



Brussels, **XXX**
SANTE/2722369/2023
[...] (2023) **XXX** draft

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

of **XXX**

**on the status of attapulgit as a feed additive within the scope of Regulation (EC) No
1831/2003 of the European Parliament and of the Council**

(Text with EEA relevance)

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

of XXX

on the status of attapulgit as a feed additive within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council

(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 on additives for use in animal nutrition¹, and in particular Article 2(3) thereof,

Whereas:

- (1) For the substance attapulgit, there is uncertainty whether it is a feed additive within the scope of Regulation (EC) No 1831/2003. This uncertainty results from various questions or doubts expressed by national competent authorities responsible for official controls or by economic operators concerning the classification of that substance, which is currently included in the Catalogue of feed materials established by Commission Regulation (EU) No 68/2013².
- (2) Such uncertainty about the status of a product with regard to feed additives may jeopardise the marketing of feed products throughout the Union, since the distinction between feed additives and other feed products has a major role as regards the conditions of their placing on the market, under the respective applicable legislation.
- (3) In order to allay the uncertainty regarding the status of attapulgit as a feed additive, it is appropriate to adopt a relevant measure under Regulation (EC) No 1831/2003, determining that status. Such measure would bring consistency in the treatment of the substance concerned and would facilitate the work of the national competent authorities responsible for official controls, while helping the interested economic operators to act in a framework providing for an appropriate level of legal certainty.
- (4) To determine whether a product is a feed additive within the scope of Regulation (EC) No 1831/2003, it is appropriate to refer to the guidelines for the distinction between feed additives, feed materials and other products, established by Recommendation 2011/25/EU³. In particular, those guidelines provide for several criteria to be simultaneously considered in a case-by-case evaluation, in order to create a profile of each specific product, taking into account all its characteristics. Among the criteria for the differentiation between feed additives and feed materials are the production and processing method, the chemical definition and the level of standardisation or purification, the safety and mode of use and the functionality of the product concerned.

¹ OJ L 268, 18.10.2003, p. 29.

² Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1).

³ Commission Recommendation 2011/25/EU of 14 January 2011 establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (OJ L 11, 15.1.2011).

In addition, for the sake of consistency, products with similar properties should be classified by analogy.

- (5) Based on an examination of the criteria in Recommendation 2011/25/EU, it has been concluded that attapulgite should be considered as a feed additive within the scope of Regulation (EC) No 1831/2003. Attapulgite is essentially used in order to perform technological functions in feed, such as binding, anti-caking or reducing mycotoxins contamination of feed, or even zootechnical functions by affecting animals' gastrointestinal flora or digestibility of feed, which are typical of feed additives' functionality. In addition, the characteristics and properties of attapulgite are very similar to those of other clay minerals which are considered as feed additives. Therefore, the classification by analogy of attapulgite as a feed additive would bring consistency in the treatment of those similar products.
- (6) As a consequence of the classification of attapulgite as a feed additive within the scope of Regulation (EC) No 1831/2003, it is appropriate to provide for a transitional period which would allow interested parties to adapt to the status of that substance, including for the purposes of submission of an application for authorisation as a feed additive, and the further processing of such application in accordance with Regulation (EC) No 1831/2003.
- (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

Attapulgite is a feed additive within the scope of Regulation (EC) No 1831/2003.

Article 2

The substance referred to in Article 1 may continue to be placed on the market and used in accordance with the rules applicable to feed materials until *[OP please insert the date = 7 years after the date of entry into force of this Regulation]*.

Article 3

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