COMMISSION IMPLEMENTING REGULATION (EU) 2021/428

of 10 March 2021

adopting standard data formats for the submission of applications for the approval or the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 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 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 ([1]) and in particular Article 39f(2)(b) thereof,

Whereas:

(1) Regulation (EU) 2019/1381 of the European Parliament and of the Council ([2]) amended, among others, Regulation (EC) No 178/2002 and Regulation (EC) No 1107/2009 of the European Parliament and of the Council ([3]) in order to strengthen the transparency and the sustainability of the Union risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') conducts a scientific risk assessment.

(2) Article 7(1) of Regulation (EC) No 1107/2009 provides that an application for the approval of an active substance or for an amendment to the conditions of an approval are to be submitted in accordance with standard data formats.

(3) The Authority has drawn up draft standard data formats, based on the IUCLID software package, for the purposes of the applications for approval and for the amendment to the conditions of approval of active substances, as provided for in Regulation (EC) No 1107/2009 and relevant requests for a scientific output.

(4) In order to ensure a high level of transparency in the activities of the Authority, it is appropriate to enable the efficient processing of requests to the Authority for a scientific output and to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements set out in Union law. Consequently, standard data formats should be adopted for the submission of applications within the meaning of Article 7(1) of Regulation (EC) No 1107/2009.

(5) As this Regulation implements provisions of Regulation (EC) No 178/2002 which apply from 27 March 2021, it should apply from the same date.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([1]) OJ L 31, 1.2.2002, p. 1.

([2]) 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).

([3]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation adopts standard data formats for the submission of applications for the approval or for the amendment to the conditions of approval of active substances, within the meaning of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, in accordance with Article 7 of that Regulation.

2. It shall apply to applications, referred to in paragraph 1, submitted on or after 27 March 2021.

Article 2

Adoption of standard data formats

The standard data formats for the approval of an active substance and those for the amendment to the conditions of such an approval, as proposed by the Authority, based on the IUCLID software package and linked with the central submission system to be established in accordance with Article 7(1) of Commission Implementing Regulation (EU) 2020/1740 ([4]), are hereby adopted.

Article 3

Entry into force and application

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

It shall apply from 27 March 2021.

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

Done at Brussels, 10 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

([4]) Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).