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COMMISSION IMPLEMENTING REGULATION (EU) 2026/1968

of 7 September 2026

renewing the approval of the active substance phosphine 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) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 1043/2012 ([2]) approved the active substance phosphane and listed it in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]).

(2) The approval of the active substance phosphane, as set out in Part B of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 March 2027.

(3) An application for the renewal of the approval of the active substance phosphane, under the name phosphine, which is the same substance and has the same CAS number as phosphane, was submitted to Spain, the rapporteur Member State, and Germany, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([4]) within the time period provided for in that Article.

(4) The applicant submitted the supplementary dossier 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.

(5) 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 23 December 2021. In that draft renewal assessment report, the rapporteur Member State proposed to renew the approval of phosphine.

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

([2]) Commission Implementing Regulation (EU) No 1043/2012 of 8 November 2012 approving the active substance phosphane, 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 310, 9.11.2012, p. 24, ELI: http://data.europa.eu/eli/reg_impl/2012/1043/oj).

([3]) 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).

([4]) 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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of 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 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.

(7) On 10 December 2024, the Authority communicated to the Commission its conclusion ([5]) on whether phosphine can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(8) The Authority identified a critical area of concern for the potential genotoxicity (clastogenicity) of phosphine. However, this concern does not preclude renewal of approval, because the implementation of risk mitigation measures eliminates the exposure of humans, animals and the environment to phosphine.

(9) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 10 December 2025 and 5 May 2026, respectively.

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

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance phosphine that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied, provided that the conditions and restrictions of use specified in Annex I to this Regulation are complied with.

(12) It is therefore appropriate to renew the approval of phosphine.

(13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions to eliminate any exposure of humans, animals and the environment to phosphine. Phosphine, which is applied by fumigation, should only be used in gas-tight chambers or rooms, where gas tightness is verified and phosphine is supplied from outside, thus avoiding that operators come into contact with the active substance. After fumigation, the remaining phosphine should be removed using appropriate filter technology to ensure that no phosphine is released into the environment. The products on which phosphine is applies should be removed from the gas-tight chambers or rooms only after ventilation, and only if phosphine residue concentrations are at or below the limit of quantification ('LOQ').

(14) Moreover, it is appropriate to require confirmatory information on the genotoxicity potential of phosphine to increase confidence in the decision that phosphine is unlikely to lead to genotoxic effects under relevant conditions of use.

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

(16) Commission Implementing Regulation (EU) 2025/2316 ([6]) extended the approval period of phosphine to 15 March 2027 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 renewal of the approval of phosphine has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(17) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

([5]) EFSA (European Food Safety Authority), 'Peer review of the pesticide risk assessment of the active substance phosphine', in *EFSA Journal* 2025, 23(1): e9177, https://doi.org/10.2903/j.efsa.2025.9177.

([6]) Commission Implementing Regulation (EU) 2025/2316 of 17 November 2025 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium silicate, difenoconazole, diflufenican, disodium phosphonate, extract from tea tree, flurochloridone, indolylbutyric acid, maltodextrin, phosphane, plant oils/clove oil, plant oils/spear mint oil, potassium phosphonates and triclopyr (OJ L, 2025/2316, 18.11.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/2316/oj).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance phosphine, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 October 2026.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 September 2026.

For the Commission
The President
Ursula VON DER LEYEN

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Phosphine/Phosphane (no ISO common name allocated) CAS No: 7803-51-2 CIPAC No: 127	Phosphine	970 g/kg	1 October 2026	30 September 2041	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on phosphine, and in particular Appendices I and II thereto, shall be taken into account. When granting authorisations for plant protection products containing phosphine, Member States shall pay particular attention to eliminate any exposure of humans, animals and the environment to phosphine. For that purpose, when authorising plant protection products, the following conditions and restrictions shall be imposed: — application of products shall only be carried out by well-trained authorised personnel, possessing the corresponding certificate of competence and fumigation licences according to the respective national legislation, — application of products shall only be carried out in gas-tight chambers or rooms and gas tightness of the chamber or room is tested, and the fumigation is initiated by supplying phosphine into the chamber or room from outside, — a safety zone shall be established from which all persons must be evacuated, and it must be monitored with appropriate certified detection devices that a concentration of 0,01 ppm for PH3 in the air at the border of the zone is not exceeded, to ensure protection of bystanders and residents, — entering the treated chambers or rooms shall be prohibited. However, in case of emergency personal protective equipment must be worn by operators and workers entering treated chambers, for example self-contained breathing apparatus (SCBA), — it must be ensured that, following fumigation, remaining phosphine is pumped off by special filter technology suitable for capturing phosphine to ensure that no phosphine is emitted into the environment, — fumigation shall only be considered fully complete once the phosphine level in the air of the treated chamber or room is below the limit of detection (0,01 ppm of PH3), — products present in the chamber or room during treatment shall only be removed after ventilation if phosphine residue concentrations in these products are at or below LOQ levels, — treated containers shall not be transported until fumigation is fully completed.

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit to the Commission, the Member States and the Authority the following confirmatory information about the potential genotoxicity of phosphine: (1) either information confirming, on the basis of existing studies or scientific literature, that genotoxicity testing of phosphine *in vivo* is not appropriate because: (a) the observed severe clinical symptoms or the mortality resulting from exposure to phosphine are expected to prevent a clear interpretation of the results as regards specifically genotoxicity; and (b) positive genotoxicity results are only observed close to high toxicity concentrations, based on dose-response or mode of action analysis; (2) or, if the information in point (1) cannot be provided, a new *in vivo* Micronucleus test by inhalation following short-term exposure according to the OECD Test Guidelines 474. The applicant shall submit to the Commission, the Member States and the Authority the requested confirmatory information by 28 September 2028.

(1) Further details on the identity and specification of the active substance are provided in the renewal report.

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, row 28 on phosphane is replaced by the following:

No	Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
‘28	Phosphine/Phosphane (no ISO common name allocated) CAS No: 7803-51-2 CIPAC No: 127	Phosphine	970 g/kg	1 October 2026	30 September 2041	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on phosphine, and in particular Appendices I and II thereto, shall be taken into account. When granting authorisations for plant protection products containing phosphine, Member States shall pay particular attention to eliminate any exposure of humans, animals and the environment to phosphine. For that purpose, when authorising plant protection products, the following conditions and restrictions shall be imposed: — application of products shall only be carried out by well-trained authorised personnel, possessing the corresponding certificate of competence and fumigation licences according to the respective national legislation, — application of products shall only be carried out in gas-tight chambers or rooms and gas tightness of the chamber or room is tested, and the fumigation is initiated by supplying phosphine into the chamber or room from outside, — a safety zone shall be established from which all persons must be evacuated and it must be monitored with appropriate certified detection devices that a concentration of 0,01 ppm for PH3 in the air at the border of the zone is not exceeded, to ensure protection of bystanders and residents, — entering the treated chambers or rooms shall be prohibited. However in case of emergency personal protective equipment must be worn by operators and workers entering treated chambers, for example self-contained breathing apparatus (SCBA), — it must be ensured that, following fumigation, remaining phosphine is pumped off by special filter technology suitable for capturing phosphine to ensure that no phosphine is emitted into the environment,

ELI: http://data.europa.eu/eli/reg_impl/2026/1968/oj

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						— fumigation shall only be considered fully complete once the phosphine level in the air of the treated chamber or room is below the limit of detection (0,01 ppm of PH3), — products present in the chamber or room during treatment shall only be removed after ventilation if phosphine residue concentrations in these products are at or below LOQ levels, — treated containers shall not be transported until fumigation is fully completed. The applicant shall submit to the Commission, the Member States and the Authority the following confirmatory information about the potential genotoxicity of phosphine: (1) either information confirming, on the basis of existing studies or scientific literature, that genotoxicity testing of phosphine *in vivo* is not appropriate because: (a) the observed severe clinical symptoms or the mortality resulting from exposure to phosphine are expected to prevent a clear interpretation of the results as regards specifically genotoxicity; and (b) positive genotoxicity results are only observed close to high toxicity concentrations, based on dose-response or mode of action analysis; (2) or, if the information in point (1) cannot be provided, a new *in vivo* Micronucleus test by inhalation following short-term exposure according to the OECD Test Guidelines 474. The applicant shall submit to the Commission, the Member States and the Authority the requested confirmatory information by 28 September 2028.’

(1) Further details on the identity and specification of the active substance are provided in the renewal report.