Commission Implementing Regulation (EU) 2020/1761 of 25 November 2020 concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1761

of 25 November 2020

concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 as a feed additive for all animal species

(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 L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) This application concerns the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.
- (4) The applicant requested the feed additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 in water for drinking should not be allowed. The fact that of L-cysteine hydrochloride monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2020⁽²⁾ that, under the proposed conditions of use L-cysteine hydrochloride

Changes to legislation: There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1761. (See end of Document for details)

monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 do not have adverse effects on animal health, consumer health or the environment. The Authority concluded for L-cysteine hydrochloride monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 that although users' exposure via inhalation is unlikely due to the low dusting potential, the product is proposed to be classified as respiratory irritant due to its low pH when in solution. In addition, based on the results of the studies provided, it should be classified as skin irritant and that it can cause serious eye damage. L-cysteine hydrochloride monohydrate is not a dermal sensitiser. The Authority also concluded, that since Lcysteine hydrochloride monohydrate produced by fermentation with Escherichia coli KCCM 80109 and KCCM 80197 is used in food as flavouring, it is to be expected that it can provide a similar function in feed and no further demonstration of efficacy is necessary when used in feed. 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 additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (6) The assessment of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 should be authorised as specified in the Annex to this Regulation.
- (7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) 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 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

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.

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Done at Brussels, 25 November 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX

Identific	atikame	Additive	e Compos	sitSopne,cies	Maximu	ınMinimu	mMaximı	ınOther	End	
number	of the		chemica	ıl or	age	content	content	provisio	nof	
of the	holder		formula	, categor		mg of a	ctive	•	period	
additive	of		descript	iconf.	1	substance/kg			of	
	authoris	ation		alanimal		of comp			authorisation	
			method			feedingstuff				
						with a moisture				
							of 12 %			
C-4		1 1:4:	. Г4	1	. E1					
Category: Sensory additives. Functional group: Flavouring compounds										
2b920i		L-	Additive					1.	Total 2.2030	
			composi	tāoi mal					additive	
		hydrochl	dride	species					shall	
		monohyo	dcatsteine						be	
			hydrochl	oride					incorporated	
			monohy	drate					into	
				erisation					the	
			of the						feed	
			active						in	
			substan	ce					the	
			L-						form	
			cysteine						of	
			hydroch	oride					a	
			monohy						premixture.	
			Produce					2.	În	
			by						the	
			fermenta	tion					directions	
			with						for	
			Escheric	hia					use	
			coli						of	
			KCCM						the	
			80109						additive	
			and						and	
			KCCM						premixture,	
			80197						the	
			Purity:						storage	
			\geq 98,5						conditions	
			%						and	
			assay						the	
			Chemica	1					stability	
			formula:	1					to	
				₂ S•HClH	0				heat	
			CAS	25 110111	_k				treatment	
			number:						shall	
			7048 - 04	6					be	
			/048-04	- 0.					indicated.	
									muicateu.	

a 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

b Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

FLAVIS	3.	On
number:		the
17.032		label
Method		of
of		the
analysis		additive
For the		the
identification		following
of L-		shall
cysteine		be
hydrochloride		indicated:
monohydrate		'Recommended
in the		maximum
feed		content
additive:		of
ion-		the
		active
exchange chromatography		substance
coupled		of
with		complete
		feedingstuff
post- column		with
derivatisation		a
and		moisture
		content
photometric detection		of
		12
(IEC-		%:
VIS), Ph.Eur.		25
6.6-2.2.56-		mg/
Method		kg'
1	4.	The
For the	٦.	functional
quantification		group,
of L-		the
		identification
cysteine hydrochloride		number,
monohydrate		the
in the		name
feed		and
additive:		the
ion-		added
exchange		amount
chromatography		of
coupled		the
with		active
post-		substance
column		shall
derivatisation		be
and		
anu		

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optical			indicated
detection			on
(IEC-			the
VIS/			label
FD)			of
For the			the
quantification			premixtures,
of L-			if
cysteine			the
hydrochloride			following
monohydrate			content
in			of
premixtures:			the
ion-			active
exchange			substance
chromatography			in
coupled			complete
with			feedingstuff
post-			with
column			a
derivatisation			moisture
and			content
photometric			of
detection			12
(IEC-			%
VIS),			is
Commission			exceeded:
Regulation			25
(EC)			mg/
No			kg.
152/2009 ^b Annex		5.	For
III, F)			users
			of
			the
			additive
			and
			premixtures,
			feed
			business
			operators
			shall
			establish
			operational
			procedures
			and
			organisational
			measures
			to
			address

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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) EFSA Journal 2020;18(4):6101.

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