



EUROPEAN
COMMISSION

Brussels, XXX
SANTE/80205/2024
[...] (2023) XXX draft

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

of XXX

correcting Implementing Regulation (EU) 2022/415 concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for certain animal species

(Text with EEA relevance)

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(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 nutrition¹, and in particular Article 9(2) thereof,

Whereas:

- (1) The use of acetic acid, sodium diacetate and calcium acetate as feed additives was authorised for a 10-year period by Commission Implementing Regulation (EU) 2022/415² for poultry, pigs and pets with a maximum content of 2 500 mg/kg of complete feedingstuff with a moisture content of 12%, and for all other animal species other than fish with no maximum content. However, according to the opinions adopted by the European Food Safety Authority on 1 February 2012³ and 6 May 2021⁴, only for ruminants the safety of use of the three additives concerned was demonstrated without a need to establish a maximum content.
- (2) In the Annex to Implementing Regulation (EU) 2022/415 regarding the additive sodium diacetate (identified as “1a262”) and calcium acetate (identified as “1a263”) an entry related to non-volatile matter was wrongly added in the column “Composition, chemical formula, description, analytical method” under the heading “Characterisation of the active substance”.

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

² Commission Implementing Regulation (EU) 2022/415 of 11 March 2022 concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for certain animal species (OJ L 85, 14.3.2022, p. 6; http://data.europa.eu/eli/reg_impl/2022/415/oj).

³ EFSA Journal 2012;10(2):2571.

⁴ EFSA Journal 2021;19(6):6615.

- (3) In the Annex to Implementing Regulation (EU) 2022/415 regarding the additive sodium diacetate (identified as “1a262”) the additive composition and the characterisation of the active substance were erroneously indicated.
- (4) In the Annex to Implementing Regulation (EU) 2022/415 regarding the additive lactic acid (identified as 1a270), the column “Maximum content” should refer to the level of active substance, not of the additive.
- (5) Implementing Regulation (EU) 2022/415 should therefore be corrected accordingly.
- (6) Since safety reasons do not require the immediate application of the corrections to the terms of the authorisation of the additives acetic acid, sodium diacetate and calcium acetate, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the requirements resulting from those corrections.
- (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 **Corrections**

The Annex to Implementing Regulation (EU) 2022/415 is corrected as follows:

- (1) the third column “Composition, chemical formula, description, analytical method” is corrected as follows:
 - (a) in the entry 1a263 on calcium acetate, from the text under the heading “Characterisation of the active substance”, the wording “Non volatile matter \leq 30 mg/kg” is deleted;
 - (b) the entry 1a262 on sodium diacetate, the text under the headings “Additive composition” and “Characterisation of the active substance” is replaced by the following:

‘Additive composition
Sodium diacetate \geq 97 %
Solid form
Characterisation of the active substance
Sodium diacetate (anhydrous and trihydrate) $\text{NaC}_4\text{H}_7\text{O}_4$
CAS no 126-96-5
Sodium acetate \geq 58%
Acetic acid \geq 39 %
Water \leq 2%
Formic acid and its salts and other oxidisable material \leq 1g/kg
Produced by chemical synthesis’;
- (2) in the fourth column “Species or category of animal”, in the entries 1a260 on acetic acid, 1a262 on sodium diacetate and 1a263 on calcium acetate, the category of animals

“Poultry, pigs, pets” is replaced by “All animal species other than fish and ruminants” and the category of animals “All other animals other than fish” by “Ruminants”;

- (3) in the sixth column “Minimum content/Maximum content”, in the entry 1a270 on lactic acid, the title “mg/kg of complete feedingstuff with a moisture content of 12%” is replaced by “mg active substance/kg of complete feedingstuff with a moisture content of 12%”.

Article 2

Transitional measures

1. The additives acetic acid (identified as 1a260), sodium diacetate (identified as 1a262) and calcium acetate (identified as 1a263) and premixtures containing them, which are produced and labelled before [*6 months after the date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*], may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the additives or premixtures referred to in paragraph 1, which are produced and labelled before [*12 months after the date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*], may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the additives or premixtures referred to in paragraph 1, which are produced and labelled before [*24 months after the date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*date of entry into force of this correcting Regulation – Date to be inserted by the Service responsible for the publication*], may continue to be placed on the market and used until the existing stocks 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