

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1251**of 19 July 2022****renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, 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) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2008/127/EC ⁽²⁾ included Straight Chain Lepidopteran Pheromones as active substances 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 substances Straight Chain Lepidopteran Pheromones, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2022.
- (4) Straight Chain Lepidopteran Pheromones are substances which are naturally produced by insects of the order of Lepidoptera. They share a common structural definition and mechanism of action and can be composed of acetates, aldehydes or alcohols.
- (5) Applications for the renewal of the approval of the active substances Straight Chain Lepidopteran Pheromones were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (6) Applicants 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.
- (7) 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 3 June 2019.

⁽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) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (9) On 19 May 2021, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether Straight Chain Lepidopteran Pheromones can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority's conclusion differentiated between acetates, aldehydes and alcohols within the Straight Chain Lepidopteran Pheromones.
- (10) The Commission presented its renewal report and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on the 1 December 2021 and 30 March 2022 respectively.
- (11) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with Article 14(1), third paragraph, of Implementing Regulation (EU) No 844/2012 ⁽⁷⁾, on the renewal report. The applicants submitted their comments, which have been carefully examined.
- (12) The Commission considers that it has been established with respect to one or more representative uses of at least one plant protection product containing the active substances Straight Chain Lepidopteran Pheromones (acetates, aldehydes or alcohols) that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (13) The Commission further considers that Straight Chain Lepidopteran Pheromones (acetates) are low-risk active substances pursuant to Article 22 of Regulation (EC) No 1107/2009, as they are not substances of concern and fulfil the conditions set in point 5 of Annex II to that Regulation.
- (14) It is therefore appropriate to renew the approval of Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances and the approval of Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) as active substances.
- (15) 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, it is, however, necessary to provide for certain conditions.
- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) This Regulation should apply from the day after the date of expiry of the approval of Straight Chain Lepidopteran Pheromones (acetates), Straight Chain Lepidopteran Pheromones (aldehydes and alcohols).
- (18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ EFSA (European Food Safety Authority), Conclusion on the peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs). *EFSA Journal* 2021;19(6):6656, 24 pp. doi:10.2903/j.efsa.2021.6656. Available online: <http://www.efsa.europa.eu>

⁽⁷⁾ This Regulation was replaced by Regulation (EU) 2020/1740, however, it shall continue to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substances Straight Chain Lepidopteran Pheromones (acetates), Straight Chain Lepidopteran Pheromones (aldehydes) and Straight Chain Lepidopteran Pheromones (alcohols) is renewed, subject to conditions set out in Annex I.

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 September 2022.

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

Done at Brussels, 19 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
Straight Chain Lepidopteran Pheromones (acetates)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
Straight Chain Lepidopteran Pheromones (aldehydes)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.
Straight Chain Lepidopteran Pheromones (alcohols)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.

ANNEX II

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

- (1) in Part A, entry 255 on Straight Chain Lepidopteran Pheromones is deleted;
 (2) in Part B, the following entries are added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'153	Straight Chain Lepidopteran Pheromones (aldehydes)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'
'154	Straight Chain Lepidopteran Pheromones (alcohols)	Review Report SANTE SANTE/10828/2021	Review Report SANTE SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'

(3) in Part D, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'38	Straight Chain Lepidopteran Pheromones (acetates)	Details are provided in the Review Report SANTE/10828/2021	Details are provided in the Review Report SANTE/10828/2021	1 September 2022	30 August 2037	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 Straight Chain Lepidopteran Pheromones, and in particular Appendices I and II thereof, shall be taken into account. Member States shall pay particular attention to the efficacy of plant protection products containing either the individual single substances or blends thereof when evaluating applications for authorisation. Conditions of use shall include risk mitigation measures, where appropriate.'