Adopted: 31 January 2024

DOI: 10.2903/j.efsa.2024.8638

efsa JOURNAL

SCIENTIFIC OPINION

Safety of a feed additive consisting of propyl gallate for all animal species (FEFANA ABL)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) | **Vasileios Bampidis** | **Giovanna Azimonti** | **Maria de Lourdes Bastos** | **Henrik Christensen** | **Mojca Durjava** | **Birgit Dusemund** | **Maryline Kouba** | **Marta López-Alonso** | **Secundino López Puente** | **Francesca Marcon** | **Baltasar Mayo** | **Alena Pechová** | **Mariana Petkova** | **Fernando Ramos** | **Roberto Edoardo Villa** | **Ruud Woutersen** | **Jaume Galobart** | **Matteo Innocenti** | **Georges Bories** | **Jürgen Gropp**

Correspondence: feedap@efsa.europa.eu

Abstract

Following a request from the European Commission, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety of propyl gallate as a technological feed additive for all animal species. In its previous opinions on the safety and efficacy of the product, the FEEDAP Panel could not conclude on a safe level of propyl gallate for cats and on the safety for the consumer. Based on the new data provided, the FEEDAP Panel concluded that propyl gallate at a maximum concentration of 71 mg/kg complete feed is safe for cats. Propyl gallate is considered safe for the consumer when used in complete feed for all animal species at the concentrations considered safe for the target species.

KEYWORDS

cats, consumer, propyl gallate, safety, technological additive

CONTENTS

Abstract 1
1. Introduction 3
1.1. Background and Terms of Reference as provided by the European Commission 3
1.2. Additional information 3
2. Data and Methodologies 3
2.1. Data 3
2.2. Methodologies 3
3. Assessment 4
3.1. Safety 4
3.1.1. Safety for cats 4
3.1.2. Safety for the consumer 5
3.1.2.1. Residue studies 5
3.1.2.1.1. Cattle for fattening. 5
3.1.2.1.2. Dairy cows. 6
3.1.2.1.3. Laying hens. 6
3.1.2.1.4. Salmonids. 6
3.1.2.2. Assessment of consumer exposure and consumer safety assessment 7
3.1.2.3. Conclusions on safety for the consumer 8
4. Conclusions 8
Abbreviations 8
Conflict of interest 8
Requestor 8
Question number 8
Copyright for non-EFSA content 8
Panel members 8
Legal notice 8
References 8
Appendix A 10

1 | INTRODUCTION

1.1 | Background and Terms of Reference as provided by the European Commission

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 hereof defines the terms of the authorisation by the Commission.

The applicant FEFANA ASBL[2] is seeking a Community authorisation of propyl gallate as a feed additive to be used as antioxidant for all animal species (Table 1).

TABLE 1 Description of the additive.

Category of additive	Technological additive
Functional group of additive	Antioxidants
Description	Propyl gallate
Target animal category	All animal species
Applicant	FEFANA ASBL
Type of request	New opinion

On 2 July 2020, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ('Authority'), in its opinion on the safety and efficacy of the product, could not conclude on a safe level for cats and on the safety for the consumer. Also, the FEEDAP Panel did not see a reason for the use of propyl gallate as an antioxidant in water for drinking.

The Commission gave the possibility to the applicant to submit supplementary information and data in order to complete the assessment and to allow a revision of the EFSA's opinion. The new data have been received on 31 March 2023 and the applicant has been requested to transmit them to EFSA as well.

In view of the above, the Commission asks EFSA to deliver a new opinion on propyl gallate as a feed additive for all animal species based on the supplementary information and data submitted by the applicant, in accordance with Article 29(1)(a) of Regulation (EC) No 178/2002.

1.2 | Additional information

Propyl gallate (E310) is authorised as a technological feed additive (functional group: antioxidants) in feeds for all animal species.[3]

EFSA issued an opinion on the safety and efficacy of propyl gallate (EFSA FEEDAP Panel, 2020).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of supplementary information[4] to a previous application on the same product.[5] The dossier was received on 20 April 2023 and the general information and supporting documentation are available in Open.EFSA at https://open.efsa.europa.eu/questions/EFSA-Q-2023-00231.

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, other scientific reports and experts' knowledge, to deliver the present output.

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of propyl gallate is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the assessment of the

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2]Name and address of the applicant (FEFANA asbl, Rue de Treves 45, 1040 Brussels, Belgium).

[3]Commission Directive of 12 April 1991 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs (91/248/EEC). OJ L 124, 18.05.1991, p. 1.

[4]Dossier reference: EFSA-Q-2023-00231.

[5]Dossier reference: FAD-2010-0078.

[6]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.

safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b).

3 | ASSESSMENT

Propyl gallate is intended to be used as a technological additive (functional group: antioxidants) in feed for all animal species, with a maximum content of 40 mg/kg complete feed for food-producing animals and 100 mg/kg complete feed for non-food-producing animals.

The additive, which is specified to contain ≥ 97% propyl gallate, was re-evaluated by the FEEDAP Panel in 2020 (EFSA FEEDAP Panel, 2020). In that opinion, the additive was fully characterised and the Panel concluded on safe levels for all animal species except cats. However, in the absence of reliable residue data, the Panel could not conclude on the safety for the consumers. The Panel concluded that the additive is irritant to skin and eyes, is a dermal sensitiser and hazardous by inhalation, and that it is safe for the environment.

In order to address the limitations in the data submitted in the original application, the applicant provided new data on the safety for cats and on the residues of the additive in food of animal origin. The applicant asked to set a maximum content in feed for cats of 71 mg propyl gallate/kg complete feed.[7]

3.1 | Safety

3.1.1 | Safety for cats

In its previous opinion, the FEEDAP Panel concluded on the maximum safe concentration of propyl gallate in feed for all animal species based on the results of a subchronic oral toxicity study. However, considering that cats are particularly inefficient in glucuronidation of many phenolic and aromatic compounds, due to the known lack of at least two functional uridindiphospho-glucuronyltransferase (UGT)s isoforms, in the absence of specific data, the Panel could not conclude on the safety of propyl gallate for cats. In the current application, the applicant provided a tolerance study in cats, which is described below.

After an adaptation period of 4 weeks, a total of 60 healthy cats (mixed sex, between 1 and 9 years old, body weight 2–7 kg, domestic short/long hair breeds) were allocated in groups of 15 cats, to four dietary treatments: a basal diet without supplemented propyl gallate or the basal diet supplemented with 71 (1× use level), 355 (5×) or 710 (10×) mg propyl gallate/kg feed, respectively. The analysis of the content of propyl gallate in the feed did not fully confirm the intended levels: 74, 287 and 546 mg propyl gallate/kg feed for the use level, the 5x and the 10x, respectively.

The basal diet consisted mainly of [redacted] and contained by analysis approximately [redacted] without relevant differences between the experimental diets. Propyl gallate was applied as a spray post-extrusion. The cats were fed two 30-minute meals per day (50% of maintenance energy requirement each) while housed individually and were given ad libitum access to deionised filtered water for drinking.

Individual food intake was measured at each meal daily. Body weight and body condition scores were recorded weekly. Blood samples were collected at day 1 and on days 7, 14 and 28 of the study from all cats. Haematology[8] and measurement of Lactate Dehydrogenase (LDH) and Serum Amyloid A (SAA) were made at baseline and at study end, and biochemistry[9] at baseline and on days 7, 14, 21, and 28.

The study was conducted consecutively, starting with a group of 20 cats (5 from each experimental group), the remaining cats were fed the basal diet, and since no adverse effects (including haematology and serum biochemistry) were identified on day 7, the rest of the cats were recruited onto the study at day 11 and 12 post-study start, and then kept in the study until the completion of the 28-day experimental period.

Haemoglobin, red blood cells (RBC), feed intake and body weight were modelled using linear mixed effects models and diet as the main fixed effect. Age, weight, sex and room were also included as fixed effects. Regarding haemoglobin and RBC, the results of the treated groups were compared to those of the control diet; a two one-sided test methodology (TOST) was used to test equivalence, with the limits specified as a fold change of 1.2. Regarding feed intake and body weight, a TOST methodology was used to test equivalence of the changes between baseline and 28 days for each treatment group.

No cats were removed from the trial. No effects on health, behaviour or faecal consistency were observed. Sporadic incidences of vomiting were observed: 1 cat fed the control diet, and 6, 3 and 1 cats fed the diets containing 74, 287 and 546 mg propyl gallate/kg feed, respectively. Thus, no dose–response effect of dietary propyl gallate levels on the number of vomiting incidences was observed.

[7] Supplementary information December 2023.

[8] RBC; Haematocrit; Haemoglobin (g/L); MCV; MCH; MCHC; RDW; Reticulocyte; Reticulocytes; Reticulocyte Haemoglobin; WBC; Neutrophils; Lymphocytes; Monocytes; Eosinophils; Basophils; Neutrophils; Lymphocytes; Monocytes; Eosinophils; Basophils; Platelets; Fibrinogen; Prothrombin Time; Partial Thromboplastin Time.

[9] Glucose; symmetric dimethyl arginine (SDMA); Creatinine; Urea (BUN); Phosphorus; Calcium; Magnesium; Sodium; Potassium; Na:K Ratio; Chloride; Bicarbonate; Total protein; Albumin; Globulin; Albumin: Globulin ratio; ALT; AST; ALP; GGT; Bilirubin – Total; Bilirubin – Conjugated; Cholesterol; Triglyceride; Amylase; Lipase; Creatine Kinase.

Food intake and body weight on day 28 were significantly equivalent compared to the start of the study for all groups.

Haemoglobin and RBC values remained within the reference ranges,[10] with the exception of two cats fed the 10× overdose (one cat with RBC below (6.8×10^{12}/L) and one cat with RBC above (11.9×10^{12}/L) the reference range of 7.1–11.5×10^{12}/L). Significant equivalence between the control and the experimental groups on day 28 was observed for both endpoints.

Symmetric dimethyl arginine (SDMA) levels were above the upper reference range throughout the study for most cats. The equivalence between the control (day 1, 15.1 µg SDMA/dL; day 28, 15.5 µg SDMA/dL) and the groups with 74 and 546 mg propyl gallate/kg feed was confirmed by equivalence analysis. The group with 287 mg propyl gallate/kg feed showed higher value for SDMA compared to the control on day 28 (17.4 vs. 15.5 µg SDMA/dL); this result, however, was not dose dependent and is not considered as relevant. All data for creatinine and urea, remaining within the respective reference ranges, were equivalent between the control and the experimental groups on day 28.

Most of the haematological and routine biochemistry parameters were within the reference range and significantly equivalent between the treated groups and the control. Although there were a few parameters not significantly equivalent following 28 days of exposure (e.g. reticulocytes, monocytes, neutrophils, eosinophils, basophils, lymphocytes, glucose, AST, LDH) and/or outside the respective reference ranges (also at start and in the control group), these changes were not considered relevant. The endpoints were not affected in a clinically relevant magnitude or direction.

In conclusion, the results of the tolerance study indicate that a 28-day dietary exposure did not result in any adverse effects in adult cats fed diets with 93% dry matter and containing 74, 287 or 546 mg propyl gallate/kg. These concentrations would correspond, when considering a standardised complete feed with a dry matter content of 88%, to 70, 271, 516 mg propyl gallate/ kg complete feed, respectively. The FEEDAP Panel concludes that propyl gallate is safe at the use level of 71 mg/kg complete feed with a margin of safety of ~8.

3.1.2 | Safety for the consumer

In its opinion, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) (EFSA ANS Panel, 2014) proposed an acceptable daily intake (ADI) of 0.5 mg/kg bw per day for propyl gallate based on the no observed adverse effect level (NOAEL) of 135 mg/kg bw per day derived from a 90-day toxicity study in rats and applying an uncertainty factor (UF) of 300 for extrapolation from subchronic to chronic data and due to the limitations in the reproductive toxicity database. The ANS Panel concluded that 'The high level of exposure exceeded the ADI in adults and the elderly. However, given the conservatism of the exposure assessment, the Panel concluded that the use of propyl gallate as food additive at the current uses and use levels is not of safety concern'. The ANS Panel also noted that additional analytical data would be needed to refine the exposure assessment and that in case the 'refined exposure assessment remained greater than the ADI, or if additional uses and use levels were proposed, the Panel considered that given the uncertainties identified, additional toxicological data would be requested'.

In its previous opinion (EFSA FEEDAP Panel, 2020), the FEEDAP Panel considered that the ADI for propyl gallate of 0.5 mg/kg bw per day identified by the EFSA ANS Panel (EFSA ANS Panel, 2014) was applicable to assess the safety of propyl gallate for the consumer of foods of animal origin. In the same opinion, the FEEDAP Panel assessed residue studies aimed at quantifying the residues of propyl gallate and its two metabolites (gallic acid and 4-O-methyl gallic acid) in tissues of cattle for fattening, eggs and tissues of laying hens and milk of cows. However, the analytical method used was not considered of sufficient quality, and therefore, the results of the studies could not be used to estimate a consumer exposure.

In the current submission, new residue studies in cattle for fattening, laying hens (including eggs), salmonids and milk from dairy cows were submitted. In the four studies, the propyl gallate concentrations in feed for the respective species were in line with the maximum concentrations considered safe for the target species by the FEEDAP Panel (cattle for fattening, dairy cows and salmonids: 40 mg/kg, laying hens: 20 mg/kg) (EFSA FEEDAP Panel, 2020).

3.1.2.1 | *Residue studies*

3.1.2.1.1 | *Cattle for fattening*

After an adaptation period of 3 weeks, a total of 12 crossbred Holstein bulls (345 days of age, 483 kg bw) were allocated to two groups (in 6 pens with 1 bull each), fed a basal concentrate feed (consisting mainly of maize, corn gluten feed, barley, wheat and wheat middlings) or the basal concentrate supplemented with 40 mg propyl gallate/kg feed (confirmed by analysis) for 28 days. At the end of the study, all animals were slaughtered, and liver, kidney, muscle and fat samples were collected.

The residues of propyl gallate and its metabolites 4-O-methylgallate and gallic acid were determined in five or six samples of each tissue, using a validated LC–MS/MS analytical method. The results are shown in Table 2. In all tissues, concentrations of propyl gallate, 4-O-methylgallate and gallic acid were below the respective limits of quantification (LOQ) of the analytical method.

[10]Reference ranges as provided by the laboratory.

TABLE 2 Residues of propyl gallate, 4-O-methyl gallate and gallic acid (μg/kg fresh tissue) in cattle tissues from animals administered 30 mg propyl gallate/kg complete feed for 28 days.

Tissues (no. of samples)	Propyl gallate, (μg/kg)	4-O-methylgallate (μg/kg)	Gallic acid (μg/kg)
Liver (6)	< 11	< 11	< 26
Kidney (5)	< 40	< 42	< 92
Muscle (6)	< 15	< 11	< 24
Fat (5)	< 11	< 12	< 25

Abbreviation: <, below the respective LOQs.

3.1.2.1.2 | *Dairy cows*

A total of 16 lactating dairy cows (Holstein breed, between 24 and 60 months old, 662 kg bw, parity 1.6, days in milk (DIM) = 137), group housed, were included in the 28-day study, after an adaptation period of 10 days. All cows were fed the same totally mixed ration (TMR) (55% dry matter [DM]) consisting mainly of rye-grass silage, corn silage, wheat silage, corn meal, wheat meal and soybean meal. The cows were allocated to two treatments: a control group fed only the basal diet, and a treated group, in which the animals were fed daily, after morning milking, propyl gallate via a vegetable pill containing 1 g of propyl gallate. The dose was intended to correspond to 40 mg/kg DM assuming average DM intake of 25 kg. The TMR DM intake of the propyl gallate supplemented cows during the 28-day study period was 21.5 kg, to which 1 kg soybean was added in the milking parlour. This would result in a feed intake of approximately 25.5 kg complete feed and a propyl gallate concentration corresponding to the intended concentration. At day 28 of the study, two samples of 50 mL of pooled milk from the morning and afternoon milking were obtained and kept at −80°C until residue analyses.

Propyl gallate, 4-O-methylgallate and gallic acid were determined in milk using a validated LC–MS/MS analytical method. The results showed values below the respective LOQs for 4-O-methylgallate (< 9 μg/kg) and gallic acid (< 9 μg/kg). Propyl gallate was found to be below the LOQ of 20 μg/kg in six out of eight samples, and quantified at 28 and 62 μg/kg, respectively, in two other samples. The overall average concentration of propyl gallate in milk, calculated considering the LOQ as the measured concentration for the six samples in which it was below the LOQ, would be 26.3 (± 14.4) μg/kg.

3.1.2.1.3 | *Laying hens*

After an adaptation period of 15 days with an unsupplemented basal diet (consisting mainly of wheat, soybean and sunflower meal), a total of 20 laying hens (Hy-Line brown, 45 weeks old) were allocated in a randomised complete block design to two dietary treatments with 10 replicates each (1 hen/replicate). The control group was fed the unsupplemented basal diet, the propyl gallate group the basal diet supplemented with 20 mg propyl gallate/kg (confirmed by analysis) for 30 days.

The residues of propyl gallate and its metabolites 4-O-methylgallate and gallic acid were determined in eggs (from all the animals in the study), and samples of liver, kidney, muscle and fat (in six hens per group) using a validated LC–MS/MS analytical method. The results are shown in Table 3. In all tissues, concentrations of propyl gallate, 4-O-methylgallate and gallic acid were below the respective LOQs of the analytical method, as well as those of 4-O-methylgallate and gallic acid in eggs. Propyl gallate was only detected/quantified in eggs.

TABLE 3 Residues of propyl gallate, 4-O-methyl gallate and gallic acid (μg/kg fresh tissue) in eggs and hens' tissues from animals administered 25 mg propyl gallate/kg feed for 30 days.

Tissues (no. of samples)	Propyl gallate (μg/kg)	4-O-methylgallate (μg/kg)	Gallic acid (μg/kg)
Liver (6)	< 13	< 16	< 30
Kidney (6)	< 14	< 14	< 28
Muscle (6)	< 12	< 12	< 24
Skin/fat (6)	< 14	< 16	< 32
Whole eggs (10)	34.6 ± 9.0*	< 10	< 11

Abbreviation: <, below the respective LOQs.

*Average ± SD.

3.1.2.1.4 | *Salmonids*

A total of 90 Atlantic salmon (*Salmo salar*, Salmo Breed, 15 months old, 354 g bw, mixed sex) was allocated to three tanks of 30 fish each. The three groups were fed a basal diet without supplemented propyl gallate, or diets supplemented with 40 or 65 mg propyl gallate/kg feed (confirmed by analysis), respectively, for 30 days. Feed (extruded pellets), consisting mainly of vegetable protein (from soybeans and peas, wheat gluten), fish oil and rapeseed oil, fishmeal and wheat, was given three

times/day in slight excess using automatic belt feeders. Muscle samples were collected by filleting the left and right side fillet of 10 individual salmon per group at days 0, 16 and 30.

The residues of propyl gallate and its metabolites 4-O-methylgallate and gallic acid were determined in fish flesh using a validated LC–MS/MS analytical method. The results indicate that the residues in fish flesh were below the respective LOQs for (i) propyl gallate: < 11 μg/kg, (ii) 4-O-methylgallate: < 13 μg/kg and (iii) gallic acid: < 20 μg/kg, independently from the supplementation level and duration of exposure.

3.1.2.2 | *Assessment of consumer exposure and consumer safety assessment*

In the current assessment, the FEEDAP Panel performed an exposure assessment following the methodology described in the Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a) (Appendix A), using the residue data in edible tissues from cattle for fattening, in eggs and edible tissues/organs from laying hens, in fish flesh and in milk from dairy cows (see Section 3.1.2.1). The exposure to the sum of propyl gallate and its metabolites was calculated based on the highest reliable percentile (HRP) of food consumption (raw agricultural food commodities), expressed in mg/kg bw per day for the different population categories and compared with the ADI of 0.5 mg/kg bw per day established by the EFSA ANS Panel (EFSA ANS Panel, 2014). The propyl gallate total residue (TR) was calculated as the sum of the respective residue data for propyl gallate, 4-O-methylgallate and gallic acid, for each tissue/product considered. When results of the analysis indicated residue concentrations < LOQ, the LOQ value was considered and used for the estimate of the exposure. The input data of propyl gallate TR content used to estimate exposure are reported in Table 4.

TABLE 4 Input data on propyl gallate total residue (sum of propyl gallate and its metabolites 4-O-methylgallate and gallic acid) content in food of animal origin used for the consumer exposure assessment.

Animal product	Sum of propyl gallate and its metabolites 4-O-methylgallate and gallic acid (mg/kg wet tissue/product)
Birds fat tissue	0.062
Birds liver	0.059
Birds meat[a]	0.049
Birds offals and slaughtering products (other than liver)[b]	0.056
Mammals fat tissue	0.048
Mammals liver	0.048
Mammals meat[c]	0.050
Mammals offals and slaughtering products (other than liver)[b]	0.174
Fish flesh	0.044
Milk	0.073
Whole eggs	0.074

[a]Calculated by default as 90% muscle and 10% skin + fat.
[b]Kidney values taken by default.
[c]Calculated by default as 80% muscle and 20% fat tissue.

The results of the dietary exposure to propyl gallate and its metabolites for the different population categories from the use of propyl gallate as a feed additive are reported in Table 5.

TABLE 5 Chronic human dietary exposure to propyl gallate deriving from the use of propyl gallate as feed additive. Maximum highest reliable percentile expressed in mg/kg bw per day.

Population class	Maximum highest reliable percentile	% ADI*
Infants	0.0093	1.9
Toddlers	0.0092	1.8
Other children	0.0119	2.4
Adolescents	0.0046	0.9
Adults	0.0025	0.5
Elderly	0.0023	0.5
Very elderly	0.0025	0.5

*ADI: Acceptable daily intake: 0.5 mg/kg body weight and day.

The exposure of the consumer to propyl gallate and its residues from tissues and products of animals fed the additive ranged from 0.5% to 2.4% of the ADI. The population class with the highest exposure is 'other children' with an intake amounting to about 2.4% of the ADI; the exposure of the population classes adults, elderly and very elderly ranged around

0.5% of the ADI. The FEEDAP Panel considers that the contribution of the residues of the additive in food of animal origin to the total human exposure to propyl gallate (and its metabolites) is negligible, in particular for those population classes (adults and elderly) for which a possible exceedance of the exposure compared to the ADI via the food additive use was identified by the ANS Panel (EFSA ANS Panel, 2014). Taking into account the results of the residue analysis and the consequent exposure of the consumer, the FEEDAP Panel does not consider that the absence of information on residue in tissues from other animal species (e.g. pigs, chickens for fattening) is a limitation for the assessment of the consumer safety.

3.1.2.3 | *Conclusions on safety for the consumer*

The FEEDAP Panel considers that the use of propyl gallate in feeds for all animal species at the concentrations considered safe for the target species is of no concern for the safety of the consumer.

4 | CONCLUSIONS

Based on the results of a tolerance study, the FEEDAP Panel conclude that propyl gallate at a maximum concentration of 71 mg/kg complete feed is safe for cats.

The use of propyl gallate in animal nutrition at the concentrations in complete feed considered safe for the target species is of no concern for consumer safety.

ABBREVIATIONS

ADI	acceptable daily intake
ANS	EFSA Scientific Panel on Additives and Nutrient Sources added to Food
BW	body weight
DM	dry matter
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
LOQ	limit of quantification
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
NOAEL	no observed adverse effect level

CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

EFSA-Q-2023-00231

COPYRIGHT FOR NON-EFSA CONTENT

PANEL MEMBERS

Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Mojca Durjava, Birgit Dusemund, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Roberto Edoardo Villa, and Ruud Woutersen.

LEGAL NOTICE

REFERENCES

EFSA ANS Panel (EFSA Panel on Food additives and Nutrient Sources added to Food). (2014). Scientific opinion on the re-evaluation of propyl gallate (E 310) as a food additive. *EFSA Journal*, *12*(4), 3642. https://doi.org/10.2903/j.efsa.2014.3642

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Innocenti, M. L. (2017a). Guidance on the assessment of the safety of feed additives for the consumer. *EFSA Journal*, *15*(10), 5022. https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen, G., Aquilina, G., Azimonti, G., Bampidis, V., Bastos, M. L., Bories, G., Chesson, A., Cocconcelli, P. S., Flachowsky, G., Gropp, J., Kolar, B., Kouba, M., López-Alonso, M., López Puente, S., Mantovani, A., Mayo, B., Ramos, F., Saarela, M., … Martino, L. (2017b). Guidance on the assessment of the safety of feed additives for the target species. *EFSA Journal*, *15*(10), 5021. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Kos Durjava, M., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Aquilina, G., … Innocenti, M. L. (2020). Scientific opinion on the safety and efficacy of propyl gallate for all animal species. *EFSA Journal*, *18*(4), 6069. https://doi.org/10.2903/j.efsa.2020.6069

How to cite this article: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Durjava, M., Dusemund, B., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Villa, R. E., Woutersen, R., Galobart, J., Innocenti, M., … Gropp, J. (2024). Safety of a feed additive consisting of propyl gallate for all animal species (FEFANA ABL). *EFSA Journal*, *22*(2), e8638. https://doi.org/10.2903/j.efsa.2024.8638

APPENDIX A

Detailed results of chronic exposure calculation

TABLE A.1 Chronic dietary exposure of consumers to residues of propyl gallate and its metabolites 4-O-methylgallate and gallic acid per population class, country and survey (mg/kg body weight per day) based on residue data.

Population class	Survey's country	Number of subjects	Highest reliable percentile value	Highest reliable percentile description
Infants	Bulgaria	523	0.00934	95th
Infants	Germany	142	0.00496	95th
Infants	Denmark	799	0.00717	95th
Infants	Finland	427	0.00575	95th
Infants	Italy	9	0.00239	50th
Infants	United Kingdom	1251	0.00455	95th
Toddlers	Belgium	36	0.00791	90th
Toddlers	Bulgaria	428	0.00774	95th
Toddlers	Germany	348	0.00729	95th
Toddlers	Denmark	917	0.00789	95th
Toddlers	Spain	17	0.00475	75th
Toddlers	Finland	500	0.00920	95th
Toddlers	Italy	36	0.00619	90th
Toddlers	Netherlands	322	0.00683	95th
Toddlers	United Kingdom	1314	0.00753	95th
Toddlers	United Kingdom	185	0.00735	95th
Other children	Austria	128	0.01194	95th
Other children	Belgium	625	0.00700	95th
Other children	Bulgaria	433	0.00628	95th
Other children	Germany	293	0.00607	95th
Other children	Germany	835	0.00452	95th
Other children	Denmark	298	0.00589	95th
Other children	Spain	399	0.00467	95th
Other children	Spain	156	0.00524	95th
Other children	Finland	750	0.00673	95th
Other children	France	482	0.00638	95th
Other children	Greece	838	0.00617	95th
Other children	Italy	193	0.00496	95th
Other children	Latvia	187	0.00466	95th
Other children	Netherlands	957	0.00558	95th
Other children	Netherlands	447	0.00467	95th
Other children	Sweden	1473	0.00555	95th
Other children	Czechia	389	0.00684	95th
Other children	United Kingdom	651	0.00485	95th
Adolescents	Austria	237	0.00346	95th
Adolescents	Belgium	576	0.00243	95th
Adolescents	Cyprus	303	0.00210	95th
Adolescents	Germany	393	0.00335	95th
Adolescents	Germany	1011	0.00247	95th
Adolescents	Denmark	377	0.00287	95th
Adolescents	Spain	651	0.00269	95th
Adolescents	Spain	209	0.00302	95th
Adolescents	Spain	86	0.00221	95th
Adolescents	Finland	306	0.00320	95th
Adolescents	France	973	0.00331	95th
Adolescents	Italy	247	0.00292	95th
Adolescents	Latvia	453	0.00309	95th

TABLE A.1 (Continued)

Population class	Survey's country	Number of subjects	Highest reliable percentile value	Highest reliable percentile description
Adolescents	Netherlands	1142	0.00304	95th
Adolescents	Sweden	1018	0.00337	95th
Adolescents	Czechia	298	0.00460	95th
Adolescents	United Kingdom	666	0.00239	95th
Adults	Austria	308	0.00240	95th
Adults	Belgium	1292	0.00210	95th
Adults	Germany	10,419	0.00221	95th
Adults	Denmark	1739	0.00194	95th
Adults	Spain	981	0.00211	95th
Adults	Spain	410	0.00206	95th
Adults	Finland	1295	0.00253	95th
Adults	France	2276	0.00220	95th
Adults	Hungary	1074	0.00174	95th
Adults	Ireland	1274	0.00174	95th
Adults	Italy	2313	0.00180	95th
Adults	Latvia	1271	0.00186	95th
Adults	Netherlands	2055	0.00213	95th
Adults	Romania	1254	0.00173	95th
Adults	Sweden	1430	0.00203	95th
Adults	Czechia	1666	0.00226	95th
Adults	United Kingdom	1265	0.00161	95th
Elderly	Austria	67	0.00175	95th
Elderly	Belgium	511	0.00228	95th
Elderly	Germany	2006	0.00213	95th
Elderly	Denmark	274	0.00190	95th
Elderly	Finland	413	0.00218	95th
Elderly	France	264	0.00188	95th
Elderly	Hungary	206	0.00177	95th
Elderly	Ireland	149	0.00203	95th
Elderly	Italy	289	0.00152	95th
Elderly	Netherlands	173	0.00191	95th
Elderly	Netherlands	289	0.00183	95th
Elderly	Romania	83	0.00143	95th
Elderly	Sweden	295	0.00196	95th
Elderly	United Kingdom	166	0.00175	95th
Very elderly	Austria	25	0.00130	75th
Very elderly	Belgium	704	0.00249	95th
Very elderly	Germany	490	0.00228	95th
Very elderly	Denmark	12	0.00122	75th
Very elderly	France	84	0.00181	95th
Very elderly	Hungary	80	0.00200	95th
Very elderly	Ireland	77	0.00180	95th
Very elderly	Italy	228	0.00163	95th
Very elderly	Netherlands	450	0.00192	95th
Very elderly	Romania	45	0.00160	90th
Very elderly	Sweden	72	0.00220	95th
Very elderly	United Kingdom	139	0.00204	95th