Commission Implementing Regulation (EU) 2020/2120 of 16 December 2020 amending Implementing Regulation (EU) 2016/1964 as regards the authorisation of a preparation of montmorilloniteillite as feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2120

of 16 December 2020

amending Implementing Regulation (EU) 2016/1964 as regards the authorisation of a preparation of montmorillonite-illite as 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 13(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 or modifying such authorisation.
- (2) The use of a preparation of montmorillonite-illite as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) 2016/1964⁽²⁾.
- In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of a preparation of montmorillonite-illite as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. The modification relates to the current authorisation for the use of the additive as anticaking agent in complementary feedingstuffs. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinions of 30 October 2014⁽³⁾, 10 September 2015⁽⁴⁾ and 20 March 2020⁽⁵⁾ that the proposed modification to the terms of authorisation of the preparation of montmorillonite-illite does not modify the previous conclusions that the additive does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that dust generated during normal handling of the additive has the potential to expose the whole of the respiratory tract of users to harmful substances (crystalline silica) for which no safe levels of exposure have been identified and that in the absence of data on the effects on skin and eyes, must be considered as irritant to skin and eyes and as a potential dermal sensitiser. Therefore, the

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Commission Implementing Regulation (EU) 2020/2120. (See end of Document for details)

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. The Authority has also concluded that the additive is efficacious as an anti-caking agent. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of the proposed modification to the authorisation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (6) Implementing Regulation (EU) 2016/1964 should therefore be amended accordingly.
- (7) 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 Annex to Implementing Regulation (EU) 2016/1964 is amended in accordance with the Annex to this Regulation.

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, 16 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX

In the Annex to Implementing Regulation (EU) 2016/1964, the entry concerning the additive montmorillonite-illite with the identification number 1g557 is replaced by the following:

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		≥ 75 %						use
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		of active						macrolides
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		≥ 75 %:						avoided",
		≥ 35 %						in "In
		montmorille	onite-					addition,
		illite	Office					for
		(swellable)						poultry,
		≥ 30 %						the
		illite/						simultaneous
		muscovite						use
		≤ 15 %						with
		kaolinite						robenidine
		(non-						shall
		swellable)						be
								avoided".
		Quartz ≤ 20 %					2.	For
		Iron						poultry:
		(structural)						the
		3,6 %						simultaneous
		(average)						oral
		Free of						use
		asbestos						with
								coccidiostats

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

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Analytical method ^a For the determination in feed additive: — X- ray diffraction (XRD) — Inductively coupled plasma atomic emission spectroscopy (ICP- AES)	other than robenidine is contraindicated with level of montmorillonite- illite above 10 000 mg/ kg of complete feed. 3. In the labelling of feed additive and premixtures containing it, the following shall be indicated: "The additive, montmorillonite- illite, is rich in (inert) iron". 4. For users of the additive
	the

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								sources of montmorillonite- illite in complete feedingstuff shall not exceeded the permitted maximum
								level of
								20
								000
								mg/ kg
								kg of
								complete
								feedingstuff.
number of the additive	tiAndditive	chemical formula, description analytica method	category omf l animal	Maximui age inctional g	mMinimur content mg of add kg of con feedingst with a mo content o	content ditive/ nplete uff oisture f 12 %	provision	End of authorisation
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15337	Illite	composit Preparatio of montmori illite mixed layer clay mineral: phyllosilic ≥ 75 % Characte of active substance	ianimal onpecies Illonite- cates			20 000		instructions fa026' use shall indicate the following: — "The simultaneous oral use with macrolides shall
i i		Substance	-					Silaii

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	llonite-	7				The additive shall be used at a minimum level of:	be avoided", "In addition, for poultry, the simultaneous use with robenidine shall be avoided". 10 0000 mg/kg when it is used as anticaking agent directly in complementary feedingstuffs, 20 000 mg/kg when it is used as anticaking agent directly in complementary feedingstuffs, 20 000 mg/kg when it is used as anticaking
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				agent in complete feedingstuffs.
			3.	For
				poultry: the
				simultaneous
				oral
				use with
				coccidiostats
				other
				than robenidine
				is
				contraindicated.
			4.	In
				the labelling
				of
				feed
				additive and
				premixtures
				containing
				it,
				the
				following shall
				be
				indicated:
				"The
				additive, montmorillonite-
				illite,
				is rich
				in
				(inert)
				iron".
			5.	For
				users of
				the
				additive
				and
				premixtures, feed
				business
	 			operators

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				shall
				establish
				operational
				operational
				procedures
				and
				organisational
				measures
				to
				address
				potential
				risks
				resulting
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				use.
				Where
				those
				risks
				cannot
				be
				eliminated
				or
				reduced
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				protective
				equipment,
				including
				breathing
				protection
			6.	The
				total
				amount
				of
				different
				sources

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				of
				montmorillonite-
				illite
				in
				complete
				feedingstuff
				shall
				not
				exceeded
				the
				permitted
				maximum
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				complete
				feedingstuff.

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- (1) OJ L 268, 18.10.2003, p. 29.
- (2) Commission Implementing Regulation (EU) 2016/1964 of 9 November 2016 concerning the authorisations of a preparation of dolomite-magnesite for dairy cows and other ruminants for dairy production, weaned piglets and pigs for fattening and a preparation of montmorillonite-illite for all animal species as feed additives (OJ L 303, 10.11.2016, p. 7).
- (3) EFSA Journal 2014;12(11):3904
- (4) EFSA Journal 2015;13(9):4237
- (5) EFSA Journal 2020;18(5):6095.

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Changes to legislation:

There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/2120.