



Brussels, **XXX**
SANTE/12602/2020 Rev 1
[...](2021) **XXX** draft

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

of **XXX**

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

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

of **XXX**

concerning the non-renewal of the approval of the active substance phosmet, 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/EEC¹, and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2007/25/EC² included phosmet as an active substance in Annex I to Council Directive 91/414/EEC³.
- (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 540/2011⁴.
- (3) The approval of the active substance phosmet, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2022.
- (4) An application for the renewal of the approval of the active substance phosmet was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012⁵ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

¹ OJ L 309, 24.11.2009, p. 1.

² OJ L 106, 24.4.2007, p. 34 and OJ L 56M, 29.2.2008, p. 326.

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).

- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 29 September 2020.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public and launched a public consultation on it. On 20 August 2020, the Authority communicated to the Commission its conclusion⁶ on whether phosmet can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (8) The Authority identified an unacceptable risk to operators, workers, bystanders and residents, even with the use of personal protective equipment or application of available mitigation measures. It also identified a high acute and chronic risk to consumers and aquatic organisms and a high risk to birds, mammals and non-target arthropods (including bees).
- (9) Furthermore, the Authority could not carry out a complete consumer risk assessment because neither all commodities nor all potentially relevant metabolites could be assessed based on the information provided by the applicant. Lastly, the Authority concluded that the assessment of developmental neurotoxicity could not be finalised since no appropriate study was submitted by the applicant.
- (10) The Commission presented a renewal report on 26 January 2021 and a draft Regulation regarding phosmet to the Standing Committee on Plants, Animals, Food and Feed on 24 March 2021.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) 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.
- (12) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.
- (13) 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 phosmet in accordance with Article 20(1)(b) of that Regulation.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing phosmet.
- (16) For plant protection products containing phosmet, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 6 months from the date of entry into force of this Regulation.

⁶ Peer review of the pesticide risk assessment of the active substance phosmet (EFSA Journal 2021;19(3):6237).

- (17) Commission Implementing Regulation (EU) XXX/XXX⁷ extended the approval period of phosmet to 31 July 2022 in order to allow the renewal process to be completed before the expiry of the approval period. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.
- (18) This Regulation does not prevent the submission of a further application for the approval of phosmet pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (19) 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 phosmet 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 153, on phosmet, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing phosmet as an active substance by ... [*Office of Publications please insert date 3 months from the date of entry into force*].

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 6 months from the date of entry into force*].

Article 5

Entry into force

This Regulation shall enter into force on the seventh 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.

⁷ {To add reference once available} OJ L

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN