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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of riboflavin 5'-phosphate monosodium salt (vitamin B_2), produced by *Bacillus subtilis* KCCM 10445, as a feed additive 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 an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of riboflavin 5'-phosphate monosodium salt (vitamin B_2), produced by *Bacillus subtilis* KCCM 10445. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of riboflavin 5'-phosphate monosodium salt, produced by *Bacillus subtilis* KCCM 10445, as feed additive for all animal species, requesting that additive to be classified in the category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. The applicant also requested the additive to be authorised for use in water for drinking.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022[2] that, under the proposed conditions of use, riboflavin 5'-phosphate monosodium salt (vitamin B_2) is safe for all animal species, consumers and the environment. It also concluded that is not a skin/eye irritant, and it is not considered a respiratory sensitiser and that riboflavin is a known photosensitiser which may elicit skin and eye photoallergic reactions. The Authority further concluded that riboflavin 5'-phosphate monosodium salt is effective in covering the animals' requirements for vitamin B_2, when administered via feed and/or water for drinking. It did not consider that there is a need for specific requirements of post-market monitoring. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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

[2] EFSA Journal 2022;20(11):7608.

(5) In view of the above, the Commission considers that riboflavin 5'-phosphate monosodium salt (vitamin B_2) produced by *Bacillus subtilis* KCCM 10445 satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects the health of the users of the additive.

(6) 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 substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
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