



2024/1755

26.6.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/1755

of 25 June 2024

concerning the authorisation of acetic acid, calcium acetate and sodium diacetate as feed additives for fish

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances acetic acid, calcium acetate and sodium diacetate were authorised without a time limit in accordance with Directive 70/524/EEC, as feed additives for all animal species. Those substances were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of acetic acid, calcium acetate and sodium diacetate for fish. The applicant requested the additives to be classified in the additive category 'technological additive' and in the functional group 'preservatives'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 July 2023 ⁽³⁾ that acetic acid (and its salts) are safe for all fish at the maximum recommended level of 2 500 mg acetic acid/kg complete feed. The Authority concluded in its previous opinions of 1 February 2012 ⁽⁴⁾ and 6 May 2021 ⁽⁵⁾ that acetic acid, sodium diacetate and calcium acetate do not have an adverse effect on consumer safety or the environment and that the risks for users handling acetic acid depend on the concentration and include skin, eyes, and respiratory tract irritation (10–25 % solution) and corrosion (> 25 % solution) and that the salts of acetic acid are considered as strongly irritant and a particular risk for the eyes. The Authority further concluded that acetic acid and its salts have the potential to act as preservatives in feedingstuffs. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the above, the Commission considers that acetic acid, calcium acetate and sodium diacetate satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of those substances should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ EFSA Journal 2023;21(7):8176.

⁽⁴⁾ EFSA Journal 2012;10(2):2571.

⁽⁵⁾ EFSA Journal 2021;19(6):6615.

- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'preservatives', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. Acetic acid, calcium acetate and sodium diacetate, as authorised pursuant to Directive 70/524/EEC and premixtures containing these additives, which are produced and labelled before 16 January 2025 in accordance with the rules applicable before 16 July 2024 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for fish.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 16 July 2025 in accordance with the rules applicable before 16 July 2024 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing fish.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before 16 July 2026 in accordance with the rules applicable before 16 July 2024 may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing fish.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identi- fication number of the feed additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives								
1a260	Acetic acid	<i>Additive composition</i> Acetic acid ≥ 99,8 % Liquid form <i>Characterisation of the active substance</i> Acetic acid ≥ 99,8 % C ₂ H ₄ O ₂ CAS no 64-19-7 Water ≤ 0,15 % Non volatile matter ≤ 30 mg/kg Formic acid and its salts and other oxidisable material ≤ 0,5 g/kg Produced by chemical synthesis including cellulose production (as a by-product) <i>Method of Analysis</i> ⁽¹⁾ For the determination of acetic acid as total acetic acid in the feed additive, premixtures and compound feed: Ion Chromatography with Conductiv- ity Detection, IC-CD (EN 17294)	Fish	-	-	2 500	1. The mixture of different sources of acetic acid shall not exceed the per- mitted maximum levels in complete feedingstuffs. 2. For users of the additive and premix- tures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks resulting from its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. 3. In the directions for use of the addi- tive, premixture and related fee- dingstuffs, the following labelling provisions shall be indicated: 'The simultaneous use of different or- ganic acids is contraindicated where one or more of them is used at or near the maximum permitted con- tent'.	16 July 2034
⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en								

Identi- fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives								
1a262	Sodium diace- tate	<i>Additive composition</i> Sodium diacetate ≥ 97 % Solid form <i>Characterisation of the active substance</i> Sodium diacetate (anhydrous and trihydrate) NaC ₄ H ₇ O ₄ CAS no 126-96-5 Sodium acetate ≥ 58 % Acetic acid ≥ 39 % Water ≤ 2 % Formic acid and its salts and other oxidisable material ≤ 1 g/kg Produced by chemical synthesis <i>Method of Analysis</i> ⁽¹⁾ For the determination of sodium in the feed additive: EN ISO 6869: atomic absorption spectrometry (AAS) or EN 15510: inductively coupled plasma-atomic emis- sion spectrometry (ICP-AES) For the determination of sodium diacetate as total acetic acid in the feed additive, premixtures and compound feed: Ion Chromatography with Conductivity Detection, IC-CD (EN 17294)	Fish	-	-	2 500 (as acetic acid)	1. The mixture of different sources of acetic acid shall not exceed the permitted maximum levels in complete feedingstuffs. 2. For users of the additive and pre- mixtures, feed business opera- tors shall establish operational procedures and appropriate or- ganisational measures to address the potential risks resulting from its use. Where those risks cannot be eliminated by such proce- dures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. 3. In the directions for use of the additive, premixture and related feedingstuffs, the following la- belling provisions shall be indi- cated: 'The simultaneous use of different organic acids is contra- indicated where one or more of them is used at or near the maximum permitted content'.	16 July 2034
⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en								

Identi-fication number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of additive/kg of complete feedingstuff with a moisture content of 12 %			
Category: technological additives. Functional group: preservatives								
1a263	Calcium acetate (anhydrous and monohydrate)	<i>Additive composition</i> Calcium acetate ≥ 98,7 % Solid form <i>Characterisation of the active substance</i> Calcium acetate ≥ 98,7 % C₄H₆CaO₄ CAS no 62-54-4 Water ≤ 6 % Formic acid and its salts and other oxidisable material ≤ 1g/kg Produced by chemical synthesis <i>Method of Analysis ⁽¹⁾</i> For the determination of calcium in the feed additive: EN ISO 6869: atomic absorption spectrometry (AAS) or EN 15510: inductively coupled plasma-atomic emission spectrometry (ICP-AES) For the determination of calcium acetate as total acetic acid in the feed additive, premixtures and compound feed: Ion Chromatography with Conductivity Detection, IC-CD (EN 17294)	Fish	-	-	2 500 (as acetic acid)	1. The mixture of different sources of acetic acid shall not exceed the permitted maximum levels in complete feedingstuffs. 2. For users of the additive and pre-mixtures, feed business opera-tors shall establish operational procedures and appropriate or-ganisational measures to address the potential risks resulting from its use. Where those risks cannot be eliminated by such proce-dures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment. 3. In the directions for use of the additive, premixture and related feedingstuffs, the following la-belling provisions shall be indi-cated: 'The simultaneous use of different organic acids is contra-indicated where one or more of them is used at or near the maximum permitted content'.	16 July 2034

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en