COMMISSION IMPLEMENTING REGULATION (EU) 2019/481

of 22 March 2019

approving the active substance flutianil, 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 23 February 2011 an application from Otsuka AgriTechno Co., Ltd for the approval of the active substance flutianil.

(2) In accordance with Article 9(3) of that Regulation, 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 21 October 2011 of the admissibility of the application.

(3) On 19 June 2013, 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 2 June 2014.

(5) On 29 July 2014, the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance flutianil 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) The Authority concluded that flutianil should be classified as carcinogen category 2 and reproductive toxicant (for the development) category 2. The active substance was therefore deemed not to fulfil the approval criteria referred to in Article 4(1) of Regulation (EC) No 1107/2009.

(7) On 4 December 2014, the rapporteur Member State notified its intention to launch a request for harmonised classification under the provisions of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]). According to that proposal, it was not appropriate to classify flutianil as carcinogen or reproductive toxicant and therefore flutianil was deemed to fulfil the approval criteria referred to in Article 4(1) of Regulation (EC) No 1107/2009. The application was submitted by the United Kingdom to the European Chemicals Agency on 23 February 2015.

(8) On 10 December 2015, the Commission presented a draft review report for non-approval of flutianil to the Standing Committee on Plants, Animals, Food and Feed. Given the potential implication for decision-making, the Commission decided to await the outcome of the classification process under Regulation (EC) No 1272/2008 before presenting a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) EFSA Journal 2014;12(8):3805 [89 pp.]. doi: 10.2903/j.efsa.2014.3805.
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(9) In March 2016, the Risk Assessment Committee of the European Chemicals Agency proposed no classification as carcinogenic or toxic to reproduction for the active substance flutianil ([4]). On request of the European Commission, the Authority published on 5 July 2018 a 'Statement on the impact of the harmonised classification on the conclusion on the peer review of the pesticide risk assessment of the active substance flutianil' ([5]). In that statement, the Authority acknowledged that the harmonised classification proposed by the Risk Assessment Committee of the European Chemicals Agency was, based on new additional information, different from the provisional classification used in the Authority's conclusion. On 4 October 2018, the active substance flutianil was included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 with no classification as carcinogenic or toxic to reproduction ([6]).

(10) The Commission revised the draft review report in order to align it with the outcome of the classification process and submitted it for comments to the applicant together with a draft Regulation on 20 March 2018. The documents were presented to the Standing Committee on Plants, Animals, Food and Feed on 21 March 2018.

(11) Following the publication of the Authority's statement, on 24 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed a revised review report and a draft Regulation providing that flutianil is approved.

(12) The applicant was given the possibility to submit comments on the revised review report and on the Authority's statement.

(13) As regards the new criteria to identify endocrine disrupting properties set in Commission Regulation (EU) 2018/605 ([7]), which became applicable on 10 November 2018, and the Joint guidance document to identify endocrine disrupting substances ([8]), the information contained in the conclusions of the Authority allow to infer that it is highly unlikely that flutianil is an endocrine disruptor via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. Although effects on the thyroid (weight increase) were observed, these occurred only at the top doses exceeding the maximum recommended doses for the type of study where the effects were observed. Testicular, prostate and uterus effects observed (histopathological changes) were within the historical control values or they were not replicated in the two-generation reproductive toxicity study, nor affected fertility parameters. The two-generation reproductive toxicity study was performed following the test protocol according to the latest OECD Guidelines ([9]), as prescribed by the Joint guidance document to identify endocrine disrupting substances and did not detect any endocrine sensitive reproductive and developmental parameters such as oestrous cycle length, mating index, mean number of implantation sites, preputial separation and vaginal opening.

(14) 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.

(15) It is therefore appropriate to approve flutianil.

(16) 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, amongst others to confirm that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in order to increase the confidence, in accordance with Point 2(2)(b) of Annex II to Regulation (EC) No 1107/2009, in the conclusion drawn by the Commission in recital 13.

([4]) Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Flutianil (ISO);(2Z)-{[2-fluoro-5-(trifluoromethyl)phenyl]thio}[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene] acetonitrile, EC Number: -, CAS Number: 958647-10-4 CLH-O-0000001412-86-101/F. Adopted 10 March 2016. https://echa.europa.eu/documents/10162/efc05a0b-a819-51d6-6f43-5396ee76e29f.

([5]) EFSA Journal 2018;16(7):5383 [19 pp.]. doi: 10.2903/j.efsa.2018.5383.

([6]) Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

([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]) Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5311.

([9]) OECD (Organisation for Economic Cooperation and Development), 2001. Test No 416: Two-Generation Reproduction Toxicity. In: OECD Guidelines for the Testing of Chemicals, Section 4. OECD Publishing, Paris. 13 pp. https://doi.org/10.1787/9789264070868-en.

(17) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([10]) should be amended accordingly.

(18) 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 flutianil, 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, 22 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

([10]) 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
Flutianil CAS No [958647-10-4] CIPAC No 835	(*Z*)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene](α,α,α,4-tetrafluoro-*m*-tolylthio)acetonitrile	≥ 985 g/kg	14 April 2019	14 April 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 flutianil, 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, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. 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. 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; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors (2). The applicant shall submit the information: — referred to in point 1 by 14 April 2020;

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					— referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and — referred to in point 3 by 14 April 2021.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) 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; ECHA-18-G-01-EN.

ANNEX II

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

'133	Flutianil CAS No [958647-10-4] CIPAC No 835	(Z)-[3-(2-methoxyphenyl)-1,3-thiazolidin-2-ylidene](α,α,α,4-tetrafluoro-*m*-tolylthio)acetonitrile	≥ 985 g/kg	14 April 2019	14 April 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 flutianil, 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, — the risk to aquatic organisms, — the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions. 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. 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; 3. an updated assessment of the information submitted and, where relevant further information, confirming that flutianil is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, applying also the ECHA and EFSA guidance for identification of endocrine disruptors (*). The applicant shall submit the information: — referred to in point 1 by 14 April 2020;

						— referred to in point 2 within two years from the date of publication, from the Commission, of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater; and — referred to in point 3 by 14 April 2021.

(*) 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; ECHA-18-G-01-EN.'