

COMMISSION IMPLEMENTING REGULATION (EU) 2021/129**of 3 February 2021****renewing the approval of the active substance garlic extract 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/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included garlic extract 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 garlic extract, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2021.
- (4) An application for the renewal of the approval of the active substance garlic extract was submitted 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 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 European Food Safety Authority ('the Authority') and the Commission on 28 March 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.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

⁽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).

- (8) On 16 April 2020, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether garlic extract can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented to the Standing Committee on Plants, Animals, Food and Feed a renewal report for garlic extract on 16. and 17 July 2020 and a draft Regulation providing for the renewal of approval of that active substance on 4 December 2020.
- (9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ⁽⁷⁾, the Authority concluded that garlic extract is considered not to meet the criteria for endocrine disruption for humans and for non-target organisms, as laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, respectively.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance garlic extract that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The risk assessment for the renewal of the approval of the active substance garlic extract is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing garlic extract may be authorised.
- (13) It is therefore appropriate to renew the approval of garlic extract.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Commission Implementing Regulation (EU) 2020/1160 ⁽⁸⁾ extended the approval period of garlic extract to 31 August 2021 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 renewal of the approval has been taken ahead of that extended expiry date, this Regulation shall apply from 1 March 2021.
- (16) 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

Renewal of the approval of the active substance

The approval of the active substance garlic extract is renewed as set out in Annex I.

⁽⁶⁾ Conclusion on the peer review of the pesticide risk assessment of the active substance garlic extract *EFSA Journal* 2020;18(6):6116 <https://doi.org/10.2903/j.efsa.2020.6116>.

⁽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⁾ Commission Implementing Regulation (EU) 2020/1160 of 5 August 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, blood meal, calcium carbonate, carbon dioxide, extract from tea tree, fat distillation residues, fatty acids C7 to C20, garlic extract, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, kieselgur (diatomaceous earth), plant oils/rape seed oil, potassium hydrogen carbonate, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 257, 6.8.2020, p. 29).

*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 March 2021.

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

Done at Brussels, 3 February 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Garlic extract Marker components: diallylsulfide (DAS1), diallyldisulfide (DAS 2), diallyltrisulfide (DAS3), diallyltetrasulfide (DAS 4) CAS No 8000-78-0; 8008-99-9 CIPAC No 916	Garlic extract	1 000 g/kg	1 March 2021	29 February 2036	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 garlic extract, and in particular Appendices I and II thereto, shall be taken into account. On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate: — The risk to aquatic organisms.

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

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 231 on garlic extract is deleted;
 (2) in Part B, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'144	Garlic extract Marker components: diallylsulfide (DAS1), diallyldisulfide (DAS 2), diallyltrisulfide (DAS3), diallyltrasulfide (DAS 4) CAS No 8000-78-0 8008-99-9 CIPAC No 916	Garlic extract	1 000 g/kg	1 March 2021	29 February 2036	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 garlic extract, and in particular Appendices I and II thereto, shall be taken into account. On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate: — The risk to aquatic organisms.'

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