CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance carvone (substance evaluated d-carvone)

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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, the Netherlands and co-rapporteur Member State, Sweden, for the pesticide active substance carvone are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative use of carvone (substance evaluated d-carvone) as a plant growth regulator on seed potatoes. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed.

Keywords: carvone, d-carvone, peer review, risk assessment, pesticide, plant growth regulator

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') 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. Carvone is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), the Netherlands, and the co-rapporteur Member State (co-RMS), Sweden, received an application from Agri Services International B.V. for the renewal of approval of the active substance carvone. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Sweden), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on carvone in the renewal assessment report (RAR), which was received by EFSA on 31 May 2017. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Agri Services International B.V., for comments on 6 September 2017. 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 7 November 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of residues and environmental fate and behaviour.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether carvone can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of carvone (substance evaluated d-carvone) as a plant growth regulator on seed potatoes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the uses of d-carvone according to the representative uses proposed at European Union (EU) level result in a sufficient sprout regulation efficacy.

In the section of identity, physical, chemical and technical properties and analytical methods data gaps were identified for further data on the identification of one unknown impurity in the technical d-carvone, for the determination of the surface tension of the undiluted representative product, for the final report of the new shelf life study and for monitoring methods of the compounds in the residue definition for body fluids and tissues.

In the area of mammalian toxicology and non-dietary exposure, a data gap and issue that could not finalised was identified to further address the toxicological relevance of one impurity, once it is identified.

Based on the representative use on seed potatoes, the exposure resulting from the pesticide use of d-carvone was found to be significantly lower than the exposure resulting from the other food chain-related sources and the inclusion of d-carvone in Annex IV to the Regulation (EC) No 396/2005 is confirmed. The representative use of d-carvone on seed potatoes does not require the setting of a maximum residue level (MRL) on potatoes and there is no need to perform a consumer dietary risk assessment. The consumer risk assessment is, however, not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water that might contain d-carvone and its metabolites (see Section 4). It is also concluded that the residues of d-carvone in pollen and bee products are expected to be negligible.

The data available on environmental fate and behaviour were sufficient to carry out the required environmental exposure assessment at EU level for the representative use, with the notable exception for information on the effect of water treatment processes on the nature of residues potentially present in surface water, when surface water is abstracted for drinking water.

In the area of ecotoxicology, a number of data gaps were identified. The risk assessment for non-target terrestrial plants could not be finalised.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. 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 up to 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS, the Netherlands, and co-RMS, Sweden, received an application from Agri Services International B.V. for the renewal of approval of the active substance carvone. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Sweden), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on carvone in the RAR, which was received by EFSA on 31 May 2017 (Netherlands, 2017).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Agri Services International B.V, for consultation and comments on 6 September 2017. 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 7 November 2017. At the same time, the collated comments were 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's 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 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 14 December 2017. 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 residues and environmental fate and behaviour.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in June–July 2018.

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 use of carvone as a plant growth regulator on seed potatoes, as proposed by the applicant. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

[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] 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.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2018), 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 (14 December 2017);
- the evaluation table (9 July 2018);
- 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 (Netherlands, 2018), 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 report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Carvone is the ISO common name for (*RS*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (*RS*)-*p*-mentha-6,8-dien-2-one (IUPAC).

The definition of carvone was changed within the scope of the substance renewal. The substance is redefined as d-carvone only; d-carvone is (*S*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (*S*)-*p*-mentha-6,8-dien-2-one (IUPAC). It should be noted that there is not an ISO common name available for d-carvone.

The representative formulated product for the evaluation was 'Talent', a liquid to be applied undiluted (AL), containing 923 g/kg d-carvone. The material is fogged, therefore, more appropriate formulation codes would be either HN or KN (hot or cold fogging concentrate).

The use of the pesticide carvone (d-carvone/l-carvone, 100:1) was authorised for treatment during the storage of seed potatoes before planting. The representative use evaluated with the current submission comprises applications by fogging, as a plant growth regulator (sprout regulator) in seed potatoes during storage in the EU. Full details of the good agricultural practices (GAP) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of d-carvone according to the representative use proposed at EU level result in a sufficient sprout regulation efficacy following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014a).

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: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/825/00 rev. 8.1 (European Commission, 2010) and SANCO/11470/2012 rev. 8 (European Commission, 2014b).

Although the text in the inclusion Commission Directive 2008/44/EC[3] refers to 'carvone', it is stated that the active substance shall have a minimum purity of 930 g/kg d-carvone in the technical product with a d/l ratio of at least 100:1. Therefore, it is actually d-carvone that is included in Annex I. At the renewal of the approval, the substance was redefined to be d-carvone, and as a consequence, the isomeric ratio is no longer relevant; l-carvone is now considered an impurity. d-Carvone is produced by fractional distillation of caraway oil. The specification is based on batch data from industrial scale production. The proposed minimum purity of the technical material was 923 g/kg of d-carvone. The reference specification needs to be amended as the substance carvone was redefined to d-carvone. No Food and Agriculture Organization of the United Nations (FAO) specification exists.

[3] Commission Directive 2008/44/EC of 4 April 2008 amending Council Directive 91/414/EEC to include benthiavalicarb, boscalid, carvone, fluoxastrobin, Paecilomyces lilacinus and prothioconazole as active substances. OJ L 94, 5.4.2008, p. 13–20.

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 d-carvone. However, the ISO common name should be redefined to only include d-carvone, and data gaps were identified for further data on the identification of one unknown impurity in the technical d-carvone, for the determination of the surface tension of the undiluted representative product and for the final report of the new shelf-life study. The main data regarding the identity of d-carvone and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of d-carvone in the technical material and the representative formulation.

Analytical methods for the determination of residues in plant materials, foodstuff of animal origin are not required due to the fact that no residue definitions are proposed. The residue definition for monitoring in the environmental compartments was defined as carvone (sum of isomers). Adequate gas chromatography-mass spectrometry (GC-MS) methods are available for the determination of carvone residues in soil, water and air with limit of quantification (LOQs) of 0.05 mg/kg, 0.1 μg/L and 7.5 $\mu g/m^3$, respectively. The methods are not enantioselective. The residue definition for monitoring in body fluids and tissues was defined as carvone, carvonic acid, dihydrocarvonic acid and uroterpenolone. A data gap was identified for analytical methods for the determination of the compounds of the residue definition in body fluids and tissues.

2. Mammalian toxicity

The toxicological profile of d-carvone has been assessed by the EFSA Scientific Committee (EFSA Scientific Committee, 2014). The acceptable daily intake (ADI) was set at 0.6 mg/kg body weight (bw) per day. Under the renewal assessment, EFSA followed the EFSA Opinion of 2014 since in the meantime, no new critical information or studies were made available. The RMS did not agree with the assessment done by the EFSA Scientific Committee. The main comments done by the RMS were the selection of the critical effect for the point of departure, the use of benchmark dose approach, the extrapolation from short-term to long-term exposure and the oral absorption of d-carvone. EFSA considered that the comments by the RMS were properly addressed already in the Scientific Committee Opinion, and there is no need to revise the ADI, which was proposed by the Scientific Committee (see reporting table point 2(41) for further details).

EFSA proposed to set the acceptable operator exposure level (AOEL) on the same data, that were used for the setting of the ADI, i.e. 0.6 mg/kg bw per day with no correction factor for oral absorption. The RMS did not agree on the AOEL setting (see reporting table point 2(41) for further details). An acute reference dose (ARfD) or acute acceptable operator level (AAOEL) was not considered necessary based on the available data. The ADI and AOEL are different to those originally set by the European Commission (2008; i.e. 0.025 mg/kg bw per day) since the toxicological profile of d-carvone was reconsidered by the Scientific Committee in 2014.

A data gap for further identification of one impurity was set (see Section 1). Once the impurity is identified, its toxicological relevance should be assessed. Due to the lack of data, a data gap was identified leading to issue that could not be finalised. It is noted that the impurity content of d-carvone is unknown in the majority of toxicity studies. Therefore, a conclusion on whether the batches used in toxicity studies compared to the technical specification cannot be made. Since all other identified impurities (above 10 g/kg) are considered not relevant from the toxicological point of view, a critical area of concern is not identified.

d-Carvone is not classified or proposed to be classified as toxic for reproduction category 2 or carcinogenic category 2, in accordance with the provisions of Regulation (EC) No 1272/2008[4], and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. With regard to the scientific risk assessment, d-carvone is unlikely to be an endocrine disruptor.

Considering the representative use on seed potatoes (storage treatment), the non-dietary exposure for operators, workers, bystander and residents was calculated to be below the AOEL without the use of personal protective equipment for operators and workers.

[4] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355. Harmonised classification on carvone (ATP07 – (25/7/2015), 1/1/2017).

With regard to the worker risk assessment and looking at the isomeric composition, it is considered unlikely that conversion to l-carvone will occur for the representative use. Most of the toxicity studies were performed with carvone containing predominantly d-carvone and only limited levels of the impurity l-carvone. In addition, studies are available which were performed with isolated isomers of either d-carvone or l-carvone indicating l-carvone is not more toxic than d-carvone.

Toxicity studies on some metabolites are summarised in the list of end points. These metabolites are not considered relevant regarding the representative use (see also Sections 3 and 4).

3. Residues

The assessment in the section on residues is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (MRL) calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Carvone was discussed at the Pesticides Peer Review experts' meeting 176 (April 2018).

Although metabolism data using radiolabelled d-carvone were not submitted to address the fate of d-carvone in potatoes, non-radiolabelled studies were made available to determine the residues of d-carvone and l-carvone and their degradation products in potatoes following application during storage. At several weeks after the treatment, 93% of the total residues measured remained on the peel and the d-carvone residues accounted for up to 90% of the total residue measured in whole potato. Besides the parent compound, the metabolites dihydrocarvone and neo/iso-dihydrocarveol were also identified but occurred at much lower concentrations compared to d-carvone residues (< 10% of the total residues concentration). Since these studies were not conducted with ^{14}C-radiolabelled d-carvone, it is not known whether the fate of the parent compound was sufficiently investigated in potatoes. However, from the available data, d-carvone is shown to be the predominant compound of the total residues in treated potatoes and a very low translocation of the residues from the peel to the pulp is observed. The experts were of the opinion that further radiolabelled metabolism data conducted according to the current recommendations are not required to support the use of d-carvone on seed potatoes.

GAP compliant residue trials analysing for residues of d-carvone and its degradation products in seed potatoes and in the daughter potatoes grown from treated seed potatoes were not available. However, considering the observed low residues, translocation from peel to pulp significant residues of d-carvone are not expected in the daughter tubers following treatment of the seed potatoes according to the representative use and no further residue trials are required.

Since residues of d-carvone are expected to be negligible in daughter potatoes grown from the treated seed potatoes, a livestock exposure assessment to d-carvone residues is not triggered.

Hydrolysis studies addressing the nature of the residues in processed commodities are not required since residues of d-carvone are expected to be negligible in potatoes grown from the treated seed potatoes.

Confined rotational crops metabolism studies are not required provided that carvone is not persistent in soil (DT_{50} range: 0.2–5 days) (see Section 4).

The EFSA Scientific Committee (EFSA Scientific Committee, 2014) estimated the consumer exposure to d-carvone from its use as a pesticide on seed potatoes and on ware and starch potatoes, respectively, and concluded that the exposure resulting from the use of d-carvone as a pesticide on seed potatoes and on ware and starch potatoes was lower than the exposure resulting from all other uses than pesticides. Based on this assessment, the experts agreed that additional residue trials compliant with the representative use on seed potatoes and on daughter potatoes grown from the treated seed potatoes are not required and the inclusion of d-carvone in Annex IV to the Regulation (EC) No 396/2005 as previously stated in the statement of EFSA on carvone (EFSA, 2016) remains appropriate for the representative use on seed potatoes. There is, therefore, no need to perform a consumer dietary risk assessment. The consumer risk assessment is, however, not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface water that might contain d-carvone and its metabolites (see Section 4).

It is, however, emphasised that the decision to waive metabolism studies and sufficient GAP compliant residue trials on seed potatoes and daughter potatoes is specific to the representative use

and should be reconsidered in case of any future use that would trigger a reassessment of the available data.

As very low translocation of d-carvone residues from potato peel to pulp is observed, residues of d-carvone and its degradation products are expected to be negligible in the flowers of the daughter tubers grown from the treated seed potatoes according to the representative use. It can, therefore, be concluded that the residues of d-carvone in pollen and bee products are expected to be negligible.

4. Environmental fate and behaviour

Carvone was discussed at the Pesticides Peer Review teleconference 174 (May 2018).

The information presented in the dossier was insufficient to address the potential different environmental behaviour of each individual isomer and/or if conversion from d-carvone to l-carvone occurs in soil and/or in the aquatic compartment. However, it is considered that the margin of safety on the risk assessments for the representative uses is large enough that the uncertainty on the relative toxicity and the contribution to the total residue levels of the isomers do not change the conclusion of low-aquatic risk and low risk for soil organisms. The rates of degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance.

No studies were submitted on the route of aerobic degradation of d-carvone in soil. However, the peer review agreed that metabolites formed in soil on the pathway to carbon dioxide may be regarded as transient, and therefore, studies to determine the exact route of degradation in soil were not considered essential for the risk assessment. In soil laboratory incubations under aerobic conditions in the dark, d-carvone exhibited very low to low persistence. A quantitative structure–activity relationship (QSAR)-estimated soil adsorption measurement indicated that it would be of high mobility in soil.

d-Carvone is hydrolytically stable at pH 4, 7 and 9 and though not classified as ready biodegradable, it can be considered inherently biodegradable. No water/sediment studies were submitted. The DT_{50} value in water to be used in the risk assessment was estimated with the version 2.1.2 of EUSES tool according to the guidance used for the environmental risk assessment of industrial chemicals (ECHA, 2016) and biocides (European Commission, 2003b).

Predicted Environmental Concentrations (PEC) in soil, surface water and groundwater were estimated through indirect exposure consequent to deposition to soil in the vicinity of potato stores, following venting of the atmosphere of the potato store to the outside. The amount of d-carvone in soil that could result from this scenario was estimated based on a deposition percentage of 0.05% as proposed by the FOCUS Air Guidance document (FOCUS, 2008) for indoor application, combined with the information on the dimensions and potato content of an average storage room as specified in a study submitted by the applicant. Additionally, direct exposure to soil was estimated at time of planting seed potatoes that were treated with d-carvone during storage. In this case, the amount of residue of d-carvone at time of planting was estimated from the available residue trials with seed potatoes and the maximum seeding density for seed potatoes (5,000 kg seed potatoes/ha). The peer review questioned the information supporting the residue value measured in these trials that was selected to estimate the application rate, expressed as g a.s./ha, to perform the exposure assessment, and therefore, a data gap has been identified. The RMS does not agree with the data gap. However, taking into consideration, the quite large margin of safety of the risk assessment for the representative use, it is very unlikely that the use of a more conservative residue value measured in the available residue trials would significantly change the risk assessment (see Experts' consultation 4.2 of the Evaluation Table).

The necessary surface water and sediment exposure assessments as a result of planting seed potatoes were carried out using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). PECsw and PECsed were also calculated taking into consideration the exposure resulting from volatilisation and deposition (0.05% default value) onto a standard water body (100 m long, 1 m wide and 30 cm deep). PECgw were calculated for d-carvone using the FOCUS (2009) groundwater scenarios and the FOCUS PELMO 5.5.3 and FOCUS PEARL 4.4.4 models. The potential for groundwater exposure from the representative uses by d-carvone 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. All the PECs as described here are included in Appendix A.

The applicant has not 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 and then subjected to processes such as ozonation and chlorination. This has been identified as a data gap and as an issue that could not be finalised.

5. Ecotoxicology

The following documents were considered in the risk assessment: European Commission (2002a,b), EFSA (2009).

The highest exposure level for all relevant environmental compartments (soil, water and plant) resulted from estimations via areal deposition after ventilation of the store rooms. It is noted that the environmental exposure via this route is limited in space (i.e. will be significant only around the store rooms, which density in the agriculture areas is assumed to be low). According to the GAP, the highest application rate is used during the winter period (November–December) when the exposure of many of the non-target organisms is less likely (e.g. no or low foraging activity of bees). In addition, this period is out of the intensive reproduction phase of most of the organisms (e.g. aquatic plankton). However, some emission from the store rooms may happen also in spring, and there are other relevant exposure routes to the non-target organisms.

Acute and long-term toxicity data were available for mammals; however, no studies were available for birds. Based on the hypothesis that d-carvone is not more toxic to **birds** than to **mammals**, the available toxicity data for mammals was used in the risk assessments for birds. This hypothesis was supported with data from the open literature which demonstrated that caraway seeds are used in commercial feed seed mixtures for birds (d-carvone is produced by fractional distillation of caraway oil, see Section 1). In the dietary risk assessments for birds and mammals, different exposure scenarios were considered: consumption of potato seedlings, consumption of feed items contaminated via areal deposition, consumption of seed potato (relevant only for mammals). A low risk was concluded for all these exposure routes with the exception for the long-term risk to small herbivorous mammal that consume feed items contaminated via areal deposition close by to the storehouse (toxicity exposure ratio (TER) value was 4.2). No refinement for this scenario was available (data gap); however, it was argued that a number of parameters considered in this non-standard risk assessment were likely conservative.

The risk from bioaccumulation or via water consumption was assessed as low.

As regards to **aquatic organisms**, acute toxicity data were available for fish and aquatic invertebrates; moreover, laboratory studies were available for algae (3 days) and aquatic plants (8 days). Exposure estimations were available considering that the potato tubers are planted out to the field (FOCUS steps 1–2) and considering direct contamination via areal deposition. The risk assessments considering the available data indicated a low risk. No chronic studies for fish and aquatic invertebrates were available. An argumentation to waive chronic toxicity data and to consider the chronic risk as covered by the acute risk assessment was provided in the dossier. The RMS supported the argumentation together with some other Member States during the peer review process. However, EFSA was on the opinion (for further discussion, see data requirement 5.2 in the evaluation table) that the waiver of the data requirements is not justified (data gap).

No standard toxicity studies and comprehensive risk assessments were available for **bees** (data gap). It is noted, however, that information from open literature indicated that bees are naturally exposed to d-carvone. A study indicated no acute mortality of honeybees after the test animals were over sprayed with d-carvone or l-carvone in laboratory conditions (spray concentrations were 100–150 ppm).

No standard toxicity studies were available for **non-target arthropods**. However, exposure to foliar-dwelling arthropods cannot be excluded (data gap). It is noted that some acute contact bioassays from the open literature were available and indicated a low acute toxicity to spider mites (the exposure levels were estimated to be higher than the theoretical exposure from the representative use). However, this information was not considered to be sufficient to address the risk to foliar-dwelling arthropods. The risk to non-target arthropods exposed via soil (i.e. risk to soil-dwelling arthropods) was considered to be covered by the available assessments on soil organisms.

As regards to **soil macro- and microorganisms**, an acute toxicity data on earthworms, chronic studies on collembolan and soil mites; moreover, a nitrogen transformation test were available. Exposure estimations were available considering that the potato tubers are planted out to the field and considering soil contamination via areal deposition. The risk assessments considering the available data indicated a low risk. No chronic study for earthworms was available. An argumentation to waive chronic toxicity data and consider the chronic risk as covered by the acute risk assessment was provided. This argumentation was supported by the RMS and some other Member States during the

peer review process. However, EFSA was on the opinion (for further discussion, see data requirement 5.5 in the evaluation table), that the waiver of the data requirement is not justified (data gap).

Considering that carvone is a plant growth regulator, seedling emergence and vegetative vigour test were triggered however not available (data gap). Therefore, the risk assessment for **non-target terrestrial plants** could not be finalised.

A low risk was concluded for the organisms involved in biological methods for **sewage treatment**.

Based on the information in Section 2, it is unlikely that d-carvone is an **endocrine disruptor** for mammals. However, further data might be necessary to address the potential endocrine-disrupting properties for non-target organisms other than mammals.

6. 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)	Persistence	Ecotoxicology
d-carvone	Very low to low persistence Single first order DT_{50} 0.2–5.0 days (20°C pF2 soil moisture)	Data gap

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
d-carvone	High mobility K_{doc} 111 mL/g (based on QSAR estimation)	No	Yes	Yes

(a): FOCUS scenarios or relevant lysimeter

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
d-carvone	Data gap

Table 4: Air

Compound (name and/or code)	Toxicology
d-carvone	Low acute inhalation toxicity to rats (Rat LC_{50} inhalation > 5.66 mg/L air/4 h)

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Further data on the identification of impurity 6 in the technical d-carvone and its toxicological relevance (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 2).
- Determination of the surface tension of the undiluted representative product (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Final report of the new shelf-life study (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1)
- Analytical methods for the compounds of the residue definition in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- Information on potential conversion of d-carvone to the l-isomer in the environmental compartments (concluded as not being necessary to finalise the risk assessment for all the representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- 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 (not needed for any of the representative uses evaluated when following the EU environmental exposure assessment guidance, though a data requirement; submission date proposed by the applicant: unknown; see Section 4 of the evaluation table contained in the peer review report [EFSA, 2018]).
- The effect of water treatment processes on the nature of residues present in surface, when surface water is abstracted for drinking water (Article 4 (approval criteria for active substances) 3. (b) of Regulation (EC) No 1107/2009) has not been assessed. In the first instance, a consideration of the processes of ozonation and chlorination may be considered appropriate. If an argumentation is made that concentrations at the point of extraction for drinking water purposes will be low, this argumentation should cover metabolites predicted to be in surface water as well as the active substance (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Comprehensible and complete information on the efficacy trial B176 ((AN-645) by Hartmans (1996) to support the estimation of the application rate of 16 g a.s./ha used to perform the direct exposure of soil through planting of seed potatoes treated with d-carvone (concluded as not being necessary to finalise the risk assessment for all the representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- Further data to address the long-term risk to small herbivorous mammals (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Chronic studies for fish and aquatic invertebrates (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further data to address the risk to bees (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further data to address the risk to non-target arthropods (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Chronic study on earthworms (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Seedling emergence and vegetative vigour test (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see Section 5).

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- During fogging with the product, no individuals should be present in the storeroom. After the first application with 25 mL product/ton potatoes, it is not allowed to enter the storage room.

Thereafter, at the end of the treatment, entry of the treated room is only authorised after a ventilation period of at least 24 h (see GAP table in the Appendix A).

9. Concerns

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 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[5] 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.

1) Identity of d-carvone is pending based on further identification of impurity 6. Once the impurity 6 is identified, its toxicological relevance should be assessed. However, it is noted that the impurity content of d-carvone is unknown in the majority of toxicity studies and all other identified impurities are considered not relevant from the toxicological point of view (see Section 2).
2) The available information is insufficient to conclude whether carvone will have no immediate or delayed harmful/effects on human health, including vulnerable groups, or on animal health, through drinking water (taking into account substances resulting from water treatment, see Sections 3 and 4).
3) The available information is insufficient to conclude on the risk for non-target terrestrial plants (see Section 5).

9.2. Critical areas of concern

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

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

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

- No critical areas of concern were identified.

9.3. Overview of the concerns identified for each representative use considered

(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 5.)

[5] 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 5: Overview of concerns

Representative use		Seed potatoes
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	χ^2
Risk to wild non-target terrestrial vvvertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	χ^3
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	
	Parametric value of 10 μg/L[(b)] breached	
	Assessment not finalised	

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

(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 (2003a).

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Abbreviations

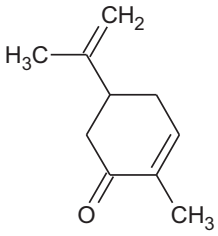
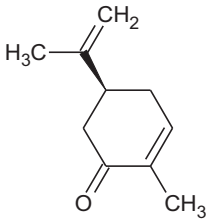
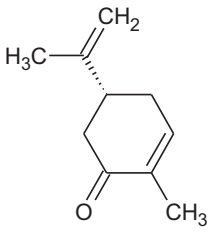
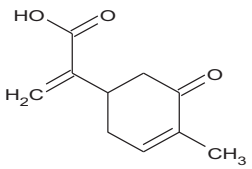
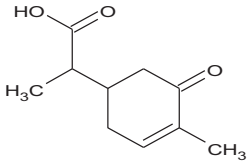
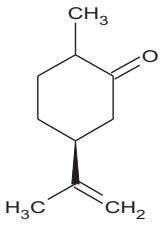
a.s.	active substance
ADI	acceptable daily intake
AAOEL	acute acceptable operator exposure level
AL	liquid to be applied undiluted
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
co-RMS	co-rapporteur Member State
DT_{50}	period required for 50% dissipation (define method of estimation)
ECHA	European Chemicals Agency
EEC	European Economic Community
EUSES	European Union System for the Evaluation of Substances
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
GC-MS	gas chromatography – mass spectrometry

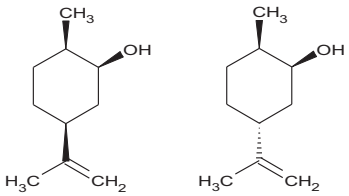
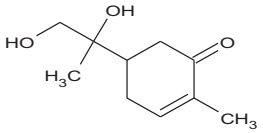
HN	hot fogging concentrate
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
KN	cold fogging concentrate
LC_{50}	lethal concentration, median
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
ppm	parts per million (10^{-6})
QSAR	quantitative structure–activity relationship
r^2	coefficient of determination
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
TER	toxicity exposure ratio
WHO	World Health Organization

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

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5390

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula[b]
Carvone	(*RS*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (*RS*)-*p*-mentha-6,8-dien-2-one CC1=CCC(CC1=O)C(C)=C ULDHMXUKGWMISQ-UHFFFAOYSA-N	
d-carvone *S*-(+) L	(5*S*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (*S*)-*p*-mentha-6,8-dien-2-one CC1=CC[C@@H](CC1=O)C(C)=C ULDHMXUKGWMISQ-VIFPVBQESA-N	
l-carvone *R*-(-) D	(5*R*)-5-isopropenyl-2-methylcyclohex-2-en-1-one or (*R*)-*p*-mentha-6,8-dien-2-one CC1=CC[C@H](CC1=O)C(C)=C ULDHMXUKGWMISQ-SECBINFHSA-N	
carvonic acid	2-[(1*RS*)-4-methyl-5-oxocyclohex-3-en-1-yl]prop-2-enoic acid OC(=O)C(=C)C1CC(=O)C(C)=CC1 BPJKNHQCPHBIAR-UHFFFAOYSA-N	
dihydrocarvonic acid	(2*RS*)-2-[(1*RS*)-4-methyl-5-oxocyclohex-3-en-1-yl] propanoic acid CC1=CCC(CC1=O)C(C)C(=O)O WBPNIFAWLPCWGX-UHFFFAOYSA-N	
dihydrocarvone	(5*S*)-2-methyl-5-(prop-1-en-2-yl)cyclohexanone CC(=C)[C@@H]1CC(=O)C(C)CC1 AZOCECCLWFDTAP-GKAPJAKFSA-N	

Code/trivial name	Chemical name/SMILES notation[a]	Structural formula[b]
neo/iso-dihydrocarveol	(1*S*,2*R*,5*S*)-2-methyl-5-(prop-1-en-2-yl)cyclohexanol C[C@@H]1CC[C@@H](C[C@@H]1O)C(=C)C KRCZYMFUWVJCLI-UTLUCORTSA-N (1S,2R,5R)-2-methyl-5-(prop-1-en-2-yl)cyclohexanol C[C@@H]1CC[C@H](C[C@@H]1O)C(=C)C KRCZYMFUWVJCLI-BBBLOLIVSA-N	
uroterpenolone	(5*RS*)-5-[(2*RS*)-1,2-dihydroxypropan-2-yl]-2-methylcyclohex-2-en-1-one CC1=CCC(CC1=O)C(O)(C)CO AOKPDATZUBLDMG-UHFFFAOYSA-N	

(a): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 06 Sep 2017).
(b): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 Feb 2018).