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CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance fatty acids from hydrolysed vegetable oils

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts.

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, Greece, and co-rapporteur Member State, Austria, for the pesticide active substance fatty acids from hydrolysed vegetable oils 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 uses of the active substance as an acaricide and insecticide on strawberry, tomato, cucumber, pome fruits and stone fruit, fruiting vegetables, pulses, ornamentals (annual and perennial), brassica vegetable, leafy and stem vegetable, root and tuber vegetable, bulb vegetable and berry fruit. 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

acaricide, fatty acids from hydrolysed vegetable oils, fatty acids potassium salts, insecticide, peer review, pesticide, risk assessment

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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. Fatty acids from hydrolysed vegetable oils[1] are 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), Greece, and co-rapporteur Member State (co-RMS), Austria, received an application from De Sangosse[2] and W. Neudorff GmbH KG for the renewal of approval of the active substance fatty acids from hydrolysed vegetable oils.

An initial evaluation of the dossier on fatty acids from hydrolysed vegetable oils 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 representative uses of fatty acids from hydrolysed vegetable oils as an acaricide and insecticide on strawberry, tomato, cucumber, pome fruits and stone fruit, fruiting vegetables and pulses, ornamentals (annual and perennial), Brassica vegetable (leafy and stem vegetable, root and tuber vegetable), bulb vegetable and berry fruit as proposed at EU level result in a sufficient efficacy against the target pests.

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 **identity, physical–chemical and technical properties** of the active substance and the formulation for representative uses and **analytical methods**.

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

No critical area of concerns or data gaps were identified in the **residue** section. A quantitative consumer risk assessment was provided but is deemed not necessary since health-based guidance values were not needed for fatty acids from hydrolysed vegetable oils. Fatty acids from hydrolysed vegetable oils meet criteria 3 and 4 of five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2.

The **environmental exposure assessment** for fatty acids from hydrolysed vegetable oils (C14-C24) was conducted using the end points of oleic acid (C18:1) as lead compound.

In the field of **ecotoxicology**, a high chronic risk to bees was identified for all representative uses and a high chronic risk to soil organisms was concluded for the representative uses in ornamentals. In addition, the risk assessment for aquatic organisms (invertebrates) could not be finalised for some representative uses.

Fatty acids from hydrolysed vegetable oils do not meet the criteria for **endocrine disruption** for humans and non-target organisms 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.

[1]Active substance formerly named as '*Fatty acids C7-C18 and C18 unsaturated potassium salts*'.

[2]Original applicant was Alpha Biopesticides and as of 5th January 2026 De Sangosse.

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012,[3] as amended by Commission Implementing Regulation (EU) No 2018/1659[4] (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.[5] This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicants 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 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 a minimum of 3 months, not exceeding 30 months, depending on the type of information requested.

In accordance with Article 1 of the Regulation, the RMS, Greece, and co-RMS, Austria, received an application from De Sangosse and W. Neudorff GmbH KG for the renewal of approval of the active substance fatty acids from hydrolysed vegetable oils. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicants, the co-RMS (Austria), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on fatty acids from hydrolysed vegetable oils, in the RAR, which was received by EFSA on 14 July 2021 (Greece, 2022).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, De Sangosse and W. Neudorff GmbH KG, for consultation and comments on 31 March 2023. 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 30 May 2023. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' responses 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 teleconference between EFSA, the RMS and the European Commission on 6 September 2023. 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 expert consultation in the areas of identity, physical/chemical/technical properties and methods of analysis, mammalian toxicology, environmental fate and behaviour and ecotoxicology.

The outcome of the teleconference, 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 took place with Member States via a written procedure in September 2026.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulations for representative uses, evaluated on the basis of the representative uses of fatty acids from hydrolysed vegetable oils as an acaricide and insecticide on strawberry, tomato, cucumber, pome fruits and stone fruit, fruiting vegetables & pulses, ornamentals (annual and perennial), Brassica vegetable (leafy and stem vegetable, root and tuber vegetable), bulb vegetable and berry fruit, 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.

A list of the relevant end points for the active substance and the formulations is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for fatty acids from hydrolysed vegetable oils 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, 2026), 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

[3]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.

[4]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.

[5]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.

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 (9 October 2023);
- the evaluation table (28 September 2026);
- 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 (Greece, 2026), 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 FORMULATIONS FOR REPRESENTATIVE USES

The identity and name of the active substance was discussed in the Pesticide Peer Review Experts' Teleconference (TC) 140 (June, 2024).[6] This active substance was previously approved as '*Fatty acids C7-C18 and C18 unsaturated potassium salts*'; however, the experts agreed that the active substance is the fatty acids mixture and not their potassium salts, as the formation of the potassium salts is part of the formulation process. Experts also agreed that the non-ISO name '*Fatty acids from hydrolysed vegetable oils*' should be used for this active substance in combination with the specific names: *'Fatty acids from hydrolysed olive oil'* and '*Fatty acids from hydrolysed rapeseed oil'*. '*Fatty acids from hydrolysed olive oil'* is a mixture of 13 fatty acids[7] and '*Fatty acids from hydrolysed rapeseed oil'* of 17.[8]

The formulations for the representative uses were 'ABP 617' and 'NEU 1128 I'.

'ABP 617' is an emulsion, oil in water (EW) formulation containing potassium salts of 'Fatty acids from hydrolysed olive oil'. The applicant declared a pure salt content of 479.8 g/L based on the potassium salts of only five fatty acids. However, as the 'Fatty acids from hydrolysed olive oil' contain additional fatty acids a **data gap** was set for the content of 'Fatty acids from hydrolysed olive oil' (pure and technical) and the equivalent potassium salts in the formulation considering all the fatty acids included in the active substance (see Section 10).

'NEU 1128 I' is a soluble concentrate (SL) formulation containing potassium salts of 'Fatty acids from hydrolysed rapeseed oil'. The applicant declared a pure content of 463.5 g/L based on the potassium salts of only five fatty acids. However, as the 'Fatty acids from hydrolysed rapeseed oil' contains additional fatty acids a **data gap** was set for the content of 'Fatty acids from hydrolysed rapeseed oil' (pure and technical) and the equivalent potassium salts in the formulation considering all the fatty acids included in the active substance (see Section 10).

The information on the active substance and the formulations for representative uses, including the co-formulants in these formulations, was considered in the overall assessment during the peer review. None of the co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009;[9] however, a co-formulant in 'NEU 1128 I' is a currently approved active substance under Regulation (EC) 1107/2009.[10] However, as it is approved for a different function, is not expected to contribute to the efficacy of the product as an insecticide, acaricide.[11] Details on the composition of the formulations cannot be reported in conclusions because of the provisions in Article 63(2)(d) of Regulation (EC) No 1107/2009; however, this information was fully available and evaluated during the peer review. A proposal for classification of the formulations according to Regulation (EC) 1272/2008 was provided by the applicant and assessed by the RMS (please see Volumes 3 CP of the RAR).

The representative uses evaluated for 'ABP 617' comprise professional field spray applications as an insecticide and acaricide on field tomato and on strawberry, tomato and cucumber grown in greenhouses and non-permanent protected structures.

The representative uses evaluated for 'NEU 1128 I' comprise professional and non-professional field spray applications as an insecticide and acaricide on strawberry, fruiting vegetable and pulses, ornamentals, vegetable and berry fruit and

[6]Please refer to the Pesticides Peer Review Experts' Teleconference 140 (Experts' consultation 1.1) (EFSA, 2026).

[7]Myristic acid, palmitic acid, palmitoleic acid, margaric acid, heptadecenoic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, arachidic acid, lignoceric acid, docosanoic acid and gondoic acid; see Appendix B for their respective minimum–maximum specification range.

[8]Myristic acid, palmitic acid, palmitoleic acid, heptadecenoic acid, margaric acid, stearic acid, oleic acid, linoleic acid, linolenic acid, arachidic acid, gondoic acid, eicosadienoic acid, docosanoic acid, C22:2 lignoceric acid and nervonic acid; see Appendix B for their respective minimum–maximum specification range.

[9]Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and Council listing co-formulants which are not accepted for inclusion in plant protection products. OJ L 74, 4.3.2021, p. 7–26.

[10]Please see Regulation (EC) No 1107/2009 for acceptability criteria for co-formulants and Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA Supporting Publication, EN-1623. https://doi.org/10.2903/sp.efsa.2019.EN-1623.

[11]However, further discussion is needed to reach a definitive conclusion (see also Section 2.13.6 of the Technical report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods (EFSA, 2019).

non-professional spray application as an insecticide and acaricide on pome fruit. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix B. Data were submitted to conclude that the representative uses of 'fatty acids from hydrolysed vegetable oils' proposed at EU level result in a sufficient insecticidal and acaricidal efficacy against the target pests following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

CONCLUSIONS OF THE EVALUATION

GENERAL ASPECTS

With regard to the mammalian toxicity of the formulations for representative uses 'ABP 617' and 'NEU 1128 I', studies addressing acute toxicity were available. Sufficient toxicological data were provided for all components and/or co-formulant(s) of each formulation. The experts considered that the available toxicological information did sufficiently address the genotoxicity and repeated dose toxicity potential of 'ABP 617'[12] and 'NEU 1128 I'[13] over the short and long term and no concerns were identified.

The availability of ecotoxicity data with the formulations for representative uses was discussed at the experts' meeting.[14] The data retrieval search and the available data for the individual components were also discussed and the experts concluded that no concerns were identified.

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).

The active substance was discussed in the Pesticide Peer Review Experts' Teleconference (TC) 140 (June 2024).

For the '*Fatty acids from hydrolysed olive oil*', the experts agreed that the fatty acids to be considered as part of the active substance, and consequently to account for the minimum purity, should be based on the fatty acids listed in the CODEX for virgin olive oil. The range of fatty acids should likewise comply with CODEX for virgin olive oil.

For the '*Fatty acids from hydrolysed rapeseed oil*', the experts agreed that the fatty acids to be considered as part of the active substance, and consequently to account for the minimum purity, should be based on the fatty acids listed in the CODEX for rape seed oil (low erucic acid), except erucic acid, as it is considered a relevant impurity (see Section 2). The range of fatty acids, except erucic, should likewise comply with CODEX for rape seed oil (low erucic acid).

Based on provided industrial scale batches, a minimum purity of 980 g/kg was proposed for '*Fatty acids from hydrolysed olive oil*'; whereas for '*Fatty acids from hydrolysed rapeseed oil*', a minimum purity of 900 g/Kg was proposed based on industrial scale batches, with oleic, linoleic and linolenic acid being its major components.

Erucic acid was considered as a relevant impurity only for '*Fatty acids from hydrolysed rapeseed oil*' specified at 20 g/kg (See Section 2). Lead (Pb), arsenic (As), mercury (Hg) and cadmium (Cd) were also considered relevant impurities for both '*Fatty acids from hydrolysed olive oil*' and '*Fatty acids from hydrolysed rapeseed oil*' with the following specified maximum levels[15]: 0.05 mg/kg for As, Pb, Hg, while a specification level for cadmium could not be proposed due to its missing batch analysis data for '*Fatty acids from hydrolysed olive oil*'; 0.0267 mg/kg for As, Pb, Hg and Cd for '*Fatty acids from hydrolysed rapeseed oil*' (See Section 2). A **data gap** is set for batch data to demonstrate compliance with the proposed lead, arsenic, mercury and cadmium specification levels and for validated analytical methods with a sufficient low LOQs for the proposed specification levels (see Section 10).[16]

A **data gap** was set for the detailed manufacturing process of the '*Fatty acids from hydrolysed rapeseed oil*' (see Section 10). Based on these data gaps, it is proposed to consider the proposed specifications as provisional. An FAO specification does not exist for '*Fatty acids from hydrolysed vegetable oils*'.

The main data regarding the identity of '*Fatty acids from hydrolysed vegetable oils*' and its physical and chemical properties are given in Appendix B. Several **data gaps** were set for the physical and chemical properties of the active substance and the formulations for the representative uses (see Section 10).

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance and impurities in all technical materials and for the determination of the active substance in the formulations for representative uses. A data gap was set for validated methods for the determination of the relevant impurities lead, arsenic, mercury and cadmium in the formulations for the representative uses (**data gap**, see Section 10). Adequate methods are available for the determination of erucic acid in the technical 'Fatty acids from hydrolysed rapeseed oil' and the formulation 'NEU 1128 I'. Methods for the analysis of residues in food and feed of plant and animal origin, in body fluids, body tissues, soil, air and water are not required as no residue definition was set.

[12]Please refer to the Pesticides Peer Review Experts' Teleconference 164 (discussion point 1.1) (EFSA, 2026).

[13]Please refer to the Pesticides Peer Review Experts' Teleconference 164 (discussion point 1.2) (EFSA, 2026).

[14]Please refer to the Pesticides Peer Review Experts' Teleconference 173 (discussion point 1.1) (EFSA, 2026).

[15]Please refer to the Pesticides Peer Review Experts' Teleconference 164 (discussion point 2.2) (EFSA, 2026).

[16]It is noted that the levels of arsenic, mercury and lead in the provided renewal batches from all manufacturing sources complied with the levels set under Commission Regulation (EU) 231/2012 for E570 fatty acids and proposed by the RMS for specification.

2 | MAMMALIAN TOXICITY

The assessment is based on the following guidance documents: European Commission (2012), EFSA (2014, 2017), and ECHA (2017).

Fatty acids from hydrolysed vegetable oils were discussed at the Pesticides Peer Review Experts' meeting Teleconference 164 in March 2025.

Regarding the proposed reference specification, the impurity erucic acid is identified as relevant (myocardial lipidosis) in 'Fatty acids from hydrolysed rapeseed oil' with a maximum acceptable level specified at 20 g/kg (see Section 1). Moreover, the impurities lead, arsenic, mercury and cadmium[17] are also identified as relevant impurities, being heavy metals of known toxicological concern and maximum levels are proposed.[18] It is stressed in the EFSA opinion for food additive that the current specification limits for Pb, As and Hg in fatty acids as food additive (E 570) (Commission Reg 231/2012) are not sufficiently protective (EFSA ANS Panel, 2017).[19] Consequently, lower values were considered and set based on the values proposed by the applicant (see Section 1).

For inorganic arsenic, the EFSA CONTAM Panel derived a $BMDL_{05}$[20] of 0.06 μg/kg bw per day based on increased incidence of skin cancer (EFSA CONTAM Panel, 2024). For lead, the EFSA CONTAM Panel derived a $BMDL_{01}$[21] of 0.5 μg/kg bw per day for neurodevelopmental effects in children (close to the $BMDL_{10}$[22] for nephrotoxic effects in adults) (EFSA CONTAM Panel, 2010). In both cases, the EFSA CONTAM Panel (2012) recommended a margin of exposure (MOE) approach.[23] For inorganic mercury, the lowest health-based guidance value (HBGV) derived by the EFSA CONTAM Panel (2012) is the tolerable weekly intake (TWI) of 4 μg/kg bw (corresponding to 0.57 μg/kg bw per day), based on kidney effect.

Fatty acids are authorised in the EU as a food additive (E 570)[24] and their safety was re-evaluated by EFSA in 2017 (EFSA ANS Panel, 2017). Fatty acids are primarily regarded as nutrients and they are present in all living organisms. They have a main role in energy metabolism and they are essential structural components of every cell.

No specific **ADME** studies for fatty acids from hydrolysed vegetable oils were available in the renewal dossier. However, the metabolic pathways of fatty acids are well established and similar for all of them. Fatty acids are rapidly absorbed (> 80%) and widely distributed. They are either metabolised completely for energy production giving rise to water and carbon dioxide or converted to fat suitable for storage. They do not produce any metabolites and they have no potential for accumulation.

No new toxicological studies were submitted for fatty acids from hydrolysed vegetable oils by the applicant. Based on the publicly available data, there is no indication of **acute oral, dermal** or **inhalation toxicity**. Fatty acids from hydrolysed vegetable oils do not have a harmonised classification under Regulation (EU) No 1272/2008[25]; they have notified classifications as skin irritant 2 [H315] and eye irritant 2 [H319].[26] Fatty acids from hydrolysed vegetable oils are devoid of phototoxic potential since they do not absorb electromagnetic radiation in the range of 290–700 nm.

Based on the available **genotoxicity** data, fatty acids from hydrolysed vegetable oils are unlikely to be genotoxic. Testing for photomutagenicity is not required, since their UV/vis molar extinction coefficient is below 1000 $L \times mol^{-1} \times cm^{-1}$.

As fatty acids are natural body constituents, toxicological studies, e.g. **short-term, long-term, reproductive (fertility/development) toxicity and neurotoxicity** studies, are not necessary and can be waived.

As regards **medical data**, there is no evidence of adverse effects from consumption of at least 821 mg/kg bw per day through diet (ECHA, 2012).

Health-based guidance values (ADI, ARfD, (A)AOEL) cannot be established on the basis of the data submitted and they are not required in view of the lack of adverse effects from consumption of at least 821 mg/kg bw per day through diet (ECHA, 2012).

The **non-dietary exposure** estimates were calculated with the EFSA model (EFSA, 2022) for representative indoor uses of the product 'ABP 617' in high vegetables (covering also the use on low berries). Non-dietary exposure estimates were calculated with the EFSA model (EFSA, 2014)[27] for the representative outdoor uses of the product 'NEU 1128 I' in low berries and high ornamentals. Predictions for operators, using manual hand-held, knapsack and vehicle mounted applications, are below the background dietary exposure level (821 mg/kg bw per day) with the use of standard workwear. For the workers, exposure estimates are below the background dietary exposure level even without workwear during re-entry activities. For the representative outdoor uses of the product 'NEU 1128 I', potential exposure for operators and workers, used to estimate exposure during non-professional uses in the absence of an EU validated model, is below the background dietary exposure. Predictions for resident exposure (children and adult) are below the background dietary exposure level without

[17]Cadmium was not included in the provisional non-dietary and consumer risk assessment conducted for the heavy metals (presented in the paragraphs below) as this element is not part of the EU specifications of the food additive E 570 (Commission Regulation (EU) No 231/2012) which had originally been used as starting point for setting specifications for the heavy metals in the active substance.

[18]Please refer to the Pesticides Peer Review Experts' Teleconference 164 (discussion point 2.2) (EFSA, 2026).

[19]See experts' consultation 2.3 of Pesticides Peer Review Experts' Teleconference 164 (EFSA, 2026).

[20]Dose where the change in response is likely to be smaller than 5%.

[21]Dose where the change in response is likely to be smaller than 1%.

[22]Dose where the change in response is likely to be smaller than 10%.

[23]Arsenic: 'An MOE of 1 would correspond to an exposure level that is associated with a 5% increase relative to the background incidence for skin cancer, based on the available data' (EFSA CONTAM Panel, 2024).

[24]Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, pp. 16–33.

[25]Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[26]https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/126417.

[27]Last version of calculator 2015.

specific risk mitigation measures. Regarding the acute exposure, in the absence of an acute health-based guidance value, the exposure assessment for residents covers also bystanders.

Regarding the non-dietary exposure to heavy metals (As, Pb and Hg), based on the proposed maximum levels (see Section 1) and the representative uses, the calculated estimates do not exceed the BMDLs or TWI (MoE ranging from 6 to 14,989). It is noted that such estimates are provisional as there are several uncertainties such as the applicability to heavy metals of the default dermal absorption value used for fatty acids, the unknown actual levels of these metal impurities in the five-batch analysis due to the lack of validated analytical methods (see data gap in Section 1) and the limitations of the approach of comparing non-dietary exposure estimates with tolerable intake levels for heavy metals.

3 | RESIDUES

The active substance 'fatty acids from hydrolysed vegetable oils' (derived from rapeseed oil (Neudorff) or olive oil (Alpha BioPesticides)) is proposed as insecticide/acaricide for a multitude of representative uses (strawberries, tomato, cucumber, pome and stone fruit, fruiting vegetables, pulses, brassica vegetable, leafy and stem vegetable, root and tuber vegetable, bulb vegetables and berries). Residue data and studies with 'fatty acids from hydrolysed vegetable oils' have not been provided by the applicants based on the argument that fatty acids are naturally occurring in plants and animals and residues remaining on/in plants and animals from use as active substance would be indistinguishable from fatty acids from other sources. It is agreeable that they are not required.

Given the high number of proposed representative uses and the high application rates (up to 24 kg a.s./ha), a consideration of the relevance of the additional contribution of 'fatty acids from hydrolysed vegetable oils' via treated food to the natural level was requested. The applicants submitted an estimation of exposure to humans from the additional use of 'fatty acids from hydrolysed vegetable oils' via food considering the application rate and yield for the various proposed uses. A maximum exposure of 100 mg/kg bw per day was estimated for NL toddlers. This is understood as sum of the mono-, poly-unsaturated fatty acids (MUFA, PUFA) and saturated fatty acids (SFA).[28] In the context of the re-evaluation of the food additive, fatty acids (E 570), the (highest) minimum–maximum intakes of SFA via the regular diet was estimated to be in the range of 1100–1300 mg/kg bw per day for toddlers (EFSA ANS Panel, 2017). Intakes for MUFAs via the regular diet could not be calculated, but it can reasonably be assumed that this figure would be a similar order of magnitude of the one for SFA (EFSA, 2010). From these sources and calculations, it seems that the intake via diet will be higher than the one resulting from the representative uses. The applicant for 'NEU 1128 I' presented a consumer risk assessment for the relevant impurity erucic acid using the maximum specification value of 20 g erucic acid/kg fatty acid and the TDI for erucic acid of 7 mg/kg bw per day (EFSA CONTAM Panel, 2016).

A worst-case scenario (max content, total transfer to crops) resulted in 28% of the TDI for NL toddlers. With regard to the five assessment criteria according to the Commission guidance SANCO/11188/2013 Rev. 2 (European Commission, 2015) for potential inclusion of an active substance in Annex IV of Regulation (EC) No 396/2005, i.e. approval as basic substance (criterion 1), listed in Annex I of Regulation (EC) No 396/2005 (criterion 2), having no identified hazardous properties (criterion 3), natural exposure is higher than the one linked to the use as plant protection product (criterion 4) and consumer exposure is not expected considering the representative uses (criterion 5), two criteria were considered to be met for 'fatty acids from hydrolysed vegetable oils' for the following reasons:

- Health-based guidance values are not required for 'fatty acids from hydrolysed vegetable oils' (criterion 3).
- The natural exposure to fatty acids through consumption of plant and animal fats can be considered to result in higher amounts of fatty acids after digestion than the one linked to the use as plant protection product (criterion 4).

It is noted that 'fatty acids from hydrolysed vegetable oils' are not approved as basic substance (criterion 1), not listed in Annex I (criterion 2), and from the representative use, exposure to consumer can be expected (criterion 5).

Consumer exposure to the relevant impurities, lead (Pb), arsenic (As) and mercury (Hg) was estimated.[29] Using PRIMo 3.1, the consumer exposure was estimated to be 0.15 µg/kg bw per day for As and 0.05 µg/kg bw per day for each, Pb and Hg. Based on the estimates, the margins of exposure (MoE) are 0.4 for As (relative to the BMDL05 of 0.06 µg/kg bw per day) and 10 for Pb (relative to the BMDL05 of 0.06 µg/kg bw per day). For Hg, the estimated dietary intake accounted for 8% of the tolerable weekly intake (TWI) of 4 µg/kg bw per week (equivalent to 0.57 µg/kg bw per day). It is noted that this exposure assessment represents a worst-case scenario. Higher MoEs are achieved when using the specified maximum levels proposed in the technical specification submitted by the applicant (see Section 1) instead of the higher limits for fatty acids as food additive. However, considering the high application rates and the multitude of the proposed representative uses, the contribution of these heavy metal impurities to the overall background consumer exposure could become significant.

[28]The MUFA are the major fatty acids in olive oil (55%–85%) and in rapeseed oil (ca 60%), whereas the PUFA contribute to up to ca 20% and up to 30%, respectively. SFA play a minor role (EFSA, 2010).

[29]See Evaluation table Section 3 (EFSA, 2026).

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

Fatty acids from hydrolysed vegetable oils were discussed at the Pesticides Peer Review Experts' TC 166 in March 2025, during the same meeting in which two other fatty acids—capric and caprylic acid—were also addressed.

The active substance 'fatty acids from hydrolysed vegetable oils' (derived from rapeseed oil (Neudorff; PPP: NEU 1128 I) or olive oil (Alpha BioPesticides; PPP: ABP-617)) is proposed as insecticide/acaricide for a multitude of representative uses in field (NEU 1128 I and ABP-617) and in both permanent and non-permanent greenhouses (ABP-617). These mixtures contain fatty acids in the range C14–C24, being C18 components the majoritarian ones. Oleic acid and linoleic acid have been considered as lead compounds for the exposure assessment. Endpoints derived from oleic acid and linoleic acid are used to model the fate and behaviour into the environment of these mixtures.

In general, fatty acids are degraded and used as a source of energy by cells of all kinds of living organisms. From scientific literature, the degradation pathway of fatty acids in cell mitochondria has been established. Its degradation involves β-oxidation leading to shorter chain fatty acids and ultimately to mineralisation.

Three studies investigating the degradation in soil are available. These studies confirm the degradation pathway of the fatty acids by stepwise elimination of C2-fragments (β-oxidation). Consequently, the major soil metabolites of a given fatty acid would be other fatty acids with shorter chains. Although mineralisation was not measured in the available studies, formation of CO_2 is the expected terminal step of this process. The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. Linoleic acid and oleic acid were very low to low persistent in soil under aerobic conditions. Anaerobic conditions are not likely to occur for the representative uses of fatty acids from hydrolysed vegetable oils. Due to the fast microbial degradation of fatty acids from hydrolysed vegetable oils under aerobic soil conditions, soil photolysis is not considered to be a relevant route of degradation.

Oleic and linoleic acid salts were considered to exhibit very low mobility in soil based on studies performed with OECD 121 guideline method (HPLC). In these studies, no effect of pH was observed in the range of pH 3.3 and 7.3 (alkaline conditions were not tested). Similar results were obtained in a study with the same method (OECD, 2001, Test No. 121) performed to determine the Koc values on acidic and neutral pH for three of the minor components (palmitoleic [C16:1], palmitic [C16:0] and stearic [C18:0] acids) of the test item. The use of the OECD 106 (OECD, 2000) direct method (batch test) to investigate the adsorption desorption of oleic acid was shown to be not feasible in a separate study due to precipitation of the test item. During the Pesticides Peer Review Experts' TC 166, the measured Koc = 5444 mL/g (OECD 121) for oleic acid was agreed as representative end point for adsorption in soil of the fatty acid derived from hydrolysed vegetable oils (rapeseed and olive oil), as already proposed by the RMS.

Photochemical degradation (direct and indirect photolysis) is considered that does not contribute to the degradation of the fatty acids from hydrolysed vegetable oils components of the active substance in water. Fatty acids from hydrolysed vegetable oils are considered as readily biodegradable substances.

An aerobic mineralisation study in surface water (OECD, 2004, Test No. 309) was not submitted neither for fatty acids from hydrolysed vegetable oils nor for any of its individual components (**data gap**, see Section 10).

A water/sediment study (OECD, 2002, test No. 308) using non-radiolabelled fatty acids from hydrolysed vegetable oils is available. The study suffers from serious limitations that prevent to directly derive risk assessment end points. During the Pesticides Peer Review Experts' TC 166, it was agreed to use a DT_{50}(water) = 3 days for the aquatic exposure assessment, as already proposed by the RMS.

Information or data to address the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water is not available (**data gap**, see Section 10).

Information on the natural background concentrations of fatty acids in water and sediment in EU surface water bodies, as well as an assessment of the impact of residues resulting from the representative uses of the PPPs on these background levels, was not available (**data gap**, see Section 10).

Worst-case PECsoil were calculated for the worst-case uses in field of strawberries, tomatoes ('ABP 617') and ornamentals ('NEU 1128 I SL'). However, PEC soil for other uses of 'NEU 1128 I SL' is not available (**data gap**, see Section 10).

The experts in Pesticides Peer Review Experts' TC 166 agreed that the behaviour of the fatty acids produced from hydrolysed vegetable oils could be modelled using standard FOCUS SW/sed approaches as no surface film is formed in the surface of the water (in opposition to the behaviour observed for the oils). The exposure assessment was provided up to FOCUS step 3 (for 'ABP 617' uses) and up to Step 4 (for 'NEU 1128 I' uses) considering up to 20 m buffer spray drift and vegetative strip run-off mitigation and including contribution from volatilization and deposition. All deposition values were generated using the EVA 3 tool. FOCUS Step 1 and 2 calculations were provided to address the exposure to water bodies from non-professional uses.

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. using end points of oleic acid, as agreed representative compound for the fatty acids from hydrolysed vegetable oils. According to these modelling, the potential for groundwater exposure from the representative uses of 'ABP 617' and 'NEU 1128 I' by oleic acid above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios.

Risk managers should be aware that applicants did not provide scientifically sound evidence that the available environmental exposure assessments based on the adsorption endpoints for oleic acid (as lead compound) represent a worst case

with respect to the environmental exposure assessments that would be expected for components with shorter chains, taking into consideration that available information suggest that ionised forms of shorter chain metabolites may be significantly more mobile than the longer chain compounds that constitute the parent compound (**data gap**, see Section 10).

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 (2002), SETAC (2001), EFSA (2009, 2013) and EFSA PPR Panel (2013).

The applicant clarified that the formulation 'ABP 617' is intended for use on strawberries, tomatoes and cucumbers in both permanent and non-permanent greenhouses. Consequently, the risk assessment for these uses was performed as for the field applications, since environmental exposure to fatty acids from hydrolysed vegetable oils cannot be excluded.

Several aspects related to the ecotoxicological risk assessment of fatty acids derived from hydrolysed vegetable oils were discussed at the Pesticides Peer Review Teleconferences 167 (March 2025) and 173 (May 2025).

The equivalence between the two formulations for the representative uses, i.e. 'NEU 1128 I' and 'ABP 617', was discussed by the experts.[30] Based on the compositions of the two formulations, the experts agreed that extrapolation could be made from 'NEU 1128 I SL' to 'ABP 617' (and not vice versa).

No acute or long-term studies with either the active substance or the formulations for the representative uses 'ABP 617' and 'NEU 1128 I SL' were available for **birds** and **mammals**. The available evidence to address the risk was discussed at the experts' meeting.[31] A low acute and long-term risk from exposure to fatty acids from hydrolysed vegetable oils was concluded for both birds and mammals and for all representative uses based on a qualitative weight-of-evidence approach that considered the following arguments (i) fatty acids are authorised as food additives and feeding studies with avian species supplemented with fatty acids showed no adverse effects on health or reproduction, (ii) fatty acids occur naturally in the diet of birds and mammals (e.g. in arthropods, seeds, nuts) and exposure through residues on treated plants represents only a small fraction of natural dietary lipid intake and (iii) fatty acids are essential nutrients and part of the metabolism of birds and mammals, which have evolved mechanisms to process varying amounts and types of fatty acids.

No relevant metabolites plant was identified for fatty acids from hydrolysed vegetable oils, and therefore, a risk assessment was not required.

For **aquatic organisms**, studies with 'NEU 1128 I SL' were available for fish (acute and chronic), aquatic invertebrates (acute only), sediment-dwelling organisms and algae. For 'ABP 617', chronic studies with aquatic invertebrates and studies with sediment-dwelling organisms were available. No aquatic toxicity studies were available for the active substance. The validity of the early-life stage study with 'NEU 1128 I SL' was confirmed by the experts,[32] who also agreed on the approach for expressing the endpoints from the toxicity studies.[33]

For all representative uses of 'ABP 617', the risk assessment indicated a low risk at $FOCUS_{sw}$ Step 3, without the need for risk mitigation measures.

The risk assessment for the uses with 'NEU 1128 I SL' indicated:

- Professional uses: Low risk at $FOCUS_{sw}$ Step 3 for strawberry, fruiting vegetables, pulses, leafy vegetables, root vegetables, potatoes and bulb vegetables and berry fruits (early applications). Low risk was indicated at $FOCUS_{sw}$ Step 4 for the uses on berry fruits (late applications) and on ornamentals, when considering risk mitigation measures (see Table 6).
- Non-professional uses: Low risk at $FOCUS_{sw}$ Step 1 for all uses.
- Long-term risk to aquatic invertebrates: The assessment for all uses of 'NEU 1128 I SL' could not be finalised because a relevant endpoint was not available (**data gap**; see Section 9.1).

No relevant metabolites were identified for fatty acids from hydrolysed vegetable oils, and therefore, a risk assessment was not required.

Acute (oral and contact) studies with **honey bee** adults and 22-day repeated-exposure studies with honey bee brood were available for both the active substance and the formulation 'NEU 1128 I SL'. In addition, chronic studies with adult honey bees were available for both 'NEU 1128 I SL' and 'ABP 617'. Two semi-field (tunnel) studies with 'NEU 1128 I SL' were also submitted. The endpoints from the bee studies and the approach for the risk assessment were agreed by the experts.[34] The outcome of the risk assessment is presented in Table 1.

[30]Please refer to the Pesticides Peer Review Experts' Teleconference 167 (discussion point 5.1) (EFSA, 2026).
[31]Please refer to the Pesticides Peer Review Experts' Teleconference 167 (discussion point 5.1) (EFSA, 2026).
[32]Please refer to the Pesticides Peer Review Experts' Teleconference 173 (discussion point 5.4) (EFSA, 2026).
[33]Please refer to the Pesticides Peer Review Experts' Teleconference 173 (discussion point 5.2) (EFSA, 2026).
[34]Please refer to the Pesticides Peer Review Experts' Teleconference 167 (discussion point 5.6) (EFSA, 2026).

TABLE 1 Outcome of the screening and tier 1 risk assessment for bees.

	Acute exposure				Chronic exposure	
	SANCO (European Commission, 2002)		EFSA (2013)		EFSA (2013)	
Use	Oral	Contact	Oral	Contact	Adults	Brood
'ABP 617'						
Strawberry	Low	Low	Low	Low	High (TC, W, SC)[a]	High (TC, W)
Tomato	Low	Low	Low	Low	High (TC, W)	High (W)
Cucumber	Low	Low	Low	Low	High (TC, W, SC)[a]	High (TC, W)
'NEU 1128 I'						
Pome/stone fruit	Low	High[b]	High (TC)	High (TC, W)[b]	High (TC, W, SC)[a]	High (TC, W, SC)[a]
Strawberry	Low	High[b]	High (TC)	High (TC, W)[b]	High (TC, W, SC)[a]	High (TC, W, SC)[a]
Fruiting vegetables & pulses	Low	High[b]	High (TC)	High (TC, W)[b]	High (TC, W)	High (TC, W)
Ornamentals	Low	High[b]	High (TC)	High (TC, W)[b]	High (TC, W, SC)[a]	High (TC, W, SC)[a]
Brassica vegetable	Low	High[b]	Low	High (TC, W)[b]	High (TC, W, SC)[a]	High (TC, W)
Bulb vegetable	Low	High[b]	Low	High (TC, W)[b]	High (TC, W)	High (TC, W)
Berry fruit	Low	High[b]	Low	High (W)[b]	High (TC, W, SC)[a]	High (TC, W)

Note: Green colour indicates low risk. Red colour indicates high risk.

Abbreviations: SC, succeeding crop; TC, treated crop; W, weeds in the treated field.

[a]The risk identified for the succeeding crop (SC) scenario could be refined considering the low DT_{50s} of the main components of fatty acids derived from hydrolysed vegetable oils in soil (refer to the List of endpoints for actual DT_{50} values).

[b]Further refined by the semi-field tunnel study.

The acute risk assessment conducted in accordance with the SANCO guidance document (2002) indicated a low risk from both oral and contact exposure for all representative uses of 'ABP 617', and a low risk from oral exposure for the uses of 'NEU 1128 I SL'. However, a high risk from contact exposure was identified for the uses of 'NEU 1128 I SL'.

According to the EFSA guidance document (2013), the screening acute risk assessment indicated a low risk from oral and contact exposure for all uses of 'ABP 617'. For 'NEU 1128 I SL', a high risk from contact exposure was indicated for all uses, and a high risk from oral exposure was identified for pome and stone fruits, strawberries, fruiting vegetables, pulses and ornamentals. A low acute risk from oral exposure could be concluded for the uses in berry fruits, *Brassica* vegetables, leafy and stem vegetables, root and tuber vegetables and bulb vegetables with 'NEU 1128 I SL'.

At Tier 1, a high chronic risk to adult bees and a high risk to bee brood were identified for all representative uses with both formulations.

The experts considered that one of the available semi-field studies was suitable to demonstrate the absence of short-term effects on worker bees after application of 'NEU 1128 I SL'. This study was therefore used to refine the acute contact risk from both formulations and for all representative uses, including the risk from direct overspray.[35] However, EFSA and some experts at the meeting were of the opinion that none of the available semi-field studies was suitable to refine the acute or chronic oral risk and that evidence was insufficient to support a qualitative risk assessment. In conclusion, the acute risk from contact exposure was refined and concluded to be low also for the uses with 'NEU 1128 I SL', whereas the high chronic risk remained for all representative uses with both formulations.

An assessment of cumulative effects was not available. No metabolites potentially present in pollen and nectar were identified for fatty acids derived from hydrolysed vegetable oils; therefore, no further risk assessment was required. Toxicity studies with bumble bees were not available.

To assess the risk to **non-target arthropods other than bees**, glass plate studies were conducted with *Aphidius rhopalosiphi* and *Chrysoperla carnea* using the formulation 'NEU 1128 I SL'. Extended laboratory studies were performed with several species and both formulations for the representative uses. Specifically, 'NEU 1128 I SL' was tested with *A. rhopalosiphi*, *Typhlodromus pyri*, *C. carnea*, *Coccinella septempunctata* and *Trichogramma cacoeciae*, while 'ABP 617' was tested with *A. rhopalosiphi*, *T. pyri* and *C. carnea*. An additional extended laboratory study examined using Neudosan Neu (considered equivalent to 'NEU 1128 I SL'). Finally, an aged residue study was conducted using *T. pyri* and 'NEU 1128 I SL'.

[35]Please refer to the Pesticides Peer Review Experts' Teleconference 167 (discussion point 5.6) (EFSA, 2026).

Based on the available data and risk assessment, a low in-field risk was concluded for all uses with 'ABP 617' and for the uses with 'NEU 1128 I SL' on bulb vegetables. A high in-field risk was indicated for all other uses with 'NEU 1128 I SL'.

For the off-field assessment, a low risk was concluded for all uses with both 'ABP 617' and 'NEU 1128 I SL'. However, for the uses in pome and stone fruit with 'NEU 1128 I SL', a low risk can only be achieved when appropriate mitigation measures are implemented (Table 6).

It should be noted that standard tests – where test species are exposed to either fresh or dried residues sprayed on glass plates or plant leaves – are not adequately designed to assess the potential effects of sprayed insecticides with a physical mode of action, such as fatty acids. In particular, these tests may underestimate the risk from exposure via drift. This limitation is particularly relevant for the off-field risk assessment, as standard tests can be considered as aged-residue studies (with ageing times of 1–2 h or more), which can be used to assess the potential for in-field recovery but not the off-field risk assessment. Consequently, uncertainty remains in the off-field risk characterisation due to limitations in standard testing methods. Should any of the highlighted uncertainties arising from the standard tests be impacting on national registration of products, MSs may consider the need of additional clarifications (**data gap**; see Section 10).

For **soil organisms**, chronic studies for earthworms were available with both formulations for representative uses. In addition, chronic studies with the Collembola *Folsomia candida* and the predatory mite *Hypoaspis aculeifer* with 'NEU 1128 I SL' were submitted. The endpoints used in the risk assessment were agreed at the meeting.[36] The risk assessment indicated a low risk to soil organisms for all uses of fatty acids from hydrolysed vegetable oil, except for the uses of 'NEU 1128 I SL' on ornamentals, for which a high risk to Collembola was identified.

A soil nitrogen transformation study with 'NEU 1128 I SL' was available to assess the risk to **soil microorganisms**. A low risk was concluded for all representative uses.

No relevant soil metabolites were identified for fatty acids from hydrolysed vegetable oils; therefore, no further risk assessment was required.

To assess the risk to **non-target terrestrial plants**, a vegetative vigour study with the formulation 'NEU 1128 I' and a seedling emergence study with the formulation 'ABP 811', different that the ones for the representative uses, was available. The seedling emergence study as well as the endpoints from both studies were accepted by the experts.[37] A low risk was concluded for all representative uses. For the uses on pome/stone fruits with 'NEU 1128 I SL', the low risk is indicated when applying risk mitigation measures (Table 6).

A low risk to organisms involved in **biological methods for sewage treatment** was concluded for all representative uses in field and in non-permanent greenhouses. A **data gap** was identified (see Section 10) for the uses of 'ABP 617' in permanent greenhouses since exposure cannot be excluded and no data were provided.

6 | ENDOCRINE DISRUPTION PROPERTIES

The endocrine-disrupting properties (ED) of fatty acids from hydrolysed vegetable oils for human and non-target organisms were discussed in the Peer Review Experts TC 172 (March 2025).[38]

With regard to the assessment of the endocrine disruption (ED) potential of fatty acids from hydrolysed vegetable oils **for humans** and **non-target organisms** (NTOs) according to the ECHA/EFSA guidance (2018), the oestrogen, androgen, steroidogenesis and thyroid (EATS) mediated adversity/activity were not sufficiently investigated. The submission of further (eco)toxicological data was considered as not scientifically necessary[39] based on the following: (i) fatty acids are ubiquitous in the environment, (ii) there is a lack of toxicological concern based on the available data with substances of similar chain length (e.g. long-chain fatty acids with similar carbon chain length to the testing substance (EFSA, 2025)), which support the waiver for studies on general toxicity in mammalian toxicology,[40] (iii) the general knowledge on the toxicological properties of fatty acids.[41] Overall, when considering all the available evidence, it was considered unlikely that fatty acids from hydrolysed vegetable oils have endocrine-disrupting properties for both humans and NTOs.

Considering the above, it can be concluded that fatty acids from hydrolysed vegetable oils do not meet the criteria for endocrine disruption for humans and non-target organisms 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.[42]

[36]Please refer to the Pesticides Peer Review Experts' Teleconference 173 (discussion point 5.8) (EFSA, 2026).

[37]Please refer to the Pesticides Peer Review Experts' Teleconference 167 (discussion point 5.9) (EFSA, 2026).

[38]Please refer to the Pesticides Peer Review Experts' Teleconference 172 (discussion point 2.1) (EFSA, 2026).

[39]Please refer to the Pesticides Peer Review Experts' Teleconference 172 (discussion points 2.1 and 5.10) (EFSA, 2026).

[40]Please refer to the Pesticides Peer Review Experts' Teleconference 164 (EFSA, 2026).

[41]Fatty acids (E570) are authorised as food additives in the European Union (EU) in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008, with no safety concern at the reported uses and use levels (EFSA ANS Panel, 2017).

[42]Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 2–5)

TABLE 2 Soil.

Compound (name and/or code)	Ecotoxicology
Fatty acids from hydrolysed vegetable oils	Low risk to soil organisms for all uses, except for the uses on ornamentals with 'NEU 1128 I SL' (high risk for Collembola)

TABLE 3 Groundwater.[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
Oleic acid	No	Yes	–	–	Yes

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

[b]FOCUS scenarios or relevant lysimeter. Ranges indicated for FOCUS scenarios include the result from the model giving the highest concentration at each scenario, as needed to comply with European Commission (2014a) guidance.

TABLE 4 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Fatty acids from hydrolysed vegetable oils	Low risk to aquatic organisms for all uses Long-term risk to aquatic invertebrates not finalised for all uses with 'NEU 1128 I SL'

TABLE 5 Air.

Compound (name and/or code)	Toxicology
Fatty acids from hydrolysed vegetable oils	LC_{50} > 1.82 mg/L

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 6 Risk mitigation measures proposed for the representative uses assessed.

	'NEU 1128 I'							
Use	**Pome and stone fruit**	**Strawberry**	**Fruiting vegetables and pulses**	**Ornamentals annual and perennial**	**Brassica vegetable leafy and stem**	**Brassica vegetable leafy & stem, root and tuber**	**Bulb vegetable**	**Berry fruit**
Risk to aquatic organisms				RMM equivalent to 95% drift reducing nozzle +20 m vegetated spray buffer zone, for runoff situations combined with a 10 m vegetated buffer for 5/7 scenarios[a] (professional uses only)				RMM equivalent to 95% drift reducing nozzle +20 m vegetated spray buffer zone, for runoff situations combined with a 10 m vegetated buffer for 3/5 scenarios[b] (late applications and professional uses only)
Risk to non-target arthropods other than bees	RMM consisting on 5 m buffer zone or 50% drift reduction technology							
Risk to non-target terrestrial plants	RMM consisting on 5 m buffer zone							

[a]D3/ditch, D4/stream, D5/stream, R1/stream, R2/stream, R3/stream, R4/stream.

[b]D6/ditch, R2/stream, R3/stream.

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[43] 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:

1. The chronic risk to aquatic invertebrates could not be finalised for any of the representative uses with 'NEU 1128 I SL' (see Section 5).

   a. Data were not available to assess the chronic risk to aquatic invertebrates (relevant for all representative uses evaluated with 'NEU 1128 I SL', 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.

[43]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.

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:

No critical area of concern was identified.

9.3 | Overview of the concerns identified for each representative use considered (Table 7)

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 7.

TABLE 7 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 uses: ABP-617/FLiPPER		**Strawberry**	**Strawberry**	**Tomato**	**Tomato**	**Tomato**	**Cucumber**	**Cucumber**
		Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray	Foliar spray
		G (permanent)	G (non-permanent)	G (permanent)	G (non-permanent)	F	G (permanent)	G (non-permanent)
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		X[c]		X[c]	X[c]		X[c]
	Assessment not finalised							
Risk to aquatic organisms	Risk identified							
	Assessment not finalised							
Groundwater exposure to active substance	Legal parametric value breached							
	Assessment not finalised							
Groundwater exposure to metabolites	Legal parametric value breached[a]							
	Parametric value of 10 µg/L[b] breached							
	Assessment not finalised							

Note: 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]Based on classification made in the context of this evaluation procedure under Regulation (EC) No 1107/2009. It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

[b]Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).

[c]High chronic risk to bees (adults and brood) indicated at Tier 1 based on EFSA (2013).

Representative uses: NEU 1128 I SL		Pome fruit and stone fruit	Strawberry	Strawberry	Fruiting vegetable and pulses	Fruiting vegetable and pulses	Ornamentals annual and perennial	Ornamentals annual and perennial	Brassica vegetable leafy and stem vegetable root and tuber vegetable	Brassica vegetable leafy and stem vegetable root and tuber vegetable	Bulb vegetable	Bulb vegetable	Berry fruit	Berry fruit
		Manual Spraying upward	Tractor-drawn Spraying downward	Manual Spraying downward	Tractor-drawn Spraying upward	Manual Spraying Upward	Tractor-drawn Spraying up–/downwards	Manual Spraying up–/downwards	Tractor-drawn Spraying up–/downwards	Manual Spraying up–/downwards	Tractor-drawn Spraying downward	Manual Spraying downward	Tractor-drawn Spraying upward	Manual Spraying upward
		Fn	F	Fn	F	Fn	F	Fn	F	Fn	F	Fn	F	Fn
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	X[a,b]	X[a,b]	X[a,b]	X[a,b]	X[a,b]	X[a,b,c]	X[a,b,c]	X[a]	X[a]	X[a]	X[a]	X[a]	X[a]
	Assessment not finalised													
Risk to aquatic organisms	Risk identified													
	Assessment not finalised	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]	X[1]
Groundwater exposure to active substance	Legal parametric value breached													
	Assessment not finalised													
Groundwater exposure to metabolites	Legal parametric value breached[a]													
	Parametric value of 10 µg/L[b] breached													
	Assessment not finalised													

Note: 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.

Abbreviation: Fn, non-professional field use.

[a] High chronic risk to bees (adults and brood) indicated at Tier 1 based on EFSA (2013).

[b] High acute oral risk to bees indicated at Tier 1 based on EFSA (2013).

[c] High risk to soil organisms (Collembola).

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:

- The content of 'Fatty acids from hydrolysed olive oil' (pure and technical), and the equivalent potassium salts, in the formulation 'ABP 617' considering all the fatty acids included in the active substance was not provided (see the section the active substance and the formulations for representative uses).
- The content of 'Fatty acids from hydrolysed rapeseed oil' (pure and technical), and the equivalent potassium salts, in the formulation 'NEU 1128 I' considering all the fatty acids included in the active substance was not provided (see the section the active substance and the formulations for representative uses).
- Batch data to demonstrate compliance with the proposed lead, arsenic, mercury and cadmium specification levels and for validated analytical methods with a sufficient LOQs i.e. at least 20% lower than the corresponding specification levels (relevant for all representative uses, see Section 1).
- The manufacturing process of the '*Fatty acids from hydrolysed rapeseed oil*' was not provided (relevant for the uses of 'NEU 1128 I', see Section 1).
- Data on the melting point, boiling point and freezing point, spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity, partition coefficient n-octanol/water and surface tension using the 'Fatty acids from hydrolysed rapeseed oil' as manufactured or its main fatty acid as a testing material, were not provided (relevant for the uses of 'NEU 1128 I', see Section 1).
- Data on the appearance, solubility in organic solvents, oxidising and explosive properties, flash point and autoflammability for 'Fatty acids from hydrolysed rapeseed oil' as manufactured were not provided (relevant for the uses of 'NEU 1128 I', see Section 1).
- Dilution stability and pH data for the formulation 'NEU1128I' were not provided (relevant for the uses of 'NEU 1128 I', see Section 1).
- Data on viscosity at two shear rates, and accelerated storage stability data on pH, alkalinity and emulsion stability of the formulation ABP 617 in COEX HDPE/PA packaging were not provided (relevant for the uses of 'ABP 617', see Section 1).
- Validated methods for the determination of the relevant impurities lead, arsenic, mercury and cadmium in the formulations for the representative uses (relevant for all representative uses, see Section 1).
- Appropriate PEC soil for 'NEU 1128 I SL' (Neudorff) for uses other than ornamentals are not available (relevant for the uses of 'NEU 1128 I SL', see Section 4).
- An aerobic mineralisation study in surface water (OECD 309) was not submitted neither for fatty acids from hydrolysed vegetable oils nor for any of its individual components (see Section 4).
- Applicants did not provide scientifically sound evidence that the available environmental exposure assessments based on the adsorption endpoints for oleic acid (the lead component of the mixture) represent a worst case with respect to the environmental exposure assessments that would be expected for components with shorter chains, taking into consideration that available information suggest that ionised forms of shorter chain metabolites may be significantly more mobile than the longer chain compounds that constitute the parent compound (e.g. in Urbani 2016a (Report No.: CH-742/2016)) (relevant for all representative uses, see Section 4).
- Information on the natural background concentrations of fatty acids from hydrolysed vegetable oils in water and sediment in EU surface water bodies, as well as an assessment of the impact of residues resulting from the representative uses of the PPPs on these background levels, was not available (relevant for all representative uses, see Section 4).
- The applicants have not addressed the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water (relevant for all representative uses, see Section 4).
- Further data may be needed to address the off-field risk to non-target arthropods other than bees from exposure via overspray (relevant for all representative uses, see Section 5).
- Further data are needed to address the risk to organisms involved in biological methods for sewage treatment (relevant for uses in permanent greenhouses with 'ABP 617', see Section 5).

ABBREVIATIONS

1/*n*	slope of Freundlich isotherm
AAOEL	acute acceptable operator exposure level
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AhR	aryl hydrocarbon receptor

AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AOP	adverse outcome pathway
AP	alkaline phosphatase
AR	androgen receptor
AR	applied radioactivity
ARfD	acute reference dose
ARSTTA	Stably Transfected Human Androgen Receptor Activation Assay
a.s.	active substance
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
C&L	classification and labelling
CAS	Chemical Abstracts Service
CFU	colony-forming units
ChE	cholinesterase
CHO	Chinese hamster ovary cells
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
Cmax	concentration achieved at peak blood level
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
DM	dry matter
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
EAS	oestrogen, androgen and steroidogenesis modalities
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemicals Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ERO	ecological recovery option
ERSTTA	Stably Transfected Human Oestrogen Receptor-alpha Transcriptional Activation Assay
ETO	ecological threshold option
ETR	exposure toxicity ratio
ETR_{acute}	exposure toxicity ratio for acute exposure
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharygeal glands
ETR_{larvae}	exposure toxicity ratio for chronic exposure
ETR_{larvae}	exposure toxicity ratio for larvae
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	Time-weighted average factor
FAO	Food and Agriculture Organization of the United Nations
FID	flame ionisation detector
FIR	food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	Fish Short-Term Reproduction Assay
GAP	Good Agricultural Practice
GC	gas chromatography

GCPF	Global Crop Protection Federation (formerly known as International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathione
Hb	haemoglobin
Hct	haematocrit
HGPRT	hypoxanthine-guanine phosphoribosyl transferase
HPG	hypopharygeal glands
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
HR	hazard rate
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LAGDA	Larval Amphibian Growth and Development Test
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LDH	lactate dehydrogenase
LH	luteinizing hormone
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification
M&K	Maximisation test of Magnusson & Kligman
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MEOGRT	Medaka Extended One-Generation Reproduction Test
mm	millimetre (also used for mean measured concentrations)
mN	milli-newton
MOA	mode of action
MOE	Margin of exposure
MRL	maximum residue level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water-holding capacity
NESTI	national estimated short-term intake
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen–phosphorus detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content

Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
PHED	pesticide handler's exposure data
PHI	preharvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
Tmax	time until peak blood levels achieved
TMDI	theoretical maximum daily intake
ToxCAST	(US EPA) Toxicity Forecaster
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
TWA	time-weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
WHO	World Health Organization
ε	decadic molar extinction coefficient
λ	Wavelength

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NOTE/UPDATE

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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APPENDIX A

Consideration of cut-off criteria for fatty acids from hydrolysed vegetable oils according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[a]
CMR	**Carcinogenicity (C)**	Fatty acids from hydrolysed vegetable oils are not considered to be carcinogens (category 1A or 1B) according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009, based on: no harmonsied nor notified classification for carcinogenicity according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]
	Mutagenicity (M)	Fatty acids from hydrolysed vegetable oils are not considered to be mutagens (category 1A or 1B) according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009, based on: no harmonsied nor notified classification for carcinogenicity according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]
	Toxic for Reproduction (R)	Fatty acids from hydrolysed vegetable oils are not considered to be toxic for reproduction (category 1A or 1B) according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009, based on: no harmonsied nor notified classification for carcinogenicity according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended]
Endocrine-Disrupting properties		Fatty acids from hydrolysed vegetable oils 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** **Bioaccumulation** **Long-range transport**	Fatty acids from hydrolysed vegetable oils are not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Fatty acids from hydrolysed vegetable oils are 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.
vPvB	**Persistence** **Bioaccumulation**	Fatty acids from hydrolysed vegetable oils are not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.

[a]For CMR endpoints: https://chem.echa.europa.eu/100.060.830/overview.

APPENDIX B

List of end points for the active substance and the formulations for representative uses

Appendix B can be found in the online version of this output ('Supporting Information' section): https://doi.org/10.2903/j.efsa.2026.10383.

APPENDIX C

Clarification of the wording used in Sections 4 and 5

Wording EFSA used in section 4 of this conclusion, in relation to DT and Koc 'classes' exhibited by each compound assessed

Wording	DT_{50} normalised to 20°C for laboratory incubations[44] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT50 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

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_{oc} (either K_{Foc} or K_{doc}) mL/g
Very High Mobility	0–50
High Mobility	51–150
Medium Mobility	151–500
Low Mobility	501–2000
Slight Mobility	2001–5000
Immobile	> 5000

Note: Based on McCall et al. (1980).

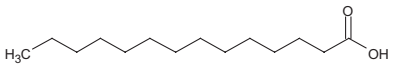
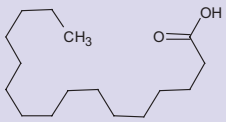
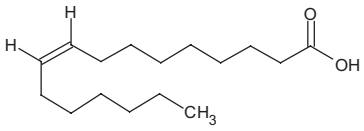
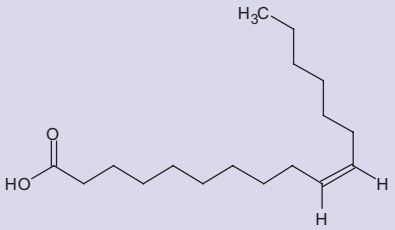
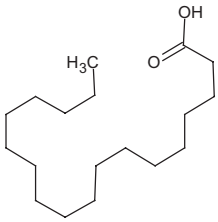
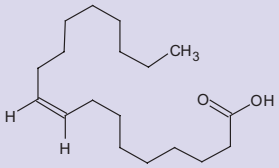
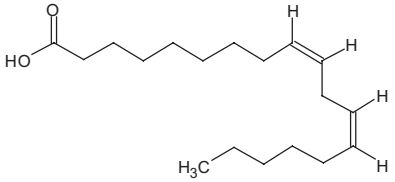
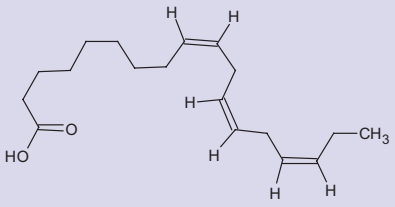
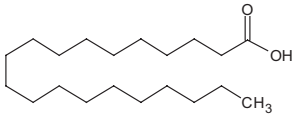
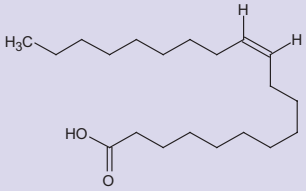
Wording used in Section 5 of this conclusion to communicate the outcome of the environmental risk assessment

Wording	Interpretation
Low risk	A low risk to the non-target organism was indicated based on screening, Tier 1 or higher Tier assessment.
High risk	A high risk to the non-target organism was indicated based on either Tier 1 or higher Tier assessment.
High risk not excluded	Only a screening level assessment was available, which did not show a low risk. This assessment is not considered to confirm a high risk to the non-target organism.
Pending an identified data gap in another section, further consideration may be needed	Based on the available information, it is not known if a risk assessment for non-target organisms is triggered.

[44] 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.

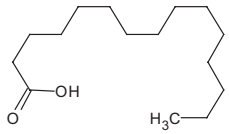
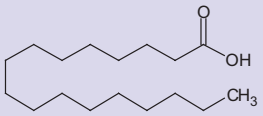
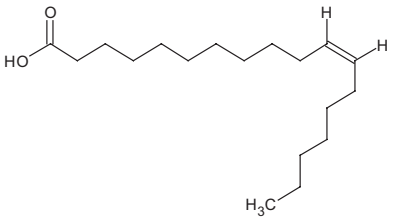
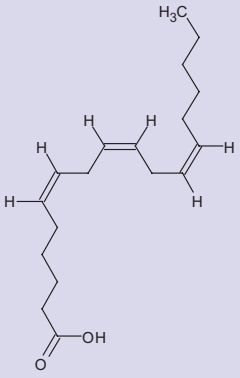
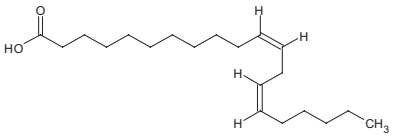
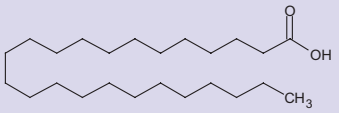
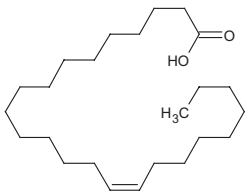
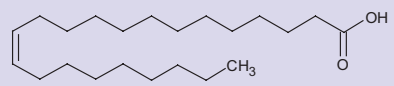
APPENDIX D

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Myristic acid, C14:0	tetradecanoic acid OC(=O)CCCCCCCCCCCCC TUNFSRHWOTWDNC-UHFFFAOYSA-N	
Palmitic acid, C16:0	hexadecanoic acid OC(=O)CCCCCCCCCCCCCCC IPCSVZSSVZVIGE-UHFFFAOYSA-N	
Palmitoleic acid, C16:1	(9*Z*)-hexadec-9-enoic acid OC(=O)CCCCCCC\C=C/CCCCCC SECPZKHBENQXJG-FPLPWBNLSA-N	
Heptadecenoic acid,	(10*Z*)-heptadec-10-enoic acid OC(=O)CCCCCCCC\C=C/CCCCCC GDTXICBNEOEPAZ-FPLPWBNLSA-N	
Stearic acid	octadecanoic acid OC(=O)CCCCCCCCCCCCCCCCC QIQXTHQIDYTFRH-UHFFFAOYSA-N	
Oleic acid	(9*Z*)-octadec-9-enoic acid OC(=O)CCCCCCC\C=C/CCCCCCCC ZQPPMHVWECSIRJ-KTKRTIGZSA-N	
Linoleic acid	(9*Z*,12*Z*)-octadeca-9,12-dienoic acid O=C(O)CCCCCCC\C=C/C\C=C/CCCCC OYHQOLUKZRVURQ-HZJYTTRNSA-N	
Linolenic acid	(9*Z*,12*Z*,15*Z*)-octadeca-9,12,15-trienoic acid O=C(O)CCCCCCC\C=C/C\C=C/C\C=C/CC DTOSIQBPPRVQHS-PDBXOOCHSA-N	
Arachidic acid	icosanoic acid OC(=O)CCCCCCCCCCCCCCCCCCC VKOBVWXKNCXXDE-UHFFFAOYSA-N	
Gondoic acid	(11*Z*)-icos-11-enoic acid OC(=O)CCCCCCCCC\C=C/CCCCCCCC BITHHVVYSMSWAG-KTKRTIGZSA-N	

(Continues)

(Continued)

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Pentadecanoic acid	pentadecanoic acid OC(=O)CCCCCCCCCCCCCC WQEPLUUGTLDZJY-UHFFFAOYSA-N	
Margaric acid	heptadecanoic acid OC(=O)CCCCCCCCCCCCCCCC KEMQGTRYUADPNZ-UHFFFAOYSA-N	
cis-vaccenic acid	(11*Z*)-octadec-11-enoic acid OC(=O)CCCCCCCCC\C=C/CCCCCC UWHZIFQPPBDJPM-FPLPWBNLSA-N	
γ-linolenic acid	(6*Z*,9*Z*,12*Z*)-octadeca-6,9,12-trienoic acid OC(=O)CCCC\C=C/C\C=C/C\C=C/CCCCC VZCCETWTMQHEPK-QNEBEIHSSA-N	
Eicosadienoic acid	(11*Z*,14*Z*)-icosa-11,14-dienoic acid OC(=O)CCCCCCCCC\C=C/C\C=C/CCCCC XSXIVVZCUAHUJO-HZJYTTRNSA-N	
Lignoceric acid	tetracosanoic acid OC(=O)CCCCCCCCCCCCCCCCCCCCCCCC QZZGJDVWLFXDLK-UHFFFAOYSA-N	
Nervonic acid	(15*Z*)-tetracos-15-enoic acid OC(=O)CCCCCCCCCCCCCC\C=C/CCCCCCCCC GWHCXVQVJPWHRF-KTKRTIGZSA-N	
Erucic acid	(13*Z*)-docos-13-enoic acid O=C(O)CCCCCCCCCCCC\C=C/CCCCCCCCC DPUOLQHDNGRHBS-KTKRTIGZSA-N	

[a]The name in bold is the name used in the conclusion.

[b]ACD/Name 2024.2.3 ACD/Labs 2024.2.3 (File Version N25E41, Build 142837, 21 January 2025).

[c]ACD/ChemSketch 2024.2.3 ACD/Labs 2024.2.3 (File Version C45H41, Build 142855, 22 January 2025).