



2026/154

26.1.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/154

of 23 January 2026

concerning the authorisation of sepiolitic clay as a feed additive for all animal species other than ruminants for milk production or reproduction, weaned piglets of porcine species, porcine species for fattening, salmonids and chickens for fattening amending Implementing Regulation (EU) 2023/263 as regards the terms of the authorisation of sepiolitic clay as a feed additive for salmonids and chickens for fattening

(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) and Article 13(3) 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(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substance sepiolitic clay was authorised for a period of 10 years as a feed additive for dairy ruminants, weaned and fattening Suidae, salmonids and chickens for fattening by Commission Implementing Regulation (EU) 2023/263 ⁽³⁾.
- (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 sepiolitic clay as a feed additive for all animal species other than dairy ruminants, weaned and fattening Suidae, salmonids and chickens for fattening, requesting the additive to be classified in the additive category 'technological additives' and in the functional groups 'binders' and 'anticaking agents'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, an application was submitted for the modification of the terms of the authorisation of sepiolitic clay as laid down in Implementing Regulation (EU) 2023/263 as regards the use for salmonids and chickens for fattening. The modification concerns an increase of the maximum content to 20 000 mg per kg of complete feed, instead of the currently authorised levels of 17 600 mg/kg for salmonids and 10 000 mg/kg for chickens for fattening. Supplementary data were provided to demonstrate that the additive meets the conditions for authorisation at the proposed level. That modification is to be considered within the context of the re-evaluation of the substance.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1, ELI: <http://data.europa.eu/eli/dir/1970/524/oj>).

⁽³⁾ Commission Implementing Regulation (EU) 2023/263 of 7 February 2023 concerning the authorisation of sepiolitic clay as a feed additive for dairy ruminants, weaned and fattening Suidae, salmonids and chickens for fattening (OJ L 37, 8.2.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/263/oj).

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 March 2025 ⁽⁴⁾ that, the use of sepiolitic clay at 20 000 mg/kg complete feed is safe for all animal species, consumers and the environment. The Authority also concluded that the additive is not considered an eye or skin irritant. However, it was considered a respiratory and dermal sensitiser. Due to the dusting potential and its silica content, the additive was considered a risk by inhalation. The Authority concluded that the additive is efficacious as a binder and anticaking agent in feed for all animal species under the proposed conditions of use. It did not consider that there is a need for specific requirements of post-market monitoring.
- (6) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 4 May 2022 ⁽⁵⁾ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005 ⁽⁶⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (7) In view of the above, the Commission considers that sepiolitic clay satisfies the conditions for authorisation provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that additive should be authorised for all animal species other than ruminants for milk production or reproduction, weaned piglets of porcine species, porcine species for fattening, salmonids and chickens for fattening. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (8) In addition, in view of the above, the Commission considers that the authorisation of sepiolitic clay still meets the conditions provided for in Article 5 of Regulation (EC) No 1831/2003 when modifying the terms thereof as regards the use for salmonids and chickens for fattening, by increasing the maximum content to 20 000 mg per kg of complete feed. Implementing Regulation (EU) 2023/263 should therefore be amended accordingly.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of sepiolitic clay for salmonids and chickens for fattening, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the modification of the authorisation concerned.
- (10) 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

Authorisation

The substance specified in Annex I, belonging to the additive category 'technological additives' and to the functional groups 'binders' and 'anticaking agents' is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) 2023/263

The Annex to Implementing Regulation (EU) 2023/263 is replaced by Annex II to this Regulation.

⁽⁴⁾ EFSA Journal 2025; 23:e9365. <https://doi.org/10.2903/j.efsa.2025.9365>.

⁽⁵⁾ EFSA Journal 2022; 20(5):7344. <https://doi.org/10.2903/j.efsa.2022.7344>.

⁽⁶⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8, ELI: <http://data.europa.eu/eli/reg/2005/378/oj>).

*Article 3***Transitional measures**

1. The substance sepiolitic clay, as authorised by Implementing Regulation (EU) 2023/263, and premixtures containing this substance, which are intended for salmonids and chickens for fattening, and which are produced and labelled before 15 August 2026 in accordance with the rules applicable before 15 February 2026 may continue to be placed on the market and used until the stocks concerned are exhausted.
2. Compound feed and feed materials containing the substance referred to in paragraph 1, which are intended for salmonids and chickens for fattening, and which are produced and labelled before 15 February 2027 in accordance with the rules applicable before 15 February 2026 may continue to be placed on the market and used until the stocks concerned are exhausted.

*Article 4***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.

Done at Brussels, 23 January 2026.

For the Commission
The President
Ursula VON DER LEYEN

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
Category: technological additives. Functional group: binders								
1g563	Sepiolitic clay	<i>Additive composition</i> Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite. Powder form. <i>Characterisation of the active substance</i> Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Einecs number: 264-465-3 Chemical formula: Mg ₄ Si ₆ O ₁₅ (OH) ₂ ·6H ₂ O. Illite (potassium and iron aluminium silicate): ≥ 25 % CAS number: 12173-60-3 Einecs number: 601-803-4 Chemical formula: (K,H ₃ O)(Al,Mg,Fe) ₂ (Si,Al) ₄ O ₁₀ [(OH) ₂ ·(H ₂ O)] Carbonates (dolomite, calcium and magnesium carbonate): ≤ 35 % Free of asbestos ⁽¹⁾ Impurities: Nickel ≤ 20,3 mg/kg	All animal species other than ruminants for milk production or reproduction, weaned piglets of porcine species, porcine species for fattening, salmonids and chickens for fattening		-	20 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection. Particular attention shall be given to compliance with Union legislation on the protection of workers from the inhalation risks related to exposure to crystalline silica and nickel.	15 February 2036

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
		<i>Analytical method ⁽²⁾</i> For the characterisation of the feed additive: — X-ray diffraction (XRD) and — X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS).						

⁽¹⁾ The methods employed were: X-Ray diffraction and Scanning electron microscopy (SEM) with punctual Energy Dispersive X-Ray Analysis (EDAX).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			

Category: technological additives. Functional group: anticaking agents

1g563	Sepiolitic clay	<i>Additive composition</i> Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite. Powder form. <i>Characterisation of the active substance</i> Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Einecs number: 264-465-3	All animal species other than ruminants for milk production or reproduction, weaned piglets of porcine species, porcine species for fattening, salmonids and chickens for fattening		-	20 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks	15 February 2036
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Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
		Chemical formula: Mg ₄ Si ₆ O ₁₅ (OH) ₂ ·6H ₂ O. Illite (potassium and iron aluminium silicate): ≥ 25 % CAS number: 12173-60-3 Einecs number: 601-803-4 Chemical formula: (K,H ₃ O)(Al,Mg, Fe) ₂ (Si,Al) ₄ O ₁₀ [(OH) ₂ ·(H ₂ O)] Carbonates (dolomite, calcium and magnesium carbonate): ≤ 35 % Free of asbestos ⁽¹⁾ Impurities: Nickel ≤ 20,3 mg/kg <i>Analytical method</i> ⁽²⁾ For the characterisation of the feed additive: — X-ray diffraction (XRD) and — X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS).					resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection. Particular attention shall be given to compliance with Union legislation on the protection of workers from the inhalation risks related to exposure to crystalline silica and nickel.	

⁽¹⁾ The methods employed were: X-Ray diffraction and Scanning electron microscopy (SEM) with punctual Energy Dispersive X-Ray Analysis (EDAX).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

ANNEX II

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
Category: technological additives. Functional group: binders								
1g563	Sepiolitic clay	<i>Additive composition</i> Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite. Powder form. <i>Characterisation of the active substance</i> Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Einecs number: 264-465-3 Chemical formula: $Mg_4Si_6O_{15}(OH)_2 \cdot 6H_2O$. Illite (potassium and iron aluminium silicate): ≥ 25 % CAS number: 12173-60-3 Einecs number: 601-803-4 Chemical formula: $(K,H_3O)(Al,Mg,Fe)_2(Si,Al)_4O_{10}[(OH)_2 \cdot (H_2O)]$ Carbonates (dolomite, calcium and magnesium carbonate): ≤ 35 % Free of asbestos ⁽¹⁾ Impurities: Nickel ≤ 20,3 mg/kg	— Ruminants for milk production or reproduction — Weaned piglets of porcine species — Porcine species for fattening — Salmonids — Chickens for fattening		-	20 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection. Particular attention shall be given to compliance with Union legislation on the protection of workers from the inhalation risks related to exposure to crystalline silica and nickel.	28 February 2033

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
		Analytical method ⁽²⁾ For the characterisation of the feed additive: — X-ray diffraction (XRD) and — X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS).						

⁽¹⁾ The methods employed were: X-Ray diffraction and Scanning electron microscopy (SEM) with punctual Energy Dispersive X-Ray Analysis (EDAX).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			

Category: technological additives. Functional group: anticaking agents

1g563	Sepiolitic clay	<i>Additive composition</i> Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite. Powder form. <i>Characterisation of the active substance</i> Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Einecs number: 264-465-3	— Ruminants for milk production or reproduction — Weaned piglets of porcine species		-	20 000	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks	28 February 2033
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Identification number of the feed additive	Name of the 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 feed with a moisture content of 12 %			
		Chemical formula: Mg ₄ Si ₆ O ₁₅ (OH) ₂ ·6H ₂ O. Illite (potassium and iron aluminium silicate): ≥ 25 % CAS number: 12173-60-3 Einecs number: 601-803-4 Chemical formula: (K,H ₃ O)(Al,Mg, Fe) ₂ (Si,Al) ₄ O ₁₀ [(OH) ₂ ·(H ₂ O)] Carbonates (dolomite, calcium and magnesium carbonate): ≤ 35 % Free of asbestos ⁽¹⁾ Impurities: Nickel ≤ 20,3 mg/kg <i>Analytical method</i> ⁽²⁾ For the characterisation of the feed additive: — X-ray diffraction (XRD) and — X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS).	— Porcine species for fattening — Salmonids — Chickens for fattening				resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protection. Particular attention shall be given to compliance with Union legislation on the protection of workers from the inhalation risks related to exposure to crystalline silica and nickel.	

⁽¹⁾ The methods employed were: X-Ray diffraction and Scanning electron microscopy (SEM) with punctual Energy Dispersive X-Ray Analysis (EDAX).

⁽²⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.