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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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 all 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 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 authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[2].

(2) DL-malic acid, citric acid, 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 and calcium lactate were authorised without a time limit as feed additives for all animal species in accordance with Directive 70/524/EEC. Those additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) 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, applications were submitted for the re-evaluation of DL-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), *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for all animal species.

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1 OJ L 268, 18.10.2003, p. 29.

2 Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

(4) The applicants requested those additives to be classified in the additive category 'technological additives' and in the functional group 'preservatives' or 'acidity regulators'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in it opinion of 29 January 2014[3] that, under the proposed conditions of use, DL-malic acid does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is irritant to skin, mucosa and eyes and the exposure via inhalation is a risk. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that it is effective as a feed preservative.

(6) The Authority concluded in its opinions of 27 January 2015[4] that, under the proposed conditions of use, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive has potentially hazardous effects on skin, mucosa, eyes and the exposure via inhalation is a risk. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the substance might have the potential to act as an acidity regulator in feedingstuff. However, its efficacy as a preservative, although well recognised in food, has not been sufficiently demonstrated due to the lack of statistical analysis provided by the design study.

(7) Despite the weakness of statistical demonstration of the provided studies, the authorisation already granted to citric acid for food use for the same function has been considered as a sufficient indication of the effectiveness of the substance as a preservative, under the conditions of Commission Regulation (EC) No 429/2008[5].

(8) The Authority concluded in its opinions of 1 July 2014[6] and 8 September 2015[7] that, under the proposed conditions of use, sorbic acid and potassium sorbate do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additives are irritant to skin, eyes and respiratory tract. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives. The Authority also concluded that sorbic acid and potassium sorbate are authorised food additives in the Union for use as preservatives. It is reasonable to expect that the effect in food will be observed in feed when they are used at comparable concentrations and under similar conditions.

(9) The Authority concluded in its opinion of 1 February 2012[8] and 6 May 2021[9] that, under the proposed conditions of use, acetic acid, sodium diacetate and calcium

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3 EFSA Journal 2014;12(2):3563.

4 EFSA Journal 2015;13(2):4009 and EFSA Journal 2015;13(2):4010.

5 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. 57).

6 EFSA Journal 2014;12(7):3792.

7 EFSA Journal 2015;13(9):4239.

8 EFSA Journal 2012;10(2):2571.

9 EFSA Journal 2021;19(5):6615

acetate do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that dilute acid is considered to be an irritant, while at higher concentrations it is corrosive and has a particular risk for the eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that acetic acid, sodium diacetate and calcium acetate are authorised food additives in the Union for use as preservatives. It is reasonable to expect that the effect in food will be observed in feed when they are used at comparable concentrations and under similar conditions.

(10) The Authority concluded in its opinion of 16 November 2011[10] that, under the proposed conditions of use, propionic acid, sodium propionate, calcium propionate and ammonium propionate do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the propionic acid and sodium propionate, calcium propionate and ammonium propionate are corrosive to skin and mucous membranes and corrosive for eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives. The Authority also concluded that propionic acid, sodium propionate, calcium propionate and ammonium propionate have the potential to act as preservatives in feedingstuff.

(11) The Authority concluded in its opinions of 17 September 2014[11], 11 March 2015[12], 18 March 2020[13], 7 May 2020[14], 19 March 2020[15], 24 October 2014[16] and 7 May 2020[17] that, under the proposed conditions of use, formic acid, sodium formate, calcium formate and ammonium formate do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the formic acid, sodium formate, and ammonium formate are corrosive. Calcium formate and sodium formate are non-irritant to skin, but mildly irritant to eyes, and are respiratory irritant with a potential for sensitisation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives. The Authority also concluded formic acid, sodium formate, calcium formate and ammonium formate have the potential to act as preservatives in feed.

(12) The Authority concluded in its opinions of 9 July 2015[18], 5 July 2017[19] and 12 November 2019[20] that, under the proposed conditions of use, lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate do not have an adverse effect on animal health, consumer safety or the environment. It also concluded that lactic acid is irritant to eyes and skin corrosive and respiratory irritant tract. Calcium lactate should be considered irritant to skin, eyes, and respiratory tract. Therefore, the Commission considers that appropriate protective measures should be taken to prevent

10 EFSA Journal 2011;9(12):2446.
11 EFSA Journal 2014;12(10):3827.
12 EFSA Journal 2015;13(5):4056.
13 EFSA Journal 2020;18(4):6076.
14 EFSA Journal 2020;18(5):6139.
15 EFSA Journal 2020;18(4):6077.
16 EFSA Journal 2014;12(11):3898.
17 EFSA Journal 2020;18(5):6137.
18 EFSA Journal 2015;13(12):4198.
19 EFSA Journal 2017;15(7):4938.
20 EFSA Journal 2019;17(12):5914.

adverse effects on human health, in particular as regards the users of the additives. The Authority also concluded that, since lactic acid and calcium lactate are used in food as preservative, it is reasonable to expect that the effect seen in food will be observed in feed when these additives are used at comparable concentrations and under similar conditions.

(13) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(14) The assessments 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 produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of malic acid, citric acid, 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 and calcium lactate should be authorised.

(15) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of malic acid, citric acid, 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 and calcium lactate, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(16) The fact that citric acid, sorbic acid and potassium sorbate, acetic acid, propionic acid, sodium propionate, ammonium propionate, formic acid, ammonium formate, sodium formate, calcium formate and lactic acid are not authorised for use as preservatives in water for drinking as well as citric acid as acidity regulator does not preclude their use in compound feed, which is administered via water.

(17) 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 additives specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘preservatives’ or ‘acidity regulators’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Transitional measures

1. The additives specified in the Annex and premixtures containing this additive, which are produced and labelled before [*6 months after the date of entry into force of this Regulation – Date to be inserted by the OP]* in accordance with the rules applicable before *[the date of entry into force of this Regulation – Date to be inserted by the OP*] 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 as specified in the Annex which are produced and labelled before [*12 months after the date of entry into force of this Regulation – Date to be inserted by the OP*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the OP*] 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 as specified in the Annex which are produced and labelled before [*24 months after the date of entry into force of this Regulation – Date to be inserted by the OP*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the OP*] 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