CONCLUSION ON PESTICIDES PEER REVIEW

EFSA Journal

APPROVED: 19 May 2021

doi: 10.2903/j.efsa.2021.6656

Peer review of the pesticide risk assessment of the active substance Straight Chain Lepidopteran Pheromones (SCLPs)

European Food Safety Authority (EFSA),
Fernando Alvarez, Maria Anastassiadou, Maria Arena, Domenica Auteri, Alba Brancato, Laszlo Bura, Luis Carrasco Cabrera, Anna Federica Castoldi, Eugenia Chaideftou, Arianna Chiusolo, Angelo Colagiorgi, Mathilde Colas, Federica Crivellente, Chloe De Lentdecker, Mark Egsmose, Gabriella Fait, Luna Greco, Alessio Ippolito, Frederique Istace, Samira Jarrah, Dimitra Kardassi, Aude Kienzler, Renata Leuschner, Roberto Lava, Linguadoca Alberto, Christopher Lythgo, Oriol Magrans, Iris Mangas, Ileana Miron, Tunde Molnar, Laura Padovani, Juan Manuel Parra Morte, Ragnor Pedersen, Hermine Reich, Miguel Santos, Rachel Sharp, Csaba Szentes, Andrea Terron, Manuela Tiramani, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Italy and co-rapporteur Member State France for the pesticide active substances that are Straight Chain Lepidopteran Pheromones (SCLPs) and the considerations as regards the inclusion of the substances in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of representative uses of some SCLPs as semiochemicals used to protect grapes, pome fruits, walnuts, rice and any other crop (where *Chilo suppressalis* may be a pest) (all field uses). The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

Keywords: Straight Chain Lepidopteran Pheromones (SCLPs), peer review, risk assessment, pesticide, semiochemical

Requestor: European Commission

Question number: EFSA-Q-2017-00273

Correspondence: pesticides.peerreview@efsa.europa.eu

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgments: EFSA wishes to thank the rapporteur Member State Italy for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Alvarez F, Anastassiadou M, Arena M, Auteri D, Brancato A, Bura L, Carrasco Cabrera L, Castoldi AF, Chaideftou E, Chiusolo A, Colagiorgi A, Colas M, Crivellente F, De Lentdecker C, Egsmose M, Fait G, Greco Lna, Ippolito A, Istace F, Jarrah S, Kardassi D, Kienzler A, Leuschner R, Lava R, Alberto L, Lythgo C, Magrans O, Mangas I, Miron I, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Reich H, Santos M, Sharp R, Szentes C, Terron A, Tiramani M, Vagenende B and Villamar-Bouza L, 2021. 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, 30 pp. https://doi.org/10.2903/j.efsa.2021.6656

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Straight Chain Lepidopteran Pheromones (SCLPs) is one of the active substances listed in these Regulations. Within the entry for SCLPs, the group of related compounds as described in this conclusion had been included.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Italy, and co-rapporteur Member State (co-RMS), France, received an application from Suterra Europe Biocontrol S.L. and the Joint SCLP Renewal Task Force (comprising of BASF SE, Bedoukian Research Inc., Shin-Etsu International Europe B.V., represented by CBC (Europe) S.r.l., Certis Europe B.V., Isagro S.p.A., Laboratorios Agrochem S.L., M2i Life Sciences, Provivi Inc., SEDQ Healthy Crops S.L. and Russell IPM Ltd.) for the renewal of approval of the active substance SCLPs. In addition, the applicants submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on SCLPs was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of SCLPs, according to the representative uses as semiochemicals applied via active and passive dispensers and/or foliar spray application on grapes, pome fruits, walnut, rice and any other field crop (where *Chilo suppressalis* may be a pest), as proposed at the European Union (EU) level result in a sufficient mating disruption efficacy against the target Lepidopteran species.

Assessments/risk characterisations were available for the SCLP compounds for which example products and good agricultural practice/representative use information was available. This applies to fiveof the compounds: (*E,Z*)-7,9-dodecadien-1-yl acetate; (*E,E*)-8,10-dodecadien-1-ol; (*Z*)-9-hexadecenal; (*Z*)-11-hexadecenal; (*Z*)-13-octadecenal. But assessments/risk characterisations were not available for 34 of the SCLP compounds as good agricultural practice/representative use information and other necessary details of plant protection products containing these 34 compounds were not made available. This applies to the SCLP compounds: (*E*)-5-decen-1-yl acetate; (*Z*)-7-dodecen-1-yl acetate; (*E*)-8-dodecen-1-yl acetate; (*Z*)-8-dodecen-1-yl acetate; (*Z*)-9-dodecen-1-yl acetate; tetradecyl acetate; (*E*)-11-tetradecen-1-yl acetate;(*Z*)-8-tetradecen-1-yl acetate;(*Z*)-9-tetradecen-1-yl acetate; (*Z*)-11-tetradecen-1-yl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; (*Z,E*)-9,11-tetradecadien-1-yl acetate; (*Z,E*)-9,12-tetradecadien-1-yl acetate; (*E,Z,Z*)-3,8,11-Tetradecatrien-1-yl acetate; hexadecyl acetate; (*Z*)-11-hexadecen-1-yl acetate; (*Z,E*)-7,11-hexadecadien-1-yl acetate; (*Z,Z*)-7,11-hexadecadien-1-yl acetate; (*E,Z*)-2,13-octadecadien-1-yl acetate; (*E,Z*)-3,13-octadecadien-1-yl acetate; (*Z,Z*)-3,13-octadecadien-1-yl acetate; (*E*)-5-decen-1-ol; dodecan-1-ol; (*Z*)-8-dodecen-1-ol; tetradecan-1-ol; (*Z*)-8-tetradecen-1-ol; (*Z*)-9-tetradecen-1-ol; (*Z*)-11-hexadecen-1-ol; (*Z*)-7-tetradecenal.

The assessment of the data package revealed no issues that need to be included as critical areas of concern or issues not finalised with respect to the identity, physical, chemical and technical properties of SCLPs or the representative formulations.

In the area of mammalian toxicology, no critical areas of concerns or issues not finalised were identified.

For the residue section the consumer risk assessment for (*E,E*)-8,10-dodecadien-1-ol from its use in apples via spray application is provisional. An maximum residue level (MRL) application for inclusion of SCLPs into Annex IV of Regulation (EC) No 396/2005 has also been submitted. A general suggestion for inclusion of SCLPs to Annex IV cannot be given as for the use of (*E,E*)-8,10-dodecadien-1-ol in combination with spray application, residues in apples cannot be excluded.

In the area of environmental fate and behaviour, there were estimations missing for SCLP compounds: tetradecyl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; hexadecyl acetate; dodecan-1-ol; tetradecane-1-ol and (*Z*)-9-tetradecen-1-ol, due to there being no information assessed on which species release these compounds and the occurrence of these unknown species in agricultural or horticultural cropping systems, therefore the assessments for these compounds could not be finalised.

In the area of ecotoxicology, the risk assessment for aquatic organisms could not be finalised for the representative spray uses of a product containing (*E,E*)-8,10-dodecadien-1-ol.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that SCLPs are not endocrine disruptors.

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Background

Commission Implementing Regulation (EU) No 844/2012[1], as amended by Commission Implementing Regulation (EU) No 2018/1659[2], (hereinafter referred to as 'the Regulation'), lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[3]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3). Furthermore, in accordance with Article 13(3a), where the information available in the dossier is not sufficient to conclude the assessment on whether the approval criteria for endocrine disruption are met, additional information can be requested to be submitted in a period of minimum 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS Italy and co-RMS France received an application from Suterra Europe Biocontrol S.L. and the Joint SCLP Renewal Task Force (comprising of BASF SE, Bedoukian Research Inc., Shin-Etsu International Europe B.V., represented by CBC (Europe) S.r.l., Certis Europe B.V., Isagro S.p.A., Laboratorios Agrochem S.L., M2i Life Sciences, Provivi Inc., SEDQ Healthy Crops S.L. and Russell IPM Ltd.) for the renewal of approval of the active substances defined as Straight Chain Lepidopteran Pheromones (SCLPs). In addition, the applicants submitted an application for inclusion of the substance group in Annex IV of Regulation (EC) No 396/2005[4]. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (France), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on SCLPs in the RAR, which was received by EFSA on 3 June 2019 (Italy, 2019). The RAR included a proposal for inclusion of the substances that have been defined as SCLPs in Annex IV of Regulation (EC) No 396/2005.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, Suterra Europe Biocontrol S.L. and the Joint SCLP Renewal Task Force, for consultation and comments on 20 December 2019. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 26 February 2020. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a written procedure between EFSA and the RMS on 8 April 2020. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an

[1] 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. 26–32.

[2] Commission Implementing Regulation (EU) No 2018/1659 of 7 November 2018 amending Implementing Regulation (EU) No 844/2012 in view of the scientific criteria for the determination of endocrine disrupting properties introduced by Regulation (EU) 2018/605.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

expert consultation in the areas of identity, physical/chemical/technical properties and methods of analysis, mammalian toxicology, residues and ecotoxicology.

The outcome of the written procedure with the RMS, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the proposal for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 took place with Member States via a written procedure in March – April 2021.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substances that have been defined and previously approved as SCLPs, evaluated on the basis of the representative uses of five of the SCLP compounds as semiochemicals included in four representative products that have uses protecting grapes, pome fruits and walnuts, rice and any other crop (where *Chilo suppressalis* may be a pest) (all field uses), as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion.

The lists of the relevant end points for the active substances and representative formulations are provided in Appendix B. In addition, the considerations as regards the cut-off criteria for the SCLPs according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2021), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (8 April 2020);
- the evaluation table (26 April 2021);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Italy, 2021), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

SCLPs are a group of pheromones consisting of unbranched aliphatics having a chain of 9–18 carbons, containing up to three double bonds and ending in an alcohol, acetate or aldehyde functional group. This structural definition encompasses the majority of known pheromones produced by insects in the order Lepidoptera, which includes butterflies and moths. SCLPs are considered by the International Organization for Standardization not to require common names. The IUPAC names of the compounds assessed in this conclusion are the following:

a) **SCLP acetate group**: (*E*)-5-decen-1-yl acetate, (*Z*)-7-dodecen-1-yl acetate, (*E*)-8-dodecen-1-yl acetate, (*Z*)-8-dodecen-1-yl acetate, (*Z*)-8-tetradecen-1-yl acetate, (*Z*)-9-dodecen-1-yl acetate, (*E*,*Z*)-7,9-dodecadien-1-yl acetate, tetradecyl acetate, (*E*)-11-tetradecen-1-yl acetate, (*Z*)-9-tetradecen-1-yl acetate, (*Z*)-11-tetradecen-1-yl acetate, (*E*,*Z*)-3,8-tetradecadien-1-yl acetate, (*Z*,*E*)-9,11-tetradecadien-1-yl acetate, (*Z*,*E*)-9,12-tetradecadien-1-yl acetate, (*E*,*Z*,*Z*)-3,8,11-tetradecatrien-1-yl acetate, hexadecyl acetate, (*Z*)-11-hexadecen-1-yl acetate, (*Z*,*E*)-7,11-hexadecadien-1-yl acetate, (*Z*,*Z*)-7,11-hexadecadien-1-yl acetate, (*E*,*Z*)-2,13-

octadecadien-1-yl acetate, (*E*,*Z*)-3,13-octadecadien-1-yl acetate, (*Z*,*Z*)-3,13-octadecadien-1-yl acetate;

b) **SCLP alcohol group**: (*E*)-5-decen-1-ol, dodecan-1-ol, (*Z*)-8-dodecen-1-ol, (*E*,*E*)-8,10-dodecadien-1-ol, tetradecan-1-ol, (*Z*)-8-tetradecen-1-ol, (*Z*)-9-tetradecen-1-ol, (*Z*)-11-hexadecen-1-ol;

c) **SCLP aldehyde group**: (*Z*)-7-tetradecenal, (*Z*)-9-hexadecenal, (*Z*)-11-hexadecenal, (*Z*)-13-octadecenal.

The representative formulated products for the evaluation were 'CheckMate® CM-F' a capsule suspension (CS) containing 141 g/L (144 g/kg) (*E*,*E*)-8,10-dodecadien-1-ol; 'BioSelibate™ CS' a vapour-releasing product (VP) containing 99.7 g/kg (250 mg a.s./unit) (*Z*)-11-hexadecenal, (*Z*)-9-hexadecenal, (*Z*)-13-octadecenal (sum of the components); 'Isomate CM MISTER X841', an aerosol dispenser (AE) containing 206 g/kg (*E*,*E*)-8,10-dodecadien-1-ol and 'Isonet L TT', a vapour-releasing product (VP) containing 758 g/kg (380 mg a.s./unit) (*E*,*Z*)-7,9-dodecadien-1-yl acetate. For the other active substances not contained in these formulations formulation data were not provided.

SCLPs are used in agriculture for mating disruption of different lepidopteran species in all the crops where these lepidopteran species may be a pest. The representative uses for 'CheckMate® CM-F' comprise high-volume or low-volume spray applications in pome fruit and walnut against codling moth in southern Europe. The representative use for 'Isomate CM MISTER X841' was application using active dispensers in pome fruit and walnut against codling moth. The representative uses for 'BioSelibateTM CS' were applications using passive dispensers in rice and any other crop in southern Europe where *Chilo suppressalis* (rice stem borer) may be a pest. The representative use for 'Isonet L TT' comprises application using passive dispensers in grapes against *Lobesia botrana* in southern Europe. Full details of the good agricultural practices (GAPs) can be found in the lists of endpoints in Appendix B, for the alcohol, acetate and aldehyde groups, respectively.

For the other active substances not contained in these formulations representative GAPs were not available. Therefore GAPs/representative use information was not available for the SCLP compounds: (*E*)-5-decen-1-yl acetate; (*Z*)-7-dodecen-1-yl acetate; (*E*)-8-dodecen-1-yl acetate; (*Z*)-8-dodecen-1-yl acetate; (*Z*)-9-dodecen-1-yl acetate; tetradecyl acetate; (*E*)-11-tetradecen-1-yl acetate; (*Z*)-8-tetradecen-1-yl acetate; (*Z*)-9-tetradecen-1-yl acetate; (*Z*)-11-tetradecen-1-yl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; (*Z,E*)-9,11-tetradecadien-1-yl acetate; (*Z,E*)-9,12-tetradecadien-1-yl acetate; (*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate; hexadecyl acetate; (*Z*)-11-hexadecen-1-yl acetate; (*Z,E*)-7,11-hexadecadien-1-yl acetate; (*Z,Z*)-7,11-hexadecadien-1-yl acetate; (*E,Z*)-2,13-octadecadien-1-yl acetate; (*E,Z*)-3,13-octadecadien-1-yl acetate; (*Z,Z*)-3,13-octadecadien-1-yl acetate; (*E*)-5-decen-1-ol; dodecan-1-ol; (*Z*)-8-dodecen-1-ol; tetradecan-1-ol; (*Z*)-8-tetradecen-1-ol; (*Z*)-9-tetradecen-1-ol; (*Z*)-11-hexadecen-1-ol and (*Z*)-7-tetradecenal. Consequently, assessments/risk characterisation could not be finalised for these SCLP compounds (see Section 9.1).

Data were submitted to conclude that the representative uses of the SCLPs contained in the representative formulations proposed at European level result in a sufficient mating disruptive effect, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the relevant metabolites/breakdown products of (*E*,*E*)-8,10-dodecadien-1-ol from the proposed spray application uses and on their potential side effects on health to address the metabolism of (*E*,*E*)-8,10-dodecadien-1-ol and/or the magnitude of residues of the respective metabolites/breakdown products in plants. The search should cover publication within the 10 years before the data of submission of the dossier and should be conducted and reported in accordance with the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: European Commission (2000a, 2000b, 2010, 2013).

The principles of setting the reference specifications were discussed in the Pesticide Peer Review Experts' Teleconference TC 33 (10 November 2020).

It was proposed to define the reference specifications based on the renewal batch data considering that there were not acceptable specifications at the time of the first evaluation due to missing batch data. The individual isomers of SCLPs were considered as active substances. Blends or mixtures of individual SCLPs or their isomers are not considered as an active substance, even if these blends/ mixtures are produced by a single and continuous manufacturing process. Mixtures/blends were considered as formulations.

The minimum purity of the individual SCLPs was based on the lowest available minimum purity measured in all sources and this value was proposed as reference specification. The minimum purities of the individual SCLPs assessed are listed in the list of endpoints (Appendix B). There was only one hexadecyl acetate source and one tetradecyl acetate source; their full assessment was not possible due to the insufficient characterisation of impurities, thus EFSA proposed a minimum purity for each source. The minimum purity of hexadecyl acetate source was based on the available batch data, for the tetradecyl acetate source the batches analysed were older than five years and additional quality control data were used to support the EFSA proposed minimum purity for this source.

Butylated hydroxytoluene (BHT), was considered as a relevant impurity with the maximum level of 20 g/kg (see Section 2). There are not FAO specifications for the SCLPs.

Several data gaps were identified for additional batch data, QC data, additional data on methods used in the batch analysis, validation data for the determination of hexadecyl acetate and tetradecylacetate content in their technical materials, information on formation and identification of impurities in several technical materials, information about stabilisers used, information on purity of starting materials and identification data for several notified SCLPs (see Section 10). A data gap for solubility in organic solvents (at least solubility in hexane and acetone) for the aldehyde SCLP active substances: (*Z*)-7-tetradecenal, (*Z*)-9-hexadecenal, (*Z*)-11-hexadecenal and (*Z*)-13-octadecenal was also identified (see Section 10). It can be mentioned however that it was the view of member states that these data gaps can be addressed at member state level during assessments for product authorisations.

Satisfactory methods were available for the generation of pre-approval data required for the risk assessment. Satisfactory methods using gas chromatography with flame ionisation detection (GC-FID) were provided for the determination of the active substance content in most of the technical materials and in the representative formulations. Several data gaps were identified for the analytical methods used to determine several SCLP active substances in the technical materials of BASF SE, a detailed description is given under Section 10. The content of the relevant impurity BHT in the technical materials can be determined by GC-FID. Data gaps were identified for the applicant CBC (Europe) S.r.l for the analytical methods used for the determination of the relevant impurity BHT in the technical materials of various SCLPs, a detailed description is given under Section 10. No validated analytical methods were provided for the determination of the relevant impurity BHT in the representative formulations. Methods for the analysis of residues in food and feed of plant and animal origin, in body fluids and body tissues are not required as no residue definitions were set. Methods for the analysis of residues in the environment are not required as no residue definitions were set, however pending on the final residue definition of SCLP alcohols for monitoring in surface water, analytical methods might be needed.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: European Commission (2003, 2012, 2016), EFSA (2014a), EFSA PPR Panel (2012), ECHA (2017) and OECD (2018).

SCLPs were discussed at the Pesticide Peer Review Experts' Meeting TC 32 in November 2020.

The analytical profile of the batches used in toxicological studies was in compliance with the technical specifications provided. BHT has been identified as a relevant impurity on the basis of the toxicological data available and since it exhibits a different and more severe toxicological profile than SCLPs; however, at the level specified in the proposed technical specifications, BHT does not pose a concern.

Reduced data requirements for SCLPs have been proposed by the RMS and agreed by EFSA and the member state experts according to their non-toxic and targeted mode of action, their typically low rates of application expected to result in a low human exposure and their low toxicological concern.[5]

[5] For full details of the expert discussion, please refer to expert consultation point 2.1 of the Pesticides Peer Review Experts' Meeting TC 32 in November 2020 (EFSA, 2021).

However, this rationale is applicable when long-term exposure above the background level can be excluded (OECD, 2001). The same approach has been used in the previous EU assessment (EFSA, 2014b) as well by other regulatory bodies such as the US EPA (US EPA, 2008). The waiving of long-term toxicity and carcinogenicity studies for SCLPs was accepted by the peer review as well, in the absence of adverse effects in the genotoxicity or short-term studies.

Bridging of studies within a chemical group, i.e. within acetate, alcohol and aldehyde SCLPs was considered appropriate.

ADME studies were not available for SCLPs, however information was borrowed from the known metabolism of fatty acids (it is expected that SCLPs follow similar or strictly related metabolism), and in agreement with the guidelines available on pheromones and semiochemicals (European Commission, 2016; OECD 2018). In addition, the EFSA Panel on Food Additives and Flavourings (FAF) has recently published an updated Opinion (EFSA FAF Panel, 2019) on Flavouring Group Evaluation 5 (Revision 3), containing 54 flavouring substances some of which are considered to be very similar to SCLP structures. The EFSA FAF Panel concluded that these flavouring substances are metabolised through common metabolic routes and that the expected metabolic intermediates are endogenous and, therefore, the end products can be considered innocuous.[5]

Acute toxicity (by the oral, dermal and inhalation routes) studies were provided on a number of SCLPs (i.e. acetates, alcohols, aldehydes and blends). SCLPs presented low acute toxicity by the oral, dermal or inhalation routes, except for the aldehyde group that was found to be harmful by inhalation: criteria for classification for acute inhalation cat. 4, H332 might therefore be met. (*E,E*)-8,10-dodecadien-1-ol exhibited signs of transient narcotic effects and criteria for classification for specific target organ toxicity category 3 for narcotic effects after single exposure (STOT-SE Category 3; H336: may cause drowsiness or dizziness) might be met for (*E,E*)-8,10-dodecadienol and all the SCLPs belonging to the group of alcohols.

Criteria for classification as skin irritant might be met for (*Z*)-9-tetradecen-1-yl acetate and all alcohols. No potential for eye irritation was observed, except for (*E,E*)-8,10-dodecadien-1-ol and therefore criteria for classification for eye irritation might be met for alcohols only. Potential for skin sensitisation was observed in the alcohol group and could be attributed also to the aldehyde group based on the QSAR predictions for skin sensitisation; therefore, criteria for classification for skin sensitisation might be met for SCLPs belonging to the alcohol and aldehyde groups.

Studies on phototoxicity were considered unnecessary since the large majority of SCLPs do not absorb electromagnetic radiation in the range of 290–700 nm (except for the active substance (*Z*)-11-hexadecenal) and the molar extinction/absorption coefficient is less than 10 litre $\times$ mol^{-1} $\times$ cm^{-1}. However, (*Z*)-11-hexadecenal is intended for use only in retrievable dispensers which prevent the active substance to be in contact with eyes or light-exposed areas of skin.

Due to the nature of the active substance and the specific mode of action and the physico-chemical properties of SCLPs (see Section 1), the provision of **short-term** studies was not required in agreement with reduced data requirements agreed for SCLPs. The only short-term study toxicity study available was a 28-day oral limit dose test conducted with (*E,E*)-8,10-dodecadien-1-ol administered at 1,000 mg/kg body weight (bw) per day. This dose level was considered a no observed adverse effect level (NOAEL) for females, and a lowest observable adverse effect level (LOAEL) for males, based on erosion of the glandular mucosa of the stomach, kidney papilla mineralisation, tubule dilatation and vacuolisation, and some clinical chemistry and urinalysis changes.

According to the basic battery of *in vitro* **genotoxicity** tests for each of the chemical classes, negative results were obtained. During the experts' meeting not enough evidence of bone marrow exposure was concluded for the *in vivo* micronucleus test in mice performed by using the alcohol (*E,E*)-8,10-dodecadien-1-ol; however, considering the type of molecules (SCLPs being very similar to fatty acids) the need for submission of an *in vivo* study was not considered necessary and overall the *in vitro* studies were considered sufficient (covering all genotoxic endpoints and being all negative) to conclude that fatty alcohols and SCLPs in general are not genotoxic.[6]

Waiving of further repeated dose studies, **long-term, reproductive and developmental studies**, including the setting of reference values was proposed by the RMS and agreed, also in compliance with the OECD Guidance (2001). Due to the nature of the active substance and the specific mode of action and the physico-chemical properties of SCLPs (see Section 1), the provision of

[6] For full details of the expert discussion, please refer to expert consultation 2.2 of Pesticides Peer Review Experts' Meeting TC 32 in November 2020 (EFSA, 2021).

long-term, reproductive and developmental studies was not required, as reduced data requirements were agreed.

However, during the residues experts' meeting (Pesticide Peer Review Meeting TC 36), the experts discussed the issue of exceedance of background levels specifically for the alcohol (*E,E*)-8,10-dodecadien-1-ol and for its aldehyde and acid metabolites, and requested further toxicological assessment for these substances.

After having further consulted the RMS and the experts participating in the Pesticide Peer Review Experts' Meeting TC 32 (November 2020) via written procedure (in January 2021),[7] EFSA proposed an acceptable daily intake (**ADI)** of 0.33 mg/kg bw per day for (*E,E*)-8,10-dodecadien-1-ol, based on the effects observed in males (erosion of the glandular mucosa of the stomach, kidney papilla mineralisation, tubule dilatation and vacuolisation and some clinical chemistry and urinalysis changes) at the LOAEL and by applying an UF of 3,000 (100 default factor for inter- and intra-species variability, 10 for both extrapolation from short- to medium-/long term and for limited database and an extra 3 for the absence of a NOAEL). In the absence of acute effects for (*E*,*E*)-8,10-dodecadien-1-ol, an acute reference dose (**ARfD**) is not needed. The same value of the ADI would apply to the setting of the acceptable operator exposure level (**AOEL**). This was in agreement with the proposal by a few MSs and the RMS (although using slightly different uncertainty factors); the other two MS experts expressed some reservation to set reference values on the basis of a limit test study. The RMS preferred option was to suggest the use of threshold for toxicological concern (TTC) methodology in line with the stepwise approach as applied by the EFSA FAF Panel in the updated Opinion on Flavouring Group Evaluation 5 (Revision 3) (EFSA FAF Panel, 2019). Since SCLPs are naturally occurring compounds considered of low-risk and presumably metabolised through common metabolic pathways, the RMS was of the opinion that the use of the TTC approach may be considered for these type of molecules as well as for those intentionally added in the food chain such as food additives and flavourings.

Toxicological data were not available for the aldehyde and acid metabolite of (*E,E*)-8,10-dodecadien-1-ol; however, no issues for consumers is foreseen in the absence of a genotoxicity concern for each of the chemical classes of SCLPs and considering that the metabolism of these molecules should follow common metabolic pathways as of those of fatty acids, producing innocuous metabolites. Reference values were not set for any SCLPs during the previous evaluation (EFSA, 2014b) (waiving of reference values was agreed).

With regard to **non-dietary exposure** estimates for the representative uses of 'CheckMate® CM-F' by spray application on pome fruit and walnuts, predicted exposure levels are below the AOEL for workers and operators wearing only work-wear, and also for residents (with the use of spray drift to reduce applications particularly for children). In the absence of an acute acceptable operator exposure level (AAOEL), bystanders' exposure is considered covered by the residents' risk assessment.

For the representative products that are dispensers (active or passive), the risk characterisation can be considered satisfactorily completed in line with the Guidance European Commission (2016)/OECD (2018) for bystanders and residents (see Section 4) as well as for operators (wearing gloves) and workers.

For a number of SCLP compounds, GAP information has not been provided and risk characterisation was therefore not available. This has led to the identification of an assessment not finalised (see Section 9.1).

3. Residues

The assessment in the residue section is based on the following guidance documents: European Commission (2016, 2017) and OECD (2018).

SCLPs were discussed at the Pesticide Peer Review Experts' Meeting TC 36 in November 2020.

Representative uses employing two different application modes, dispensers and spray application, are proposed. The various application modes using dispensers (both active and passive) to release: (*E,E*)-8,10-dodecadien-1-ol (pome fruit and walnut), a mixture of (*Z*)-11-hexadecenal, (*Z*)-9-hexadecenal, (*Z*)-13-octadecenal (rice and any other crop where *Chilo suppressalis* may be present) and (*E,Z*)-7,9-dodecadien-1-yl acetate (grape) were estimated to be below or within one order of magnitude of the background level of the respective pheromone compounds from the presence of lepidoptera in crop

[7] See Appendix 2 (Post meeting commenting table) of the Report of the Pesticide Peer Review Experts' Meeting TC 32; EFSA, 2021.

growing areas (see Section 4 for further details). Hence, in line with the provisions of the SANTE guidance document (European Commission, 2016) and OECD (2018), metabolism studies with plants and animals and residue trials are not required for these proposed uses with dispensers. This is because European Commission (2016)/OECD (2018) considers that the residue situation in crops where dispensers are deployed in the way discussed above, can be considered comparable to those in crops where dispensers are not present. Hence the guidance considers consumer exposure and consequently risk, as being comparable, independent of the presence of dispensers, provided that dispenser deployment is in line with GAP.

To support the other proposed use of spray application (high and low volume) of (*E,E*)-8,10-dodecadien-1-ol ('CheckMate® CM-F' capsule suspension) on pome fruit and walnuts, the applicants have submitted residue field trials covering the critical GAP conditions and supported by storage stability data. In one of the five trials with apple residues of 0.02 mg/kg were reported at preharvest interval (PHI) 0, 1 and 3 days. In the other trials residues were between limit of detection (LOD) of 0.003 mg/kg and limit of quantification (LOQ) of 0.01 mg/kg.

Plant metabolism studies were not presented and not considered necessary as the metabolic pathway of (*E,E*)-8,10-dodecadien-1-ol is assumed to be similar to long-chain fatty acids resulting in unsaturated, long-chain acetates, alcohols or aldehydes and fatty acids. Provided that the literature search for which a data gap was set (see Section 10) will not reveal different results, no further metabolism studies are required. A data gap is identified (see Section 10) for a sufficient number of residue trials with apples compliant with the critical GAP conditions for spray application and analysing for (*E,E*)-8,10-dodecadien-1-ol and its postulated degradation products within a period covered by storage stability data as the minimum number of 8 trials for a major crop has not been provided (see evaluation table Section 3; EFSA 2021). A sufficient number of 4 trials with walnuts was presented and residues were always below both the LOQ (0.01 mg/kg) and LOD (0.003 mg/kg).

The dietary burden calculation is provisional pending on the presentation of sufficient residue trials with apples (see data gap above).

A provisional dietary risk assessment for (*E,E*)-8,10-dodecadien-1-ol was conducted considering the available data on apple (with extrapolation to pome fruit) and walnuts using the ADI value of 0.33 mg/kg bw per day. The calculated theoretical maximum daily intakes (TMDIs) were below the ADI, thus, chronic exposure of consumers to residues of (*E,E*)-8,10-dodecadien-1-ol is not expected to result in any adverse health effect.

Given that for the spray application the max number of applications is quite high (12) and the application period (from before the flight of the 1st generation until harvest) covers the flowering period of all representative uses (pome fruit and walnut), residues in bee products cannot be excluded and the hypothetical calculations provided by the applicants are lacking scientific basis. Therefore, a data gap is identified to submit information against the data requirement on residue levels in pollen and in bee products for human consumption resulting from residues taken up by honeybees from crops at blossom resulting from the spray application of (*E,E*)-8,10-dodecadien-1-ol to apples and walnut (see Section 10).

The criteria for the inclusion of SCLPs in the Annex IV of Regulation (EC) No 396/2005 are not met as consumer exposure cannot be excluded.

4. Environmental fate and behaviour

The SCLPs being assessed have vapour pressures reported in the range 0.001–1.36 Pa at 20°C (though data gaps for vapour pressure values for some of the compounds were identified in the RAR by the RMS). Consequently these pheromone compounds fall into the classes of medium volatility to volatile, with most being volatile (FOCUS, 2008). Satisfactory information was provided to indicate that the SCLPs being assessed would not be subject to long range atmospheric transport due to their calculated short atmospheric half-lives (calculated for the process of indirect photochemical oxidative degradation) of 0.83–21.16 h, being less than 2 days (FOCUS, 2008).

The applicants' dossiers were prepared following European Commission (2016)/OECD (2018) semiochemicals guidance. Using information from the scientific literature included in the applicants' dossiers appropriate calculations of Lepidoptera emission rates from horticultural and rice-growing areas with populations of Lepidoptera that cause damage to crops were provided for all the SCLP compounds that are the subject of this application except for tetradecyl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; hexadecyl acetate; dodecan-1-ol; tetradecane-1-ol and (*Z*)-9-tetradecen-1-ol. For these six compounds, information on which species release these compounds and the occurrence of these unknown species in

agricultural or horticultural cropping systems was not provided. This has led to the identification of an assessment not finalised (see Section 9.1). GAP information was available for the four representative products included in the applicants' dossiers that contain the SCLP compounds (*E,E*)-8,10-dodecadien-1-ol; (*Z*)-11-hexadecenal; (*Z*)-9-hexadecenal; (*Z*)-13-octadecenal and (*E,Z*)-7,9-dodecadien-1-yl acetate. For these SCLP compounds, and the three representative products that are dispensers (active or passive), the GAP emission rates resulting from deployment of the dispensers were below or within one order of magnitude of the emission rates of the pertinent SCLP compounds calculated as originating for agricultural/horticultural areas with lepidopteran pests present. Thus, for these uses of these representative products, in accordance with the provisions set out in European Commission (2016)/OECD (2018) semiochemical guidance, the risk characterisations can be considered satisfactorily completed for all groups of non-target organisms (NTOs) including human bystanders and residents. For the SCLP compounds for which GAP information has not been provided, risk characterisations in line with European Commission (2016)/OECD (2018) semiochemical guidance were not available. This has led to the identification of an assessment not finalised (see Section 9.1).

For the spray application product containing the SCLP compound (*E,E*)-8,10-dodecadien-1-ol, studies on the route and rate of degradation in soils and natural sediment water systems were provided. The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, (*E,E*)-8,10-dodecadien-1-ol exhibited very low persistence, forming the major (> 10% applied radioactivity (AR)) metabolite M4 (unidentified, max. 12.2% AR), which also exhibited very low persistence. Mineralisation of the [8-^{14}C] radiolabel to carbon dioxide accounted for 20–42% AR after 15 days. The formation of unextractable residues (not extracted by methanol followed by microwave methanol/water and subsequently dichloromethane and acetone) for this radiolabel accounted for 42–55% AR after 15 days. (*E,E*)-8,10-dodecadien-1-ol exhibited low mobility in soil. It was concluded that the adsorption of (*E,E*)-8,10-dodecadien-1-ol was not pH dependent.

In laboratory incubations in dark aerobic natural sediment water systems, (*E,E*)-8,10-dodecadien-1-ol exhibited very low persistence, forming the major metabolites M1 (unidentified, max. 13% AR sediment, exhibiting low persistence), M2 (unidentified, max. 14% AR in sediment), M3 (unidentified, max. 15% AR in water, exhibiting very low persistence) and M7 (unidentified, max. 17% AR in water, that exhibited moderate persistence). The unextractable sediment fraction (not extracted using the same extraction steps as already described for soil) was a sink for the [8- ^{14}C] radiolabel, accounting for 37–44% AR at study end (14 days). Mineralisation of this radiolabel accounted for 43–46% AR at the end of the study. For the product where the GAP employs spray application, the necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for the unidentified metabolites M1, M2, M3, M4 and M7, using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1-2 in FOCUS calculator). For the active substance (*E,E*)-8,10-dodecadien-1-ol, contained in the product where the GAP employs spray application, appropriate step 3 (FOCUS, 2001) calculations were available.[8]

For the product where the GAP employs spray application, the necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.[8] The potential for groundwater exposure from the representative uses by (*E,E*)-8,10-dodecadien-1-ol and soil metabolite unidentified M4 above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

The applicant provided an appropriate case that at the points of abstraction of groundwater and surface water for the production of drinking water residues of the SCLP compounds (including transformation products of (*E,E*)-8,10-dodecadien-1-ol) in the water would be negligible (below the parametric drinking water standard of 0.1 μg/L). Consequently the levels of any water treatment process disinfection by products would also be negligible.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed for the product where the GAP employs spray application can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compounds assessed can be found in Appendix C of this conclusion.

[8] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b, 2016), SETAC et al. (2001), EFSA (2009, 2013), EFSA PPR Panel (2013) and OECD (2018). Some specific aspects related to the risk assessment of SCLPs were discussed in the Pesticide Peer Review Experts' Teleconference 37 in November 2020.

The batches used in the ecotoxicity studies were deemed sufficiently representative of the technical specification.

For the SCLP compounds listed above in the section on the active substance and the formulated product for which GAP information was not provided, a risk characterisation was not available. This has led to the identification of an assessment not finalised (see Section 9.1).

The representative uses of SCLPs for which GAP information was available that utilise dispensers, will lead to an exposure below or within one order of magnitude of the exposure levels in the available estimates for agricultural/horticultural areas with lepidopteran pests present (see Section 4). Thus, for those uses, in accordance with the provisions set out in European Commission (2016)/OECD (2018) semiochemical guidance, the risk characterisations can be considered satisfactorily completed as discussed in Section 4. A low risk can be concluded for all groups of NTOs.

For the representative uses of the SCLP (*E,E*)-8,10-dodecadien-1-ol as a spray, environmental exposure estimations were necessary and PEC have been calculated (see Section 4). Ecotoxicity studies were available for some groups of NTOs.

Acute toxicity studies with the active substance (*E,E*)-8,10-dodecadien-1-ol were submitted for both **birds** and wild **mammals**. No studies were available with the representative formulation (i.e. 'CheckMate® CM-F'). The acute risk to birds and mammals was assessed as low based on a screening level assessment. Long-term oral endpoints were not available for either birds or wild mammals. However, due to the nature of the active substance and the specific mode of action and the physico-chemical properties of SCLPs, the provision of long-term studies on these NTOs was not needed and a low long-term risk to both birds and mammals was concluded for the representative uses. No relevant plant metabolites were identified and therefore exposure to plant metabolites has not been considered further.

Acute toxicity data for assessing the toxicity of (*E,E*)-8,10-dodecadien-1-ol were provided for **fish** (*Brachydanio rerio*), **aquatic invertebrates** (*Daphnia magna*) and the green **algae** (*Pseudokirchneriella subcapitata* and *Scenedesmus subspicatus*). In addition, an acute algal study (*P. subcapitata*) was available with 'CheckMate® CM-F'. The validity of the aquatic toxicity tests and their use in the risk assessment was discussed in the experts' meeting.[9] Overall, the experts considered that the studies conducted with the active substance were unreliable since there was no analytical measurement of the test item or the study did not meet the validity criteria of the applicable test guideline (data gap for aquatic organisms[10]). As for the algal study with 'CheckMate® CM-F', the experts agreed that the derived endpoint could not be used for tier 1 risk assessment as (1) analytical measurements of the test item showed exposure below the limit of detection by the end of the test for all test concentrations, and (2) no interim measurements were available. However, since the exposure was sufficiently representative of the predicted exposure profile, the experts agreed to use the endpoint expressed in initial measurement concentration in a higher tier risk assessment. On the basis of the lack of reliable toxicity data, the risk assessment for fish and aquatic invertebrates could not be finalised, whereas a low risk for algae was concluded for the representative uses of SCLPs as spray by using FOCUS Step 1. Regarding the relevant aquatic metabolites (M1, M2, M3, M4 and M7), the risk to algae was assessed assuming metabolites to be 10 times more toxic than the parent. Although this is not a standard approach in higher tier risk assessment, it was considered appropriate given the magnitude of the margin of safety obtained with the parent compound. The risk to algae was concluded as low (FOCUS Step 2). In the absence of any valid studies, this approach could not be followed for fish and aquatic invertebrates and, thus, the risk assessment could not be finalised (see Section 9.1).

Acute and chronic toxicity tests on **honey bees** were available for (*E,E*)-8,10-dodecadien-1-ol. Besides, acute data were submitted for the representative formulation. The risk assessment performed

[9] For full details of the expert discussion, please refer to expert consultation 5.2 of Pesticides Peer Review Experts' Meeting TC 37 in November 2020 (EFSA, 2021).

[10] Regulation No 283/2013 establishes that acute toxicity data with active substances should always be submitted for fish, aquatic invertebrates and algae.

in line with the EFSA bee guidance document (EFSA, 2013) showed a low risk to adult honey bees from contact and oral exposure for all the representative uses as spray (the same conclusion would be reached by applying the guidance document on terrestrial ecotoxicology (European Commission, 2002b)). Unlike for adults, the Tier 1 risk assessment indicated a high risk for honey bee larvae from exposure to residues in the treated crop (BBCH 10–69) and in weeds (BBCH < 10). However, considering the nature of the active substance and the mode of action and the physico-chemical properties of SCLPs, a low risk to honey bee larvae can also be concluded.

An assessment of accumulative effects was not available. No data were available on sublethal effects, e.g. hypopharyngeal glands (data gap, see Section 10). A low risk was concluded due to exposure to contaminated water. Toxicity data and risk assessment were not provided for bumblebees or solitary bees. No relevant plant metabolites were identified and therefore exposure to plant metabolites has not been considered further.

Tier 1 toxicity tests on the **non-target arthropods** (NTAs), namely the parasitic wasp *Aphidius rhopalosiphi* and the predatory mite *Typhlodromus pyri*, were submitted with 'CheckMate® CM-F. Based on the available data and risk assessment, a low in- and off-field risk to NTAs was concluded for the representative uses of SCLPs as spray.

A chronic toxicity test with 'CheckMate® CM-F' was available for **earthworms** and a low risk was concluded for all spray uses. No toxicity data were submitted for the pertinent soil metabolite M4. However, a low risk was concluded assuming a toxicity 10 times than that of the parent.

Toxicity data evaluating the effects of SCLPs on **soil macroorganisms** other than earthworms were not required as a low risk to relevant NTAs was concluded at Tier 1. Based on a study with the representative formulation and the risk assessment, a low risk to **soil microorganisms** was concluded for the representative uses as spray. Ecotoxicity studies assessing the effects to **non-target terrestrial plants** and organisms involved in **sewage treatment processes** were not available with the active substance or the representative formulation. However, based on the nature of the active substance and the specific mode of action and the physico-chemical properties of SCLPs, a low risk was concluded for both groups of NTOs for the representative uses as spray.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption (ED) potential of SCLPs for **humans** according to the ECHA/EFSA guidance (2018), the available *in vitro* and *in silico* data on ED endpoints do not indicate EATS activity for SCLP acetates; as regards SCLP alcohols and aldehydes, it was considered to be negative for activity in EATS modalities.

Waiving of further ED assessment was agreed since:

- SCLPs have chemical structures similar to components involved in the fatty acids metabolism;
- SCLPs are naturally occurring substances likely to be incorporated into normal metabolism, deriving non-toxic metabolites and fatty acids, which constitute a significant and essential part of the normal diet;
- they have a non-toxic mode of action; they do not need to be tested for short- and long-term toxicity and reproductive effects.

The exposure for humans under chronic conditions was considered unlikely to overcome the background levels or to have an effect, if any, on the endocrine systems.[11]

With regard to the assessment of the endocrine disruption potential of SCLPs **for NTOs** according to the ECHA and EFSA (2018), although no (eco)toxicological data are available to assess the endocrine-disrupting properties, this does not appear scientifically necessary since:

- SCLPs have chemical structures similar to components involved in the fatty acids metabolism. SCLPs are likely to be incorporated into normal metabolism, deriving non-toxic metabolites, fatty acids, which constitute a significant and essential part of the normal diet.

According to points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, it can be concluded that SCLPs are not endocrine disruptors.

[11] For full details of the expert discussion, please refer to expert consultation point 2.3 of the Pesticides Peer Review Experts' Meeting TC 32 in November 2020 (EFSA, 2021).

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments[12] (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
(*E,E*)-8,10-dodecadien-1-ol	Low risk to soil organisms
Unidentified M4	Low risk to soil organisms

Table 2: Ground water[(a)]

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses[(b)] Step 2	Biological (pesticidal) activity/ relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
(*E,E*)-8,10-dodecadien-1-ol	No	Not applicable for semiochemicals[(c)]	–	–	Yes
Unidentified M4	No	Not triggered	Not triggered	No	No for the representative uses assessed

RA: Risk Assessment.
(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
(b): FOCUS scenarios or a relevant lysimeter.
(c): Attractants and repellents are not defined as pesticides in Council Directive 98/83/EC[13]

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
(*E,E*)-,10-dodecadien-1-ol	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data
Unidentified M1	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data
Unidentified M2	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data
Unidentified M3	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data
Unidentified M4	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data
Unidentified M7	Low risk to algae, assessment to fish and aquatic invertebrates not finalised due to the lack of reliable data

Table 4: Air

Compound (name and/or code)	Toxicology
(*E,E*)-8,10-dodecadien-1-ol (due to aerosols during spraying)	LC_{50} > 5.26 mg/L air per 4 h (whole body) LC_{50} > 3.24 mg/L air per 4 h (nose-only)

LC_{50}: lethal, concentration

[12] According to European Commission (2016) and OECD (2018) guidance documents where effects data have only been triggered for the spray uses for the GAP that have been assessed.
[13] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1988, p. 32–54.

8. Particular conditions proposed to be taken into account by risk managers

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level).

Table 5: Risk mitigation measures proposed for the representative uses assessed

Representative use	**CheckMate® CM-F (spray application)**
	Pome fruits and walnuts
Operator risk	–
Worker exposure	–
Bystander/resident exposure	Drift reduction for resident children

9. Concerns and related data gaps

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[14] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether any individual SCLP active substance compound can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following issues or assessments that could not be finalised have been identified, together with the reasons including the associated data gaps where relevant, which are reported directly under the specific issue to which they are related:

1) Risk characterisation for SCLP compounds: (*E*)-5-decen-1-yl acetate; (*Z*)-7-dodecen-1-yl acetate; (*E*)-8-dodecen-1-yl acetate; (*Z*)-8-dodecen-1-yl acetate; (*Z*)-9-dodecen-1-yl acetate; tetradecyl acetate; (*E*)-11-tetradecen-1-yl acetate; (*Z*)-8-tetradecen-1-yl acetate; (*Z*)-9-tetradecen-1-yl acetate; (*Z*)-11-tetradecen-1-yl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; (*Z,E*)-9,11-tetradecadien-1-yl acetate; (*Z,E*)-9,12-tetradecadien-1-yl acetate; (*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate; hexadecyl acetate; (*Z*)-11-hexadecen-1-yl acetate; (*Z,E*)-7,11-hexadecadien-1-yl acetate; (*Z,Z*)-7,11-hexadecadien-1-yl acetate; (*E,Z*)-2,13-octadecadien-1-yl acetate; (*E,Z*)-3,13-octadecadien-1-yl acetate; (*Z,Z*)-3,13-octadecadien-1-yl acetate; (*E*)-5-decen-1-ol; dodecan-1-ol; (*Z*)-8-dodecen-1-ol; tetradecan-1-ol; (*Z*)-8-tetradecen-1-ol; (*Z*)-9-tetradecen-1-ol; (*Z*)-11-hexadecen-1-ol; (*Z*)-7-tetradecenal due to there being no GAP/ representative use information for plant protection products containing these compounds (see section on 'Active substance and formulated product', relevant for Sections 2, 3, 4 and 5).
    a) GAP/representative use information was not available for the SCLP compounds: (*E*)-5-decen-1-yl acetate; (*Z*)-7-dodecen-1-yl acetate; (*E*)-8-dodecen-1-yl acetate; (*Z*)-8-

[14] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

dodecen-1-yl acetate; (*Z*)-9-dodecen-1-yl acetate; tetradecyl acetate; (*E*)-11-tetradecen-1-yl acetate; (*Z*)-8-tetradecen-1-yl acetate; (*Z*)-9-tetradecen-1-yl acetate; (*Z*)-11-tetradecen-1-yl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; (*Z,E*)-9,11-tetradecadien-1-yl acetate; (*Z,E*)-9,12-tetradecadien-1-yl acetate; (*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate; hexadecyl acetate; (*Z*)-11-hexadecen-1-yl acetate; (*Z,E*)-7,11-hexadecadien-1-yl acetate; (*Z,Z*)-7,11-hexadecadien-1-yl acetate; (*E,Z*)-2,13-octadecadien-1-yl acetate; (*E,Z*)-3,13-octadecadien-1-yl acetate; (*Z,Z*)-3,13-octadecadien-1-yl acetate; (*E*)-5-decen-1-ol; dodecan-1-ol; (*Z*)-8-dodecen-1-ol; tetradecan-1-ol; (*Z*)-8-tetradecen-1-ol; (*Z*)-9-tetradecen-1-ol; (*Z*)-11-hexadecen-1-ol and (*Z*)-7-tetradecenal. This information was needed to advise the Commission for each compound, the release rates from the use of each compound for plant protection, that needs to be compared to the estimates of their natural emissions from Lepidoptera; (see section on 'Active substance and formulated product' and Section 4).

2) Risk characterisation for SCLP compounds: tetradecyl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; hexadecyl acetate; dodecan-1-ol; tetradecane-1-ol and (*Z*)-9-tetradecen-1-ol due to there being no information assessed on which species release these compounds and the occurrence of these unknown species in agricultural or horticultural cropping systems (see Section 4).
    a) Estimates of background release rates for the SCLP: tetradecyl acetate; (*E,Z*)-3,8-tetradecadien-1-yl acetate; hexadecyl acetate; dodecan-1-ol; tetradecane-1-ol and (*Z*)-9-tetradecen-1-ol or justifications to extrapolate estimates for these compounds from those for which calculations are already available were not available. This would require a comparison of the biology of the different target species and population dynamics in the relevant crops, which was not provided (see Section 4).
3) Risk assessment for aquatic organisms (fish and aquatic invertebrates) for the representative spray uses of SCLP (*E,E*)-8,10-dodecadien-1-ol as a spray could not be finalised (see Section 5).
    a) Lack of reliable toxicity data on aquatic organisms for both the SCLP (*E,E*)-8,10-dodecadien-1-ol and its unidentified metabolites (see Section 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

The following critical areas of concern are identified, together with any associated data gaps, where relevant, which are reported directly under the specific critical area of concern to which they are related:

Critical areas of concern have not been identified.

9.3. Overview of the concerns identified for each representative use considered (Table 6)

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6.)

Table 6: Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios

SCLP compounds and associated products		**(*E,Z*)-7,9-dodecadien-1-yl acetate Isonet L TT'**	**(*E,E*)-8,10-dodecadien-1-ol Isomate CM MISTER**	**(*E,E*)-8,10-dodecadien-1-ol CheckMate® CM-F**	**(*E,E*)-8,10-dodecadien-1-ol CheckMate® CM-F**	**(*Z*)-9-hexadecenal; (*Z*)-11-hexadecenal; (*Z*)-13-octadecenal BioSelibate CS**
Representative use		**Grapes**	**Pome fruit and walnuts**	**Pome fruit and walnuts**	**Pome fruit and walnuts**	**Rice and any other crop where *Chilo suppressalis* may be a pest**
		Manual distribution of 200–300 passive dispensers/ha	**Manual placement of 2–3 aerosol devices/ha (active dispensers)**	**Spray application 12 × 0.0125 kg a.s./ha**	**Spray application 6 × 0.025 kg a.s./ha**	**Manual distribution of 31–100 passive dispensers/ha**
Operator risk	Risk identified					
	Assessment not finalised					
Worker risk	Risk identified					
	Assessment not finalised					
Resident/ bystander risk	Risk identified					
	Assessment not finalised					
Consumer risk	Risk identified					
	Assessment not finalised					
Risk to wild non-target terrestrial vertebrates	Risk identified					
	Assessment not finalised					
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified					
	Assessment not finalised					

SCLP compounds and associated products		(*E,Z*)-7,9-dodecadien-1-yl acetate Isonet L TT'	(*E,E*)-8,10-dodecadien-1-ol Isomate CM MISTER	(*E,E*)-8,10-dodecadien-1-ol CheckMate® CM-F	(*E,E*)-8,10-dodecadien-1-ol CheckMate® CM-F	(*Z*)-9-hexadecenal; (*Z*)-11-hexadecenal; (*Z*)-13-octadecenal BioSelibate CS
Representative use		**Grapes**	**Pome fruit and walnuts**	**Pome fruit and walnuts**	**Pome fruit and walnuts**	**Rice and any other crop where *Chilo suppressalis* may be a pest**
		Manual distribution of 200–300 passive dispensers/ha	**Manual placement of 2–3 aerosol devices/ha (active dispensers)**	**Spray application 12 × 0.0125 kg a.s./ha**	**Spray application 6 × 0.025 kg a.s./ha**	**Manual distribution of 31–100 passive dispensers/ha**
Risk to aquatic organisms	Risk identified					
	Assessment not finalised			X[3]	X[3]	
Ground water exposure to active substance	Legal parametric value breached					
	Assessment not finalised					
Ground water exposure to metabolites	Legal parametric value breached[(a)]					
	Parametric value of 10 μg/L[(b)] breached					
	Assessment not finalised					

Note: for the SCLP compounds not indicated in this table risk assessment scenarios were not available due to the absence of GAP information for products containing these other SCLP compounds.
The superscript numbers relate to the numbered points indicated in Section 9.1.
(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

10. List of other outstanding issues

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer to the representative uses assessed or to compounds for which a representative use was not available and are listed in the order of the sections:

- Representative formulations and GAP uses for the SCLPs: **acetate group**: (*E*)-5-decen-1-yl acetate, (*Z*)-7-dodecen-1-yl acetate, (*E*)-8-dodecen-1-yl acetate, (*Z*)-8-dodecen-1-yl acetate, (*Z*)-8-tetradecen-1-yl acetate, (*Z*)-9-dodecen-1-yl acetate, n-tetradecyl acetate, (*E*)-11-

tetradecen-1-yl acetate, (*Z*)-9-tetradecen-1-yl acetate, (*Z*)-11-tetradecen-1-yl acetate, (*E,Z*)-3,8-tetradecadien-1-yl acetate, (*Z,E*)-9,11-tetradecadien-1-yl acetate, (*Z,E*)-9,12-tetradecadien-1-yl acetate, (*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate, hexadecyl acetate, (*Z*)-11-hexadecen-1-yl acetate, (*Z,E*)-7,11-hexadecadien-1-yl acetate, (*Z,Z*)-7,11-hexadecadien-1-yl acetate, (*E,Z*)-2,13-octadecadien-1-yl acetate, (*E,Z*)-3,13-octadecadien-1-yl acetate, (*Z,Z*)-3,13-octadecadien-1-yl acetate; **SCLP alcohol group**: (*E*)-5-decen-1-ol, dodecan-1-ol, (*Z*)-8-dodecen-1-ol, tetradecan-1-ol, (*Z*)-8-tetradecen-1-ol, (*Z*)-9-tetradecen-1-ol, (*Z*)-11-hexadecen-1-ol; **SCLP aldehyde group**: (*Z*)-7-tetradecenal (see section on 'The active substance and the formulated product').

- Search of the scientific peer-reviewed open literature on the relevant metabolites/breakdown products of (*E,E*)-8,10-dodecadien-1-ol from the proposed spray application uses and on their potential side effects on health should be provided to address the metabolism of (*E,E*)-8,10-dodecadien-1-ol and/or the magnitude of residues of the respective metabolites/breakdown products in plants, in accordance with the EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011) and the appendix to the said guidance (see section on 'The active substance and the formulated product').
- Applicant (M2i) to provide additional batch data or QC data for (*Z*)-11-hexadecen-1-ol and for (*Z*)-11-hexadecenal, and the report M2iD-ANA-2020-02 (see Section 1).
- Applicant (Certis and M2i) to provide additional validation data for impurity analysis in (*E,E*)-8,10-dodecadien-1-ol technical material (see Section 1).
- Final reports on data validation, batch characterisation, including impurities assessment for the active substance (*Z*)-11-tetradecen-1-yl acetate (relevant for applicant Provivi) (see Section 1).
- Applicants to provide, where missing and relevant, CAS/EC number, identity, structure, molecular formula, and molar mass of all impurities in the technical materials (relevant for BASF SE, M2i and Provivi) (see Section 1).
- Method validation data for impurity analysis in the technical materials of tetradecylacetate, hexadecylacetate and (*E,E*)-8,10-dodecadien-1-ol (relevant for BASF SE) (see Section 1).
- Applicant (CBC) to submit validation data, according to SANCO/3030/99 rev.4., for the determination of impurities in the (*E*)-5-decen-1-ol batches (see Section 1).
- Applicants (Certis, M2i) to provide, where missing, the purity of the starting materials (see Section 1).
- Identity information for the following SCLP active substances: (*E*)-8-dodecen-1-yl acetate, (*E*)-11-tetradecen-1-yl acetate, (*Z,E*)-9,11-tetradecadien-1-yl acetate, (*Z,E*)-7,11-hexadecadien-1-yl acetate, (*Z,Z*)-7,11-hexadecadien-1-yl acetate, (*E,Z*)-2,13-octadecadien-1-yl acetate, (*E,Z*)-3,13-octadecadien-1-yl acetate, (*Z,Z*)-3,13-octadecadien-1-yl acetate, (*Z*)-8-dodecen-1-ol, (*Z*)-11-hexadecen-1-ol and (*Z*)-7-tetradecenal, (*Z*)-9-hexadecenal, (*Z*)-13-octadecenal (relevant for the applicant Suterra Europe Biocontrol S.L.) (see Section 1).
- Information on the minimum content of the stabiliser used in the technical materials of (*Z,E*)-7,11-hexadecadien-1-yl acetate and (*Z,Z*)-7,11-hexadecadien-1-yl acetate (relevant for CBC (Europe) S.r.l), (*E,E*)-8,10-dodecadien-1-ol (relevant for BASF SE), (*Z*)-7-tetradecenal (relevant for Agrochem) and (*E,E*)-8,10-dodecadien-1-ol (relevant for SEDQ) (see Section 1).
- Information, where missing, on the origin/formation of non SCLP-like and SCLP-like impurities in the technical materials of the applicants: BASF SE, Bedoukian Research, Inc., ShinEtsu/CBC (Europe) srl, Certis Europe B.V., M2i, Provivi Inc., SEDQ S.L. and Suterra Europe Biocontrol S.L (see Section 1).
- Data for solubility in organic solvents (at least in hexane and acetone) for the aldehyde SCLP active substances: (*Z*)-7-tetradecenal, (*Z*)-9-hexadecenal, (*Z*)-11-hexadecenal and (*Z*)-13-octadecenal (relevant for the Joint SCLP Renewal Task Force and the applicant Suterra Europe Biocontrol S.L.) (see Section 1).
- Information on validation for analytical methods, at the appropriate concentration level, for hexadecyl acetate and tetradecylacetate determination in their technical materials (relevant for the applicant BASF SE) (see Section 1).
- Analytical methods for the determination of the relevant impurity BHT in the technical materials of: (*E*)-11-tetradecen-1-yl acetate, (*Z,E*)-9,12-tetradecadien-1-yl acetate, (*Z,E*)-7,11-hexadecadien-1-yl acetate, (*Z,Z*)-7,11-hexadecadien-1-yl acetate, (*Z,Z*)-3,13-octadecadien-1-yl acetate, (*E,Z*)-3,8-tetradecadien-1-yl-acetate, (*Z*)-8-dodecen-1-ol, (*Z*)-9-tetradecen-1-ol, (*Z*)-9-hexadecenal, (*Z*)-13-octadecenal, (*E*)-5-decenyl acetate, (*E,Z*)-7,9-dodecadien-1-yl acetate,

(*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate, (*E,Z*)-3,13-octadecadien-1-yl acetate, (*E*)-5-decen-1-ol, (*Z*)-7-tetradecenal, (*Z*)-11-hexadecenal (relevant for the applicant CBC (Europe) S.r.l) (see Section 1).

- Analytical methods for the determination of the relevant impurity BHT in the representative formulations (relevant for the Joint SCLP Renewal Task Force and the applicant Suterra Europe Biocontrol S.L.) (see Section 1).
- Information for method accuracy at adequate levels for the significant impurities present in the (*Z*)-8- dodecen-1-yl acetate (relevant for Bedoukian, Certis and M2i) and (*E*)-8-dodecen-1-yl acetate (relevant for Bedoukian) batches (see Section 1).
- A sufficient number of residue trials with apples covering the critical GAP conditions analysing for (*E,E*)-8,10-dodecadien-1-ol and its postulated degradation products (aldehyde and acid) within a period covered by storage stability data is needed (see Section 3).
- Information against the data requirement on residue levels in pollen and in bee products for human consumption resulting from residues taken up by honeybees from crops at blossom resulting from the spray application of (*E,E*)-8,10-dodecadien-1-ol to apples and walnut is requested (see Section 3).
- Information to address the risk to bees from sublethal effects (relevant for the representative spray uses; see Section 5).

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Abbreviations

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AE	aerosol dispenser
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CAS	Chemical Abstracts Service
CS	capsule suspension
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GC	gas chromatography
InChiKey	International Chemical Identifier Key
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PHI	preharvest interval
RA	Risk Assessment
SCLPs	Straight Chain Lepidopteran Pheromones
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TMDI	theoretical maximum daily intake
TTC	threshold for toxicological concern
VP	vapour-releasing product
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for Straight Chain Lepidopteran Pheromones (SCLPs) according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Classification criteria not met. SCLPs are not considered to be carcinogenic, mutagenic or toxic for reproduction according to points 3.6.2, 3.6.3 and 3.6.4 of Annex II of Regulation (EC) 1107/2009
	Mutagenicity (M)	
	Toxic for Reproduction (R)	
Endocrine-disrupting properties		SCLPs are not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	The SCLP compounds assessed are not considered to be persistent organic pollutants (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	**Persistence**	The SCLP compounds assessed are not considered to be persistent, bioaccumulative and toxic (PBT) substances according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	**Persistence**	The SCLP compounds assessed are not considered to be very persistent, very bioaccumulative substances according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	

(a): Origin of data to be included where applicable (e.g. EFSA, ECHA RAC, Regulation).

Appendix B – List of end points for the active substance and the representative formulation

Appendix B can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2021.6656

Appendix C – Wording EFSA used in Section 4 of this conclusion, in relation to DT and K_{oc} 'classes' exhibited by each compound assessed

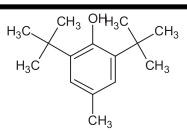
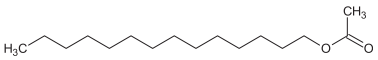
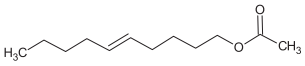
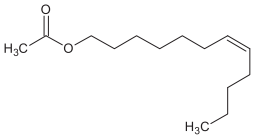
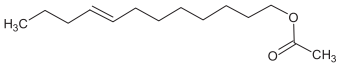
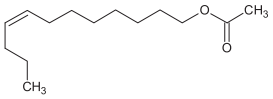
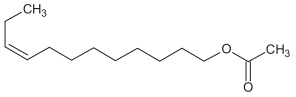
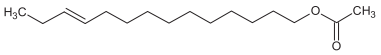
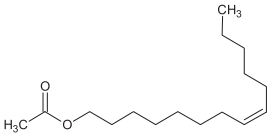
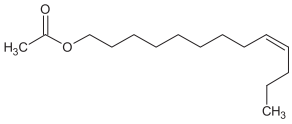
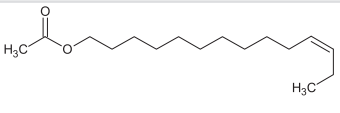
Wording	DT_{50} normalised to 20°C for laboratory incubations[(a)] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT_{50} when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

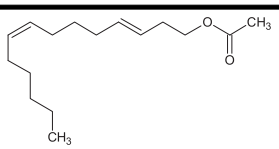
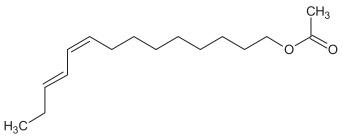
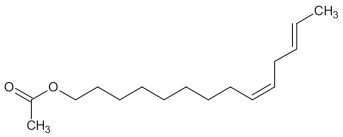
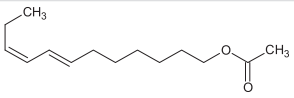
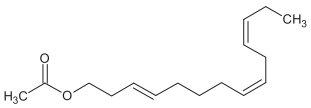
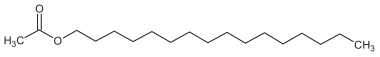
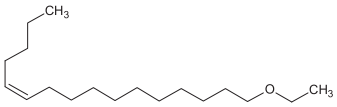
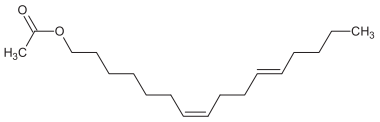
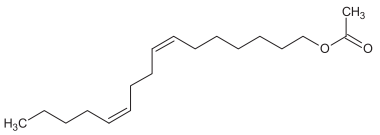
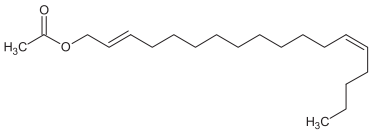
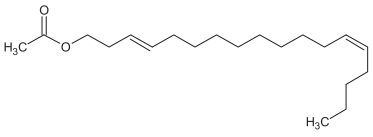
DT_{50}: period required for 50% dissipation; DT_{90}: period required for 50% dissipation; SFO: single first-order.
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.
(a): For laboratory soil incubations, normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

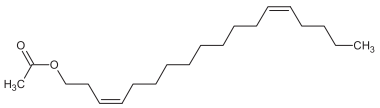
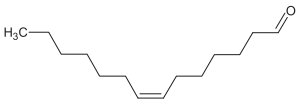
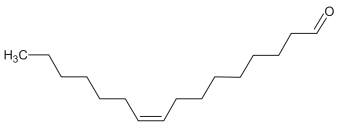
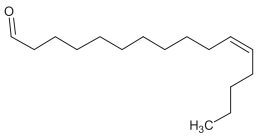
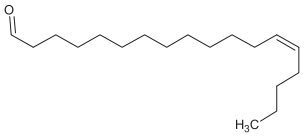
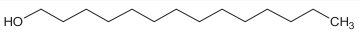
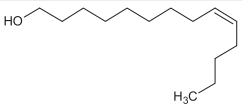
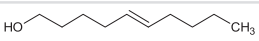
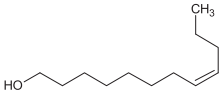
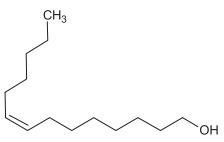
Wording	K_{oc} (either K_{Foc} or K_{doc}) mL/g
Very high mobility	0–50
High mobility	51–150
Medium mobility	151–500
Low mobility	501–2,000
Slight mobility	2,001–5,000
Immobile	> 5,000

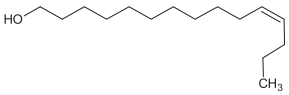
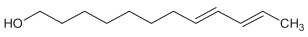
K_{oc}: organic carbon adsorption coefficient; K_{Foc}: Freundlich organic carbon adsorption coefficient; K_{doc}: organic carbon linear adsorption coefficient.
Based on McCall et al. (1980).

Appendix D – Used compound codes

Code/trivial name	IUPAC name/SMILES notation/ InChiKey[a]	Structural formula[b]
butylated hydroxytoluene (BHT)	2,6-di-*tert*-butyl-4-methylphenol CC(C)(C)c1cc(C)cc(c1O)C(C)(C)C NLZUEZXRPGMBCV-UHFFFAOYSA-N	
tetradecyl acetate	tetradecyl acetate CC(=O)OCCCCCCCCCCCCCC IOUUIFSIQMVYKP-UHFFFAOYSA-N	
(*E*)-5-decen-1-yl acetate	(*E*)-5-decen-1-yl acetate CC(=O)OCCCC\C=C\CCCC VTUFOIHYMMMNOM-VOTSOKGWSA-N	
(*Z*)-7-dodecen-1-yl acetate	(*Z*)-7-dodecen-1-yl acetate CC(=O)OCCCCCC\C=C/CCCC MUZGQHWTRUVFLG-SREVYHEPSA-N	
(*E*)-8-dodecen-1-yl acetate	(*E*)-8-dodecen-1-yl acetate CC(=O)OCCCCCCC\C=C\CCC SUCYDSJQVVGOIW-AATRIKPKSA-N	
(*Z*)-8-dodecen-1-yl acetate	(*Z*)-8-dodecen-1-yl acetate C.CC(=O)OCCCCCCC\C=C/CCC UITUNPOMRICGNT-YSMBQZINSA-N	
(*Z*)-9-dodecen-1-yl acetate	(*Z*)-9-dodecen-1-yl acetate CC(=O)OCCCCCCCC/C=C\CC MFFQOUCMBNXSBK-PLNGDYQASA-N	
(*E*)-11-tetradecen-1-yl acetate	(*E*)-11-tetradecen-1-yl acetate CC(=O)OCCCCCCCCCC\C=C\CC YJINQJFQLQIYHX-SNAWJCMRSA-N	
(*Z*)-8-tetradecen-1-yl acetate	(*Z*)-8-tetradecen-1-yl acetate CC(=O)OCCCCCCC\C=C/CCCCC VZGHIFSDFDWSOD-FPLPWBNLSA-N	
(*Z*)-9-tetradecen-1-yl acetate	(*Z*)-9-tetradecen-1-yl acetate CC(=O)OCCCCCCCC/C=C\CCCC XXPBOEBNDHAAQH-SREVYHEPSA-N	
(*Z*)-11-tetradecen-1-yl acetate	(*Z*)-11-tetradecen-1-yl acetate CC(=O)OCCCCCCCCCC/C=C\CC YJINQJFQLQIYHX-PLNGDYQASA-N	

Code/trivial name	IUPAC name/SMILES notation/ InChiKey[a]	Structural formula[b]
(*E,Z*)-3,8-tetradecadien-1-yl acetate	(*E,Z*)-3,8-tetradecadien-1-yl acetate CC(=O)OCC\C=C\CCC\C=C/CCCCC WWXVCCMNRBSSKV-LQZWXTFHSA-N	
(*Z,E*)-9,11-tetradecadien-1-yl acetate	(*Z,E*)-9,11-tetradecadien-1-yl acetate CC(=O)OCCCCCCCC/C=C\C=C\CC RFEQLTBBKNKGGJ-DEQVHDEQSA-N	
(*Z,E*)-9,12-tetradecadien-1-yl acetate	(*Z,E*)-9,12-tetradecadien-1-yl acetate CC(=O)OCCCCCCCC/C=C\C\C=C\C ZZGJZGSVLNSDPG-FDTUMDBZSA-N	
(*E,Z*)-7,9-dodecadien-1-yl acetate	(*E,Z*)-7,9-dodecadien-1-yl acetate CC(=O)OCCCCCC/C=C/C=C\CC LLRZUAWETKPZJO-SCFJQAPRSA-N	
(*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate	(*E,Z,Z*)-3,8,11-tetradecatrien-1-yl acetate CC(=O)OCC\C=C\CCC\C=C/C/C=C\CC HWPJPNQEVWTZSJ-XBZOLNABSA-N	
hexadecyl acetate	hexadecyl acetate CC(=O)OCCCCCCCCCCCCCCCC LSTDYDRCKUBPDI-UHFFFAOYSA-N	
(*Z*)-11-hexadecen-1-yl acetate	(*Z*)-11-hexadecen-1-yl acetate CC(=O)OCCCCCCCCCC/C=C\CCCC BTKXLQSCEOHKTF-SREVYHEPSA-N	
(*Z,E*)-7,11-hexadecadien-1-yl acetate	(*Z,E*)-7,11-hexadecadien-1-yl acetate CC(=O)OCCCCCC\C=C/CC\C=C\CCCC BXJHOKLLMOYSRQ-WFKFFMJQSA-N	
(*Z,Z*)-7,11-hexadecadien-1-yl acetate	(*Z,Z*)-7,11-hexadecadien-1-yl acetate CC(=O)OCCCCCC\C=C/CC/C=C\CCCC BXJHOKLLMOYSRQ-QOXWLJPHSA-N	
(*E,Z*)-2,13-octadecadien-1-yl acetate	(*E,Z*)-2,13-octadecadien-1-yl acetate CC(=O)OC\C=C\CCCCCCCCC/C=C\CCCC NWRSOYAGXTXEMK-NHRIVICHSA-N	
(*E,Z*)-3,13-octadecadien-1-yl acetate	(*E,Z*)-3,13-octadecadien-1-yl acetate CC(=O)OCC\C=C\CCCCCCCC/C=C\CCCC VVJPJXKHBZNADP-ZSTZHTMOSA-N	

Code/trivial name	IUPAC name/SMILES notation/ InChiKey[a]	Structural formula[b]
(*Z*,*Z*)-3,13-octadecadien-1-yl acetate	(*Z*,*Z*)-3,13-octadecadien-1-yl acetate CC(=O)OCC/C=C\CCCCCCCC/C=C\CCCC VVJPJXKHBZNADP-DNNFRFAMSA-N	
(*Z*)-7-tetradecenal	(*Z*)-7-tetradecenal CCCCCC/C=C\CCCCCC=O AVHNDAZRNRAYTP-FPLPWBNLSA-N	
(*Z*)-9-hexadecenal	(*Z*)-9-hexadecenal CCCCCC\C=C/CCCCCCCC=O QFPVVMKZTVQDTL-FPLPWBNLSA-N	
(*Z*)-11-hexadecenal	(*Z*)-11-hexadecenal CCCC\C=C/CCCCCCCCCC=O AMTITFMUKRZZEE-WAYWQWQTSA-N	
(*Z*)-13-octadecenal	(*Z*)-13-octadecenal CCCC\C=C/CCCCCCCCCCCC=O QIRGIHPYVVKWTO-WAYWQWQTSA-N	
dodecan-1-ol	dodecan-1-ol CCCCCCCCCCCCO LQZZUXJYWNFBMV-UHFFFAOYSA-N	
tetradecane-1-ol	tetradecane-1-ol CCCCCCCCCCCCCCO HLZKNKRTKFSKGZ-UHFFFAOYSA-N	
(*Z*)-9-tetradecen-1-ol	(*Z*)-9-tetradecen-1-ol CCCC\C=C/CCCCCCCCO GSAAJQNJNPBBSX-WAYWQWQTSA-N	
(*E*)-5-decen-1-ol	(*E*)-5-decen-1-ol CCCC\C=C\CCCCO WYPQHXVMNVEVEB-AATRIKPKSA-N	
(*Z*)-8-dodecen-1-ol	(*Z*)-8-dodecen-1-ol CCC/C=C\CCCCCCCO YEQONIQGGSENJQ-PLNGDYQASA-N	
(*Z*)-8-tetradecen-1-ol	(*Z*)-8-tetradecen-1-ol CCCCC/C=C\CCCCCCCO USXIHYYSGSBNAK-SREVYHEPSA-N	

Code/trivial name	IUPAC name/SMILES notation/ InChiKey[a]	Structural formula[b]
(*Z*)-11-hexadecen-1-ol	(*Z*)-11-hexadecen-1-ol CCCC\C=C/CCCCCCCCCO RHVMNRHQWXIJIS-WAYWQWQTSA-N	
(*E,E*)-8,10-dodecadien-1-ol	(*E,E*)-8,10-dodecadien-1-ol C\C=C\C=C\CCCCCCCO CSWBSLXBXRFNST-MQQKCMAXSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(b): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).