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Safety and efficacy of a feed additive consisting of acetic acid for all animal species

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Abstract

In 2012, the EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued an opinion on the safety and efficacy of acetic acid when used as a technological additive (preservative) for all animal species. The characterisation and condition of use of the additive are the same as those already assessed by the FEEDAP Panel in the previous opinion on acetic acid. Acetic acid produced with the new manufacturing process complies with the specifications set by Commission Regulation (EU) No 231/2012. The FEEDAP Panel considers that the conclusions reached in the previous assessment apply to the acetic acid produced by the new manufacturing process. The FEEDAP Panel concluded that the additive is considered safe for poultry, pigs and pet animals at a maximum concentration of 2.5 g acetic acid/kg complete feed (or 1 g/L water for drinking). The known high endogenous production of acetic acid in the ruminants shows that the tolerance of these target animals is considerably higher. No data is available for salmonids. The use of the additive in animal nutrition is of no concern for consumer safety. The risks for users handling the additive depend on the concentration and include skin, eyes, and respiratory tract irritation (10–25% solution) and corrosion (> 25% solution). The use of the additive as a feed additive is considered safe for the environment. The Panel concluded that the additive has a potential to be efficacious as preservative in feedingstuffs and water for drinking. The FEEDAP Panel has some reservations about the effectiveness of acetic acid as preservative in dry feedingstuffs with a typical moisture content of $\leq 12\%$.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

On 1 February 2012, the European Food Safety Authority (“the Authority”)’s Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted an opinion on the safety and efficacy of acetic acid as preservative for feed (EFSA FEEDAP Panel, 2012). That opinion was issued further to the submission of an application in accordance with Article 10(2) of the Regulation (EC) No 1831/2003 concerning acetic acid as an existing product.

On 27 February 2020, the Commission received information and data on a new manufacturing process to produce acetic acid (Table 1).

Table 1: Description of the substances

Category of additive	Technological additives
Functional group of additive	Preservative
Description	Acetic acid
Target animal category	All animal species
Type of request	New opinion

After a verification of the method already evaluated by the Authority in view of the above-mentioned opinion of 1 February 2012 it seems that the new manufacturing process apparently does not have the same characteristics as those described in the Authority’s opinion.

The relevant information and data have also been sent directly to the Authority by the operator in support of this application.²

In view of the above, the Commission requests the Authority to deliver a new opinion on whether the conditions for the authorisation laid down in Article 5 of Regulation (EC) No 1831/2003 are still met for the use of acetic acid as a feed additive belonging to the functional group of preservatives, based on an assessment of the information and data on a new method of production of the additive.

1.2. Additional information

Acetic acid is authorised in the European Union (EU) as a technological additive (functional group: preservatives; code: E260)³ and as a sensory additive (flavouring compounds; code: 2b08002; FLAVIS number 08.002) for use in feed for all animal species and categories.⁴

Acetic acid (E 260) is authorised in the EU as a food additive to Regulation (EC) No 1333/2008, belonging to group I additives.⁵ Its use is permitted in several food categories at *quantum satis*.

The European Food Safety Authority (EFSA) Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) adopted two opinions on the safety and efficacy of acetic acid, as a technological additive for all animal species (EFSA FEEDAP Panel, 2012) and as a feed flavouring (EFSA FEEDAP Panel, 2013).

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 LENZING AG. Werkstrasse 2, 4860, Lenzing, Austria.

³ Commission Directive of 8 July 1985 amending the Annexes to Council Directive 70/524/EEC concerning additives in feedingstuffs. OJ L 245, 12.9.1985, p. 1.

⁴ 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-butenate, 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, p. 1.

⁵ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1.

The EFSA Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) delivered in 2018 an opinion on the safety and efficacy of the organic acids lactic and acetic acids to reduce microbiological surface contamination on pork carcasses and pork cuts (EFSA CEP Panel, 2018).

The EFSA Panel on Food Additives and Flavourings (FAF) adopted in 2020 an opinion re-evaluating the safety of acetic acid as food additives (EFSA FAF Panel, 2020).

2. Data and methodologies

2.1. Data

The present assessment is based on the data submitted by the operator in the form of additional information⁶ following a previous application for the same product.⁷

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of acetic acid is in line with the principles laid down in Regulation (EC) No 429/2008⁸ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive under assessment is acetic acid and is intended to be used as a technological additive (functional group: preservative) in feedingstuffs and water for drinking for all animal species without restrictions.

The FEEDAP Panel assessed the safety and efficacy of acetic acid as a technological additive in a previous opinion (EFSA FEEDAP Panel, 2012). [REDACTED]

[REDACTED] The present opinion deals with a request to consider an additional manufacturing process to obtain acetic acid [REDACTED].

3.1. Characterisation

3.1.1. [REDACTED]

[REDACTED]

⁶ FEED dossier reference: FAD-2021-0013.

⁷ FEED dossier reference: FAD-2010-0161.

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.

3.1.2. Characterisation of the additive

Acetic acid (ethanoic acid, CH₃COOH, CAS 64-19-7, EINECS 200-58-7) is a colourless liquid which in its concentrated form is often referred to as glacial acetic acid. It has a molecular weight of 60.05 g/mol. Acetic acid is manufactured to meet the specification for the food additive (E 260) set by Commission Regulation (EU) No 231/2012 of not less than 99.8% (w/w) purity.⁹

Analytical data to confirm the specifications were provided for five batches of the additive.¹⁰ All the batches showed a content of 99.9% acetic acid and 0.02% of water (range 0.01–0.03%).

Commission Regulation (EU) No 231/2012 also sets maximum limits for process and other contaminants including non-volatile residue (not more than 100 mg/kg), formic acid ((including its salts and other oxidisable material) not more than 1,000 mg/kg), arsenic (not more than 1 mg/kg), lead (not more than 0.5 mg/kg) and mercury (not more than 1 mg/kg).

Analytical data from eight batches¹¹ of the additive showed that heavy metals (cadmium, lead and mercury) and arsenic were below the respective limits of detection (LODs)¹² and limit of quantification (LOQ).^{13,14} Fluorine was analysed in three batches (two of the previous ones,¹⁵ plus an additional one¹⁶) resulting below the LOQ.¹⁷

Formic acid was 0.03% (range 0.02–0.03%) while aldehydes, as acetaldehyde, and non-volatile residue were below the LOQ.¹⁸

Polychlorinated dibenzo-*p*-dioxin and dibenzofuran (PCDD/F) and dioxin-like polychlorinated biphenyls (DL-PCBs) determined in four batches of acetic acid (upper bond) were calculated to be 0.006 ng WHO-PCDD/F-TEQ/kg (range 0.001–0.006) and 0.025 ng WHO-PCB-TEQ/kg (range 0.010–0.040), respectively.^{19,20}

The FEEDAP Panel considers that the detected amounts of the above described undesirable substances do not raise safety concerns.

The additive produced with the new manufacturing process complies with the specification of the product already assessed by EFSA in 2012 (EFSA FEEDAP Panel, 2012).

3.1.3. Physical properties of the additive

The additive appears as a colourless solution with a density of 1.045 g/cm³ (at 25°C), viscosity of 0.0011 N·s/m² and a vapour pressure of 2.079 kPa (at 25°C). Acetic acid results highly soluble in water (602.9 g/L at 25°C).

3.1.4. Stability and homogeneity

The shelf life of three batches of the additive was tested when kept in brown, glass bottles for one year at ambient temperatures. No changes were observed in the concentration of acetic acid over storage. However, no certificates of analysis were provided.

No data were submitted on the stability of acetic acid in feedingstuffs or on its capacity to homogeneously distribute in feed.

3.1.5. Conditions of use

Acetic acid is intended for use in all feedstuffs and water for drinking without restrictions.

⁹ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council OJ L 83, 22.3.2012, p. 1–295.

¹⁰ Technical dossier/Annex II/Annexes/Annex II 1.03.

¹¹ The same five batches analysed for batch to batch variation plus three additional ones.

¹² Technical dossier/Annexes/Annex II 1.03 Limits of detection (LOD) for lead, mercury, cadmium and arsenic: 0.01 mg/kg.

¹³ Technical dossier/Annexes/Annex II 1.05 Limits of quantification (LOQ) in mg/kg additive: lead 0.006, mercury 0.004, cadmium 0.002 and arsenic 0.001.

¹⁴ Technical dossier/SIn_SPONTANEOUS_160421/Annexes/2020_undesirable substances_Acetic Acid_Extra report to Annex II.10.5. and 2021_undesirable substances_Acetic Acid_Extra report to Annex II.10.5. Limits of quantification (LOQ) in mg/kg additive: lead 0.001, mercury 0.001, cadmium 0.001 and arsenic 0.0029.

¹⁵ Technical dossier/SIn_SPONTANEOUS_160421/Annexes/2020_undesirable substances_Acetic Acid_Extra report to Annex II.10.5. and 2021_undesirable substances_Acetic Acid_Extra report to Annex II.10.5.

¹⁶ Technical dossier/Annex II/Annexes/Annex II 1.05.

¹⁷ Limit of quantification (LOQ) for fluorine: 10 mg/kg.

¹⁸ Technical dossier/Annex II/Annexes/Annex II 1.03 and Annex II 1.04 Limits of quantification (LOQ) for aldehyde as acetaldehyde and non-volatile residue: 0.001 wt%.

¹⁹ Technical dossier/Annex II/Annexes/Annex II 6.

²⁰ Technical dossier/SIn_SPONTANEOUS_160421/Annexes/PCB_Dioxins_Extra Info to Annex II.1.0.6.

Acetic acid is intended to be added to feed via a premixture to reach an inclusion level in the range of 200–2,500 mg/kg complete feedingstuffs.

4. Safety

The safety of acetic acid was already assessed by the FEEDAP Panel in its previous opinion (EFSA FEEDAP Panel, 2012). In that opinion, the Panel concluded that 'based on the comparison between consumer exposure to acetic acid and target animals exposure and the limited experimental data available for chickens and dogs fed diets containing acetic acid or its salts, that a maximum concentration of 2.5 g acetic acid/kg complete feed (or 1 g/L water for drinking) is safe for poultry, pigs and pet animals. The known high endogenous production of acetic acid in the ruminants shows that the tolerance of these target animals is considerably higher. No data are available for salmonids.

Considering the extensive and rapid metabolism of acetic acid and its salts, their use in animal nutrition is not expected to essentially contribute to human exposure.

Acetic acid and its salts are bulk industrial chemicals and the hazards for those handling these substances are well known and documented. The risks for those handling the free acid and therefore the risk phrases which appear in the material safety data sheet and on labels are dependent on concentration. Thus, in the EU the dilute acid (10–25%) is considered as an irritant, while at higher concentrations it is corrosive and, when concentrations exceed 90%, flammable.

[...]

The FEEDAP Panel concludes that the use of acetic acid [...] in animal production would not pose a risk to the environment'.

The additive's characterisation – which meets the specifications set by Commission Regulation (EU) No 231/2012 – and its conditions of use are the same as the ones already assessed by the FEEDAP Panel in the previous opinion on acetic acid (EFSA FEEDAP Panel, 2012). The Panel considers that the safety for the target species, consumers, users and environment would not be affected by the new manufacturing process.

5. Efficacy

The efficacy of acetic acid was already assessed by the FEEDAP Panel in its previous opinion (EFSA FEEDAP Panel, 2012). In that opinion the Panel had 'reservations about the effectiveness of acetic acid and its salts as preservatives in complete feedingstuffs with a typical moisture content of $\leq 12\%$. However, it is recognised that under practical conditions of storage the moisture content of all or part of the feed may rise above this level. Under these circumstances, the additive could be effective in preventing or reducing the extent of deterioration'.

The characterisation and the conditions of use of the additive are the same as the ones already assessed in the previous opinion. The Panel considers that the efficacy of the product would not be affected by the new manufacturing process and therefore, the same conclusions would apply to the acetic acid produced by this manufacturing process.

6. Conclusions

Acetic acid produced with the new manufacturing process complies with the specifications set by Commission Regulation (EU) No 231/2012. The FEEDAP Panel considers that the conclusions reached in the previous assessment apply to the acetic acid produced by the new manufacturing process.

The FEEDAP Panel concludes that a maximum concentration of 2.5 g acetic acid/kg complete feed (or 1 g/L water for drinking) is safe for poultry, pigs and pet animals. The known high endogenous production of acetic acid in the ruminants shows that the tolerance of these target animals is considerably higher. No data is available for salmonids.

Acetic acid used in animal nutrition is not expected to essentially contribute to human exposure.

The risks for users handling the additive depend on the concentration and include skin, eyes, and respiratory tract irritation (10–25% solution) and corrosion ($> 25\%$ solution).

The FEEDAP Panel concludes that the use of acetic acid, in animal production would not pose a risk to the environment.

Acetic acid has the potential to act as preservative in feedingstuffs and water for drinking. The FEEDAP Panel has some reservations about the effectiveness of acetic acid as preservative in dry feedingstuffs with a typical moisture content of $\leq 12\%$.

7. Documentation provided to EFSA/Chronology

Date	Event
17/03/2020	Reception mandate from the European Commission
19/02/2021	Dossier received by EFSA. Acetic acid Submitted by Lenzing AG
02/03/2021	Start of the scientific assessment
16/04/2021	Submission of spontaneous supplementary information
06/05/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CEP	EFSA Scientific Panel on Food Contact Materials, Enzymes and Processing Aids
DL-PCB	dioxin-like polychlorinated biphenyl
EINECS	European Inventory of Existing Chemical Substances
EURL	European Union Reference Laboratory
FAF	EFSA Scientific Panel on Food Additives and Flavourings
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
FLAVIS	The EU Flavour Information System
LOD	limit of detection
LOQ	limit of quantification
PCDD/F	polychlorinated dibenzo- <i>p</i> -dioxin and dibenzofuran
WHO	World Health Organization