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## Peer review of the pesticide risk assessment of the active substance rape seed oil

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### Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State the Netherlands and co-rapporteur Member State Finland for the pesticide active substance rape seed oil and the considerations as regards the inclusion of the substance 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 the representative professional and non-professional uses of rape seed oil as an acaricide on pome fruit trees (field use), berries, vegetables, ornamentals (greenhouse and field uses) and as an insecticide on potatoes (field use). 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.

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## 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. Rape seed oil is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), The Netherlands, and co-rapporteur Member State (co-RMS), Finland, received an application from Task Force Rape Seed Oil (TF-RSO), consisting of W. Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH, for the renewal of approval of the active substance rape seed oil. 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 rape seed oil 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 the European Food Safety Authority (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 rape seed oil according to the representative uses as an acaricide applied via foliar sprayer on pome fruit (field use), berry (field and greenhouse uses), ornamental (field and greenhouse use) and vegetable crops (field and greenhouse use), as proposed at the European Union (EU) level result in a sufficient acaricidal efficacy against the target spider mites. In addition, the use of rape seed oil according to the representative use as an insecticide applied via foliar sprayer to potato crops, as proposed at EU level result in a sufficient insecticidal efficacy against the target Colorado beetles.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to the section **identity, physical-chemical and technical properties** of the active substance and the representative formulation and **analytical methods**.

In the area of **mammalian toxicology**, no critical area of concern or issue that could not be finalised were identified.

In the **residues section**, an assessment was conducted for the representative uses and in parallel for authorised uses according to Article 12 of Regulation (EC) No 396/2005. No critical area of concern or issue that could not be finalised were identified. With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, two criteria were considered to be met for rape seed oil.

The data available on environmental fate and behaviour were sufficient to carry out the required **environmental exposure assessments** at EU level for the representative uses assessed.

Although no critical area of concern is concluded in the area of **ecotoxicology**, high risk was concluded for bees, non-target arthropods other than bees and soil macroorganisms other than earthworms for a number of the representative uses. Low risk was identified for birds and mammals, earthworms, non-target terrestrial plants, soil microorganisms for all the representative uses.

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 rape seed oil is unlikely to be an endocrine disruptor.

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## Background

Commission Implementing Regulation (EU) No 844/2012<sup>1</sup>, as amended by Commission Implementing Regulation (EU) No 2018/1659<sup>2</sup>, (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<sup>3</sup>. 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 The Netherlands and co-RMS Finland received an application from Task Force Rape Seed Oil (TF-RSO), consisting of W. Neudorff GmbH KG and Evergreen Garden Care Deutschland GmbH, for the renewal of approval of the active substance rape seed oil. In addition, the applicants submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005<sup>4</sup>. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Finland), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on rape seed oil in the RAR, which was received by EFSA on 24 March 2020 (The Netherlands, 2020). Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 30 September 2020 EFSA invited the Member States and United Kingdom<sup>5</sup> to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, TF-RSO, for consultation and comments on 7 September 2020. 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 3 December 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 telephone conference between EFSA, the RMS on 9 February 2021. On the basis of the comments received, the

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and with the established transition period, the EU requirements on data reporting also apply to the United Kingdom data collected until 31 December 2020.

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 expert consultation in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology.

The outcome of the telephone conference, 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 Article 12 MRL review of Regulation (EC) No 396/2005 took place with Member States via a written procedure in March 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative professional and non-professional uses of rape seed oil as an acaricide on fruit pome trees (field use), berries, vegetables, ornamentals (greenhouse and field use) and as an insecticide on potatoes (field use), 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. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 30 September 2020 EFSA invited the Member States and UK to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for rape seed oil 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, 2022), 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 (24 March 2021);
- the evaluation table (30 March 2022);
- 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 (The Netherlands, 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 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

Rape seed oil is a common name for this active substance,<sup>6</sup> there is no ISO common name. Rape seed oil is a mixture of triglycerides of fatty acids, it is obtained from the seeds of rape (*Brassica napus* and *Brassica rapa*) that contain less than 5% erucic acid.

<sup>6</sup> ECHA CLP database refers to this active substance as 'Fatty acids, rape-oil, erucic acid-low', see <https://echa.europa.eu/it/information-on-chemicals/cl-inventory-database/-/discli/details/87961>



The representative formulated product for the evaluation was 'NEU 1160 I' an emulsifiable concentrate (EC) containing 883 g/L of rape seed oil. The representative EU uses evaluated comprise of professional and non-professional spray applications as an acaricide on pome fruit (field use), berry, ornamental, and vegetable (greenhouse and field use) crops against spider mites, and professional and non-professional spray application as an insecticide on potatoes (field use) against Colorado beetles. Full details of the GAPs can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of rape seed oil according to the representative uses proposed at EU level results in a sufficient acaricidal and insecticidal activity for protection against spider mites and Colorado beetles, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

## 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,b,2010)

The purity of rape seed oil was based on batches from industrial scale production and was in accordance with the values stated for German Pharmaceutical Authorities Codex (Bundesvereinigung Deutscher Apothekerverbände - ABDA, 1994) and European Pharmacopoeia (Ph. Eur. 5, 2005) (Council of Europe, 2005). Based on the renewal batch data all current specifications are kept, in line with the German Pharmaceutical Authorities Codex (Bundesvereinigung Deutscher Apothekerverbände - ABDA, 1994) and European Pharmacopoeia (Ph. Eur. 5, 2005) (Council of Europe, 2005), except that no relevant impurities are specified, the current specified value of a physicochemical characteristic was updated to a lower value, and a range was proposed for the physicochemical characteristics for which no specified value was included in the current reference specification. Thus, it is suggested to update the reference specification to the specification proposed by the RMS. The batches used in the ecotoxicological assessment do not fully support the original reference and the newly proposed reference specification (see Section 5). As regards mammalian toxicology the specification is supported from the toxicological point of view.

The main data regarding the identity of rape seed oil and its physical and chemical properties are given in Appendix B.

Adequate methods are available for the generation of pre-approval data required for the risk assessment, except for a validated analytical method for the determination of the rate of chemical degradation of rape seed oil in aerobic soil systems (**data gap**, see Section 10). Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulation. Methods for the analysis of residues in food and feed of plant origin, animal products, in body fluids and body tissues and environmental compartments are not required as residue definitions were not set.

### 2. Mammalian toxicity

The toxicological profile of the active substance rape seed oil was discussed at the Pesticides Peer Review Experts' Teleconference (TC) 64 and assessed based on the following guidance documents (European Commission, 2003,2012; EFSA, 2014; EFSA PPR Panel, 2012; EFSA Scientific Committee, 2019; ECHA, 2017).

The specification of rape seed oil technical material is in accordance with the European Pharmacopoeia (see Section 1). This specification does not contain relevant impurities and is acceptable from the toxicological point of view. The limited data package provided indicated that rape seed oil is of low acute oral, dermal and inhalation toxicity and not irritant to eyes and skin, or a skin sensitiser. The genotoxic potential of rape seed oil was discussed at the Pesticides Peer Review Experts' TC 64 in November 2021: the experts agreed with the RMS that the available information does not raise concerns for genotoxicity.<sup>7</sup>

Based on (i) the observed low toxicity profile of rape seed oil to mammals in the available toxicity data package, (ii) the use of rape seed oil as a food additive (EFSA FAF Panel, 2019), and (iii) that

<sup>7</sup> See experts' consultation point 2.1 in the evaluation table, Column E 'EFSA conclusion'.

adverse effects were not observed in studies from open literature, all other toxicological studies were waived; the setting of reference values was considered not necessary, and a non-dietary risk assessment is not needed. This conclusion is in line with the previous EFSA conclusion on this active substance (EFSA, 2013b).

### 3. Residues

For residues, specific studies or data were not submitted and are not requested. The scientific argumentation was supported with articles from public literature and calculations.

The representative uses of rape seed oil on pome trees, berry bushes, vegetables and potato applied via spraying from very early growth stage until harvest is unlikely to lead to residues in food other than the active substance itself or its degradation products such as fatty acids which cannot be distinguished from endogenous plant compounds. The potential formation of products of photo-oxidation and other degradation processes which might happen under the proposed conditions of use on pome fruits, berries and vegetables with application from early growth stage (BBCH 10) to harvest was not investigated. For details see Evaluation Table Section 3, Residues.

As rape seed oil is used as a food item, a conventional **consumer dietary risk assessment** is not considered necessary. It is noted that no information was provided whether the active substance rape seed oil is of food grade quality. For the assessed specification of the technical material, the setting of reference values for rape seed oil as such was not considered necessary (see section 2).

However, erucic acid is a natural constituent of rape seed oil and legally permitted up to a maximum level of 20.0 g/kg (European Commission, 2019). Considering the representative uses and the uses proposed in the context of Article 12 MRL review the level of erucic acid from the use of rape seed oil would not lead to an exceedance of the Tolerable Daily Intake (TDI) for consumers established by EFSA (EFSA CONTAM Panel, 2016). For details see Evaluation Table Section 3, Residues.

The authorised uses from the European Member States were collected by EFSA in the context of Article 12 of Regulation (EC) No 396/2005.

A multitude of uses covering a wide range of crops (pome and stone fruits, berries and small fruit, root and tuber, bulb, fruiting, brassica and leaf vegetables and spices) were reported. The application is foreseen as foliar treatment (broadcast spraying) from very early growth stage until harvest at maximal seasonal rates which do not exceed those from the representative uses. Also from the Article 12 uses, relevant residues are unlikely to occur.

With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion I), listed in Annex I of Regulation (EC) No 396/2005 (criterion II), having no identified hazardous properties (criterion III), natural exposure is higher than the one linked to the use as a plant protection product (criterion IV) and consumer exposure is not expected considering the representative uses (criterion V), two criteria were considered to be met for rape seed oil for the following reasons:

Toxicological reference values are not required for rape seed oil (criterion III) (see Section 2). The exposure from uses as food item and food ingredient is expected to be higher than the one linked to the uses as plant protection product (criterion IV). The other three criteria (criteria I, II and V) are not fulfilled.

### 4. Environmental fate and behaviour

Rape seed oil was discussed at the Pesticides Peer Review Experts' TC 65 in November 2021.

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, rape seed oil exhibited low persistence. It should be noted that a data gap was set for a validated analytical method for the determination of the rate of chemical degradation of rape seed oil in aerobic soil systems (see Section 1). However, the study was considered acceptable to derive degradation endpoints for rape seed oil, as considering the uncertainties of the method the  $DT_{50}$  could had been shorter. The initial degradation of triglycerides of rape seed oil is expected to result mainly in the free fatty acids such as oleic acid, linoleic acid and linolenic acid. In soil, and under aerobic conditions, the fatty acids that compose rape seed oil are expected to be degraded by microorganisms by beta-oxidation, hydrolysis and hydroxylation. Oleic acid (C18) was selected as representative fatty acid since it is the predominant fatty acid (ca. 55–60%) of rape seed oil. Information was provided



demonstrating that free fatty acids will be degraded by beta-oxidation producing long- and short-chain free fatty acids from chain length of C24 to C5 (mainly carbon chains with even numbers). Soil incubations of potassium salts of free fatty acids demonstrated that these exhibit low persistence. QSAR  $K_{oc}$  values were calculated for rape seed oil and its metabolites based on experimental Log Pow values. Rape seed oil and oleic acid (used as a representative compound for the metabolite fatty acids) exhibited immobility. It was concluded that the adsorption of rape seed oil and its metabolites was not pH dependent. The fast rate of degradation of rape seed oil and its soil metabolites estimated from laboratory degradation studies did not trigger the request for field dissipation studies.

No water/sediment study with rape seed oil was available; however based on the classification of this active substance as being readily biodegradable, the default value half-life for biodegradation in surface water was used. Rapid biological degradation of rape seed oil in aquatic systems was confirmed by new submitted studies concerning the aerobic mineralisation in surface water. No readily biodegradable test was available for oleic acid, the model fatty acid of rape seed oil. However, considering that pelargonic acid (C9) is biodegradable, then the use of the default half-life for biodegradation in surface water was considered appropriate also for the metabolites of rape seed oil. The necessary surface water and sediment exposure assessments (predicted environmental concentration (PEC) calculations) were carried out for rape seed oil using FOCUS (2001) steps 1 and 2 (version 3.2 of the steps 1–2 in FOCUS calculator). Considering this particular substance with a high  $K_{oc}$  and applied together with an emulsifier, Step 3 (and further) calculations were deemed not appropriate because of the instantaneous partitioning to the sediment considered in TOXSWA. Step 2 calculations, with a drift-only scenario, do not consider instantaneous partitioning to the sediment, and therefore were considered appropriate (see point 4.2 of the Pesticide Peer Review meeting report TC 65; EFSA, 2022). Therefore, it was agreed to consider mitigation measures based on no spray buffer zones at Step 2.

For the representative protected use, the necessary surface water and sediment exposure assessments (PEC) were appropriately carried out considering the maximum instantaneous PEC surface water value calculated immediately after the last application, which was then modified by post processing the spray drift input results (no runoff or drainage considered) to obtain a 0.5% emission of rape seed oil from greenhouses being re-deposited on adjacent surface water bodies, which is a conservative factor compared to the 0.1% emission of greenhouses normally used. This approach was agreed by Member State experts (see point 4.2 of the Pesticide Peer Review meeting report TC 65; EFSA, 2022).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3. The potential for groundwater exposure from the representative uses by rape seed oil above the parametric drinking water limit of 0.1  $\mu\text{g/L}$  was concluded to be low in geoclimatic situations that are represented by all the relevant FOCUS groundwater scenarios. No  $\text{PEC}_{\text{gw}}$  calculations were provided for Châteaudun scenario using the model FOCUS MACRO (**data gap**, see Section 10).

The applicant provided information to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed 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.

## 5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009, 2013c) and EFSA PPR Panel (2013).

No information was available to confirm whether the batches used in the ecotoxicological toxicity studies are compliant with the technical specification of the active substance (**data gap**; see Section 10).

Several aspects pertaining to the risk assessment for rape seed oil were discussed at the Pesticide Peer Review Experts' TC 67 (November 2021).

The uses of rapeseed oil in berry bushes, vegetables and (woody) ornamentals include uses in professional and non-professional greenhouses. For the non-professional uses, greenhouses were considered 'semi-protected' and consequently exposure of non-target organisms could not be excluded. For the professional uses in greenhouses, the applicant clarified that these are to permanent structures. For such uses, limited exposure to rape seed oil was considered for all groups of terrestrial organisms.

No toxicity studies were available for **birds**; therefore, no quantitative risk assessments were performed. Considering other available information, such as (i) the fact that fatty acids (degradation products of triglycerides) are routinely used in feed commodities, (ii) that the mode of action to target organisms (i.e. spider mites or the Colorado potato beetles) is mechanical rather than chemical, and (iii) the low acute toxicity endpoint for mammals (see Section 2), it was concluded that the acute and long-term risk to birds from the representative uses of rape seed oil is low. No quantitative risk assessments were performed for wild **mammals** either. However, on the basis of the same argumentations as for birds, low risk was concluded for non-target terrestrial vertebrates other than birds. Considering the biodegradability and low toxicity of rape seed oil, low risk from secondary poisoning was also concluded for both birds and mammals.

To address the risk for **aquatic organisms**, valid acute and chronic studies for fish (*Oncorhynchus mykiss* (acute) and *Danio rerio* (chronic)), for aquatic invertebrates (*Daphnia magna*) and for algae (*Desmodesmus subspicatus*) were available with the representative formulation NEU 1160 I. In addition, an acute study with the aquatic invertebrate *Chironomus riparius* was submitted with a formulation comparable to the representative one. No reliable endpoints could be derived from studies with the active substance since analytical determination was not possible. However, the experts at the Pesticide Peer Review Experts' TC 67 concluded that, considering the low solubility of rape seed oil in water, data requirements were sufficiently addressed with the available data on NEU 1160 I.

The risk to aquatic organisms was assessed using PEC<sub>SW</sub> values based on FOCUS Step 1 and 2 [drift-only (no drainage, no run-off)] with mitigation measures (see Section 4). Low acute and chronic risk was indicated for all representative uses of rape seed oil. Except for the uses on woody ornamentals, low risk was only reached when considering mitigation measures based on crop free buffer zones (between 1 and 30 m depending on the representative use) (Table 1). The risk assessment to sediment-dwelling organisms was not triggered.

The available aquatic risk assessment may need further adaptations at Member State (MS) level when considering formulations others than emulsions.

**Table 1:** Outcome of the quantitative risk assessment for aquatic organisms for the representative uses of rape seed oil

Use		Fish		Aquatic invertebrates		Algae
		Acute	Chronic	Acute	Chronic	
Pome fruit	Early application	Low – Step 2 (5 m)	Low – Step 2 (5 m)	Low – Step 2 (10 m)	Low – Step 2 ( <b>30 m</b> )	Low – Step 2 (3 m)
	Late application	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 (5 m)	Low – Step 2 ( <b>20 m</b> )	Low – Step 2 (3 m)
Berry bushes	Early application	Low – Step 1	Low – Step 1	Low – Step 2 (3 m)	Low – Step 2 ( <b>5 m</b> )	Low – Step 1
	Late application	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 ( <b>10 m</b> )	Low – Step 1
Ornamentals	Early application	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 ( <b>5 m</b> )	Low – Step 1
	Late application	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 (3 m)	Low – Step 2 ( <b>10 m</b> )	Low – Step 2 (3 m)
Woody ornamentals		Low	Low	Low	Low	Low
Vegetables		Low – Step 1	Low – Step 1	Low – Step 1	Low – Step 2 ( <b>3 m</b> )	Low – Step 1
Potatoes		Low – Step 1	Low – Step 1	Low – Step 1	Low – Step 2 ( <b>1 m</b> )	Low – Step 1

Values presented in brackets indicate the no-spray buffer zone needed to reach a low risk. For each representative use, the no-spray buffer zone needed to reach a low risk is indicated in bold. For a particular representative use and aquatic taxa, light green indicates low risk without the need of implementing mitigation measures and dark green indicates that low risk can be reached only when applying mitigation measures.

Acute (oral and contact) data on **honeybees** were available for rape seed oil. For honey bee larvae and adults, chronic studies were conducted with the representative formulation.<sup>8</sup> It must be noted that

<sup>8</sup> See Experts' consultation point 5.2 at Pesticide Peer Review Experts' TC 67 (November 2021).

the *in vitro* larval test with repeated exposure ended at day 8 and, therefore, did not cover the full life-cycle (**data gap**, see Section 10).

The acute (oral and contact) risk assessment following the SANCO Guidance on Terrestrial ecotoxicology (European Commission, 2002a) indicated a low risk for all representative uses, except for the uses in woody ornamentals in non-permanent greenhouses for which a high risk via contact exposure was concluded (Table 2). The quantitative risk assessment according to EFSA (2013c) for the different exposure routes is also summarised in Table 2.

**Table 2:** Outcome of the quantitative risk assessment for honey bees for the representative field and non-professional uses in greenhouses of rape seed oil following the SANCO Guidance on Terrestrial ecotoxicology or the EFSA bee guidance

Use	Route of exposure (Scenario)						
	Contact		Oral				Contaminated water
			Acute		Chronic		
	SANCO	EFSA	SANCO	EFSA	Larvae <sup>(a)</sup>	Adult	
EFSA							
Pome fruit	Low	Low	Low	Low	High (T, W)	High (T, W)	Low
Berry bushes	Low	Low	Low	Low	High (T)	High (T)	Low
Ornamentals	Low	Low	Low	Low	High (T,W)	High (T, W)	Low
Woody ornamentals	High	High (T)	Low	High (T)	High (T, W)	High (T, W)	Low
Vegetables	Low	Low	Low	Low	High (T, W)	High (T)	Low
Potatoes	Low	Low	Low	Low	Low	Low	Low

T: 'Treated crop' scenario; W: 'Flowering weeds in the treated field' scenario.

For the professional uses in permanent greenhouses in berry bushes, vegetables and (woody ornamentals), a low risk to rape seed oil was concluded on the basis of limited exposure. For a particular representative use and route of exposure, green color indicates "low risk" and red color indicates "high risk".

(a): **Indicative** risk assessment conducted with an endpoint derived from a 8-day larval study. A data gap has been set to provide a 22-day larval study according to OECD TG 239.

High risk from acute oral and contact exposure for the uses in woody ornamentals in non-permanent greenhouses was concluded at Tier-1. High risk to honey bee larvae and adults was indicated for all field and non-professional uses, except for the uses on potatoes.<sup>9</sup> For the representative uses in permanent greenhouses, low risk was concluded based on limited exposure.

The chronic risk to larvae was discussed at the Peer Review experts' TC 67 using a weight-of-evidence approach with the following lines of evidence: (i) a semi-field (tunnel) study on *Phacelia tanacetifolia* with the formulation NEU 1128 I showing no effects on colony strength; (ii) the expected low oral toxicity given the mechanical mode of action of rape seed oil; and (iii) the expected low levels of exposure for bee brood in the hive.<sup>8</sup> However, EFSA disagreed with the outcome of the experts' consultation and considered that there is not enough evidence to refine risk as the semi-field study did not evaluate relevant parameters such as brood termination rate, brood index and compensation index. In addition, the rates applied in the semi-field study only covers the uses in potatoes (for which low risk was indicated at Tier 1) and berry bushes. On this basis, low chronic risk to bees could only be concluded for the uses in potatoes and the professional uses in berry brushes, vegetables and (woody) ornamentals in permanent greenhouses (see Table 2).

Low risk due to exposure to contaminated water was concluded for all uses. A suitable assessment for accumulative and sublethal effects (e.g. hypopharyngeal glands) was not available (**data gap**, see Section 10). Finally, toxicity data were not available for bumblebees and solitary bees.

For **non-target arthropods other than bees**, the representative formulation was tested in extended laboratory studies with the standard species, *Aphidius rhopalosiphi* and *Typhlodromus pyri*, as well as with the green lacewing *Chrysoperla carnea* and the ladybird *Coccinella septempunctata*. In addition, an aged-residue test was available with *T. pyri*, which was considered the most sensitive species. Based on all available data and higher tier risk assessment, a low in-field risk was indicated for

<sup>9</sup> The risk assessment to larvae was conducted with an endpoint derived from a 8-day larval study and should be considered indicative. A data gap has been set to provide a 22-day larval study according to OECD TG 239.

all representative uses of rape seed oil except for those in pome fruit (professional and non-professional uses) and woody ornamentals (non-professional uses) for which a high risk was concluded since the concentration tested in the aged-residue study was lower than the expected in-field rate. High off-field risk was concluded for all field and non-professional uses in greenhouses. For the professional uses of rape seed oil in permanent greenhouses, a low in- and off-field risk could be concluded on the basis of limited exposure.

Chronic toxicity studies were available for **earthworms** with the representative formulation and a formulation comparable to NEU 1160 I to conclude a low risk for all representative uses. For other **soil macroorganisms** (i.e. the collembolan *Folsomia candida* and the predatory mite *Hypoaspis aculeifer*), low risk was only indicated for the uses in berry bushes and potatoes based on the available data with a formulation containing rape seed oil as the only active substance and tier 1 risk assessment. The risk was further refined for *F. candida* by lowering the correction factor of 2 for soil organic matter to 1 after pondering the uncertainty around the correction factor as the toxicity study was conducted using 5% organic matter and the lack of lethal and sub-lethal effects observed at any of the concentrations tested in the chronic study.<sup>10</sup> Low risk was then concluded for all uses except for the non-professional uses in woody ornamentals for which high risk was still indicated. For the professional uses of rape seed oil in permanent greenhouses, low risk was concluded considering the limited exposure.

A low risk to **soil microorganisms** and **non-target terrestrial plants** was concluded for all representative uses of rape seed oil.

No data or assessments for biological methods for **sewage treatments** were available. For the field uses it was considered that the exposure of organisms involved in biological methods for sewage treatment was negligible, and therefore, low risk was concluded for such uses. A **data gap** was identified for the representative greenhouse uses (see Section 10).

## 6. Endocrine disruption properties

The endocrine-disrupting properties of rape seed oil were discussed at the Peer Review meeting TC 64.

With regard to the assessment of the endocrine disruption potential of rape seed oil for **humans** and **non-target organisms** in line with the ECHA/EFSA guidance (ECHA and EFSA, 2018), no (eco)toxicological data were available to assess the endocrine disrupting properties. However, this does not appear scientifically necessary since.

- i) the active substance occurs naturally in the environment;
- ii) it shows a low toxicity profile in the available (eco)toxicology data package which supports the waiver for studies of general toxicity;
- iii) the use of rape seed oil as a food additive (EFSA ANS Panel, 2017);
- iv) no adverse effects were observed in studies from the open literature.

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 rape seed oil is unlikely to be an endocrine disruptor.

## 7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 3–6)

**Table 3:** Soil

Compound (name and/or code)	Ecotoxicology
<b>Triolein</b> (representative compound for rape seed oil)	Low risk to earthworms
<b>Oleic acid</b> (representative compound for fatty acids)	High risk to soil macroorganisms other than earthworms <sup>(a)</sup>

(a): High risk was concluded only for the non-professional uses in woody ornamentals.

<sup>10</sup> At the meeting, the experts considered that the semi-field study was acceptable for this particular case in a weight of evidence approach. See Experts' consultation point 5.4 at Pesticide Peer Review Experts' TC 67 (November 2021) for further details.

**Table 4:** Groundwater<sup>(a)</sup>

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative uses <sup>(b)</sup> Step 2	Biological (pesticidal) activity/relevance Step 3a.	Hazard identified Steps 3b. and 3c.	Consumer RA triggered Steps 4 and 5	Human health relevance
<b>Triolein</b> (representative compound for rape seed oil)	No	Not triggered	Not triggered	Not triggered	Not triggered
<b>Oleic acid</b> (representative compound for fatty acids)	No	Not triggered	Not triggered	Not triggered	Not triggered

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).

(b): FOCUS scenarios or a relevant lysimeter.

**Table 5:** Surface water and sediment

Compound (name and/or code)	Ecotoxicology
<b>Triolein</b> (representative compound for rape seed oil)	Low risk to aquatic organisms <sup>(a)</sup>
<b>Oleic acid</b> (representative compound for fatty acids)	

(a): Except for the professional uses in permanent greenhouses, a low risk was indicated provided that mitigation measures (no spray buffer zone) are implemented.

**Table 6:** Air

Compound (name and/or code)	Toxicology
<b>Triolein</b> (representative compound for rape seed oil)	Rat, Acute inhalation LC <sub>50</sub> , 4 h > 2.36 mg/L (for 90% rape seed oil, 2% pyrethrum)
<b>Oleic acid</b> (representative compound for fatty acids)	Rat, Acute inhalation LC <sub>50</sub> , 4 h > 2.36 mg/L (for 90% rape seed oil, 2% pyrethrum)

LC: lethal concentration, 50%.

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

Risk mitigation measures (RMMs) identified following consideration of 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 7:** Risk mitigation measures (RMM) proposed for the representative uses assessed

Use	Pome fruit	Berry bushes	Vegetables	Ornamentals	Woody ornamentals	Potatoes
<b>Risk to aquatic organisms</b>	RMM equivalent to 30 m (early applications) and 20 m (late applications) no-spray buffer zone	RMM equivalent to 5 m (early applications) and 10 m (late applications) no-spray buffer zone	RMM equivalent to 3 m no-spray buffer zone	RMM equivalent to 5 m (early applications) and 10 m (late applications) no-spray buffer zone		RMM equivalent to 1 m no-spray buffer zone

## 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, even 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<sup>11</sup> 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 the active substance 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:**

Issues or assessments that could not be finalised were not identified.

### 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 were not identified.

<sup>11</sup> 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.



### 9.3. Overview of the concerns identified for each representative use considered (Table 8)

(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 8.)

**Table 8:** 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

Representative use		Pome fruit	Berry bushes		Vegetables		Ornamentals		Woody ornamentals	Potatoes
		Field use	Field use	Green house	ield use	Green house	Field use	Green house	Green house	Field use
<b>Operator risk</b>	Risk identified									
	Assessment not finalised									
<b>Worker risk</b>	Risk identified									
	Assessment not finalised									
<b>Resident/ bystander risk</b>	Risk identified									
	Assessment not finalised									
<b>Consumer risk</b>	Risk identified									
	Assessment not finalised									
<b>Risk to wild non-target terrestrial vertebrates</b>	Risk identified									
	Assessment not finalised									
<b>Risk to wild non-target terrestrial organisms other than vertebrates</b>	Risk identified	X <sup>(a),(c)</sup>	X <sup>(a),(d)</sup>	X <sup>(a),(d)</sup>	X <sup>(a),(d)</sup>	X <sup>(a),(d)</sup>	X <sup>(a),(d)</sup>	X <sup>(a),(d)</sup>	X <sup>(b),(c),(e)</sup>	
	Assessment not finalised									
<b>Risk to aquatic organisms</b>	Risk identified									
	Assessment not finalised									
<b>Groundwater exposure to active substance</b>	Legal parametric value breached									
	Assessment not finalised									
<b>Groundwater exposure to metabolites</b>	Legal parametric value breached <sup>(f)</sup>									
	Parametric value of 10 µg/L <sup>(g)</sup> breached									
	Assessment not finalised									

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–7 for further information.

- (a): For bees, high risk for the field and non-professional uses in non-permanent greenhouses was only indicated according to EFSA (2013c), i.e. low risk was concluded according to European Commission (2002a). For the representative professional uses in permanent greenhouses, low risk was concluded based on limited exposure.
- (b): For the non-professional uses in woody ornamentals in non-permanent greenhouses a high risk to honeybees via contact exposure was concluded according to both EFSA (2013c) and European Commission (2002a). High risk from acute oral and high chronic risk was also concluded according to EFSA (2013c). For the representative professional uses in permanent greenhouses, low risk was concluded based on limited exposure.
- (c): For non-target arthropods other than bees, high in-field risk was concluded for pome fruit and woody ornamentals (non-professional uses in non-permanent greenhouses).
- (d): For non-target arthropods other than bees, high off-field risk was concluded for all field and non-professional uses in non-permanent greenhouses.
- (e): For soil macroorganisms other than earthworms, high risk was concluded for woody ornamentals (non-professional uses in non-permanent greenhouses).
- (f): 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.
- (g): 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 only to the representative uses assessed and are listed in the order of the sections**

- A validated analytical method for the determination of the rate of chemical degradation of rape seed oil in aerobic soil systems (relevant for all representative uses evaluated; see Section 1).
- A detailed summary and evaluation of the acute dermal report with the formulation NEU 1160 I (relevant for the representative uses evaluated; see Evaluation Table Section 2) EFSA, 2022.
- A detailed summary and evaluation of the 1990 study related to the aerobic rate of degradation (relevant for the representative uses evaluated; see Evaluation Table Section 4: EFSA, 2022).
- PEC<sub>gw</sub> calculations for Châteaudun scenario using the model FOCUS MACRO were not available (relevant for the representative uses evaluated; see Section 4).
- Information to address the compliance of the batches used in the ecotoxicology studies with the technical specification (relevant for the representative uses evaluated; see Section 5).
- Specific toxicity study with honey bee larvae following the OECD Testing Guideline 239 is considered necessary (relevant for all uses except professional uses in permanent greenhouses; see Section 5).
- Further data to address the risk to honeybees from sublethal effects, e.g. effects on hypopharyngeal glands (relevant for all uses except professional uses in permanent greenhouses; see Section 5).
- An assessment of the potential effects on biological methods for sewage treatment (relevant for the representative greenhouse uses; see Section 5).

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## Abbreviations

AMA	Amphibian Metamorphosis Assay
BBCH	Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie
DT <sub>50</sub>	period required for 50% dissipation (define method of estimation)
DT <sub>90</sub>	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
EEC	European Economic Community
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
InChiKey	International Chemical Identifier Key
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K <sub>doc</sub>	organic carbon linear adsorption coefficient
K <sub>Foc</sub>	Freundlich organic carbon adsorption coefficient
LC <sub>50</sub>	lethal concentration, median
MRL	maximum residue level
MS	Member State
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in groundwater
PEC <sub>sed</sub>	predicted environmental concentration in sediment

PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
RAR	Renewal Assessment Report
RMM	risk mitigation measure
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TDI	Tolerable Daily Intake
WHO	World Health Organization

## Appendix A – Consideration of cut-off criteria for rape seed oil according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion <sup>(a)</sup>
CMR	<b>Carcinogenicity (C)</b>	Rape seed oil is not considered to be mutagenic, carcinogenic, 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, respectively.
	<b>Mutagenicity (M)</b>	
	<b>Toxic for Reproduction (R)</b>	
Endocrine disrupting properties		Rape seed oil is 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	<b>Persistence</b>	Rape seed oil is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	<b>Bioaccumulation</b>	
	<b>Long-range transport</b>	
PBT	<b>Persistence</b>	Rape seed oil is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
	<b>Bioaccumulation</b>	
	<b>Toxicity</b>	
vPvB	<b>Persistence</b>	Rape seed oil is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.
	<b>Bioaccumulation</b>	

(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.2022.7305>

## Appendix C – Wording EFSA used in Section 4 of this conclusion, in relation to DT and K<sub>oc</sub> 'classes' exhibited by each compound assessed

Wording	DT <sub>50</sub> normalised to 20°C for laboratory incubations <sup>12</sup> or not normalised DT <sub>50</sub> for field studies (SFO equivalent, when biphasic, the DT <sub>90</sub> was divided by 3.32 to estimate the DT50 when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1–<10 days
Moderate persistence	10–<60 days
Medium persistence	60–<100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

DT<sub>50</sub>: period required for 50% dissipation; DT<sub>90</sub>: period required for 90% dissipation.

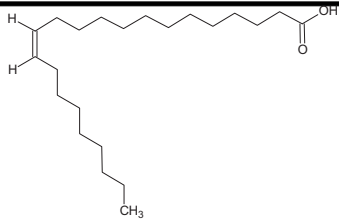
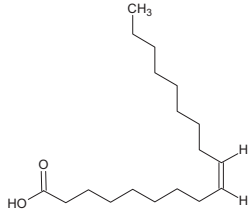
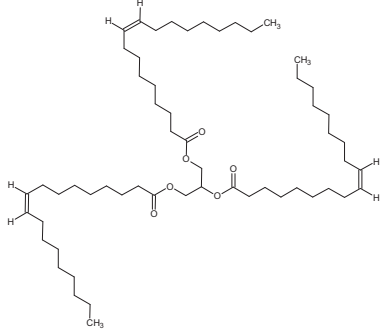
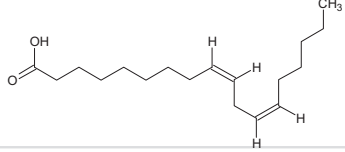
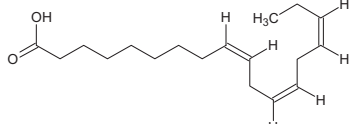
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

Wording	K <sub>oc</sub> (either K <sub>Foc</sub> or K <sub>doc</sub> ) 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

Based on McCall et al. (1980).

<sup>12</sup> For laboratory soil incubations normalisation was also to field capacity soil moisture (pF2/10kPa). For laboratory sediment water system incubations, the whole system DT values were used.

## Appendix D – Used compound codes

Code/trivial name <sup>(a)</sup>	IUPAC name/SMILES notation/InChiKey <sup>(b)</sup>	Structural formula <sup>(c)</sup>
<b>Erucic acid</b>	(13Z)-docos-13-enoic acid <chem>O=C(O)CCCCCCCCC/C=C\CCCCCCCC</chem> DPUOLQHNDNGRHBS-KTKRTIGZSA-N	
<b>Oleic acid</b>	(9Z)-octadec-9-enoic acid <chem>O=C(O)CCCCC/C=C\CCCCCCC</chem> ZQPPMHVWECSIRJ-KTKRTIGZSA-N	
<b>Triolein</b>	propane-1,2,3-triyl (9Z,9'Z,9''Z)tri-octadec-9-enoate <chem>O=C(CCCCCC/C=C\CCCCCCC)OC(COC(=O)CCCCC/C=C\CCCCCCC)COC(=O)CCCCC/C=C\CCCCCCC</chem> PHYFQTYBJUILEZ-IUPFWZBJSAN	
<b>Linoleic acid</b>	(9Z,12Z)-octadeca-9,12-dienoic acid <chem>O=C(O)CCCCC/C=C\C/C=C\CCCC</chem> OYHQLOLUKZRVURQ-HZJYTTRNSA-N	
<b>Linolenic acid</b>	(9Z,12Z,15Z)-octadeca-9,12,15-trienoic acid <chem>O=C(O)CCCCC/C=C\C/C=C\C/C=C\CC</chem> DTOSIQBPPRVQHS-PDBXOOCHSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2021.1.3 ACD/Labs 2021 Release (File version N15E41, Build 123232, 7 July 2021).

(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021 Release (File version C25H41, Build 123835, 28 August 2021).