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Peer review of the pesticide risk assessment of the active substance *Trichoderma atroviride* strain AGR2

European Food Safety Authority (EFSA),
Fernando Alvarez, Maria Arena, Domenica Auteri, Anna Federica Castoldi, Arianna Chiusolo,
Angelo Colagiorgi, Mathilde Colas, Federica Crivellente, Chloe De Lentdecker, Mark Egsmose,
Gabiella Fait, Varvara Gouliarmou, Franco Ferilli, Alessio Ippolito, Frederique Istace,
Samira Jarrah, Dimitra Kardassi, Aude Kienzler, Roberto Lava, Renata Leuschner,
Alberto Linguadoca, Christopher Lythgo, Oriol Magrans, Iris Mangas, Ileana Miron,
Tunde Molnar, Laura Padovani, Juan Manuel Parra Morte, Rositsa Serafimova, Rachel Sharp,
Csaba Szentes, Andrea Terron, Anne Theobald, Manuela Tiramani and Laura Villamar-Bouza

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, France, for the pesticide active substance *Trichoderma atroviride* strain AGR2 and the considerations as regards the inclusion of the substance in Annex IV of Regulation (EC) No 396/2005 are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative use of *Trichoderma atroviride* strain AGR2 as a fungicide on winter and spring oil seed rape (field use). The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Trichoderma atroviride strain AGR2 is a new active substance for which, in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the rapporteur Member State (RMS), France, received an application from Agrolor on 24 April 2018 for approval. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 5 June 2018.

An initial evaluation of the dossier on *Trichoderma atroviride* strain AGR2 was provided by the RMS in the draft assessment report (DAR) and subsequently, a peer review of the pesticide risk assessment on the RMS evaluation was conducted by EFSA in accordance with Article 12 of Regulation (EC) No 1107/2009. The following conclusions are derived.

The use of *Trichoderma atroviride* strain AGR2 according to the representative use by field spray applications as a fungicide on winter and spring oilseed rape, as proposed at EU level results in a sufficient fungicidal efficacy against the target *Sclerotinia sclerotiorum*. Considering the limited data provided, more detailed consideration will be fully assessed in the context of subsequent applications for products authorisation.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of the representative formulation.

In the area of mammalian toxicology, the risk assessment for metabolites from non-dietary exposure could not be finalised due to lack of identification/quantification and toxicological assessment.

In the area of residues, threefold overdosed residue trials demonstrated that viable residues of *Trichoderma atroviride* strain AGR2 on rapeseeds following treatment according to the representative use (outdoor foliar application on oilseed rape: 1×10^{11} CFU/ha at the stage of flowering, i.e. BBCH 60 up to a BBCH of 69) are below 1 CFU/g seeds at harvest. Nevertheless, a data gap was identified for qualitative and quantitative information on possible occurrence of metabolites of potential health concern. This leads to the consumer risk assessment not finalised for the representative use.

Further risk management considerations are required to decide whether *Trichoderma atroviride* strain AGR2 can be included into Annex IV of Regulation (EC) No 396/2005.

Satisfactory information was not provided to demonstrate that, under the conditions of the proposed representative use, any secondary metabolites/toxins produced by *Trichoderma atroviride* strain AGR2 will not occur in the environmental compartments in concentrations considerably higher than under natural conditions. Consequently, further data on the persistence, transformation and mobility of these compounds may be needed in order to assess the potential level of environmental exposure including the exposure of groundwater.

The risk assessment to non-target organisms: birds, wild mammals, aquatic organisms, honeybees, non-target arthropods, earthworms and other soil macro- and microorganisms could not be finalised.

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Background

Regulation (EC) No 1107/2009 of the European Parliament and of the Council¹ (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the draft assessment report (DAR), provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

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

Trichoderma atroviride strain AGR2 is a new active substance for which, in accordance with Article 7 of the Regulation, the RMS, France (hereinafter referred to as the 'RMS'), received an application from Agrolor on 24 April 2018 for approval. In addition, the applicant submitted an application for inclusion of the substance in Annex IV of Regulation (EC) No 396/2005². Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 5 June 2018.

The RMS provided its initial evaluation of the dossier on *Trichoderma atroviride* strain AGR2 in the DAR, which was received by EFSA on 23 June 2020 (France, 2020). The peer review was initiated on 21 October 2020 by dispatching the DAR to the Member States and the applicant, Agrolor, for consultation and comments. EFSA also provided comments. In addition, EFSA conducted a public consultation on the DAR. The comments received were collated by EFSA and forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant'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 12(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 24 February 2021. 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 written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

In accordance with Article 12 of the Regulation, EFSA should adopt a conclusion on whether *Trichoderma atroviride* strain AGR2 can be expected to meet the approval criteria provided for in Article 4 of the Regulation, taking into consideration recital (10) of the Regulation.

A final consultation on the conclusions arising from the peer review of the risk assessment and on the consideration as regards inclusion of the substance into Annex IV of Regulation (EC) No 396/2005 took place with Member States via a written procedure in January–February 2022.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use of *Trichoderma atroviride* strain AGR2 as a fungicide on winter and spring oil seed rape (field use), as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk

¹ 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.

² Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

mitigation options identified in the DAR and considered during the peer review, if any, are presented in the conclusion.

Furthermore, this conclusion also addresses the requirement for an assessment by EFSA under Article 12 of Regulation (EC) No 396/2005, provided that the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment. In the event of a non-approval of the active substance or an approval with restrictions that have an impact on the residue assessment, the Annex IV proposal, if any, from this conclusion might no longer be relevant and a new assessment under Article 12 of Regulation (EC) No 396/2005 will be required.

A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

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

- the comments received on the DAR;
- the reporting table (24 February 2021);
- the evaluation table (11 February 2022);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR, including its revisions (France, 2022), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

The identity of the microorganism and the properties of the formulated product

Trichoderma atroviride strain AGR2 is a filamentous fungus deposited at the French National Collection of Microorganisms Cultures (CNCM; Pasteur institute in Paris, France), under the accession number I-2738. It is a wild-type strain isolated from plant fragments in a cultivated soil in France.

The representative formulated product for the evaluation was 'AG902', a wettable powder (WP) containing 1×10^{12} CFU/kg *Trichoderma atroviride* strain AGR2.

The representative use evaluated comprise field spray applications on winter and spring oil seed rape, as a fungicide against *Sclerotinia sclerotiorum*. Full details of the good agricultural practice (GAP) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the use of *Trichoderma atroviride* strain AGR2 according to the representative use proposed at EU level results in a sufficient fungicidal efficacy against the target organisms, following the guidance document SANCO/10054/2013 - rev. 3 (European Commission, 2013). Considering the limited data provided, more detailed consideration will be fully assessed in the context of subsequent applications for products authorisation.

Conclusions of the evaluation

1. Identity of the microorganism/biological properties/physical and technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion (European Commission, 2000, 2012; EFSA FEEDAP Panel, 2018).

The microbial pest control agent (MPCA) manufactured contains min. 5×10^{11} to max. 1×10^{13} CFU/kg *Trichoderma atroviride* strain AGR2.

The levels of contaminating microorganisms in commercially produced batches comply with the requirements of SANCO/12116/2012 rev.0 (European Commission, 2012).

Molecular methods are available to distinguish *Trichoderma atroviride* strain AGR2 from other strains of the same species. Internal transcriber spacer (ITS) and translation-elongation factor 1 (*tef-1*)

full length sequences obtained by whole genome sequencing (WGS) were used for identification at species level of *Trichoderma atroviride* strain AGR2. The markers identified by the results of the *in silico* analyses were applicable for the identification of *Trichoderma atroviride* AGR2 at the strain level and suitable for laboratory controls.

There is no evidence of relationships of *Trichoderma atroviride* strain AGR2 to known plant, animal or human pathogens.

Trichoderma species have been reported to produce many toxins/secondary metabolites. The presence of genes encoding for such secondary metabolites in the genome of the strain *Trichoderma atroviride* strain AGR2 has not been investigated. There was insufficient evidence to unequivocally demonstrate that *Trichoderma atroviride* strain AGR2 does not produce secondary metabolites of potential concern (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins). As a consequence, a data gap was identified to address the possibility for the MPCA to contain secondary metabolites of potential concern. *Trichoderma atroviride* species are able to produce 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone), a volatile antifungal compound. Five batches of *Trichoderma atroviride* strain AGR2 were analysed for the 6-pentyl-2-pyrone content, which was lower than the limit of detection (0.02% w/w). Information on production of potentially toxic metabolites *in situ* was missing.

Horizontal genetic transfer (HGT) can convey large gene clusters encoding enzymes with linked metabolic functions between fungi, however, based on a study commissioned by EFSA (Mugdal et al., 2013), it was concluded that those evidences of HGT between fungi did not concern species used as biocontrol agents.

Trichoderma atroviride strain AGR2 was shown to be able to grow at 26°C and 30°C but was unable to grow at 35°C, 37°C and 39°C. The *Trichoderma atroviride* species were shown to be able to grow in the pH range of 2–11; however, data were not available for the strain AGR2.

Trichoderma atroviride strain AGR2 is susceptible to amphotericin B and voriconazole and it is resistant to ketoconazole, fluconazole, caspofungin, flucytosine and itraconazole.

The supported shelf-life of the product is 2 years at temperatures between 0°C and 4°C in the original packaging. Considering the technical properties of the microbial pest control product (MPCP), it should be mentioned on the label to shake the mixture at least 3 min before application and all along the application.

Acceptable methods are available for the determination of the microorganism in the technical material, formulation, and for the determination of the content of contaminating microorganisms.

Residue definitions were not applicable for *Trichoderma atroviride* strain AGR2; therefore, post-registration monitoring methods are not needed.

2. Mammalian toxicity

General data

As regards **medical information**, there is no evidence that *Trichoderma atroviride* species cause infection in immunocompetent healthy humans. One case of infection with *Trichoderma atroviride* was reported in a severely immunocompromised transplanted patient for which a contamination of the sample cannot be excluded.

No adverse **health effects** have been reported in workers as a result of exposure to *Trichoderma atroviride* strain AGR2 during production and handling.

Trichoderma atroviride species are not recommended for the **Qualified Presumption of Safety** list (EFSA BIOHAZ Panel, 2020).

Toxicity/Infectivity/Pathogenicity studies

The available methods for testing **dermal sensitisation** are not suitable for testing microorganisms and there are no validated test methods for sensitisation by inhalation. Based on their characteristics, microorganisms such as *Trichoderma atroviride* strain AGR2 may have the potential to provoke sensitising reactions.

No signs of **toxicity, pathogenicity or infectivity** have been detected with *Trichoderma atroviride* strain AGR2 after acute administration by oral, intratracheal, intraperitoneal or dermal routes in rats. Microbial analysis of faeces, fluids and tissues/organs demonstrated that the microorganism is completely and rapidly cleared; few exceptions at the 10⁻¹ dilution were observed, which cannot be considered as a significant presence. No **skin or eye irritation** potential has been identified.

Secondary metabolites/toxins

A data gap was identified to address the possibility for the MPCA to contain secondary metabolites of potential concern (see Section 1). Moreover, a data gap is also identified in Section 4 since it is not known to what extent *Trichoderma atroviride* strain AGR2 will produce any metabolites following their application once the conidia reach soil. Therefore, pending identification and quantification of secondary metabolites both in the product and produced *in situ*, further toxicological data/information might be needed to finalise the risk assessment (data gap). A complementary literature search was conducted for specific metabolites only (i.e. peptaibols, viridofungin and trichothecene); however, no papers were identified as being relevant after detailed assessment of the full-text document.

With regard to **6-pentyl-2H-pyran-2-one** (6-pentyl-2-pyrone), it is noted that it is a volatile organic compound (of low concern by diet), which is approved as a food flavouring substance (FL no. 10.031) by Commission Implementing Regulation (EU) No 872/2012³ adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96. However, considering that the metabolite is potentially involved in the microorganism's mode of action and its production *in situ* is thus plausible (see also Section 4), more information is needed to conclude on the toxicity profile of 6-pentyl-2-pyrone by inhalation (data gap). It is also noted that reports of potential adverse effects, including irritation and effect on histamine release in the respiratory tract are available in the published literature (see e.g. Larsen et al., 1998; Polizzi et al., 2011).

Reference values and non-dietary exposure

For the **microorganism *per se***, the data package is insufficient to derive reference values; nevertheless, acceptable daily intake (ADI), acceptable operator exposure level (AOEL) or acute reference dose (ARfD) values are not needed as *Trichoderma atroviride* strain AGR2 is considered to be of low toxicological concern. Therefore, exposure considerations are not necessary. In the absence of a quantitative risk assessment, the use of personal protective equipment (PPE) and respiratory protective equipment (RPE) for the operators and workers might be considered to reduce the non-dietary exposure (dermal and inhalation).

Concerning **secondary metabolites**, the risk assessment for operators, workers, residents and bystanders cannot be finalised in the absence of their identification/quantification in the technical product and their *in situ* production after application of the microorganism. Regarding 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone), the risk assessment for workers and residents by inhalation exposure cannot be finalised in the absence of quantification of the amount produced after application.

3. Residues

A representative use on oilseed rape has been proposed for *Trichoderma atroviride* strain AGR2. The outdoor field use foresees one application by foliar treatment at growth stages of BBCH 60 up to BBCH 69. The application has a maximum application rate of 1×10^{11} CFU/ha.

The growth stage of BBCH 69, at which the treatment is performed, represents the end of flowering period of the plant and is well before ripe seeds are being formed which are intended for harvest. Notably, it is not known which metabolites can be produced by *Trichoderma atroviride* strain AGR2 (see data gap in Section 1) and whether such residues would occur in oilseed rape at harvest. The toxicological relevance of potentially formed metabolites for humans also resulted in a data gap (see Section 2).

Two outdoor supervised residue trials on rapeseeds have been provided which were performed in Northern and Southern France with *Trichoderma atroviride* strain AGR2 at a threefold higher application rate than the rate for the representative use. Both trials demonstrated that viable residues of *Trichoderma atroviride* strain AGR2 in rapeseed at harvest are below 1 CFU/g seeds at a preharvest interval (PHI) of 60 days.

Concerning potentially formed metabolites, it seems unlikely that non-viable residues, noting also measured viable residues of *Trichoderma atroviride* strain AGR2 at harvest (see paragraph above), would augment on the rapeseed plant and the seeds intended for harvest to critical amounts, which would lead to a potential health concern for the consumer. Nevertheless, noting the data gaps related to the assessment of potentially occurring metabolites of human health concern (see Sections 1 and 2), information on relevant metabolites at harvest is required (data gap). Consequently, unless this

³ Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC. OJ L 267, 2.10.2012, p. 1–161.

information is provided, the consumer risk assessment cannot be finalised for the representative use on rapeseeds (see Section 8.1). It is to be noted that the RMS considers the consumer risk assessment as finalised and concludes that considering the representative use (early stage), no residues (viable and non-viable) are expected on rape following the use of the MPCA at the intended GAP and therefore considers the consumer exposure as negligible. The view of the RMS is supported by two Member States.

With regard to the five assessment criteria according to Commission guidance SANCO/11188/2013 rev. 2 (European Commission, 2015) for potential inclusion of an active substance in Annex IV of Regulation (EC) No 396/2005, none of the three criteria relevant for microorganisms (having no identified hazardous properties (criterion 3); natural exposure is higher than the one linked to the use as plant protection product (criterion 4) or consumer exposure is not expected (criterion 5)) was considered to be met for *Trichoderma atroviride* strain AGR2 for the following reasons:

- *Trichoderma atroviride* AGR2 can form metabolites for which potential health concern cannot be excluded (see Sections 1 and 2);
- It is known that viable residues of *Trichoderma atroviride* strain AGR2 used as plant protection product do not lead to a significant increase of background levels on the edible commodity; however, it is not demonstrated whether this is as well the case for non-viable residues (metabolites) of *Trichoderma atroviride* strain AGR2 (data gap on occurrence and quantification of potential metabolites of concern). It is to be noted that the RMS reiterates that, with regard to the representative GAP only, the MPCA is not persistent and is unlikely to multiply on oilseed rape. In addition, it is not expected to increase in soil above the natural occurrence. Therefore, in the view of the RMS and two Member States, the criterion 4 may be considered as fulfilled.
- Consumer exposure to *Trichoderma atroviride* strain AGR2 and its metabolites cannot be excluded for the representative use on oilseed rape, i.e. outdoor foliar application on oil seed rape: 1×10^{11} CFU/ha at the stage of flowering (BBCH 60 up to a BBCH of 69). It is to be noted that the RMS and two Member States consider that viable and non-viable residues are unlikely to occur at harvest and consequently, with regard to the representative GAP only, consumer exposure is negligible and criterion 5 may be considered as fulfilled.

Overall, considering that none of the criteria laid down in the guidance were deemed to be met because of pending information due to the identified data gaps for information on potential metabolites of health concern, further risk management considerations are required to decide whether *Trichoderma atroviride* strain AGR2 can be included into Annex IV of Regulation (EC) No 396/2005.

4. Environmental fate and behaviour

Satisfactory information has been provided in relation to potential interference of *Trichoderma atroviride* strain AGR2 with the analytical systems for the control of the quality of drinking water provided for in Directive 98/83/EC⁴ (see specific Annex VI decision-making criteria in Part II of Commission Regulation (EU) No 546/2011⁵). As these methods require pathogenic bacteria to be identified and confirmed as absent, it was considered unlikely that filamentous fungi or their conidia would interfere with methodologies used for such determinations.

Being a mitotic asexual fungus (no sexual recombination or meiosis having been observed in its life cycle), in which plasmids are absent from the cell cytoplasm (only mitochondrial plasmids are known), *Trichoderma atroviride* strain AGR2 would not be expected to have the potential for transfer of genetic material to other organisms.

4.1. Fate and behaviour in the environment of the microorganism

No specific studies on the **persistence and multiplication in soil** of *Trichoderma atroviride* strain AGR2 were available. The assessment presented in the DAR is based on information retrieved from the open literature on *Trichoderma* species and *Trichoderma atroviride*. Overall, these data are considered sufficient to conclude that *Trichoderma atroviride* strain AGR2 will respect the uniform

⁴ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 32–54.

⁵ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

principles criterion of not being expected to persist in soil in concentrations considerably higher than the natural background levels, taking into account repeated applications over the years. Predicted environmental concentrations (PEC) in soil have been calculated (see Appendix A).

With respect to the **persistence and multiplication in water**, published peer-reviewed literature studies in the dossier indicated that *Trichoderma* species are able to survive in aquatic environments under favourable conditions. However, germination and population growth are likely to be prevented in most cases due to the relatively low availability of nutrients or competition with aquatic fungi in most natural surface water systems. Due to the method of application assessed via foliar spraying, the *Trichoderma atroviride* strain AGR2 applied has the potential to reach surface water via spray drift. The maximum PEC in surface water (PEC_{sw}) estimated under worst-case assumptions at 1 m drift distance is 9.23×10^3 CFU/L (see Appendix A), which is slightly below the upper limit of the range of natural background levels of *Trichoderma* species in river water (i.e. 0.1×10^2 – 1×10^4 CFU/L).

Published peer-reviewed literature studies in the dossier indicate that *Trichoderma* species have been isolated from the **air** both indoors and outdoors. The genera appear to occur naturally in the air, though the concentrations detected were usually low compared to other fungal genera.

No specific data on the **mobility** of *Trichoderma atroviride* strain AGR2 are available. However, based on information derived from studies with *Trichoderma* species in environmental compartments, it can be concluded that although vertical movement of the fungus in soil appears possible, survival in deeper soil layers is expected to be limited. Horizontal spread over the soil and to above ground plant parts was indicated to occur but to a limited extent.

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

Certain *Trichoderma* species are able to produce a lot of different metabolites such as polyketides, sesquiterpenes (including the mycotoxin group of trichothecenes), viridofungins and peptaibols. Some of these are inhibitory to fungi or bacteria, others have proven toxicity to mammals.

A data gap is identified since it is not known to what extent *Trichoderma atroviride* strain AGR2 will produce any metabolites (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins, and 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone)) following the application once the conidia reach soil. It is not clear if such metabolites might fulfil the criteria according to Part B section 7 (iv) of Commission Regulation (EU) No 283/2013⁶ namely:

- the relevant metabolite is stable outside the microorganism;
- a toxic effect of the relevant metabolite is independent of the presence of the microorganism;
- the relevant metabolite is expected to occur in the environment in concentrations considerably higher than under natural conditions.

Therefore, data on the potential for *Trichoderma atroviride* strain AGR2 to produce metabolites in relation to these criteria are necessary to assess if the further data requirements and the corresponding risk assessment according to Commission Regulation (EU) No 283/2013, part A, section 7 (standard data requirements and assessment mandatory for chemical plant protection active substances) are triggered. Consequently, this resulted in a data gap and assessment that could not be finalised (see Section 8.1).

5. Ecotoxicology

No information was provided for assessing the possible infectivity and pathogenicity of *Trichoderma atroviride* strain AGR2 to **birds**. The applicant provided sufficient information on the optimal growth temperature for *Trichoderma atroviride* strain AGR2 supporting that the strain does not grow at 35°C or above. As birds have higher body temperatures than 35°C, it is unlikely that the strain can infect or cause pathogenic effects in birds and a low risk was concluded for the representative use. Information to assess potential risk from *Trichoderma atroviride* strain AGR2 to vertebrates with lower body temperatures e.g. amphibians and reptiles was not available.

⁶ Commission Regulation (EU) 283/2013 of 1 March 2013 setting out the data requirements for active substances in accordance with 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 93, 3.4.2013, p. 1–84.

As concluded in Section 2, sufficient information is available to finalise the assessment for infectivity and pathogenicity of *Trichoderma atroviride* strain AGR2 in **mammals**. A low risk to wild mammals was concluded (relevant for the representative use).

For **aquatic organisms**, adequate data were available for freshwater invertebrates and algae from *Trichoderma atroviride* strain AGR2 resulting in a low risk for these organism groups for the representative use. Acute toxicity studies were available for fish with *Trichoderma atroviride* strain AGR2 and low toxicity was observed; however, the study was not considered to be of sufficient duration to address potential infectivity and pathogenicity to fish. No information was available for assessing the possible adverse effects from the strain to aquatic plants other than algae. A data gap leading to an assessment not finalised was identified for the potential infectivity and pathogenicity to fish and potential adverse effects to aquatic plants other than algae from *Trichoderma atroviride* strain AGR2 for the representative use (see Section 8.1).

Acute oral and contact toxicity studies for **honeybees** with *Trichoderma atroviride* strain AGR2 were available. Laboratory studies with foliar-dwelling species of **non-target arthropods** (*Typhlodromus pyri* and *Aphidius rhopalosiphii*) exposed to *Trichoderma atroviride* strain AGR2 were available. These studies on honeybees and non-target arthropods indicated low toxicity from *Trichoderma atroviride* strain AGR2. However, in all the available studies on honeybees and non-target arthropods, potential infectivity and pathogenicity were not reported. Therefore, a data gap leading to an assessment that could not be finalised was identified for the potential infectivity and pathogenicity to honeybees and non-target arthropods from *Trichoderma atroviride* strain AGR2 for the representative use (see Section 8.1).

An acute toxicity study for earthworms with *Trichoderma atroviride* strain AGR2 was available. Potential infectivity and pathogenicity were not reported in the study. Acute studies on earthworms are not considered to be of sufficient duration to assess infectivity and pathogenicity. Therefore, insufficient data were available to address infectivity and pathogenicity to **earthworms** and other **soil macroorganisms** from *Trichoderma atroviride* strain AGR2. In addition, insufficient data were available for assessing the potential adverse effects of *Trichoderma atroviride* strain AGR2 on **soil microorganisms**. This resulted in a data gap and assessment that could not be finalised for earthworms, other soil macroorganisms and soil microorganisms for the representative use (see Section 8.1).

The risk assessment for **toxins/secondary metabolites** (see Section 4.2) could not be finalised for terrestrial non-target organisms (birds, wild mammals, honeybees, non-target arthropods, earthworms, other soil macro- and microorganisms) and aquatic organisms (fish, freshwater invertebrates, algae and aquatic plants other than algae) for the representative use. Toxicity data were not available for toxins/secondary metabolites to perform a hazard characterisation (resulting in a data gap and issue not finalised, see Section 8.1).⁷

6. Overview of the risk assessment of the organism or metabolite 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
<i>Trichoderma atroviride</i> strain AGR2	A data gap leading to an assessment not finalised was identified for earthworms, other non-target soil macro- and microorganisms for the representative use.
Toxins/secondary metabolites (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins, and 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone))	A data gap leading to an assessment not finalised was identified for earthworms, other non-target soil macro- and microorganisms for the representative use.

⁷ For freshwater invertebrates, data on acute toxicity of the peptaibols (alamethicin and paracelsin) from a published paper was available indicating low risk when comparing with the concentrations of peptaibols in the formulated product. However, limited details on identity of the peptaibols measured in the formulated product and/or *in situ* after application were available (see Section 1), resulting in the risk assessment for aquatic invertebrates from these peptaibols (alamethicin and paracelsin) not finalised (relevant for the representative use).

Table 2: Groundwater^(a)

Compound (name and/or code)	> 0.1 µg/L at 1 m depth for the representative use ^(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
Toxins/secondary metabolites (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins, and 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone))	Data gap pending on their identification and quantification	Open	Open	Open	Open

(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
<i>Trichoderma atroviride</i> strain AGR2	A data gap leading to an assessment not finalised was identified for the potential infectivity and pathogenicity to fish and potential adverse effects to aquatic plants other than algae for the representative use.
Toxins/secondary metabolites (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins, and 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone))	A data gap leading to an assessment not finalised was identified for aquatic organisms for the representative use.

Table 4: Air

Compound (name and/or code)	Toxicology
<i>Trichoderma atroviride</i> strain AGR2	LC ₅₀ > 11.7 mg/L air/4 h (corresponding to 1.17 × 10 ⁵ CFU/L air/4 h*); the study was considered as supplemental.
Toxins/secondary metabolites (which may include trichothecenes and peptaibols such as trichorzianines, atroviridins, neoatroviridins, alamethicins and paracelsins, and 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone))	Data gap and risk assessment not finalised from non-dietary exposure of operators, workers, residents and/or bystanders due to lack of identification/quantification and toxicological assessment.

*: Density of the suspension of AGR2 not given in the study report – conversion from mg to mL based on a default density of 1.

7. 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.

Particular measures may be considered by Member States during the application: it needs to be mentioned on the label to shake the mixture at least for 3 min before application and all along the application.

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

Representative use	Oilseed rape
	Foliar spray
Operator risk	Use of PPE/RPE might be considered to reduce dermal and inhalation exposure (for the sensitisation potential).
Worker exposure	Use of PPE/RPE might be considered to reduce dermal and inhalation exposure (for the sensitisation potential)

8. Concerns and related data gaps

8.1. 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 546/2011⁵ 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 risk assessment for operators, workers, residents and bystanders potentially exposed to secondary metabolites cannot be finalised (see Section 2) considering the identified data gaps:
 - a) Information to address the possibility for the MPCA to contain secondary metabolites of potential concern. The absence of genes encoding the identified metabolites of potential concern evidenced by employing appropriate genomics methods must be investigated to exclude the absence of a hazard from those metabolites (relevant for the representative use; see Section 1).
 - b) Pending identification and quantification of secondary metabolites both in the product (see Section 1) and produced *in situ* (see Section 4), further toxicological data/information might be needed to finalise the risk assessment (relevant for the representative use, see Section 2).
- 2) The non-dietary risk assessment for workers and residents potentially exposed to 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone) by inhalation cannot be finalised (see Section 2) considering the identified data gaps:
 - a) Quantification of 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone) *in situ* is required (relevant for the representative use, see Section 4).
 - b) Pending quantification of 6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone) produced *in situ* (see Section 4), further toxicological data/information might be needed to finalise the risk assessment by inhalation (relevant for the representative use, see Section 2).

- 3) The dietary consumer risk assessment cannot be finalised considering the identified data gap (see Section 3):
 - a) Further information on qualitative and quantitative occurrence of metabolites of potential health concern linked to the representative use of *Trichoderma atroviride* strain AGR2 on oilseed rape and which can be present at harvest is required (relevant for the representative use, see Section 3). The RMS and two Member States support the position that significant residues (viable and non-viable) are not expected on oilseed rape following the use of the MPCA at the representative GAP, and therefore, consumer exposure can be considered as negligible.
- 4) Satisfactory information was not available on the production of toxins/secondary metabolites (see Section 4.2) and their levels present in the environment (including potential for exposure to groundwater) after application and their potential toxicity in order to conclude on the risk assessment for non-target terrestrial organisms (birds, wild mammals, honeybees, non-target arthropods, earthworms, other soil macro- and microorganisms) and non-target aquatic organisms (fish, freshwater invertebrates, algae and aquatic plants other than algae), leading to an assessment not finalised (see Sections 4.2 and 5) considering the identified data gap:
 - a) Pending on further investigations on the production of toxins/secondary metabolites (see Section 4.2) and their levels present in the environment after application, further considerations will have to be given to their potential toxicity in order to conclude on the risk assessment for terrestrial non-target organisms (birds, wild mammals, honeybees, non-target arthropods, earthworms, other soil macro- and microorganisms) and aquatic organisms (fish, freshwater invertebrates, algae and aquatic plants other than algae) and on the groundwater exposure assessment (relevant for the representative use; see Sections 4.2 and 5).⁸
- 5) Satisfactory information was not available for the potential infectivity, pathogenicity and adverse effects to non-target terrestrial organisms (honeybees, non-target arthropods, earthworms and other soil macro- and microorganisms) and aquatic organisms (fish and aquatic plants other than algae) from *Trichoderma atroviride* strain AGR2 for the assessment of the representative use, leading to an assessment not finalised considering the identified data gap (see Section 5):
 - a) Data and information for the assessment of the potential infectivity and pathogenicity to non-target terrestrial organisms (honeybees, non-target arthropods, earthworms and other soil macro- and microorganisms) and aquatic organisms (fish and aquatic plants other than algae) from *Trichoderma atroviride* strain AGR2 (relevant for the representative use, see Section 5).

8.2. 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.

⁸ For freshwater invertebrates data on acute toxicity of the peptaibols (alamethicin, and paracelsin) from a published paper was available indicating low risk when comparing with the concentrations of peptaibols in the formulated product. However, limited details on identity of the peptaibols measured in the formulated product and/or *in situ* after application were available (see Section 1), resulting in the risk assessment for aquatic invertebrates from these peptaibols (alamethicin and paracelsin) not finalised (relevant for the representative use).

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:

Critical areas of concern were not identified

8.3. Overview of the concerns identified for each representative use considered (Table 6)

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

Representative use	Winter and spring oilseed rape	
		foliar spray
Operator risk	Risk identified	
	Assessment not finalised	X ¹
Worker risk	Risk identified	
	Assessment not finalised	X ^{1,2}
Resident/bystander risk	Risk identified	
	Assessment not finalised	X ^{1,2}
Consumer risk	Risk identified	
	Assessment not finalised	X ³
Risk to wild non-target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X ⁴
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	
	Assessment not finalised	X ^{4,5}
Risk to aquatic organisms	Risk identified	
	Assessment not finalised	X ^{4,5}
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	X ⁴

The superscript numbers relate to the numbered points indicated in Section 8.1.

(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).

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 7, has been evaluated as being effective, then 'risk identified' is not indicated in Table 6)

9. 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 uses assessed and are listed in the order of the sections:

Other outstanding issues were not identified.

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Abbreviations

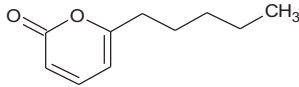
λ	wavelength
E	decadic molar extinction coefficient
μg	microgram
μm	micrometer (micron)
AMA	Amphibian Metamorphosis Assay
a.s.	active substance
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
AR	androgen receptor
ARfD	acute reference dose
CABI	Centre for Agricultural Bioscience International
CFU	colony forming units
Cm	centimetre
CNCM	Collection Nationale de Cultures de Micro-organismes
d	day
DAR	draft assessment report
DNA	deoxyribonucleic acid

FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	Good Agricultural Practice
h	hour(s)
ha	hectare
hL	hectolitre
ISO	International Organization for Standardization
ITS	internal transcribed spacer
IUPAC	International Union of Pure and Applied Chemistry
iv	intravenous
kg	kilogram
L	litre
LC ₅₀	lethal concentration, median
m	metre
M	mol
mg	milligram
mL	millilitre
mm	millimetre (also used for mean measured concentrations)
MPCA	active agent of the microbial pest control product
MPCP	microbial pest control product
ng	nanogram
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PEC	predicted environmental concentration
PEC _{sw}	predicted environmental concentration in surface water
pH	pH-value
PHI	preharvest interval
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
QSAR	quantitative structure–activity relationship
r ²	coefficient of determination
RPE	respiratory protective equipment
S	svedberg, S (10 ⁻¹³ s)
SD	standard deviation
SMILES	simplified molecular-input line-entry system
STMR	supervised trials median residue
t _{1/2}	half-life (define method of estimation)
TC	technical material
<i>tef1</i>	translation elongation factor 1 α gene
TER	toxicity exposure ratio
TER _A	toxicity exposure ratio for acute exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
WGS	whole genome sequencing
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.2022.7199>

Appendix B – Used compound codes

Code/trivial name ^(a)	IUPAC name/SMILES notation/InChiKey ^(b)	Structural formula ^(c)
6-pentyl-2H-pyran-2-one (6-pentyl-2-pyrone) (6-PP)	6-pentyl-2H-pyran-2-one <chem>O=C1C=CC=C(CCCCC)O1</chem> MAUFTTLGOUBZNA-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).