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

of **XXX**

concerning the authorisation of microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose as feed additives for all animal species

(Text with EEA relevance)

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

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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) 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/EEC².
- (2) The substances microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose were authorised without a time limit pursuant to 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, applications were submitted for the authorisation of microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose as feed additives for all animal species. The applicants requested microcrystalline cellulose, methyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose to be classified in the additive category 'technological additives' and in the functional groups 'emulsifiers', 'stabilizers', 'thickeners' and 'gelling agents'; ethyl cellulose in the additive category 'technological additives' and in the functional group 'stabilizers' and hydroxypropyl cellulose in the additive category 'technological additives' and in the functional groups 'emulsifiers', 'stabilizers', 'thickeners' and 'gelling agents'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) In addition, in accordance with Article 7 of Regulation (EC) No 1831/2003, applications were submitted for the authorisation of microcrystalline cellulose, methyl

¹ OJ L 268, 18.10.2003, p. 29, ELI: <https://eur-lex.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>).

Feltkode ændret

cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose as feed additives for all animal species, requesting them to be classified in the additive category ‘technological additives’ and in the functional group ‘binders’. Those 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 its opinions of 2 July 2020³ and 31 January 2024⁴ that, under the proposed conditions of use, microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose, are safe for all animal species, the consumer and the environment. In the absence of data, it was not in the position to conclude on the safety for the user. No specific data on the efficacy of these additives in feedingstuffs were provided, but as they are all authorised for use as food additives, the Authority concluded that the effect seen when those substances are used in food could reasonably be expected to be seen when they are used as additives in feed. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) In view of the above, the Commission considers that microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl cellulose 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.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, as far as they belong to the functional groups ‘emulsifiers’, ‘stabilisers’, ‘thickeners’ and ‘gelling agents’, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) 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 the functional groups ‘emulsifiers’, ‘stabilisers’, ‘thickeners’, ‘gelling agents’ or ‘binders’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2 **Transitional measures**

1. The feed additives microcrystalline cellulose, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose and sodium carboxymethyl

³ EFSA Journal 2020;18(7):6209; EFSA Journal 2020;18(7):6212; EFSA Journal 2020;18(7):6210; EFSA Journal 2020;18(7):6213; EFSA Journal 2020;18(7):6234; EFSA Journal 2020;18(7):6211.

⁴ EFSA Journal 2024;22:e8625; EFSA Journal 2024;22:e8637; EFSA Journal 2024;22:e8636; EFSA Journal 2024;22:e8626

cellulose, 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