

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)****(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 authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a canthaxanthin. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of canthaxanthin as a feed additive for breeder hens to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 December 2012 ⁽²⁾ that, under the proposed conditions of use, the preparation of canthaxanthin does not have an adverse effect on animal health, human health or the environment, and that it has a potential to stabilise the reproductive performance of breeder hens. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of canthaxanthin shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1***Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2013; 11(1):3047.

Article 2

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, 20 June 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

Identification number of the 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	<p><i>Additive composition</i></p> <p>Preparation containing minimum: 10 % of canthaxanthin; ≤ 2,2 % ethoxyquin; dichloromethane: ≤ 10 mg/kg additive.</p> <p><i>Characterisation of the active substance</i></p> <p>canthaxanthin C₄₀H₅₂O₂ CAS No: 514-78-3 Assay: Minimum 96 % Produced by chemical synthesis</p> <p><i>Analytical method</i> ⁽¹⁾</p> <p>— For the determination of canthaxanthin in the feed additive: spectrophotometry (426 nm)</p> <p>— For the determination of canthaxanthin in premixtures and feedingstuffs: Normal Phase High Performance Liquid Chromatography coupled to VIS detection (NP-HPLC-VIS, 466 nm)</p>	Breeder hens	—	6	6	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixture, indicate the storage conditions and stability to heat processing. 2. The mixture of different sources of canthaxanthin shall not exceeded 6 mg canthaxanthin/kg of complete feedingstuff. 3. The mixture of this preparation with canthaxanthin and other carotenoids is allowed provided that the total concentration of the mixture does not exceed 80 mg/kg of complete feedingstuff. 4. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 	10 July 2024	15 mg canthaxanthin/kg liver (wet tissue) and 2,5 mg canthaxanthin/kg skin/fat (wet tissue)

⁽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