EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2024/2373 CIS
(POOL/G5/2024/2373/2373-EN
CIS.docx)
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 152/2009 as regards the determination of carbonates in feed

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 152/2009 as regards the determination of carbonates in feed

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)[1], and in particular Article 34(6) thereof,

Whereas:

(1) Commission Regulation (EC) No 152/2009[2] lays down methods of sampling and analysis for the official control of feed.

(2) Commission Implementing Regulation (EU) 2024/771[3] deleted the method of analysis for the determination of carbonates in feed. However, the quantification of carbonates in the authorised feed additive lanthanum carbonate octahydrate requires the use of the deleted method of analysis.

(3) Furthermore, Commission Regulation (EU) No 68/2013[4] provides for the compulsory declaration of calcium carbonate for certain feed materials. It is necessary to use the deleted method of analysis to determine the quantity of calcium carbonate in those feed materials.

(4) It is therefore appropriate to reintroduce the method of analysis for the determination of carbonates in feed.

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1 OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj.

2 Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down 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).

3 Commission Implementing Regulation (EU) 2024/771 of 29 February 2024 amending Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (OJ L, 2024/771, 15.3.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/771/oj).

4 Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1, ELI: http://data.europa.eu/eli/reg/2013/68/oj).

(5) 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

Annex III to Regulation (EC) No 152/2009 is amended in accordance with the Annex to this Regulation.

Article 2

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

EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2024/2373 ANNEX CIS
(POOL/G5/2024/2373/2373-EN
ANNEX CIS.docx)
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ANNEX

ANNEX

to the

Commission Implementing Regulation (EU) .../... of XXX

amending Regulation (EC) No 152/2009 as regards the determination of carbonates in feed

ANNEX

In Annex III to Commission Regulation (EC) No 152/2009, the following part is added after part 'O. DETERMINATION OF CHLORINE FROM CHLORIDES':

'P. DETERMINATION OF CARBONATES

1. Purpose and Scope

This method makes it possible to determine the amount of carbonates, conventionally expressed as calcium carbonate, in feed with the exception of feed where iron carbnate is present.

2. Principle

The carbonates are decomposed in hydrochloric acid; the carbon dioxide released is collected in a graduated tube, and its volume compared with that released under the same conditions by a known quantity of calcium carbonate.

3. Reagents

3.1. Hydrochloric acid, density 1,10 g/ml.

3.2. Pure calcium carbonate.

3.3. Sulphuric acid, approximately 0,05 mol/litre, coloured with methyl red.

4. Apparatus

Scheibler-Dietrich apparatus (see diagram in the Appendix) or equivalent apparatus (calcimeter).

5. Procedure

Depending on the sample's carbonate content, weigh a portion of the sample as shown below:

(a) 0,5 g for products containing from 50 % to 100 % of carbonates, expressed as calcium carbonate;
(b) 1 g for products containing from 40 % to 50 % of carbonates, expressed as calcium carbonate;
(c) 2 g to 3 g for other products.

Hydochloric acid (point 3.1, above) is added to the portion of the sample to decompose any carbonates present. The volume of carbon dioxide is measured by using a Scheibler-Dietrich apparatus or equivalent apparatus (calcimeter) and is compared with the volume of carbon dioxide produced by 0.5 g pure calcium carbonate (point 3.2, above).

All determinations shall be carried out under the same conditions in order to avoid making corrections for differences in temperature and pressure. The determination should be preferably carried out in a temperature-controlled room.

The procedure making use of the Scheibler-Dietrich apparatus is described in detail in the Appendix.

6. Calculation

The content of carbonates, expressed as pure calcium carbonate, is calculated by using the formula:

$$X = \frac{V \times 100}{V_1 \times 2m}$$

where:

X = % (w/w) of carbonates in the sample, expressed as calcium carbonate

V = ml of CO_2 released by the portion of the sample

V_1 = ml of CO_2 released by 0,5 g of CaCO3

m = weight, in grammes, of the portion of the sample.

7. Observations

7.1. If the Scheibler-Dietrich apparatus is used and the sample weighs more than 2 g, first place 15 ml of distilled water in the flask (item 4 in the diagram in the Appendix, below) and mix before beginning the test by adding hydrochlooric acid (point 3.1, above). Use the same volume of distilled water for the control test.

7.2. If the apparatus used has a different volume from that of the Scheibler-Dietrich apparatus, the portions taken from the sample and from the control substance and the calculation must be adapted accordingly.

Appendix

Detailed procedure making use of the Scheibler-Dietrich apparatus

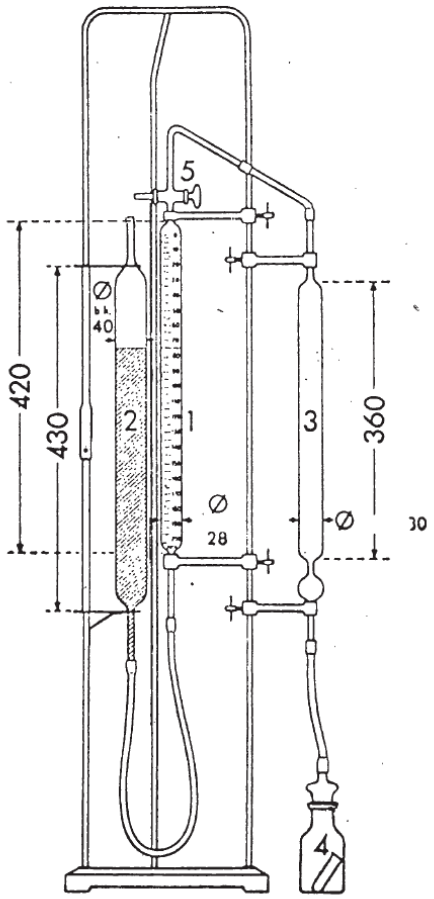
Place the portion of the sample in the special flask (item 4 in the diagram) of the apparatus, fitted with a small tube of unbreakable material containing 10 ml of hydrochloric acid (point 3.1, above), and connect the flask to the apparatus. Turn the three-way cock (item 5 in the diagram) so that the graduated tube (item 1 in the diagram) connects with the outside. Using the mobile tube (item 2 in the diagram), which is filled with coloured sulphuric acid (point 3.3, above) and is connected to the graduated tube (item 1 in the diagram), bring the level of the liquid up to the zero mark. Turn the three-way cock (item 5 in the diagram) in order to connect up the tubes (items 1 and 3 in the diagram) and check that the level is at zero.

Run the hydrochloric acid (point 3.1, above) slowly over the portion of the sample, tilting the special flask (item 4 in the diagram). Make the pressure equal by lowering the mobile tube (item 2 in the diagram). Shake the special flask (item 4 in the diagram) until the release of carbon dioxide has stopped completely.

Restore the pressure by bringing the liquid back to the same level in the tubes (items 1 and 2 in the diagram). After a few minutes, when the volume of gas has become constant, take the reading.

Carry out a control test in the same conditions on 0,5 g of calcium carbonate (point 3.2, above).

SCHEIBER-DIETRICH APPARATUS FOR THE DETERMINATION OF CO_2



(measured in mm)

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/9870522/2024 CIS
(POOL/G5/2024/9870522/9870522-EN CIS.docx)
[…](2024) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

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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.

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.

(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 [*6 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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 [24 *months after the date of entry into force of this Regulation – Date to be inserted by*

the Service responsible for the publication] in accordance with the rules applicable before [*the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication*] 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,

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Identi-fication 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 authorisa-tion
						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	***Additive composition*** Lanthanum carbonate octahydrate At least 85 % lanthanum carbonate octahydrate as active substance. ***Characterisation of the active substance*** Lanthanum carbonate octahydrate $La_2(CO_3)_{3*}8H_2O$ CAS number 6487-39-4 ***Analytical method*** **([1])** For the quantification of carbonate in the feed additive: Union method, introduced by Commission Regulation (EC) No 152/2009. For the quantification of lanthanum in the feed additive and compound feed: Inductively coupled plasma-atomic emission spectrometry (ICP-AES).	Cats	–	1500	7500	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	25 June 2029

								used with personal breathing protective equipment.	

([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.

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	***Additive composition*** Lanthanum carbonate octahydrate having at least 85 % lanthanum carbonate octahydrate as active substance. Solid form. ***Characterisation of the active substance*** Lanthanum carbonate octahydrate $La_2(CO_3)_3{*}8H_2O$ CAS number 6487-39-4 ***Analytical method*** ([1]) For the quantification of carbonate in the feed additive: Union method, introduced by Commission Regulation (EC) No 152/2009. For the quantification of	Cats	-	1500	7500	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	26 September 2032

			lanthanum in the feed additive and compound feed: Inductively coupled plasma-atomic emission spectrometry (ICP-AES).					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.	

([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.