CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance tolclofos-methyl

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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, Sweden, and co-rapporteur Member State, Denmark, for the pesticide active substance tolclofos-methyl 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 uses of tolclofos-methyl as a fungicide on potatoes, lettuce and ornamentals. 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: tolclofos-methyl, peer review, risk assessment, pesticide, fungicide

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Erratum/Corrigendum: A corrigendum was issued for what concern the aquatic assessment for tolclofos-methyl. Some of the results were wrongly reported for representative use in ornamental crops for protected structures, the results of the numbers of relevant FOCUS scenario were corrected in particular in Table 5 page 18 and LoEP (i.e. D4 scenario with 10 m deposition). To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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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. Tolclofos-methyl is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Sweden, and co-rapporteur Member State (co-RMS), Denmark, received an application from Sumitomo Chemical Agro Europe S.A.S. for the renewal of approval of the active substance tolclofos-methyl. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Denmark), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on tolclofos-methyl in the renewal assessment report (RAR), which was received by EFSA on 11 November 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Sumitomo Chemical Agro Europe S.A.S., for comments on 12 January 2017. 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 15 March 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether tolclofos-methyl 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 uses of tolclofos-methyl as a fungicide on potato and on lettuce and ornamentals, respectively, as field and greenhouse applications, as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

The uses of tolclofos-methyl according to the representative uses proposed at the European Union (EU) level result in a sufficient fungicidal efficacy against *Rhizoctonia*.

In the area of identity, physical-chemical properties and analytical methods, data gaps were identified for the industrial scale 5 batch data for one of the sources, for the final report of shelf-life study for one of the representative formulations, for the log P_{ow} for metabolite DM-TM-CH_2OH and for data demonstrating that matrix effects are not significant in soil.

The assessment on the representativeness of the batches used in the (eco)toxicological assessment for the specification is not concluded (See Sections 2 and 5). No conclusion could be drawn regarding the equivalence of (eco)toxicity studies compared to the technical specification leading to a critical area of concern.

In the area of mammalian toxicology and non-dietary exposure, further data are needed to address the toxicological profile of some metabolites and impurity 1. A data gap is identified for a developmental neurotoxicity study on tolclofos-methyl and to assess the phototoxicity potential of tolclofos-methyl at ultraviolet B (UVB) ranges.

Several data gaps were identified in the residue section. Furthermore, the finalisation of the toxicological risk assessment of the metabolites TM-CH_2OH and ph-CH_3, which are part of the residue definition for risk assessment, is pending. Therefore and due to the lack of field trials on lettuce and potato proposed uses, the consumer risk assessment is only provisional.

With respect to fate and behaviour in the environment, the necessary information to produce the exposure assessment for the representative uses was available except for the dustable powder (DP) formulation, for which a data gap was identified to address the potential exposure by dust drift.

In the area of ecotoxicology, data gaps were identified for further information to address the risk to wild mammals, aquatic organisms and honeybees.

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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 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, Sweden, and co-RMS, Denmark, received an application from Sumitomo Chemical Agro Europe S.A.S. for the renewal of approval of the active substance tolclofos-methyl. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Denmark), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on tolclofos-methyl in the RAR, which was received by EFSA on 11 November 2016 (Sweden, 2016).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Sumitomo Chemical Agro Europe S.A.S., for consultation and comments on 12 January 2017. 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 15 March 2017. 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 27 April 2017. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology.

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

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November–December 2017.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulations, evaluated on the basis of the representative uses of tolclofos-methyl as a fungicide on potatoes, lettuce and ornamentals, as proposed by the

[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.

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

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2017), 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 (27 April 2017);
- the evaluation table (6 November 2017);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Sweden, 2017), 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 active substance and the formulated product

Tolclofos-methyl is the ISO common name for *O*-2,6-dichloro-*p*-tolyl *O,O*-dimethyl phosphorothioate (IUPAC).

The representative formulated products for the evaluation were 'Tolclofos-methyl 50 WP', a wettable powder (WP) containing 500 g/kg tolclofos-methyl; 'Tolclofos-methyl 50 SC', a suspension concentrate (SC) containing 500 g/L tolclofos-methyl and 'Tolclofos-methyl 10 DP', a dustable powder (DP) containing 100 g/kg tolclofos-methyl.

The representative uses evaluated were tuber dressing, soil spray/drench and cover soil mixing applications in potato, lettuce and ornamentals, respectively, against *Rhizoctonia*. Full details of the good agricultural practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of tolclofos-methyl according to the representative uses proposed at the EU level result in a sufficient fungicidal efficacy against *Rhizoctonia*, 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/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The proposed specification was supported by batch data from industrial scale production for one source and reduced scale production for the second source; therefore, a data gap for industrial scale 5 batch data was identified. The proposed minimum purity of the technical material is 960 g/kg. Methanol is considered a relevant impurity with a maximum content of 1 g/kg (see Section 2), as a consequence, the reference specification should be updated. It should be noted that the relevance of impurity 1 is not concluded (see Section 2). There is no FAO specification available for tolclofos-methyl.

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 tolclofos-methyl or the representative formulations; however, data gaps were identified for the final report of shelf-life study for one of the representative formulations and for log P_{ow} for metabolite DM-TM-CH_2OH (see Section 3). The main data regarding the identity of tolclofos-methyl and its physical and chemical properties are given in Appendix A.

Adequate methods are available for the generation of pre-approval data required for the risk assessment. Methods of analysis are available for the determination of the active substance in the technical material and in the representative formulation and for the determination of the respective impurities in the technical material. However, pending the conclusion on the relevance of the impurities, methods for analysis of the relevant impurities in the plant protection products might be required.

Tolclofos-methyl residues can be monitored in food and feed of plant origin by the QuEChERS method using liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with limit of quantification (LOQ) of 0.01 mg/kg in each commodity group. Tolclofos-methyl residues in food of animal origin can be determined by the QuEChERS method using HPLC–MS/MS with a LOQ of 0.01 mg/kg in all animal matrices. It should be noted that residue definition for animal products is provisional (see Section 3) and additional monitoring methods might be required should new components be included in the residue definition.

Tolclofos-methyl residues in soil can be monitored by gas chromatography with flame photometric detector (GC–FPD) with LOQs of 0.01 mg/kg. However, a data gap was identified for data demonstrating that matrix effects are not significant.

Appropriate HPLC–MS/MS method exists for monitoring of tolclofos-methyl residues in water with a LOQ of 0.1 μg/L. Tolclofos-methyl residue in air can be monitored by GC–FPD with a LOQ of 1 $\mu g/m^3$.

The QuEChERS method using HPLC–MS/MS with a LOQ of 0.01 mg/L can be used for monitoring of tolclofos-methyl in body fluids. The methods for monitoring of tolclofos-methyl in animal products can be used for determination of tolclofos-methyl residues in body tissues.

However, the residue definitions for animal products and body fluids are considered provisional and additional monitoring methods might be required should, new components, be included in the residue definitions.

2. Mammalian toxicity

The toxicological profile of the active substance tolclofos-methyl and its metabolites was discussed at the Pesticides Peer Review Experts' Meeting 162 (Session 2) and assessed based on the following guidance documents: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003–rev. 10.1 (European Commission, 2012), Guidance on Dermal Absorption (EFSA PPR Panel, 2012) and Guidance on the Application of the CLP criteria (ECHA, 2015).

To assess the toxicological profile of the **active substance** tolclofos-methyl, the applicant submitted a set of valid toxicity studies. Given that the impurity profile of the toxicity studies was not available and the toxicological relevance of impurities was not clearly excluded, it is not possible to conclude on whether the toxicity studies can support the proposed technical specification for the active substance and associated impurities, leading to a critical area of concern (see Sections 5 and 9). Further data (data gap) should be provided to support the maximum content of impurity 1 (i.e. impurity 1 showed alerts for clastogenicity in quantitative structure–activity relationship (QSAR) analysis; it is expected to inhibit cholinesterase activity, it cannot be excluded to be more potent than the active substance, and structure differences with the active substance, i.e. additional functional groups, do not allow to assume similarity to the active substance). Methanol should be considered relevant based on current hazard classification; however, the maximum content proposed in the technical specification is of no toxicological concern.

In the toxicokinetic studies, tolclofos-methyl was rapidly absorbed. Oral absorption was estimated to be greater than 90% in both rats and mice. There was no evidence for accumulation. Excretion of the substance was predominantly through the urine. Tolclofos-methyl was mainly metabolised via oxidative desulfuration of the P=S group to P=O, oxidation of 4-methyl group and cleavage of P–O–aryl and P–O–methyl linkages. Metabolic patterns in the different species were similar. No unique human metabolite expected (human and rat liver microsomes). EFSA noted that given the extensive metabolism in mammals, to consider only tolclofos-methyl the appropriate residue definition for body fluids (e.g. urine or blood) might not be appropriate and should be considered provisional, leading to a data gap (see also Section 1).

In the acute toxicity studies, the substance has low acute toxicity when administered orally, dermally or by inhalation to rats. It is not a skin or eye irritant but a skin sensitiser. Tolclofos-methyl did not show phototoxic potential in the OECD 3T3 NRU-PT test. The OECD 3T3 NRU-PT test might not be an appropriate test for ultraviolet B (UVB) absorbers such as tolclofos-methyl. However, no validated methods are available to address properly UVB absorbers such as tolclofos-methyl (data gap).

In short-term oral toxicity studies, the liver and the kidneys were the target organs in the rat, and the liver was also a target organ in the dog. In the mouse, the liver, kidney and adrenals were target organs, while in the rabbit, the kidney was the target organ. Mice were the most sensitive species to erythrocyte cholinesterase inhibition being also a critical effect at the lowest observable adverse effect level (LOAEL). The relevant short-term oral no observed adverse effect level (NOAEL) is 3.8 mg/kg body weight (bw) per day (9-month mouse study).

Based on available genotoxicity studies, the substance is unlikely to be genotoxic.

In long-term toxicity and carcinogenicity studies with rats and mice, the critical effects included erythrocyte cholinesterase inhibition and kidney toxicity in mice. No adverse effects were observed in rats up to 42 mg/kg bw per day. The relevant long-term NOAEL is 6.4 mg/kg bw per day (2-year mouse study). The substance showed no carcinogenic potential in either species.

In reproductive toxicity studies, fertility and overall reproductive performance was not impaired up to the dose level of 668 mg/kg bw per day (highest dose level tested). Reduced body weight in the F_1 generation was attributed to a higher intake in pups and length of exposure when compared to parents and consequently not due to higher sensitivity of pups. The agreed parental NOAEL is 173 mg/kg bw per day, whereas the offspring NOAEL is 70.6 mg/kg bw per day. In the developmental toxicity studies, the relevant maternal and developmental NOAELs are 300 mg/kg bw per day for the rat and rabbit.

In general toxicity studies, tolclofos-methyl showed cholinesterase inhibition activity. The mice were the most sensitive species to this effect. In acute and subchronic neurotoxicity studies in rats, acetyl

cholinesterase inhibition and reduced locomotor activity were observed at high-dose levels (around 700 mg/kg bw per day and above). No signs of delayed neurotoxicity were observed in domestic hens. Despite the low neurotoxic potency of tolclofos-methyl in rats (i.e. weak cholinesterase inhibition activity), the majority of experts agreed that a developmental neurotoxicity study in mice should be provided leading to a data gap.

Tolclofos-methyl did not show evidence of immunotoxicity in specific immunotoxicity studies.

Tolclofos-methyl is not classified (harmonised) or proposed to be classified as toxic for reproduction category 2 or carcinogenic category 2, in accordance with the provisions of Regulation (EC) No 1272/2008[3], and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. With regard to the scientific risk assessment, the experts agreed that there was no evidence of endocrine-mediated effects *in vivo*; therefore, the experts concluded that tolclofos-methyl is unlikely to have endocrine disrupting properties.

The agreed acceptable daily intake (ADI) is 0.064 mg/kg bw per day, on the basis of the relevant long-term NOAEL of 6.4 mg/kg bw per day in the 2-year study in mice based on erythrocyte cholinesterase inhibition and kidney toxicity at 32.2 mg/kg bw per day. An uncertainty factor (UF) of 100 was applied. The ADI is the same as the value set previously (EFSA, 2005; European Commission, 2006).

The agreed acute reference dose (ARfD) is 0.14 mg/kg bw based on the NOAEL of 13.8 mg/kg bw per day for cholinesterase inhibition observed at 564 mg/kg bw per day on day 14 in the 9-month toxicity study in mice. An UF of 100 was applied. The experts acknowledged that dose spacing (ratio NOAEL/LOAEL of 40) in the study and the use of a 14-day data time point lead to a conservative approach. The ARfD provides a margin of exposure of 4,000 relative to the LOAEL for cholinesterase inhibition in mice, and therefore, the experts considered not necessary to increase the UF because of lack of developmental neurotoxicity in mice. Establishment of an ARfD was not deemed to be necessary during the first review (EFSA, 2005; European Commission, 2006).

The agreed systemic acceptable operator exposure level (AOEL) is 0.064 mg/kg bw per day on the basis of the relevant long-term NOAEL of 6.4 mg/kg bw per day in the 2-year study in mice based on erythrocyte cholinesterase inhibition and kidney toxicity at 32.2 mg/kg bw per day. An UF of 100 was applied. No correction factor for oral absorption is needed to derive the AOEL. The AOEL changed compared to the previously set value (EFSA, 2005; European Commission, 2006). The experts agreed to reduce the AOEL from 0.2 mg/kg bw per day to 0.064 mg/kg bw per day because the mouse was considered the most sensitive species for erythrocyte cholinesterase inhibition and because this effect was already observed at week 28 in the 2-year mouse study.

The experts agreed that acute acceptable operator exposure level (AAOEL) of 0.14 mg/kg bw should be set on the same basis as the ARfD.

The RMS estimated **non-dietary exposure** (i.e. operator, worker, bystander and resident) for the representative formulations considering dermal absorption values of tolclofos-methyl in 'Tolclofos-methyl WP 50' of 0.6% for the concentrate and 6% for the dilution, in 'Tolclofos-methyl SC 50' of 0.02% for the concentrate and 0.9% for the dilution and in 'Tolclofos-methyl 10DP' of 0.9% as input values.

Considering the representative uses with '**Tolclofos-methyl WP 50**' as a fungicide in **potato,** the maximum estimated operator exposure was below the AOEL (from 41% to 97% of the AOEL, depending on the model or study) with the use of personal protective equipment (PPE) during mixing and loading and application (type of PPE including personal respiratory equipment (PRE) depends on the model or study; see Appendix A). No re-entry worker exposure is anticipated according to the representative uses. Bystander and resident exposure was below the AOEL (maximum 4.9% of the AOEL; adult bystander).

Considering the representative uses with '**Tolclofos-methyl SC 50**' as a fungicide in **potato**, **lettuce** and **ornamentals,** the maximum estimated operator exposure (i.e. considering all crops) was below the AOEL (97% of the AOEL; before planting potato, application rate of 0.675 kg a.s/ha) with the use of PPE during mixing and loading and application according to a field study. Maximum re-entry worker (i.e. considering lettuce and ornamentals) was below the AOEL (28.1% of the AOEL, lettuce). No re-entry worker exposure is anticipated in potato. Bystander and resident exposure was below the

[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.

AOEL (maximum exposure 5.65% of the AOEL; child resident; potato). Depending on the type of greenhouse structure (lettuce and ornamental uses), there might be exposure to bystander and resident (EFSA, 2014b); however, exposure is expected to be much lower than representative uses on potato.

Considering the representative uses with '**Tolclofos-methyl 10 DP**' as a fungicide in **potato**, the estimated operator exposure was below the AOEL (30.9% of the AOEL) with the use of PPE during mixing and loading and application according to a field study. No re-entry worker exposure is anticipated according to the representative uses. Bystander and resident exposure was not calculated since no model is available for this formulation type. However, no risk for bystanders and resident exposure is expected based on calculations performed for the products Tolclofos-methyl WP 50 and SC 50.

Mammalian metabolism of tolclofos-methyl and available information including toxicity studies with the **metabolites** indicated that the following residues found in crops and/or livestock can be considered covered by the toxicological profile of the parent: DM-TM, DM-TM-COOH, DM-TMO, DM-TM-CH_2OH, TMO-COOH, TMO-CH_2OH and ph-COOH. Regarding metabolite TM-CH_2OH, the available information indicated that it is unlikely to be genotoxic; however, further data would be needed to conclude on general toxicity (data gap). The majority of experts considered that a similar conclusion as drawn on TM-CH_2OH can also be drawn for metabolite ph-CH_3 and its structurally similar compound ph-CH_2OH (i.e. data gap for general toxicity). However, some experts considered that there was some uncertainty regarding evidence of bone marrow exposure in the *in vivo* micronucleus (MN) test on ph-CH_3 and considered the lack of an *in vitro* MN test a data gap, in particular for aneugenicity since the available *in vivo* Comet assay could cover clastogenicity too. Overall, the experts supported a data gap for an *in vitro* MN test to reduce uncertainties regarding aneugenicity of ph-CH_3.

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (MRL) calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2017) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Tolclofos-methyl was discussed at the Pesticides Peer Review Expert Meeting 164 in September 2017.

Metabolism was investigated in root and tuber (potato) and in leafy vegetable (lettuce) crop groups. Radiolabelled tolclofos-methyl (^{14}C-Phenyl) was applied at the surface of seed potatoes in a newly available study at 1N and 5N rate and to lettuce seedlings at BBCH 14 as soil treatment at 1N and 5N rate and a preharvest interval (PHI) of 34 days. The studies analysed foliage, roots, parent and daughter tubers. While tolclofos-methyl is the major residue in the treated parent tuber (89–96% total radioactive residue (TRR)), it is not present in the daughter tubers in significant proportions and levels (< 10% TRR and < 0.002 mg/kg). Translocation through the plant to the foliage and the daughter tubers is limited. Metabolites DM-TM-CH_2OH and DM-TM-COOH were main metabolites in the foliage (15% TRR and 13% TRR, respectively) and daughter tubers (12% and 10% TRR, respectively), both accounting for less than 0.05 mg eq/kg in these tissues. In lettuce, besides parent (37–40% TRR, 0.08–0.31 mg/eq/kg), TM-CH_2OH-conjugate (14–15%; 0.03–0.11 mg eq/kg) and ph-CH_3-conjugate (20–23%; 0.05–0.15 mg eq/kg) were major. The aglycon of TM-CH_2OH-conjugate was found only mainly in foliage and in daughter tubers up to 2% and 0.258 mg eq/kg. The individual metabolism studies in lettuce and potato are acceptable and sufficient to address the metabolism in leafy crops (soil treatment) and root crops (tuber treatment), respectively, and leading to the conclusion that the similarity in metabolism under these conditions cannot be assumed. Hence, the **residue definitions for risk assessment** differ. For leafy crops (lettuce) and soil treatment, it includes tolclofos-methyl and the metabolites TM-CH_2OH conjugate and metabolite ph-CH_3-conjugate and is preliminary pending on toxicological information on the metabolites and/or field trials. For root and tuber (potato), the residue definition includes tolclofos-methyl and metabolite DM-TM-CH_2OH expressed as tolclofos-methyl. The **residue definitions for monitoring** include for both applications tolclofos-methyl only.

It is noted that the residue definition for risk assessment for root and tuber crops (potato) for tuber treatment has changed in comparison to the preliminary definition set during the first peer-review (EFSA, 2005) and MRL review (EFSA, 2014a) due to availability of additional data.

Since tolclofos-methyl and its soil metabolites, DM-TM and ph-CH_3, showed low soil persistence with DT_{90} values below 100 days, confined rotational crop studies are not required.

Under standard hydrolysis conditions, a conversion of tolclofos-methyl up to 87% to TM-DM (87% TRR) was observed. Therefore, tolclofos-methyl and TM-DM is included in the residue definition for processing. The residue definition for processing is only provisional and can be finalised only when the requested field trials in lettuce and potato are available (see data gap for field trials below) with actual residue levels of the metabolites in the commodities to be processed. If the metabolites exceed the trigger, further processing data on the nature of residues might be required too.

The GAP for lettuce in greenhouse as soil drench foresees two different PHI (28 days for summer and 56 days for winter lettuce). The presented residue trials (one study with four summer and four winter trials) have several drawbacks, e.g. PHI not according to critical GAP (cGAP), some studies are replicates and latest growth stage of application (BBCH 18–19) resulting in foliar application. The latter might be more critical in terms of residues; the acceptability of these trials to address the representative use in lettuce is questioned in view of the principle 'As Low As Reasonably Achievable' (ALARA) for MRL setting. Another cGAP-compliant study (application BBCH 14, PHI 28) with four trials in summer lettuce (head lettuce, closed variety) in the greenhouse is available. The residue data set indicates that summer lettuce is likely to lead to a more critical residue outcome; however, the GAP is different for summer and winter lettuce and the number of available data points is insufficient for a reliable statistical analysis. Therefore, eight GAP-conform residue trials in summer lettuce and four trials in winter lettuce analysing all compounds of the residue definition in the greenhouse are required to complete the data set for lettuce, bearing in mind the need to sufficiently address residues in open-leaf lettuce varieties if extrapolation is intended in the future (data gap). Sixteen GAP-compliant potato trials for the northern Europe (NEU) and eight GAP-conform trials for southern Europe (SEU) are available with results below or at the LOQ of 0.01 mg/kg (SEU) and up to 0.1 mg/kg (NEU) analysing only for parent. Although the NEU GAP is less critical than the SEU GAP in terms of application rate, it leads to higher residue levels. As all available trials are analysing only for tolclofos-methyl and not for the metabolite DM-TM-CH_2OH that was included in the residue definition for risk assessment, eight trials for NEU and eight trials for SEU according to the agreed residue definition for risk assessment are required (data gap).

Storage stability of tolclofos-methyl has been demonstrated in potato and lettuce up to 22 and 18 months, respectively, and covers the storage periods in the respective residue trials. Storage stability for the metabolites, TM-CH_2OH conjugate, ph-CH_3-conjugate, DM-TM-CH_2OH and TM-DM covered by the residue definitions are not presented (data gap). In case animal feeding studies are triggered, storage stability data for tolclofos-methyl and ph-COOH in animal matrices are required.

Metabolism studies conducted with animals dosed with ^{14}C-phenyl-labelled tolclofos-methyl at 10 mg/kg dry matter over 7 (goat) or 14 (poultry) consecutive days were presented. Most of the radioactivity was found in excreta (> 85% TRR) and less than 0.46% TRR of the applied dose in edible tissues (including egg and milk) of the animals. Tolclofos-methyl was the major residue in egg yolk, fat and skin (29–76% TRR/0.01–0.03 mg eq/kg) but was recovered only up to 4% TRR (0.01 mg eq/kg) and 12% TRR (0.03 mg eq/kg) in goat liver and kidney, respectively. The only major metabolite is ph-COOH occurring in goat liver and kidney (10–13% TRR/0.03 mg eq/kg) and all poultry tissues (except egg yolk) up to 18% (0.08 mg eq/kg). Its toxicological profile is covered by the parent's toxicological profile. The **provisional residue definition for risk assessment** was derived as tolclofos-methyl and ph-COOH, expressed as parent and **for monitoring** is confirmed as tolclofos-methyl only. Finalisation of the residue definitions in animals is pending on the recalculation of the dietary burden upon finalisation of the residue definition for risk assessment for feed items (full information is not available on the magnitude of metabolite residue DM-TM-CH_2OH in the feed item potato). Using the results for tolclofos-methyl from the current potato residue trial triggers feeding studies for ruminant, swine and poultry but not a fish metabolism study. However, neither data on the occurrence in potato nor the log Pow of the major metabolite, DM-TM-CH_2OH, are available (data gap) to conclude whether a fish metabolism study is required. Residues of parent were also found above the trigger value for feeding studies of 0.01 mg/kg in the metabolism study with goat (provisionally calculated as 1N). Upon final calculation of animal dietary burden, animal feeding studies might be requested.

Information on residue levels in pollen and in bee products for human consumption was not presented (data gap). Although applied as seed treatment, metabolism studies on potatoes have shown the potential to translocate in the plant.

Provisional consumer risk assessment was carried out using the EFSA PRIMo rev.2 model considering only exposure from potato given the uncertainties associated with residues in lettuce. Exposure from potato was calculated taking into account the ratio 1:4 between the parent and DM-TM-CH_2OH from the potato metabolism study. No risk was identified for the consumer from this use only; the highest chronic intake was estimated to be 3.1% of the ADI (FR toddler) and the highest acute intake was 55% of the ARfD (UK infant).

It is noted that in the framework of the peer review of tolclofos-methyl, an ARfD was established (see Section 2). Pending on the final decision on the expression of the risk assessment residue definition, the established MRLs under Article 12 of Regulation (EC) No 396/2005 and the overall consumer exposure and risk assessment might need to be revised.

4. Environmental fate and behaviour

Tolclofos-methyl was discussed at the Pesticides Peer Review Meeting 163 in September 2017.

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil under dark aerobic conditions, tolclofos-methyl exhibited low to moderate persistence yielding two main metabolites, DM-TM (max. 13.3% applied radioactivity (AR), very low to low persistence) and ph-CH_3 (max. 8% AR, very low to moderate persistence). Non-extractable residues were formed at a maximum of 63% AR. CO_2 was formed at a maximum of 44.5% AR at study end. At anaerobic conditions, tolclofos-methyl exhibited moderate to medium persistence (DT_{50} = 35.4–78.3 days). Photolysis is not envisaged to significantly contribute to the overall degradation of tolclofos-methyl in soil under environmental conditions.

Batch adsorption/desorption studies indicated that tolclofos-methyl is expected to be immobile to low mobile in soil, whereas metabolites DM-TM and ph-CH_3 are expected to exhibit very high mobility in soil.

Tolclofos-methyl is not prone to hydrolysis under environmental conditions. Aqueous photolysis could slightly enhance degradation in aquatic systems. Tolclofos-methyl was not readily degraded in a ready biodegradability test.

Degradation within the water/sediment systems proceeded via cleavage of the P-O methyl and P-O aryl linkages to form DM-TM and ph-CH_3. In these experiments, tolclofos-methyl declined rapidly in the water phase mainly due to partitioning to sediment. Residues of tolclofos-methyl within sediment rose up to 72.9% AR after 3 days. In the total system, tolclofos-methyl exhibited moderate to medium persistence. Metabolite DM-TM was the sole metabolite detected in significant quantities in both water and sediment. No reliable half-life was determined for this metabolite. Metabolite ph-CH_3 was detected at significant levels only in the sediment (6% AR after 30 days). Unextractable residues in sediment occurred at maxima of 26–35% AR. Carbon dioxide increased throughout the study up to 36–53% AR. Tolclofos-methyl was detected as volatiles up to 12–22% AR.

The necessary surface water and sediment exposure assessments Predicted environmental concentrations (PEC) calculations were carried out for the metabolites DM-TM and ph-CH_3 using the FOCUS (FOCUS, 2001) step 3. For the active substance tolclofos-methyl, appropriate step 3 (FOCUS, 2001) calculations have been performed including inputs from volatilisation/deposition, using EVA 3 (rev 2e) following FOCUS AIR (FOCUS 2008)[4] and the EFSA opinion on emissions from greenhouses (EFSA, 2014b) for the representative uses in protected crops (lettuce and ornamentals).

The potential for groundwater contamination was assessed by calculation of 20 years 80th percentile leachate concentration at 1 m depths using FOCUS GW models PEARL 4.4.4 and PELMO 5.5.3 with the relevant scenarios for the representative uses. On the basis of these simulations, neither tolclofos-methyl nor DM-TM or ph-CH_3 is expected to exceed the parametric drinking water limit of 0.1 μg/L in groundwater when used according to GAPs for the representative uses proposed.

The applicant provided appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater (i.e. TMO-COOH and DM-TMO), when surface water or groundwater is abstracted for drinking water. The conclusion of this consideration was that neither tolclofos-methyl nor any of its degradation products that trigger assessment (DM-TM and ph-CH_3) would be expected to undergo any substantial transformation yielding substances of a higher potential health concern than the ones assessed for these substances (see toxicological profile of metabolites in Section 2).

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

The compound may partition from soil, moist surfaces and water to air. This was also confirmed in the water/sediment study. However, a calculation according to the Atkinson method shows that the degradation half-life in air is 2.1 h not giving rise to long range transport concerns. For short-term transport, volatilisation and deposition have been adequately considered.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

During the written procedure on additional information, a Member State observed that one of the representative products initially presented as dispersible powder was actually a DP. For this kind of formulation, the exposure route of dust spray should have been considered. Consequently, EFSA identified a data gap to address the route of exposure by dust drift for the DP formulation.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). According to Regulation (EU) No. 283/2013, data should be provided regarding the acute and chronic toxicity to honeybees and data to address the development of honeybee brood and larvae. As the European Commission (2002a) does not provide a risk assessment scheme which is able to use the chronic toxicity data for adult honeybees and the honeybee brood, when performing the risk assessment according to European Commission (2002a), the risk to adult honeybees from chronic toxicity and the risk to bee brood could not be finalised due to the lack of a risk assessment scheme. Therefore, the EFSA (2013) was used for risk assessment in order to reach a conclusion for the representative uses.

No conclusion on whether the (eco)toxicity studies were representative of the proposed technical specification for the active substance and associated impurities could be drawn.

It is noted that the representative uses included uses in greenhouse on lettuce and ornamentals. During the peer review, it was clarified that these uses cover exclusively permanent structures; therefore, a full risk assessment for birds and mammals, honeybees, non-target arthropods and non-target terrestrial plants was not considered necessary for these uses. Instead, due to the concerns on the potential volatilisation of tolclofos-methyl, risk assessments for soil and aquatic organisms, honeybees (exposure via surface water) were considered necessary (see Section 4). In addition, a risk assessment for exposure via secondary poisoning for birds and mammals was triggered.

Toxicity studies were not available for the representative formulation 'Tolclofos-methyl 10DP', a bridging statement to demonstrate the comparability between the 50 SC, 50 WP and DP formulations was provided by the applicant which was considered acceptable. Further consideration on this point might be needed at Member State level. It is nevertheless noted that pending on the data gap to address the route of exposure by dust drift for the DP formulation, a risk assessment for this representative use should be performed (see Section 4).

The end points to be used in the long-term risk assessment for **birds and mammals** and the risk assessment for the potatoes' tuber dressing uses were discussed at the Pesticides Peer Review meeting 165. A first-tier risk assessment was performed by considering the 'large granivorous' birds and 'small omnivorous' mammals scenarios as a surrogate. By using this approach, a low acute risk to birds and mammals was concluded for all the representative uses on potatoes, whilst a high long-term risk could not be excluded for birds for the use on potatoes at the highest application rate and for mammals for all potatoes' uses. The experts considered the secondary poisoning as a more relevant route of exposure for birds than the exposure via treated tubers. In the case of the mammals, the direct exposure to treated tubers was considered relevant and the wild boar and the badger were considered as appropriate focal species. Considering the above, a high long-term risk to mammals for all uses on potatoes was concluded (data gap). A low risk via secondary poisoning and via consumption of contaminated water for birds and mammals for tolclofos-methyl was concluded for all the representative uses. A low risk to birds and mammals was concluded for tolclofos-methyl metabolites.

A low acute and chronic risk to **aquatic organisms** for tolclofos-methyl were concluded for the representative uses on potatoes and lettuce, whilst a high acute and chronic risk was identified for 2/3 FOCUS scenarios for the use on ornamentals (data gap). It is noted that the available acute data on aquatic invertebrates indicated a significantly higher sensitivity of *Americamysis bahia* with respect to *Daphnia magna.* This issue was discussed at the Pesticide Peer Review meeting 165 and the experts agreed to set a data gap for a chronic study on *A. bahia* (data gap). It is, however, noted that, considering the high margin of safety, this study is not considered as necessary to finalise the risk

assessment for the use on potatoes whilst uncertainties remain for the uses on lettuce and ornamentals. A low acute and chronic risk to aquatic organisms was concluded for the pertinent surface water metabolites DM-TM and ph-CH_3.

The risk assessment for honey**bees** was discussed at the Pesticides Peer Review meeting 165. By performing a risk assessment in line with EFSA (2013), a low acute (oral and contact) risk to bees was concluded for the uses on potatoes. During the meeting, the weeds and succeeding crop scenarios were considered not relevant; however, from the available information in the residues section, translocation in the plant cannot be excluded. By considering these scenarios, a high chronic risk to honeybees was concluded for the weeds and succeeding crop scenarios at the highest application rate on potatoes and for the weeds scenario only for the lowest application rates for the use at planting. For the use before planting, a high chronic risk to bees was concluded for the succeeding crop scenario for all the application rates (data gap). For all the other scenarios, the risk was concluded to be low provided that an application with deflector is considered. In the available study on larvae, statistically significant effects on the larvae survival were observed at all the concentration tested; therefore, an end point could not be established (data gap). No data were available for sublethal effect assessment (i.e. hypopharyngeal glands (HPG)); therefore, a data gap was identified. Due to the relatively high predicted exposure concentrations in surface water for the greenhouse uses, a risk assessment via exposure to contaminated water was performed also for these uses, for exposure via surface water only. A low risk to bees via exposure to contaminated water was concluded for all the representative uses. No data were provided for the assessment of accumulative effects. No data were available on bumblebees and solitary bees. Regarding the risk to bees for metabolites formed in pollen and nectar, it is noted that a risk assessment was provided by the applicant for the plant metabolites DM-TM-COOH and DM-TM-CH_2OH; however, only an evaluation of the risk assessment was provided in the RAR whilst detailed calculations were not provided. Therefore, a peer review of the provided assessment was not possible. In addition, it is noted that also metabolites TM-CH_2OH-conjugate and ph-CH_3-conjugate are major plant metabolites and should be further considered (data gap).

The risk assessment for **non-target arthropods** was discussed at the Pesticides Peer Review meeting 165. The standard approach for the non-target arthropods risk assessment was not considered appropriate for assessing the risk of the representative uses of tolclofos-methyl. Considering the main exposure route, the risk assessment for non-target arthropods could be considered covered by the available soil risk assessment; therefore, a low risk could be concluded. The additional data available on soil arthropods (*Poecilius cupreus* L., *Aleochara bilineata*) further support this conclusion.

A low risk to **earthworms** and other **soil macro-organisms** and **microorganisms** for tolclofos-methyl and its soil metabolites was concluded for all the representative uses.

Due to the low potential for exposure, a low risk to **non-target terrestrial plants** could be concluded for all the representative uses. Low risk to **biological methods of sewage treatment** was concluded for all the representative uses assessed.

With regard to the literature review, a literature search was provided and fully evaluated by the RMS. However, it is noted that a study was excluded from the literature review since good laboratory practice (GLP) studies were available in the dossier. This is not considered a sufficient reason to exclude a literature paper and a formal data gap is, therefore, identified.

The potential endocrine disruption of tolclofos-methyl was discussed at the Pesticides Peer Review meeting 165. Overall, the expert concluded that further data are not needed, see also Section 2. However, a firm conclusion for birds and fish or other non-target vertebrates cannot be drawn.

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
Tolclofos-methyl	Low to moderate (DT_{50} = 2.1–31.0 days)	Low risk
DM-TM	Very low to low (DT_{50} = 0.08–3.6 days)	Low risk
ph-CH_3	Very low to moderate (DT_{50} = 0.04–13.8 days)	Low risk

DT_{50}: period required for 50% dissipation.

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
Tolclofos-methyl	Immobile to low mobile	FOCUS GW: No	Yes	Yes
DM-TM	Very high mobility	FOCUS GW: No	No data	Assessment not triggered
ph-CH_3	Very high mobility	FOCUS GW: No	No data	Assessment not triggered

FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use; GW: ground water.
(a): FOCUS scenarios or a relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Tolclofos-methyl	High risk for the use on ornamentals for 2/3 FOCUS scenarios, low risk for the uses on potatoes and lettuce
DM-TM	Low risk
ph-CH_3	Low risk

Table 4: Air

Compound (name and/or code)	Toxicology
Tolclofos-methyl	Low acute inhalation toxicity to rats (Rat LC_{50} inhalation > 2.07 mg/L (nose only)).

LC_{50}: lethal concentration, median.

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

- Industrial scale 5 batch data for one of the manufacturing plants (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- The final report of the shelf-life study for 'Tolclofos-methyl 50 WP' (relevant for 'Tolclofos-methyl 50 WP'; submission date proposed by the applicant: unknown; see Section 1).
- Data demonstrating that matrix effects are not significant in soil for the monitoring method in soil (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 1).
- The residue definition for body fluids should be reconsidered taking into account the extensive metabolism in mammals (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 1 and 2).
- Toxicological relevance of impurity 1 and its maximum content, in particular genotoxicity and neurotoxicity (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further phototoxicity assessment on tolclofos-methyl at UVB ranges (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Developmental neurotoxicity study on tolclofos-methyl in mice (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further assessment of the toxicological profile of metabolite TM-CH_2OH to allow comparison with the parent or setting specific reference values (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further assessment of the aneugenic potential of metabolite ph-CH_3, i.e. *in vitro* MN test (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Further assessment of the toxicological profile of metabolite ph-CH_3 to allow comparison with the parent or setting specific reference values (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).
- Log POW of the metabolite DM-TM-CH_2OH in order to conclude on the need for a fish metabolism study (relevant for the uses in potatoes; submission date proposed by the applicant: unknown; see Sections 1 and 3).
- Storage stability studies for the metabolites included in the residue definitions (relevant for the uses in potatoes and lettuce; submission date proposed by the applicant: unknown; see Section 3).
- Eight cGAP-conform field trials covering all compounds of the residue definition for risk assessment for potato for each of the zone NEU and SEU (relevant for the uses in potatoes; submission date proposed by the applicant: unknown; see Section 3).
- Eight cGAP-conform field trials covering all compounds of the residue definition for risk assessment for summer lettuce and four trials in winter lettuce are required, bearing in mind the need to sufficiently address residues in open-leaf lettuce varieties if extrapolation is intended in the future. (Relevant for the use in lettuce; submission date proposed by the applicant: unknown; see Section 3).
- Data or information on residue levels in pollen and in bee products for human consumption (relevant for the uses in potatoes; submission date proposed by the applicant: unknown; see Section 3).
- Applicant to address the route of exposure by dust drift for the DP formulation. Further consideration on the risk assessment is also needed (relevant for the use in potatoes with a DP formulation; no submission date proposed by the applicant; see Sections 4 and 5).
- Further data to address the long-term risk to mammals for tolclofos-methyl (relevant for the uses on potatoes; submission date proposed by the applicant: unknown; see Section 5).

- Further data to address the acute and chronic risk to aquatic organisms for tolclofos-methyl, (relevant for the use on ornamentals; submission date proposed by the applicant: unknown; see Section 5).
- A chronic study for the active substance with the most sensitive species *A. bahia* (relevant for the uses on ornamentals and lettuce; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the chronic risk to honeybees (relevant for the uses on potatoes; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the effects on honeybee larvae and the sublethal effects on honeybees (i.e. HPG) of tolclofos-methyl (relevant for the all the representative; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address of the risk to bees from tolclofos-methyl metabolites (relevant for the uses on potatoes; submission date proposed by the applicant: unknown; see Section 5).
- Further justification is needed in support of the exclusion of the relevant articles from the literature search (relevant for the all the representative uses; submission date proposed by the applicant: unknown; see Section 5).

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

8.1. Particular conditions proposed for the representative uses evaluated

Mitigation measures up to 10 meter buffer zone is needed to conclude low risk to aquatic organisms for the representative use in ornamental crops in protected structure to mitigate the risk to aquatic organisms, for scenario D4. This mitigation measure is not sufficient to mitigate the risk identified for scenarios D3 and D6 (see Section 5).

- Tolclofos-methyl 50 WP: operator should use personal PPE (see Section 2 and list of end points) to reduce exposure below the AOEL.
- Tolclofos-methyl SC 50: operator should use PPE (See Section 2 and list of endpoints) to reduce exposure below the AOEL for potato before planting.
- Tolclofos-methyl 10 DP: operator should use PPE (see Section 2 and list of endpoints) to reduce exposure below the AOEL.

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[5] 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 consumer risk assessment could not be finalised considering the outstanding data to finalise the residue definitions for risk assessment in primary crops and processed commodities and the required GAP-compliant residue trials on lettuce and potato (see Section 3).
2) The route of exposure by dust drift for the DP formulation and the corresponding risk assessment valid for the exposure and effects needs to be finalised (see Sections 4 and 5).

[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.

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 the 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.

3) No conclusion on whether the (eco)toxicity studies were representative of the proposed technical specification for the active substance and associated impurities could be drawn (see Sections 2 and 5).

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.)

All columns are grey, as it was not possible to conclude whether the technical material specification proposed was comparable to the material used in the testing that was used to derive the (eco)toxicological reference values.

Table 5: Overview of concerns

Representative use		Potatoes 1.125 kg a.s./ha	Potatoes 0.675 kg a.s./ha	Potatoes 0.5625 kg a.s./ha	Lettuce	Ornamentals (flower bulbs, rhizomes)
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	X[1]	X[1]	X[1]	X[1]	
Risk to wild non-target terrestrial vertebrates	Risk identified	X	X	X		
	Assessment not finalised					
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X	X	X		
	Assessment not finalised					
Risk to aquatic organisms	Risk identified					2/3 FOCUS scenarios
	Assessment not finalised					
Groundwater exposure to active substance	Legal parametric value breached					
	Assessment not finalised					

Representative use		Potatoes 1.125 kg a.s./ha	Potatoes 0.675 kg a.s./ha	Potatoes 0.5625 kg a.s./ha	Lettuce	Ornamentals (flower bulbs, rhizomes)
Groundwater exposure to metabolites	Legal parametric value breached[(a)]					
	Parametric value of 10 μg/L[(b)] breached					
	Assessment not finalised					

a.s.: active substance; FOCUS: Forum for the Co-ordination of Pesticide Fate Models and their Use.
Columns are grey if no safe use can be identified. 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

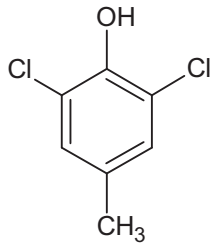
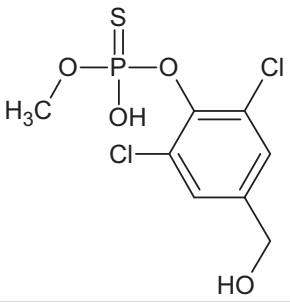
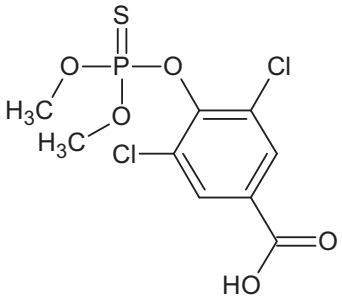
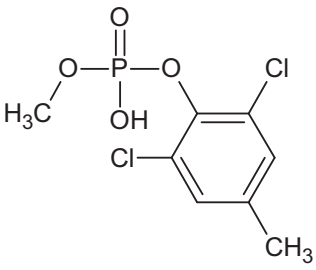
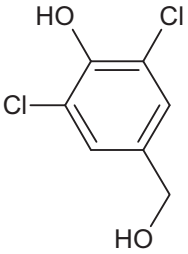
a.s.	active substance
AAOEL	acute acceptable operator exposure level
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CLP	classification, labelling and packaging
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EEC	European Economic Community
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FPD	Flame photometric detector
GAP	Good Agricultural Practice

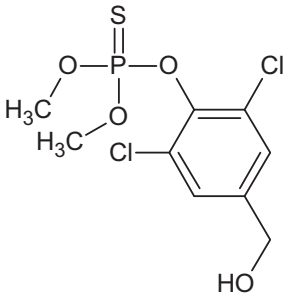
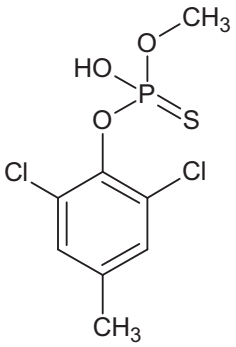
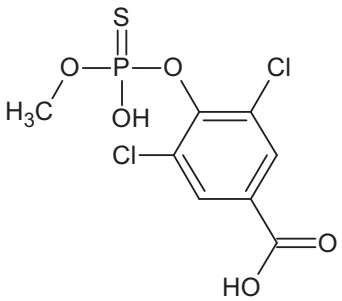
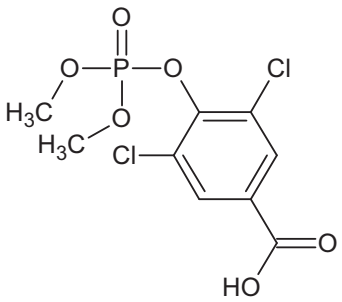
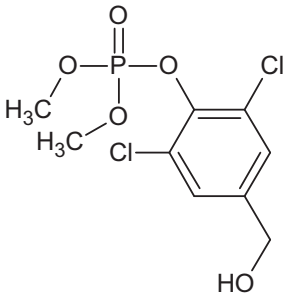
GC	gas chromatography
GLP	good laboratory practice
HPG	hypopharyngeal glands
HPLC–MS/MS	high-pressure liquid chromatography with tandem mass spectrometry
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LC_{50}	lethal concentration, median
LOAEL	lowest observable adverse effect level
LOQ	limit of quantification
MN	micronucleus
MRL	maximum residue level
MS	mass spectrometry
NEU	northern Europe
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure–activity relationship
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAR	Renewal Assessment Report
SC	suspension concentrate
SEU	southern Europe
TRR	total radioactive residue
UF	uncertainty factor
UVB	ultraviolet B
WHO	World Health Organization
WP	wettable powder

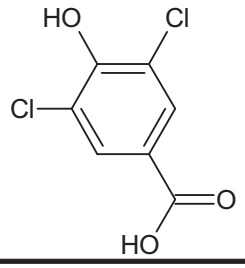
Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5130

Appendix B – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation	Structural formula
ph-CH_3	2,6-dichloro-4-methylphenol Clc1cc(C)cc(Cl)c1O	
DM-TM–CH_2OH	*O*-methyl *O*-hydrogen O-[2,6-dichloro-4-(hydroxymethyl) phenyl] phosphorothioate Clc1cc(cc(Cl)c1OP(O)(=S)OC)CO	
TM-COOH	*O,O-dimethyl O*-(2,6-dichloro-4-carboxyphenyl) phosphorothioate Clc1cc(cc(Cl)c1OP(=S)(OC)OC)C(=O)O	
DM-TMO	*O*-methyl *O*-hydrogen *O*-(2,6-dichloro-4-methylphenyl) phosphate Clc1cc(C)cc(Cl)c1OP(=O)(O)OC	
ph-CH_2OH	3,5-dichloro-4-hydroxybenzyl alcohol Clc1cc(cc(Cl)c1O)CO	

Code/trivial name[a]	Chemical name/SMILES notation	Structural formula
TM–CH_2OH	*O*,O-dimethyl *O*-[2,6-dichloro-4-(hydroxymethyl)phenyl] phosphorothioate Clc1cc(cc(Cl)c1OP(=S)(OC)OC)CO	
DM-TM	*O*-methyl *O*-hydrogen *O*-(2,6-dichloro-4-methylphenyl) phosphorothioate Clc1cc(C)cc(Cl)c1OP(O)(=S)OC	
DM-TM-COOH	*O*-methyl *O*-hydrogen *O*-(2,6-dichloro-4-carboxyphenyl) phosphorothioate Clc1cc(cc(Cl)c1OP(O)(=S)OC)C(=O)O	
TMO-COOH	*O*,*O*-dimethyl *O*-(2,6-dichloro-4-carboxyphenyl) phosphate Clc1cc(cc(Cl)c1OP(=O)(OC)OC)C(=O)O	
TMO-CH_2OH	*O*,*O*-dimethyl *O*-2,6-dichloro-4-(hydroxymethyl) phenylphosphate Clc1cc(cc(Cl)c1OP(=O)(OC)OC)CO	

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
ph-COOH	3,5-dichloro-4-hydroxybenzoic acid Clc1cc(cc(Cl)c1O)C(=O)O	

SMILES: simplified molecular-input line-entry system.
(a): The compound name in bold is the name used in the conclusion.