COMMISSION IMPLEMENTING REGULATION (EU) 2021/129
of 3 February 2021


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


Whereas:


(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).


(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.

(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.

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\(^8\) 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, gibberelic acid, gibberelins, hydrolysed proteins, iron sulphate, kieselgu (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
<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (1)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garlic extract Marker components: diallylsulfide (DAS1), diallyldisulfide (DAS 2), diallyltrisulfide (DAS 3), diallyltetrasulfide (DAS 4)</td>
<td>Garlic extract</td>
<td>1 000 g/kg</td>
<td>1 March 2021</td>
<td>29 February 2036</td>
<td>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.</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Number</th>
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<th>IUPAC Name</th>
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<td>'144</td>
<td>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</td>
<td>Garlic extract</td>
<td>1 000 g/kg</td>
<td>1 March 2021</td>
<td>29 February 2036</td>
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