COMMISSION IMPLEMENTING REGULATION (EU) 2019/158

of 31 January 2019

renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, 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 24 in conjunction with Article 20(1) thereof,

Whereas:

(1) Commission Directive 2005/3/EC ([2]) included methoxyfenozide 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 methoxyfenozide, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 July 2019.

(4) An application for the renewal of the approval of methoxyfenozide 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 4 August 2016.

(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 10 August 2017 the Authority communicated to the Commission its conclusions ([6]) on whether methoxyfenozide 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 for methoxyfenozide to the Standing Committee on Plants, Animals, Food and Feed on 25 May 2018.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Directive 2005/3/EC of 19 January 2005 amending Council Directive 91/414/EEC to include imazosulfuron, laminarin, methoxyfenozide and s-metolachlor as active substances (OJ L 20, 22.1.2005, p. 19).
([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 2017;15(9):4978.

(9) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([7]), which became applicable on 10 November 2018, the conclusion of the Authority infers that it is highly unlikely that methoxyfenozide is an endocrine disrupter via the estrogenic, androgenic and steroidogenic modalities. Furthermore, the available evidence (amphibian metamorphosis assay) indicates that methoxyfenozide is unlikely to be an endocrine disruptor via the thyroid modality. Thus, the Commission considers that methoxyfenozide is not to be considered as having endocrine disrupting properties.

(10) The applicant was given the opportunity to submit comments on the draft renewal report.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing methoxyfenozide 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 methoxyfenozide.

(12) The risk assessment for the renewal of the approval of methoxyfenozide is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing methoxyfenozide may be authorised. It is therefore appropriate to remove the restriction for use only as an insecticide.

(13) The Commission, however, considers that methoxyfenozide is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Methoxyfenozide is a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in soil and water is greater than 120 days and the long-term no-observed effect concentration for freshwater organisms is less than 0,01 mg/L. Methoxyfenozide therefore fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(14) It is therefore appropriate to renew the approval of methoxyfenozide as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(15) 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 include certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing methoxyfenozide to greenhouses in order to minimise the exposure for groundwater and non-target organisms and to require further confirmatory information.

(16) Although it can be reasonably expected that metoxyfenozide is highly unlikely to have endocrine disrupting properties based on the available scientific information summarised in the conclusion of the Authority, in order to increase the confidence in this conclusion, in accordance with Point 2(2)(b) of Annex II to Regulation (EC) No 1107/2009, the applicant should provide an updated assessment of the information submitted and, where relevant, further information to confirm the absence of thyroid endocrine activity.

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

(18) Commission Implementing Regulation (EU) 2018/917 ([8]) extended the approval period of methoxyfenozide to 31 July 2019 in order to allow the renewal process to be completed before the expiry of the approval of that substance. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation should apply from 1 April 2019.

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

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([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) 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, *Gliocladium catenulatum* strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor (OJ L 163, 28.6.2018, p. 13).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance as a candidate for substitution

The approval of the active substance methoxyfenozide, as a candidate for substitution, 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.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2019.

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

Done at Brussels, 31 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Methoxyfenozide CAS No 161050-58-4 CIPAC No 656	N-tert-Butyl-N′-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	≥ 970 g/kg The following impurities must not exceed the following levels in the technical material: Tert-butylhydrazine < 0,001 g/kg RH-116267 < 2 g/kg	1 April 2019	31 March 2026	Only uses in 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 review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the risk of accumulation in soil; — the protection of non-target arthropods, sediment dwelling and aquatic organisms; 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: 1. a comparative in vitro metabolism study on methoxyfenozide, by 1 April 2020; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 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. The applicant shall also provide an updated assessment of the information submitted and, where relevant, further information to confirm the absence of thyroid endocrine activity in accordance with 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 (2), by 1 February 2021.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) 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).

ANNEX II

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

(1) in Part A, entry 96 on methoxyfenozide is deleted;

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

No.	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'11	Methoxyfenozide CAS No 161050-58-4 CIPAC No 656	N-tert-Butyl-N′-(3-methoxy-o-toluoyl)-3,5-xylohydrazide	≥ 970 g/kg The following impurities must not exceed the following levels in the technical material: Tert-butylhydrazine < 0,001 g/kg RH-116267 < 2 g/kg	1 April 2019	31 March 2026	Only uses in 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 review report on methoxyfenozide, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the protection of groundwater when the substance is applied in regions with vulnerable soil and/or climate conditions; — the risk of accumulation in soil; — the protection of non-target arthropods, sediment dwelling and aquatic organisms; 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: 1. a comparative in vitro metabolism study on methoxyfenozide, by 1 April 2020; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater is abstracted for drinking water, within 2 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.

No.	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall also provide an updated assessment of the information submitted and, where relevant, further information to confirm the absence of thyroid endocrine activity in accordance with 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 (2) by 1 February 2021.

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

(2) 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).'