Adopted: 1 February 2024

DOI: 10.2903/j.efsa.2024.8642

efsa JOURNAL

SCIENTIFIC OPINION

Modification of the terms of authorisation regarding the maximum inclusion level of a feed additive consisting of nonanoic acid for all pigs and poultry species (Anitox Corporation)

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** | **Jordi Ortuño Casanova** | **Matteo Lorenzo Innocenti** | **Paola Manini** | **Maria Vittoria Vettori** | **Fabiola Pizzo**

Correspondence: feedap@efsa.europa.eu

Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the proposed modification of the terms of the authorisation regarding the maximum inclusion level of a feed additive consisting of nonanoic acid for all pigs and poultry species. Nonanoic acid is currently authorised for use as a sensory additive (functional group: flavouring compounds) for all animal species at a recommended maximum content of 5 mg/kg complete feed. The applicant is requesting a modification of the authorisation to increase the recommended maximum content of the active substance from 5 to 100 mg/kg complete feed for all poultry and pig species. In support of the safety of the additive at the new proposed level, the applicant provided tolerance trials in the target species. The FEEDAP Panel concludes that nonanoic acid is safe for all growing poultry species and Suidae at 100 mg/kg feed. The Panel cannot conclude on the safety of the new proposed level (100 mg/kg complete feed) for laying hens, turkeys for breeding, minor poultry species for laying/breeding and reproductive Suidae. However, FEEDAP Panel considered that nonanoic acid is safe at 10 mg/kg complete feed in laying hens, turkeys for breeding, minor poultry species for laying/breeding and 20 mg/kg complete feed for reproductive Suidae. The use of the feed additive in animal nutrition under the conditions of use proposed is of no concern for the consumer and the environment. Due to the lack of data, the FEEDAP Panel cannot conclude on the potential of the additive to be a skin and eye irritant neither a dermal nor respiratory sensitiser. No further demonstration of efficacy is necessary.

KEYWORDS

flavouring compounds, poultry, safety, sensory additives, Suidae

CONTENTS

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 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States.

The European Commission received a request from Anitox Corporation[2] for the modification of the terms of the authorisation of the additive consisting of nonanoic acid when used as a feed additive for all poultry species and Suidae (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 13(3) (modification of the authorisation of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 10 March 2023.

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 feed additive consisting of nonanoic acid when used under the proposed conditions of use (see **Section 3.1.2**).

1.2 | Additional information

EFSA issued an opinion on the safety and efficacy of straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes (chemical group 1), including nonanoic acid, when used as flavourings for all animal species (EFSA FEEDAP Panel, 2013).

The additive is currently authorised as a sensory additive (flavouring compounds) for use for all animal species (2b08029).[3]

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[4] in support of the authorisation request for the use of nonanoic acid as a feed additive. The dossier was received on 8/9/2022 and the general information and supporting documentation is available at https://open.efsa.europa.eu/questions/EFSA-Q-2022-00547.

The confidential version of the technical dossier was subject to a target consultation of the interested Member States from 10 March 2023 to 10 June 2023 for which the received comments were considered for the assessment.

In accordance with Article 38 of the Regulation (EC) No 178/2002[5] and taking into account the protection of confidential information and of personal data in accordance with Articles 39 to 39e of the same Regulation, and of the Decision of EFSA's Executive Director laying down practical arrangements concerning transparency and confidentiality,[6] a non-confidential version of the dossier has been published on Open.EFSA.

According to Article 32c(2) of Regulation (EC) No 178/2002 and to the Decision of EFSA's Executive Director laying down the practical arrangements on pre-submission phase and public consultations, EFSA carried out a public consultation on the non-confidential version of the technical dossier from 14 December 2023 to 4 January 2024 for which no comments were received.

[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]NutraSteward (on behalf of Anitox Corporation), 20 Harcourt Street Dublin – Ireland.

[3]Commission Implementing Regulation (EU) 2017/53 of 14 December 2016 concerning the authorisation of butan-1-ol, hexan-1-ol, octan-1-ol, nonan-1-ol, dodecan-1-ol, heptan-1-ol, decan-1-ol, pentan-1-ol, ethanol, acetaldehyde, propanal, butanal, pentanal, hexanal, octanal, decanal, dodecanal, nonanal, heptanal, undecanal, 1,1-diethoxyethane, formic acid, acetic acid, propionic acid, valeric acid, hexanoic acid, octanoic acid, decanoic acid, dodecanoic acid, oleic acid, hexadecanoic acid, tetradecanoic acid, heptanoic acid, nonanoic acid, ethyl acetate, propyl acetate, butyl acetate, hexyl acetate, octyl acetate, nonyl acetate, decyl acetate, dodecyl acetate, heptyl acetate, methyl acetate, methyl butyrate, butyl butyrate, pentyl butyrate, hexyl butyrate, octyl butyrate, ethyl decanoate, ethyl hexanoate, propyl hexanoate, pentyl hexanoate, hexyl hexanoate, methyl hexanoate, ethyl formate, ethyl dodecanoate, ethyl tetradecanoate, ethyl nonanoate, ethyl octanoate, ethyl propionate, methyl propionate, ethyl valerate, butyl valerate, ethyl hex-3-enoate, ethyl hexadecanoate, ethyl *trans*-2-butenoate, ethyl undecanoate, butyl isovalerate, hexyl isobutyrate, methyl 2-methylbutyrate, hexyl 2-methylbutyrate, triethyl citrate, hexyl isovalerate and methyl 2-methylvalerate as feed additives for all animal species. OJ L 13, 17.1.2017.

[4]Dossier reference: FEED-2021-1574.

[5]Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–48.

[6]Decision available at: https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements

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' (elicitation) knowledge, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the nonanoic acid in animal feed are valid and applicable for the current application.[7]

In addition, the EURL was requested by the FEEDAP Panel to evaluate the method of analysis for the quantification of nonanoic acid in the feedingstuffs used in the tolerance studies (see Section 3.2.2).

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety of nonanoic acid is in line with the principles laid down in Regulation (EC) No 429/2008[8] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3 | ASSESSMENT

Nonanoic acid is currently authorised for use as a sensory feed additive (functional group: flavouring compounds) for all animal species at a recommended maximum content of 5 mg/kg complete feed.

The applicant is requesting a modification of the 'other provisions' of the authorisation to increase the recommended maximum content of the active substance up to 100 mg/kg complete feed for all poultry and pig species.

3.1 | Characterisation

3.1.1 | Characterisation of the additive

Nonanoic acid is a colourless oily liquid obtained by [redacted]. It is identified with the single Chemical Abstracts Service (CAS) number 112–05-0, the EU Flavour Information System (FLAVIS) number 08.029, the Council of Europe (CoE) number 29 and the Flavor Extract Manufacturers Association (FEMA) number 2784.

The chemical formula is $C_9H_{18}O_2$ and the molecular weight is 158.24 g/mol.

Its boiling point is at 254°C and viscosity at 20°C is 9.0 mm^2/s. It is insoluble in water (0.3 g/L) but soluble in vegetable oils and organic solvents (ethanol, hexane).[9]

The additive was characterised during the previous evaluation (EFSA FEEDAP Panel, 2013). The additional data provided in the context of this application is reported below.

The current authorisation of nonanoic acid sets a specification of a purity > 98%. The applicant has provided analytical data on three batches of the product reporting an average value of nonanoic acid of 98.2% (range: 98.1%–98.2%).[10] The analyses demonstrated that the product complies with the existing specifications.

The levels of arsenic, lead, mercury and cadmium were measured on the same three batches and were all below < 0.01 mg/kg except for a single batch which reported a value of 0.021 mg/kg for lead.[11] Iodine and iron were also analysed and the average values were 3.3 g/kg (range: 2.0–4.0 g/kg) and 0.063 mg/kg (range: 0.06–0.07 mg/kg), respectively.[12]

Polychlorinated dibenzo-*p*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), dioxin-like polychlorinated biphenyls (PCBs) and non-dioxin-like PCBs were analysed in three batches. All values were below the corresponding limits of quantification (LOQs). The calculated upper bound concentration was 0.160 pg WHO-PCDD/F-TEQ/g fat for the sum of

[7]Evaluation report available on the EU Science Hub https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en

[8]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.

[9]'ECHA 2020'.

[10]Annex_S-1A, Annex_S-1B, Annex_S-1C.

[11]RFI Apr_Qn 2_Annex_S-1D_CoA_HMs Dioxins&PCBs_3 Lots_CONF.pdf.

[12]Annex_S-1A, Annex_S-1B, Annex_S-1C.

dioxins, and 0.226 pg WHO PCCD/F + PCB-TEQ/g fat for the sum of dioxins and dioxin-like PCBs. The upper bound for the sum of non-dioxin-like PCBs was 0.60 ng/g fat (all expressed as TEQ in fat).[13,14]

The Panel considered that the amounts of the detected impurities do not raise safety concerns.

The applicant provided a study[15] to support stability of nonanoic acid when included at [redacted] in a premixture (3 batches), containing other flavouring compounds, stored at 27°C for 24 months. After the storage period, the loss on nonanoic acid was on average 0.05%.

3.1.2 | Conditions of use

The additive is currently authorised to be used in feed for all animal species without a minimum or maximum content. Under other provisions it is stated:

1. The additive shall be incorporated into the feed in the form of a premixture.
2. In the directions for use of the additive and premixtures, the storage and stability conditions shall be indicated.
3. The recommended maximum content of the active substance shall be 5 mg/kg of complete feedingstuff with a moisture content of 12%.
4. On the label of the additive, the recommended maximum content of the active substance in complete feed shall be indicated.
5. Where the maximum recommended content is exceeded; the name of the functional group, the name of the additive, the identification number and the added amount of the active substance shall be indicated on the labelling of the premixtures, feed materials and compound feedingstuff.

The applicant is requesting to increase the maximum recommended content from 5 to 100 mg/kg complete feed for all pigs and poultry species.

3.2 | Safety

In the previous assessment (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded that nonanoic acid is safe for all the animal species at 5 mg/kg complete feed based on a group no observed adverse effect level (NOAEL) of 120 mg/kg body weight (bw) per day derived from the toxicological data of sub-chronic studies available for several compounds in CG 1. The additive was also considered safe for the consumer and the environment. Regarding user safety, the FEEDAP Panel considered prudent, in absence of experimental data, to treat nonanoic acid as an irritant to skin, eyes and respiratory tract and as a skin sensitiser.

3.2.1 | Literature search

For the current assessment, a literature search was conducted by the applicant to identify any relevant data for the safety of nonanoic acid for the target species, the consumer, the user and the environment, with no limit time. Web of Science, PubMed and Google Scholar were used for the literature search. A specific search was also conducted in order to retrieve any previous assessments on nonanoic acid from international agencies (e.g. ECHA, JECFA, US EPA, OECD SIDS, NTIS). The keywords used and the inclusion and exclusion criteria applied through the search were provided by the applicant.[16]

One paper was identified as concerned with the safety of the additive for chickens (Cave, 1982) but was not considered relevant to the risk assessment, as only levels far above the maximum proposed use level (300x) were tested.

Some existing assessments were retrieved for the use of the additive as flavouring and fragrances. However, the toxicological data cited were from unpublished studies that were not made available to the FEEDAP Panel.

No relevant papers were identified to the safety for the consumers, the user and environment.

3.2.2 | Safety for the target species

The applicant submitted four tolerance trials conducted in chickens for fattening, laying hens, turkeys for fattening and weaned piglets to support the safety of the additive at the new maximum recommended use level of 100 mg/kg feed. However, in the trial in laying hens, it is acknowledged some issues during the blood sampling collection, which led to a

[13]RFI Apr_Qn 2_Annex_S-1D_CoA_HMs Dioxins&PCBs_3 Lots_CONF.pdf.

[14]Upper bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification. TEQ = toxic equivalency factors for dioxins, furans and dioxin-like PCBs established by WHO in 2005 (Van den Berg et al., 2006).

[15]RFI Apr_Qn 2_Annex_S-3_Finio Real Time Storage Stability Report_CONF.pdf.

[16]RFI Apr_Qn3_Annex III-1_Lit Search_Safety Data (Amended).

low number of samples available and high variability of the results in the analysed ones.[17] Therefore, the Panel considered that the blood haematology and biochemistry dataset provided was not reliable for the safety assessment. Considering that the maximum level of nonanoic acid tested was < 10× maximum use level proposed by the applicant, and this information is a requirement of the Guidance on the assessment of the safety of feed additives (EFSA FEEDAP Panel, 2018), the tolerance trial in hens was not considered further as evidence for the assessment.

The Panel noted that the recovery rates of nonanoic acid in the experimental feeds in all trials was low. The EURL assessed the in-house validated method of analysis for the quantification of nonanoic acid in feed for laying hens, chickens for fattening, turkeys for fattening and weaned piglets, and considered the method as appropriate and sound. Therefore, for all trials, the conclusions are based on the analytical content of the additive in feed, and not on the intended ones.

3.2.2.1 | *Chickens for fattening*

A total of 1100 male and female (50:50) one-day-old Ross 308 chicks were distributed to 50 floor-pens in groups of 22 chickens (mixed sexes), and randomly allocated to five groups (10 replicates per group).[18] Two basal mash feeds (starter, from 1 to 21 days; finisher, from 22 to 42 days) based on maize and soya bean meal were either not supplemented (control) or supplemented with nonanoic acid at 100 (1× maximum recommended use level), 300 (3×), 500 (5×) and 1000 (10×) mg/kg complete feed. The analyses of the experimental feeds showed recovery rates of nonanoic acid ranging from 24% to 50%; the maximum level tested being 2.4-fold the maximum recommended level.[19] The experimental feeds were offered ad libitum in mash form for 42 days.

The animal health status and mortality were monitored throughout the trial, and the most likely cause of death or reason for culling recorded. The body weight and feed consumption were registered on pen basis on Days 1, 7, 21 and 42. The average daily feed intake, average daily gain and feed-to-gain ratio calculated and corrected for mortality for the whole period. On Day 42, blood was sampled from one bird per pen for haematology[20] and clinical chemistry. [21] The same bird was killed, organs subjected to gross pathology [22] and tissues sampled, to histopathology.[23]

[redacted]

The health status of the animals was good during the whole trial. Overall mortality and culling were low (ranging from 0% to 2.27%), and no differences were observed between groups. The supplementation with nonanoic acid did not result in any adverse effects on any of the zootechnical parameters measured (values for the control group: average daily feed intake = 93.3 g, average daily gain = 54.9 g, body weight = 2.35 kg, or feed-to-gain ratio = 1.70). No significant effects on the blood haematology and biochemistry parameters analysed were observed in any of the supplemented groups compared with the control. The gross pathology and histopathology evaluation did not reveal any relevant lesion.

Based on the results of the tolerance trial and considering that no adverse effects were seen in chickens for fattening receiving the additive at analysed levels of 240 mg/kg feed, the Panel concludes that nonanoic acid is well tolerated by chickens for fattening at 100 mg/kg with a margin of safety of 2.4.[24] This conclusion can be extended to chickens reared for laying.

3.2.2.2 | *Turkeys for fattening*

[redacted][25] [redacted] were either not supplemented (control) or supplemented with nonanoic acid to provide 100 (1×), 300 (3×) or 1000 (10×) mg/kg complete feed. The analyses of the experimental feeds showed recovery rates of nonanoic acid ranging from 62% to 67%; the maximum level tested representing 6.3-fold the maximum recommended level.[26] [redacted]

[redacted]

[17] Annex III-3B_XAH2249 Final Report Layers_CONF.pdf.

[18] Bento et al 2021a.pdf.

[19] Nonanoic acid concentration in feed (mg/kg) = < 0.5, 50, 144 and 241, for control, 1×, 3× and 10× groups, respectively.

[20] Red blood cells, white blood cells, haemoglobin concentration, mean cell volume, differential leucocyte count.

[21] [redacted].

[22] [redacted].

[23] [redacted].

[24] The margin of safety is established based on the analytical recovery of nonanoic in the 10× feed.

[25] Annex_III-4B _Gi66 Final Report Turkeys.

[26] Nonanoic acid concentration in feed (mg/kg) = 7, 62, 202 and 630, for control, 1×, 3× and 10× groups, respectively. The EURL assessed the in-house validated method of analysis for the quantification of nonanoic acid in feed for laying hens, chickens for fattening, turkeys for fattening and weaned piglets. The EURL considered that the method has valid protocol and good performance characteristic.

[redacted][27] [redacted][28] However, considering that since a sufficient set of blood parameters were assessed in the study in chickens for fattening, the FEEDAP Panel considered that this limitation would not exclude the assessment of the present study. [redacted][29] [redacted]

The health status of the animals was good during the whole trial. Overall mortality and culling were low (2.2%) and not affected by treatment. The supplementation with nonanoic acid did not result in any adverse effects on any of the zootechnical parameters measured (values in the control group: average daily feed intake = 126.2 g, average daily gain = 75.5 g, body weight = 4.28 kg, feed-to-gain ratio = 1.67). The inclusion of nonanoic acid in the feed of turkeys showed no significant effects on the blood haematology and biochemistry parameters analysed, except for a lower alanine aminotransferase (ALT) activity in all supplemented groups (4.4, 4.1 and 4.3 U/L for 1×, 3× and 10×) compared to the control (5.0 U/L). The reduction of the ALT activity in serum at those levels is not considered an adverse effect, and thus, was not considered relevant. The gross pathology and histopathology evaluations did not reveal any relevant lesion.

No adverse effects were seen in turkeys fed diets with 630 mg nonanoic acid/kg feed.

3.2.2.3 | *Weaned piglets*

A total of 384 weaned piglets [Tempo × (Large White × Landrace)] [redacted] were blocked by sex and initial body weight and distributed in 64 pens of six pigs each, which were randomly allocated to four groups (16 replicates per group; eight of each sex).[30] [redacted] were either not supplemented (control) or supplemented with nonanoic acid at 100 (1×), 300 (3×) or 1000 (10×) mg/kg complete feed. The analyses of the experimental feeds showed recovery rates of nonanoic acid ranging from 58% to 72%; the maximum level tested being 7.2-fold the maximum recommended level.[31] [redacted] for 42 days.

[redacted] Thereafter, body weight and feed consumption were recorded [redacted] and the average daily feed intake, average daily gain, and feed-to-gain ratio [redacted]. On Day 42, two piglets per pen were randomly blood sampled for haematology[32] and biochemistry[33] analyses. One of those animals was killed, necropsied for gross pathology and organs and tissues were sampled.[34] The organs were weighted and subjected to histopathology.

[redacted]

The overall health status of the animals was good during the whole trial. Only one animal from the 10× group died during the trial, and the rate of veterinary treatments was low (< 1%). No adverse effects were observed in any of the zootechnical parameters (values for the control group: feed intake = 0.79 kg/day, average daily gain = 0.60 kg; final body weight 26.7 kg, feed-to-gain ratio = 1.33). Similarly, no significant differences were observed between treatments on the haematology and biochemistry parameters analysed, which were within normal physiological ranges, or in the gross pathology and histopathology.

Based on the results of the tolerance trial, in which no adverse effects were observed in weaned piglets fed diets with nonanoic acid levels up to 724 mg/kg feed, the Panel concludes that nonanoic acid is safe for weaned piglets at 100 mg/kg with a margin of safety of 7.2.[35] This conclusion can be extended to suckling piglets and pigs for fattening and extrapolated to minor growing porcine species.

[27] [redacted]

[28] [redacted]

[29] Liver, kidneys, spleen, gastrointestinal tract, lungs and heart.

[30] Annex_III-5B_1759 VOD-58 Final Report Piglets_CONF.pdf.

[31] Nonanoic acid concentration in feed (mg/kg) = < 12, 58, 193 and 724, for control, 1×, 3× and 10× groups, respectively.

[32] [redacted]

[33] [redacted]

[34] Stomach, liver, kidney, ileum and duodenum.

[35] The margin of safety is established based on the analytical recovery of nonanoic in the 10× feed.

3.2.2.4 | *Conclusions on the safety for the target species*

No adverse effects were observed in chickens for fattening when the test item was included at 240 mg/kg feed and in turkeys for fattening at 630 mg/kg feed. Considering all the data together, the FEEDAP Panel concludes that nonanoic acid is safe for chickens and turkeys for fattening at 100 mg/kg. This conclusion is extended to chickens and turkeys reared for laying/breeding and can be extrapolated to minor poultry species for fattening or reared for laying/breeding.

The Panel also concludes that the additive is safe in weaned piglets at 100 mg/kg feed. This conclusion can be extended to suckling piglets and pigs for fattening and extrapolated to minor growing porcine species.

In the absence of adequate data in the current application, the Panel cannot conclude on the safety of the new proposed level (100 mg/kg complete feed) for laying hens, turkeys for breeding, minor poultry species for laying/breeding and reproductive Suidae. However, the Panel notes that in the previous opinion (EFSA FEEDAP Panel, 2013), the safe concentration in feed for laying hens and sows was calculated to be 10 and at 20 mg/kg complete feed, respectively, using the NOAEL derived from a toxicological study. Therefore, the FEEDAP Panel considered that nonanoic acid is safe at 10 mg/kg complete feed in laying hens, turkeys for breeding, minor poultry species for laying/breeding and 20 mg/kg complete feed for reproductive Suidae.

3.2.3 | Safety for the consumer

In the previous assessment in 2013 (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded on the safety for the consumer, as follows: *Straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes are rapidly absorbed, distributed, metabolised and excreted. Mammals, birds and fish share a similar metabolic capacity to handle these compounds. Consequently, no safety concern would arise for the consumer from the use of these compounds up to the highest safe level in feeds*.

The FEEDAP Panel considers that the modification of the existing authorisation of the additive, as requested by the applicant, would not have any significant impact on the conclusions previously reached. Therefore, the Panel concludes that the use of nonanoic acid in feed for all poultry species and Suidae up to 100 mg/kg feed is safe for the consumer.

3.2.4 | Safety for the users

No data were provided by the applicant in support of the safety of the additive for the users. Due to the lack of data, the FEEDAP Panel cannot conclude on the potential of the additive to be a skin and eye irritant. No conclusions can be drawn on the potential of the additive to be a dermal and respiratory sensitiser.

3.2.5 | Safety for the environment

In the previous assessment in 2013 (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded on the safety for the environment, as follows: *The compounds considered to be safe for the target species are extensively metabolised by the target species and excreted as innocuous metabolites and carbon dioxide. Therefore, no risk for the safety for the environment is foreseen*.

The FEEDAP Panel considers that the modification of the existing authorisation of the additive, as requested by the applicant, would not have any significant impact on the conclusions previously reached.

3.3 | Efficacy

In the previous assessment (EFSA FEEDAP Panel, 2013), the FEEDAP Panel concluded that since nonanoic acid is used in food as a flavouring compound and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary. The FEEDAP Panel reiterates the same conclusions.

4 | CONCLUSIONS

The FEEDAP Panel concludes that nonanoic acid is safe for all growing poultry species and porcine at 100 mg/kg feed. The Panel cannot conclude on the safety of the new proposed level (100 mg/kg complete feed) for laying hens, turkeys for breeding, minor poultry species for laying/breeding and reproductive Suidae. However, FEEDAP Panel considered that nonanoic acid is safe at 10 mg/kg complete feed in laying hens, turkeys for breeding, minor poultry species for laying/breeding and 20 mg/kg complete feed for reproductive Suidae.

The use of the feed additive in animal nutrition under the conditions of use proposed is of no concern for the consumer and the environment.

Due to the lack of data, the FEEDAP Panel cannot conclude on the potential of the additive to be a skin and eyes irritant. No conclusions can be drawn on the potential of the additive to be a dermal and respiratory sensitiser.

Since nonanoic acid is used in food as flavouring and its function in feed is essentially the same as that in food, no further demonstration of efficacy is necessary.

ABBREVIATIONS

bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
CG	chemical group
CoE	Council of Europe
ECHA	European Chemicals Agency
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FEMA	Flavor Extract Manufacturers Association
FLAVIS	The EU Flavour Information System
FL-no	FLAVIS number
IUPAC	International Union of Pure and Applied Chemistry
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOQ	limit of quantification
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo-*p*-dioxin
PCDF	polychlorinated dibenzofurans
TEQ	toxic equivalents
WHO	World Health Organization

ACKNOWLEDGEMENTS

The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Daniel Pagès Plaza

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-2022-00547

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.

REFERENCES

Cave, N. (1982). Effect of dietary short-and medium-chain fatty acids on feedintake by chicks. *Poultry Science*, *61*, 1147–1153.

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

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed). (2013). Scientific opinion on the safety and efficacy of straight-chain primary aliphatic alcohols/aldehydes/acids, acetals and esters with esters containing saturated alcohols and acetals containing saturated aldehydes (chemical group 01) when used as flavourings for all animal species. *EFSA Journal*, *11*(4), 3169. https://doi.org/10.2903/j.efsa.2013.3169

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., … Innocenti, M. L. (2017b). Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal*, *15*(10), 5023. https://doi.org/10.2903/j.efsa.2017.5023

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. (2017c). 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), 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. (2018). Guidance on the assessment of the efficacy of feed additives. *EFSA Journal*, *16*(5), 5274. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Bastos, M., Christensen, H., Dusemund, B., Kouba, M., Kos Durjava, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Brock, T., de Knecht, J., … Azimonti, G. (2019). Guidance on the assessment of the safety of feed additives for the environment. *EFSA Journal*, *17*(4), 5648. https://doi.org/10.2903/j.efsa.2019.5648

Van den Berg, M., Birnbaum, L. S., Denison, M., De Vito, M., Farland, W., Feeley, M., Fiedler, H., Hakansson, H., Hanberg, A., Haws, L., Rose, M., Safe, S., Schrenk, D., Tohyama, C., Tritscher, A., Tuomisto, J., Tysklind, M., Walker, N., & Peterson, R. E. (2006). The 2005 World Health Organization reevaluation of human and Mammalian toxic equivalency factors for dioxins and dioxin-like compounds. *Toxicological Sciences : An Official Journal of the Society of Toxicology*, *93*(2), 223–241. https://doi.org/10.1093/toxsci/kfl055

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., Casanova, J. O., Innocenti, M. L. … Pizzo, F. (2024). Modification of the terms of authorisation regarding the maximum inclusion level of a feed additive consisting of nonanoic acid for all pigs and poultry species (Anitox Corporation). *EFSA Journal*, *22*(2), e8642. https://doi.org/10.2903/j.efsa.2024.8642