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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2198

of 4 September 2024

renewing the approval of the active substance folpet in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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 2007/5/EC ([2]) included folpet 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 folpet, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 15 February 2025.

(4) An application for the renewal of the approval of the active substance folpet was submitted to Austria, the rapporteur Member State, and Italy, the co-rapporteur Member State, 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 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') 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 Authority and the Commission on 14 March 2018. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of folpet.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.
([2]) Commission Directive 2007/5/EC of 7 February 2007 amending Council Directive 91/414/EEC to include captan, folpet, formetanate and methiocarb as active substances (OJ L 35, 8.2.2007, p. 11, ELI: http://data.europa.eu/eli/dir/2007/5/oj).
([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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).
([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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).
([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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

(7) The Authority also communicated the draft 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 October 2019, the Authority requested additional information from the applicant on the endocrine disrupting properties of folpet pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. The applicant submitted information for the Authority to assess whether the scientific criteria for the determination of endocrine disrupting properties set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605 ([6]), were met.

(9) In May 2022, the rapporteur Member State made an updated draft renewal assesment report available to the Authority, the Member States and the Commission. In its updated draft renewal assessment report, the rapporteur Member State considered the additional information regarding the criteria to identify endocrine disrupting properties and proposed to renew the approval of folpet.

(10) On 12 July 2023, the Authority communicated to the Commission its conclusion ([7]) on whether folpet can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a renewal report on 20 March 2024 and a draft of this Regulation on 22 May 2024 to the Standing Committee on Plants, Animals, Food and Feed.

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

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

(14) Although the risk assessment for the renewal of the approval of the active substance folpet is based on a limited number of representative uses, this does not restrict the uses for which plant protection products containing folpet may be authorised. It is therefore appropriate not to maintain the restriction to use folpet as a fungicide.

(15) It is therefore appropriate to renew the approval of folpet.

(16) It is, however, necessary to provide for certain conditions 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 and the outcome of the risk assessment. Considering the high acute risk to fish and aquatic invertebrates identified in the risk assessment, it is appropriate to require minimum risk mitigation measures to protect those aquatic organisms from exposure to folpet unless the outcome of the risk assessment undertaken for specific plant protection product uses indicates that such risk mitigation measures are not needed or can be lowered. Furthermore, to finalise the consumer exposure assessment, it is in particular appropriate to request confirmatory information to determine the levels of phthalic acid deriving from the use of folpet taking into account the background levels of phthalic acid present in wheat and barley during residue field trials for the uses listed in Appendix II of the renewal report only.

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

([6]) 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, ELI: http://data.europa.eu/eli/reg/2018/605/oj).

([7]) *EFSA Journal* 2023, 21(8), 1–32. Available online: www.efsa.europa.eu.

(18) Commission Implementing Regulation (EU) 2023/918 ([8]) extended the approval period of folpet to 15 February 2025 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 the renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.

(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

Renewal of the approval of the active substance

The approval of the active substance folpet, as specified in Annex I to this Regulation, 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 November 2024.

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

Done at Brussels, 4 September 2024.

For the Commission
The President
Ursula VON DER LEYEN

([8]) Commission Implementing Regulation (EU) 2023/918 of 4 May 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aclonifen, ametoctradin, beflubutamid, benthiavalicarb, boscalid, captan, clethodim, cycloxydim, cyflumetofen, dazomet, diclofop, dimethomorph, ethephon, fenazaquin, fluopicolide, fluoxastrobin, flurochloridone, folpet, formetanate, Helicoverpa armigera nucleopolyhedrovirus, hymexazol, indolylbutyric acid, mandipropamid, metalaxyl, metaldehyde, metam, metazachlor, metribuzin, milbemectin, paclobutrazol, penoxsulam, phenmedipham, pirimiphos-methyl, propamocarb, proquinazid, prothioconazole, S-metolachlor, Spodoptera littoralis nucleopolyhedrovirus, Trichoderma asperellum strain T34 and Trichoderma atroviride strain I-1237 (OJ L 119, 5.5.2023, p. 160, ELI: http://data.europa.eu/eli/reg_impl/2023/918/oj).

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Folpet CAS No: 133-07-3 CIPAC No: 75	N-[(trichloromethyl) thio]phthalimide	≥ 940 g/kg The following impurities shall not exceed the following levels in the technical material: — (trichloro(chlorosulfanyl) methane) (PCMM): 2 g/kg — carbon tetrachloride: 2 g/kg — captan: 3 g/kg — carbon disulphide: 2,5 g/kg	1 November 2024	31 October 2039	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 folpet, 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 aquatic organisms, ensuring a minimum of 95 % spray drift reduction next to water bodies such as that provided by a 20 m no spray buffer zone unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift; — the protection of operators (use of PPE for operators during mixing, loading and application) and workers (use of workwear and protective gloves for re-entry activities); and — the protection of bystanders and residents, ensuring that conditions of use include the adequate risk mitigation measures, such as drift reduction equipment, with the aim of minimising exposure. Conditions of use shall include risk mitigation measures, where appropriate.

ELI: http://data.europa.eu/eli/reg_impl/2024/2198/oj

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit confirmatory information to determine the levels of phthalic acid deriving from the use of folpet taking into account the background levels of phthalic acid in wheat and barley during residue field trials for the uses listed in Appendix II of the renewal report only. The applicant shall submit to the Commission, the Member States and the Authority this information by 25 March 2025.

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

ANNEX II

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

(1) in Part A, entry 146 on folpet 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
‘172	Folpet CAS No: 133-07-3 CIPAC No: 75	N-[(trichloromethyl)thio]phthalimide	≥ 940 g/kg The following impurities shall not exceed the following levels in the technical material: — (trichloro(chlorosulfanyl) methane) (PCMM): 2 g/kg — carbon tetrachloride: 2 g/kg — captan: 3 g/kg — carbon disulphide: 2,5 g/kg	1 November 2024	31 October 2039	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 folpet, 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 aquatic organisms, ensuring a minimum of 95 % spray drift reduction next to water bodies such as that provided by a 20 m no spray buffer zone unless the outcome of the risk assessment undertaken for the specific plant protection product use indicates that such risk mitigation measures are not needed or can be lowered because there are no unacceptable risks caused by spray drift; — the protection of operators (use of PPE for operators during mixing, loading and application) and workers (use of workwear and protective gloves for re-entry activities); and — the protection of bystanders and residents, ensuring that conditions of use include the adequate risk mitigation measures, such as drift reduction equipment, with the aim of minimising exposure. Conditions of use shall include risk mitigation measures, where appropriate.

No	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit confirmatory information to determine the levels of phthalic acid deriving from the use of folpet taking into account the background levels of phthalic acid in wheat and barley during residue field trials for the uses listed in Appendix II of the renewal report only. The applicant shall submit to the Commission, the Member States and the Authority this information by 25 March 2025.

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