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Peer review of the pesticide risk assessment of the active substance pelargonic acid (nonanoic acid)

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Abstract

The conclusions of the 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 pelargonic acid (nonanoic acid) and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative use of pelargonic acid as a herbicide on vineyards, potatoes, paths and places with woody plants, ornamental shrubs, ornamentals lawn, home gardens and allotments, paths and open areas with tree growth, woody ornamentals, decorative lawns, turf (field use). The reliable end points appropriate for use in regulatory risk assessment are presented. Assessments not finalised and missing information identified as being required by the regulatory framework are listed.

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Summary

Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659, lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Fatty acids – pelargonic acid is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Greece, and co-rapporteur Member State (co-RMS), Austria, received an application from the BCN Task Force (Belchim Crop Protection NV/SA, Compo GmbH, W. Neudorff GmbH KG) and Pelargonic Acid Task Force (Evergreen Garden Care France SAS, Emery Oleochemicals LLC, Bayer S.A.S., Grupo Agrotecnología SL, SBM Développement SAS, Alpha Bio Pesticides Ltd. T/A AlphaBio Control Ltd./ 'AlphaBio Control', Seipasa, S.A., Industrias Afrasa, S.A., Novamont SpA) for the renewal of approval of the active substance pelargonic acid. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on pelargonic acid 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 were derived.

The uses of pelargonic acid according to the representative professional and non-professional uses as hand-held field spray applications in paths, places with woody plants, ornamental shrubs, ornamentals, lawn, home gardens and allotments, as proposed at EU level, result in a sufficient herbicidal efficacy against the target annual and perennial monocotyledonous and dicotyledonous weeds, algae and mosses. The representative uses of pelargonic acid as field vehicle mounted spray application for the control of annual broad-leaved weeds, vine shoots and suckers in vineyards and as desiccant for potato haulm, as proposed at EU level, result in a sufficient herbicidal efficacy against the target weeds.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of pelargonic acid or the representative formulations.

In the area of mammalian toxicology and non-dietary exposure, no critical area of concerns or data gaps were identified.

No critical area of concerns or data gaps were identified in the residue section. A quantitative consumer risk assessment is not necessary since pelargonic acid is a naturally occurring compound for which toxicological reference values were not needed. The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported.

In the area of the environmental fate and behaviour, the information available was considered sufficient to complete the assessments necessary regarding the environmental exposure assessment at the EU level for the representative uses assessed. There is exceedance of the parametric drinking water value for some scenarios and crops only for situations where vulnerable aquifers occur under predominantly alkaline soils.

In the ecotoxicology section, high risk was concluded for aquatic organisms, bees and non-target arthropods for a number of the representative uses. No critical area of concern has been identified.

Pelargonic acid does 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.

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Background

Commission Implementing Regulation (EU) No 844/2012¹, as amended by Commission Implementing Regulation (EU) No 2018/1659², (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 1107/2009³. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

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

In accordance with Article 1 of the Regulation, the RMS, Greece, and co-RMS, Austria, received an application from the BCN Task Force and Pelargonic Acid Task Force for the renewal of approval of the active substance pelargonic acid. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005⁴. 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 pelargonic acid in the RAR, which was received by EFSA on 5 May 2020 (Greece, 2020).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicants, BCN Task Force and Pelargonic Acid Task Force, for consultation and comments on 14 July 2020. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 16 September 2020. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicants were invited to respond to the comments received. The comments and the applicants' response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicants in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 27 October 2020. On the basis of the comments received, the applicants' response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicants, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

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

¹ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

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

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

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

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

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

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of pelargonic acid as a herbicide on vineyards, potato, paths and places with woody plants, ornamental shrubs, ornamentals, lawn, home gardens and allotments, paths and open areas with tree growth, woody ornamentals, decorative lawns, turf (field use), as proposed by the applicants. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review, if any, are presented in the conclusion.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for pelargonic acid according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

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

- the comments received on the RAR;
- the reporting table (22 October 2020);
- the evaluation table (DD Month 2021);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

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

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

The active substance and the formulated product

Pelargonic acid is the ISO common name for the fatty acid nonanoic acid (IUPAC).

The representative formulated products for the evaluation were the 'ABP-811', 'MON 74134', 'NEU 1170 H', 'COM 508 16 H EW' and 'VVH 86086/BCP1004D'. 'ABP-811' is an emulsifiable concentrate (EC) containing 498.3 g/L pelargonic acid; 'MON 74134' is a ready to use liquid formulation (AL) containing 18.3 g/L pelargonic acid; 'NEU 1170 H' is an emulsifiable concentrate containing 186.7 g/L of pelargonic acid as an ammonium salt (equivalent to 206.9 g/L of the ammonium salt of pelargonic acid); 'COM 508 16 H EW' is an emulsion, oil in water (EW) containing 237.59 g/L pelargonic acid and 'VVH 86 086/ BCP1004D' is an emulsifiable concentrate (EC) containing 680 g/L pelargonic acid.

The representative uses evaluated for 'ABP-811' comprise professional field applications by spraying with tractor-mounted equipment as a preharvest desiccant in potato, and as a herbicide for the control of vine shoots and suckers in vineyard crops. The representative uses evaluated for 'MON 74134' comprise professional and non-professional field applications using hand-held sprayer equipment as a herbicide in home gardens and allotments against annual and perennial monocotyledonous and dicotyledonous weeds. The representative uses evaluated for 'NEU 1170 H' comprise professional and non-professional field applications as a herbicide, using hand-held sprayer and watering can, for the control of monocotyledonous and dicotyledonous weeds, algae⁵ and mosses in paths and open areas with tree growth, woody ornamentals and decorative lawns, turf. The representative uses evaluated for 'COM 508 16 H EW' comprise non-professional field applications as a herbicide, using hand-held

⁵ Risk managers may wish to consider whether algae control is falling in the scope of Regulation (EC) No 1107/2009.

sprayer, for the control of monocotyledonous and dicotyledonous weeds, algae and mosses in paths and places with woody plants, ornamental shrubs, ornamentals and lawn. The representative uses evaluated for 'VVH 86 086/ BCP1004D' comprise professional field applications by spraying with tractor-mounted equipment as a desiccant for potato haulm, and as a herbicide against annual monocotyledonous and dicotyledonous weeds in vineyards. 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 pelargonic acid proposed at EU level result in a sufficient herbicidal efficacy as a non-selective herbicide against annual and perennial mono- and dicotyledonous weeds, potato haulms, grapevine sprouts, mosses and algae following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

Conclusions of the evaluation

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

The following guidance documents were followed in the production of this conclusion (European Commission 2000a,b, 2010, 2012).

The minimum purity of pelargonic acid technical material is 889 g/kg. The proposed specification is based on batch data from industrial scale production and on quality control (QC) data to support the specification for the impurities. Hexanoic acid, heptanoic acid and octanoic acid (caprylic acid) are considered relevant impurities, specified as a sum with a maximum specification of 50 g/kg (see Section 2). Based on the renewal data and the changes in the impurity profile and the food grade quality of the technical material (i.e. purity criteria as outlined in Regulation (EU) No 231/2012⁶ (E570 Fatty Acids, see also see Section 2), it is proposed to update the reference specification. An FAO specification does not exist for pelargonic acid.

The main data regarding the identity of pelargonic acid and its physical and chemical properties are given in Appendix B.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. A data gap was identified for validation data for the analytical method used in the n-octanol/water partition coefficient study (relevant for BCN Task Force, see Section 10). Methods of analysis are available for the determination of the active substance in the technical materials and in the representative formulations. For one of the sources of the BCN Task Force, a data gap was identified for validation data of the GC-MS method used for the determination of pelargonic acid in the technical material (see Section 10). Methods of analysis are available for the determination of the relevant impurities in the technical materials and in the representative formulation 'ABP-811'. Data gaps were identified for analytical method(s) for the determination of the relevant impurities in the plant protection products 'NEU 1170 H', 'VVH86086/BCP1004D' and 'COM 508 16 EW' (relevant for BCN Task Force), and in the plant protection product 'MON 74134' (relevant for the Pelargonic Acid Task Force) (see Section 10). Methods for the analysis of residues in food and feed of plant and animal origin, in body fluids, body tissues and the environment are not required as no residue definition was set.

2. Mammalian toxicity

The toxicological profile of the active substance pelargonic acid was discussed at the Pesticides Peer Review Experts' Meeting TC 48 in April 2021 and assessed based on the following guidance documents (European Commission, 2003, 2012; EFSA 2014; EFSA PPR Panel, 2012; ECHA, 2017).

The specification of pelargonic acid technical material is of food grade quality (i.e. purity criteria as outlined in Regulation (EU) No 231/2012⁶ (E570 Fatty Acids, see also Section 1), and therefore, the conclusions on mammalian toxicology apply only to pelargonic acid of food grade quality. EFSA noted that during the previous peer review, the compliance as food grade quality was not demonstrated (EFSA, 2013b).

The available toxicity studies indicated that pelargonic acid is unlikely to be genotoxic and is of low acute and short-term oral (NOAEL \geq 1,000 mg/kg body weight (bw) per day) toxicity to rats. Other toxicity studies including reproductive toxicity studies and long-term toxicity studies were not available and not required considering the nature of pelargonic acid (i.e. it being of food grade quality). The

⁶ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

only hazards of the different groups of fatty acids including pelargonic acid as plant protection products would be the irritation properties dependent on their chain length. On this basis, hexanoic acid, heptanoic acid and octanoic acid (caprylic acid) as impurities in the technical specification are relevant impurities (maximum content 5%, see Section 1).

In addition, the use of pelargonic acid as a food additive can be considered safe when using comparative assessment vs. other fatty acids (EFSA ANS Panel, 2017). Pelargonic acid is also approved as a food additive according to Commission Regulation (EU) No 872/2012⁷.

The majority of experts agreed that setting of reference values is not required, considering that the technical material pelargonic acid is of food grade quality and that the available studies do not raise toxicological concerns. Although a quantitative non-dietary risk assessment would be not triggered, the RMS performed an indicative quantitative risk assessment comparing the non-dietary exposure to pelargonic acid arising from the use as a plant protection product with normal dietary intakes of fatty acids (821 mg/kg bw per day). This assessment, under worst-case scenarios, indicates that the use as a plant protection product would not have an impact compared to normal dietary intakes.

3. Residues

The assessment in the residue section is based on the following guidance documents (OECD, 2009, 2011; European Commission, 2011; JMPR, 2004, 2007).

Metabolism studies in plants and animals were not necessary for pelargonic acid (nonanoic acid) which is a naturally occurring compound, of food grade quality and it does not raise toxicological concern for the consumer (see Section 2). A study on the natural presence of pelargonic acid was conducted in samples of lettuce, potatoes, oilseed rape, wheat and plums to investigate pelargonic acid levels in these commodities. Significant levels were only determined in oilseed rape (0.104 mg/kg in whole plant, 0.35 mg/kg in straw and 0.45 mg/kg in seed) and wheat (1.22 mg/kg in whole plant, 2.21 mg/kg in straw and 0.135 mg/kg in grain), while in the other crops investigated the levels were below the limit of quantification. Pelargonic acid is also approved as a food additive according to Commission Regulation (EU) No 872/2012.

The proposal to maintain pelargonic acid in Annex IV of Regulation (EC) No 396/2005 is supported.

4. Environmental fate and behaviour

Pelargonic acid was discussed at the Pesticides Peer Review Experts' TC 49 in April 2021.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil, pelargonic acid is expected to be degraded by microorganisms by a sequential elimination of C₂ fragments, indicating that major soil metabolites of the fatty acid pelargonic acid would be other fatty acids with shorter chains which further degrade to the final product CO₂. In soil laboratory incubations under aerobic conditions in the dark, pelargonic acid exhibited very low to low persistence. Mineralisation of the aniline ring ¹⁴C radiolabel to carbon dioxide accounted for 69–73% applied radioactivity (AR) after 7 days. The formation of unextractable residues (not extracted by acetonitrile/water) for this radiolabel accounted for 13–22% AR after 7 days. It was concluded that studies on degradation products were not required. Anaerobic conditions are not likely to occur for the intended uses of the products, i.e. application from spring through to autumn during the weed growing period on paths; places with woody plants, ornamental shrubs, lawns, vineyards and potatoes. Even if exposure to anaerobic conditions would occur, extensive biodegradation according to the same mechanisms as under aerobic would still be expected. Therefore, it was concluded that an anaerobic soil degradation study was not needed. Due to the fast microbial degradation of pelargonic acid under aerobic soil conditions, soil photolysis is not considered to be a relevant route of degradation.

Pelargonic acid exhibited very high to low mobility in soil. A relationship between the adsorption of pelargonic acid and soil pH was observed. It was agreed that the adsorption values to be used for soils with $pH_{CaCl_2} \leq 6.2$ would be 95 mL/g ($1/n = 1$), whilst for soils with $pH > 6.2$, it was agreed that a geometric mean value of 8.4 mL/g ($1/n = 0.987$) should be selected.

⁷ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC. OJ L 267, 2.10.2012, p. 1–161.

An aerobic mineralisation in surface water study or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur was not available. Neither was an aerobic sediment water study. However, a river die-away test that investigated biodegradation of several fatty acids in river water was available. Based on these data, the majority of the experts in the Pesticides Peer Review Experts' TC 49⁸ agreed that for pelargonic acid, the result for the C10 chain length (being the most representative result for pelargonic acid) should be selected. After normalisation to the reference temperature of 20°C, the resulting DT₅₀ value is 1.6 days, indicating low persistence. In the absence of a guideline sediment water system experiment becoming available, the majority of the experts agreed 1.6 days to be the best value to be used in predicted environmental concentration (PEC) calculations.

It is noted that the maximum background concentration in surface water monitoring was found to be 7.6 µg/L though, being mostly below the limit of quantification (LOQ) (= 5 µg/L).

For the representative uses, the necessary surface water and sediment exposure assessments (PEC calculations) were appropriately carried out using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the steps 1–2 in FOCUS calculator), and step 3 and step 4 approach where nozzle reduction, vegetative buffer strips and no spray buffer up to 20 m were implemented in simulations.

Risk managers and others may wish to note that surface water and sediment exposure assessment calculations for the representative use on ornamentals only cover plants less than 50 cm in height.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4.⁹ The potential for pelargonic acid groundwater exposure (80th percentile annual average recharge concentrations moving below 1 m) from the representative uses of the five representative formulations 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 when vulnerable aquifers occur under predominantly acidic soils.

For the formulation 'ABP-811' where vulnerable aquifers occur under predominantly alkaline soils, two out of seven scenarios exceeded the parametric drinking water limit of 0.1 µg/L (max 1.159 µg/L in Porto scenario) for the representative use on vines with 3 early (spring application) applications at 19.06 kg a.s./ha and one out of nine scenarios (0.221 µg/L in Jokioinen scenario) for the representative use on potatoes with 2 applications at 38.67 kg a.s./ha.

For the formulation 'MON 74134', being the intended use for spot treatment applications to lawn and garden, predicted environmental concentrations of pelargonic acid in soil were calculated at the application rate of 18.3 kg a.s./ha, but calculations with 10% and 5% spot treatment application rates were also provided. For the representative use on grass/alfalfa, used as a surrogate for the uses in home gardens and allotments, with eight applications at 18.3 kg a.s./ha for situations where vulnerable aquifers occur under predominantly alkaline soils, the potential for groundwater exposure by pelargonic acid above the parametric drinking water limit of 0.1 µg/L was exceeded for six out of nine scenarios L (max 13.29 µg/L in Jokioinen scenario) for grass/alfalfa spring application (8 × 18.3 kg a.s./ha) and for four out of nine scenarios for summer application (8 × 18.3 kg a.s./ha) (max 2.901 µg/L in Jokioinen). For alkaline soils, with a spot treatment of 8 × 0.915 kg a.s./ha, PEC_{GW} for pelargonic acid at 1 m soil depth were < 0.1 µg/L in all scenarios, except for Jokioinen (summer and spring application) and Piacenza (spring application). The potential for groundwater exposure from the representative uses by pelargonic 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 for the representative use in home gardens and allotments situations with eight applications at 0.915 kg a.s./ha (only alkaline soils were used in the modelling).

The potential for groundwater exposure from the representative uses by pelargonic acid above the parametric drinking water limit of 0.1 µg/L for the representative uses of the product 'COM 508 16 H EW' was concluded to be low for the representative uses in paths and places with woody plants, considering four early applications with 21-day interval in geoclimatic situations that are represented by all nine FOCUS groundwater scenarios except three out of nine scenarios for alkaline soil conditions. PEC_{GW} values were above the parametric drinking water limit of 0.1 µg/L in six out of nine scenarios considering four late applications with 21-day interval and in six out of nine scenarios with 30-day interval in Tier 2 (40% interception) (max. 1.687 µg/L Piacenza). For the representative use in ornamental shrubs, PEC_{GW} values were above the parametric drinking water limit of 0.1 µg/L in two

⁸ See experts' consultation 4.2 at the Pesticide Peer Review Teleconference 49 (EFSA, 2021).

⁹ Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7

out of seven scenarios considering four early applications (21- and 30-day interval) and for five out of seven scenarios considering four late applications (21- and 30-day interval) (max. 1.193 µg/L Piacenza). For applications to ornamentals (cabbage and onions used as surrogate), PEC_{GW} values were above the trigger for two out of seven scenarios when considering late applications and one out of six scenarios when considering early applications. For lawn (grass/alfalfa used as surrogate), PEC_{GW} values were below the trigger apart from the scenario Piacenza considering early (spring) application.

The estimations of concentrations in groundwater using different model calculations for 'NEU 1170 H' demonstrate that no exceedance of concentrations > 0.1 µg/L of the active ingredient pelargonic acid into groundwater is to be expected in most scenario locations in Tier 2 (40% interception) but two out of nine scenarios (late applications) and one out of nine (early application) in paths and open areas with tree growth (max. 0.840 µg/L Jokioinen), one out of seven scenarios in woody ornamentals and in one out of nine scenarios in decorative lawns, turf (early applications, Piacenza), all in alkaline soil conditions.

For the formulation 'VVH-86086/BCP1004D' and the representative uses in vineyards and potatoes, the PEC_{gw} values were below the parametric drinking water limit of 0.1 µg/L for all crops in all available FOCUS scenarios.

The applicant provided appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water. At the point of abstraction of surface water to produce drinking water, concentrations of pelargonic acid are expected to be low consequent to its partitioning to sediment and degrading in natural surface water. Any low level of pelargonic acid residue present in the surface water would be expected to be stable during the disinfection processes of ozonation and chlorination based on the scientific literature presented, so would not form transformation products.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix B. A key to the persistence and mobility class wording used, relating these words to numerical DT and Koc endpoint values can be found in Appendix C.

5. Ecotoxicology

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

Some specific aspects related to the environmental risk assessment of pelargonic acid were discussed in the Pesticide Peer Review Experts' Teleconference 51 in April 2021.

The assessment of the compliance of the batches used in the ecotoxicological studies and the proposed reference specification was supported (see also Section 2).

Ecotoxicity studies with pelargonic acid were available for **birds** and **mammals**.¹⁰ The risk to birds and wild mammals was discussed at the experts' meeting.¹¹ The experts noted that the residue concentrations of pelargonic acid measured in plant values were notably higher relative to natural background levels due to the high application rate in the proposed uses. However, a low acute and long-term risk to birds and wild mammals was concluded for all representative uses based on a qualitative weight-of-evidence approach that considered the following arguments (i) pelargonic acid is considered as being of food grade quality (see Section 2), (ii) it occurs naturally in food of birds and mammals and it is very similar to other fatty acids used in bird feed; therefore, it can be expected that birds and mammals are exposed to pelargonic acid through their diet, (iii) fatty acids are part of the metabolism of birds and mammals and (iv) pelargonic acid dissipates quickly in soil and water (see Section 4).

For **aquatic organisms**, standard toxicity data with the active substance were available with fish (acute and chronic), aquatic invertebrates (acute and chronic), algae and aquatic macrophytes. Several studies were also submitted with the formulated products except for the product 'ABP-11' (data gap, see Section 10).

During the peer review process, the validity of some of the studies with aquatic organisms was discussed.¹² Some of the experts noted that the derivation of endpoints for aquatic organisms is pH dependent; thus, Member States may pay particular attention to this when requesting further testing with pelargonic acid-based products for granting product authorisations at zonal level. Besides, some

¹⁰ Studies were considered not suitable to address the risk from pelargonic acid. For further information see Evaluation Table, open point 5.1 (EFSA, 2021).

¹¹ See experts' consultation point 5.1 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

¹² See experts' consultation points 5.2 and 5.3 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

of the studies were not considered suitable for Tier 1 risk assessment as the concentrations of the substance were not sufficiently maintained throughout the duration of the studies. Therefore, it was agreed that those studies can only be considered as toxicity studies with a refined exposure regime (Tier 2c)¹³; however, in the absence of the comparison of the exposure profile in the different tests and the relevant FOCUS exposure profiles, these studies could not be used for further refinement of the risk assessment (data gap, see Section 10).

All available data suggest that the aquatic risk assessment of pelargonic acid is driven by aquatic invertebrates and tier 1 risk assessment has been conducted as described below.

Low acute risk to fish and aquatic invertebrates as well as low chronic risk to fish, algae and aquatic plants was concluded for the representative use in lawn. For this use, high chronic risk to aquatic invertebrates was concluded following FOCUS Step 3 for the D1 scenario (1/7 FOCUS scenarios). Besides, for the use in decorative lawn, turf, high acute and chronic risk to fish and aquatic invertebrates as well as for algae have been identified for the scenarios D1 and D2 (2/7 FOCUS scenarios) at FOCUS Step 3. The risk to aquatic plants for the use in decorative lawn, turf was considered as low.

For the representative uses in paths and open areas with tree growth as well as between woody ornamentals, low acute risk was concluded for fish and aquatic invertebrates. Moreover, low chronic risk for algae and aquatic plants. However, high chronic risk to fish (D4) and aquatic invertebrates (D4, R2 and R4) at FOCUS Step 3 scenarios. By considering 10 m run-off reduction at FOCUS Step 4, the risk could be refined for aquatic invertebrates for both R scenarios, but not for the remaining scenario. Therefore, high chronic risk to fish and aquatic invertebrates (1/7 FOCUS scenarios) was concluded for such uses following four applications.

Low acute and chronic risk was concluded to all groups of aquatic organisms (fish, aquatic invertebrates, algae and aquatic plants) for the representative uses in paths and places with woody plants, ornamental and ornamental shrubs and for the use in home gardens and allotments.

For the use in potatoes as preharvest desiccant¹⁴ including one to two applications, high chronic risk to fish and aquatic invertebrates was concluded for the D6 and R3 scenarios (2/6 FOCUS scenarios) at FOCUS Step 4 as well as high acute risk to aquatic invertebrates for the D6 scenario (1/6 FOCUS scenarios) when two applications are conducted and the above-mentioned mitigation measures in place.¹⁵ For the representative uses in potatoes and vineyards and the use pattern with one to two applications when mitigation measures (20 m no spray zones and vegetative strips) are implemented, low risk could also be concluded to all aquatic organisms.¹⁶ Likewise, for the use of vineyards following three applications, the chronic risk was concluded as high for fish (1/5 FOCUS scenarios, R3 stream) and for aquatic invertebrates (4/5 FOCUS scenarios; all FOCUS scenarios except R1 pond) considering the application of mitigation measures (20 m no spray buffer and 20 m vegetative strip) for the early spring application. For the summer application, the risk could not be refined at FOCUS Step 4 by using the same mitigation measures, and therefore, high chronic risk was concluded for fish and aquatic invertebrates for the scenario D6 (1/5 FOCUS scenarios). Low risk to algae and aquatic plants was concluded for all the uses of pelargonic acid in potatoes and vineyards.

Acute (contact and oral) data on honey **bees** were available for pelargonic acid as well as for the representative formulations. Chronic studies for honey bee larvae were conducted for pelargonic acid and 'MON 74134', whereas chronic studies for adults were performed for 'COM 508 16 H EW' and 'MON 74134'. Two semi-field (tunnel) studies were available for 'COM 508 16 H EW' and 'NEU 1170 H' to refine the risk to honey bees. However, both studies presented several limitations (e.g. untreated plants or untreated sugar syrup and pollen supplement were offered as food sources) and were not considered suitable for refining the risk to honey bees.

Based on the SANCO guidance (European Commission, 2002a,b), low acute (oral and contact) risk could only be identified to honey bees for the uses with 'VVH-8086/BCP1004D' in potatoes and vineyards. For the rest of the uses, high acute oral and contact risk was concluded. The outcome of the

¹³ For further information, please see experts' consultation point 5.2 at the Pesticide Peer Review Teleconference 51 and Evaluation Table for pelargonic acid (experts' consultation 5.2) (EFSA, 2021). This is the case for the toxicity study with *Lemna sp.* that were not considered suitable for Tier 1 risk assessment. Tier 1 risk assessment for aquatic plants was conducted with *Myriophyllum sp.*

¹⁴ There are two uses in potatoes with one to two applications; however, the use as preharvest desiccant was conducted with product 'ABP-811' while the other use described below in the text refers to the use for the product 'VVH-8086/BCP1004D'.

¹⁵ When, for this use, one application is conducted, the same risks as for the two applications were identified but at FOCUS Step 2. For that use pattern, no refinement with FOCUS Step 3 was available.

¹⁶ Without the mitigation measure, high chronic risk was identified to aquatic invertebrates at FOCUS Step 3 (R3; 1/6 scenarios).

quantitative risk assessment following the EFSA (2013a) bee guidance indicated a high acute and/or chronic risk to honey bees for all the representative uses of pelargonic acid (Table 1). However, for the uses in home gardens and allotments, a low acute and chronic risk was concluded considering that (i) pelargonic acid causes extremely rapid and non-selective burn-down of green tissues (as revealed in the semi-field studies) rendering treated plants and flowering weeds unattractive to bees shortly after its application, and that (ii) application of the ready-to-use 'MON 74134' formulation normally is expected to cover part of the overall area.¹⁷ Also, for highly managed lawn and turf where mowing is routinely done, the experts considered that the 'treated crop' and 'flowering weeds in the treated crop' scenarios are not relevant.¹⁸ Therefore, a low chronic risk could also be concluded for such uses. For all the other uses, including less managed lawns/turf, mitigation measures might be needed. Appropriate measures should be considered at MS level and may need the provision of additional formulation-specific data since information showing the effectiveness of such measures was not provided.¹⁸

Exposure to plant metabolites throughout contaminated pollen and nectar has not been considered further as relevant metabolites of pelargonic acid were not identified. A suitable assessment for accumulative effects and sublethal effects (e.g. hypopharyngeal glands) was not available (data gap, see Section 10). A low risk was concluded from exposure to contaminated water (Table 1). No information was available on bumblebees and solitary bees.

Table 1: Outcome of the risk assessment for honey bees considering all relevant routes of exposure to pelargonic acid following the EFSA (2013a) bee guidance

Formulation	Use	Route of exposure (Scenario)				
		Contact	Acute	Oral		Contaminated water
				Larvae	Adult	
ABP-811	Vineyards	High (W)	High (W)	High (W)	High (W)	High (G) ^(c)
	Potatoes	High (W)	Low	High (W)	High (W)	High (G) ^(c)
MON 74134	Home gardens and allotments	High (W) ^(a)	High (W) ^(a)	High (W) ^(a)	High (W) ^(a)	Low
COM 508 16 H EW	Paths and places with woody plants, ornamentals, ornamental shrubs	High (W)	High (W)	High (W)	High (W)	Low
	Lawn ^(b)	High (T, W)	High (T, W)	High (T, W)	High (T, W)	High (G) ^(c)
NEU 1170 H	Paths and open areas with tree growth, woody ornamentals	High (W)	High (W)	High (W)	High (W)	Low
	Decorative lawns, turf ^(b)	High (T, W)	High (T, W)	High (T, W)	High (T, W)	High (G) ^(c)
VVH-86086/ BCP1004D	Vineyards	Low	Low	High (W)	High (W)	High (G) ^(c)
	Potatoes	Low	Low	High (W)	High (W)	High (G) ^(c)

G: 'Guttation fluid' scenario. T: 'Treated crop' scenario. W: 'Flowering weeds in the treated field' scenario.

(a): A low risk was concluded following a qualitative weight-of-evidence approach.

(b): At the Pesticide Peer Review Teleconference 51, the experts agreed that the 'treated crop' and 'in-field weeds' scenarios are only relevant for less managed lawns/turf and not for highly managed lawns/turf (see experts' consultation 5.5; EFSA, 2021).

(c): A low risk was concluded considering the mode of action of pelargonic acid.

For **non-target arthropods** (NTAs), tier 1 (glass plate) and/or extended laboratory studies on the standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri* were available with the representative formulations. Additionally, extended assays with *Aleochara bilineata*, *Chrysoperla*

¹⁷ See experts' consultation point 5.6 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

¹⁸ See experts' consultation point 5.5 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

carnea, *Orius laevigatus* and *Poecilus cupreus* were submitted for some formulations. Based on the available studies and risk assessment, a low in-field risk was concluded for the uses of 'NEU 1170 H' on paths and open areas with tree growth, woody ornamentals, decorative lawns and turf, and for the uses of 'VVH-8086/BCP1004D' on vineyards and potatoes. A high in-field risk was indicated for all the uses with 'ABP-811' and 'MON 74134'. A low off-field risk was concluded for all the representative uses. However, for the uses of 'COM 508 16 H EW' in paths and places with woody plants, ornamentals and ornamental shrubs and lawn, and of 'VVH-8086/BCP1004D' in vineyards, a low risk was identified provided that mitigation measures up to equivalent to 5 m no-spray buffer zone or 50% drift reduction are implemented (see Section 8).

Suitable chronic toxicity studies with **earthworms** were conducted with pelargonic acid and all the representative formulations. Toxicity/exposure ratios using the lowest endpoint between the active substance and the respective formulation were below the trigger value, indicating a high risk for all representative uses. However, for the uses in home gardens and allotments with 'MON 74134', a low risk was concluded based on a qualitative weight-of-evidence approach that took into account (i) the localised spot application, (ii) the fact that the product has a limited pack size and is a ready-to-use trigger spray; and (iii) the fast degradation of pelargonic in soil (half-life of 1.6 days).¹⁹ For **soil macroorganisms other than earthworms**, a high chronic risk was concluded for all representative uses except for the home and garden uses (by using the same lines of evidence as for the risk assessment to earthworms) and the uses on potatoes with both 'ABP-811' and 'VVH-86086/BPC1004D' based on the outcome of a soil mesofauna field study.²⁰ A low risk to **soil microorganisms** was concluded for all the representative uses.

The risk to **non-target terrestrial plants** was concluded as low for all the representative uses. For the uses of 'COM 508 16 H EW' in paths, places with woody plants, ornamentals and ornamental shrubs, mitigation measures are needed equivalent to 5 m no-spray buffer zone (see Section 8). A study was not available for assessing the effects of pelargonic acid to organisms involved in **sewage treatment processes**; however, considering the ready biodegradability of pelargonic acid, a low risk was concluded.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of fatty acids – pelargonic acid for **humans** and **non-target organisms** according to the ECHA/EFSA guidance (2018), no (eco)toxicological data are available to assess the endocrine-disrupting properties. However, this does not appear scientifically necessary since (i) the substance is ubiquitous in the environment, (ii) the use of pelargonic acid as a food additive can be considered safe when using comparative assessment versus other fatty acids (EFSA ANS Panel, 2017) and pelargonic acid is considered as having the same food grade quality (see Sections 1 and 2), (iii) there is a recognised high dietary intake for both humans and non-target organisms, for which exposure through its use as a pesticide is considered of not having a significant impact and (iv) the active substance shows a low toxicity profile in the available toxicology data package which support the waiver for studies of general toxicity. In addition, there is negative evidence of endocrine mediated activity for both thyroid (T)- and oestrogen, androgen and steroidogenesis (EAS)-mediated activity in ToxCast, also supported by the negative outcome from *in silico* QSAR applications.²¹

Considering the above, it can be concluded that pelargonic acid does 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) 2018/605²².

¹⁹ See experts' consultation 5.8 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

²⁰ See experts' consultation 5.7 and 5.8 at the Pesticide Peer Review Teleconference 51 (EFSA, 2021).

²¹ See experts' consultation 5.9 in the Pesticide Peer Review Teleconference report 51 (EFSA, 2021) and experts' consultation 2.4 in the Pesticide Peer Review Teleconference report 48 (EFSA, 2021).

²² 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
Pelargonic acid	High risk to soil organisms except for the home and garden uses

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
Pelargonic acid	Yes (for some scenarios)	Yes	–	–	Yes

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

(b): FOCUS scenarios or relevant lysimeter.

Table 4: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Pelargonic acid	High risk to aquatic organisms identified for several uses.

Table 5: Air

Compound (name and/or code)	Toxicology
Pelargonic acid	Low acute inhalation toxicity in rats, LC ₅₀ > 5 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

Representative use	Vineyards	Vineyards	Potato	Potato	Paths and places with woody plants	Paths and places with woody plants	Ornamental shrubs	Ornamental shrubs	Ornamentals	Lawn	Home gardens and allotments	Paths and open areas with tree growth	Paths and open areas with tree growth	Woody ornamentals	Decorative lawns, turf
	ABP-811	VVH-86086/BCP10 04D	ABP-811	VVH-86086/BCP10 04D	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW	COM 508 16 H EW	MON 74134	NEU1 170H (weeds)	NEU1 170H (algae, mosses)	NEU1170H	NEU1170H
Risk to aquatic organisms	20 m no spray zones and vegetative strips	20 m no spray zones and vegetative strips	20 m no spray zones and vegetative strips	20 m no spray zones and vegetative strips								10 m run-off reduction ^(c)	10 m run-off reduction ^(c)	10 m run-off reduction ^(c)	
Risk to bees	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^(a)		RMM ^(a)	RMM ^(a)	RMM ^(a)	RMM ^{(a)(b)}
Risk to non-target arthropods other than bees		RMM equivalent to 5 m no-spray buffer zone or 50% drift reduction			RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction	RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction	RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction	RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction	RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction	RMM equivalent to 5 m no-spray buffer zone or 10% drift reduction					

Representative use	Vineyards	Vineyards	Potato	Potato	Paths and places with woody plants	Paths and places with woody plants	Ornamental shrubs	Ornamental shrubs	Ornamentals	Lawn	Home gardens and allotments	Paths and open areas with tree growth	Paths and open areas with tree growth	Woody ornamentals	Decorative lawns, turf
		ABP-811	VVH-86086/BCP10 04D	ABP-811	VVH-86086/BCP10 04D	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW	COM 508 16 H EW	MON 74134	NEU1 170H (weeds)	NEU1 170H (algae, mosses)	NEU1170H
Risk to non-target terrestrial plants					RMM equivalent to 5 m no-spray buffer zone	RMM equivalent to 5 m no-spray buffer zone	RMM equivalent to 5 m no-spray buffer zone	RMM equivalent to 5 m no-spray buffer zone	RMM equivalent to 5 m no-spray buffer zone						

- (a): Appropriate measures should be considered at zonal and national level and may need the provision of additional formulation-specific data since information showing the effectiveness of such measures was not provided.
- (b): Except for highly managed lawn and turf (see Section 5).
- (c): only addressing the R 2 and R4 scenarios.

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 546/2011²³ and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

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

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

Issues not finalised were not identified.

9.2. Critical areas of concern

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

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

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

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

Critical areas of concern were not identified.

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.)

²³ 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.

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 use		Vineyards	Vineyards	Potato	Potato	Paths and places with woody plants	Paths and places with woody plants	Ornamental shrubs	Ornamental shrubs	Ornamentals	Lawn	Home gardens and allotments	Paths and open areas with tree growth	Paths and open areas with tree growth	Woody ornamentals	Decorative lawns, turf
		ABP-811	VVH-86086/BCP1004D	ABP-811	VVH-86086/BCP1004D	COM 508 16 H EW 21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW	COM 508 16 H EW	MON 74134	NEU1 170H (weeds)	NEU1 170H (algae, mosses)	NEU1 170H	NEU1170H
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 ^(d)	X ^(c)	X ^(d)	X ^(d)	X ^(d)	X ^(d)	X ^(d)	X ^(d)	X ^(d)	X ^(e)	X ^(d)	X ^(d)	X ^(d)	X ^(d)
	Assessment not finalised															

Representative use		Vineyards	Vineyards	Potato	Potato	Paths and places with woody plants	Paths and places with woody plants	Ornamental shrubs	Ornamental shrubs	Ornamentals	Lawn	Home gardens and allotments	Paths and open areas with tree growth	Paths and open areas with tree growth	Woody ornamentals	Decorative lawns, turf
		ABP-811	VVH-86086/BCP1 004D	ABP-811	VVH-86086/BCP1 004D	COM 508 16 H EW 21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW (21 days interval)	COM 508 16 H EW (30 days interval)	COM 508 16 H EW	COM 508 16 H EW	MON 74134	NEU1 170H (weeds)	NEU1 170H (algae, mosses)	NEU1 170H	NEU1170H
Risk to aquatic organisms	Risk identified	$\chi^{(f),(g),(i)}$ 1/5 FOCUS scenarios $\chi^{(f),(g),(i)}$ 4/5 FOCUS scenarios		$\chi^{(f),(g)}$ 2/6 FOCUS scenarios							$\chi^{(g)}$ 1/7 FOCUS scenarios		$\chi^{(f),(g)}$ 1/7 FOCUS scenarios	$\chi^{(f),(g)}$ 1/7 FOCUS scenarios	$\chi^{(f),(g)}$ 1/7 FOCUS scenarios	$\chi^{(f),(g),(h)}$ 2/7 FOCUS scenarios
	Assessment not finalised															
Groundwater exposure to active substance	Legal parametric value breached	2/7 FOCUS, early appl., alkaline soils		1/9 FOCUS scenarios, alkaline soils		3/9, 6/9 FOCUS scenarios, early and late appl. resp., alkaline soils	6/9 FOCUS scenarios, late appl., alkaline soils	2/7, 5/7 FOCUS scenarios, early and late appl. resp., alkaline soils	2/7 5/7 FOCUS scenarios, early and late appl. resp., alkaline soils	1/6, 2/7 FOCUS scenarios, early and late appl. resp., alkaline soils	1/9 FOCUS scenarios, early appl., alkaline soil	6/9, 4/9 FOCUS scenarios, early and late application resp., alkaline soils*	1/9, 2/9 FOCUS scenarios early and late appl. resp., alkaline soils	1/9, 2/9 FOCUS scenarios early and late appl. resp., alkaline soils	1/7 FOCUS scenarios, early appl., alkaline soils	1/9 FOCUS scenarios, early appl., alkaline soils
	Assessment not finalised															
Groundwater exposure to metabolites	Legal parametric value breached ^(a)															
	Parametric value of 10 µg/L ^(b) breached															
	Assessment not finalised															

See also Sections 2–7 for further information.

*: For alkaline soils, with a spot treatment of 8×0.915 kg a.s./ha, PEC_{gw} for pelargonic acid at 1 m soil depth were below 0.1 µg/L in all model/scenario combinations, except for Jokioinen (summer and spring application) and Piacenza (spring application).

- (a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
- (b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003).
- (c): Risk identified to bees, non-target arthropods and soil organisms.
- (d): Risk identified to bees (except for highly-managed lawn and turf) and soil organisms.
- (e): Risk identified to non-target arthropods.
- (f): Risk identified to fish.
- (g): Risk identified to aquatic invertebrates.
- (h): Risk identified to algae.
- (i): For the summer application only.
- (j): For the spring application only.

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:

- Applicant to provide validation data according to SANCO/3029/99 for the analytical method used in the n-octanol/water partition coefficient study for the determination of pelargonic acid in n-octanol and aqueous solutions (relevant for BCN Task Force, see Section 1).
- Applicants to provide analytical method(s) for the determination of the relevant impurities heptanoic acid, hexanoic acid and octanoic acid in the plant protection products 'NEU 1170 H', 'VVH86086/ BCP1004D' and 'COM 508 16 EW' (relevant for BCN Task Force, see Section 1).
- Applicant to provide analytical method for the determination of the relevant impurities heptanoic acid, hexanoic acid and octanoic acid in the plant protection product 'MON 74134' (relevant for Pelargonic Acid Task Force, see Section 1).
- Applicant to provide validation data according to SANCO 3030/99 rev. 4 (linearity, precision and specificity) for the GC-MS method used for the determination of pelargonic acid in the 5-batch analysis study in one of the sources of the BCN Task Force (relevant for BCN Task Force, see confidential evaluation table and Section 1).
- Ecotoxicity studies for aquatic organisms with the formulation 'ABP-11' were not available (relevant for the uses with ABP-11 in potatoes and vineyards, see Section 5).
- The comparison of exposure profiles to conduct a tier 2C risk assessment was not available; therefore, further data to address the risk to aquatic organisms are necessary (relevant for the uses with 'ABP-11' in potatoes and vineyards, the use with 'COM 508 16 H EW' in lawn; the use with 'NEU1170H' in paths and open areas with tree growth, between woody ornamentals and in decorative lawns, turf; see Section 5).
- Further data were not available to address the risk to honeybees from sublethal effects (e.g. effects on hypopharyngeal glands) (relevant for all representative uses, see Section 5).

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Abbreviations

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
a.s.	active substance
ADE	actual dermal exposure
AF	assessment factor
AR	applied radioactivity
AR	androgen receptor
AST	aspartate aminotransferase (SGOT)
AUC	area under the blood concentration/time curve
AV	avoidance factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary cells
CI	confidence interval
CL	confidence limits
DAR	draft assessment report
DAT	days after treatment
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)
EAS	oestrogen, androgen and steroidogenesis modalities
ECHA	European Chemicals Agency
EEC	European Economic Community
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
GAP	Good Agricultural Practice
GC	gas chromatography
GM	geometric mean
GS	growth stage
HR	hazard rate
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
LC	liquid chromatography
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
M/L	mixing and loading
mm	millimetre (also used for mean measured concentrations)

MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PHI	preharvest interval
PIE	potential inhalation exposure
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure–activity relationship
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
SC	suspension concentrate
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TK	technical concentrate
TWA	time-weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WHO	World Health Organization

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

Properties		Conclusion ^(a)
CMR	Carcinogenicity (C)	Not classified (Harmonised classification according to Regulation (EC) No 1272/2008).
	Mutagenicity (M)	Not classified (Harmonised classification according to Regulation (EC) No 1272/2008).
	Toxic for Reproduction (R)	Not classified (Harmonised classification according to Regulation (EC) No 1272/2008).
Endocrine-disrupting properties		Pelargonic acid does 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
POP	Persistence	Pelargonic acid is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Long-range transport	
PBT	Persistence	Pelargonic acid is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	
	Toxicity	
vPvB	Persistence	Pelargonic acid is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.
	Bioaccumulation	

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

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

Appendix B can be found in the online version of this output ('Supporting information' section):
<https://doi.org/10.2903/j.efsa.2021.6813>

Appendix C – 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 ^(a) 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–< 10 days
Moderate persistence	10–< 60 days
Medium persistence	60–< 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

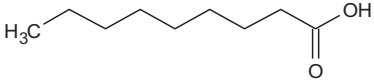
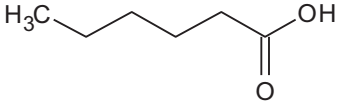
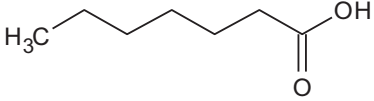
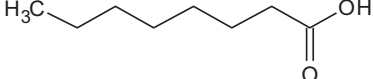
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

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

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

Based on McCall et al. (1980).

Appendix D – Used compound codes

Code/trivial name ^(a)	IUPAC name/SMILES notation/ InChiKey ^(b)	Structural formula ^(c)
Pelargonic acid	Nonanoic acid O=C(O)CCCCCCCC FBUKVWPVBMHYJY-UHFFFAOYSA-N	
Hexanoic acid	Hexanoic acid CCCCCC(=O)O FUZZWVXGSFPMH-UHFFFAOYSA-N	
Heptanoic acid	Heptanoic acid CCCCCCC(=O)O MNWFXJYAOYHMED-UHFFFAOYSA-N	
Octanoic acid (caprylic acid)	Octanoic acid O=C(O)CCCCCCC WWZKQHOCKIZLMA-UHFFFAOYSA-N	

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

(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N50E41, Build 110555, 18 July 2019).

(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H411, Build 110712, 24 July 2019).