CONCLUSION ON PESTICIDES PEER REVIEW

EFSA Journal

APPROVED: 17 December 2018

doi: 10.2903/j.efsa.2019.5575

Peer review of the pesticide risk assessment of the active substance *Verticillium albo-atrum* strain WCS850

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Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Sweden and co-rapporteur Member State the Netherlands for the pesticide active substance *Verticillium albo-atrum* strain WCS850 are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative use of *Verticillium albo-atrum* strain WCS850 as a fungicide on elm trees. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed.

Keywords: *Verticillium albo-atrum* strain WCS850, peer review, risk assessment, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2017-00296

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Update: This scientific output, approved on 17 December 2018, supersedes the previous output published on 30 January 2013 (EFSA, 2013).

Acknowledgement: EFSA wishes to thank the rapporteur Member State Sweden for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Arena M, Auteri D, Barmaz S, Brancato A, Brocca D, Bura L, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, Ctverackova L, De Lentdecker C, Egsmose M, Fait G, Ferreira L, Gatto V, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Magrans JO, Medina P, Messinetti S, Mineo D, Miron I, Nave S, Molnar T, Padovani L, Parra Morte JM, Pedersen R, Raczyk M, Reich H, Ruocco S, Saari KE, Sacchi A, Santos M, Serafimova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Vainovska P, Van Dijk J, Verani A and Villamar-Bouza L, 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance *Verticillium albo-atrum* strain WCS850. EFSA Journal 2019;17(1):5575, 13 pp. https://doi.org/10.2903/j.efsa.2019.5575

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.

Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012 as amended by Commission Implementing Regulation (EU) 2016/183. *Verticillium albo-atrum* strain WCS850 is one of the active substances listed in Regulation (EU) No 2016/183.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Sweden, and the co-rapporteur Member State (co-RMS), the Netherlands, received an application from BTL Bomendienst B.V. for the renewal of approval of the active substance *Verticillium albo-atrum* strain WCS850. 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 the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on *Verticillium albo-atrum* strain WCS850 in the renewal assessment report (RAR), which was received by EFSA on 1 November 2017. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BTL Bomendienst B.V., for comments on 30 January 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 4 April 2018.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that there was no need to conduct an expert consultation.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether *Verticillium albo-atrum* strain WCS850 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of *Verticillium albo-atrum* strain WCS850 as a fungicide on elm trees, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the use of *Verticillium albo-atrum* strain WCS850 according to the representative use proposed at the European Union (EU) level results in a sufficient efficacy to prevent Dutch elm disease.

A data gap was identified for an updated assessment of the literature review relevant for all sections except that of residues, including clear justification of the search terms and databases used, as well as further assessment of the studies/articles on pathogenic strains of *Verticillium albo-atrum*.

In the area of identity, a data gap was identified for a method for an unequivocal identification at strain level.

In the area of mammalian toxicology, no concern was identified on the basis of the available data and considering the representative use for which exposure of operators, workers, residents and bystanders is not expected.

Considering the proposed use on ornamental elm trees by direct injection into the tree trunk, residues on edible plant parts and/or on succeeding crops are not expected. Therefore, a dietary consumer risk assessment is not required.

Experimental findings showed that *Verticillium albo-atrum* strain WCS850 is expected to be confined to the area of the site of injection and could not be isolated 2 weeks after vaccination. A data gap is identified in relation to the transport and life-cycle of *Verticillium albo-atrum* strain WCS850.

No strain specific ecotoxicology studies for *Verticillium albo-atrum* strain WCS850 or quantitative risk assessment were required due to low expected levels of environmental exposure and the fact that there are no indications that *Verticillium albo-atrum* strain WCS850 is of concern for humans or animals based on mode of action or the information on human or animal pathogenicity found in the available literature. Therefore, the risk to birds and mammals, aquatic organisms, bees, non-target arthropods, earthworms, soil macro-, meso- and microorganisms, was considered to be low.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of up to 3 months where additional information is required to be submitted by the applicant in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS Sweden and co-RMS the Netherlands received an application from BTL Bomendienst B.V. for the renewal of approval of the active substance *Verticillium albo-atrum* strain WCS850. 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 *Verticillium albo-atrum* strain WCS850 in the RAR, which was received by EFSA on 1 November 2017 (Sweden, 2017).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, BTL Bomendienst B.V., for consultation and comments on 30 January 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 4 April 2018. At the same time, the comments were forwarded to the RMS for further consideration. In addition, the applicant was invited to respond to the comments received. The considerations by both the applicant as well as the RMS of the comments are reflected in the reporting table.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS on 23 May 2018. 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.

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

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of all points identified during the peer review, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the reporting 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 September-October 2018.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative use of *Verticillium albo-atrum* strain WCS850 as a fungicide on elm trees, as proposed by the applicant. In accordance with Article 12(2) of Regulation (EC) No 1107/2009, risk mitigation options identified in the RAR and considered during the peer review are presented in the conclusion. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

A key supporting document to this conclusion is the peer review report (EFSA, 2018), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer

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

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

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 reporting table (23 May 2018) containing all the comments received on the RAR together with their evolution and follow-up during the peer review;
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Sweden, 2018), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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

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

Verticillium albo-atrum strain WCS850 is a fungus deposited at the Westerdijk Fungal Biodiversity Institute (CBS-KNAW), Utrecht, The Netherlands, under accession number CBS 276.92. *Verticillium albo-atrum* strain WCS850 is a natural hyaline mutant of the parent *V. albo-atrum*. It differs from the parent in the sense that *Verticillium* WCS850 has lost the capacity to produce resting structures (resting mycelium). This strain originates from a diseased potato field in the Netherlands and was preliminary identified as *Verticillium dahliae*. *V. albo-atrum* has a wide-spread geographical distribution, especially in temperate regions.

The representative formulated product for the evaluation was 'Dutch Trig', an ultra-low volume suspension (SU) containing 1×10^7 colony forming units(CFU)/mL (declared range 0.7–1.5 $\times$ 10^7 CFU/mL) *Verticillium albo-atrum* strain WCS850. An FAO specification does not exist for this product.

The representative use evaluated comprises applications by injection into the trunk of the elm trees, using a special tree-injection-device, against Dutch elm disease (*Ophiostoma novo-ulmi*) in city and street lining elm trees. 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 *Verticillium albo-atrum* strain WCS850 according to the representative use proposed at EU level results in a sufficient efficacy to prevent Dutch elm disease, following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

A data gap was identified for an updated assessment of the literature review regarding plant, animal or human pathogens, environment and production of metabolites and resistance/sensitivity to antibiotics and other antimicrobial agents, including a clear justification of the search terms and used databases, as well as further assessment of the studies/articles on pathogenic strains of *Verticillium albo-atrum* (EFSA, 2011).

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: SANCO/12116/2012–rev. 0 (European Commission, 2012) and 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 product 'Dutch Trig', containing minimum 0.7 $\times$ 10^7 CFU/mL.

Whole genome analysis by amplified fragment length polymorphism (AFLP) and single gene analysis of rDNA-ITS can distinguish between species of *Verticillium,* and places strain WCS850 within *V. albo-atrum* strains and not with strains of *V. dahlia.* However, these techniques do not distinguish between different strains of the species. A whole genome sequencing approach is under development for the identification of *Verticillium albo-atrum* strain WCS850 at strain level. As a consequence, a data gap was identified for an unequivocal identification at strain level.

The analysis of contaminating microorganisms in all commercially produced batches does not entirely comply with the requirements in SANCO/12116/2012 rev.0; however, as the representative use is for treatment of elms, and no human exposure is anticipated, this was considered acceptable.

V. albo-atrum is able to secrete antimicrobial compounds; however, there was no information for metabolite production in the *Verticillium albo-atrum* strain WCS850. *V. albo-atrum* is sensitive to several antimicrobial compounds, including cycloheximide, natamycin (pimaricin), flavone and other flavonoids.

The optimal growth temperature for *Verticillium albo-atrum* strain WCS850 is 23°C and growth was not seen above 30°C.

Specific information addressing the issue of resistance/sensitivity to antibiotics and other antimicrobial agents of *Verticillium albo-atrum* strain WCS850 has not been presented (data gap).

Acceptable methods are available for the determination of the microorganism content in the formulation.

A residue definition was not applicable for *Verticillium albo-atrum* strain WCS850; therefore, post-registration monitoring methods are not needed.

2. Mammalian toxicity

General data

In the literature, *Verticillium* is not a known human or mammalian pathogen. Several papers have reported medical cases of human infection in immunocompromised people, related to *Verticillium* but not specifically to *Verticillium albo-atrum* strain WCS850. Medical surveillance on manufacturing plant personnel did not reveal any pathogenic or allergenic effects amongst those involved.

Toxicity studies

One acute intraperitoneal toxicity study has been performed where *Verticillium albo-atrum* strain WCS850 did not induce any sign of toxicity in the treated rats. The clearance was not investigated but the microorganism is not expected to be infective in humans since it does not grow at temperatures above 30°C.

As for other microorganisms-based products, the warning phrase 'Microorganisms may have the potential to provoke sensitising reactions', can be applied taking into account that hazard statements applicable to chemicals (according to Regulation (EC) No 1272/2008[3]) are not appropriate for microorganisms.

Secondary metabolites/toxins

Verticillium albo-atrum can produce several phytotoxins (e.g. including alboatrin). No data are available (data gap) in relation to their toxicity for humans or animals (EFSA BIOHAZ Panel, 2011).

Reference values and non-dietary exposure

Considering that no mixing and loading is foreseen, and that the operators will use a close injection tool during tree trunk injection, it can be concluded that there will be no exposure of the operators, workers and bystanders. As a consequence, no reference values need to be derived for this microorganism and the toxicological profile of the toxins does not need to be further investigated for this representative use.

3. Residues

Residues on edible plants parts are not expected and an impact on succeeding crops does not need to be considered in this context. Therefore, a dietary consumer risk assessment is not required.

4. Environmental fate and behaviour

Experimental findings showed that *Verticillium albo-atrum* strain WCS850 is expected to be confined to the area of the site of injection and could not be isolated 2 weeks after vaccination. If these findings of the transport and life-cycle of *Verticillium albo-atrum* strain WCS850 can be confirmed through experimental investigations carried according to Good Laboratory Practice (GLP) or a

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

recognised testing facility the exposure from the representative use of the formulation assessed to the environmental compartments (soil, groundwater, surface water systems and air) by the organism or its metabolites may be concluded to be negligible.

5. Ecotoxicology

Only a qualitative risk assessment based on the effects on non-target organisms was performed.

The potential of *Verticillium albo-atrum* strain WCS850 pathogenicity and toxicity to birds and mammals is considered unlikely since growth no longer occurs at temperatures above 30°C (see Section 1) and therefore it cannot proliferate in warm blooded organisms. No strain-specific ecotoxicology studies for *Verticillium albo-atrum* strain WCS850 or quantitative risk assessment were submitted or required due to low expected levels of environmental exposure (see Section 4) and the fact that there are no indications that Verticillium *albo-atrum* strain WCS850 is of human or animal concern based on the mode of action or information on human or animal pathogenicity found in the available literature. Therefore, based on the available information and considering the representative use assessed, the risk to aquatic organisms, bees, non-target arthropods, earthworms, soil macro-, meso- and microorganisms, was considered to be low.

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
None	–	–

Table 2: Groundwater

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

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

- A data gap was identified for an updated assessment of the literature review, including clear justification of the search terms and used databases, as well as further assessment of the studies/articles on pathogenic strains of *V. albo-atrum* (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1, 2, 4 and 5).
- Method for an unequivocal identification of *Verticillium albo-atrum* strain WCS850 at strain level (relevant for all representative uses evaluated; see Section 1).
- Information addressing the issue of resistance/sensitivity to antibiotics and other antimicrobial agents of *Verticillium albo-atrum* strain WCS850 (relevant for all representative uses evaluated; see Sections 1 and 2).
- Data on investigations on transport and life-cycle of *Verticillium albo-atrum* WCS850 in treated elm trees under GLP or, as per derogation foreseen in the regulation by an officially recognised testing facility as required under points 3.2 and 3.3 of the Annex to Commission Regulation (EU) No 284/2013 were not available (relevant for all representative uses evaluated; see Section 4).

8. Particular conditions proposed to be taken into account to manage the risk 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[4] 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) None identified.

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

[4] 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.

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.

1) None identified.

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

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

Table 5: Overview of concerns

Representative use		Elm trees
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	
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. In this case no superscript number occurs, 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

AFLP	amplified fragment length polymorphism
CFU	colony forming units
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
ITS	internal transcribed spacer
MPCA	active agent of the microbial pest control product
MPCP	microbial pest control product
SU	ultra-low volume suspension

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.2019.5575