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)

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[(1)], and in particular Article 7(4) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Commission Regulation (EC) No 429/2008[(2)] 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[(3)] 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[(4)] 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,

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[(5)], 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.;

(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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1773. (See end of Document for details)*

Done at Brussels, 26 November 2020.

For the Commission

The President

Ursula VON DER LEYEN