COMMISSION IMPLEMENTING REGULATION (EU) 2022/698

of 3 May 2022

renewing the approval of the active substance bifenazate 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)(a) thereof,

Whereas:

(1) Commission Directive 2005/58/EC ([2]) included bifenazate 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 bifenazate, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 July 2022.

(4) An application for the renewal of the approval of the active substance bifenazate was submitted to the 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 in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

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

([2]) Commission Directive 2005/58/EC of 21 September 2005 amending Council Directive 91/414/EEC to include bifenazate and milbemectin as active substances (OJ L 246, 22.9.2005, p. 17).

([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) 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 29 January 2016.

(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 4 January 2017, the Authority communicated to the Commission its conclusion ([6]) on whether bifenazate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, where EFSA identified high risk to birds, mammals and non-target arthropods for all representative uses and in addition, a high risk to operators and workers for a majority of the representative uses. Furthermore, the risk assessment could not be finalised for aquatic organisms and consumers.

(9) The Commission mandated EFSA in 17 November 2020 to assess the risk when bifenazate is applied once a year using the lowest dose presented in the dossier. The rapporteur Member State updated its draft Renewal Assessment Report accordingly and the Authority updated its conclusion on 30 August 2021 ([7]) in which it identified a high risk to birds via long term exposure to bifenazate for all representative uses. Furhtermore, the consumer risk assessment could not be finalised. The Commission presented a renewal report regarding bifenazate to the Standing Committee on Plants, Animals, Food and Feed on 19 July 2017 and 22 October 2021 and a draft of this Regulation on 1 December 2021.

(10) The Commission invited the applicant to submit its comments on both conclusions of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012 ([8]), on the renewal report. 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 bifenazate that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(12) It is therefore appropriate to renew the approval of bifenazate.

(13) 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 and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing bifenazate to non-edible crops in permanent greenhouses and to require further confirmatory information.

(14) The restriction to use on non-edible crops will exclude dietary exposure of consumers and is required since the consumer risk assessment could not be finalised. As a high risk was identified to birds via long term exposure to bifenazate, a restriction to use in greenhouses as defined in Article 3 of Regulation (EC) No 1107/2009 will ensure that birds are not exposed to bifenazate. In addition, as the Authority identified a high risk to mammals for some representative uses and a high chronic risk to bees based on the available data, the restriction to use only in greenhouses will also prevent exposure to those non-target organisms as well as in drinking water.

([6]) EFSA Journal 2017;15(1):4693. Available online: www.efsa.europa.eu.

([7]) EFSA Updated peer review of the pesticide risk assessment of the active substance bifenazate EFSA Journal 2021;19(8):6818.

([8]) Implementing Regulation (EU) No 844/2012 was replaced by Implementing Regulation (EU) 2020/1740 (OJ L 392, 23.11.2020, p. 20). However, it shall continue to apply to the procedure for the renewal of the approval of the active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

(15) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([9]), on the basis of the available scientific information summarised in the conclusion of the Authority, the Commission considers that bifenazate is not to be considered as having endocrine disrupting properties.

(16) In order to increase the confidence in the conclusion that bifenazate 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, and in accordance with the guidance for the identification of endocrine disruptors ([10]).

(17) The risk assessment for the renewal of the approval of the active substance bifenazate is based on representative uses as an acaricide. In the light of this risk assessment, it is not necessary to maintain the restriction to use only as an acaricide.

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

(19) Commission Implementing Regulation (EU) 2021/745 ([11]) extended the approval period of bifenazate to 31 July 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 shall apply as soon as possible.

(20) 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 bifenazate, as specified in Annex I, is renewed subject to the conditions and restrictions 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.

([9]) 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).

([10]) 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.

([11]) Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distilation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/ sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 160, 7.5.2021, p. 89).

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 July 2022.

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

Done at Brussels, 3 May 2022.

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
Bifenazate 149877-41-8 736	isopropyl 2-(4-methoxybiphenyl-3-yl) hydrazinoformate	980 g/kg Toluene is of toxicological concern and must not exceed 0,7 g/kg in the technical material.	1 July 2022	30 June 2037	Only uses on non-edible crops in permanent greenhouses shall be authorised. 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 bifenazate, and in particular Appendices I and II thereof, 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 protective equipment; — the risk to bees and bumble bees released for pollination in permanent greenhouses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 24 May 2024 to the Commission, the Member States and the Authority confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity.

[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 109 on bifenazate 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
'*152*	Bifenazate 149877-41-8 736	isopropyl 2-(4-methoxybi-phenyl-3-yl) hydrazinofor-mate	980 g/kg Toluene is of toxicological concern and must not exceed 0,7 g/kg in the technical material.	1 July 2022	30 June 2037	Only uses on non-edible crops in permanent greenhouses shall be authorised. 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 bifenazate, and in particular Appendices I and II thereof, 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 protective equipment; — the risk to bees and bumble bees released for pollination in permanent greenhouses. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit by 24 May 2024 to the Commission, the Member States and the Authority confirmatory information as regards points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, in particular an updated assessment of the information submitted previously and, where relevant, further information to confirm the absence of endocrine activity.'

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