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CONCLUSION ON PESTICIDES PEER REVIEW

Peer review of the pesticide risk assessment of the active substance quinolin-8-ol

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Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Spain, and co-rapporteur Member State, the Netherlands, for the pesticide active substance quinolin-8-ol 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 quinolin-8-ol as a fungicide and bactericide against soil-borne pathogens in tomato cultivation in permanent greenhouses applied by drip irrigation. 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 reported where identified.

KEYWORDS

bactericide, fungicide, peer review, pesticide, quinolin-8-ol, risk assessment

CONTENTS

SUMMARY

Commission Implementing Regulation (EU) No 844/2012 lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) No 2016/183. Quinolin-8-ol is one of the active substances listed in that Regulation.

In accordance with Article 1 of Regulation (EU) No 844/2012, the rapporteur Member State (RMS), Spain, and co-rapporteur Member State (co-RMS), the Netherlands, received an application from Probelte S.A.U. for the renewal of approval of the active substance quinolin-8-ol.

An initial evaluation of the dossier on quinolin-8-ol was provided by the RMS in the renewal assessment report (RAR); 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 part of the renewal procedure, the RMS requested additional information to the applicant Probelte S.A.U. (as per Article 11(5) of Commission Regulation (EU) No 844/2012) to submit evidence regarding the necessity of quinolin-8-ol to control a serious danger to plant health which cannot be contained by other available means as in accordance with Article 4(7) of Regulation (EC) No 1107/2009. The evaluation of the data regarding this derogation request is presented in Appendices E and F of this conclusion. Overall, it can be concluded that, for specific crop–disease combinations, the derogation is scientifically supported: *Clavibacter michiganensis* in greenhouse tomato (Bulgaria, Belgium Cyprus, Greece, Portugal), *Fusarium* in greenhouse tomato (Malta), *Phytopthora*, *Pythium* and *Rhizoctonia* in greenhouse tomato (Bulgaria), *Verticillium* in greenhouse tomato (Belgium, Bulgaria, Malta), fruiting vegetables (tomato, cucumber, zucchini, bush pumpkin, melon, pumpkin, bottle gourd, giant pumpkin, musky gourd) against bacterial and fungal soil-borne pathogens (Germany), *Phytopthora* and *Verticillium* in greenhouse Okra's lady fingers (Belgium), *Verticillium* in greenhouse strawberry (Belgium), *Phytopthora*, *Pseudomonas* and *Pythium* in strawberry (Austria), bacterial and fungal soil-borne pathogens in greenhouse strawberry (Germany), disinfection against *Botrytis cinerea* and fungi of the ESCA-complex in grapevine (grafting material and 1-year-old plants).

Following completion of the peer review process, the following conclusions are derived.

The use of quinolin-8-ol according to the representative use as a fungicide and bactericide in tomato cultivation in permanent greenhouses applied by drip irrigation, as proposed at EU level, results in a sufficient fungicidal and bactericidal efficacy against the target soil-borne pathogens.

The assessment of the data package revealed no issues that could not be finalised or that need to be included as critical areas of concern with respect to **identity, physical/chemical properties and analytical methods**.

In the area of **mammalian toxicology**, a critical area of concern was identified for the harmonised classification of quinolin-8-ol in category 1B for reproductive toxicity. The non-dietary exposure of bystander and resident children cannot be concluded since the predicted exposure estimates with the applied EFSA model (120% of (A)AOEL) are very likely overestimated due to the model assumptions.[1] The available field study was concluded as not reliable and it did not allow an ad hoc approach for the non-dietary exposure assessment.

In the area of **residues**, the consumer dietary risk assessment was provisionally carried out using toxicological reference values derived by EFSA,[2] pending data gaps for rotational crop studies and additional field trials to be addressed.

The data available on **environmental fate and behaviour** are sufficient to carry out the required environmental exposure assessments at EU level for the representative drip irrigation use in permanent greenhouses.

In the area of **ecotoxicology**, a DT90 in soil > 1 year cannot be excluded. Therefore, in situations where soil is removed and used outside and/or the structure is removed up to after 12 months from the last application, a high risk to soil macroorganisms, i.e. collembola, cannot be excluded when considering the PECsoil over 5 cm and when the structure or the soil is removed and used outside.

Based on the available data, quinolin-8-ol is not considered to meet **the criteria** for **endocrine disruption** (ED) as laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

[1]The EU representative use of drip irrigation supported for the renewal of approval of quinoline-8-ol is not covered by the EFSA model, but the model was based on data for spray application use.

[2]Quinolin-8-ol genotoxic potential was judged inconclusive (for mutagenicity, clastogenicity and aneugenicity) by the majority of the peer review experts. In this respect, EFSA acknowledged that in 2015 ECHA RAC did not propose to classify quinolin-8-ol for germ cell mutagenicity on the basis of the same data set (ECHA, 2015). Since the classification proposed by RAC is legally applicable in the EU, EFSA derived toxicological reference values (not peer reviewed).

BACKGROUND

Commission Implementing Regulation (EU) No 844/2012[3] (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.[4] 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).

In accordance with Article 1 of the Regulation, the RMS, Spain, and co-RMS, the Netherlands, received an application from Probelte S.A.U. for the renewal of approval of the active substance quinolin-8-ol.

As part of the renewal procedure, the RMS requested additional information to the applicant Probelte S.A.U. (as per Article 11(5) of Commission Regulation (EU) No 844/2012) to submit evidence regarding the necessity of quinolin-8-ol to control a serious danger to plant health which cannot be contained by other available means as in accordance with Article 4(7) of Regulation (EC) No 1107/2009. The evaluation of the data regarding this derogation request is presented in Appendices E and F of this conclusion.

Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (the Netherlands), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on quinolin-8-ol in the RAR, which was received by EFSA on 9 July 2021.

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Probelte S.A.U., for consultation and comments on 17 March 2022. 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 23 May 2022. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of reporting table. In addition, the applicant was invited to respond to the comments received. 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 11 July 2022. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

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

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 November–December 2023.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the formulation for representative uses, evaluated on the basis of the representative use of quinolin-8-ol as a fungicide and bactericide against soil-borne pathogens in tomato cultivation in greenhouses (permanent) applied via drip-irrigation, 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, if any, are presented in the conclusion.

A list of the relevant end points for the active substance and the formulation is provided in Appendix B. In addition, the considerations as regards the cut-off criteria for quinolin-8-ol according to Annex II of Regulation (EC) No 1107/2009 are summarised in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2024), 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:

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

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

- the comments received on the RAR;
- the reporting table (14 July 2022);
- the evaluation table (24 July 2023);
- 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 (Spain, 2023), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

THE ACTIVE SUBSTANCE AND THE FORMULATION FOR REPRESENTATIVE USE

The IUPAC name of the active substance is quinolin-8-ol, 8-hydroxyquinoline is a non-ISO, trivial name of this active substance. The active substance is manufactured as quinolin-8-ol and used in the formulation for representative use as bis(8-hydroxyquinolinium)sulfate (IUPAC). To note that a trivial name for bis(8-hydroxyquinolinium)sulfate is 8-hydroxyquinoline sulfate. The International Organization for Standardization does not require a common name for this sulfate salt.

The formulation for representative use supported for the evaluation was 'Beltanol', a soluble concentrate (SL) containing 500 g/L of bis(8-hydroxyquinolinium)sulfate equivalent to 375 g/L of quinolin-8-ol. The information on the active substance, the formulation for representative use and co-formulants has been considered in the overall assessments during the peer review. None of the co-formulants is an unacceptable co-formulant listed in Annex III of Regulation (EC) No 1107/2009.

The representative use evaluated was drip-irrigation application as a fungicide and bactericide against soil-borne pathogens in tomato cultivation in greenhouses (permanent structures). Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix B.

Data were submitted to conclude that the use of bis(8-hydroxyquinolinium) sulfate according to the representative use proposed at EU level results in a sufficient fungicidal and bactericidal efficacy against the target pests, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

CONCLUSIONS OF THE EVALUATION

1 | IDENTITY, PHYSICAL/CHEMICAL/TECHNICAL PROPERTIES AND METHODS OF ANALYSIS

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

The proposed specification for quinolin-8-ol is based on batch data from industrial scale production. The applicant and RMS have proposed to maintain the current reference specification with a minimum purity of the technical material of 990 g/kg. The batches used in the (eco)toxicological assessment support the original reference specification (see Sections 2 and 5). There is no FAO specification available for quinolin-8-ol.

The main data regarding the identity of quinolin-8-ol and its physical and chemical properties are given in Appendix B.

Adequate methods are available for the generation of data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the formulation for representative use and the impurities in the technical material.

Quinolin-8-ol residues in food and feed of plant origin can be monitored by high-pressure liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Quinolin-8-ol in food of animal origin can be determined by HPLC–MS/MS with an LOQ of 0.01 mg/kg in all animal matrices.

Quinolin-8-ol in soil could be monitored by HPLC–MS/MS with a LOQ of 0.05 mg/kg. Quinolin-8-ol residues could be analysed in water by HPLC–MS/MS with a LOQ of 0.1 µg/L. An appropriate HPLC–MS/MS method exists for monitoring of quinolin-8-ol in air with a LOQ of 1.5 µg/m^3, as an AOEL could not be set (see Section 2), compliance of the method LOQ with European Commission (2010) could not be confirmed.

An HPLC–MS/MS method was provided for monitoring of quinolin-8-ol in body fluids (urine) with a LOQ of 0.05 mg/L. The RMS accepted this method as adequate; however, EFSA considers that this method is not sufficient to measure free and conjugated quinolin-8-ol residues in body fluids (see **data gap**, Section 10). Quinolin-8-ol residues in body tissues can be determined by using the monitoring methods for residues in food of animal origin.

2 | MAMMALIAN TOXICITY

The toxicological profile of the active substance quinolin-8-ol was discussed at the Pesticides Peer Review Experts' Teleconference 110 in June 2023. The assessment is based on the following guidance documents: European Commission (2003, 2012); EFSA (2014a, 2017); EFSA PPR Panel (2012); ECHA (2017).

Regarding the proposed reference specification, no toxicologically relevant impurities were identified. The test material used in toxicity studies can be considered representative of the original reference specification for the active substance and associated impurities (see also Section 1).

The oral **absorption** of quinolin-8-ol was estimated to account for more than 80% of the administered dose (based on urinary excretion), while the systemic bioavailability was determined to be 63.4% by comparison of the area under the curve after administration by both oral and intravenous routes. In the rat, quinolin-8-ol has a limited distribution throughout the body without evidence of bioaccumulation. It has also been demonstrated to be extensively metabolised into sulfate and glucuronide conjugates after intravenous administration, being excreted mainly in urine and to a lesser extent in bile (with demonstrated enterohepatic circulation). Considering the limitations in the available comparative in vitro metabolism study, the need of a new study including the four representative species (rat, dog, rabbit and human material) performed with primary hepatocytes and identifying all unique human metabolites, or disproportionate human metabolites present above 5%, was identified[5] (data gap, see Section 10).

The **residue definition** for body fluids includes the active substance, the sulfate and glucuronide conjugates; no residue definition is triggered for tissues since only negligible levels were detected.

Quinolin-8-ol has a high **acute** oral toxicity in mice (Acute Tox 3),[6] a low acute dermal toxicity, it is not skin irritant; however, it can cause serious eye damage (Eye Dam. 1)[4] and allergic skin reaction (Skin Sens. 1).[4] Testing of acute toxicity by inhalation could be waived due to the physico-chemical properties of the active substance (low vapour pressure and liquid formulation) and the intended use (drip irrigation). As quinolin-8-ol is phototoxic in vitro, further assessment of its photomutagenic potential should be performed (**data gap**, see Section 10). However, it is acknowledged that there is currently no validated test guideline or guidance that can be suggested to address this endpoint.[7]

Short-term oral toxicity studies were provided for rats, mice and dogs. In rats, the overall short-term no observed adverse effect level (NOAEL) is 97.7 mg/kg body weight (bw) per day based on increased relative spleen weight and altered haematologic parameters. In mice, the short-term NOAEL is 113 mg/kg bw per day based on decreased food consumption and body weight gain. In dogs, the overall short-term NOAEL is 10 mg/kg bw per day based on increased relative thyroid with parathyroid weight.[8]

Based on the available **genotoxicity** data package, taking into account the acceptability of the different studies, quinolin-8-ol was shown to be clastogenic in vitro with and without metabolic activation, while no conclusion could be reached about its mutagenic potential (equivocal in mammalian cell gene mutation test in vitro and no in vivo mutagenicity studies available). Based on the available in vivo studies, presenting limitations, the clastogenic and aneugenic potential of quinolin-8-ol could not be concluded. The view of the RMS was that the in vivo study (chromosome aberration study in spermatogonial cells) is sufficiently robust to contravene the positive results observed in vitro for chromosome aberration; however, the majority of the experts was of the opinion that clastogenicity in vivo cannot be concluded.[9] The experts also agreed that the metabolism of quinolin-8-ol could not be adequately covered by the intraperitoneal route of administration used in the negative and guideline-compliant in vivo micronucleus study, and therefore that the evidence in vivo is not sufficiently robust to conclude on the clastogenic/aneugenic potential of quinolin-8-ol. Based on the same data set, ECHA RAC (ECHA, 2015) concluded that classification is not triggered for germ cell mutagenicity.

After **long-term exposure**, no carcinogenic effect was observed in rats or mice and quinolin-8-ol was concluded unlikely to be carcinogenic for humans. In the 2-year rat study, the NOAEL for systemic toxicity was 73 mg/kg bw per day, based on reduced body weight (gain) and feed consumption, atrophy of splenic follicles and pituitary angiectases observed at 143 mg/kg bw per day. In the 2-year mouse study, the NOAEL for chronic toxicity was 217 mg/kg bw per day based on reduced body weight (gain) and food consumption, lung epithelial hyperplasia and pituitary gland dilation observed at 396 mg/kg bw per day. It is noted that both studies were concluded to be supplementary because of significant limitations to address chronic toxicity (only two dose levels tested, lack of haematological, clinical chemistry, urinalysis and organ weights data); however, it was agreed that new data should not be required, but an additional uncertainty factor could be applied for the derivation of the toxicological reference values.[10]

From the **reproductive toxicity** studies, a parental NOAEL of 98.43 mg/kg bw per day was identified in the two-generation rat study, based on reduced body weight gain and food consumption, increased relative spleen weight and decreased absolute prostate weight at 282.8 mg/kg bw per day. The reproductive and offspring toxicity lowest observable

[5]Refer to experts' consultation 2.1 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[6]Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1494841630097&uri=CELEX:32017R0776

[7]Refer to experts' consultation 2.3 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[8]Refer to experts' consultation 2.2 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[9]Refer to experts' consultation 2.4 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[10]Refer to experts' consultation 2.5 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

adverse effect levels (LOAELs) were 98.43 mg/kg bw per day, based on reduced litter size and mean number of viable pups at birth at this dose level (lowest tested).[11]

With regard to **developmental toxicity** studies in rats, the lowest dose tested of 100 mg/kg bw per day was identified as maternal and developmental LOAEL based on decreased corrected maternal body weight change, increased number of skeletal retardations (in sternebrae), reduced number of foetal ossification centres and reduced placental weight. In the rabbit teratogenicity study, the maternal NOAEL was 5 mg/kg bw per day based on the clinical signs reported in dams (nervous system excitation after dosing followed by lethargy), while the developmental LOAEL was 5 mg/kg bw per day based on the increased number of fetuses with skeletal retardations observed at this low dose level, as agreed by all experts. According to Regulation (EC) No 1272/2008, quinolin-8-ol has a harmonised classification as **Repr. 1B (H360D)**[12] on the basis of the increased incidence of omphalocele observed at 15 and 60 mg/kg bw per day in this rabbit study[13] (**critical area of concern**, see Section 9.1.2).

With respect to **neurotoxicity**, quinolin-8-ol showed some indications of potential neurotoxicity in the standard regulatory studies (e.g. in teratogenicity studies by gavage administration). It was agreed that no neurotoxicity study should be required, but this should be taken into account when deriving the toxicological reference values.[14] With regard to immunotoxicity, no related effect was observed in the available studies.

Toxicological reference values (**acceptable daily intake** (ADI), **acceptable operator exposure level** (AOEL), **acute reference dose** (ARfD) and **acute AOEL** (AAOEL)) applicable to quinolin-8-ol were not established during the peer review meeting since the majority of the experts considered the genotoxicity potential of the active substance to be inconclusive. EFSA acknowledged that in 2015 ECHA RAC did not propose to classify quinolin-8-ol for germ cell mutagenicity on the basis of the same data set. Since the classification proposed by RAC is legally applicable in the EU,[15] after the peer review meeting EFSA derived the following toxicological reference values (not peer reviewed)[16]: for the ADI and the ARfD, based on the LOAEL of 5 mg/kg bw per day in the rabbit teratogenicity study, a value of 0.017 mg/kg bw per day is obtained when applying an increased uncertainty factor (UF) of 300 (taking into account the use of a LOAEL). For the AOEL and the AAOEL, based on the same study, a value of 0.01 mg/kg bw per day is obtained when applying an increased UF of 300 (taking into account the use of a LOAEL) and a correction for an oral bioavailability of 63.4%. Additionally, considering that the quinolin-8-ol sulfate is a major metabolite of quinolin-8-ol in the absorption, distribution, metabolism and excretion (ADME) studies with rats, it can be concluded that its toxicological profile will be covered by the that of the parent compound.

Dermal absorption of quinolin-8-ol in the formulation for representative use ('Beltanol') has been assessed in an in vitro study with human skin. Based on the EFSA guidance (EFSA, 2017), the dermal absorption values to be used for risk assessment are 0.97% for the concentrate and 42% for the in-use dilution.[17]

For the **non-dietary exposure** estimates (see details in Appendix G), the exposure of operators is predicted to be below 10% of the proposed (A)AOEL in case of automated drip irrigation in permanent greenhouse (with the absence of operators during the application phase). For workers performing re-entry activities with or without contact with the treated soil, the exposure estimates are below 10% of the proposed AOEL with use of standard professional workwear. For residents and bystanders, the exposure of children to vapour is predicted to exceed the proposed (A)OEL (the submitted specific field study was not considered sufficiently reliable for a refinement). However, the predicted exposure estimates with the EFSA model are very likely overestimated due to the model assumptions as it is based on data for spray application and not for drip irrigation (issue not finalised, see Section 9.1.1).[18]

With regard to the toxicological information available for the formulation for representative use 'Beltanol', studies were performed on acute toxicity endpoints. With regard to the **co-formulants** contained in 'Beltanol', sufficient toxicological data for genotoxicity, repeated-dose toxicity information over short- and long-term were available for all components. The experts considered that the available toxicological information is sufficient to conclude on the safety of the formulation and no concern was identified.[19]

3 | RESIDUES

The assessment in the residue section is based on the following guidance documents: OECD (2009, 2011), European Commission (2003, 2019), JMPR (2004, 2007).

[11]Refer to experts' consultation 2.6 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

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

[13]Refer to experts' consultation 2.7 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[14]Refer to experts' consultation 2.9 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[15]Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures: https://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1494841630097&uri=CELEX:32017R0776

[16]The RMS proposed toxicological reference values in the RAR, on the basis of the previous setting of a developmental NOAEL of 5 mg/kg bw per day in the rabbit developmental toxicity study, applying only the standard uncertainty factor of 100 (ADI and ARfD of 0.05 mg/kg bw [per day]).

[17]Refer to experts' consultation 2.10 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[18]Refer to expert's consultation 2.11 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[19]Refer to experts' consultation 2.12 in the Report of the Pesticide Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

Metabolism in primary crops was investigated in tomato (fruit), with quinolin-8-ol labelled in ^{14}C-benzene ring following drip irrigation. Quinolin-8-ol was the major residue in shoots, green and ripe fruits found up to 38% TRR. Quinolin-8-ol occurred also under 'conjugated' forms (M1 and M2)[20] up to 31% TRR in ripe tomato, while these two conjugated forms were not further identified.

Even though the proposed use is for permanent greenhouses, tomatoes can be grown in rotation with other food crops in greenhouse. Since no studies were submitted to investigate the metabolism of quinolin-8-ol in rotational crops (**data gap**, see Section 9.1.1), no residue definitions for rotational crops could be proposed.

Based on the above consideration, the **residue definition for risk assessment** in primary crops is proposed as quinolin-8-ol free and conjugated and its salts expressed as quinolin-8-ol. The residue definition for **enforcement** in primary crops is proposed as quinolin-8-ol and its salts expressed as quinolin-8-ol. In view of the low occurrence (< 0.01 mg/kg) of conjugates in the residue trials for the representative use, quinolin-8-ol alone is considered a sufficiently good marker for enforcement. It should be noted that the proposed monitoring method is capable of measuring the sum of free and conjugated residues of quinolin-8-ol, and therefore, conjugates could be considered in the residue definition for enforcement if necessary. The residue definitions are limited to fruit crops only following drip irrigation.

The submitted trials were insufficient to support the representative GAP. Although the residue levels in the four ripe tomato trials conducted according to the GAP were < LOQ in one sample of green tomato residues were found at 0.02 mg/kg. Since the consumption of green tomato via dietary intake cannot be excluded, additional four GAP compliant residue trials reflecting the worst-case situation are needed to complete the data set (**data gap**, see Section 9.1.1). The available trials were covered by validated analytical methods and storage stability data.

The nature of quinolin-8-ol residues under standard hydrolysis conditions and magnitude of residues in processed commodities were not investigated as residues above 0.01 mg/kg were not measured in ripe tomatoes. However, residues above 0.01 mg/kg were found in green tomatoes which could be used for human consumption and may be processed, thus processing studies might be needed. Moreover, as data in rotational crops were not submitted, processing studies might also be required in case of residues occurrence above the LOQ in rotated crops potentially processed.

Investigation of quinolin-8-ol residues in livestock and fish was not necessary since tomato is not a feed item. However, as no data were submitted in rotational crops, this may need to be reconsidered upon addressing data gaps.

The requirement on residue trials in honey and bee products was waived based on the justification of the applicant on the use in permanent greenhouses and the non-attractiveness of tomatoes to bees. This justification was considered appropriate.

In view of the properties of quinolin-8-ol (see section 2), a negligible exposure assessment was attempted, but it could not be concluded due to the data gaps identified on magnitude of residues in primary crop, rotational crops and consequently the update of the animal dietary burden calculation. However, the available data indicate residues in edible commodities above the LOQ, pending further confirmation by the requested data. As a consequence of the data gaps identified, only a provisional consumer risk assessment could be carried out. Using toxicological reference values derived by EFSA (see Section 2), the consumer exposure assessment was carried out using the EFSA PRIMo version 3.1. (see Appendix G). The maximum chronic intake was calculated to be 0.2% of the ADI (GEMS/Food G06) and the highest acute intake is 7% of the ARfD for tomatoes (BE toddlers).

A screening of the impact on the peer review outcome on the Article 12 maximum residue level (MRL) review according to Regulation (EC) No 396/2005 (EFSA, 2021) was made. The residue definitions for enforcement and risk assessment proposed under the renewal process and the ones applied in the Article 12 MRL review are the same (no conjugates included in the residue definition for enforcement). Using the new ADI of 0.017 mg/kg bw per day and ARfD of 0.017 mg/kg bw for quinolin-8-ol derived by EFSA, which are lower than the ones used in the Art.12 review,[21] the acute and chronic consumer dietary risk assessment for the MRLs assessed in the Art.12 review did not result in an exceedance of the TRVs derived by EFSA (0.8% of the ADI, GEMS/ Food G06 and 18% of the ARfD for melons [BE toddlers]).

4 | ENVIRONMENTAL FATE AND BEHAVIOUR

The environmental fate and behaviour of quinolin-8-ol was based on studies performed on its sulfate salt and it was discussed at the Pesticides Peer Review Meeting TC 111 in June 2023.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, quinolin-8-ol exhibited high to very high persistence in soil when considering the inclusion of the unextractable residues. No major metabolites (> 10% applied test item) were formed. Mineralisation of the ^{14}C-benzene ring radiolabel to carbon dioxide accounted for 10%–12% AR after 120 days. The formation of unextractable residues (not extracted by methanol/H_2SO_4) for this radiolabel was a significant sink and accounted for 61%–79% AR after 120 days. Quinolin-8-ol dissipated rapidly by forming unextractable residues and its chelating properties potentially led to the quick formation of complexes with colloidal particles and with

[20]Quinolin-8-ol as neutral or negatively charged ligand in complex structure with two- and three-fold cations, under acidic conditions quantitatively transferred to protonated quinolin-8-ol.

[21]ADI 0.05 mg/kg bw per day and ARfD 0.05 mg/kg bw (EFSA, 2011).

metal oxide minerals available in the soil. Experts during the Pesticides Peer Review Meeting TC 111[22] agreed that the bioavailability of the complexes formed is uncertain, and this uncertainty should be taken into account in the risk assessment for soil-dwelling organisms and for possible uptake of soil residues by following crops. For the soil-dwelling organism risk assessment, this is because a change of destination of the soil within the structure in the longer term can be foreseen (EFSA, 2014b). It should be noted that the approach to consider unextractable residues when deriving DT50 should be only used to conclude on wording for persistence and to obtain PECsoil calculations.[23] Anaerobic soil incubation studies were considered unnecessary based on the proposed use in permanent greenhouses and photodegradation does not play a role in the degradation of quinolin-8-ol in soil. Quinolin-8-ol exhibited immobility in soil based on K_d/K_{doc} values. However, a **data gap** for adsorption studies to derive reliable K_F and K_{Foc} values using the direct method according to the OECD TG 106 (OECD, 2000) was identified by experts during the Pesticides Peer Review Meeting TC 111[24] (see Section 10), who however agreed to finalise the risk assessment for approval using K_d/K_{doc} values from the pre-test used for the mass balance determination and the value of 1 as 1/*n*.

In laboratory incubations in dark aerobic natural sediment water systems, quinolin-8-ol exhibited high persistence, with a rapid dissipation from the water column to the sediment compartment where it remained stable until the end of the study and without the formation of major metabolites. The unextractable sediment fraction (not extracted by methanol/2% H_2SO_4) was the major sink for the ^{14}C-benzene ring radiolabel, accounting for 12%–40% AR at study end (100 days). Mineralisation of this radiolabel accounted for 4.3%–10% AR at the end of the study. Direct photochemical degradation cannot occur under normal conditions of use of quinolin-8-ol. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) calculations were carried out using step 1 and step 2 (version 3.2 of the Steps 1–2 in FOCUS calculator), and step 3 approaches (FOCUS, 2001a, 2001b, 2001c).[25] Experts agreed[26] that, for drip irrigation application directly to soil in permanent greenhouses, modelling with the D6 scenario for surface water used for walk-in tunnel structures are sufficiently conservative to identify a safe situation (EFSA, 2014b). This was considered possible for the drip irrigation use because the substance Henry's Law constant is below 1 Pa m^3 mol^{-1}; this indicates active substance volatilisation would be low, so minimising the possibility for its condensation on greenhouse structures. Modelling approaches such as use of the greenhouse emission models (GEM) covering NL situations (but not necessarily all MS situations), would need to have been used if substance condensation on greenhouse structures had not been concluded as having a low potential; and it could still be used should a refinement of aquatic exposure be needed by MS at national level.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (European Commission, 2014a) scenarios and the models PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4. The potential for groundwater exposure from the representative use by quinolin-8-ol above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all five FOCUS groundwater scenarios defined for uses on tomatoes.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for the production of drinking water. The conclusion of this consideration was that, because the active substance exhibited immobility in soil/sediment compartments forms complexes with organic and inorganic colloidal particles of the suspended materials, together with the intended use applied for being by drip irrigation in permanent greenhouses, the available concentration of quinolin-8-ol in surface water will be very limited, and therefore, the risk associated with the formation of residues resulting from water treatment processes was considered low.

The PEC in soil, surface water, sediment and groundwater covering the representative use assessed can be found in Appendix B of this conclusion. A key to the wording used to describe the persistence and mobility of the compound assessed can be found in Appendix C of this conclusion.

5 | ECOTOXICOLOGY

The risk assessment was based on the following documents: European Commission (2002), EFSA PPR Panel (2013), SETAC (2001), EFSA (2013) and some aspects were discussed at the Peer Review Experts' TC 113 (29 June 2023).

The information available to assess the compliance of the batches used in the ecotoxicological studies with the original reference specification was considered sufficient and the batches were found compliant with it (see Section 1). Due to the physico-chemical properties of the active substance (poor solubility), all the studies used in the ecotoxicological risk assessment were carried out with the formulation for representative use (soluble in water), except the studies for birds and mammals, which were carried out only with the active substance, due to the corrosive properties of the formulation (pH 2). Suitable ecotoxicity data with the formulation for representative use were available for the assessment of non-target organisms according to the requirements of Regulation (EU) No 284/2013. Based on the composition of the formulation for representative use and the available information, it was considered that no difference of toxicity is expected between the

[22]Refer to experts' consultation 4.1 in the Report of the Pesticides Peer Review Experts' Teleconference TC 111 in June 2023 (EFSA, 2024).

[23]The approach to consider NER is not meant to be used for deriving modelling endpoints and for the comparison with the cut-off criteria of the properties according to Annex II of Regulation (EC) No 1107/2009 related to the assessment of the potential persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and persistent organic pollutants (POP) properties (European Commission, 2012b).

[24]Refer to experts' consultation 4.2 in the Report of the Pesticides Peer Review Experts' Teleconference TC 111 in June 2023 (EFSA, 2024).

[25]Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

[26]Refer to experts' consultation 4.2 in the Report of the Pesticides Peer Review Experts' Teleconference TC 111 in June 2023 (EFSA, 2024).

active substance and the formulation for representative use; and that data on the formulation could be used for the risk assessment for aquatic organisms.[27] In addition, available data for the individual components were retrieved and they were discussed at the Peer-review meeting TC 113.[28] From the available data, no concerns were identified with respect to the acute and chronic toxicity.[29]

Based on the representative use of quinolin-8-ol and in line with EFSA (2015), low exposure, hence low risk was concluded for birds and mammals, bees, non-target arthropods other than bees and terrestrial plants.

Suitable aquatic acute and chronic toxicity data were available (fish, aquatic invertebrates and algae).

In addition, chronic toxicity data were also available for sediment-dwelling organisms.

A low risk was concluded for all aquatic organisms using Focus PECsw steps 1–3 for the representative use.

Available chronic toxicity data showed that amphibians might be more sensitive than fish. However, only screening data were available with amphibian (level 3 study), and these are not suitable for endpoint setting. Therefore overall, there are uncertainties on whether the available chronic risk assessment with fish sufficiently covers amphibians.[30]

Extractable metabolites of quinolin-8-ol were not identified in soil or natural water sediment systems (see Section 4).

Therefore, for the representative use of quinolin-8-ol, exposure to soil organisms (earthworms, soil macro-organisms and soil microorganisms) is not expected and low risk can be concluded. However, as pointed out in Section 4, considering the physico-chemical properties of the active substance, a DT90 in soil > 1 year cannot be excluded. Therefore, in situations where soil is removed and used outside and/or the structure is removed up to after 12 months from the last application, a high risk to soil macro-organisms, i.e. collembola, could occur when considering the PECsoil over 5 cm. When considering PECsoil over 20 cm, assuming soil mixing by cultivation, a low risk was identified.

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

6 | ENDOCRINE DISRUPTION PROPERTIES

With regard to the assessment of the endocrine disruption potential of quinolin-8-ol **for humans** according to the ECHA/EFSA guidance (2018), in determining whether quinolin-8-ol interacts with the oestrogen, androgen and steroidogenesis (EAS) and thyroid (T) mediated pathways, the number and type of effects induced and the magnitude and pattern of responses observed across studies were considered. Additionally, the conditions under which effects occur were considered, in particular, whether or not endocrine-related responses occurred at dose(s) that also resulted in overt toxicity. The assessment is therefore providing a weight-of-evidence analysis of the potential interaction of quinoline-8-ol with the EAS and T-signalling pathways using the available evidence in the data set.

With regard to T modality, the data set was considered complete, and a pattern of T-mediated adversity was not identified. Some active hits were observed in the assays available in ToxCast database (i.e. thyroid hormone receptor antagonistic activity and TPO inhibition); however, they were regarded as unlikely to be selective and overall, there is no T-mediated endocrine activity.

With regard to the EAS-modalities, the data set was considered complete, and a pattern of EAS-mediated adversity and activity was not observed.

Therefore, based on the available and sufficient data set, it was concluded that the ED criteria are not met for the EATS modalities (Scenario 1a of the EFSA/ECHA (2018) ED Guidance).[31]

The outcome of the assessment reported above for humans also applies to **wild mammals as non-target organisms**.

For non-target organisms other than mammals,[32] an Amphibian Metamorphosis Assay (AMA, OECD TG 231) and in vitro ToxCast data and a Fish short-term reproduction assay (FSTRA, OECD TG 229) were available for investigating the endocrine activity through the T-modality and the EAS-modalities, respectively. Both in vivo studies were performed with the representative formulation Beltanol. As reported above in Section 5, studies with the formulated product were accepted as it was considered equivalent to the active substance.

The available AMA was considered reliable with restrictions due to a number of drawbacks, e.g. analytical measurements at the intermediate concentrations, high incidence of scoliosis in control animals, etc. Nevertheless, the experts agreed that the study can still be used for drawing a conclusion on the ED potential through the T-modality. Overall, in the study, a clear pattern of systemic toxicity in several organs and endpoints were observed, while a clear pattern of T-endocrine activity could not be established. The change observed in the thyroid histopathology, i.e. atrophy of the gland, was more associated with systemic toxicity rather than to an ED mode of action (MoA). The available ToxCast in vitro data also pointed in the same direction, i.e. they did not show any selective inhibition but rather the decrease in the signal was considered to be caused by cytotoxicity.

Overall, it was concluded that the available data does not suggest a pattern of T-endocrine activity.

Therefore, in line with the EFSA/ECHA ED guidance (ECHA/EFSA, 2018), the ED criteria were not met for the T-modality.

[27]Refer to experts' consultation 5.2 in the Report of the Pesticides Peer Review Experts' Teleconference TC 113 in June 2023 (EFSA, 2024).

[28]Refer to experts' consultation 5.3 in the Report of the Pesticides Peer Review Experts' Teleconference TC 113 in June 2023 (EFSA, 2024).

[29]Refer to Section 2 for consideration of the data obtained for mammals.

[30]Refer to experts' consultation 5.1 in the Report of the Pesticides Peer Review Experts' Teleconference TC 113 in June 2023 (EFSA, 2024).

[31]Refer to experts' consultation 2.8 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2024).

[32]Refer to experts' consultation 5.2 in the Report of the Pesticides Peer Review Experts' Teleconference TC 113 in June 2023 (EFSA, 2024).

In the FSTRA, effects on some of the investigated parameters were observed at the highest tested concentrations only, concomitantly to circa 10% mortality and were therefore attributed to systemic toxicity. At the low and intermediate concentrations, no pattern of EAS-endocrine activity was observed.

Therefore, it was concluded that no endocrine activity has been identified for EAS-modalities. In line with the EFSA/ECHA ED guidance (ECHA/EFSA, 2018), the ED criteria are not met for the EAS-modalities.

Based on the above considerations, quinolin-8-ol is not considered to meet the ED criteria as laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605.

7 | OVERVIEW OF THE RISK ASSESSMENT OF COMPOUNDS LISTED IN RESIDUE DEFINITIONS TRIGGERING ASSESSMENT OF EFFECTS DATA FOR THE ENVIRONMENTAL COMPARTMENTS (TABLES 1–4)

TABLE 1 Soil.

Compound (name and/or code)	Ecotoxicology
Quinolin-8-ol and its salts	High risk to soil organisms[a]

[a]High risk only in case the soil is removed and used outside and/or the structure is removed and the PECs soil is calculated over 5 cm (see Section 5).

TABLE 2 Groundwater[a].

Compound (name and/or code)	>0.1 μg/L at 1 m depth for the representative uses[b] Step 2	Biological (pesticidal) activity/relevance Step 3a	Hazard identified Steps 3b and 3c	Consumer RA triggered Steps 4 and 5	Human health relevance
Quinolin-8-ol and its salts	No	Yes	–	–	Yes

[a]Assessment according to European Commission guidance of the relevance of groundwater metabolites (2003).
[b]FOCUS scenarios or relevant lysimeter.

TABLE 3 Surface water and sediment.

Compound (name and/or code)	Ecotoxicology
Quinolin-8-ol and its salts	Low risk to aquatic organisms

TABLE 4 Air.

Compound (name and/or code)	Toxicology
Quinolin-8-ol	No data – not required due to the physico-chemical properties of the active substance and the intended use (drip irrigation)

8 | PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT BY RISK MANAGERS

Risk mitigation measures (RMMs) identified following consideration of Member State (MS) and/or applicant's proposal(s) during the peer review, if any, are presented in this section. These measures applicable for human health and/or the environment leading to a reduction of exposure levels of operators, workers, bystanders/residents, environmental compartments and/or non-target organisms for the representative uses are listed below. The list may also cover any RMMs as appropriate, leading to an acceptable level of risks for the respective non-target organisms.

It is noted that final decisions on the need of RMMs to ensure the safe use of the plant protection product containing the concerned active substance will be taken by risk managers during the decision-making phase. Consideration of the validity and appropriateness of the RMMs remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions at national level.

8.1 | Particular conditions proposed for the representative use evaluated

Use of personal protective equipment (gloves) by operators during the task of mixing/loading is required in order to have predicted exposure estimates below 10% of the (A)AOEL.

9 | CONCERNS AND RELATED DATA GAPS

9.1 | Concerns and related data gaps for the representative use evaluated

9.1.1 | Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for one or more of the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[33] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

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

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

1. The non-dietary exposure of bystanders and resident children cannot be concluded since the predicted exposure estimates with the EFSA model are very likely overestimated due to the model assumptions (based on data for spray application and not for drip irrigation) (see Section 2). The available field study was concluded as not reliable and did not allow an ad hoc approach for the non-dietary exposure assessment.

   a. A more reliable and realistic assessment of the non-dietary exposure (e.g. through the submission of a new field study) is required for the supported representative use.

2. The consumer dietary risk assessment was provisionally carried out using toxicological reference values derived by EFSA (see Section 2). Sufficient field residue trials compliant with the representative use on tomatoes and analysing for all compounds included in the risk assessment residue definition for fruit crops were not available (see Section 3). Having regard to the high to very high persistence of the parent compound in soil (see Section 4), studies were not available to investigate the metabolism of quinolin-8-ol in rotational crops (see Section 3).

   a. Four additional GAP compliant residue trials in tomato, analysed with validated analytical method and covered by storage stability data, are required (see Section 3).
   b. Confined rotational crops metabolism data addressing the fate of the parent compound in leafy, cereals small grains and root crops at the different plant back intervals are required (see Section 3).

9.1.2 | Critical areas of concern

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

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

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

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

[33]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.

3. Quinolin-8-ol has a harmonised classification as reproductive toxicant category 1B (H360D *'may damage the unborn child'*).[34]

9.1.3 | Overview of the concerns identified for each representative use considered (Table 5)

TABLE 5 Overview of concerns reflecting the issues not finalised, critical areas of concerns and the risks identified that may be applicable for some but not for all uses or risk assessment scenarios.

Representative use		Tomato Drip irrigation in permanent greenhouses
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Resident/bystander risk	Risk identified	
	Assessment not finalised	X[1]
Consumer risk	Risk identified	
	Assessment not finalised	X[2]
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[a]
	Assessment not finalised	
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached	
	Parametric value of 10 µg/L[b] breached	
	Assessment not finalised	

Note: The superscript numbers relate to the numbered points indicated in Sections 9.1.1 and 9.1.2. Where there is no superscript number, see Sections 2–7 for further information.

[a]High risk only in case the soil is removed and used outside and/or the structure is removed; and the PECs soil is calculated over 5 cm (see Section 5).

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

10 | LIST OF OTHER OUTSTANDING ISSUES

Remaining data gaps not leading to critical areas of concern or issues not finalised but considered necessary to comply with the data requirements, and which are relevant for some or all of the representative uses assessed at EU level. Although not critical, these data gaps may lead to uncertainties in the assessment and are considered relevant.

These data gaps refer only to the representative use assessed (unless otherwise specified) and they are listed in the order of the sections:

- An analytical method for monitoring quinolin-8-ol residues (free and conjugated) in body fluids (see Section 1).
- An in vitro comparative metabolism study including the four representative species (rat, dog, rabbit and human material) performed with primary hepatocytes and identifying all unique human metabolites or disproportionate human metabolites present above 5% (see Section 2).

[34]According to the Annex II of Regulation (EC) No 1107/2009 point 3.6.4, an active substance shall only be approved if it is not classified as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance in a plant protection product, under realistic proposed conditions of use is negligible; or in accordance with the Art 4(7) where on the basis of documented evidence included in the application it is necessary to control serious danger to plant health which cannot be contained by other available means including non-chemical methods.

- Further assessment of the photomutagenic potential of quinolin-8-ol as it is phototoxic in vitro (see Section 2).
- An OECD 106 guideline Freundlich adsorption study conducted for quinolin-8-ol at least on four soils using the direct method (not essential to finalise the risk assessment for the representative use assessed, see Section 4).

ABBREVIATIONS

a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AF	assessment factor
AMA	Amphibian Metamorphosis Assay
AOEL	acceptable operator exposure level
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary cells
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
ECHA	European Chemicals Agency
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FSTRA	Fish Short-Term Reproduction Assay
GAP	Good Agricultural Practice
HPLC	high-pressure liquid chromatography or high-performance liquid chromatography
HPLC-MS	high-pressure liquid chromatography–mass spectrometry
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_d	Distribution coefficient for adsorption
K_{doc}	organic carbon linear adsorption coefficient
K_{Foc}	Freundlich organic carbon adsorption coefficient
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
Pa	pascal
PEC	predicted environmental concentration
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
RAC	regulatory acceptable concentration
RAR	Renewal Assessment Report
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
SFO	single first-order
SMILES	simplified molecular-input line-entry system
TG	test guideline
TK	technical concentrate
TRR	total radioactive residue
TSH	thyroid-stimulating hormone (thyrotropin)
UF	uncertainty factor
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

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SUPPORTING INFORMATION

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

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APPENDIX A

Consideration of cut-off criteria for quinolin-8-ol according to Annex II of Regulation (EC) No 1107/2009 of the European Parliament and of the Council

Properties		Conclusion
CMR	**Carcinogenicity (C)**	Quinolin-8-ol is not considered to be a carcinogen according to point 3.6.3 of Annex II of Regulation (EC) No 1107/2009
	Mutagenicity (M)	Quinolin-8-ol is not considered to be a mutagen according to point 3.6.2 of Annex II of Regulation (EC) No 1107/2009
	Toxic for Reproduction (R)	Quinolin-8-ol has a harmonised classification as Reproductive toxicant category 1B (H360D '*may damage the unborn child*') according to Regulation (EC) No 1272/2008 (ATP10–[4/5/2017])
Endocrine disrupting properties		Quinolin-8-ol is not considered to meet the criteria for endocrine disruption for human health and non-target organisms according to points 3.6.5 and 3.8.2 of Annex II of Regulation No 1107/2009, as amended by Commission Regulation (EU) 2018/605
POP	**Persistence** **Bioaccumulation** **Long-range transport**	Quinolin-8-ol is not considered to be a persistent organic pollutant (POP) according to point 3.7.1 of Annex II of Regulation (EC) 1107/2009
PBT	**Persistence** **Bioaccumulation** **Toxicity**	Quinolin-8-ol is not considered to be a persistent, bioaccumulative and toxic (PBT) substance according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009
vPvB	**Persistence** **Bioaccumulation**	Quinolin-8-ol is not considered to be a very persistent, very bioaccumulative substance according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009

APPENDIX B

List of end points for the active substance and the formulation(s) for representative uses

Appendix B can be found in the online version of this output ('Supporting information S1' section): https://doi.org/10.2903/j.efsa.2024.8670

APPENDIX C

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

Wording	DT_{50} normalised to 20°C for laboratory incubations[a] or not normalised DT_{50} for field studies (SFO equivalent, when biphasic, the DT_{90} was divided by 3.32 to estimate the DT50 when deciding on the wording to use)
Very low persistence	< 1 day
Low persistence	1 to < 10 days
Moderate persistence	10 to < 60 days
Medium persistence	60 to < 100 days
High persistence	100 days to < 1 year
Very high persistence	A year or more

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

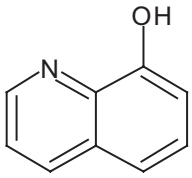
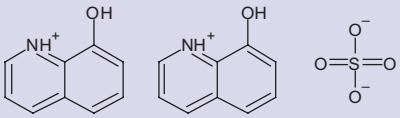
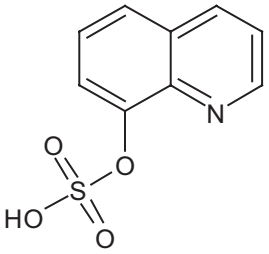
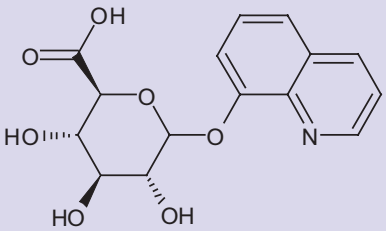
[a]For laboratory soil incubations, normalisation was also to field capacity soil moisture (pF2/10 kPa). For laboratory sediment water system incubations, the whole system DT values were used.

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

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

APPENDIX D

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
quinolin-8-ol, 8-hydroxyquinoline	quinolin-8-ol Oc1cccc2cccnc12 MCJGNVYPOGVAJF-UHFFFAOYSA-N	
bis(8-hydroxyquinolinium) sulfate, quinoline-8-ol sulfate, 8-hydroxyquinoline sulfate	bis(8-hydroxyquinolinium) sulfate [O-]S([O-])(=O)=O.Oc1cccc2ccc[nH+]c12.Oc1cccc2ccc[nH+]c12 YYVFXSYQSOZCOQ-UHFFFAOYSA-N	
quinolin-8-ol sulfate conjugate	quinolin-8-yl hydrogen sulfate O=S(=O)(O)Oc1cccc2cccnc12 OVVVIXKMDXTHQB-ADIAMYLASA-N	
quinolin-8-ol glucuronide conjugate	quinolin-8-yl D-glucopyranosiduronic acid O=C(O)[C@H]1OC(Oc2cccc3cccnc23)[C@H](O)[C@@H](O)[C@@H]1O DPEGQJDYRIQRHI-HXMBFPRCSA-N	

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

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 29 August 2021).

APPENDIX E

Evaluation of data concerning the necessity of quinolin-8-ol as fungicide and bactericide to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods

Appendix E can be found in the online version of this output ('Supporting information S2' section): https://doi.org/10.2903/j.efsa.2024.8670

APPENDIX F

Data collection set

Validated Excel files submitted by MS and evaluated by EFSA in the context of the assessment of the evaluation of data under Art 4(7) of Regulation (EC) No 1107/2009 concerning the necessity of quinolin-8-ol as fungicide/bactericide to control a serious danger to plant health which cannot be contained by other available means.

Appendix F can be found in the online version of this output ('Supporting information S3' section): https://doi.org/10.2903/j.efsa.2024.8670

APPENDIX G

Non-dietary exposure and consumer dietary exposure calculations

G.1 | NON-DIETARY EXPOSURE CALCULATIONS

Based on the toxicological reference values proposed by EFSA (AOEL and AAOEL of 0.01 mg/kg bw [per day], see also chapter 2), non-dietary exposure calculations are provided below, including also further consideration of negligible exposure since quinolin-8-ol has a harmonised classification as Repr. 1B (H360D).

During the peer review meeting,[35] it was considered that the representative use of drip irrigation in permanent greenhouses is not fully represented in the EU validated models (including only outdoor uses) at the time of dossier submission. Furthermore, the experts agreed that the submitted field study had several limitations and it could only be considered as supportive evidence for negligible exposure.

As a consequence, the predicted exposure estimates with the new EFSA calculator 2022 (EFSA, 2022) are provided here, acknowledging that it does not cover the scenario of drip irrigation in greenhouses. Therefore, for operators, only exposure during mixing/loading was considered; for workers, exposure to soilborne residues was considered; for bystanders and residents, only exposure to vapour was considered.

Product name	Beltanol
Formulation type	Soluble concentrates, etc.
Product category	Other
Name of active substance	Quinolin-8-ol
Concentration of active substance (g a.s./L)	374
Inhalation absorption (%)	100
Oral absorption (%)	63.4
Dermal absorption (%) (concentrate)	0.97
Dermal absorption (%) (dilution 0.19 g a.s./L)	42

Crops	Max. application rate of the product (L/ha)	Max. no. of applications	Interval between applications (days)	Volume water (L/ha)	Indoor/ outdoor	Application method	Application technique	Buffer strip (m)
Bare arable land	4	2	14	7500	Indoor	Downward spraying	Manual-hand held	2–3
Bare arable land	4	2	14	7500	Indoor	Downward spraying	Manual-knapsack	2–3

a. Operator

- Scenario 1: manual-hand held application.

Activity	Systemic short-term exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**1.7**	**0.01**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.01**	**0.01**
	Head protection	*None*	*None*
	Head exposure	**0.02**	**0.02**
	Inhalation protection	*None*	*None*
	Inhalation exposure	**0.06**	**0.06**

(Continues)

[35]Refer to experts' consultation 2.11 in the Report of the Pesticides Peer Review Experts' Teleconference TC 110 in June 2023 (EFSA, 2023).

(Continued)

Activity	Systemic short-term exposure per body part	With workwear	With workwear + PPE/RPE
Application (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**23.1**	**0.03**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**2.3**	**2.3**
	Head protection	*None*	*None*
	Head exposure	**0.4**	**0.4**
	Inhalation protection	*None*	*None*
	Inhalation exposure	**2**	**2**
Total	Systemic exposure during ML	0.00179	0.0001
	Total systemic exposure (mg/kg bw per day)	0.03	0.005
	% of AOEL during ML	17.9	1
	% of AOEL during ML and A	295	47.5

Activity	Systemic acute exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**6**	**0.3**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.08**	**0.08**
	Head protection	*None*	*Fp2, p2 and similar*
	Head exposure	**0.09**	**0.07**
	Inhalation protection	*None*	*Fp2, p2 and similar*
	Inhalation exposure	**0.2**	**0.02**
Application (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**72.6**	**0.2**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**11.2**	**11.2**
	Head protection	*None*	*Fp2, p2 and similar*
	Head exposure	**0.7**	**0.5**
	Inhalation protection	*None*	*Fp2, p2 and similar*
	Inhalation exposure	**3.3**	**0.3**
Total	Systemic exposure during ML	0.00637	0.00048
	Total systemic exposure (mg/kg bw per day)	0.09	0.01
	% of AAOEL during ML	63.7	4.8
	% of AAOEL during ML and A	941	127

- Scenario 2: manual-knapsack application.

Activity	Systemic short-term exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**1.5**	**0.003**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.004**	**0.004**
	Head protection	*None*	*None*
	Head exposure	**0.0009**	**0.0009**
	Inhalation protection	*None*	*None*
	Inhalation exposure	**0.6**	**0.6**

(Continued)

Activity	Systemic short-term exposure per body part	With workwear	With workwear + PPE/RPE
Application (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**23.1**	**0.03**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**2.3**	**2.3**
	Head protection	*None*	*None*
	Head exposure	**0.4**	**0.4**
	Inhalation protection	*None*	*None*
	Inhalation exposure	**2**	**2**
Total	Systemic exposure during ML	0.002	0.0006
	Total systemic exposure (mg/kg bw per day)	0.03	0.005
	% of AOEL during ML	21	6
	% of AOEL during ML and A	298	52.4

Activity	Systemic acute exposure per body part	With workwear	With workwear + PPE/RPE
Mixing and loading (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**4.1**	**0.03**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**0.02**	**0.02**
	Head protection	*None*	*Fp2, p2 and similar*
	Head exposure	**0.002**	**0.001**
	Inhalation protection	*None*	*Fp2, p2 and similar*
	Inhalation exposure	**0.6**	**0.06**
Application (µg/kg bw per day)	*Hand protection*	*None*	*Protected hands*
	Hands exposure	**72.6**	**0.2**
	Body protection	*Workwear*	*Workwear*
	Body exposure	**11.2**	**11.2**
	Head protection	*None*	*Fp2, p2 and similar*
	Head exposure	**0.7**	**0.5**
	Inhalation protection	*None*	*Fp2, p2 and similar*
	Inhalation exposure	**3.3**	**0.3**
Total	Systemic exposure during ML	0.005	0.0001
	Total systemic exposure (mg/kg bw per day)	0.09	0.01
	% of AAOEL during ML	47	1
	% of AAOEL during ML and A	925	124

As first approach, it is considered that drip irrigation is automated and that operators will only be exposed during mixing/loading. This results in exposure estimates up to 6% of the AOEL and up to 5% of the AAOEL with use of gloves in addition to workwear.

If it cannot be excluded that operators are exposed during application (e.g. for technical incidents), the exposure could reach up to 53% of the AOEL and up to 127% of the AAOEL with use of gloves and respiratory protective equipment (FP2, P2 and similar) during mixing/loading and application.

b. Worker

Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AOEL	Re-entry restriction (days)
Contact with treated soil/NA/Indoor Work rate: 8 h/day TC: NA cm^2/h TSF: NA mg a.s./h/kg a.s./ha			

(Continues)

(Continued)

Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AOEL	Re-entry restriction (days)
Quinolin-8-ol	Number of applications & application rate: 2 × 1.496 kg a.s./ha Dermal absorption: 42% DFR: 3 µg/cm^2 foliage per kg a.s./ha DT50: 30 days		
Potential	0.003	25.4	0
Workwear			
Workwear and gloves			

Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AOEL	Re-entry restriction (days)
Inspection without contact with treated soil/NA/Indoor Work rate: 2 h/day TC: NA cm^2/h TSF: NA mg a.s./h/kg a.s./ha			
Quinolin-8-ol	Number of applications & application rate: 2 × 1.496 kg a.s./ha Dermal absorption: 42% DFR: 3 µg/cm^2 foliage per kg a.s./ha DT50: 30 days		
Potential	0.0006	6.3	0
Workwear			
Workwear and gloves			

For workers, in case of re-entry activities involving a contact with the treated soil (soilborne residues), the predicted estimates are 25% of the AOEL for the potential exposure and it can be expected to be below 10% of the AOEL with use of standard professional workwear. In case of re-entry for inspection without contact with treated soil, the predicted estimates are 6% of the AOEL for the potential exposure without workwear.

c. Resident/Bystander

Resident data	Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AOEL
Buffer zone: 2–3 m Drift reduction technology: 0% NA			
Quinolin-8-ol	Number of applications and application rate: 2 × 1.496 kg a.s./ha Dermal absorption: 42% DFR: 3 µg/cm^2 foliage per kg a.s./ha DT50: 30 days		
Resident child body weight: 10 kg	Drift (75th perc.)	NA	NA
	Vapour (75th perc.)	0.01	120
	Deposits (75th perc.)	NA	NA
	Re-entry (75th perc.)	NA	NA
	Sum (mean)	NA	NA
Resident adult body weight: 60 kg	Drift (75th perc.)	NA	NA
	Vapour (75th perc.)	0.004	40.5
	Deposits (75th perc.)	NA	NA
	Re-entry (75th perc.)	NA	NA
	Sum (mean)	NA	NA

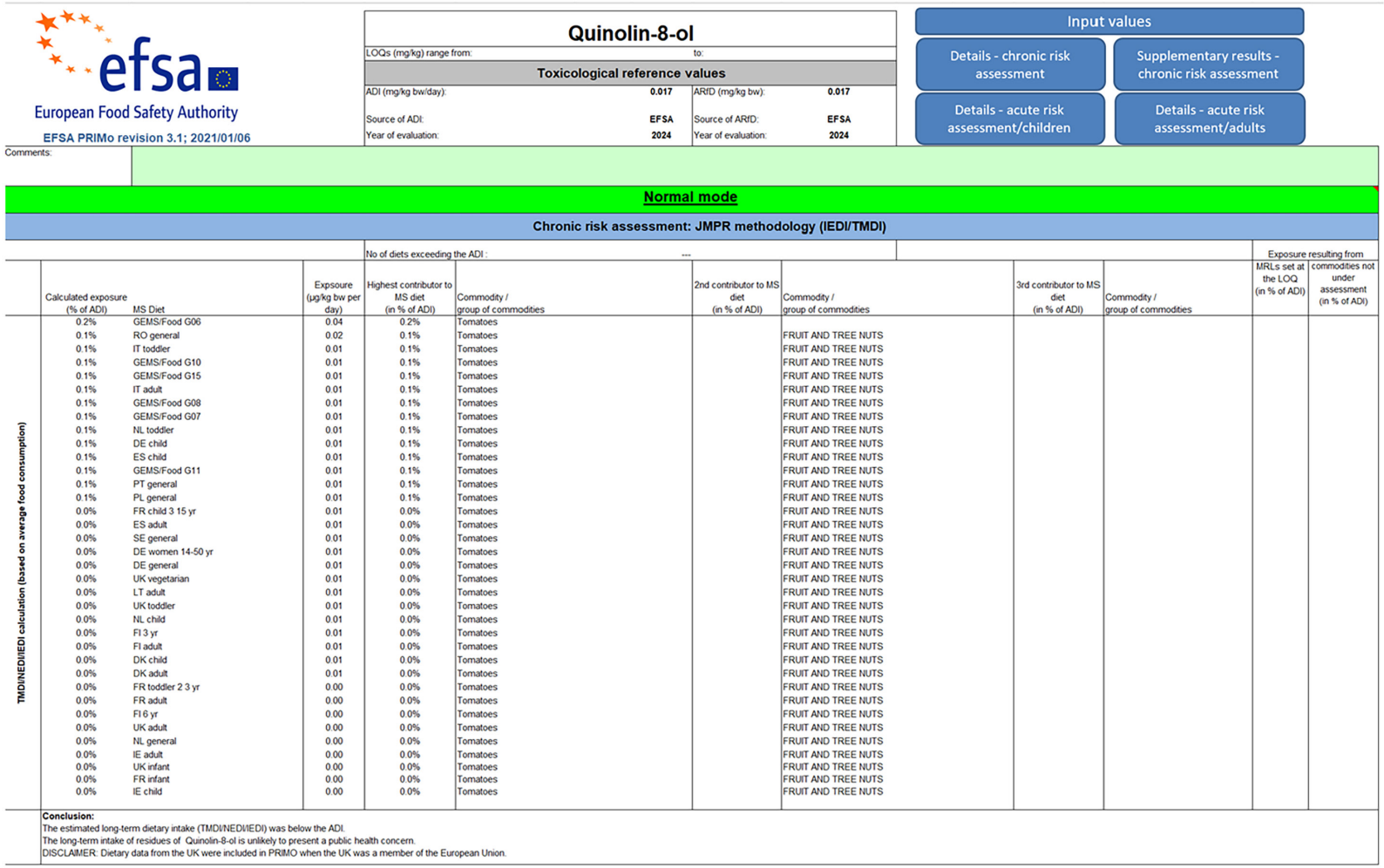
Bystander data	Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AAOEL
Buffer zone: 2–3 m Drift reduction technology: 0%			
Quinolin-8-ol	Number of applications and application rate: 2 × 1.496 kg a.s./ha Dermal absorption: 42% DFR: 3 µg/cm^2 foliage per kg a.s./ha DT50: 30 days		

(Continued)

Bystander data	Level of PPE	Total absorbed dose (mg/kg bw per day)	% of systemic AAOEL
Bystander child Body weight: 10 kg	Drift (95th perc.)	NA	NA
	Vapour (95th perc.)	0.01	120
	Deposits (95th perc.)	NA	NA
	Re-entry (95th perc.)	NA	NA
Bystander adult Body weight: 60 kg	Drift (95th perc.)	NA	NA
	Vapour (95th perc.)	0.004	40.5
	Deposits (95th perc.)	NA	NA
	Re-entry (95th perc.)	NA	NA

For both residents and bystanders, it is acknowledged that the EFSA calculator does not cover the scenario of drip irrigation in greenhouses. Exposure to drift and deposits is not relevant since the application is by drip irrigation, and it is not expected that bystanders and residents will re-enter the greenhouses (no re-entry). Predicted exposure to vapour is exceeding the (A)AOEL for children, but these values are very likely overestimated due to the model assumptions as it is based on data for spray application and not for drip irrigation. (RMS suggested that the product should only be applied in high-technology greenhouses, preventing the exchange of vapours of the active substance with the outside. During the peer review meeting, the experts agreed that this should be considered at Member State level for national authorisations).

G.2 | CONSUMER DIETARY EXPOSURE CALCULATION WITH PRIMO 3.1



European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Quinolin-8-ol

LOQs (mg/kg) range from: to:

Toxicological reference values

ADI (mg/kg bw/day):	0.017	ARfD (mg/kg bw):	0.017
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2024	Year of evaluation:	2024

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment

Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
0.2%	GEMS/Food G06	0.04	0.2%	Tomatoes						
0.1%	RO general	0.02	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	IT toddler	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G10	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G15	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	IT adult	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G08	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G07	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	NL toddler	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	DE child	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	ES child	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	GEMS/Food G11	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	PT general	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.1%	PL general	0.01	0.1%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FR child 3 15 yr	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	ES adult	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	SE general	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	DE women 14-50 yr	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	DE general	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	UK vegetarian	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	LT adult	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	UK toddler	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	NL child	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FI 3 yr	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FI adult	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	DK child	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	DK adult	0.01	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FR toddler 2 3 yr	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FR adult	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FI 6 yr	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	UK adult	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	NL general	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	IE adult	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	UK infant	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	FR infant	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				
0.0%	IE child	0.00	0.0%	Tomatoes		FRUIT AND TREE NUTS				

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Quinolin-8-ol is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

	Acute risk assessment /children	Acute risk assessment / adults / general population
	Details - acute risk assessment /children	Details - acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Un

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI): ---				**Results for adults** No. of commodities for which ARfD/ADI is exceeded (IESTI): ---			
IESTI				**IESTI**			
Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
7%	Tomatoes	0 / 0.02	1.2	2%	Tomatoes	0 / 0.02	0.32
Expand/collapse list							
Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)							