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Modification of the existing maximum residue level for tolclofos-methyl in potatoes

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Sumitomo Chemical Agro Europe S.A.S submitted a request to the competent national authority of Finland to modify the existing maximum residue level (MRL) for the active substance tolclofos-methyl in potatoes. The data submitted in support of the request were found to be sufficient to derive an MRL proposal of 0.2 mg/kg. An amendment of the existing MRLs for food of animal origin was not found necessary. Adequate analytical enforcement methods are available to control the residues of tolclofos-methyl in potatoes. Based on the risk assessment results, EFSA concluded that the proposed use of tolclofos-methyl on potatoes will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a consumer health risk.

Keywords: tolclofos-methyl, potatoes, pesticide, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Finland received an application from Sumitomo Chemical Agro Europe S.A.S. to modify the existing maximum residue level (MRL) for the active substance tolclofos-methyl in potatoes. The MRL for potatoes was recently lowered from 0.2 mg/kg to 0.01 mg/kg by Regulation (EU) No 2016/156. To accommodate for the intended use of tolclofos-methyl in potatoes, Finland proposed to raise the existing MRL again to 0.2 mg/kg. Finland drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 February 2016.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on tolclofos-methyl, the conclusion on the peer review of the pesticide risk assessment of the active substance tolclofos-methyl as well as the conclusion from the previous EFSA opinion on tolclofos-methyl regarding the review of the existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005. Tolclofos-methyl is an active substance currently assessed for the renewal of the approval (AIR III).

The metabolism of tolclofos-methyl in primary crops has been investigated in root and leafy crop groups following soil/foliar applications. From these studies, the peer review established the residue definition for enforcement and risk assessment as tolclofos-methyl parent compound. Additional data provided during the MRL review allowed EFSA to derive a tentative residue definition for risk assessment as sum of tolclofos-methyl and its sugar conjugates Ph-CH_3 and TM-CH_2OH, expressed as tolclofos-methyl. The residue definition was proposed as tentative due to the lack of data concerning the toxicological profile of the conjugated sugars. From the metabolism studies, conversion factors were derived to recalculate residue concentrations of the parent tolclofos-methyl to the risk assessment residue definition. In the case of potatoes, the conversion factor is 1 since these metabolites were found to be of low relevance. For the use on potatoes, EFSA concludes that the metabolism of tolclofos-methyl in primary crops has been sufficiently addressed and that the residue definitions derived previously are applicable.

Adequate analytical enforcement methods are available to monitor the residues of tolclofos-methyl in potatoes at the validated limit of quantification (LOQ) of 0.01 mg/kg.

EFSA concludes that the residue trials submitted in the framework of the MRL review are sufficient to derive a MRL proposal of 0.2 mg/kg for potatoes.

One study investigating the nature of tolclofos-methyl residues under standard hydrolysis conditions has been assessed in the framework of this application; this study showed the active substance to be progressively degraded to *O*-(2,6-dichloro-4-methylphenyl) *O*-methyl hydrogen phosphorothioate (DM-TM) under standard processing conditions. Information on the toxicological properties of the metabolites suggests that the toxicological endpoints of the parent compound can cover the toxicity of the metabolite; for processed products, the residue definition is proposed as sum of tolclofos-methyl and DM-TM, expressed as tolclofos-methyl.

Specific studies investigating the magnitude of tolclofos-methyl residues in processed commodities are not required, since the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

The occurrence of tolclofos-methyl residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP).

As potatoes and their by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. In the framework of this MRL application, the applicant provided metabolism studies lactating goat and laying hens investigating the nature of tolclofos-methyl residues in livestock. The metabolite Ph-COOH was detected in several animal matrices accounting for more than 10% total radioactive residue (TRR); this metabolite is therefore a potential candidate to be included in the residue definition of animal commodities for risk assessment purposes. Since specific studies on the toxicological properties of the metabolite Ph-COOH are not available, tentative residue definitions are proposed for food of animal origin, i.e. tolclofos-methyl for enforcement and sum as tolclofos-methyl and Ph-COOH, expressed as tolclofos-methyl with a tentative character.

Based on the estimated dietary burden and the results of metabolism studies in animals, it is not expected that residues exceeding 0.01 mg/kg occur in animal matrices.

The toxicological profile of tolclofos-methyl was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.064 mg/kg body weight (bw) per day. No acute reference dose (ARfD) was deemed necessary. The toxicological properties of the metabolites and degradation products of tolclofos-methyl should be further discussed in the framework of the renewal of the approval process which is currently in progress, in particular for the metabolites Ph-CH_3, TM-CH_2OH and Ph-COOH and the degradation product DM-TM in order to confirm the proposed residue definitions.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) using the current residue definition tolclofos-methyl. A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be less than 2% of the ADI (Dutch diet, children). The contribution of residues in potatoes accounted for less than 1% of the ADI. An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for tolclofos-methyl.

EFSA concludes that the intended use of tolclofos-methyl on potatoes will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a health risk to consumers.

The process of renewal of the approval of tolclofos-methyl in accordance with Regulation (EC) No 1107/2009 is currently ongoing; thus, the conclusions derived in this reasoned opinion might need to be reconsidered in the light of the outcome of the conclusions of the renewal process.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Tolclofos-methyl[(F)]				
0211000	Potatoes	0.01*	0.2	The intended use in potatoes is sufficiently supported by data. Based on the NEU residue data, a MRL of 0.2 mg/kg is derived No consumer concern was identified for the intended use
1010000 1020000 1030000	Animal products – tissues, milk and eggs	0.01*	No change	Residues are unlikely to occur in animal matrices at levels above the LOQ (0.01 mg/kg). Therefore, there is no need to amend the existing MRLs

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, a number of data gaps have been identified. With this application, data have been submitted which sufficiently addressed the following data gaps:

- animal metabolism studies investigating the nature of the tolclofos-methyl residues in commodities of animal origin (ruminants and poultry);
- validation of the analytical method for enforcement of the residues in food of animal origin;
- method validation for the determination of the residues in several matrices of plant origin;
- standard hydrolysis study investigating the nature of the tolclofos-methyl residues in processed commodities.

The data gap concerning further investigation on the toxicological profile of the metabolites Ph-CH_3 and TM-CH_2OH that occur mainly in leafy crops is still open.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at the European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[2], repealed by Regulation (EC) No 1107/2009[3], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

Finland, hereafter referred to as the evaluating Member State (EMS), received an application from the company Sumitomo Chemical Agro Europe S.A.S.[4] to modify the existing MRL for the active substance tolclofos-methyl in potatoes which was recently lowered to the limit of quantification (LOQ) of 0.01 mg/kg. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 5 February 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00126 and the following subject:

Tolclofos-methyl – Modification of existing MRLs in potato

Finland proposed to raise the MRL of tolclofos-methyl in potatoes from the LOQ of 0.01 mg/kg to the value of 0.2 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, provide a reasoned opinion on the risks to the consumer associated with the application. The evaluation report submitted by the EMS (Finland, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

The active substance and its use pattern

The detailed description of the intended use of tolclofos-methyl in potatoes in Northern and Southern EU Member States are reported in Appendix A. To derive the MRL proposals, EFSA assessed the most critical GAPs (cGAPs) for the NEU and SEU zone (i.e. seed treatment of tuber with 0.25 kg a.s./tonne, corresponding to 1.125 kg a.s./ha (SEU) and 0.2 kg a.s./tonne, corresponding to 0.9 kg a.s./ha (NEU)).

Tolclofos-methyl is the ISO common name for *O*-2,6-dichloro-*p*-tolyl *O,O*-dimethyl phosphorothioate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B.

Tolclofos-methyl was evaluated in the framework of Directive 91/414/EEC with Sweden designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2006/39/EC[5], which entered into force on 1 February 2007 for use as a fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011[6], tolclofos-methyl is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were tuber (seed) treatment for potatoes and soil application for lettuce in order to control *Rhizoctonia* infections. The draft assessment report (DAR)

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

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 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.

[4] Sumitomo Chemical Agro Europe S.A.S, Parc d'Affaires de Crécy, 10A rue de la Voie Lactée 69370, SAINT DIDIER AU MONT D'OR, France.

[5] Commission Directive 2006/39/EC of 12 April 2006 amending Council Directive 91/414/EEC to include clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole as active substances, OJ L 104, 13.4.2006, p. 30–35.

[6] Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

has been peer reviewed by EFSA (EFSA, 2005). Currently, the process of renewal of the approval is ongoing; the assessment report prepared by RMS for this process has been submitted to EFSA on 11 November 2016.

The EU MRLs for tolclofos-methyl are established in Annex II of Regulation (EC) No 396/2005. EFSA has completed the MRL review of the existing maximum residue levels (MRLs) according to Article 12 of Regulation (EC) No 396/2005. The use of tolclofos-methyl in potatoes has been evaluated. A risk management decision was taken to lower the MRL from 0.2 mg/kg to the LOQ of 0.01 mg/kg.[7]

For the current application, EFSA has based its assessment on the evaluation report submitted by the EMS (Finland, 2016), the DAR (and its final addendum) prepared under Directive 91/414/EEC (Sweden, 2004, 2005), the Commission review report on tolclofos-methyl (European Commission, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance tolclofos-methyl (EFSA, 2005), as well as the conclusion from a previous EFSA opinion on tolclofos-methyl (EFSA, 2014) where the existing uses were assessed. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011, 2013).

The process of renewal of the approval of tolclofos-methyl in accordance with Regulation (EC) No 1107/2009 is currently ongoing; thus, the conclusions derived in this reasoned opinion might need to be reconsidered in the light of the outcome of the conclusions of the renewal process.

1. Method of analysis

1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of tolclofos-methyl residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2005) and during the review of the existing MRLs (EFSA, 2014).

The multiresidue QuEChERS method described in the European Standard EN 15662:2008 using liquid chromatography with tandem mass spectrometry (LC–MS/MS) detection is applicable to quantify tolclofos-methyl residues in high water, high acid, high oil content commodities and in dry/protein and dry/starch matrices at the LOQ of 0.01 mg/kg (CEN, 2008; EURL, 2014; Finland, 2016). Methods based on gas chromatography with mass spectrometry (GC–MS) detection can be used to analyse residues of tolclofos-methyl at LOQ of 0.02 mg/kg (EFSA, 2014). Sufficient validation and independent laboratory validation (ILV) data were submitted under this application to conclude that the analytical method has been adequately validated to enforce the tolclofos-methyl residues (Finland, 2016).

As potatoes belong to high water content commodities group, EFSA concluded that sufficiently validated analytical methods are available for enforcing the proposed MRL for tolclofos-methyl in potatoes.

1.2. Methods for enforcement of residues in food of animal origin

The analytical methods for the determination of tolclofos-methyl residues in commodities of animal origin were evaluated during the peer review under Directive 91/414/EEC (EFSA, 2005) and during the review of existing MRLs (EFSA, 2014). An analytical method using LC–MS/MS was proposed for the determination of tolclofos-methyl in animal matrices (milk, meat, liver, egg and fat) with an LOQ of 0.01 mg/kg. However, a data gap was identified concerning the ILV and the confirmatory method.

Under the current application, ILV data as well as one study investigating the extraction efficiency of tolclofos-methyl from animal matrices have been submitted (Finland, 2016). Based on the data provided, EFSA concluded that the method suggested for the enforcement of tolclofos-methyl MRLs in animal tissues is sufficiently validated; the LOQ of the method is 0.01 mg/kg.

[7] Commission Regulation (EU) 2016/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products.

[8] 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.

2. Mammalian toxicology

2.1. Toxicological profile of parent compound

The toxicological profile of the active substance tolclofos-methyl was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2005). The data were sufficient to derive toxicological reference values of tolclofos-methyl compiled in Table 1.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Uncertainty factor
Tolclofos-methyl					
ADI	EFSA	2005	0.064 mg/kg bw per day	2-year mouse study	100
ARfD	EFSA	2005	Not necessary		

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

The setting of the acceptable daily intake (ADI) and acute reference dose (ARfD) might be reconsidered in the framework of the renewal of the approval of tolclofos-methyl which is currently on-going.

2.2. Toxicological profile of metabolites and degradation products

During the review of existing MRLs, it was highlighted that further data investigating the toxicological profiles of the sugar conjugate of the metabolites Ph-CH_3 and TM-CH_2OH are required (EFSA, 2014). Since new data regarding these two metabolites were not submitted under the current application, the data gap is still open. It is noted that these metabolites were identified as relevant in the metabolism study in leafy crops and occurred in very low levels (< 0.002 mg eq/kg) in potatoes.

In standard hydrolysis studies, tolclofos-methyl was shown to degrade to DM-TM (see Section 3.1.1.3); in the metabolism studies in lactating goat and laying hens, one metabolite was identified occurring in concentrations exceeding 10% of total radioactive residue (TRR), i.e. Ph-COOH (see Section 3.2.2). Both compounds should be considered for the setting of the residue definition for processed products and animal commodities.

Both metabolites were detected in the excreta portion in a metabolism study in rat previously peer-reviewed by EFSA (EFSA, 2005). DM-TM accounted for up to 8.4% in urine after repeated low administration and up to 27.6% after single high dose level administration; Ph-COOH was found in urine of rats (up to 9.9% after repeated low dose level administration and up to 26.1% after single high dose level administration) (Sweden, 2005). Based on these results, DM-TM and Ph-COOH can be considered covered by the toxicological endpoints of tolclofos-methyl parent compound. However, no specific toxicity data on the metabolites are available.

The toxicological properties of the metabolites and degradation products of tolclofos-methyl should be further discussed in the framework of the renewal of the approval of tolclofos-methyl which is currently in progress.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of tolclofos-methyl in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (EFSA, 2005) and during the MRL review (EFSA, 2014) in the fruit, root/tuber and leafy crop groups.

An overview of all the key parameters of the available metabolism studies is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comments
Root	Potato	Seed treatment: 1 × 125 mg/kg	27, 129 DAT_1	Source: EFSA, 2005
		Seed treatment: 1 × 250 mg/kg Seed treatment: 1 × 1250 mg/kg	118 DAT_1	Source: EFSA, 2014
Leafy	Lettuce	Foliar: 1 × 2 kg/ha Foliar: 1 × 10 kg/ha	34 DAT_1	Source: EFSA, 2005

DAT: Day(s) after treatment.

The peer review suggested parent tolclofos-methyl as definition for enforcement and risk assessment (EFSA, 2005). Additional data were presented in the framework of the MRL review and the residue definition for enforcement was confirmed as tolclofos-methyl parent compound (EFSA, 2014). For risk assessment, EFSA proposed to include additional metabolites in the residue definition (i.e. sum of tolclofos-methyl, sugar conjugate of Ph–CH_3 and sugar conjugate of TM-CH_2-OH, expressed as tolclofos-methyl). However, due to the lack of data on the toxicological properties of the sugar conjugates of Ph–CH_3 and TM-CH_2-OH, the residue definition for risk assessment was considered as tentative (EFSA, 2014). It is noted that these two metabolites included in the residue definition (sugar conjugate of Ph–CH_3 and sugar conjugate of TM-CH_2-OH) were observed mainly in the lettuce metabolism study and not in potatoes. Overall, the transfer of residues from the treated tuber to the potato daughters is considered very low; thus, the occurrence of these metabolites in the consumable parts of the crop is not expected.

The current enforcement residue definition for plant commodities in the MRL regulation covers only parent tolclofos-methyl. Considering that in the potato metabolism study the metabolites included in the risk assessment residue definition were not identified, a conversion factor for enforcement to risk assessment (CF) of 1 was derived which applies exclusively for the seed treatment of potatoes (EFSA, 2014).

For the uses on potatoes, EFSA concludes that the metabolism of tolclofos-methyl is sufficiently addressed and the residue definitions for enforcement and risk assessment are applicable.

3.1.1.2. Magnitude of residues

The most critical NEU and SEU GAPs for potatoes and the supporting residue trials were already assessed and validated during the MRL review (EFSA, 2014). Therefore, no additional residue trials were submitted in support of the MRL application.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 3; more detailed information is available in the EFSA reasoned opinion under Art 12 of Regulation (EC) No 396/2005 (EFSA, 2014).

The stability of tolclofos-methyl residues in plant matrices under storage conditions prior to analysis was demonstrated (EFSA, 2005, 2014). Residues of tolclofos-methyl were found to be stable in high water content commodities at $\leq -18°C$ for 22 months. The storage stability of residues in matrices with high water content was assessed and validated during the MRL review (EFSA, 2014) and no further information has been considered necessary.

Table 3: Overview of the available residues trials data

Crop (GAPs)	Region/ indoor[a]	Residue levels observed in the supervised residue trials[b] (mg/kg)	Recommendations/comments[c]	MRL proposal (mg/kg)	HR[d] (mg/kg)	STMR[e] (mg/kg)
Potatoes	NEU	RD Mo: 13× < 0.01; 0.013; 5× 0.02; 2× 0.03; 3× 0.04; 2× < 0.05; 0.06; 0.08; 0.18 RD RA: –	Complete residue data set assessed and validated during the MRL review (EFSA, 2014) reflecting the critical NEU and SEU GAPs Enforcement residue definition (RD Mo): tolclofos-methyl Risk assessment residue definition (RD RA): sum of tolclofos-methyl, sugar conjugate of Ph-CH_3 and sugar conjugate of TM-CH_2-OH, expressed as tolclofos-methyl (tentative) A conversion factor of 1 was derived from a metabolism study in potatoes evaluated during the MRL review (EFSA, 2014) MRL_{OECD} NEU: 0.18/0.2 MRL_{OECD} SEU: 0.02/0.02	0.2	0.18	0.02
Potatoes	SEU	RD Mo: 6× < 0.01; 2× 0.01 RD RA: –		0.02*	0.01	0.01

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development.
*: Indicates that the MRL is proposed at the limit of analytical quantification (LOQ).
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order (2× < 0.01, 0.01, 6× 0.02, 0.04, 0.08, 2× 0.10, 0.15, 0.17).
(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).
(d): HR: Highest residue level according to the residue definition for risk assessment.
(e): STMR: Median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of tolclofos-methyl residues under representative processing conditions were not assessed in previous EFSA assessments (EFSA, 2014).

One study to investigate the hydrolytic stability of [phenyl-^{14}C] tolclofos-methyl under conditions simulating normal industrial and household processing practices was submitted under the current application (Finland, 2016). Table 4 summarises the results.

Table 4: Results of the standard hydrolysis study of tolclofos-methyl

Standard hydrolysis study of tolclofos-methyl							
Processes represented	**T° (°C)**	**Time (min)**	**pH**	**Parent Initial conc. (mg/L)**	**Recoveries (% applied radioactivity)**		
					Parent	**DM-TM**	**Total**
Pasteurisation	90	20	4	0.792	74.8	23.6	98.4
Baking, Brewing, Boiling	100	60	5	0.835	47.3	52.7	100.0
Sterilisation	120	20	6	0.766	12.6	87.0	99.6

Tolclofos-methyl degraded increasingly to DM-TM with increased temperature and pH under processing conditions representative of pasteurisation, boiling and sterilisation.

Based on the new standard hydrolysis studies, EFSA suggests the inclusion of DM-TM in the residue definitions for processed commodities. This proposed residue definition should be further discussed in the framework of the AIR III process which is ongoing.

As the chronic exposure does not exceed 10% of the ADI (see also Section 4), there is no need to investigate the magnitude of residues in case of industrial and/or household processing. Studies on the effects of peeling on the residue levels in potatoes were reported in the framework of the peer review (Sweden, 2005). They have indicated that after peeling, residues of parent tolclofos-methyl in potatoes are reduced to levels at or below the LOQ (0.01 mg/kg). However, since no details are reported on this study, such as the type of application, the data are not sufficient to derive reliable processing factors for peeled potatoes.

A reliable study investigating the residue concentration in potato peel and peeled tuber would be desirable since this information would allow performing more refined calculations of the dietary burden of livestock (see Section 3.2.1).

3.1.2. Rotational crops

Potatoes may be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of tolclofos-methyl and its relevant soil metabolite (DM-TM) are expected to be less than 30 days and 3 days, respectively, which is below the trigger value of 100 days (EFSA, 2005).

According to the European guidelines on rotational crops (European Commission, 1997c), further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected (EFSA, 2014).

3.2. Nature and magnitude of residues in livestock

Potatoes are not only used for human consumption, but potatoes and their by-products may also be used for feed purposes. Thus, the possible transfer of tolclofos-methyl related residues to food of animal origin has to be assessed.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology. The input values for the dietary burden calculation were selected according to the OECD guidance document (OECD, 2013) considering the livestock intake of potatoes and its by-products.[9] It

[9] These crops that were lowered to the LOQ following the MRL review under Art. 12 of Regulation (EC) No 396/2005 were not considered in the calculation of the dietary burden, since the use of tolclofos-methyl in these crops were not supported by data and had to be withdrawn.

is noted that limited information on the distribution of residues between potato pulp and peel was provided in the framework of the peer review (Sweden, 2005) and no information was submitted with the current application. Since the available studies did not allow deriving reliable processing factors, EFSA used the default processing factors of 20 and 38 to estimate the expected residue levels in potato process waste and in potato dried pulp, respectively. The input values for the dietary burden calculation are summarised in Table 5.

Table 5: Input values for the dietary burden calculation

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Potato	0.02	STMR × CF (1) (EFSA, 2014)	0.18	HR × CF (1) (EFSA, 2014)
Cabbage (heads)	0.02	STMR (0.01) × CF (2) (EFSA, 2014)	0.02	HR × CF (2) (EFSA, 2014)
Potato (process waste)	0.40	STMR (EFSA, 2014) × PF[(a)]	0.40	STMR (EFSA, 2014) × PF[(a)]
Potato (dried pulp)	0.76	STMR (EFSA, 2014) × PF[(b)]	0.76	STMR (EFSA, 2014) × PF[(b)]

STMR: supervised trials median residue; HR: highest residue.
CF: Conversion factors derived by EFSA. They were derived based on the metabolism data for potatoes (CF = 1) and leafy vegetables (CF = 2) (EFSA, 2014).
(a): Default processing factor (PF) of 20 derived from potato to potato process waste. According to the OECD guidance, 'potatoes wastes' correspond to wet peel released during the peeling process. The efficiency of peeling processes for potatoes has been improved over the years. Moreover, the peeling loss also depends on the size of the raw product and there are a wide range of varieties of potatoes. From the different sources, there are indications that the peeling loss ranges from 5% to 20%. Therefore, a worst-case scenario would be to consider a theoretical PF coming from the most efficient technologies (5% peeling loss), giving a PF of 20.
(b): Default processing factor of 38 derived from potato to potato dried pulp. The process of potatoes 'wet milling' involves the extraction of the fibres (or potatoes pulp) in order to release starch. From 1,000 kg of potatoes, 140 kg of fibres (at 16.5% DM) can be extracted. These fibres are then dried up to 88% DM before being fed to animals as 'potatoes dried pulp'. Therefore, the mass of 'potatoes dried pulp' that can be produced from 1,000 kg of potatoes is 140 × 16.5/88 = 26 kg. This estimate is confirmed by another source where it is indicated that 1,000 kg of potatoes can yield 33 kg of dried pulp. Consequently, considering a worst-case situation where residues concentrate in this by-product, the theoretical process factor for potato dried pulp is estimated at 38.

The estimated animal dietary intakes taking into account the feed commodities listed in Table 5 are summarised in Table 6.

Table 6: Results of the dietary burden calculation

Animal	Median burden (mg/kg bw)	Maximum burden (mg/kg bw)	Maximum burden (mg/kg DM)	> 0.1 mg/kg DM (yes/no)	Highest contributing commodity[(a)]
Ram/Ewe	0.046	0.054	1.62	Yes	Potato (process waste)
Dairy cattle	0.041	0.050	1.30	Yes	Potato (process waste)
Beef cattle	0.034	0.039	1.63	Yes	Potato (process waste)
Poultry	0.013	0.019	0.26	Yes	Potato (culls)
Pigs	0.017	0.026	1.13	Yes	Potato (process waste)

bw: body weight; DM: dry matter.
(a): Considering the maximum dietary animal burden.

The maximum dietary animal intake exceeded the trigger value of 0.1 mg/kg DM for all relevant livestock species, and therefore, the occurrence of tolclofos-methyl residues in products of animal origin has to be investigated.

3.2.2. Nature of residues

The metabolism of tolclofos-methyl in lactating goat and laying chicken was previously assessed (EFSA, 2005, 2014). Several deficiencies in the animal metabolism studies were identified which did not allow deriving residue definitions for animal commodities.

Under the current application, two new metabolism studies were provided by the applicant (Finland, 2016), i.e. one study in lactating goats and one study in laying hens using ^{14}C-phenyl-labelled tolclofos-methyl. The key parameters of these metabolism studies are reported in Table 7.

Table 7: Summary of the available metabolism studies in animals

Group	Species	No animal	Application details		Sample details	
			Rate (mg/kg bw per day)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	1	0.388	7	Milk	Twice daily
					Urine and faeces	24 h prior to dosing, twice daily after the first administration and at sacrifice
					Blood	Before each administration
					Edible organs and tissues	After sacrifice
Laying poultry	Hens	10	0.915	14	Eggs	Once daily
					Excreta	Every 24 h and at sacrifice
					Edible organs and tissues	After sacrifice

bw: body weight.

A lactating goat was dosed with tolclofos-methyl (ca. 10 mg/kg dry feed, corresponding to 0.388 mg/kg body weight (bw) per day) for 7 consecutive days. This corresponds to approximately 8 times the maximum expected dose for dairy cattle and 10 times the expected exposure of beef cattle.

Approximately 85% of the administrated dose was excreted via urine and faeces. The transfer to milk and tissues was 0.08% and 0.33% of the administered dose, respectively, and the plateau level was reached after the third administration with 0.014–0.019 mg eq/kg.

The highest levels of radioactive residues were measured in liver (0.252 mg eq/kg) and kidney (0.215 mg eq/kg). The total radioactivity in muscle and fat was low (0.005 mg eq/kg in muscle and less than LOQ in fat). Due to the low concentration of radioactivity, samples of muscle and fat were not further analysed for identifying the compounds present.

Parent tolclofos-methyl was found in liver and kidney at 4.4% TRR (0.011 mg/kg) and 11.9% TRR (0.029 mg/kg). Metabolite Ph-COOH was detected in liver and kidney up to 10.2% TRR (0.026 mg/kg) and 12.5% TRR (0.031 mg/kg), respectively. Metabolite TMO-COOH was found in milk (6.7% TRR, 0.001 mg/kg)) and kidney (5.4% of TRR, 0.013 mg/kg). Metabolites Ph-CH_2OH and DM-TM were found in low levels amounting to 0.8% and 1.5% TRR in kidney only. In urine and faeces besides the metabolites mentioned earlier, additionally Ph-CH_3 (urine only) and DM-TM and DM-TMO occurred.

In the metabolism study with laying hens, the animals were dosed with [phenyl-^{14}C] tolclofos-methyl for 14 consecutive days at 10.9 mg/kg dry feed, corresponding to 0.915 mg/kg bw per day. The dose level was equivalent to approximately 50 times the expected maximum dietary burden. The major amount of radioactivity was excreted (up to 90.3%) and the total recovery at sacrifice was 90.6%. The transfer to eggs was low and the total administered radioactivity excreted via eggs was counted for 0.06%. A plateau level of 0.057–0.059 mg eq/kg was reached in egg yolk after approximately the ninth administration. In edible organs/tissues, ca. 0.3% of the administered dose was detected. The highest total radioactive residues were found in liver accounting for 0.417 mg eq/kg.

Parent tolclofos-methyl was found in all organs/tissues (fat: 75.9% TRR, 0.034 mg/kg; egg yolk: 37.4% TRR, 0.022 mg/kg; skin: 28.8% TRR, 0.021 mg/kg; muscle: 5% TRR, 0.001 mg/kg; liver: 0.5% TRR, 0.002 mg/kg) and in excreta.

Ph-COOH was the main metabolite occurring in all organs/tissues except in eggs, ranging from 3.7% TRR (fat) to 15.6% TRR (liver). In eggs, only unchanged tolclofos-methyl was detected. TMO-COOH was found in liver, skin and muscle for a maximum of 2% of the TRR and TMO-CH_2OH was detected in liver and skin counting for maximum 5.4% TRR. The metabolite Ph-CH_3 was only detected in liver in an amount of 3.5% TRR.

According to the studies evaluated, tolclofos-methyl parent compound and Ph-COOH are the two main components identified in animal matrices and are therefore considered appropriate marker substances for risk assessment purposes.

Based on the results in a metabolism study in rat previously peer-reviewed by EFSA (EFSA, 2005), Ph-COOH can be considered covered by the toxicological endpoints of tolclofos-methyl parent compound.

Thus, EFSA proposes the following residue definitions for food of animal origin:

- tolclofos-methyl (residue definition for enforcement);
- sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (Ph-COOH), expressed as tolclofos-methyl (residue definition for risk assessment).

Both proposed residue definitions should be further discussed in the framework of the renewal of the approval of tolclofos-methyl.

3.2.3. Magnitude of residues

Studies investigating the residues on food from animal origin commodities were not submitted in the current application.

The EMS proposed to use the metabolism study to estimate the expected residues in food of animal origin (Finland, 2016). From the overdosed metabolism studies, it is not expected that residues exceeding 0.01 mg/kg occur in animal matrices.

EFSA concludes that an amendment of the existing MRLs for tolclofos-methyl in food of animal origin is not necessary.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population[10] (EFSA, 2007).

In the framework of the review of the existing MRLs for tolclofos-methyl according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses supported by data at the EU level (EFSA, 2014). The previous risk assessment done by EFSA has been updated, taking into account that the MRLs proposed by EFSA for swedes, turnips, Chinese cabbage, kale, kohlrabi and celeries were not agreed by risk managers; thus, these commodities were taken out from the exposure calculation, assuming that the uses of tolclofos-methyl have been withdrawn and therefore, that these crops are unlikely to contain tolclofos-methyl residues. For potatoes, the STMR derived from the supporting trials was used as input value for the chronic risk assessment. For animal products, the exposure calculation is based on the LOQ of 0.01 mg/kg. The input values used for the dietary exposure calculation are summarised in Table 8.

An acute consumer exposure assessment was not performed, since the setting of an ARfD was concluded to be unnecessary for tolclofos-methyl.

Table 8: Input values for consumer risk assessment

Commodity	Chronic exposure assessment	
	Input (mg/kg)	Comment
Tentative risk assessment residue definition for plant origin commodities: sum of tolclofos-methyl, sugar conjugate of Ph-CH3 and sugar conjugate of TM-CH2-OH, expressed as tolclofos-methyl (EFSA, 2014)		
Potatoes	0.02	STMR (EFSA, 2014; Table 3)
Radishes	0.05	STMR (EFSA, 2014) × CF (1)[(a)]
Broccoli	0.02	STMR (EFSA, 2014) × CF (2)[(a)]
Cauliflower	0.02	STMR (EFSA, 2014) × CF (2)[(a)]
Brussels sprouts	0.02	STMR (EFSA, 2014) × CF (2)[(a)]
Head cabbage	0.02	STMR (EFSA, 2014) × CF (2)[(a)]
Lamb's lettuce	0.49	STMR (EFSA, 2014) × CF (2)[(a)]

[10] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment	
	Input (mg/kg)	Comment
Lettuce	0.42	STMR (EFSA, 2014) × CF (2)[(a)]
Scarole (broad-leaf endive)	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Cress	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Land cress	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Rocket, Rucola	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Red mustard	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Leaves and sprouts of *Brassica* spp.	0.49	STMR (EFSA, 2014) × CF (2)[(a)]
Tentative risk assessment residue definition for animal origin commodities: sum of tolclofos-methyl and Ph-COOH, expressed as tolclofos-methyl (current application)		
Swine kidney	0.01*	EU MRL
Ruminant meat	0.01*	EU MRL
Ruminant fat	0.01*	EU MRL
Ruminant liver	0.01*	EU MRL
Ruminant kidney	0.01*	EU MRL
Poultry meat	0.01*	EU MRL
Poultry fat	0.01*	EU MRL
Poultry liver	0.01*	EU MRL
Cattle milk	0.01*	EU MRL
Sheep milk	0.01*	EU MRL
Goat milk	0.01*	EU MRL
Birds' eggs	0.01*	EU MRL

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of analytical quantification.
(a): A tentative conversion factor for risk assessment (1 for root vegetables other than potatoes, 2 for leafy vegetables) is used for indicative exposure calculations.

The estimated exposure was then compared with the toxicological reference values derived for tolclofos-methyl (Table 1). A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be less than 2% of the ADI (NL, child) where the contribution of potato residues counts for less than 1%. Potatoes are the third contributor to the highest chronic intake and the main food commodity that contributes to the total exposure is of animal origin (milk).

EFSA concludes that the intended use of tolclofos-methyl on potatoes will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a health risk to consumers. Given that the setting of the ARfD might be reconsidered in the framework of the renewal of the approval of tolclofos-methyl, the current consumer risk assessment might have to be revised accordingly.

Conclusions and recommendations

The information submitted was sufficient to propose the MRLs summarised in the table below:

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Tolclofos-methyl[(F)]				
0211000	Potatoes	0.01*	0.2	The intended use in potatoes is sufficiently supported by data. Based on the NEU residue data, a MRL of 0.2 mg/kg is derived No consumer concern was identified for the intended use

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
1010000 1020000 1030000	Animal products – tissues, milk and eggs	0.01*	No change	Residues are unlikely to occur in animal matrices at levels above the LOQ (0.01 mg/kg). Therefore, there is no need to amend the existing MRLs

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.

In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, a number of data gaps have been identified. With this application, data have been submitted which sufficiently addressed the following data gaps:

- animal metabolism studies investigating the nature of the tolclofos-methyl residues in commodities of animal origin (ruminants and poultry);
- validation of the analytical method for enforcement of the residues in food of animal origin;
- method validation for the determination of the residues in several matrices of plant origin;
- standard hydrolysis study investigating the nature of the tolclofos-methyl residues in processed commodities.

The data gap concerning further investigation on the toxicological profile of the metabolites Ph-CH_3 and TM-CH_2OH that occur mainly in leafy crops is still open.

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Abbreviations

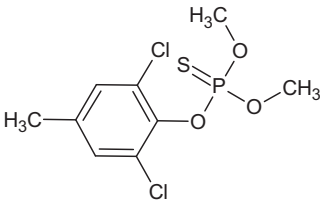
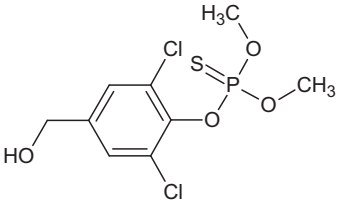
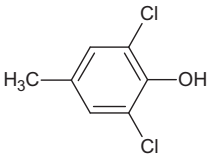
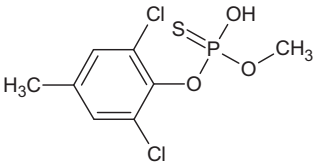
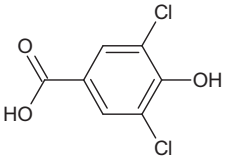
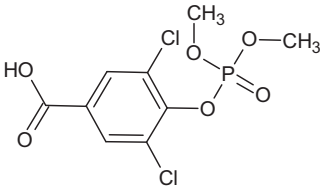
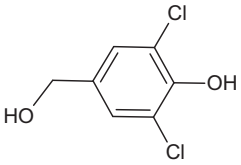
a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation)
CF	conversion factor for enforcement to risk assessment residue definition
cGAP	critical GAP
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–MS	gas chromatography with mass spectrometry
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	risk assessment
RD	residue definition
RD Mo	enforcement residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization
WP	wettable powder

Appendix A – Good Agricultural Practice (GAPs)

Crop	NEU, SEU, MS or country	F G or I (a)	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)(d)	Remarks
				Type(b)	Conc. a.s.	Method Kind	Range of growth stages & season(c)	Number min–max	Interval	kg/hL min–max	Water L/ha min–max	kg/ha min–max		
Potato	AT (NEU)	F	Rhizoctonia	DP	100 g/kg	Tuber dressing (at planting)	BBCH 00-03	1	–	n.a.	n.a.	0.900	n.a	0.2 kg a.s./tonne Max 4.5 tonne tubers/ha
Potato	AT, CZ, DK, FI, DE, SE (NEU)	F	Rhizoctonia	SC	500 g/L	Tuber dressing (before and at planting)	BBCH 00-03	1	–	0.5625–0.675	Undiluted up to 2–3 L/tonne tuber (before planting) 80–100 L/ha (at planting)	0.675	n.a	0.15 kg a.s./tonne Max 4.5 tonne tubers/ha
Potato	BE, IE, NL, SE, UK (NEU)	F	Rhizoctonia	DP	100 g/kg	Tuber dressing (at planting)	BBCH 00-03	1	–	n.a.	n.a.	0.675	n.a	0.15 kg a.s./tonne Max 4.5 tonne tubers/ha
Potato	DK (NEU)	F	Rhizoctonia	DP	100 g/kg	Tuber dressing (at planting)	BBCH 00-03	1	–	n.a.	n.a.	0.35	n.a	0.1 kg a.s./tonne Max 3.5 tonne tubers/ha
Potato	GR, IT, ES (SEU)	F	Rhizoctonia	WP	500 g/kg	Tuber dressing (before and at planting)	BBCH 00-03	1	–	0.5625–12.500	2–3 L/tonne (before planting) 165–200 L/ha (at planting)	1.125	n.a.	0.25 kg a.s./tonne Max 4.5 tonne tubers/ha
Potato	ES (SEU)	F	Rhizoctonia	DP	100 g/kg	Tuber dressing (at planting)	BBCH 00-03	1	–	n.a.	n.a.	1.125	n.a	0.25 kg a.s./tonne Max 4.5 tonne tubers/ha
Potato	FR (SEU)	F	Rhizoctonia	SC	500 g/L	Tuber dressing (before and at planting)	BBCH 00-03	1	–	n.a.–6.25	Undiluted up to 2 L/tonne tuber (before and at planting)	0.5625	n.a	0.125 kg a.s./tonne Max 4.5 tonne tubers/ha

NEU: northern European Union; SEU: southern European Union; MS; Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.

Appendix B – Used compound codes

Code/trivial name	Chemical name	Structural formula
Tolclofos-methyl	*O*-2,6-Dichloro-*p*-tolyl *O,O*-dimethyl phosphorothioate Clc1cc(C)cc(Cl)c1OP(=S)(OC)OC	
TMO-CH_2OH	*O*-[2,6-Dichloro-4-(hydroxymethyl)phenyl] *O,O*-dimethyl phosphorothioate Clc1cc(cc(Cl)c1OP(=S)(OC)OC)CO	
Ph-CH_3	2,6-Dichloro-4-methylphenol Clc1cc(C)cc(Cl)c1O	
DM-TM	*O*-(2,6-Dichloro-4-methylphenyl) *O*-methyl hydrogen phosphorothioate Clc1cc(C)cc(Cl)c1OP(O)(=S)OC	
Ph-COOH	3,5-Dichloro-4-hydroxybenzoic acid Clc1cc(cc(Cl)c1O)C(=O)O	
TMO-COOH	3,5-Dichloro-4-[(dimethoxyphosphoryl)oxy]benzoic acid Clc1cc(cc(Cl)c1OP(=O)(OC)OC)C(=O)O	
Ph-CH_2OH	2,6-Dichloro-4-(hydroxymethyl)phenol Clc1cc(cc(Cl)c1O)CO	
DM-TMO	2,6-Dichloro-4-methylphenyl methyl hydrogen phosphate Clc1cc(C)cc(Cl)c1OP(=O)(O)OC