

PAFF 09-10/10/2025



Brussels, **XXX**
SANTE/6155344/2025 CIS
(POOL/G5/2025/6155344/6155344-EN
CIS.docx)
[...](2025) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

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 and 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)

EN

EN

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

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 and 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 nutrition¹, 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/EEC².
- (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) 2023/263³.
- (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

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, <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)

Feltkode ændret

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.

- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 March 2025⁴ 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 2022⁵ are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005⁶, 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.

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>).

- (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 ‘zootechnical 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.

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 [6 months after the date of entry into force of this Regulation – Date to be inserted by the OP] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the OP] 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 [12 months after the date of entry into force of this Regulation – Date to be inserted by the OP] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the OP] 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,

For the Commission

The President

Ursula VON DER LEYEN