



COMMISSION IMPLEMENTING REGULATION (EU) 2025/647

of 2 April 2025

amending and correcting Implementing Regulation (EU) 2019/913 and correcting Implementing Regulation (EU) 2022/1471 concerning the authorisation of lanthanum carbonate octahydrate, respectively with identification numbers 4d1 and 4d23, as feed additives for cats

(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 Articles 9(2) and 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 an authorisation.
- (2) The authorisation of lanthanum carbonate octahydrate was renewed for 10 years as a feed additive for cats, with identification number 4d1, by Commission Implementing Regulation (EU) 2019/913 ⁽²⁾ (holder of authorisation: Bayer HealthCare AG). Lanthanum carbonate octahydrate was also authorised for 10 years as a feed additive for cats, with identification number 4d23, by Commission Implementing Regulation (EU) 2022/1471 ⁽³⁾ (holder of authorisation: Porus GmbH). Both additives were erroneously referred to as a preparation in the Annexes to those Implementing Regulations. In addition, the conditions of use in the Annexes to those Implementing Regulations do not properly reflect the conclusion of the European Food Safety Authority ('the Authority') in its opinions of 27 September 2007 ⁽⁴⁾ and 27 January 2022 ⁽⁵⁾ that lanthanum carbonate octahydrate is safe and efficacious for adult cats.
- (3) Implementing Regulations (EU) 2019/913 and (EU) 2022/1471 should therefore be corrected accordingly.
- (4) In addition, Bayer HealthCare AG, the holder of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats, with identification number 4d1, has submitted an application to the Commission in accordance with Article 13(3) of Regulation (EC) No 1831/2003, proposing to change the name of the holder of the authorisation for that feed additive to Elanco GmbH.
- (5) The proposed change of the terms of the authorisation concerning the name of the holder of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats, with identification number 4d1, is purely administrative in nature and does not entail a new assessment. The Authority was informed of the application.

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

⁽²⁾ Commission Implementing Regulation (EU) 2019/913 of 29 May 2019 concerning the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats and repealing Regulation (EC) No 163/2008 (holder of authorisation Bayer HealthCare AG) (OJ L 146, 5.6.2019, p. 57, ELI: http://data.europa.eu/eli/reg_impl/2019/913/oj).

⁽³⁾ Commission Implementing Regulation (EU) 2022/1471 of 5 September 2022 concerning the authorisation of lanthanum carbonate octahydrate as a feed additive for cats (holder of authorisation Porus GmbH) (OJ L 231, 6.9.2022, p. 113, ELI: http://data.europa.eu/eli/reg_impl/2022/1471/oj).

⁽⁴⁾ EFSA Journal (2007) 542.

⁽⁵⁾ EFSA Journal 2022;20(2):7168.

- (6) To allow Elanco GmbH to exploit its marketing rights in accordance with Article 9(6) of Regulation (EC) No 1831/2003, it is necessary to change the terms of the authorisation concerned by indicating its name as the holder of the authorisation for lanthanum carbonate octahydrate as a feed additive for cats, with identification number 4d1.
- (7) Implementing Regulation (EU) 2019/913 should therefore be amended accordingly.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of the authorisations of lanthanum carbonate octahydrate for cats, it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the correction of Implementing Regulations (EU) 2019/913 and (EU) 2022/1471 and the amendment to Implementing Regulation (EU) 2019/913.
- (9) 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

Correction and amendment to Implementing Regulation (EU) 2019/913

The Annex to Implementing Regulation (EU) 2019/913 is replaced by Annex I to this Regulation.

Article 2

Correction to Implementing Regulation (EU) 2022/1471

The Annex to Implementing Regulation (EU) 2022/1471 is replaced by Annex II to this Regulation.

Article 3

Transitional measures

1. The substance specified in Annexes I and II and premixtures containing that substance, which are intended for cats and which are produced and labelled before 23 October 2025 in accordance with the rules applicable before 23 April 2025 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 Annexes I and II, which are intended for cats and which are produced and labelled before 23 April 2027 in accordance with the rules applicable before 23 April 2025 may continue to be placed on the market and used until the existing stocks 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, 2 April 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Identification number of the feed additive	Name of the holder of authorisation	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: zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorous excretion via urine)									
4d1	Elanco GmbH	Lanthanum carbonate octahydrate	<i>Additive composition</i> Lanthanum carbonate octahydrate At least 85 % lanthanum carbonate octahydrate as active substance. <i>Characterisation of the active substance</i> Lanthanum carbonate octahydrate La ₂ (CO ₃) ₃ ·8H ₂ O CAS number 6487-39-4 <i>Analytical method ⁽¹⁾</i> For the quantification of carbonate in the feed additive: Union method, introduced by Commission Regulation (EC) No 152/2009 ⁽²⁾ . For the quantification of lanthanum in the feed additive and compound feed: Inductively coupled plasma-atomic emission spectrometry (ICP-AES).	Cats	—	1 500	7 500	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be fed to adult cats. 3. In the directions for use of the additive, the following shall be indicated: 'For adult cats. Avoid simultaneous use of feeds with high level of phosphorus.' 4. 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 breathing protective equipment.	25 June 2029

⁽¹⁾ 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.

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).

ANNEX II

Identification number of the feed additive	Name of the holder of authorisation	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: zootechnical additives. Functional group: other zootechnical additives (decrease in phosphorous excretion via urine)									
4d23	Porus GmbH	Lanthanum carbonate octahydrate	<i>Additive composition</i> Lanthanum carbonate octahydrate having at least 85 % lanthanum carbonate octahydrate as active substance. Solid form. <i>Characterisation of the active substance</i> Lanthanum carbonate octahydrate La ₂ (CO ₃) ₃ •8H ₂ O CAS number 6487-39-4 <i>Analytical method</i> ⁽¹⁾ For the quantification of carbonate in the feed additive: Union method, introduced by Commission Regulation (EC) No 152/2009 ⁽²⁾ . For the quantification of lanthanum in the feed additive and compound feed: Inductively coupled plasma-atomic emission spectrometry (ICP-AES).	Cats	—	1 500	7 500	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. The additive shall only be fed to adult cats. 3. In the directions for use of the additive, the following shall be indicated: 'For adult cats. Avoid simultaneous use of feeds with high level of phosphorus.' 4. 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 breathing protective equipment.	26 September 2032

⁽¹⁾ 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.

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/152/oj>).