Commission Implementing Regulation (EU) 2019/706 of 7 May 2019 renewing the approval of the active substance carvone 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) 2019/706

of 7 May 2019

renewing the approval of the active substance carvone 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 2008/44/EC[(2)] included carvone 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 carvone, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 July 2019.

(4) An application for the renewal of the approval of the active substance carvone 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 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 31 May 2017.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/706. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) The Authority communicated the 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.

(8) On 12 July 2018 the Authority communicated to the Commission its conclusion[6] on whether carvone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial draft renewal report for carvone to the Standing Committee on Plants, Animals, Food and Feed on 24 January 2019.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

(10) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[7], the conclusion of the Authority indicates that it is highly unlikely that carvone is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities. Furthermore, the available data and the scientific risk assessment performed by the Authority indicate that carvone is unlikely to have endocrine disruptive effects. Thus, the Commission considers that carvone is not to be considered as having endocrine disrupting properties.

(11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance carvone 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 carvone is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing carvone may be authorised. It is therefore appropriate not to maintain the restriction to use as a plant growth regulator. It is therefore appropriate to renew the approval of carvone.

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

(14) This Regulation should apply from the day after the date of expiry of the approval of the active substance carvone.

(15) 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 active substance

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/706. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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 August 2019.

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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/706. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

[F1Common Name, Identification Numbers	**IUPAC Name**	**Purity[a]**	**Date of approval**	**Expiration of approval**	**Specific provisions**
carvone 2244-16-8 (d-carvone = S-carvone = (+)-carvone) Carvone: 602 d-carvone: not allocated	(*S*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (S)-p-mentha-6,8-dien-2-one	923 g/kg d-carvone	1 August 2019	31 July 2034	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 carvone, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment. Conditions of use shall

a Further details on the identity and the specification of the active substance are provided in the renewal report.**]**

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2019/706. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

					include risk mitigation measures, where appropriate. In particular, consideration should be given to the necessary time period before entry into storage rooms after the application of plant protection products containing carvone. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: — the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water is abstracted

a Further details on the identity and the specification of the active substance are provided in the renewal report.**]**