Peer review of the pesticide risk assessment of the active substance garlic extract

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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, Ireland, and co-rapporteur Member State, Denmark, for the pesticide active substance garlic extract and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The conclusions were reached on the basis of the evaluation of the representative use of garlic extract as a repellent, insecticide and nematicide on a wide range of crops in agriculture, horticulture, amenity. The reliable end points, appropriate for use in regulatory risk assessment are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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Summary

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

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Ireland, and co-rapporteur Member State (co-RMS), Denmark, received an application from Ecospray Limited for the renewal of approval of the active substance garlic extract. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005.

An initial evaluation of the dossier on garlic extract was provided by the RMS in the renewal assessment report (RAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 13 of Commission Implementing Regulation (EU) No 844/2012, as amended by Commission Implementing Regulation (EU) No 2018/1659. The following conclusions are derived.

The uses of garlic extract according to the representative uses as a repellent, insecticide and nematicide on a wide range of crops in agriculture, horticulture, amenity, as proposed at European Union (EU) level result in a sufficient efficacy against the target organisms.

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 garlic extract or the representative formulations. A data gap was identified for monitoring method in groundwater.

There are no critical areas of concern identified in the mammalian toxicology area.

With respect to the residues in food and feed, the use of garlic extract as plant protection product according to the good agricultural practice (GAP), even at the most conservative estimate of potential residues, it is not expected to pose an acute or chronic health risk to the consumer. Data have also been provided showing that intake of garlic extract by lamb and other ruminants such as cattle should not pose a health risk to these animals.

A maximum residue level (MRL) application for inclusion of garlic extract into Annex IV of Regulation (EC) No 396/2005 has also been submitted. The inclusion of garlic extract into Annex IV of Regulation (EC) No 396/2005 is supported.

In the area of the environmental fate and behaviour, no critical areas of concern were identified.

In the area of ecotoxicology, the risk assessment for aquatic organisms could not be finalised for all representative uses except for the granular product to be applied below the soil surface in potatoes and parsnips (in both field and greenhouses).
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Background

Commission Implementing Regulation (EU) No 844/2012\(^1\), as amended by Commission Implementing Regulation (EU) No 2018/1659\(^2\), (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\(^3\). This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

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

In accordance with Article 1 of the Regulation, the RMS Ireland and co-RMS Denmark received an application from Ecospray Limited for the renewal of approval of the active substance garlic extract. In addition, the applicant submitted a proposal to include the substance into Annex IV of Regulation (EC) No 396/2005\(^4\). Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Denmark), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on garlic extract in the RAR, which was received by EFSA on 28 March 2019 (Ireland, 2019a). The RAR included a proposal to include the substance into Annex IV of Regulation (EC) No 396/2005. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005. On 19 August 2019, EFSA invited the Member States to submit their Good Agricultural Practices (GAPs) that are authorised nationally, in the format of specific GAP forms. All the GAPs were collected by EFSA and they are made publicly available as a background document to this conclusion, in the format of a specific GAP overview file.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Ecospray Limited, for consultation and comments on 26 April 2019. 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 1 July 2019. At the same time, the comments collated in a reporting table, in the format of an excel spreadsheet, were forwarded to the RMS for further consideration. In addition, the applicant was invited to respond to the comments received. The considerations by both the applicant as well as the RMS of the comments are reflected in the reporting table.

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 29 August 2019. On the basis of the comments received, the applicant’s response to the comments and the RMS’s evaluation thereof, it was concluded that

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

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

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

\(^4\) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

An overview of follow-up actions of the points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration is also provided in the reporting table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of all points identified during the peer review, together with the outcome of the written consultation on the assessment of additional information, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the Article 12 maximum residue level (MRL) review of Regulation (EC) No 396/2005 took place with Member States via a written procedure in March–April 2020.

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 garlic extract as a repellent, insecticide and nematicide on a wide range of crops in agriculture, horticulture, amenity, as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review are presented in the conclusion. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2020), 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 commenting table (2 September 2019) containing all the comments received on the RAR together with their evolution and follow-up during the peer review;
- the evaluation tables (15 April 2020);
- 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 (Ireland, 2019a,b), 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 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

This extract of the bulbs of garlic (Allium sativum) is considered by the International Organization for Standardization not to require a common name. Garlic extract is the given name for food grade garlic juice concentrate.

The representative formulated products for the evaluation were ‘NEMguard SC/ECOguard SC’, a suspension concentrate (SC) containing 1,000 g/kg garlic extract and ‘NEMguard Granules (GR)/ECOguard Granules (GR)’, a granule formulation (GR) containing 450 g/kg garlic extract.

The representative uses evaluated for the SC comprise applications in field, greenhouses and crops grown under cover via any type of drip, handheld or other irrigation system, before and post-planting/sowing, at transplanting and via spraying as nematicide on various fruits and vegetables and managed amenity turf; as insecticide on flowering brassica and root and tuber vegetables; as repellent against birds, mammals and insects on various fruits and vegetables. The representative uses evaluated for the granular formulation comprise applications in field, greenhouses and crops grown under cover via band application followed by irrigation or application to the soil surface by conventional granular application equipment or application beneath the soil surface at the same time as drilling by standard granular application equipment, on the same crops and against the same organisms as for the SC formulation. Full details of the GAP can be found in the list of end points in Appendix A.

Data were submitted to conclude that the representative uses of garlic extract proposed at EU level result in a sufficient nematicidal, insecticidal and repellent activity, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).
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 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 active substance is 1,000 g/kg garlic extract as defined by its manufacturing process and marker compounds. The four marker compounds are diallyl sulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide (DAS1-DAS4). The percentage of the four marker compounds is expressed as equivalents of diallyl trisulfide. The active substance is of food grade quality. No FAO specification exists for this active substance.

   The available data regarding the identity of garlic extract and its physical and chemical properties are given in Appendix A. Appropriate analytical methods exist for the determination of the content of the marker compounds of the technical product and the formulations.

   The need for methods of analysis for monitoring this compound in food of plant and animal origin, in the environment and in body fluids and tissues has been waived due to the nature of the compound; however, a data gap was identified for a monitoring method for the marker compound diallyl trisulfide residues in groundwater.

2. **Mammalian toxicity**

   Garlic extract is considered of food grade quality; indeed, garlic is used widely to flavour and season foods. It is not expected that the use of garlic extract as a plant protection product will pose a risk to consumers when comparing its use as a food (see Section 3). It is recognised that garlic has the potential to cause asthma under occupational exposure by inhalation. Available toxicity studies indicated that garlic extract is a skin sensitiser and it is not irritant to the skin and eyes. The applicant did not submit further toxicity studies on garlic extract. These studies were waived being garlic a food item for humans, reference values were not allocated and no quantitative non-dietary exposure risk assessment was considered necessary. This conclusion is in line with the previous peer review (EFSA, 2012). However, the literature search was not properly conducted leading to a data gap.

3. **Residues**

   The assessment in the residue section is based on the OECD following documents: OECD, 2009, 2011, European Commission, 2011 and JMPR 2004, 2007.

   The consumer risk assessment was conducted by comparison of the exposure due to the use of garlic extract as a plant protection product with the exposure due to consumption of the plant itself. The assessment is based on the fact that the garlic extract is of food grade quality.

   Garlic is commonly used in a variety of dishes and estimates of dietary exposure of the European population to garlic can be extracted from the EFSA PRIMo rev.3.1 (EFSA, 2018). The 36 diets listed in the EFSA PRIMo rev.3.1 calculated the exposure of garlic extract expressed as garlic as between 0.03 and 0.46 g/kg body weight (bw) per day. The largest chronic consumption of garlic is 0.0833 g/kg bw per day (RO general, equal to 4.9 g/day). The 97.5th percentile consumption was recorded as 0.64 g/kg bw per day, corresponding to an intake of 42.7 g/day (UK vegetarian) according to EFSA PRIMo rev.3.1.

   Using worst-case assumptions, RMS calculated the intake of garlic extract from use as plant protection product in diets relating to infants/toddlers/children was between 0.6 and 6.1 g garlic/day. Since a clove of garlic weighs approximately between 4 and 7 g, this is less than 2 cloves/day at most. In the diets relating to adults, the intake of garlic extract was equivalent to 2.9 and 12.2 g of garlic.
which is less than 3 cloves garlic/day at most. This is deemed to be an overestimation; however, it is found appropriate to show that the use of garlic extract as a plant protection product according to the GAP, even at the most conservative estimate of potential residues, it is not expected to pose an acute or chronic health risk to the consumer.

Applicant also provided data which show that intake of garlic extract by lamb and other ruminants such as cattle should not pose a health risk to these animals.

3.1. Maximum residue levels

No areas of concern or data gaps were identified. No MRL is proposed for this active substance.

Based on the submitted European authorised uses in different crop groups, garlic extract is proposed to be included into Annex IV of Regulation (EC) No 396/2005 since the criteria for the inclusion in the Annex IV of Regulation (EC) No 396/2005 are met. MRLs are not required for the authorised uses.

4. Environmental fate and behaviour

The active ingredient is a pasteurised garlic juice obtained from crushed cloves of garlic. Most of the components are expected to be unspecfic plant material. However, the substance is expected to be composed of a number of organopolysulfides (allyl and alkyl polysulfides), to which the biological activity as a pesticide and a repellent is attributed. Only a small number of them have been characterised and are regarded by the applicant as marker molecules: diallyl sulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide. As such, a complete and comprehensive environmental exposure assessment of the ‘active substance’ is currently not possible in this case as performing studies in line with the current OECD protocols give meaningless results as each substance of the mixture will behave independently with its own fate and behaviour characteristics upon release into the environment. Therefore, no specific environmental fate and behaviour data are available for the ‘garlic extract’ in relation to route and rate of degradation in soil, adsorption/desorption, soil photolysis or mobility in soil. Considering that the garlic extract is made up of same substances as those present in plants, it is expected to degrade in the environment like any other plant debris. The potential levels of bioactives (as Polysulfide Allin Equivalents (PAE)) in garlic being released to the environment due to a lumped application of NEMguard/ECOguard SC and NEMguard/ECOguard GR according to the proposed GAP are within the concentration range of bioactives in garlic being released to the environment due to agricultural cropping. Garlic extract as a natural substance is expected to be non-persistent in the environment. Based on the (quantitative structure-activity relationship (QSARs)) estimated $K_{oc}$ values, diallyl sulfide and diallyl disulfide are expected to display medium mobility (184 and 437 L/kg, respectively) while diallyl trisulfide and diallyl tetrasulfide exhibit low mobility (796 and 1,228 L/kg, respectively).

No relevant environmental fate and behaviour studies were available for ‘garlic extract’ in relation to route and rate of degradation in aquatic systems including chemical, photochemical and/or biological degradation, hydrolytic degradation and aqueous photochemical degradation. In line with the previous EFSA conclusion (2012), it was considered that direct exposure of surface water bodies cannot be excluded for applications via spraying, via broadcast and sprinkling irrigation systems (susension concentrate formulation), application to the soil surface by conventional granular application equipment and band applications followed by irrigation (granular formulation). Therefore, data gaps were identified for information on the hydrolytic degradation/stability, the direct photochemical degradation/stability and on the fate and behaviour in water and sediment of the four marker compounds diallyl monosulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide (see Section 8).

For the representative uses with application beneath the soil surface, the aquatic exposure assessment is considered not necessary. Predicted environmental concentrations (PEC) in surface water were carried out using the FOCUS (FOCUS, 2001) steps 1–2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator) and up to step 4 following the FOCUS (FOCUS, 2007) guidance, with the implementation of no-spray drift buffer zones and/or vegetative buffer strips of up to overall 20 m. The SWAN tool (version 5.0) was appropriately used to implement these mitigation measures in the simulations. In the absence of reliable degradation rates in both the aquatic and soil compartment, the use of the FOCUS default of 1,000 days in FOCUS surface water modelling was considered

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5 Potential Garlic Extract residue was converted to equivalent amounts of garlic by using the conversion factor provided by the applicant of 16 (1 g of concentrate per 16 g of fresh garlic).
inappropriate and overly conservative as it would suggest the substance is persistent. Consequently, a DT50 of 1 day with a safety factor of 100 to account for the uncertainty in the experimental data (e.g. volatility vs. degradations, extrapolating from short chain to long chain molecules) was used. This resulted in a DT50 of 100 days for soil, the water/sediment system and water and sediment. This could potentially be refined at product authorisation by submitting appropriate studies with the longest marker molecules (e.g. diallyl tetrasulfide) which would be expected to degrade more slowly relative to the short chain molecules (e.g. diallyl sulfide and diallyl disulfide). The adsorption coefficient of diallyl sulfide (QSAR estimated $K_{oc}$ 184 L/kg), which is the most mobile marker molecule in garlic extract was used in the modelling. However, taking into consideration that organopolysulfides with longer chain lengths (e.g. diallyl tetrasulfide) are more strongly adsorbed to sediment, the peer review concluded that the available PECs in sediment are likely to underestimate the aquatic exposure (sediment compartment) for the three marker compounds diallyl monosulfide, diallyl trisulfide and diallyl tetrasulfide (data gap, see Section 8). The RMS disagrees with the data gap and considers that it is unlikely that the available PECsed are underestimated because the entire application rate of garlic extract (as a mixture, including non-active components which represent > 90% of the extract and have no pesticidal activity) was used in the calculations. Surface water exposure assessments in line with the EFSA Guidance (2014) to address surface water exposure arising from applications to soil bound and soilless crops in high technology greenhouses were also available. In the absence of experimental data, garlic extract should be regarded as not readily biodegradable.

No groundwater exposure assessment was provided. However, the levels of polysulfides resulting from the lumped application of NEMguard/ECOguard SC and NEMguard/ECOguard GR according to the proposed GAP are within the concentration range of bioactives in garlic being released to the environment due to agricultural cropping in the event the crop is tilled back into the ground. Consequently, PEC in groundwater is considered not necessary.

5. Ecotoxicology

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

No toxicity data on birds and mammals were available with renewal dossier. These data are considered not needed in line with the previous EFSA (2012) where the risk to birds and mammals was considered low due to the repellent properties of garlic extract.

Only supportive studies were available for fish, aquatic invertebrates and algae; however, no valid studies were available. Furthermore, no chronic toxicity studies were available for fish and aquatic invertebrates. Consequently, with the information available, the risk assessment for aquatic organisms, for most of the representative uses, cannot be finalised and data gaps were identified for reliable toxicity studies (acute fish, acute aquatic invertebrates and algae). Furthermore, a data gap was identified to either demonstrate that the active substance is hydrolysed by 90% within 24 hours or for chronic toxicity data and risk assessment for fish and aquatic invertebrates. These data gaps are relevant for all representative uses other than the granular product to be applied below the soil surface to potatoes and parsnips (both in the field and glasshouses). Furthermore, without a chronic risk assessment for aquatic invertebrates, it is not possible to understand whether a risk assessment for sediment-dwelling organisms is triggered. Consequently, pending the outcome of the data gap for the chronic toxicity to aquatic invertebrates, further consideration of risk to sediment-dwelling organisms may be required.

Only acute oral and contact toxicity data on honeybees were provided with garlic extract. During the peer review, chronic data on adult and larvae honeybees were requested but not provided (data gap). Furthermore, no data are available to assess sublethal effects (hypopharyngeal glands (HPG)) (data gap) or accumulated effects to honeybees. No reliable toxicity data were available for bumblebees or solitary bees.

The acute risk assessment was performed based both on the European Commission (2002) and on the EFSA (2013). The acute hazard quotient (HQ) values based on European Commission (2002) indicated a low risk for all representative spray uses. The European Commission (2002) guidance document does not provide a risk assessment for granular products, and therefore, no assessment could be performed. The acute contact and oral risk assessment according to EFSA (2013) was not sufficient to indicate a low acute risk to honeybees for application rates of 25.7 kg a.s./ha (noting that the assessment was performed using unbounded toxicity values). A risk assessment was also presented for rates of 5.139 kg a.s./ha which resulted in a low acute risk to honeybees. No risk
assessment was presented for honeybees consuming water contaminated with residues of the active substance. Overall a data gap is concluded for a complete risk assessment according to EFSA (2013) (covering acute, chronic, honeybee larva, and sublethal effects and for all exposure routes).

Toxicity tests with the two standard species of non-target arthropods, Typhlodromus pyri and Aphidius rhopalosiphi, were available. Extended laboratory (tier 2) studies were available for A. rhopalosiphi and C. septempunctata. The tier 1 risk assessment indicated a high in-field risk for the representative uses as spray applications of 5.139 kg a.s./ha and of 25.7 kg a.s./ha. A low risk was indicated for the representative uses at 2.59 kg a.s./ha. The tier 1 risk assessment indicated a low off-field risk for all representative spray uses. A tier 2 risk assessment was available and indicated a low risk for all representative spray uses with the exception of the use to managed amenity turf at 25.7 kg a.s./ha where a high risk was indicated for one species.

No quantitative risk assessment for non-target arthropods was available for the representative uses as a granule. However, as exposure to soil is no greater than the natural background level (see Section 4), a low risk to non-target arthropods for the representative uses as a granule was concluded.

No data were available for earthworms, soil macro- and microorganisms. The exposure to soil is not expected to be likely higher than the natural background level (see Section 4); therefore, the risk can be considered as low for all representative uses.

No specific data on terrestrial non-target plants were provided. Garlic extract does not exhibit an herbicidal activity. It was reported that efficacy data indicated no phytotoxic effects; however, such screening data were not available in the RAR (Ireland, 2019a). Therefore, a data gap was identified to confirm the lack of phytotoxic effects in the efficacy screening studies. According to the European Commission (2002) guidance document no risk assessment for non-target plants for the representative use as granules is triggered and therefore the risk concluded to be low.

No studies on effects on biological methods for sewage treatment were submitted, which are needed for the representative glasshouse uses (data gap).

6. Endocrine disruption properties

With regard to the assessment of the endocrine-disrupting potential of garlic extract 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, it does not appear scientifically necessary considering that garlic is a food item for humans. This conclusion applies for both humans and non-target organisms. Therefore, it is justified to waive the assessment of endocrine-disrupting properties of this substance.

Overall, garlic extract is considered not 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) 2018/605.6

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) | Persistence | Ecotoxicology |
|-----------------------------|-------------|---------------|
| Marker compounds (diallyl sulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide) | No data available. Risk assessment based on worst case predicted initial soil concentration resulting from a single application | Low risk |

6 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. OJ L 101, 20.4.2018, p. 33–36.
8. 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).

- Monitoring method for the residues of the marker compound diallyl trisulfide in groundwater (relevant for all representative uses evaluated; see Section 1).
- A search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health 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; relevant for all representative uses evaluated).
- Information on the fate and behaviour in water and sediment of the four marker compounds diallyl monosulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide. This data gap is considered not essential to finalise the aquatic exposure (water phase) assessment (relevant for the representative uses with spray application, application via broadcast and sprinkling irrigation and application to the soil surface by conventional granular application equipment; see Section 4).
- Information on hydrolytic degradation or stability of the four marker compounds diallyl monosulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide. This data gap is considered

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Table 2: Groundwater

| Compound (name and/or code) | Mobility in soil | > 0.1 μg/L at 1 m depth for the representative uses<sup>(a)</sup> | Pesticidal activity | Toxicological relevance |
|-----------------------------|------------------|-------------------------------------------------------------|---------------------|------------------------|
| diallyl sulfide (marker compound) | QSAR estimate (KOCWIN v 2.00) 184 K/kg | No data, Not required | No data, Not required. | Yes (although no adverse effects are expected) |
| diallyl disulfide (marker compound) | QSAR estimate (KOCWIN v 2.00) 437 K/kg | No data, Not required | No data, Not required. | Yes (although no adverse effects are expected) |
| diallyl trisulfide (marker compound) | QSAR estimate (KOCWIN v 2.00) 796 K/kg | No data, Not required | No data, Not required. | Yes (although no adverse effects are expected) |
| diallyl tetrasulfide (marker compound) | QSAR estimate (KOCWIN v 2.00) 1228 K/kg | No data, Not required | No data, Not required. | Yes (although no adverse effects are expected) |

<sup>(a)</sup>: FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|-----------------------------|--------------|
| diallyl sulfide (marker compound) | Data gap |
| diallyl disulfide (marker compound) | Data gap |
| diallyl trisulfide (marker compound) | Data gap |
| diallyl tetrasulfide (marker compound) | Data gap |

Table 4: Air

| Compound (name and/or code) | Toxicology |
|-----------------------------|------------|
| Marker compounds (diallyl sulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide) | Garlic has the potential to cause asthma under occupational exposure by inhalation |
not essential to finalise the aquatic exposure (water phase) assessment (relevant for the representative uses with spray application, application via broadcast and sprinkling irrigation and application to the soil surface by conventional granular application equipment; see Section 4).

- Information on the direct photochemical degradation or stability of the four marker compounds diallyl monosulfide, diallyl disulfide, diallyl trisulfide and diallyl tetrasulfide. This data gap is considered not essential to finalise the aquatic exposure (water phase) assessment (relevant for the representative uses with spray application, application via broadcast and sprinkling irrigation and application to the soil surface by conventional granular application equipment; see Section 4).

Pending the outcome of the data gap for information to demonstrate the rapid hydrolysis or a chronic toxicity study for aquatic invertebrates, an environmental exposure (Predicted environmental concentration, PEC) of the sediment phase is needed for three marker compounds diallyl monosulfide, diallyl trisulfide and diallyl tetrasulfide (relevant for the representative uses with spray application, application via broadcast and sprinkling irrigation and application to the soil surface by conventional granular application equipment; see Section 4).

- Data and risk assessments are needed to address the acute risk to aquatic organisms (relevant for all representative uses other than the granular product to be applied below the soil surface to potatoes and parsnips (both in the field and glasshouses); see Section 5).

- Data are needed to either demonstrate that the active substance is hydrolysed by 90% within 24 h or for chronic toxicity data and risk assessment for fish and aquatic invertebrates (relevant for all representative uses other than the granular product to be applied below the soil surface to potatoes and parsnips (both in the field and glasshouses); see Section 5).

- Data assessing the chronic oral toxicity to honeybees, toxicity to honeybee larvae and sublethal effects (e.g. HPG) are needed. Furthermore, a complete risk assessment according to EFSA (2013) is needed (relevant for all representative uses; see Section 5).

- Confirmation of the lack of phytoxic effects in the efficacy screening studies is needed (relevant for representative spray uses; see Section 5).

- Data are needed to exclude a risk to biological methods for sewage treatment (relevant for the representative glasshouse uses; see Section 5).

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 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) The risk to aquatic organisms, including those dwelling in the sediment, could not be finalised with the available information (relevant for all representative uses other than the granular product to be applied below the soil surface to potatoes and parsnips (both in the field and glasshouses) (see Sections 4 and 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

7 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.
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.

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 5.)

**Table 5:** Overview of concerns

| Representative use                          | Potato, parsnip Granular application beneath soil surface Field, greenhouse | Managed Amenity Field 1 × 25700 g/ha 6 × 25700 g/ha | All other representative uses(e),(4) |
|--------------------------------------------|------------------------------------------------------------------------------|---------------------------------------------------|-------------------------------------|
| Operator risk                              | Risk identified                                                              | Assessment not finalised                           |                                     |
| Worker risk                                | Risk identified                                                              | Assessment not finalised                           |                                     |
| Resident/bystander risk                    | Risk identified                                                              | Assessment not finalised                           |                                     |
| Consumer risk                              | Risk identified                                                              | Assessment not finalised                           |                                     |
| Risk to wild non-target terrestrial vertebrates | Risk identified                                                          | Assessment not finalised                           |                                     |
| Risk to wild non-target terrestrial organisms other than vertebrates | Risk identified                                                          | Assessment not finalised                           | X                                   |
| Risk to aquatic organisms                  | Risk identified                                                              | Assessment not finalised                           | X¹                                  |
| Groundwater exposure to active substance   | Legal parametric value breached                                              | Assessment not finalised                           | X¹                                  |
| Groundwater exposure to metabolites        | Legal parametric value breached<sup>(a)</sup>                                | Parametric value of 10 µg/L<sup>(b)</sup> breached | Assessment not finalised            |

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2 to 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, 2003.
(c): NEMguard SC/ECOguard SC to Citrus fruits, Berries and small fruits (Grapes (table + wine), strawberry, blackberry, raspberry, blueberry, cranberry, currant, gooseberries), Miscellaneous fruits (figs, kiwi fruit), Root and tuber vegetables (Potatoes, carrot, swede parsnip, turnip, radish), Sugar plants (sugar beet), Flowering brassica (Broccoli/calabrese, cauliflower), Bulb vegetables (onion), Head brassica (Brussel sprouts, head cabbages), Leafy brassica (Chinese cabbages, Pak choi), Stem vegetables (Leek), Managed Amenity Turf (3 × 2.569 kg a.s./ha) (golf courses, race courses, rugby and football pitches, hockey, baseball athletic stadiums, recreational areas).

(d): NEMguard Granules/ECOguard Granules to Root and tuber vegetables on the soil surface (Potatoes, carrot, swede, parsnip, turnip, radish), Flowering Brassica (Broccoli/calabrese, cauliflower), Head brassica (Brussel sprouts, head cabbages), Bulb vegetables (onion), Leafy brassica (Chinese cabbages, Pak choi), Stem vegetables (Leek).

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**Abbreviations**

a.s. active substance  
bw body weight  
DT$_{50}$ period required for 50% dissipation (define method of estimation)  
DT$_{90}$ period required for 90% dissipation (define method of estimation)  
ECHA European Chemicals Agency  
EEC European Economic Community  
f(twa) Time-weighted average factor  
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  
GR granules  
HPG hypopharyngeal glands  
HQ hazard quotient  
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)  
mm millimetre (also used for mean measured concentrations)  
MRL maximum residue level  
OECD Organisation for Economic Co-operation and Development  
Pa pascal  
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  
PRIMo Pesticide Residue Intake Model  
QSAR quantitative structure–activity relationship  
RAR Renewal Assessment Report  
SC suspension concentrate  
SMILES simplified molecular-input line-entry system  
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.2020.6116
### Appendix B – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|---------------------------------------|-----------------------|
| diallyl sulfide (DAS1) | 3-(allylsulfanyl)prop-1-ene  
C=CCSCC=C  
UBJVUCKUDDKUJF-UHFFFAOYSA-N | H₂C≡CCCSCC≡CH₂ |
| diallyl disulfide (DAS2) | 3-(allyldisulfanyl)prop-1-ene  
C=CCSSCC=C  
PFRGXCVKLLPLIP-UHFFFAOYSA-N | H₂C≡CCCSCC≡CH₂ |
| diallyl trisulfide (DAS3) | diallyltriprisulfane  
C=CCSSSCC=C  
UBAXRAHSPKWNCX-UHFFFAOYSA-N | H₂C≡CCCSCC≡CH₂ |
| diallyl tetrasulfide (DAS4) | diallyltetrasulfane  
C=CCSSSSCC=C  
RMKCQUWJDRTEHE-UHFFFAOYSA-N | H₂C≡CCCSCC≡CH₂ |

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 Jul 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 Jul 2019).