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)

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)].

(3) 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

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

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:

Identification number of the additive	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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: binders								
‘1g557	Montmorillonite-Illite	**Additive composition** Preparations of montmorillonite-illite mixed layer clay mineral: phyllosilicates ≥ 75 % **Characterisation of active substance** Phyllosilicates ≥ 75 %: ≥ 35 % montmorillonite-illite (swellable) ≥ 30 % illite/muscovite ≤ 15 % kaolinite (non-swellable) Quartz ≤ 20 % Iron (structural) 3,6 % (average) Free of asbestos	All animal species		10 000	20 000	1. The Member States shall ensure that instructions for use shall indicate the following: — “The simultaneous oral use with macrolides shall be avoided”, — ”In addition, for poultry, the simultaneous use with robenidine shall be avoided”. 2. For poultry: the simultaneous oral use with coccidiostats	30 November 2026’

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

		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 and premixtures, feed

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								business operators shall establish operational procedures and organisational measures to address potential risks resulting from its 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 breathing protection
							5.	total amount of different

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								sources of montmorillonite-illite in complete feedingstuff shall not exceeded the permitted maximum level of 20 000 mg/kg of complete feedingstuff.

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Identification number of the additive	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 additive/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: anti-caking agent								
‘1g557	Montmorillonite-Illite	**Additive composition** Preparation of montmorillonite-illite mixed layer clay mineral: phyllosilicates ≥ 75 % **Characterisation of active substance**	All animal species			20 000	1. The instructions for use shall indicate the following: — “The simultaneous oral use with macrolides shall	30 November 2026’

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

		Phyllosilicates ≥ 75 %: ≥ 35 % montmorillonite-illite (swellable) ≥ 30 % illite/ muscovite ≤ 15 % kaolinite (non-swellable) Quartz ≤ 20 % Iron (structural) 3,6 % (average) Free of asbestos						be avoided”, — ”In addition, for poultry, the simultaneous use with robenidine shall be avoided”.
		Analytical method[a] For the determination in feed additive: — —	X-ray diffraction (XRD) Inductively coupled plasma atomic emission spectroscopy (ICP-AES)				2. The additive shall be used at a minimum level of:	— 10 000 mg/ kg when it is used as anti-caking agent directly in complementary feedingstuffs, — 20 000 mg/ kg when it is used as anti-caking

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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 procedures and organisational measures to address potential risks resulting from its 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 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 level of 20 000 mg/kg of 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.

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