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COMMISSION IMPLEMENTING REGULATION (EU) 2025/910

of 20 May 2025

concerning the non-renewal of the approval of the active substance flufenacet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulations (EU) No 540/2011 and (EU) 2015/408

(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) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2003/84/EC ([2]) included flufenacet 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 flufenacet, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 June 2025.

(4) An application for the renewal of the approval of the active substance flufenacet was submitted to Poland, the rapporteur Member State, and France, the co-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. That Regulation continues to apply for the purposes of the procedure for the renewal of the approval of flufenacet, pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 ([6]).

(5) The applicant submitted the supplementary dossiers to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances (OJ L 247, 30.9.2003, p. 20, ELI: http://data.europa.eu/eli/dir/2003/84/oj).

([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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([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, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

([6]) Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20, ELI: http://data.europa.eu/eli/reg_impl/2020/1740/oj).

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 7 June 2017. In that draft renewal assessment report, the rapporteur Member State proposed to not renew the approval of flufenacet.

(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 29 August 2024, the Authority communicated to the Commission its conclusion ([7]) on whether flufenacet can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identified several concerns. In particular, it concluded that flufenacet meets the criteria to be identified as an endocrine disruptor for the thyroid (T)-modality for humans and non-target organisms and that it has not been demonstrated that the exposure of humans and non-target organisms to that active substance in a plant protection product, under realistic proposed conditions of use, is negligible.

(10) The Authority also identified a potential for the flufenacet metabolite trifluoroacetic acid ('TFA') to contaminate groundwater at levels that significantly exceed the statutory limit of 0,1 µg/l, provided for in point 1 of Annex I to Directive 2006/118/EC of the European Parliament and of the Council ([8]), under all relevant groundwater assessment scenarios for all representative uses assessed. That limit applies to toxicologically relevant metabolites as defined in Article 3(32) of Regulation (EC) No 1107/2009, and in accordance with point 2.5.1.2. (i) of Part A of the uniform principles for evaluation and authorisation of chemical plant protection products set in the Annex to Commission Regulation (EU) No 546/2011 ([9]).

(11) Regarding the intrinsic toxicological properties of this metabolite, it is noted that some of the registrants of TFA and its salts under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([10]) updated their registration dossiers to indicate that those substances fulfil the criteria for classification as toxic for reproduction category 2 under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([11]). Furthermore, the German authorities submitted a proposal for harmonised classification and labelling of TFA as toxic for reproduction category 1B under Regulation (EC) No 1272/2008. Finally, in accordance with the applicable Guidance document on the assessment of the relevance of metabolites in groundwater ([12]), metabolites leaching into groundwater which qualify for classification under Regulation (EC) No 1272/2008 due to their reproductive toxicity, regardless of the category, are considered to be toxicologically relevant. Based on those elements, the Commission considers TFA to be a toxicologically relevant metabolite with a high potential to contaminate groundwater. Therefore, it has not been demonstrated that, in the light of the current scientific and technical knowledge, flufenacet would not have harmful effects on groundwater or any unacceptable effect on the environment.

([7]) EFSA (European Food Safety Authority), 2024. Peer review of the pesticide risk assessment of the active substance flufenacet (*EFSA Journal* 2024;22(9):8997, https://doi.org/10.2903/j.efsa.2024.8997).

([8]) Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19, ELI: http://data.europa.eu/eli/dir/2006/118/oj).

([9]) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products Text with EEA relevance (OJ L 155, 11.6.2011, p. 127, ELI: http://data.europa.eu/eli/reg/2011/546/oj).

([10]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

([11]) 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

([12]) Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC (document Sanco/221/2000 – rev.10 of 25 February 2003, https://food.ec.europa.eu/system/files/2016-10/pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr.pdf).

(12) The Authority also identified a high risk to algae for 8 out of 9 relevant scenarios for all representative uses of flufenacet. As one scenario is considered by the Authority to be acceptable, such identification does not lead to the conclusion that flufenacet does not satisfy the renewal criteria.

(13) Furthermore, the Authority concluded that the assessment of relevance of metabolites of flufenacet other than TFA in groundwater and the assessment of risks to consumers could not be finalised due to the lack of data on exposure to certain metabolites.

(14) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 4 December 2024.

(15) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into due consideration.

(16) Despite the arguments put forward by the applicant, the concerns regarding the active substance flufenacet could not be eliminated.

(17) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product containing flufenacet that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance flufenacet in accordance with Article 20(1), point (b), of that Regulation.

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

(19) Commission Implementing Regulation (EU) 2015/408 ([13]) listed flufenacet as a candidate for substitution. In the light of the non-renewal of the approval of flufenacet that listing is no longer relevant. Accordingly, flufenacet should be removed from the Annex to Implementing Regulation (EU) 2015/408.

(20) Member States should be given sufficient time to withdraw authorisations for plant protection products containing flufenacet.

(21) For plant protection products containing flufenacet, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 18 months from the date of entry into force of this Regulation.

(22) Commission Implementing Regulation (EU) 2023/1757 ([14]) extended the approval period of flufenacet to 15 June 2025 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 the non-renewal of the approval is taken ahead of the expiry date of that extended approval period, this Regulation should apply earlier than that date.

(23) This Regulation does not prevent the submission of another application for the approval of flufenacet pursuant to Article 7 of Regulation (EC) No 1107/2009.

([13]) Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2015/408/oj).

([14]) Commission Implementing Regulation (EU) 2023/1757 of 11 September 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bensulfuron, chlormequat, chlorotoluron, clomazone, daminozide, deltamethrin, eugenol, fludioxonil, flufenacet, flumetralin, fosthiazate, geraniol, MCPA, MCPB, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulfuryl fluoride, tebufenpyrad, thymol, and tritosulfuron (OJ L 224, 12.9.2023, p. 28, ELI: http://data.europa.eu/eli/reg_impl/2023/1757/oj).

(24) 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

Non-renewal of the approval of the active substance

The approval of the active substance flufenacet is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 65, on flufenacet, is deleted.

Article 3

Amendment to Implementing Regulation (EU) 2015/408

The entry for flufenacet is deleted from the Annex to Implementing Regulation (EU) 2015/408.

Article 4

Transitional measures

Member States shall withdraw authorisations for plant protection products containing flufenacet as an active substance by 10 December 2025.

Article 5

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 10 December 2026.

Article 6

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, 20 May 2025.

For the Commission
The President
Ursula VON DER LEYEN