COMMISSION IMPLEMENTING REGULATION (EU) 2021/843

of 26 May 2021

renewing the approval of the active substance cyazofamid, 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 2003/23/EC ([2]) included cyazofamid 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 cyazofamid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2021.

(4) An application for the renewal of the approval of cyazofamid 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 23 June 2015.

(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.

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

([2]) Commission Directive 2003/23/EC of 25 March 2003 amending Council Directive 91/414/EEC to include imazamox, oxasulfuron, ethoxysulfuron, foramsulfuron, oxadiargyl and cyazofamid as active substances (OJ L 81, 28.3.2003, p. 39).

([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).

(8) On 23 May 2016, the Authority communicated to the Commission its conclusion ([6]) on whether cyazofamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. Following a mandate from the Commission due to uncertainties related to non-target arthropods, the Authority updated its conclusion on 28 July 2020 ([7]). The Commission presented a renewal report regarding cyazofamid to the Standing Committee on Plants, Animals, Food and Feed on 3 December 2020 and a draft Regulation on 26 January 2021.

(9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([8]), the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that cyazofamid is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic or steroidogenic modalities. Based on the available data and current knowledge summarised in the conclusion of the Authority no adverse effects that could be related to an endocrine disruptor mode of action were observed. Therefore, the Commission concludes that cyazofamid 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 reports. The applicant submitted its comments, 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 the active substance cyazofamid 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 cyazofamid is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing cyazofamid may be authorised. It is therefore appropriate not to maintain the restriction to use as a fungicide.

(13) It is therefore appropriate to renew the approval of cyazofamid.

(14) 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, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require further confirmatory information.

(15) In order to increase the confidence in the conclusion that cyazofamid does not have endocrine disrupting properties, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, and in accordance with the guidance for the identification of endocrine disruptors ([9]).

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

(17) Commission Implementing Regulation (EU) 2020/869 ([10]) extended the approval period of cyazofamid to 31 July 2021 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. As the date of entry into force of this Regulation would be close to the date of expiry of the approval of cyazofamid this Regulation should apply from the day after the date of expiry of the approval of cyazofamid.

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

([6]) *EFSA Journal* 2016;14(6):4503 [24 pp.]. Available online:www.efsa.europa.eu

([7]) Updated peer review of the pesticide risk assessment of the active substance cyazofamid; *EFSA Journal* 2020;18(9):6232.

([8]) 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).

([9]) ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. *EFSA Journal* 2018;16(6):5311, 135 pp.

([10]) Commission Implementing Regulation (EU) 2020/869 of 24 June 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor (OJ L 201, 25.6.2020, p. 7).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance cyazofamid, 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 August 2021.

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

Done at Brussels, 26 May 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
Cyazofamid CAS No: 120116-88-3 CIPAC No: 653	4-chloro-2-cyano-N,N-dimethyl-5-p-tolylimidazole-1-sulfonamide	≥ 935 g/kg	1.8.2021	31.7.2036	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 cyazofamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the specification of the technical material as commercially manufactured; (b) the impact of processing on the consumer risk assessment; (c) the protection of non-target arthropods and earthworms. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water; 2. points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. The applicant shall submit the requested information referred to in point 1 within two years from the date of publication by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater. As regards point 2, the applicant shall provide an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity by 16 June 2023.

(1) Further details on the identity and the 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 46 on cyazofamid 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
'146	Cyazofamid CAS No: 120116-88-3 CIPAC No: 653	4-chloro-2-cyano-N,N-dimethyl-5-p-tolylimidazole-1-sulfonamide	≥ 935 g/kg	01/08/2021	31/07/2036	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 cyazofamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the specification of the technical material as commercially manufactured; (b) the impact of processing on the consumer risk assessment; (c) the protection of non-target arthropods and earthworms. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water; 2. points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605. The applicant shall submit the requested information referred to in point 1 within two years from the date of publication by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

						As regards point 2 the applicant shall provide an updated assessment of the information already submitted and, where relevant, further information to confirm the absence of endocrine activity by 16 June 2023’

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