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

of XXX

amending Implementing Regulation (EU) 2015/1486 as regards the terms of the authorisation of canthaxanthin as a feed additive for certain categories of poultry, ornamental fish and ornamental birds

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amending Implementing Regulation (EU) 2015/1486 as regards the terms of the authorisation of canthaxanthin as a feed additive for certain categories of poultry, ornamental fish and ornamental birds

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) and Article 13(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 modifying such an authorisation.
- (2) Canthaxanthin was authorised for 10 years as a feed additive for certain categories of poultry, ornamental fish and ornamental birds by Commission Implementing Regulation (EU) 2015/1486².
- (3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of canthaxanthin as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, if the terms of that authorisation were modified. The modification consists of the addition of a new production route by fermentation with *Yarrowia lipolytica* CBS 146148. The applicant stated that canthaxanthin, either synthetic or produced by fermentation, will only be placed on the market as a preparation. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinion of 26 November 2024³ that the preparation of canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148 is safe for the target species, consumer and environment under the current authorised conditions of use. It also concluded that, in the absence of data with the preparation of canthaxanthin, no conclusions could be reached regarding its safety for the user. The Authority further concluded that canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148 is efficacious as a colouring agent in feed for chickens for fattening and minor poultry species for fattening, laying poultry and poultry reared for laying, ornamental fish and ornamental birds. Finally, it

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

² Commission Implementing Regulation (EU) 2015/1486 of 2 September 2015 concerning the authorisation of canthaxanthin as feed additive for certain categories of poultry, ornamental fish and ornamental birds (OJ L 229, 3.9.2015, p. 5; ELI: http://data.europa.eu/eli/reg_impl/2015/1486/oj).

- recommended adjusting the wording of the provision of the current authorisation regarding the mixture of the preparation of canthaxanthin with other carotenoids.
- (5) In view of the above, the Commission considers that the preparation of canthaxanthin still satisfies the conditions, as provided for in Article 5 of Regulation (EC) No 1831/2003, when modifying the terms of the authorisation with the addition of a new production route by fermentation with *Yarrowia lipolytica CBS 146148*. In addition, the provision of Implementing Regulation (EU) 2015/1486 regarding the mixture of the preparation of canthaxanthin with other carotenoids should be adjusted in accordance with the recommendation of the Authority. Implementing Regulation (EU) 2015/1486 should therefore be amended accordingly.
- (6) In order to allow better control, a new identification number should be granted to canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148.
- (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 Amendment to Implementing Regulation (EU) 2015/1486

The Annex to Implementing Regulation (EU) No 2015/1486 is replaced by Annex to this Regulation.

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