



Brussels, **XXX**
SANTE/12548/2020 Rev. 1
[...] (2020) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

withdrawing the approval of the active substance alpha-cypermethrin 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 Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

withdrawing the approval of the active substance alpha-cypermethrin 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 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/EEC¹, and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2004/58/EC² included alpha-cypermethrin as an active substance in Annex I to Council Directive 91/414/EEC³. Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009.
- (2) Commission Implementing Regulation 2019/1690⁴ renewed the approval of the active substance alpha-cypermethrin as a candidate for substitution. Consequently, that active substance was listed in part E of the Annex to Commission Implementing Regulation (EU) No 540/2011⁵.
- (3) Implementing Regulation 2019/1690 required that the applicant submitted to the Commission, the Member States and the Authority confirmatory information as regards the toxicological profile of certain metabolites by 30 October 2020. In addition, confirmatory information had been required for three other points by other deadlines set out in the Annex I of the Commission Implementing Regulation (EU) 2019/1690.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Directive 2004/58/EC of 23 April 2004 amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham as active substances (OJ L 120, 24.4.2004, p. 26).

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) 2019/1690 of 9 October 2019 renewing the approval of the active substance alpha-cypermethrin, as a candidate for substitution, 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 (OJ L 259, 10.10.2019, p. 2)

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).

- (4) In October 2020, the applicant informed the Commission, the rapporteur Member State and the Authority that it would not submit any confirmatory data for any of the four points where confirmatory information were requested..
- (5) Consequently, it is appropriate to withdraw the approval of that active substance.
- (6) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (7) Member States should be provided with time to withdraw authorisations for plant protection products containing alpha-cypermethrin.
- (8) For plant protection products containing alpha-cypermethrin, 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*].
- (9) 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
Withdrawal of approval

The approval of the active substance alpha-cypermethrin is withdrawn.

Article 2
Amendment to Implementing Regulation (EU) No 540/2011

In Part E of the Annex to Implementing Regulation (EU) No 540/2011, row 12 on alpha-cypermethrin is deleted.

Article 3
Transitional measures

Member States shall withdraw authorisations for plant protection products containing alpha-cypermethrin as active substance by [*Office of Publications please insert date 6 months after entry into force*] at the latest.

Article 4
Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by [*Office of Publications please insert date 12 months from the date of entry into force*] 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