, and its function in feed is essentially the same as that in food, no further demonstration of efficacy of benzoic acid as flavouring in feed is necessary.

Documentation provided to EFSA

1) Benzoic acid. Sensory Additive for Pigs and Poultry. December 2016. Submitted by Novus Europe S.A./N.V.
2) Benzoic acid. Sensory Additive for Pigs and Poultry. Supplementary information. June 2017. Submitted by Novus Europe S.A./N.V.
3) Evaluation report of the European Union Reference Laboratory for Feed Additives on the Methods(s) of Analysis for Benzoic acid.
4) Comments from Member States.

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Abbreviations

ADI	acceptable daily intake
ANOVA	analysis of variance
ANS	EFSA Panel on Food Additives and Nutrient Sources Added to Food
bw	body weight
CAS	Chemical Abstracts Service
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
HPLC-UV	high-performance liquid chromatography coupled to spectrophotometric detection
IPCS	International Programme for Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
NOAEL	no-observed-adverse-effect-level
PCB	polychlorinated biphenyl
PCDD/F	polychlorinated dibenzo-*p*-dioxin/dibenzofuran
SCAN	Scientific Committee on Animal Nutrition
SCCP	Scientific Committee on Consumer Products
SCF	Scientific Committee on Food
TEQ	toxic equivalent
VICH	Veterinary International Conference on Harmonization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for Benzoic acid

In the current application authorisation is sought under article 4(1) for *benzoic acid* under the 'category'/'functional group' 2(b) 'sensory additives'/'flavouring compounds' according to the classification system of Annex I of Regulation (EC) No 1831/2003 for porcine and poultry species. Benzoic acid is a *feed additive* currently authorized as a chemically defined flavouring for all animal species and as zootechnical additive for porcine and poultry species. The feed additive is a white crystalline powder consisting of *benzoic acid*, with a minimum purity of 99%. It is intended to be incorporated through *premixtures* or directly in *feedingstuffs* at maximum inclusion levels of 500 or 2500 mg/kg of complete *feedingstuffs* depending on the target species.

For the characterisation of benzoic acid in the *feed additive* the Applicant submitted the European Pharmacopoeia method (01/2008.0066), where identification is based on melting point and solubility tests, while quantification is based on acid/base titration with 0.1 M sodium hydroxide. Even though no performance characteristics are provided, the EURL recommends this method for official control of *benzoic acid*.

For the quantification of benzoic acid in *premixtures* and *feedingstuffs* the Applicant submitted a single-laboratory validated and further verified method based on High Performance Liquid Chromatography coupled to spectrophotometric detection (HPLC-UV) previously evaluated and recommended by the EURL for official control of benzoic acid in premixtures and feedingstuffs.

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.