Commission Implementing Regulation (EU) 2019/1100 of 27 June 2019 concerning the non-renewal of approval of the active substance desmedipham, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1100

of 27 June 2019

concerning the non-renewal of approval of the active substance desmedipham, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 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[(1)], and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2004/58/EC[(2)] included desmedipham as an active substance in Annex I to Council Directive 91/414/EEC[(3)].

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(4)].

(3) The approval of the active substance desmedipham, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2020.

(4) An application for the renewal of the approval of desmedipham was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority (‘the Authority’) and the Commission on 21 December 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1100. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 10 January 2018, the Authority communicated to the Commission its conclusion[(6)] on whether desmedipham can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identified specific concerns. In particular, it was not possible to exclude exposure of consumers and/or livestock to residues containing free and/or conjugated aniline (classified as mutagen category 2 and carcinogen category 2) and consumer exposure to residues containing 4-aminophenol (classified as mutagen category 2) via animal commodities. In addition, the Authority concluded that a high long-term risk to mammals was identified for all representative uses, except for insectivorous mammals when the use pattern includes only one application. A high long-term risk for birds was identified for the representative uses in sugar beet/fodder beet, when the use pattern includes two or three applications.

(10) Furthermore, the Authority also concluded that the assessment of endocrine disrupting properties could not be completed based on the available information.

(11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(12) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(13) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance desmedipham in accordance with Article 20(1)(b) of that Regulation.

(14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing desmedipham.

(16) For plant protection products containing desmedipham, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should at the latest, expire on 1 July 2020.

(17) Commission Implementing Regulation (EU) 2019/707[(7)] extended the approval period of desmedipham to 31 July 2020 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on the non-renewal of the approval has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1100. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(18) This Regulation does not prevent the submission of a further application for the approval of desmedipham pursuant to Article 7 of Regulation (EC) No 1107/2009.

(19) 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

Non-renewal of the approval of active substance

The approval of the active substance desmedipham is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 86, on desmedipham, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing desmedipham as active substance by 1 January 2020 at the latest.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 1 July 2020 at the latest.

Article 5

Entry into force

This Regulation shall enter into force on the third 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.