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COMMISSION IMPLEMENTING REGULATION (EU) No 469/2013

of 22 May 2013

concerning the authorisation of DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of hydroxy analogue of methionine, isopropyl ester of hydroxy analogue of methionine, DL-methionine protected with copolymer vinylpyridine/styrene and DL-methionine protected with ethylcellulose as feed additives

(Text with EEA relevance)

(OJ L 136, 23.5.2013, p. 1)

Corrected by:

►C1 Corrigendum, OJ L 145, 31.5.2013, p. 37 (469/2013)

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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 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition ([2]).

(2) DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of hydroxy analogue of methionine, isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene were authorised without a time limit pursuant to Directive 82/471/EEC. These feed additives were subsequently entered in the European Union Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 213, 21.7.1982, p. 8.

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(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine and calcium salt of methionine hydroxy analogue as feed additives for all animal species and of isopropyl ester of methionine hydroxy analogue and DL-methionine technically pure protected with copolymer vinylpyridine/styrene as feed additives for dairy cows and, in accordance with Article 7 of that Regulation, for a change in the terms of the authorisation as regards the use of DL-methionine, DL-methionine sodium salt and the hydroxy analogue of methionine via drinking water. In addition, in accordance with Article 7 of that Regulation, the application contained the request for the authorisation of DL-methionine technically pure protected with ethylcellulose for ruminants. For all seven sources of methionine it was requested that those additives be classified in the additive category 'nutritional additives'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 6 March 2012 ([1]) that, under the proposed conditions of use, DL-methionine, DL-methionine sodium salt, hydroxy analogue of methionine, calcium salt of methionine hydroxy analogue, isopropyl ester of methionine hydroxy analogue, DL-methionine technically pure protected with copolymer vinylpyridine/styrene and DL-methionine technically pure protected with ethylcellulose do not have an adverse effect on animal health, human health or the environment, and that they are effective sources of methionine for protein synthesis in the respective target species. The Authority extrapolated this conclusion from dairy cows to all ruminants. 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 DL-methionine, DL-methionine sodium salt, the hydroxy analogue of methionine, the calcium salt of methionine hydroxy analogue, the isopropyl ester of methionine hydroxy analogue, DL-methionine technically pure protected with copolymer vinylpyridine/styrene and DL-methionine technically pure protected with ethylcellulose shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

([1]) *EFSA Journal* 2012;10(3):2623.

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(6) The Authority recommends that the use of methionine should not be authorised in water for drinking. However, this recommendation refers rather to the farm management as it concerns the way to achieve the optimal protein supply of the animal including the prevention of protein surpluses. No maximum content for the methionine sources is proposed by the Authority. Thus, it is in the case of administration of methionine sources via drinking water appropriate to instruct the user to consider all different methionine sources in order to achieve an optimal supply with the essential amino acids without affecting the performance of the animals.

(7) The Authority recommends further, to avoid the combined supplementation of feed with hydroxy analogue of methionine and cystine/cysteine. However, the settings of the animal trials on which this recommendation is based are not considered to be tangible to fully justify such a measure.

(8) Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.

(9) Since safety reasons do not require the immediate application of the modifications to the conditions of use for the already authorised sources of methionine, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(10) 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 substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

The substances specified in the Annex that are authorised pursuant to Directive 82/471/EEC and feed containing these substances, which are produced and labelled before 12 December 2013 in accordance with the rules applicable before 12 June 2013 may continue to be placed on the market and used until the existing stocks are exhausted.

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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.

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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/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues									
3c301		DL-methionine, technically pure	*Additive composition* Methionine content: minimum 99 % *Characterisation of the active substance* IUPAC name: 2-amino-4-(methylthio)butanoic acid CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$ *Analytical methods* (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed, feed materials and water: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).	all animal species				1. DL-methionine, technically pure can be also used via water for drinking. 2. Declarations to be made on the labelling of the additive and premixtures: 'If the additive is administered via water for drinking protein excess should be avoided.'	12 June 2023
3c302		Sodium DL-methionine, liquid	*Additive composition* DL-Methionine content: minimum 40 % Sodium: minimum 6,2 % Water: maximum 53,8 %	all animal species				1. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	12 June 2023

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/kg of complete feedingstuff with a moisture content of 12 %			
			Characterisation of the active substance IUPAC name: 2-amino-4-(methylthio)butanoic acid sodium salt CAS number: 41863-30-3 Chemical formula: $(C_5H_{11}NO_2S)Na$ *Analytical methods* For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed, feed materials and water: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).					2. Sodium DL-methionine, liquid can be also used via water for drinking. 3. Declarations to be made on the labelling of the additive and premixtures: — DL-Methionine content, — ‘If the additive is administered via water for drinking protein excess should be avoided.’	
3c303		DL-methionine protected with copolymer vinylpyridine/styrene	*Additive composition* Preparation with DL-Methionine: minimum 74 % Stearic acid: maximum of 19 % Copolymer poly(2-vinylpyridine) co-styrene: maximum 3 % Ethylcellulose and sodium stearate: maximum 0,5 % *Characterisation of the active substance*	Ruminants					12 June 2023

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/kg of complete feedingstuff with a moisture content of 12 %			
			IUPAC name: 2-amino-4-(methylthio)butanoic acid CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$ *Analytical methods* (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).					
3c304		DL-methionine protected with ethylcellulose	*Additive composition* Preparation with DL-Methionine: minimum 85 % Ethylcellulose: maximum 4 % Starch: maximum 8 % Sodium aluminium silicate: maximum 1,5 % Sodium stearate: maximum 1 % Water: maximum 2 %	Ruminants					12 June 2023

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/kg of complete feedingstuff with a moisture content of 12 %			
			Characterisation of the active substance IUPAC name: 2-amino-4-(methylthio)butanoic acid CAS number: 59-51-8 Chemical formula: $C_5H_{11}NO_2S$ *Analytical methods* (1) For the determination of methionine in the additives: — Ion exchange chromatography coupled with post-column derivatisation and photometric or fluorescence detection (HPLC-UV/FD) - ISO/DIS 17180. For the determination of methionine in premixtures, compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (HPLC-UV) - Commission Regulation (EC) No 152/2009 (Annex III, F).						
3c307	—	Hydroxy analogue of methionine	*Additive composition* Hydroxy analogue of methionine: minimum 88 % Water: maximum 12 % *Characterisation of the active substance* IUPAC name: 2-hydroxy-4-(methylthio)butanoic acid CAS number 583-91-5 Chemical formula: $C_5H_{10}O_3S$	All animal species	—	—	—	1. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 2. Hydroxy analogue of methionine can be also used via water for drinking.	12 June 2023

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/kg of complete feedingstuff with a moisture content of 12 %			
			Analytical methods (1) For the determination of hydroxy analogue of methionine in the additive: — Titrimetry, potentiometric titration followed by oxidation reduction reaction. For the determination of hydroxy analogue of methionine in premixtures, compound feed, feed materials and water: — High-Performance Liquid Chromatography and photometric detection (HPLC-UV).					3. Declarations to be made on the labelling of the additive and premixtures: — 'If the additive is administered via water for drinking protein excess should be avoided.' 4. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive, — Amount of the hydroxy analogue of methionine added.	
►C1 3c308 ◄	—	Calcium salt of hydroxy analogue of methionine	*Additive composition* Hydroxy analogue of methionine: minimum 84 % Calcium: minimum 11,7 % Water: maximum 1 % *Characterisation of the active substance* IUPAC name 2-hydroxy-4-(methylthio)butanoic acid, calcium salt CAS number 4857-44-7	All animal species	—	—	—	1. For user safety: breathing protection, safety glasses and gloves should be worn during handling. 2. Declarations to be made on the labelling of the additive and premixtures:	12 June 2023

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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/kg of complete feedingstuff with a moisture content of 12 %			
			Chemical formula: $(C_5H_9O_3S)_2Ca$ *Analytical methods* (1) For the determination of hydroxy analogue of methionine in the additive: — Titrimetry, potentiometric titration followed by oxidation reduction reaction. For the determination of hydroxy analogue of methionine in premixtures, compound feed and feed materials: — High-Performance Liquid Chromatography and photometric detection (HPLC-UV).					— Hydroxy analogue of methionine content. 3. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive, — Amount of the hydroxy analogue of methionine added.	
3c309	—	Isopropyl ester of hydroxy analogue of methionine	*Additive composition* Preparation of isopropyl ester of hydroxy analogue of methionine: minimum 95 % Water: maximum 0,5 % *Characterisation of the active substance* IUPAC name isopropyl ester of 2-hydroxy-4-(methylthio)butanoic acid CAS number 57296-04-5 Chemical formula: $C_8H_{16}O_3S$	Ruminants	—	—	—	1. Declarations to be made on the labelling of the additive and premixtures: — Content of hydroxy analogue of methionine 2. Declarations to be made on the labelling of feed materials and compound feed in the listing of additives, if appropriate: — Name of the additive, — Amount of the hydroxy analogue of methionine added.	12 June 2023

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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/kg of complete feedingstuff with a moisture content of 12 %			
			Analytical method For the determination of isopropyl ester of the hydroxy analogue of methionine in the feed: — High-Performance Liquid Chromatography and photometric detection (HPLC-UV).						

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/authorisation/evaluation_reports/Pages/index.aspx