

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/1773****of 26 November 2020****amending Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives****(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 <sup>(1)</sup>, and in particular Article 7(4) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Commission Regulation (EC) No 429/2008 <sup>(2)</sup> sets out detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications for the authorisation of feed additives and the assessment of such applications.
- (2) Regulation (EU) 2019/1381 of the European Parliament and of the Council <sup>(3)</sup> aims at increasing the transparency and the sustainability of Union risk assessment in the food chain. For that purpose, it amends Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup> and Regulation (EC) No 1831/2003 with a view to strengthening transparency in procedures concerning the authorisation of feed additives.
- (3) To take into account sectoral specificities, Regulation (EU) 2019/1381 amends the provisions relating to transparency and confidentiality laid down in Regulation (EC) No 1831/2003.
- (4) As regards the authorisation of feed additives, the amendments brought to Regulation (EC) No 178/2002 by Regulation (EU) 2019/1381 have also a direct impact on the requirements laid down in Regulation (EC) No 429/2008 as far as the preparation and the presentation of application dossiers are concerned, requiring the adaptation of those requirements for reasons of consistency and legal certainty. Regulation (EC) No 429/2008 should be amended to lay down the necessary additional provisions regarding the preparation and the presentation of application dossiers.
- (5) In particular, the provisions of Regulation (EC) No 429/2008 should be adapted as regards confidentiality requests, the format of the information and data supporting applications, which should be electronic and will need to comply with standard data formats, the concept of summary of the dossier due to the transparency principle laid down by Regulation (EU) 2019/1381 and the reference to studies notified in accordance with Article 32b of Regulation (EC) No 178/2002.
- (6) This Regulation should apply from 27 March 2021 and to applications and dossiers submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.
- (7) Regulation (EC) No 429/2008 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

<sup>(3)</sup> Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendments to Regulation (EC) No 429/2008**

Regulation (EC) No 429/2008 is amended as follows:

(1) in Article 2, paragraph 2 is replaced by the following:

'2. Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002 of the European Parliament and of the Council (\*), the application and the dossier shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of the standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application and the dossier shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.

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(\*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002. p. 1).';

(2) Annexes I and II are amended in accordance with the Annex to this Regulation.

*Article 2*

**Entry into force and application**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 27 March 2021 and to applications and dossiers submitted from that date.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 26 November 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

Annexes I and II to Regulation (EC) No 429/2008 are amended as follows:

(1) in Annex I, point 1.5 is replaced by the following:

**1.5. Enclosures**

- complete dossier;
- summary of the dossier in accordance with Article 7(3)(h) of Regulation (EC) No 1831/2003;
- scientific summary of the dossier;
- all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002;
- confidentiality request in accordance with Article 18 of Regulation (EC) No 1831/2003;
- copy of the administrative data of the applicant(s);
- three samples of the feed additive to the CRL in accordance with Article 7(3)(f) of Regulation (EC) No 1831/2003;
- to the CRL: material safety data sheet;
- to the CRL: certificate of identification and analysis; and
- confirmation that the fee to the CRL has been paid (Article 4 of Commission Regulation (EC) No 378/2005 (\*)).

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(\*) 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).;

(2) Annex II is amended as follows:

(a) in the part 'General aspects', the penultimate paragraph before the heading 'Safety assessment' is replaced by the following:

'Each dossier shall contain a summary and a scientific summary in order to enable the additive concerned to be identified and characterised.';

(b) in point 1.1 under Section I, the title is replaced by the following:

**'1.1. Summary in accordance with Article 7(3)(h) of Regulation (EC) No 1831/2003';**

(c) point 1.1.1(d) is replaced by the following:

'(d) studies on safety and efficacy of the additive, along with all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002;'.

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