Commission Implementing Regulation (EU) 2019/1137 of 3 July 2019 renewing the approval of the active substance dimethenamid-P 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) 2019/1137

of 3 July 2019

renewing the approval of the active substance dimethenamid-P 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) thereof,

Whereas:

(1) Commission Directive 2003/84/EC[(2)] included dimethenamid-P 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 dimethenamid-P, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.

(4) An application for the renewal of the approval of the active substance dimethenamid-P 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 11 August 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1137. 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 12 April 2018, the Authority communicated to the Commission its conclusion[(6)] on whether dimethenamid-P can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report and the Regulation proposal regarding dimethenamid-P to the Standing Committee on Plants, Animals, Food and Feed on 24 January 2019.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[(7)], the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that dimethenamid-P is an endocrine disrupter and that no additional studies are considered necessary to be carried out. Thus, the Commission concludes that dimethenamid-P is not to be considered as having endocrine disrupting properties.

(10) 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, and the Commission has carefully examined them.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance dimethenamid-P that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of dimethenamid-P.

(12) The risk assessment for the renewal of the approval of the active substance dimethenamid-P is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing dimethenamid-P may be authorised.

(13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 of that Regulation and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require further confirmatory information as regards the effects of water treatment processes on the nature of residues present in drinking water and to recommend Member States to pay attention to the protection of operators and workers, of groundwater, of aquatic organisms and small herbivorous mammals in the framework of any authorisations to be granted, as appropriate.

(14) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) Commission Implementing Regulation (EU) 2018/1262[(8)] extended the approval period of dimethenamid-P to 31 October 2019 in order to allow the renewal process to be completed before the expiry of the approval of that active substance. Given that a

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1137. 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*

decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 September 2019.

(16) 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

Renewal of the approval of active substance

The approval of the active substance dimethenamid-P, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of 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 1 September 2019.

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

Done at Brussels, 3 July 2019.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1137. 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*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Dimethenamid-P CAS No 163515-14-8 CIPAC No 638	(S)-2-chloro-N-(2,4-dimethyl-3-thienyl)-N-(2-methoxy1-methylethyl)acetamide	≥ 930 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: 1,1,1,2-Tetrachloroethane (TCE): ≤ 1,0 g/kg	1 September 2019	31 August 2034	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal

a Further details on identity and specification of active substance are provided in the renewal report.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/1137. 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*

					protective equipment; — the protection of groundwater, in particular regarding the metabolites of dimethenamid-P; — the protection of aquatic organisms and small herbivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water

a Further details on identity and specification of active substance are provided in the renewal report.