

II

(Non-legislative acts)

REGULATIONS

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

(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 an 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 without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species, belonging to the functional group 'binders, anticaking agents and coagulants'. That substance was subsequently included in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), of Regulation (EC) No 1831/2003.
- (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, 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) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 May 2022 ⁽³⁾ that, under the proposed conditions of use, sepiolitic clay is safe for dairy ruminants, weaned piglets, pigs for fattening and other growing *Suidae* at a level of 20 000 mg per kilo of complete feed, for salmonids at a level of 17 600 mg per kilo of complete feed and for chickens for fattening at a level of 10 000 mg per kilo of complete feed, and does not have an adverse effect on consumer safety or the environment. It could not conclude on the safety of the additive for other animal species and categories. The Authority also concluded that the additive poses a risk by inhalation for the user, in particular due to the presence of crystalline silica and of nickel in the additive, and that it is not irritant to the skin or eyes but should be considered as skin and respiratory sensitiser. The Authority concluded that the additive is efficacious as a binder and as an anticaking agent. It also verified the report on the method of analysis in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2022;20(5):7344.

- (5) The assessment of sepiolitic clay shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised for dairy ruminants, weaned and fattening *Suidae*, salmonids and chickens for fattening. Supplementary information has been requested by the Commission to the applicant concerning the safety of the additive for the other animal species and categories. 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. Those protective measures should comply with Union legislation on worker safety requirements.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

Authorisation

The substance specified in the Annex, 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

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which are intended for dairy ruminants, weaned and fattening *Suidae*, salmonids and chickens for fattening and are produced and labelled before 28 August 2023 in accordance with the rules applicable before 28 February 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance specified in the Annex, which are intended for dairy ruminants, weaned and fattening *Suidae*, salmonids and chickens for fattening and are produced and labelled before 28 February 2024 in accordance with the rules applicable before 28 February 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

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.

Done at Brussels, 7 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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: technological additives. Functional group: binders								
1g563	Sepiolitic clay	<p>Additive composition Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite.</p> <p>Powder form</p> <p>Characterisation of the active substance Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Einecs number: 264-465-3 Chemical formula: $Mg_4Si_6O_{15}(OH)_2 \cdot 6H_2O$.</p> <p>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 (!)</p>	— Dairy ruminants		-	20 000	<p>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated.</p> <p>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 or reduced to a minimum 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.</p>	28 February 2033
			— Weaned and fattening <i>Suidae</i>					
			Salmonids		-	17 600		
			Chickens for fattening		-	10 000		

		Analytical method ⁽²⁾ For the characterisation of the feed additive: — X-ray diffraction (XRD) and — X-ray fluorescence (XRF) or atomic absorption spectrometry (AAS)						
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⁽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 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: technological additives. Functional group: anticaking agents								
1g563	Sepiolitic clay	<p>Additive composition</p> <p>Hydrated magnesium silicate of sedimentary origin, containing ≥ 40 % sepiolite and ≥ 25 % illite.</p> <p>Powder form</p> <p>Characterisation of the active substance</p> <p>Sepiolite (hydrous magnesium silicate): ≥ 40 % CAS number: 63800-37-3 Eines number: 264-465-3 Chemical formula: $Mg_4Si_6O_{15}(OH)_2 \cdot 6H_2O$.</p> <p>Illite (potassium and iron aluminium silicate): ≥ 25 % CAS number: 12173-60-3 Eines number: 601-803-4 Chemical formula: $(K,H_3O)(Al,Mg,Fe)_2(Si,Al)_4O_{10}[(OH)_2 \cdot (H_2O)]$</p> <p>Carbonates (dolomite, calcium and magnesium carbonate): ≤ 35 % Free of asbestos ⁽¹⁾</p>	— Dairy ruminants — Weaned and fattening <i>Suidae</i>		-	20 000	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 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 or reduced to a minimum 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
			Salmonids		-	17 600		
			Chickens for fattening		-	10 000		
		<p>Analytical method ⁽²⁾</p> <p>For the characterisation of the feed additive:</p> <ul style="list-style-type: none"> — 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).

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