COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191

of 19 July 2021

renewing the approval of the active substance clopyralid 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 2006/64/EC ([2]) included clopyralid 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 clopyralid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2022.

(4) An application for the renewal of the approval of the active substance clopyralid 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 draft 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 31 May 2017.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 6 July 2018, the Authority communicated to the Commission its conclusion ([6]) on whether clopyralid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and the draft Regulation for clopyralid to the Standing Committee on Plants, Animals, Food and Feed on 24 March 2021.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances (OJ L 206, 27.7.2006, p. 110).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 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 concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([6]) *EFSA Journal* 2018;16(8):5389. Available online: www.efsa.europa.eu.

(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 clopyralid is an endocrine disrupter since no toxic effects on endocrine organs have been observed. Thus, the Commission concludes that clopyralid 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 paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments on the draft renewal report, which have been carefully examined.

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

(12) The risk assessment for the renewal of the approval of the active substance clopyralid is based on representative uses as herbicide on winter cereals and grassland. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as an herbicide, it is, however, necessary to provide, in accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, for certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

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

(14) Commission Implementing Regulation (EU) 2021/566 ([8]) extended the approval period of clopyralid to 30 April 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.

(15) 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 the active substance

The approval of the active substance clopyralid is renewed as set out in Annex I.

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.

([7]) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

([8]) Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, clopyralid, *Cydia pomonella Granulovirus* (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, mepanipyrim, *Metarhizium anisopliae* (var. anisopliae) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Streptomyces* K61 (formerly '*S. griseoviridis*'), *Trichoderma asperellum* (formerly '*T. harzianum*') strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly '*T. harzianum*') strain T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 118, 7.4.2021, p. 1).

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 October 2021.

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

Done at Brussels, 19 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine-2-carboxylic acid or 3,6dichloropicolinic acid	≥ 950 g/kg	1 October 2021	30 September 2036	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 clopyralid, 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 specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; — possible presence of clopyralid residues in rotational crops; — the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; — the protection of groundwater under vulnerable conditions. 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 drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

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

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 129 on clopyralid is deleted;

(2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
'147	Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine-2-carboxylic acid or 3,6dichloropicolinic acid	≥ 950 g/kg	1 October 2021	30 September 2036	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 clopyralid, 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 specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; — possible presence of clopyralid residues in rotational crops; — the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; — the protection of groundwater under vulnerable conditions. 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 drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

([1]) Further details on the identity and the specification of the active substance are provided in the renewal report.'