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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

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

(Text with EEA relevance)

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

## 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<sup>1</sup>, 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<sup>2</sup>.
- (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<sup>3</sup> that acetic acid (and its salts) are safe for 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<sup>4</sup> and 6 May 2021<sup>5</sup> 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%

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

<sup>2</sup> 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>).

<sup>3</sup> EFSA Journal 2023;21(7):8176.

<sup>4</sup> EFSA Journal 2012;10(2):2571.

<sup>5</sup> EFSA Journal 2021;19(6):6615.

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.
- (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 [*6 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before [*12 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the feed additives referred to in paragraph 1, which are produced and labelled before [*24 months from the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry*

*into force of this Regulation – Date to be inserted by the Service responsible for the publication]* may continue to be placed on the market and used until the stocks concerned are exhausted if they are intended for non-food producing animals.

*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,

*For the Commission*  
*The President*  
*Ursula VON DER LEYEN*