COMMISSION IMPLEMENTING REGULATION (EU) 2023/60

of 5 January 2023

concerning the authorisation of conjugated linoleic acid (t10, c12)-methylester as a feed additive for pigs for fattening and dairy cows (holder of authorisation: BASF SE)

(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) The substance conjugated linoleic acid (t10, c12)-methylester was authorised without a time limit in accordance with Council Directive 70/524/EEC ([2]) as a feed additive for all animal species, and was included in the category 'nutritional additives' and functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. That substance was subsequently entered into the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.

(3) The inclusion of conjugated linoleic acid (t10, c12)-methylester in the group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect' was based on a report of 18 March 1994 of the Scientific Committee for Animal Nutrition on the classification of vitamins in the Annex to Directive 70/524/EEC. This report considered that this substance had a similar effect to that of a vitamin.

(4) In accordance with Article 10(2) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted on 13 October 2010 for the authorisation of conjugated linoleic acid (t10, c12)-methylester as a feed additive for pigs for fattening and dairy cows. The applicant requested the additive to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 December 2015 ([3]) that, under the proposed conditions of use, conjugated linoleic acid (t10, c12)-methylester used in the nutrition of pigs for fattening and dairy cows does not have adverse effects on animal health, consumer safety or the environment. Concerning pigs for fattening, the Authority concluded that conjugated linoleic acid (t10, c12)-methylester might have a potential for an improvement of the feed to gain ratio. It effectively increases fat firmness due to an increased amount of saturated fatty acids in the subcutaneous fat. There is also an increase in intramuscular fat, its degree of saturation and in marbling score. Conjugated linoleic acid (t10, c12)-methylester might also have a potential to improve the proportion of lean meat to subcutaneous fat in the carcass. For dairy cows, the Authority concluded that conjugated linoleic acid (t10, c12)-methylester reduces milk fat content and has the potential to reduce milk fat

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).
([3]) EFSA Journal 2016;14(1):4348.

yield and milk energy output. In a further opinion of 24 January 2019 ([4]), the Authority stated that the allocation of this additive to the category 'nutritional additives' did not seem to be justified. The Commission, taking into account the considerations from the Authority and the effects of the additive on the zootechnical performance of pigs for fattening and dairy cows, has decided to classify this additive under the category 'zootechnical additives' and under the functional group 'other zootechnical additives'.

(6) The Authority concluded that the exposure of users by inhalation of the solid product is likely to be minimal. As regards the liquid product, no data on potential mist formation were provided. A beadlet formulation of the liquid product elicited mild but persistent dermal irritation, whereas it was not an eye irritant. The skin sensitisation potential was masked by the effect of the placebo. Neither the liquid nor the solid product was tested as such for skin and eye irritation and skin sensitisation. The Authority further concluded that the additive was effective. The Authority does not consider that there is a need for specific requirements of post-market monitoring. The initial method of analysis provided by the applicant was validated by the Reference Laboratory set up by Regulation (EC) No 1831/2003 and verified by EFSA. Due to the fact that maximum/minimum contents are established in the EFSA opinion, the first method of analysis was not considered sufficient for the purpose of Regulation (EC) No 1831/2003 as the method applied only to feed additives but not to premixtures and feedingstuffs and did not quantify the level of incorporation of the additive in those premixtures and feedingstuffs. The applicant submitted a second method for the quantification in premixtures and feedingstuffs that was validated by the Reference Laboratory.

(7) The assessment of conjugated linoleic acid (t10, c12)-methylester 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 substance should be authorised. The Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

(8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of conjugated linoleic acid (t10, c12)-methylester to the use of that substance in the nutrition of pigs for fattening and dairy cows, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from 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

The substance specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as a feed additive for fattening pigs and dairy cows, in accordance with the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 July 2023 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

([4]) EFSA Journal 2019;17(3):5614.

2. Feed materials and compound feed containing the substance specified in the Annex, which are intended for pigs for fattening and dairy cows and are produced and labelled before 26 January 2024 in accordance with the rules applicable before 26 January 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 5 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

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
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of Zootechnical additives. Functional group: Other zootechnical additives (improvement of zootechnical parameters/performance)									
4d895	BASF SE	Conjugated linoleic acid (t10, c12)-methylester	*Additive composition:* Preparation of omega-6-fatty acid as t10,c12-octadecadienoic acid (conjugated linoleic acid)-methylester (CLA(t10,c12)-ME). Liquid formulation: CLA (t10,c12)-ME ≥ 28 % CLA (c9,t11)-ME ≥ 28 % CLA (t10,c12) < 2 % CLA (c9,t11) < 2 % Fatty acids of sunflower oil: 38-42 % free or as methylesters and less than 1 % as trans trans isomers. Solid formulation: CLA (t10,c12)-ME: ≥ 9 % CLA (c9,t11)-ME: ≥ 9 % CLA (t10,c12): < 1 % CLA (c9,t11): < 1 % Fatty acids of sunflower oil:13-15 % (free or as methylesters). Vegetable oils (hydrogenated triglycerides, predominantly stearic acid and to a minor extent palmitic acid): 44,5 %. Colloidal silica: 15 %. Calcium sulphate: 5 %.	Pigs for fattening	-	400	5 000	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For dairy cows, the level of CLA (t10,c12)-ME in the daily ration shall not exceed 10 g/head/day. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential health risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and skin protection.	26.1.2033
				Dairy cows		175	350		
					-	-			

			Characterisation of the active substance: Conjugated linoleic acid (t10,c12)-methylester. Chemical formula: $C_{19}H_{34}O_2$ CAS number: 21870-97-3 *Analytical method :* (1) — For the determination of Omega-6-fatty acid as octadecadienoic acid (trans-10, cis-12- isomer) in feed additive: gas Chromatography coupled to Flame Ionization Detector (GC-FID) — For the quantification of CLA (t10,c12)-methylester in premixtures and feedingstuffs: — high performance liquid chromatography coupled to spectrophotometric detection (HPLC-UV)						

(1) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports.