CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance *Purpureocillium lilacinum* strain 251

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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, Hungary, and co-rapporteur Member State, the Netherlands, for the pesticide active substance *Purpureocillium lilacinum* strain 251, formerly called *Paecilomyces lilacinus* strain 251, 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 uses of *Purpureocillium lilacinum* strain 251 as a biological nematicide on tomato and cucumber (uses in the field and permanent greenhouses). 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.

Keywords: *Purpureocillium lilacinum* strain 251, peer review, risk assessment, pesticide, biological nematicide

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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. *Purpureocillium lilacinum* strain 251, formerly called *Paecilomyces lilacinus* strain 251, 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), Hungary, and co-rapporteur Member State (co-RMS), the Netherlands, received an application from Bayer CropScience AG for the renewal of approval of the active substance *Purpureocillium lilacinum* strain 251.

An initial evaluation of the dossier on *Purpureocillium lilacinum* strain 251 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 *Purpureocillium lilacinum* strain 251 according to the representative uses as a biological nematicide on tomato and cucumber (uses in the field and permanent greenhouses), as proposed at EU level result in a sufficient nematicidal efficacy against the target plant-parasitic nematodes.

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.

Critical areas of concern and issues that could not be finalised were not identified in the mammalian toxicology section.

Critical areas of concern and issues that could not be finalised were not identified in the residues section. The criteria for the inclusion of *Purpureocillium lilacinum* strain 251 in the Annex IV of Regulation (EC) No 396/2005 are met and maximum residue levels (MRLs) are not required.

The information available on environmental fate and behaviour was considered sufficient to characterise the environmental exposure of *Purpureocillium lilacinum* strain 251 for the representative uses assessed.

The ecotoxicological risk assessment for the representative uses was concluded as low for all relevant non-target organisms except for collembolans, that remains as an issue that could not be finalised for the field uses.

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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).

In accordance with Article 1 of the Regulation, the RMS, Hungary, and co-RMS, the Netherlands, received an application from Bayer CropScience AG for the renewal of approval of the active substance *Purpureocillium lilacinum* strain 251, formerly called *Paecilomyces lilacinus* strain 251. 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 *Purpureocillium lilacinum* strain 251 in the RAR, which was received by EFSA on 30 July 2018 (Hungary, 2018).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Bayer CropScience AG, for consultation and comments on 18 September 2018. 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 19 November 2018. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 29 January 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 additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

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 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 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 took place with Member States via a written procedure in June–July 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 uses of *Purpureocillium lilacinum* strain 251 as a biological nematicide on tomato and cucumber (uses in the field and permanent greenhouses), as proposed by the applicant. In accordance with Article 12(2) of

[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.

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.

In addition, 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 comments received on the RAR;
- the reporting table (29 January 2019);
- the evaluation table (17 August 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 (Hungary, 2019), 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

Purpureocillium lilacinum strain 251 is a fungus deposited at the German Collection of Microorganisms and Cell Cultures (DSMZ) in Braunschweig, Germany, under accession number DSM23289. The strain was also deposited at the Australian Government Analytical Laboratories (AGAL), in Pymble, Australia under accession number 89/030550. *Purpureocillium lilacinum* strain 251 is a naturally occurring widely distributed saprophyte strain, initially isolated from infested egg masses of a plant-parasitic nematode (*Meloidogyne* spp.) from soil from Los Banos, in the Philippines. The strain has been formerly classified as *Paecilomyces lilacinum* strain 251. Due to current findings in taxonomy, the species *Paecilomyces lilacinus* is now classified as *Purpureocillium lilacinum.*

The representative formulated product for the evaluation was 'BioAct WG', a water dispersible granule (WG) containing 60 g/kg (minimum 1×10^{13} CFU/kg, maximum 2.2×10^{13} CFU/kg) *Purpureocillium lilacinum* strain 251 viable spores. An FAO specification does not exist for this product.

The representative uses evaluated comprise applications by drip irrigation or soil drench, pre- and post-transplant (with an option for subsequent mechanical incorporation preplanting) and by dipping of seedlings at transplant for biological control of plant-parasitic nematodes (*Meloidogyne* spp) in vegetables (tomato, cucumber) both in open field and in permanent greenhouses, in Central and Southern European zones as defined by the Regulation (EC) No 1107/2009. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted that enabled it to be concluded that the uses of *Purpureocillium lilacinum* strain 251 according to the representative uses proposed, result in sufficient nematicidal efficacy against eggs, juveniles and adult females of a range of nematode species, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

Conclusions of the evaluation

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

The following guidance documents were followed in the production of this conclusion: SANCO/12116/2012–rev. 0 (European Commission, 2012), guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012).

The technical grade microbial pest control agent (MPCA) is only a hypothetical stage in the continuous production process of the end use product (MPCP). As a consequence, the specification is given only for the end use formulated product BioAct WG of min. 1×10^{13} viable spores (CFU)/kg.

Purpureocillium lilacinum strain 251 can be identified and distinguished from other isolates by random amplified polymorphic DNA analysis using large primer pairs (LP-RAPD) and further

characterisation by allozyme electrophoresis, UV resistance, colour of colonies on potato dextrose agar (PDA). Sporulating colonies of *Purpureocillium lilacinum* strain 251 produce a characteristic lilac or deep lilac colour which distinguishes them from other nematophagous fungi. CFU survival from UV irradiation is 52% for strain 251. When comparing with other strains of *Purpureocillium lilacinum*, internal transcribed spacer (ITS) and thyrotroph embryonic factor (TEF) sequences cannot be used to unequivocally identify *Purpureocillium lilacinum* strain 251.

There is no evidence of direct relationships of *Purpureocillium lilacinum* strain 251 to known plant, animal or human pathogens. From published literature, it is known that other *Purpureocillium lilacinum* isolates may cause infections in vertebrates. Some strains of *Purpureocillium lilacinum* were reported to produce paecilotoxins (leucinostatins). For *Purpureocillium lilacinum* strain 251, it was found that this strain is unlikely to produce detectable levels of paecilotoxins or other toxins with antimicrobial activity.

The analysis of contaminating microorganisms in commercially produced batches complies with the requirements of European Commission (2012).

The optimum temperature range for growth of *Purpureocillium lilacinum* strain 251 was between 21 and 27°C. *Purpureocillium lilacinum* strain 251 cannot grow at temperatures above 36°C. It can tolerate a wide pH range for growth with an optimum of pH 6.5. The possibility to exchange genetic material was considered not relevant.

Information on the resistance or sensitivity to antimicrobials of *Purpureocillium lilacinum* strain 251 was not available; as a consequence, a data gap was identified.

Acceptable methods are available for the determination of the microorganism in the formulation and for the determination of the content of contaminating microorganisms. The product is stable for at 24 months if it is stored at –20°C. The product cannot be stored at ambient temperature, if not used within a few days the suggested storage temperatures are: +4°C to –18°C.

A residue definition was not applicable for *Purpureocillium lilacinum* strain 251; therefore, post-registration monitoring methods are not needed.

2. Mammalian toxicity

General data

The available evidence from medical cases described in the literature does not exclude completely the infectivity or pathogenicity of *Purpureocillium lilacinum* strain 251 in (immunocompromised) humans, even though no strain-specific data were identified.

No indications of any toxicological or allergenic effects to the workers involved in the production or packaging of *Purpureocillium lilacinum* strain 251 since 1999 have been observed.

Toxicity studies

Laboratory studies on mammalian toxicity of *Purpureocillium lilacinum* strain 251 have been conducted in rats upon oral, dermal, intratracheal or intra-peritoneal acute single doses. Adverse effects and signs of infectivity or pathogenicity were not observed. Clearance occurred within 3 weeks after intraperitoneal treatment. As the available methods for testing dermal sensitisation are not suitable for testing microorganisms and there are no validated test methods for sensitisation by inhalation, the following warning phrase is proposed: 'Microorganisms may have the potential to provoke sensitising reactions'.

Secondary metabolites/toxins

Purpureocillium lilacinum strain 251 is unlikely to produce detectable levels of paecilotoxins or other toxins with antimicrobial activity during manufacturing (see Section 1) and after application (see Section 4). EFSA noted that an Ames test and *in vivo* micronucleus test with an extract of *Purpureocillium lilacinum* strain 251 gave negative results; however, these studies showed some limitations. A literature review on paecilomide indicated that they are cholinesterase inhibitors and may have pharmacological activity. An *in silico* assessment on paecilotoxins gave positive and negative results for the chromosome aberration end point. For the other toxicological end points assessed, the *in silico* assessment did not show any concern; however, a detailed assessment for the *in silico* prediction was not reported in the RAR. A data gap was not set given the lack of production of detectable levels of paecilotoxins.

Reference values and exposure

Based on the lack of significant toxicity, infectivity or pathogenicity in the available toxicological studies, the setting of health-based reference values for the microorganism *Purpureocillium lilacinum*

strain 251 is not needed. Based on the lack of production of detectable levels of paecilotoxins or other toxins with antimicrobial activity, further data are not required regarding the assessment of the toxicological profile of secondary metabolites/toxins.

3. Residues

It is not necessary to perform a quantitative dietary consumer risk assessment for viable and non-viable residues of *Purpureocillium lilacinum* strain 251 on the raw agricultural commodities. Health-based reference values were not needed for the microorganism. Despite production of secondary metabolites being a part of the mode of action of *Purpureocillium lilacinum* strain 251, detectable levels of secondary metabolites/toxins that might be considered relevant for consumers such as paecilotoxins or other toxins with antimicrobial activity are unlikely to be produced by *Purpureocillium lilacinum* strain 251 (see Section 2).

The criteria for the inclusion of *Purpureocillium lilacinum* strain 251 in the Annex IV of Regulation (EC) No 396/2005 are met and MRLs are not required.

4. Environmental fate and behaviour

Generic information has been provided in the RAR (Hungary, 2019) in relation to potential interference of filamentous fungi with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC[4] (see specific Annex VI decision-making criteria in Part II Commission Regulation (EU) No 546/2011[5]). As the organisms that have to be controlled in drinking water are pathogenic bacteria, it is unlikely that spores or hyphae of *Purpureocillium lilacinum* strain 251 will give false-positive results for these methods targeted at bacteria.

Purpureocillium lilacinum strain 251 is a 'wild type' and there are no marker genes in the strain which would permit analysis of a frequency of genetic exchange. As the genetic diversity and drift in the wild-type population has not been ascertained, it would not be possible to distinguish any genetic drift from that in the wild population based on the information provided. Though it is acknowledged that the possibility and effects of transfer of genetic material are not different for *Purpureocillium lilacinum* strain 251 than for other naturally occurring *Purpureocillium lilacinum* strains, transfer of genetic material by *Purpureocillium lilacinum* strain 251 after application is possible and could not be excluded based on the information included in the dossier.

4.1. Fate and behaviour in the environment of the microorganism

In relation to its **persistence and multiplication in soil,** satisfactory strain-specific measurements with *Purpureocillium lilacinum* strain 251 in different soils from scientific papers were presented in the RAR. The papers showed that CFU density of *Purpureocillium lilacinum* strain 251 decline more than 90% within 90 days after application and was below the background level of other filamentous fungi after 2 years. This information was considered sufficient to conclude that the multiplication ability in soil for strain 251 from the intended use is not high. A worst-case initial PEC soil calculation is presented in the RAR for use in the environmental risk assessment (See appendix A). For the intended uses in permanent greenhouses, a soil exposure assessment is not requested for the strain according to the EFSA guidance on protected crops (EFSA, 2014).

With respect to the **persistence and multiplication in surface water,** an unpublished non-Good Laboratory Practice (GLP) study with *Purpureocillium lilacinum* strain 251 showed that the strain does not germinate or proliferate in water. In the study, the CFU densities were reduced from about 10^6 to 10^4 CFU/ml within 73 weeks. Worst-case initial PEC surface water for use in the environmental risk assessment is presented in the RAR using the standard FOCUS (FOCUS, 2001) spray-drift procedure for open field. However, for the intended use, *Purpureocillium lilacinum* strain 251 will be applied by drip irrigation, or soil drench, resulting in the potential for dispersal via drift being low (See appendix A). Sufficient information from studies on the species *Purpureocillium lilacinum* and the strain 251 demonstrate that the mobility of the organism in soil and water is low and transport through drainage and run-off can be considered low for the intended uses. Therefore, the exposure to surface

[4] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.98, p. 32–54.

[5] Commission Regulation (EU) 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.

water is expected to be negligible for the intended use in protected cropping systems and in the open field.

A published paper showed that *Purpureocillium lilacinum* strain 251 is sensitive to exposure to natural UV-light and germination and survival of *Purpureocillium lilacinum* strain 251 will be reduced. Dispersal of spores of *Purpureocillium lilacinum* strain 251 via aerosols to **air** is expected to be negligible due to the method of the application by drip irrigation or soil drench.

4.2. Fate and behaviour in the environment of any relevant metabolite formed by the microorganism under relevant environmental conditions

Scientific papers have shown that strains of *Purpureocillium lilacinum* can produce secondary metabolites e.g. leucinostatin molecules also called paecilotoxins. It was found in a published study that *Purpureocillium lilacinum* strain 251 did not produce detectable levels of paecilotoxin. A low limit of quantification (LOQ) for aflatoxin, ochratoxin, T-2 toxin and zearaleone is provided in this study. In another published study with a not identified strain of *Purpureocillium lilacinum*, a pyridine alkaloid named paecilomide was identified. The paecilotoxin paecilomide was shown to inhibit acetyl-cholinesterase. However, neither the identity of the used strain nor the identification methods used were described. Overall, it is concluded, based on all the information available in the dossier (that included a satisfactory systematic literature review with appropriate search terms for the secondary metabolites reported to be produced by the species), that sufficient information has been provided to demonstrate that *Purpureocillium lilacinum* strain 251 is unlikely to produce detectable levels of the secondary metabolites/toxins known to be produced by the species, when cultured according to the method of manufacture. These metabolites were also shown to have not been produced in measurable amounts under culture conditions that were designed to/might have been expected to enhance their formation. Putting all this information together, it is considered that *Purpureocillium lilacinum* strain 251 is unlikely to produce measurable amounts of these known secondary metabolites/toxins after application to soil.

5. Ecotoxicology

Available information demonstrates that *Purpureocillium lilacinum* strain 251 is unlikely to produce measurable amounts of toxins/secondary metabolites in the environment (see Section 4).

As the representative uses in protected structures are restricted to permanent greenhouses where applications are conducted by dipping seedlings, drip irrigation and soil drench with an option for subsequent mechanical incorporation pre-planting, exposure to non-target organisms is not anticipated. Consequently, a low risk to these groups of non-target organisms is concluded for the representative uses in permanent greenhouses. Information for addressing the risk to introduced pollinators (e.g. bumble bees) in greenhouses is not available.

The below-mentioned risk assessment applies to the use patterns of *Purpureocillium lilacinum* strain 251 as described in the GAPs for the field uses which also uses the methods of dipping seedlings, applications via drip irrigation and soil drench with an option for subsequent mechanical incorporation pre-planting.

Ecotoxicity tests were carried out following the guidelines for the testing of chemicals. The test duration in most of the cases was not suitable for investigating infectivity and pathogenicity; thus, a data gap has been identified to demonstrate the absence of pathogenicity and infectiveness of *Purpureocillium lilacinum* strain 251 to several taxa as described below.

Acute toxicity studies were available for **birds and mammals**. Although mortality was not reported, signs of infectivity and pathogenicity of *Purpureocillium lilacinum* strain 251 were not properly investigated. The optimum temperature range for growth of *Purpureocillium lilacinum* strain 251 is between 21 and 27°C. Considering that *Purpureocillium lilacinum* strain 251 cannot grow at temperatures above 36°C, it is considered unlikely that *Purpureocillium lilacinum* would cause systemic mycosis in the intestinal tract of birds or mammals, and therefore, low risk to both birds and mammals is concluded. Uncertainty remains with regard to other terrestrial vertebrates like amphibians and reptiles which have a lower body temperature than birds and wild mammals. Available information from open literature suggests that *Purpureocillium lilacinum* could be regarded as an opportunistic fungal pathogen acting in both immune-comprised and immune-competent terrestrial cold blood organisms.

Exposure to **aquatic organisms** from *Purpureocillium lilacinum* strain 251 is expected to be negligible for the intended uses and a low risk can be concluded for aquatic organisms.

A suitable study addressing the toxicity, pathogenicity and infectiveness of *Purpureocillium lilacinum* strain 251 to honey bees was not available. In addition, ecotoxicity studies were available to address the toxicity of *Purpureocillium lilacinum* strain 251 to non-target arthropods. The mortality was below 50% for all species tested; however, information on pathogenicity and infectiveness was not reported. Studies from open literature were available and considered as supportive information. Those studies indicated that several species of plant-feeding mites (e.g. *Balaustium murorum, Tetranychus urticae, Thrips tabaci*) may be susceptible to *Purpureocillium lilacinum.* However, it is questionable whether this information can be extrapolated to the strain under assessment. Based on the type of applications according to the representative uses of the *Purpureocillium lilacinum* strain 251, exposure to **honey bees and foliar non-target arthropods** is not anticipated, and therefore, a low risk was concluded.

Due to the application methods defined for the representative uses and the mode of action of *Purpureocillium lilacinum* strain 251 (oviparasitation and endoparasitation to various growth stages of nematodes), a particular concern has been raised to **other soil-dwelling non-target organisms** including ground-dwelling arthropods and beneficial nematodes (e.g. *Heterorhabditis bacteriophora*). A long-term ecotoxicity study with earthworms was available where no sign of pathogenicity and infectiveness was observed. Based on this study, low risk to earthworms is concluded for all representative uses. In addition, the available ecotoxicity study with *Folsomia candida* showed certain effects on mortality and reproduction that cannot be excluded as a sign of pathogenicity and infectiveness. Furthermore, as *Purpureocillium lilacinum* strain 251 is a soil fungus naturally occurring in plant rhizospheres, it is expected that non-target soil organisms are already exposed to the microorganism. However, it has not been demonstrated that the exposure following the use will not be higher than the natural background levels. Therefore, based on the available information, high risk cannot be excluded for collembolans (data gap; issue that could not be finalised). An uncertainty remains with regard to the suitability of the available information to address the potential risk of *Purpureocillium lilacinum* strain 251 to the potential most sensitive life stage (i.e. eggs, larvae) of non-target organisms living or partially living in the soil compartment.

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

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Purpureocillium lilacinum, strain 251	More than 90% reduction in CFU within 90 days	High risk could not be excluded

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
None	–	–	–	–

(a): FOCUS scenarios or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
None	–

Table 4: Air

Compound (name and/or code)	Toxicology
None	–

7. Data gaps

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

7.1. Data gaps identified for the representative uses evaluated

- Information on the resistance or sensitivity of *Purpureocillium lilacinum* strain 251 to antimicrobial compounds (relevant for all representative uses evaluated; (ongoing study), see Sections 1 and 2).
- Further data are necessary to address the risk to collembolans (relevant for all representative uses; see Section 5).

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

No particular conditions are proposed for the representative uses evaluated.

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[6] 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 assessment could not be finalised for collembolans using the available information (see Section 5);

9.2. Critical areas of concern

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

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

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

- None

[6] 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.

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

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

Table 5: Overview of concerns

Representative use		Tomato, cucumber field	Tomato, cucumber greenhouse (permanent structures)
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[1]	X[1]
Risk to aquatic organisms	Risk identified		
	Assessment not finalised		
Groundwater exposure to active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure to metabolites	Legal parametric value breached[(a)]		
	Parametric value of 10 µg/L[(b)] breached		
	Assessment not finalised		

The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.

(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.

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

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Abbreviations

1/*n*	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
ADE	actual dermal exposure
AF	assessment factor
AV	avoidance factor
BUN	blood urea nitrogen
CAS	Chemical Abstracts Service
CFU	colony-forming units
CHO	Chinese hamster ovary cells
CI	confidence interval
CL	confidence limits
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GLP	good laboratory practice
GM	geometric mean
GS	growth stage
HQ	hazard quotient
HR	hazard rate
ISO	International Organization for Standardization
ITS	internal transcribed spacer
iv	intravenous
LC	liquid chromatography
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
M/L	mixing and loading
mm	millimetre (also used for mean measured concentrations)
MOA	mode of action
MRL	maximum residue level
MS	mass spectrometry
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
PD	proportion of different food types
PDA	Potato dextrose agar
PEC	predicted environmental concentration
PIE	potential inhalation exposure
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
RAR	Renewal Assessment Report

RBC	red blood cells
REACH	Registration, Evaluation, Authorisation of Chemicals Regulation
SC	suspension concentrate
SMILES	simplified molecular-input line-entry system
TEF	thyrotroph embryonic factor
TK	technical concentrate
TWA	time-weighted average
UV	ultraviolet
W/S	water/sediment
w/v	weight per unit volume
w/w	weight per unit weight
WBC	white blood cell
WG	water-dispersible granule
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.2020.6238