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COMMISSION IMPLEMENTING REGULATION (EU) 2025/1423

of 17 July 2025

amending Implementing Regulation (EU) No 684/2014 as regards the terms of the authorisation of a preparation of canthaxanthin as a feed additive for breeder hens (holder of authorisation: DSM Nutritional Products Ltd.)

(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 13(3) 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 authorisation.

(2) Commission Implementing Regulation (EU) No 684/2014 ([2]) authorised the use of a preparation of canthaxanthin as a feed additive for breeder hens for a 10-year period.

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted on 4 February 2021 for the modification of the terms of the authorisation of the preparation of canthaxanthin as a feed additive for breeder hens. The application concerned the addition of a new production route by fermentation with *Yarrowia lipolytica* CBS 146148 and the modification of the additive specifications by substituting ethoxyquin by 4,4 % butylated hydroxytoluene and increasing the limit of the impurity dichloromethane from 10 to 80 mg/kg additive. The request was accompanied by the relevant supporting data.

(4) The European Food Safety Authority ('the Authority') indicated in its opinion of 26 November 2024 ([3]) that the conclusions previously reached for synthetic canthaxanthin, in its opinion of 12 December 2012 ([4]), with regards to target animals, consumers and environment, also apply to canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148. The Authority therefore concluded that using canthaxanthin produced with *Yarrowia lipolytica* CBS 146148 in the formulation of the preparation of canthaxanthin is considered safe for the target species, consumer and environment under the current authorized conditions of use for synthetic canthaxanthin. Regarding user safety, it also concluded that canthaxanthin is not irritant to skin and eyes and unlikely to be a skin sensitiser, that no conclusion can be reached on the respiratory sensitisation of canthaxanthin, and that, in the absence of data with the preparation of canthaxanthin, no conclusions can be reached regarding the safety of that preparation for the user. The Authority further indicated that canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148 has been shown to have the same purity as canthaxanthin produced by chemical synthesis, and that it is considered as equivalent. Consequently, the conclusions reached in the opinion of 12 December 2012 on the preparation containing synthetic canthaxanthin are considered also applicable to the preparation containing canthaxanthin produced by fermentation with *Yarrowia lipolytica* CBS 146148, without the need for additional studies, and the Authority concluded that the additive is efficacious in breeder hens at 6 mg/kg complete feed. The Authority did not express concerns on the new specifications of the preparation of canthaxanthin. Finally, it recommended adjusting the wording of two provisions of the Annex to Implementing Regulation (EU) No 684/2014 regarding the mixture of different sources of canthaxanthin and regarding the mixture of the preparation of canthaxanthin with other carotenoids.

([1]) OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.
([2]) Commission Implementing Regulation (EU) No 684/2014 of 20 June 2014 concerning the authorisation of canthaxanthin as a feed additive for breeder hens (holder of the authorisation DSM Nutritional products Ltd) (OJ L 182, 21.6.2014, p. 20; ELI: http://data.europa.eu/eli/reg_impl/2014/684/oj).
([3]) *EFSA Journal* 2025;23:e9133, https://doi.org/10.2903/j.efsa.2025.9133.
([4]) *EFSA Journal* 11(1), 3047, https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2013.3047.

(5) An application for the renewal of the authorisation of the preparation of canthaxanthin was sent to the Commission on 10 July 2023, in accordance with the first paragraph of Article 14(1) of Regulation (EC) No 1831/2003. As for reasons beyond the control of the applicant no decision on the renewal of the authorisation had been taken before the expiry of the authorisation, the period of authorisation has automatically been extended in accordance with Article 14(4) of Regulation (EC) No 1831/2003.

(6) In view of the above, the Commission considers that the preparation of canthaxanthin still satisfies the conditions 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, the substitution of ethoxyquin by 4,4 % butylated hydroxytoluene and the increase the limit of the impurity dichloromethane from 10 to 80 mg/kg additive. In addition, certain provisions of the Annex to Implementing Regulation (EU) No 684/2014 should be adjusted in accordance with the recommendations of the Authority.

(7) Implementing Regulation (EU) No 684/2014 should therefore be amended accordingly.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of canthaxanthin, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the terms of the authorisation.

(9) 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) No 684/2014

The Annex to Implementing Regulation (EU) No 684/2014 is replaced by the Annex to this Regulation.

Article 2

Transitional measures

1. The feed additive canthaxanthin, as authorised by Implementing Regulation (EU) No 684/2014 and premixtures containing that additive, which are produced and labelled before 7 February 2026 in accordance with the rules applicable before 7 August 2025 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 additive referred to in paragraph 1, which are produced and labelled before 7 August 2026 in accordance with the rules applicable before 7 August 2025 may continue to be placed on the market and used until the stocks concerned are exhausted.

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, 17 July 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum residues limits in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Category of zootechnical additives. Functional group: other zootechnical additives (stabilisation of reproductive performance)										
4d161g	DSM Nutritional products Ltd, represented by DSM Nutritional Products Sp. z o.o.	Canthaxanthin	*Additive composition* Preparation containing: — minimum 10 % of canthaxanthin; — maximum 4,4 % of butylated hydroxytoluene. Impurities: — dichloromethane: ≤ 80 mg/kg additive. Solid form. *Characterisation of the active substance* Canthaxanthin produced by chemical synthesis or with *Yarrowia lipolytica* CBS 146148. Chemical formula: $C_{40}H_{52}O_2$ CAS Number: 514-78-3 Purity: minimum 96 % of total colouring matters (expressed as canthaxanthin) Carotenoids other than canthaxanthin: not more than 5 % of total colouring matters.	Breeder hens	-	6	6	1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heat treatment. 2. The mixture of different sources of the active substance canthaxanthin shall not exceed 6 mg canthaxanthin/kg of complete feedingstuff. 3. The mixture of this additive with other additives containing canthaxanthin and/or other carotenoids is allowed provided that the total concentration of the mixture does not exceed 80 mg total carotenoids/kg of complete feedingstuff.	10 July 2024	15 mg canthaxanthin/kg liver (wet tissue) and 2,5 mg canthaxanthin/kg skin/fat (wet tissue)

ELI: http://data.europa.eu/eli/reg_impl/2025/1423/oj

Identification number of the feed additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum residues limits in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			Analytical method (1) — For the determination of canthaxanthin in the feed additive: spectrophotometry (426 nm) — For the determination of canthaxanthin in premixtures and feedingtuffs: Normal Phase High Performance Liquid Chromatography coupled to VIS detection (NP-HPLC-VIS, 466 nm)					4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.		

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: www.irmm.jrc.be/eurl-feed-additives