EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of the approval of the active substance oxamyl, 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)

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(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 2006/16/EC[2] included oxamyl 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 oxamyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2023.

(4) An application for the renewal of the approval of the active substance oxamyl was submitted to Italy, 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.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2006/16/EC of 7 February 2006 amending Council Directive 91/414/EEC to include oxamyl as active substance (OJ L 36, 8.2.2006, p. 39).

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). This Regulation was replaced by 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.

(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 complete 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 15 October 2019.

(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 30 March 2022, the Authority communicated to the Commission its conclusion[6] on whether oxamyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) In its conclusion, the Authority identified a number of concerns. In particular, it concluded that there is a high risk for all the representative uses assessed to exceed the acceptable operator exposure level ('AOEL') for operators even with the use of personal protective equipment ('PPE').

(10) Furthermore, the preliminary acute consumer dietary risk assessment indicated a large exceedance of the acute reference dose ('ARfD') for all the representative uses on all edible crops. In addition, the consumer risk assessment through drinking water indicated that the theoretical maximum daily intake ('TMDI') from the groundwater metabolite IN-D2708 exceeded the acceptable daily intake ('ADI') for adults, children and infants in all representative uses and that the TMDI from the groundwater metabolite IN-A2213 exceeded the ADI for infants in all representative uses.

(11) The Commission presented a renewal report concerning the approval of oxamyl as well as a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 13 October 2022 and 8 December 2022 respectively.

(12) 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.

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

(14) 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 oxamyl.

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

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6 EFSA Journal 2022;20(5):7296.

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

(17) For plant protection products containing oxamyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should at the latest, expire on … [*Office of Publications, please insert date 12 months from the date of entry into force of this Regulation*].

(18) Commission Implementing Regulation (EU) 2022/XXXX[7] extends the approval period of oxamyl to 31 October 2023 in order to allow the renewal process to be completed before the expiry of the approval period. However, given that this process has been completed and a decision on the non-renewal of the approval taken ahead of that extended approval period, the non-renewal provided for in this Regulation should take effect earlier than that date.

(19) This Regulation does not prevent the submission of a further application for the approval of oxamyl pursuant to Article 7 of Regulation (EC) No 1107/2009.

(20) 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 oxamyl 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 116 on oxamyl is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing oxamyl as an active substance by … [*Office of Publications please insert date 6 months from the date of entry into force of this Regulation*] at the latest.

[7] XXX (OJ L XXX, XX.X.20XX, p. XX).

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 … *[Office of Publications please insert date 12 months from the date of entry into force of this Regulation]* at the latest.

Article 5
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,

For the Commission
The President
Ursula VON DER LEYEN