COMMISSION IMPLEMENTING REGULATION (EU) 2019/337

of 27 February 2019

approving the active substance mefentrifluconazole 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 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, the United Kingdom received on 29 February 2016 an application from BASF Agro B.V. for the approval of the active substance mefentrifluconazole.

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the United Kingdom, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 30 March 2016 of the admissibility of the application.

(3) On 25 April 2017, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 1 February 2018.

(5) On 5 July 2018, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance mefentrifluconazole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ([3]), which became applicable on 10 November 2018 and the joint guidance document to identify endocrine disrupting substances ([4]), the conclusion of the Authority infers that it is unlikely that mefentrifluconazole is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. Furthermore, based on the available evidence and according to the guidance for the identification of endocrine disruptors, mefentrifluconazole is unlikely to be an endocrine disruptor for fish considering that the test modalities have been appropriately covered. The Commission therefore considers that mefentrifluconazole is not to be considered as having endocrine disrupting properties.

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

([2]) EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (mefentrifluconazole). *EFSA Journal* 2018;16(7):5379, 32 pp, https://doi.org/10.2903/j.efsa.2018.5379

([3]) 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).

([4]) 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. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN.

(7) On 12 December 2018, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for mefentrifluconazole and on 25 January 2019, it presented a draft Regulation providing that mefentrifluconazole is approved.

(8) The applicant was given the possibility to submit comments on the review report.

(9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(10) It is therefore appropriate to approve mefentrifluconazole.

(11) In accordance with Article 13(2) 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 require further confirmatory information.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([5]) should be amended accordingly.

(13) 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

Approval of active substance

The active substance mefentrifluconazole, as specified in Annex I, is approved 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

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

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

Done at Brussels, 27 February 2019.

For the Commission
The President
Jean-Claude JUNCKER

([5]) 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).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Mefentrifluconazole CAS No: 1417782-03-6 CIPAC No: Not assigned	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	≥ 970 g/kg The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material. The impurity toluene shall not exceed 1 g/kg in the technical material The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material	20 March 2019	20 March 2029	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 mefentrifluconazole, 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, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water. The applicant shall submit the information referred to in point 1 by 20 March 2020 and the information referred to in point 2 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.

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

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
'132	Mefentrifluconazole CAS No: 1417782-03-6 CIPAC No: Not assigned	(2RS)-2-[4-(4-chlorophenoxy)-2-(trifluoromethyl) phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	≥ 970 g/kg The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material. The impurity toluene shall not exceed 1 g/kg in the technical material The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material	20 March 2019	20 March 2029	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 mefentrifluconazole, 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, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.

	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						The applicant shall submit the information referred to in point 1 by 20 March 2020 and the information referred to in point 2 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.'

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