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

of **XXX**

concerning the renewal of the authorisation of a preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs and the authorisation of that preparation for ruminants and repealing Implementing Regulation (EC) No 887/2009

(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) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such an authorisation.
- (2) A preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 was authorised for a period of 10 years as a feed additive by Commission Regulation (EC) No 887/2009² for chickens for fattening, turkeys for fattening, other poultry, and pigs.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for ruminants. Those applications requested 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’ and were accompanied by the particulars and documents required respectively under Article 14(2) and Article 7(3) of that Regulation.
- (4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 5 July 2023³ that under the conditions of use currently authorised the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 remains safe for chickens for fattening, turkeys for fattening, other poultry and pigs, and that it is safe for all ruminants. It concluded also that the preparation of 25-

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

² Commission Regulation (EC) No 887/2009 of 25 September 2009 concerning the authorisation of a stabilised form of 25-hydroxycholecalciferol as a feed additive for chickens for fattening, turkeys for fattening, other poultry and pigs (OJ L 254, 26.9.2009, p. 68, ELI: <http://data.europa.eu/eli/reg/2009/887/oj>).

³ EFSA Journal 2023;21(8):8168 and EFSA Journal 2023;21(8):8169.

hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is safe for the consumers and the environment. It concluded that the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is an efficient source of vitamin D₃ for all ruminants and that, since the application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of the original authorisation that would have an impact on the efficacy of the additive, there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation. The Authority also concluded that 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008 is not irritant to the skin or eyes but no conclusion on its potential to be a skin sensitiser or on its effects on the respiratory system can be reached due to absence of data. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

- (5) 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 for the application for renewal of the authorisation for chickens for fattening, turkeys for fattening, other poultry and pigs. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁴, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment concerning the same additive are valid and applicable for the current application for ruminants.
- (6) In view of the above, the Commission considers that the preparation of 25-hydroxycholecalciferol produced by *Saccharomyces cerevisiae* CBS 146008⁵ satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed for chickens for fattening, turkeys for fattening, other poultry and pigs and should be authorised for ruminants. As 25-hydroxycholecalciferol depresses the activity of 1 α -hydroxylase in the kidney, the Commission considers that the simultaneous use of 1,25-dihydroxycholecalciferol from *Solanum glaucophyllum* extract with that additive should not be allowed. The Commission further considers that the combination of the preparation of 25-hydroxycholecalciferol with cholecalciferol should be limited in order not to exceed the maximum daily intake level for vitamin D₃. The Commission considers that the restriction to use the additive via premixtures should be maintained. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the preparation of 25-hydroxycholecalciferol, Implementing Regulation (EC) No 887/2009 should be repealed.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁴ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additive [OJ L 59, 5.3.2005, p. 8] ELI: <http://data.europa.eu/eli/reg/2005/378/oj>

⁵ EFSA Journal 2023;21(8):8168

HAS ADOPTED THIS REGULATION:

Article 1
Renewal of the authorisation

The authorisation of the preparation 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 renewed for chickens for fattening, turkeys for fattening, other poultry and pigs, subject to the conditions laid down in that Annex.

Article 2
Authorisation

The preparation 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 for ruminants, subject to the conditions laid down in that Annex.

Article 3
Repeal

Implementing Regulation (EC) No 887/2009 is repealed.

Article 4

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