CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance (3*E*)-dec-3-en-2-one

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, the Netherlands, for the pesticide active substance (3*E*)-dec-3-en-2-one 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 Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative post-harvest use of (3*E*)-dec-3-en-2-one on potato as a sprouting inhibitor applied by hot fogging in potato storage rooms. The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are reported where identified.

Keywords: (3*E*)-dec-3-en-2-one, peer review, risk assessment, pesticide, plant growth regulator, MRL review

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Summary

(3*E*)-dec-3-en-2-one is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), the Netherlands, received an application from AMVAC Netherlands B.V. on 11 April 2017 for approval. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 29 August 2017.

An initial evaluation of the dossier on (3*E*)-dec-3-en-2-one was provided by the RMS in the draft assessment report (DAR), and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The post-harvest use of (3*E*)-dec-3-en-2-one, according to the representative use proposed at EU level, as sprouting inhibitor on potato applied by hot fogging in potato storage rooms with climate control[1] results in a sufficient sprout control in potatoes.

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 and chemical properties** and **analytical methods**.

In the section of **mammalian toxicology**, a data gap was identified for the genotoxicity potential and general toxicity of metabolite M 528, tentatively identified as 3-decen-2-ol (free and conjugated) which is linked to the consumer risk assessment that cannot be finalised.

For the section of **residues,** several data gaps were identified that prevented from concluding on the residue definitions in plant and animal matrices. Consequently, consumer risk assessment could not be finalised. Inclusion of the active substance into Annex IV of Regulation (EC) No 396/2005 has also been considered. It has been concluded that criteria for inclusion of (3*E*)-dec-3-en-2-one into Annex IV of Regulation (EC) No 396/2005 are currently not met.

The data available on **environmental fate and behaviour** are sufficient to carry out the required environmental exposure assessments at EU level for the representative use. However, the consumer risk assessment could not be finalised as information was not available regarding the effect of water treatment processes on the nature of residues of the (3*E*)-dec-3-en-2-one that might be present in ground and surface water, when ground and surface water are abstracted for the production of drinking water. For the indirect route of exposure from the application of sewage sludge originating from Sewage Treatment Plant, there is the critical area of concern that the potential for groundwater exposure above the parametric drinking water limit of 0.1 μg/L was assessed as high for the active substance (3*E*)-dec-3-en-2-one in the situations represented by nine out of the nine FOCUS groundwater scenarios.

In the section of **ecotoxicology,** 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.

Based on the available information, it can be concluded that (3*E*)-dec-3-en-2-one is unlikely to 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] Temperatures of 7.5–9°C.

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[2] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (The Netherlands), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

(3*E*)-dec-3-en-2-one is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, the Netherlands (hereinafter referred to as the 'RMS'), received an application from AMVAC Netherlands B.V. on 11 April 2017 for approval of the active substance (3*E*)-dec-3-en-2-one. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005[3]. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 29 August 2017.

The RMS provided its initial evaluation of the dossier on (3*E*)-dec-3-en-2-one in the DAR, which was received by EFSA on 7 November 2019 (The Netherlands, 2019). The peer review was initiated on 28 July 2020 by dispatching the DAR to the Member States and the applicant, AMVAC Netherlands B.V., for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant 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 applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 14 December 2020. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues and ecotoxicology (for the latter area, to discuss the ED potential for non-target organisms only).

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

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

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether (*E*)-3-decen-2-one can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation.

A final consultation on the conclusions arising from the peer review of the risk assessment and 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 October 2022.

[2] 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, pp. 1–50.

[3] 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, pp. 1–16.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative post-harvest use of (3*E*)-dec-3-en-2-one on potato as sprouting inhibitor applied by hot fogging in potato storage rooms with climate control[1] as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the DAR and considered during the peer review, if any, are presented in the conclusion.

In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV proposal, if any, from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required.

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 (3*E*)-dec-3-en-2-one according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2022), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR;
- the reporting table (14 December 2020);
- the evaluation table (07 October 2022);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (The Netherlands, 2022), 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 formulation for representative use

The active substance (3*E*)-dec-3-en-2-one (IUPAC) has no ISO common name. The evaluated formulation for representative use was 'SmartBlock', a hot fogging concentrate (HN) containing 980 g/kg (3*E*)-dec-3-en-2-one. (3*E*)-dec-3-en-2-one is a naturally occurring (fruits, juices, spices, vegetables, coffee and tea) acyclic aliphatic ketone that is also used as a food flavouring.

The representative use evaluated comprises post-harvest application on potato as a sprouting inhibitor applied by hot fogging in climate-controlled potato storage rooms. Full details of the representative EU use can be found in the list of end points in Appendix B.

Data were submitted to conclude that the representative post-harvest use of (3*E*)-dec-3-en-2-one proposed at EU level results in a sufficient sprouting control on potatoes stored in rooms with climate control,[1] following the guidance document SANCO/10054/2013-rev. 3 (European Commission, 2013).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

Conclusions of the evaluation

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

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

The proposed common reference specification for (3*E*)-dec-3-en-2-one was based on batch data from industrial scale production from each manufacturing source and supported by quality control (QC) data. The proposed minimum purity of the active substance as manufactured is 980 g/kg. An FAO specification does not exist for (3*E*)-dec-3-en-2-one. The batches used in the (eco)toxicological assessment support the proposed reference specification (See Sections 2 and 5).

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 (3*E*)-dec-3-en-2-one or the representative formulation. The main data regarding the identity 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. Sufficient analytical methods are available for the determination of (3*E*)-dec-3-en-2-one in the technical material and in the formulation for representative use as well as for the determination of the respective impurities in the technical material. (3*E*)-dec-3-en-2-one residue can be monitored in high water content commodities using a gas chromatography with tandem mass spectroscopy (GC–MS/MS) method with a limit of quantification (LOQ) of 0.01 mg/kg. No method(s) were provided for monitoring residues of (3*E*)-dec-3-en-2-one in dry, high acid and high oil content commodities (data gap, see Section 10). In addition, no data were provided to address the extraction efficiency of the procedure used in the monitoring method for high water content commodities (data gap, see Section 10). Extraction efficiency was also not verified for dry, high acid and high oil content commodities. However, a data gap to demonstrate extraction efficiency in these commodities was not set considering the representative use and lack of metabolism studies. Pending on the final residue definition for monitoring residues in food of animal origin (see Section 3), analytical methods might be required. (3*E*)-dec-3-en-2-one residue in soil can be monitored by GC–MS/MS with an LOQ 0.01 mg/kg. (3*E*)-dec-3-en-2-one residue in drinking and surface water can be monitored by GC–MS with LOQs 0.1 μg/L. A GC–MS method exists for monitoring of (3*E*)-dec-3-en-2-one in air with a limit of quantification (LOQ) of 0.1 mg/m^3. (3*E*)-dec-3-en-2-one residues in body fluids and tissues can be determined using a GC–MS/MS method with an LOQ of 0.01 mg/kg in body tissues and with LOQs of 0.01 mg/L in blood and urine.

2. Mammalian toxicity

The toxicological profile of the active substance (3*E*)-dec-3-en-2-one was discussed at the Pesticides Peer Review Experts' Meeting teleconference (TC) 73 in April 2022 and assessed based on the following guidance documents: European Commission, 2012; EFSA, 2014; EFSA PPR, 2012; ECHA, 2017b.

The toxicological profile of (3*E*)-dec-3-en-2-one relied on toxicity studies performed with test material which is not representative of the reference specification. The toxicological relevance of the impurities is assessed by QSAR analysis. Based on these data, no toxicological relevant impurities were identified; therefore, the proposed reference specification is acceptable from a toxicological point of view and it can be considered as covered by the test material used in the toxicity studies.

In the toxicokinetic and metabolism study in rats, the **oral bioavailability** of (3*E*)-dec-3-en-2-one is approximately 91%. The active substance is extensively and rapidly metabolised with up to 10 metabolites detected (but not characterised). As reported in the recently published EFSA Scientific Opinion of the Panel on Food Additives and Flavourings (EFSA FAF Panel, 2022), the main metabolic pathway expected for aliphatic ketones with chain length higher than five carbon atoms, such as (3*E*)-dec-3-en-2-one, would be the reduction of the carbon–carbon double bond and/or carbonyl function, followed by conjugation to glucuronic acid and excretion via urine. Though a comparative *in vitro* metabolism study is not available for (3*E*)-dec-3-en-2-one, a waiver has been accepted[4] based on the authorised use of the substance as food flavouring[5] and on the low toxicity of the active substance.

(3*E*)-dec-3-en-2-one has low **acute toxicity** when administered via oral and dermal routes and moderate toxicity when administered by inhalation to rats. (3*E*)-dec-3-en-2-one is classified as **Acute Tox. 4 (H332)** and **Skin Irrit. 2 (H315)** (RAC, 2022).[6] Phototoxicity study is not required considering that the substance does not absorb electromagnetic radiations in the range 290–700 nm.

[4] Experts' consultation 2.1 of the Pesticides Peer Review Experts' Meeting report 73 (April 2022).

[5] [FL-no: 07.121], see Annex I of Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods.

[6] 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, pp. 1–1355.

Considering the natural occurrence of (3*E*)-dec-3-en-2-one in food, the use as food flavouring and the relatively low oral toxicity of structurally similar compounds, a waiver has been accepted for **short-term** and **long-term toxicity** studies. In a 5-day inhalation toxicity study in rats, a no observed adverse effect concentration (NOAEC) of 139 μg/L (corresponding to an internal dose of 27 mg/kg body weight (bw) per day) has been established on the basis of reduced body weight, food consumption and microscopic findings in the respiratory tract, while increased lung weight and macroscopic finding in the lung are observed at higher dose(s).

Based on the available **genotoxicity** studies, (3*E*)-dec-3-en-2-one is unlikely to be genotoxic.[7]

In the **developmental toxicity** study in rats, there is no evidence of teratogenicity, and the relevant maternal no observed adverse effect level (NOAEL) is 300 mg/kg bw per day based on reduced body weight gain. The developmental NOAEL is 1,000 mg/kg bw per day (the highest dose tested). No indication of reproductive toxicity has been observed in the developmental toxicity study and no further reproductive studies were considered needed. (3*E*)-dec-3-en-2-one did not show potential for neurotoxicity and immunotoxicity in standard toxicity studies.

The agreed **acceptable daily intake** (ADI) for (3*E*)-dec-3-en-2-one is 0.5 mg/kg bw per day, on the basis of the maternal NOAEL of 300 mg/kg bw per day for decreased body weight gain at 1000 mg/kg bw per day in the developmental toxicity study in rats and applying an uncertainty factor (UF) of 600 to account for subacute to chronic exposure extrapolation. The **acute reference dose** (ARfD) is not required.

The **acceptable operator exposure concentration** (AOEC) is 1.39 mg/m^3, on the basis of the NOAEC of 139 μg/L for reduction of body weight and food consumption at 278 μg/L in the 5-day inhalation toxicity study in rats, applying an UF of 100. The corresponding acceptable operator exposure level (AOEL) was calculated to be 0.27 mg/kg bw per day, with no correction for oral absorption.[8] The **acute acceptable operator exposure level** (AAOEL) is 0.27 mg/kg bw, same as AOEL, as the effects occurred within the 5 days of exposure.

A dermal absorption value of 25% (default value) has been proposed for the representative formulation SmartBlock (hot fogging concentrate). With regard to non-dietary exposure estimates for the representative use,[9] the **operator** exposure is below the (A)AOEL for dermal exposure (based on RISKOFDERM), while the recommendation to use respiratory protective equipment is considered to be sufficiently protective during the insertion of the intake hose of the thermal fog generating equipment into the container with the product. For **residents** and **bystanders**, a first field study provided indoor measured air concentrations which, combined with models, provided predicted values for 100 m distance from the storage facility. These values were considerably lower than actual measured values at 100 m in a second field study and thus considered under-predictive. In the second field study, exposure estimates were predicted based on air concentrations measured at 10, 50 and 100 m from the storage facility, and amounted up to 249, 7.2 and 13.4% of AAOEL, respectively, in bystander children. With default DT_{50} of 30 days, a minimum of 30 days is necessary to reach exposure estimates below AAOEL for bystander children at a distance of 10 m from the storage facility. **Worker** exposure estimates were based on different field studies for dermal and inhalation exposure. During **inspection activities,** the measured exposure is below the AOEL with use of gloves. During the task '**removal of potatoes'**, the measured exposure by inhalation is below the AOEL without use of respiratory protective equipment (RPE) for an activity not exceeding a duration of 2 h. Considering the use of mechanical methods for the removal of potatoes, dermal exposure is expected not to contribute significantly to the exposure estimates.

Regarding metabolites found as residues (see Section 3), the assessment was based on QSAR analysis and literature data on structurally similar compounds that are also approved active substance (i.e. 1-decanol) and authorised for use as food flavouring substance (i.e. 2-decanone). Based on this information, the toxicological profiles of **2-decanone** and **2-decanol** were considered covered by the toxicological reference values of the parent compound.

3-decen-2-ol was (tentatively) identified as major plant metabolite based on the result of a newly submitted study (see Section 3). A data gap for genotoxicity potential and general toxicity has been identified (see Section 9).

[7] Experts' consultation 2.2 of the Pesticides Peer Review Experts' Meeting report 73 (April 2022).
[8] Experts' consultation 2.5 of the Pesticides Peer Review Experts' Meeting report 73 (April 2022).
[9] Experts' consultation 2.6 of the Pesticides Peer Review Experts' Meeting report 73 (April 2022).

3. Residues

The residues section for the active substance (3*E*)-dec-3-en-2-one was discussed at the Pesticides Peer Review Experts' Meeting TC 76 in May 2022. The assessment in the residue section is based on the following guidance documents: OECD, 2009, 2011, European Commission, 2011 and JMPR, 2004, 2007.

No standard metabolism study in plants was initially available. Instead, applicant submitted a scientific publication and one non-guideline compliant mass balance study where the metabolites 2-decanone and 2-decanol were identified after post-harvest treatment with (3*E*)-dec-3-en-2-one. Besides (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol, other residues were present in potato peel in larger quantities, which triggered the request of further metabolism data.

A new metabolism study was required and submitted in which potatoes were treated post-harvest by fogging with radiolabelled (3*E*)-dec-3-en-2-one. Besides the parent (3*E*)-dec-3-en-2-one, metabolites 2-decanone, 2-decanol and M528, tentatively identified as 3-decen-2-ol, were identified as major residue components in free and glucoside conjugated forms. The study was considered not fully guideline compliant in terms of dosing rate (0.3 N compared with the representative good agricultural practice (GAP)), number of applications (1 instead of 4) and the level of identification/characterisation was around 60%. Since the identification rate for major fractions was insufficient, a data gap was identified for the applicant to undertake all the analytical attempts to characterise and identify the unknown radioactive residues in potato rinse, peel and pulp (see Section 9). Based on the available information in metabolism studies, the experts agreed to propose provisionally the residue definition for the risk assessment as the sum of (3*E*)-dec-3-en-2-one, 2-decanone and 2-decanol (free and conjugated) and 3-decen-2-ol (free and conjugated), expressed as (*E*)-3-decen-2-one pending the toxicological assessment of metabolite 3-decen-2-ol (free and conjugated) (see data gap in Section 2). For monitoring, parent compound is considered as a valid marker of the total residues from the metabolism study and the available GAP-compliant residue trials. The residue definitions are restricted to root crops following post-harvest treatment in storage.

Conversion from (3*E*)-dec-3-en-2-one, the *trans*-stereoisomer, to its *Z*(*cis*) counterpart was not observed in available studies.

Although no standard storage stability studies were submitted, the data provided were conducted within the time and condition to avoid the volatilisation and degradation of residues.[10]

Five residue trials are available but not analysed according to residue definition for risk assessment (free and conjugated 3-decen-2-ol was not analysed). A data gap was identified for a complete data set of eight GAP-compliant residue trials considering specifically the precautionary measures to avoid volatilisation and storage stability issues and analysing for all the compounds in the residue definition for risk assessment (once it can be concluded after missing data become available, i.e. toxicological assessment of plant metabolite 3-decen-2-ol) (see Sections 2 and 9).

Provisional dietary burden calculations exceeding the trigger value of 0.004 mg/kg bw per day were available. This needs to be revised according to the final risk assessment residue definition and the submission of the requested residue trials (data gap in Section 10). A data gap has been identified for animal metabolism studies to elucidate the metabolic pattern and residue definitions in animal matrices and a potential carry-over of the relevant residues to products of animal origin (see Section 9).

As regards the nature of residues in fish, although triggered, it was not investigated (data gap in Section 10). Pending the data from the nature of residues, residue trials in fish used for human consumption might be needed (data gap in Section 10).

Fate and behaviour assessment concluded that exposure of agricultural soils, due to the representative use as result of the application of sewage sludge, is significant (see Section 4). Consequently, a data gap has been identified to provide further information on possible residues of (3*E*)-dec-3-en-2-one and its metabolites above background levels in crops planted in soils where sewage sludge with residues of (3*E*)-dec-3-en-2-one is applied (see Section 10).

The nature of (3*E*)-dec-3-en-2-one under standard hydrolysis condition was investigated showing it is stable. Processing trials are available, but they were not sufficient to propose reliable processing factors (data gap in Section 10).

An indicative consumer dietary intake was performed by using EFSA Primo (version 3.1), the proposed ADI and the results from the available residue trials. For the chronic assessment, the

[10] Experts' consultation 3.4 of the Pesticides Peer Review Experts' Meeting report 76 (May 2022).

highest TMDI accounted for 5% of the ADI (PT general). This calculation is provisional pending the addressing of the data gap set above. It is acknowledged that (3*E*)-dec-3-en-2-one may naturally occur in foods and may be added to food as a flavouring substance; however, the occurrence data and information submitted are associated with several uncertainties and no data was available for potatoes. Therefore, a conclusion on level of dietary intake exposure from the pesticidal use compared with other sources and whether the overall exposure, including pesticide residues, will be safe cannot be reached. In conclusion, consumer risk assessment cannot be finalised (see Sections 4 and 9).

The five criteria for inclusion into Annex IV of Regulation (EC) 396/2005 are not met for (*E*)-3-decen-2-one used for sprout control in ware potatoes (European Commission, 2015). In particular, the substance may have adverse toxicological effects (ADI is proposed, criteria 3 not met), a comparative dietary intake exposure from pesticide use and other sources was not provided (criteria 4 not met) and consumer exposure cannot be excluded based on the representative use and the mode of application (criteria 5 not met). It is also noted that for the crops other than potatoes and having regard to the background levels expected to occur, the setting of a default LOQ value as MRL might not be appropriate.

4. Environmental fate and behaviour

The majority of the data required to perform the environmental exposure assessment were not available. Taking into consideration that (3*E*)-dec-3-en-2-one is applied indoor, no additional information was needed to carry out the required environmental exposure assessments at EU level for the representative use assessed.

(3*E*)-dec-3-en-2-one is a volatile substance. It is expected to be stable under sterile hydrolysis conditions, but it was shown to be readily biodegradable (failing the 10 day window). Aerobic degradation of (3*E*)-dec-3-en-2-one was estimated based on Guidance documents used for the environmental risk assessment of industrial chemicals (ECHA, 2016) and biocides (European Commission, 2003b). In QSAR estimated soil adsorption measurements (3*E*)-dec-3-en-2-one exhibited medium to low mobility in soil (see Appendix C).

As the representative use of (3*E*)-dec-3-en-2-one is as post-harvest application in closed potato stores, there is no direct exposure of the environmental compartments during treatment. However, upon venting, (3*E*)-dec-3-en-2-one could be released primarily into air, whilst exposure to soil, groundwater, surface water and sediment is expected to occur only upon deposition from the air. Exposure may also occur indirectly after application of contaminated sewage sludge coming from Sewage Treatment Plant after processing of treated potatoes. Therefore, two routes of indirect exposure were considered: exposure by volatilisation and deposition following ventilation of the storage room and exposure from the Sewage Treatment Plant after processing of treated potatoes. Guidance documents on Biocidal Products (European Commission, 2003b) and industrial chemicals (ECHA, 2016, 2017a) were used as this second route of exposure is not commonly considered for plant protection products. Due to the difference of both routes in time and space, it is assumed that they do not occur simultaneously, and then, the maximum of both routes is considered for risk assessment.

The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) considering the volatilisation and deposition following ventilation of the storage room were carried out for (3*E*)-dec-3-en-2-one using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). Furthermore, an assessment was also completed using the European Commission (2003a) technical guidance document on risk assessment and the model EUSES (version 2.1) to address the exposure route from the Sewage Treatment Plant, after processing of treated potatoes leading to exposure of surface water after application of sewage sludge were carried out for (3*E*)-dec-3-en-2-one.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3. Considering the route of exposure via volatilisation and deposition following ventilation of the storage room, the potential for groundwater exposure from the representative use by (3*E*)-dec-3-en-2-one 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, except in one out of nine scenarios. Considering the route of exposure from the application of sewage sludge originating from Sewage Treatment Plant, the 80th percentile annual average recharge concentrations leaving the top 1 m soil

layer were estimated to be > 0.1 μg/L for (3*E*)-dec-3-en-2-one at nine out of nine scenarios when using the lowest adsorption endpoint and at eight out of nine scenarios when using the highest adsorption endpoint (see Section 9).

The applicant did not provide appropriate information to address the effect of water treatment processes on the nature of the residues that might be present in surface and groundwater when surface and groundwater are abstracted for drinking water. This has led to the identification of a data gap and results in the consumer risk assessment not being finalised (see Section 9).

The PEC in soil, surface water, sediment and groundwater covering the representative use assessed can be found in Appendix B of this conclusion.

5. Ecotoxicology

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

The proposed reference specification is acceptable from an ecotoxicological point of view and it can be considered as covered by the test material used in the ecotoxicity studies.

While assessing risks to non-target organisms from the representative indoor use of (*E*)-3-decen-2-one, the following lines of evidence were considered relevant:

- (3*E*)-dec-3-en-2-one is a naturally occurring acyclic aliphatic ketone that is also used as a food flavouring substance.
- It is rapidly metabolised (known to be metabolised rapidly and extensively to innocuous substances, see Section 2).
- Previous evaluations by EFSA and JFCFA considered (3*E*)-dec-3-en-2-one acceptable for use as food flavouring (EFSA FAF Panel opinion, 2019[11] and EFSA FAF Panel, 2022[12]; JECFA, 2002). Additionally, as collateral information, an evaluation by the US FDA was acknowledged to result in a GRAS (generally regarded as safe) classification.[13]
- (3*E*)-dec-3-en-2-one is readily biodegradable and its DT_{50} in air is 2 h (see Section 4).

Toxicity studies with mammals but not with birds were submitted. However, the representative use of (3*E*)-dec-3-en-2-one envisages indoor (i.e. warehouse) applications in potato, for which the dietary exposure and risks to birds and mammals can be considered as low. Conversely, the exposure via consumption of contaminated water could not be excluded (see Section 4). Similarly, considering the physical–chemical properties of the substance and the representative use, the exposure through secondary poisoning (i.e. via earthworms or fish) could not be excluded. However, the risk to birds and mammals from these exposure routes could be considered low, considering (i) the indication of low toxicity to mammals, (ii) the above-mentioned lines of evidence and (iii) the illustrative risk assessment was provided by the RMS, giving indication of low risk for birds and mammals.

Toxicity data were available for fish, aquatic invertebrates, algae, macrophytes and sediment-dwelling organisms. The long-term exposure to aquatic organisms was considered low, in light of the readily biodegradability of the substance, the low DT_{50} in air (see Section 4) and the consideration that the representative use of the active substance is indoor. Low acute risk to aquatic organisms was also indicated.

No data were available for bees, non-target arthropods, earthworms, soil organisms, non-target plants and soil microbial activity. However, (3*E*)-dec-3-en-2-one is proposed for indoor use only. Additionally, volatilization and deposition were estimated as low. Therefore, low risk was concluded for all the aforementioned organisms.

[11] In this opinion, the EFSA FAF Panel assessed only the genotoxicity potential of flavouring substance (3*E*)-3 dec 3-en-2-one, which was ruled out.

[12] In this opinion, the EFSA FAF Panel completed the safety evaluation of (3*E*)-dec-3-en-2-one through a stepwise approach that integrates information on the structure–activity relationships, intake from current uses, toxicological threshold of concern (TTC) and available data on metabolism and toxicity, as in accordance with the Procedure outlined in Commission Regulation (EC) No 1565/2000. In the present assessment, (3*E*)-dec-3-en-2-one was assigned to structural class I conversely from previous JECFA assignment to structural class II. The threshold for human intake of a structural class I food flavouring is 1800 μg/person per day.

[13] https://www.femaflavor.org/sites/default/files/11.%20GRAS%20Substances%20(3526-3596).pdf

The risks for organisms involved in the biological methods for sewage treatment was considered low.

6. Endocrine disruption properties

With regard to the assessment of the endocrine disruption potential of (3*E*)-dec-3-en-2-one for humans and non-target organisms according to the ECHA/EFSA guidance (2018), although no (eco)toxicological data are available to assess the endocrine-disrupting properties, this does not appear scientifically necessary for the following reasons:

- (3*E*)-dec-3-en-2-one is a naturally occurring (fruits, juices, spices, vegetables, coffee and tea) acyclic aliphatic ketone that is also used as a food flavouring substance.
- It is rapidly metabolised (known to be metabolised rapidly and extensively to innocuous substances).
- It is highly unlikely that any potential adverse effects on endocrine system following respiratory exposure would occur at dose levels not causing excessive local toxicity. Available data demonstrated that adverse effects are limited to local irritation effects following administration via inhalation.

In addition to the above-mentioned justifications, for non-target organisms, the arguments below were further considered:

- The substance has been evaluated by EFSA as acceptable for use as food flavouring (EFSA FAF Panel, 2019, 2022). The JECFA has also evaluated it as a food flavouring (59th JECFA report, 2002). Additionally, as collateral information, an evaluation by the US FDA was acknowledged to result in a GRAS (generally regarded as safe) classification.
- It is readily biodegradable.
- The DT50 in air is 2 h.

Additionally, although not requested, *in vitro* data (Aromatase Assay, Steroidogenesis Assay, Oestrogen Receptor-α Transactivation Assay and an Androgen Receptor Transcriptional Activation Assay) with (3*E*)-dec-3-en-2-one were performed by the applicant and submitted outside the regulatory deadline. Those were, therefore, not considered eligible and not reviewed in the context of the peer review process. Considering that the justifications provided for waiving a full ED assessment were considered robust by the RMS and the experts during the Pesticides Peer Review experts' meeting TC 73,[14] a conclusion that the substance is unlikely to meet the ED criteria was drawn. However, considering the new studies spontaneously performed by the applicant, a formal data gap is included as part of the outstanding issues (see Section 10).

Based on the available information, it can be concluded that (3*E*)-dec-3-en-2-one is unlikely to 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.

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

Table 1: Soil

Compound (name and/or code)	Ecotoxicology
(3*E*)-dec-3-en-2-one	Low risk for soil organisms

[14] Experts' consultations 2.3 (ED potential for humans) and 5.1 (ED potential for NTOs) of the Pesticides Peer Review Experts' Meeting Report 73 (April 2022).

Table 2: 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
(3*E*)-dec-3-en-2-one	Yes Route of exposure via volatilisation and deposition following ventilation: 1/9 FOCUS scenarios (0.133 μg/L) Route of exposure from the application of sewage sludge: using the lowest adsorption endpoint: 9/9 FOCUS scenarios (0.153–2.30 μg/L); using the highest adsorption endpoint: 8/9 FOCUS scenarios (0.120–2.34 μg/L)	Yes	–	–	Yes

(a): Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003a).
(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, 2014.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
(3*E*)-dec-3-en-2-one	Low risk to aquatic organisms

Table 4: Air

Compound (name and/or code)	Toxicology
(3*E*)-dec-3-en-2-one	LC50 = 0.52–2.04 mg/L (> 1 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.

8.1. Particular conditions proposed for the representative uses evaluated

Risk mitigation measures proposed for the representative use assessed.

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

Representative use	Sprout control
	Hot fogging Tuber treatment
Operator risk	Use of RPE is required[(a)]
Worker exposure	Use of PPE/RPE is required[(b)]
Bystander/resident exposure	Buffer zone of 50 m around storage facility, or buffer zone of 10 m if re-entry interval of minimum 30 days can be guaranteed

(a): RPE: respiratory protective equipment during the insertion of the intake hose of the thermal fog generating equipment into the container with the product.
(b): Gloves for inspection activities and RPE for removal of potatoes if exposure duration > 2 h.

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[15] 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 consumer dietary risk assessment could not be concluded since the risk assessment residue definitions (for plants and animals) are only provisionally proposed, and the livestock exposure assessment cannot be conducted because of the following data gaps (see Section 3):
    a) data to undertake all the analytical attempts to characterise and identify the unknown radioactive residues in potato rinse, peel and pulp (see Section 3);
    b) a toxicological assessment of metabolite 3-decen-2-ol (free and conjugated) (see Sections 2 and 3);
    c) a complete data set of eight GAP-compliant residue trials considering specifically the precautionary measures to avoid volatilisation and storage stability issues and analysing for all the compounds in the residue definition for risk assessment (see Section 3);
    d) animal metabolism studies to elucidate the metabolic pattern and establish the residue definitions in animal matrices (see Section 3).
2) The consumer risk assessment from the consumption of drinking water could not be finalised:
    a) satisfactory information to address the effect of water treatment processes on the nature of residues in surface water, when surface and groundwater is abstracted for drinking water was not available. Probably in the first instance, a consideration of the processes of ozonation and chlorination would appear appropriate. If an argumentation is made that concentrations at the point of abstraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in surface and groundwater, as well as the active substance. Should this consideration indicate that novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them should be addressed (see Section 4).

[15] 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, pp. 127–175.

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:

3) Potential groundwater contamination by active substance.

   a) The 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 µg/L in one out of nine scenarios considering the indirect route of exposure via volatilisation and deposition following ventilation of the storage room. The 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 µg/L in all scenarios when using the lowest adsorption endpoint and at eight out of nine scenarios when using the highest adsorption endpoint for the indirect route of exposure from the application of sewage sludge originating from Sewage Treatment Plant (see Section 4).

9.3. Overview of the concerns identified for each representative use considered (Table 5)

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

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

Representative use		**Potatoes**
		Indoor
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	X[1,2]
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	

Representative use		Potatoes
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	X[3]
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	
	Parametric value of 10 μg/L[(a)] breached	
	Assessment not finalised	

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–7 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission (2003a).

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 use assessed and are listed in the order of the sections:

- A data gap was identified to submit a search of the scientific peer-reviewed open literature in full compliance with the EFSA Guidance on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011) (relevant for Sections 2 and 5).
- A data gap was identified to submit a validated analytical method(s) for monitoring residues of (3*E*)-dec-3-en-2-one in dry, high acid and high oil content commodities (see Section 1).
- A data gap was identified in relation to the extraction efficiency of the procedure used in the monitoring method for high water content commodities (see Section 1).
- A data gap was identified to submit sufficient processing trials (see Section 3).
- A data gap was identified in relation to the nature and magnitude of residues in fish since they are triggered by the representative use (see Section 3).
- A data gap was identified for the revision of dietary burden calculations according to the final risk assessment residue definition and the submission of the requested residue trials (see Sections 3 and 9).
- A data gap has been identified to provide further information on possible residues of (3*E*)-dec-3-en-2-one and its metabolites above background levels in crops planted in soils where sewage sludge with residues of (3*E*)-dec-3-en-2-one is applied (see Section 3).
- *In vitro* data (Aromatase Assay, Steroidogenesis Assay, Oestrogen Receptor-α Transactivation Assay and an Androgen Receptor Transcriptional Activation Assay) with (3*E*)-dec-3-en-2-one were submitted by the applicant, though not requested, outside of the regulatory deadline and not peer reviewed; therefore, a formal data gap is introduced to acknowledge the availability of the studies (see Section 6).

References

ECHA (European Chemical Agency), 2016. Guidance on information requirements and chemical safety assessment. Chapter R.16: Environmental exposure assessment. Version 3.0.

ECHA (European Chemicals Agency), 2017a. Guidance on Information Requirements and Chemical Safety Assessment. (Parts B + C). Version 3.0 June 2017. https://doi.org/10.2823/139408

ECHA (European Chemicals Agency), 2017b. Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. Version 5.0 July 2017. Reference: ECHA-17-G-21-EN; ISBN: 978-92-9020-050-5. Available online: https://echa.europa.eu/guidance-documents/guidance-on-clp

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J, Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311, 135 pp. https://doi.org/10.2903/j.efsa.2018.5311. ECHA-18-G-01-EN.

EFSA (European Food Safety Authority), 2009. Guidance on Risk Assessment for Birds and Mammals on request from EFSA. EFSA Journal 2009;7(12):1438, 358 pp. https://doi.org/10.2903/j.efsa.2009.1438

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. https://doi.org/10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp. https://doi.org/10.2903/j.efsa.2014.3874. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2015. Peer review report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance (3 *E*)-3-decen-2-one (applied for as 3-decen-2-one). Available online: www.efsa.europa.eu

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes, M, Aquilina, G, Castle, L, Engel, K-H, Fowler, P, Frutos Fernandez, MJ, Fürst, P, Gundert-Remy, U, Gürtler, R, Husøy, T, Moldeus, P, Oskarsson, A, Shah, R, Waalkens-Berendsen, I, Wölfle, D, Benigni, R, Bolognesi, C, Chipman, K, Cordelli, E, Degen, G, Marzin, D, Svendsen, C, Carfi, M, Vianello, G and Mennes, W, 2019. Scientific Opinion on Flavouring Group Evaluation 204 Revision 1 (FGE.204Rev1): consideration of genotoxicity data on representatives for 17 monounsaturated, aliphatic, α,β-unsaturated ketones and precursors from chemical subgroup 1.2.1 of FGE.19. EFSA Journal 2019;17(7):5750, 26 pp. https://doi.org/10.2903/j.efsa.2019.5750

EFSA FAF Panel (EFSA Panel on Food Additives and Flavourings), Younes, M, Aquilina, G, Castle, L, Engel, K-H, Fowler, PJ, Frutos Fernandez, MJ, Fürst, P, Gundert-Remy, U, Gürtler, R, Husøy, T, Manco, M, Moldeus, P, Passamonti, S, Shah, R, Waalkens-Berendsen, I, Wölfle, D, Wright, M, Benigni, R, Bolognesi, C, Chipman, K, Cordelli, E, Degen, G, Marzin, D, Nørby, KK, Svendsen, C, Vianello, G and Mennes, W, 2022. Scientific Opinion on Flavouring Group Evaluation 63, Revision 4 (FGE.63Rev4): consideration of aliphatic secondary saturated and unsaturated alcohols, ketones and related esters evaluated by JECFA (59th and 69th meetings) structurally related to flavouring substances evaluated by EFSA in FGE.07Rev6. EFSA Journal 2022;20(2):7102, 46 pp. https://doi.org/10.2903/j.efsa.2022.7102

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Guidance on dermal absorption. EFSA Journal 2012;10(4):2665, 30 pp. https://doi.org/10.2903/j.efsa.2012.2665

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. https://doi.org/10.2903/j.efsa.2013.3290

European Commission, 2000a. Residues: guidance for generating and reporting methods of analysis in support of pre-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3029/99-rev. 4, 11 July 2000.

European Commission, 2000b. Technical material and preparations: guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (Part A, Section 4) and Annex III (Part A, Section 5) of Directive 91/414. SANCO/3030/99-rev. 4, 11 July 2000.

European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002.

European Commission, 2003a. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 final, 25 February 2003.

European Commission, 2003b. Technical Guidance document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Directive 1488/94/EEC on Risk Assessment for existing substances and Commission Directive 98/8/EEC of the European Parliament and of the Council concerning the placing of biocidal products on the market, Part II. Available online: https://echa.europa.eu/documents/10162/16960216/tgdpart2_2ed_en.pdf/138b7b71-a069-428 e-9036-62f4300b752f

European Commission, 2010. Guidance Document on residue analytical methods. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2011. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. SANCO 7525/VI/95-rev. 9 March 2011. p. 1–46.

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003-rev. 10.1, 13 July 2012.

European Commission, 2013. Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. SANCO/10054/2013-rev. 3, 11 July 2013.

European Commission, 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Workgroup. EC Document Reference SANCO/13144/2010-v. 3, 613 pp., as outlined in Generic guidance for tier 1 FOCUS groundwater assessment, v. 2.2 May 2014.

European Commission, 2015. Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005. SANCO/11188/2013 Rev. 2, 14 September 2015.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2001. FOCUS surface water scenarios in the EU evaluation process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios. EC Document Reference SANCO/4802/2001-rev. 2, 245 pp., as updated by Generic guidance for FOCUS surface water scenarios, v. 1.4 May 2015.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2002. Evaluation of certain food additives. Fifty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives. WHO Technical Report Series, no. 913. Geneva, 4–13 June 2002.

JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, 383 pp.

JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, 164 pp.

McCall PJ, Laskowski DA, Swann R L and Dishburger HJ, 1980. Measurements of sorption coefficients of organic chemicals and their use in environmental fate analysis. In: Test Protocols for Environmental Fate and Movement of Toxicants. In: Proceedings of the 94th Annual Meeting of the American Association of Official Analytical Chemists (AOAC). Oct 21–22, Washington, D.C. pp. 89–109.

OECD (Organisation for Economic Co-operation and Development), 2009. Guidance document on overview of residue chemistry studies. ENV/JM/MONO(2009)31, 28 July 2009.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: www.oecd.org

RAC, 2022. Committee for Risk Assessment, RAC Opinion proposing harmonised classification and labelling at EU level of (3E)-dec-3-en-2-one. EC Number: -; CAS Number: 18402-84-1; CLH-O-0000007098-68-01/F. Adopted: 18 March 2022.

The Netherlands, 2019. Draft Assessment Report (DAR) on the active substance (*E*)-3-decen-2-one prepared by the rapporteur Member State The Netherlands, in the framework of Regulation (EC) No 1107/2009, November 2019. Available online: www.efsa.europa.eu

The Netherlands, 2022. Revised Draft Assessment Report (DAR) on (*E*)-3-decen-2-one prepared by the rapporteur Member State The Netherlands in the framework of Regulation (EC) No 1107/2009, April 2022. Available online: www.efsa.europa.eu

Abbreviations

1/*n*	slope of Freundlich isotherm
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
bw	body weight
DAR	draft assessment report
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
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
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)
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC–MS	liquid chromatography–mass spectrometry
LC–MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
mN	milli-Newton
MRL	maximum residue level

MS	mass spectrometry
MSs	member states
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
Pa	pascal
PEC	predicted environmental concentration
pF2	pF value of 2 (suction pressure that defines field capacity soil moisture)
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
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RMMs	risk mitigation measures
RPE	respiratory protective equipment
SD	standard deviation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
$t_{1/2}$	half-life (define method of estimation)
TC	teleconference
UF	uncertainty factor
WHO	World Health Organization

Appendix A – Consideration of cut-off criteria for (3*E*)-dec-3-en-2-one according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion[(a)]
CMR	Carcinogenicity (C)	Criteria not met
	Mutagenicity (M)	Criteria not met
	Toxic for Reproduction (R)	Criteria not met
Endocrine disrupting properties		(3*E*)-dec-3-en-2-one is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605.
POP	**Persistence**	(3*E*)-dec-3-en-2-one 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**	(3*E*)-dec-3-en-2-one 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**	(3*E*)-dec-3-en-2-one 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.2023.7765

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 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

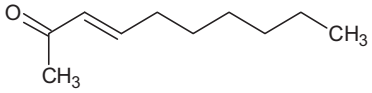
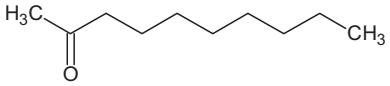
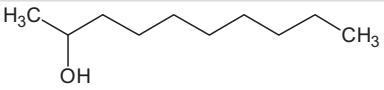
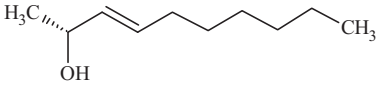
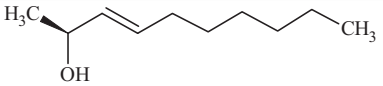
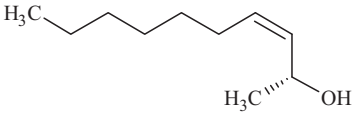
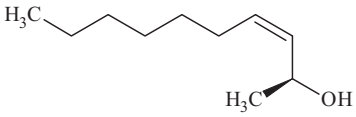
Note these classes and descriptions are unrelated to any persistence class associated with the active substance cut-off criteria in Annex II of Regulation (EC) No 1107/2009. For consideration made in relation to Annex II, see Appendix A.

(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]
(3*E*)-dec-3-en-2-one	(3*E*)-dec-3-en-2-one CC(=O)\C=C\CCCCCC JRPDANVNRUIUAB-CMDGGOBGSA-N	
2-decanone	decan-2-one CC(=O)CCCCCCCC ZAJNGDIORYACQU-UHFFFAOYSA-N	
2-decanol	decan-2-ol CC(O)CCCCCCCC ACUZDYFTRHEKOS-UHFFFAOYSA-N	
3-decen-2-ol	(2R,3E)-dec-3-en-2-ol C[C@@H](O)\C=C\CCCCCC HZRSDQXGMJFUKO-AAXQSMANSA-N	
	(2S,3E)-dec-3-en-2-ol C[C@H](O)\C=C\CCCCCC HZRSDQXGMJFUKO-DDXVTDLHSA-N	
	(2R,3Z)-dec-3-en-2-ol C[C@@H](O)/C=C\CCCCCC HZRSDQXGMJFUKO-HSTULFTRSA-N	
	(2S,3Z)-dec-3-en-2-ol C[C@H](O)/C=C\CCCCCC HZRSDQXGMJFUKO-QROTZFDESA-N	

(a): The compound name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 Release (File Version N15E41, Build 123,232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 Release (File Version C25H41, Build 123,835, 29 August 2021).