



2023/2513

17.11.2023

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2513

of 16 November 2023

concerning the non-renewal of the approval of the active substance triflusaluron-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2009/77/EC ⁽²⁾ included triflusaluron-methyl 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 triflusaluron-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 December 2023.
- (4) An application for the renewal of the approval of the active substance triflusaluron-methyl was submitted to France, the rapporteur Member State, and Denmark, 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.
- (5) The applicant submitted the supplementary dossiers required 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.
- (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 26 July 2019. In its draft renewal assessment report France proposed to not renew the approval of triflusaluron-methyl.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2009/77/EC of 1 July 2009 amending Council Directive 91/414/EEC to include chlorsulfuron, cyromazine, dimethachlor, etofenprox, lufenuron, penconazole, tri-allate and triflusaluron as active substances (OJ L 172, 2.7.2009, p. 23).

⁽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). That Implementing Regulation was replaced by Commission Implementing Regulation (EU) 2020/1740, however, it continues to apply to the procedure for the renewal of the approval of 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.

- (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 1 April 2022, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether triflusaluron-methyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Authority identified a critical concern in relation to the contamination of groundwater by one toxicologically relevant metabolite of triflusaluron-methyl, IN-JU122, which is predicted to occur above the parametric value of 0,1 µg/L in all geoclimatic conditions represented by the groundwater assessment scenarios for all proposed uses of triflusaluron-methyl. Therefore, it cannot currently be established that the presence of metabolites of triflusaluron-methyl in groundwater will have no unacceptable effects on groundwater and no harmful effects on human health, as required by Article 4(3), point (b), of Regulation (EC) No 1107/2009.
- (10) Furthermore, the Authority concluded that triflusaluron-methyl has endocrine disrupting properties that may cause adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 ⁽⁷⁾. According to the Authority, negligible exposure cannot be demonstrated for triflusaluron-methyl since residues above the default value set out in Article 18(1), point (b), of Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁸⁾ may be expected to occur in rotational crops. Therefore, the requirement set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled. The Authority also concluded that the consumer dietary risk assessment could not be finalised.
- (11) In its evaluation of whether triflusaluron-methyl is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods in accordance with Article 4(7) of Regulation (EC) No 1107/2009, the Authority concluded that for some uses and in some Member States, there may be an insufficient number of chemical alternatives available at the time of assessment. However, some non-chemical methods are available (for instance, mechanical weeding), although they may not have the same efficacy as chemical methods and/or they may present economic or other feasibility limitations. In addition, further chemical alternatives could be made available in the Member States concerned via mutual recognition of alternative products that are available in other Member States, as provided for in Article 40 of Regulation (EC) No 1107/2009. In addition, the Commission considers that no serious danger to plant health has been identified. Therefore, the Commission considers that the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009 are not fulfilled.
- (12) The Commission presented a renewal report on 14 October 2022 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 11 July 2023.
- (13) 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.
- (14) Despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

⁽⁶⁾ Peer review of the pesticide risk assessment of the active substance triflusaluron-methyl (*EFSA Journal* 2022;20(5):7303; Peer review of the pesticide risk assessment of the active substance triflusaluron-methyl (wiley.com)).

⁽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⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

- (15) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product 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 triflusaluron-methyl in accordance with Article 20(1), point (b), of that Regulation.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) Member States should be given sufficient time to withdraw authorisations for plant protection products containing triflusaluron-methyl.
- (18) For plant protection products containing triflusaluron-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 9 months from the date of entry into force of this Regulation.
- (19) Commission Implementing Regulation (EU) 2022/1480 (*) extended the approval period of triflusaluron-methyl to 31 December 2023 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance.
- (20) Taking into account that the current approval of triflusaluron-methyl expires on 31 December 2023, this Regulation should enter into force as soon as possible.
- (21) This Regulation does not prevent the submission of another application for the approval of triflusaluron-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (22) 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 triflusaluron-methyl 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 289 on triflusaluron-methyl is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing triflusaluron-methyl as an active substance by 20 February 2024.

(*) Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusaluron and tritosulfuron (OJ L 233, 8.9.2022, p. 43).

*Article 4***Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 20 August 2024.

*Article 5***Entry into force**

This Regulation shall enter into force on the third 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, 16 November 2023.

For the Commission
The President
Ursula VON DER LEYEN
