CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance tembotrione[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State Austria, for the pesticide active substance tembotrione are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of tembotrione as a herbicide on maize and sweet corn. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented.

© European Food Safety Authority, 2013

KEY WORDS

Tembotrione, peer review, risk assessment, pesticide, herbicide

[1] On request from the European Commission, Question No EFSA-Q-2009-00321, approved on 5 March 2013.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance tembotrione. EFSA Journal 2013;11(3):3131. [81 pp.] doi:10.2903/j.efsa.2013.3131. Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2013

SUMMARY

Tembotrione is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC, Austria (hereinafter referred to as the 'RMS') received an application from Bayer CropScience AG for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2006/586/EC.

The RMS provided its initial evaluation of the dossier on tembotrione in the Draft Assessment Report (DAR), which was received by the EFSA on 7 February 2007. The peer review was initiated on 14 January 2008 by dispatching the DAR for consultation of the Member States and the applicant Bayer CropScience AG. In accordance with Commission Regulation (EU) No 188/2011 Article 11(6), additional information was requested. The RMS's evaluation of the additional information was submitted to the EFSA in the format of addenda to the DAR. The addenda were dispatched for consultation of the Member States and the applicant Bayer CropScience AG on 1 February 2012.

Following consideration of the comments received on the DAR and the addenda, it was concluded that the EFSA should conduct an expert consultation and should adopt a conclusion on whether tembotrione can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of tembotrione as a herbicide on maize and sweet corn, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis no data gaps or areas of concerns were identified. It was noted that the formulation is not stable and has pourability issues.

No data gaps or areas of concerns were identified in the area of toxicology.

No data gaps or areas of concerns were identified in the area of residues.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level, for the representative uses assessed. The potential for groundwater exposure by tembotrione and three of its metabolites was concluded to be low for these representative uses. For a further two metabolites (AE 0456148, M6 and AE1392936, M2) a potential for groundwater exposure was identified consequent to these uses, but the available data and assessments indicated that these metabolites should be considered 'not relevant'.

In the area of ecotoxicology no data gaps or areas of concern were identified.

TABLE OF CONTENTS

BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC, Austria (hereinafter referred to as the 'RMS') received an application from Bayer CropScience AG for approval of the active substance tembotrione. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2006/586/EC.[6]

The RMS provided its initial evaluation of the dossier on tembotrione in the DAR, which was received by the EFSA on 7 February 2007 (Austria, 2007). The peer review was initiated on 14 January 2008 by dispatching the DAR to Member States and the applicant Bayer CropScience AG for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The comments were evaluated by the RMS in column 3 of the Reporting Table. EFSA's further consideration of the comments and the RMS response is reflected in the conclusions set out in column 4 of the Reporting Table (final version dated 20 February 2009).

All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration were compiled by the EFSA in the format of an Evaluation Table. The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table (final version dated 11 May 2012).

[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 No L 309, 24.11.2009, p. 1-50.
[4] 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, as last amended.
[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2006/586/EC of 25 August 2006 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chromafenozide, halosulfuron, tembotrione, valiphenal and Zucchini yellow mosaic virus — weak strain in Annex I to Council Directive 91/414/EEC. OJ L 236, 31.8.2012, p. 31-33.

In accordance with Commission Regulation (EU) No 188/2011 Article 11(6) additional information was requested. The RMS's evaluation of the additional information was submitted to the EFSA in the format of addenda to the DAR (Austria, 2012). The addenda were dispatched for consultation of the Member States and the applicant Bayer CropScience AG on 1 February 2012.

The comments received on the addenda were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a second Reporting Table. The applicant was invited to respond to the comments in column 3 of the second Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3 of the second Reporting Table (final version dated 11 May 2012).

The need for further expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 11 May 2012. 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 the EFSA should organise further expert consultation in the area of mammalian toxicology.

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 second 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, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of a second Evaluation Table (final version dated 1 March 2013).

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the second 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 February 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on maize and sweet corn, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, 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 (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table 1 (20 February 2009),
- the Reporting Table 2 (11 May 2012),
- the Evaluation Table 1 (11 May 2012),
- the Evaluation Table 2 (1 March 2013),
- 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 DAR including its addendum (compiled version of December 2012 containing all individually submitted addenda (Austria, 2012)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Tembotrione is the ISO common name for 2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione (IUPAC). Tembotrione exists as a pair of keto-enol tautomers and the equilibrium will depend on the conditions, with rapid conversion from one to the other as environmental parameters change.

The representative formulated product for the evaluation was 'Laudis', an oil dispersion (OD).

The evaluated representative use is as a herbicide on maize and sweet corn. Full details of the GAP can be found in Appendix A. Tembotrione is always used together with the safener isoxadifen-ethyl, which significantly improves crop tolerance.

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/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of tembotrione as manufactured should be not less than 945 g/kg. The specification of the active substance from the European source was accepted but the other source was not fully supported by the available data.

At present no FAO specification exists.

The technical material contains toluene and hydrogen cyanide, which are regarded as relevant impurities. The maximum content in the technical material should not be higher than 10 and 1 g/kg respectively. Given the nature of these compounds and the fact that they will not increase on storage of the formulation, the need for storage data and spectra can be waived. As they cannot increase on storage, methods of analysis for them in the formulation are not a requirement at this stage.

The content of tembotrione in the representative formulation is 44 g/L (pure).

The active substance appears to be inherently unstable and a circa 8 % decrease in the active substance content on 2 year storage was noted. This resulted in the formation of a breakdown product. Mammalian toxicology have considered this and concluded that the toxicity data do cover this breakdown product. It should also be noted that the formulation has a pourability issue and appropriate labelling should be considered.

Adequate methods are available to analyse tembotrione and AE 1417268 in products of plant origin and products of animal origin. Adequate methods are also available to analyse tembotrione in environmental matrices.

A method for body fluids and tissues is not required as the active substance is neither toxic nor very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 – rev. 10-final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004), SANCO/10597/2003 – rev. 8.1, May 2009 (European Commission, 2009).

Tembotrione was discussed at the Peer Review 69 and 98 Expert's Meetings on mammalian toxicology.

The technical specification evaluated is supported by the batches used in the toxicological studies; the relevance of the impurities has been adequately addressed. Impurities toluene and hydrogen cyanide were considered as toxicologically relevant. Toxicity data cover a circa 8 % decrease in the active substance content and the increase in content of a breakdown product after storage.

The oral absorption of tembotrione is rapid and greater than 90%. It is widely and uniformly distributed, with a low potential for accumulation. The excretion is almost complete after 96 h. The major pathways of metabolism include oxidative mechanisms leading to hydroxylated components on the cyclohexyl ring.

The acute toxicity of tembotrione is low, by the oral, dermal or inhalation routes. Tembotrione presented slight eye irritation and no skin irritation; but there was potential for skin sensitisation.

Tembotrione is a 4-hydroxyphenylpyruvate dioxygenase (HPPD) inhibitor. Male rats were considered more sensitive to tembotrione and primary effects in short-term and long-term studies were characterized by corneal lesions, liver and kidney effects. Corneal lesions may be a secondary effect of increased tyrosinaemia especially observed in rats and of lower relevance to humans but all other findings were considered to be relevant. The relevant oral No Observed Adverse Effect Level (NOAEL) for short-term exposure was the dose level of 0.07 mg/kg bw per d from the 90-day rat study; and after long-term exposure, the NOAEL was 0.04 mg/kg bw per d from the 2-year rat study.

No potential for genotoxicity was found. Corneal squamous cell carcinoma were observed in male rats and considered as likely to be related to prolonged irritation of the cornea and to be a rat specific finding.

No adverse effect on the reproductive parameters was shown in the multigeneration study with rats: the relevant reproductive NOAEL was 98.2 mg/kg bw per d, while only a Lowest Observed Adverse Effect Level (LOAEL) of 1.3 mg/kg bw per d could be determined for the parents and offspring. Tested in developmental toxicity studies, tembotrione showed developmental adverse effects in rats and rabbits at maternal toxic dose levels: in rats, the relevant maternal and developmental NOAEL could not be established since adverse effects were observed at all dose levels tested (LOAEL 25 mg/kg bw per d). In rabbits, the relevant parental and developmental NOAEL was 1 mg/kg bw per d.

The neurotoxicity of tembotrione was studied in acute, sub-chronic (90-d) and developmental neurotoxicity studies in rats. The acute NOAEL was established at 200 mg/kg bw based on clinical signs and decreased activity together with decreased arousal rate. The sub-chronic NOAEL was established at 16.4 mg/kg bw per d (males) based on reduced body weight and food consumption. The agreed NOAEL for both maternal and postnatal developmental effects was 0.8 mg/kg bw per d based on corneal opacities (dams and offspring), reduced absolute body weight (dams), reduced body weight gain (dams and offspring) and lower absolute brain weight in the offspring with no functional or histological impairment. There was not sufficient evidence to demonstrate a direct neurotoxic effect of tembotrione.

The effects described above suggest that classification and labelling with R43 and R48/22 would be required for tembotrione.[7]

The acceptable daily intake (**ADI**) is 0.0004 mg/kg bw per d, based on the NOAEL of 0.04 mg/kg bw per d found in the long-term toxicity study in rats and applying an uncertainty factor of 100. The acceptable operator exposure level (**AOEL**) is 0.0007 mg/kg bw per d, based on the NOAEL of 0.07 mg/kg bw per d found in the 90-day rat study and applying an uncertainty factor of 100. No correction

[7] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with 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, 1-1355.

for oral absorption is needed to derive the AOEL. The acute reference dose (**ARfD**) is 0.1 mg/kg bw based on the NOAEL for mortality observed in the rabbit developmental study (10 mg/kg bw per d), and applying an uncertainty factor of 100. The relevant dermal absorption values for 'Laudis OD' are 2% for the concentrate and 5% for the dilution.

The groundwater metabolites **AE 0456148** (M6) and **AE 1392936** (M2) were considered of non-toxicological relevance. An ADI of 0.2 mg/kg bw per d was set for M6. The plant metabolite **AE 1417268** (M5) was considered to be less potent than the parent compound and an ADI of 0.013 mg/kg bw per d and an ARfD of 0.1 mg/kg bw were set.

Considering the representative use in **maize** and **sweet corn** the estimated operator exposure is below the AOEL (35 %) when personal protective equipment (PPE) of gloves during mixing and loading, and gloves and sturdy footwear are used during application according to the German model. Worker exposure was estimated to be below the AOEL (9 %) if gloves are used. Bystander exposure was estimated to be below the AOEL (17.5 %).

3. Residues

The assessment in the residue section is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

The metabolism of tembotrione in primary crops was investigated in maize. Based on these studies the residue definition for monitoring and risk assessment was established as "the sum of tembotrione and metabolite AE 1417268 (M5), expressed as tembotrione".

The representative uses are sufficiently supported by residue data in maize grain and sweet corn. Analytical methods were sufficiently validated to determine the residues of tembotrione and its metabolite AE 1417268 (M5) in maize grain and sweet corn. Valid storage stability data are available to confirm tembotrione and metabolite AE 1417268 (M5) as being stable under freezer storage conditions.

Studies investigating the nature of residues of tembotrione and metabolite AE 1417268 (M5) in processed commodities demonstrated slight degradation of tembotrione under sterilisation conditions, but not exceeding 10% of the applied radioactivity. Metabolite AE 1417268 (M5) was stable and no degradation products were formed. Thus, for processed commodities the same residue definition as for raw commodities does apply.

A study investigating the effects of processing on the magnitude of tembotrione and metabolite AE 1417268 (M5) indicates a reduction of total residues in refined maize oil, starch, flour, and grits. A slight concentration was observed in meal with regard to metabolite AE 1417268 (M5). However, due to low residues of tembotrione and metabolite AE 1417268 (M5) in maize grain, no significant residues are expected in processed food commodities of maize. A study was also performed to investigate the magnitude of residues in the processing of maize forage to maize silage where metabolite AE 1417268 (M5) is the main residue. A reduction of metabolite AE 1417268 (M5) in silage is observed and an indicative processing factor can be derived. It is, however, not known whether additional metabolites could be formed during the fermentation process of forage, but such investigation is currently not a common data requirement.

A study investigating the nature of tembotrione in rotational crops indicates that the metabolism proceeds in a similar pathway as in primary plants. Hence, the same residue definitions apply to primary and rotational crops. In rotational crop field trials, significant residue levels were not observed in crops at plant back intervals of 90 days and 120 days. No experimental data are available for shorter plant back intervals; however they may occur in the case of crop failure, given the representative use features applications to maize plants at an early growth stage. Using expert judgement, the occurrence of significant residues at shorter plant back intervals was considered unlikely provided tembotrione is applied according to the representative use, although confidence is limited due to the lack of experimental data. Therefore, for plant back intervals shorter than 90 days risk managers may consider whether or not the implementation of a plant-back restriction for the representative uses is deemed appropriate.

Metabolism of tembotrione and its metabolite AE 1417268 (M5) was studied in livestock, and both compounds were not extensively metabolised but mainly recovered in their unchanged form. From the intake of maize silage and grain, no significant exposure and therefore no residues of tembotrione above the LOQ are expected in food of animal origin. Hence, in view of the livestock dietary burden from the representative use, the residue definition for monitoring and risk assessment in animal matrices was set as metabolite AE 1417268 (M5) alone. Based on the results of the livestock feeding study with AE 1417268 (M5) in dairy cattle, MRLs were set for AE 1417268 (M5) in animal matrices.

The consumer risk assessment performed with the EFSA Pesticides Residues Intake Model (PRIMo) indicated that the maximum chronic exposure (TMDI)) for maize, sweet corn and commodities of animal origin is less than 7 % of the ADI of tembotrione for the sum of tembotrione and metabolite AE 1417268 (M5), expressed as tembotrione. Tembotrione and metabolite AE 1417268 (M5) have to be considered together for the risk assessment since it can be reasonably assumed that both compounds share the same mode of action. However, since tembotrione and metabolite AE 1417268 (M5) have different toxicological potencies, different toxicological reference values were set for long-term exposure. Therefore to adjust the toxicity of metabolite AE 1417268 (M5) to that of tembotrione, the toxicity equivalence factor (TEF) of 0.0308 was applied to residues of metabolite AE 1417268 (M5) in the chronic risk assessment.

In an acute consumer risk assessment, the calculated maximum exposure in percentage of the ARfD was less than 2% for all maize commodities.

In addition, the consumer exposure with regard to residues of metabolite AE 0456148 (M6) in groundwater used as drinking water was assessed on the basis of the predicted PEC groundwater levels. The estimates are based on the default assumptions laid down in the WHO Guidelines for drinking water quality (WHO, 2011) for the consumer groups of adults (weighing 60 kg), toddlers (10 kg) and bottle-fed infants (5 kg) with a daily *per capita* consumption of 2 L, 1 L and 0.75 L, respectively. The intake through drinking water of AE 0456148 (M6) was less than 0.2 % of the ADI of AE 0456148 (M6) for the assessed consumer groups.

4. Environmental fate and behaviour

Tembotrione was discussed at the meeting of Member State experts for environmental fate and behaviour PRAPeR 67 in April 2009.

In soil under aerobic conditions tembotrione exhibits low to moderate persistence with its rate of degradation being pH dependent (faster degradation under alkaline conditions) forming the major soil metabolites AE 0456148 (M6) (accounting for up to 72 % of applied radioactivity (AR)) which exhibits low to medium persistence, AE 0968400 (M1) (accounting for up to 15 % of AR) which exhibits low to moderate persistence and at the soil surface as a consequence of photolysis AE 0941989 (M3) (accounting for up to 16 % of AR) which exhibits low persistence. The minor soil metabolites AE 1124336 (M7) (accounting for up to 8.7 % of AR), which exhibits moderate persistence, and AE 1392936 (M2), which exhibits low to moderate persistence, were also specifically assessed in order to ensure their leaching potential to groundwater could be adequately assessed.

Mineralisation of both the phenyl and cyclohexyl rings to carbon dioxide accounted for 13 – 77 % AR after 91 – 120 days. The formation of unextractable residues (not extracted by acetonitrile / water) was a sink, accounting for 17 – 39 % AR after 91 – 120 days. Tembotrione and AE 0968400 (M1) exhibit very high to high mobility in soil, with soil adsorption decreasing with increasing soil pH. Experts agreed that it could be appropriate to use the following linear regression relationship in exposure calculations:

- Tembotrione: K_{Foc} (mL/g) = -53.7 • pH(H_2O) + 445, min/max: 26.2/144
- AE 0968400 (M1) : K_{Foc} (mL/g) = -97.6 • pH(H_2O) + 749, min/max: 26.8/105

The other metabolites did not exhibit pH dependent adsorption but were characterised as having very high mobility [AE 0456148 (M6) and AE 1392936 (M2)], medium mobility [AE 1124336 (M7)] and medium to low mobility [AE 0941989 (M3)].

Field soil dissipation studies (applications to bare soil but grass drilled before application which subsequently emerged) were provided from 6 sites (4 in northern and 2 in southern Europe) where applications were made between May and July. The residue levels of parent tembotrione and AE 0456148 (M6) determined over the whole core sampled (0 – 50 cm, though residues were usually not detected deeper than 20cm, limit of detection (LOD) 1.5 µg/kg equivalent to 1 % of the target amount applied) were used to characterise the field behaviour. The loss of measured tembotrione was characterised by a biphasic decline pattern. An explanation for this initially more rapid decline might be that photolysis is occurring at the soil surface in these experiments. The metabolites AE 0968400 (M1) and AE 1392936 (M2) were not detected at any sampling time (LOD 1.5 µg/kg, equivalent to 1 % of the target amount of tembotrione applied). The other known soil metabolites were not analysed for. Appropriate kinetic fitting procedures following FOCUS (2006) kinetics guidance utilising a time step normalisation to FOCUS reference conditions (20 ºC and pF2 soil moisture[8]), were carried out. After this time step normalisation the pattern of decline of tembotrione remained biphasic. The applicant carried out a linear regression analysis to address the impact of soil pH on the rate of decline of tembotrione, formation fraction of AE 0456148 (M6) and subsequent decline of AE 0456148 (M6). The applicant established the following equations to describe this relationship:

- Rapid DFOP compartment: Norm. SFO-DegT_{50} (d) = -0.433 • pH(H_2O) + 3.64, min/max: 0.11/1.23
- Slow DFOP compartment: Norm. SFO-DegT_{50} (d) = -8.27 • pH(H_2O) + 73.7, min/max: 6.4/27.8
- g(k1) (0 .. 1) = -0.14 • pH(H_2O) + 1.49, min/max: 0.35/0.71
- ff (0 .. 1) = 0.303 • pH(H_2O) – 1.55, min/max: 0.14/0.91

These equations describe the observation that tembotrione degrades more slowly in acidic soils (apparent in both the laboratory and field studies) and there is a lower formation fraction of AE 0456148 (M6) in acidic soils (this relationship is observed in the field dissipation studies but is not clear in the laboratory incubations).

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the model PEARL 4.4.4.[9] For tembotrione and AE 0456148 (M6) field degradation rates were used as modelling input, with the degradation rate of tembotrione and formation fraction of M6 being considered pH dependent (pH correlations as described above). For the other metabolites (AE 0968400 (M1), AE 1124336 (M7) AE 1392936 (M2), AE 0941989 (M3, from soil photolysis)), laboratory degradation rates were utilised in the simulations. The adsorption of tembotrione and AE 0968400 (M1) were considered pH dependent (pH correlations as described above). In order to account for the biphasic degradation (DFOP) of tembotrione observed in the field dissipation studies (even after normalising to FOCUS reference conditions), two separate modelling runs (including the entire degradation pathway) were performed for each scenario and each intended use with tembotrione following SFO kinetics based on the rapid DFOP and on the slow DFOP compartment, respectively. The application rate was multiplied by 2 and partitioned into the two

[8] With the assumptions of a Q10 of 2.2 and also a Q10 of 2.58, Walker equation coefficient of 0.7.

[9] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7, though for tembotrione and AE 0456148 (M6) the FOCUS (2006) time step normalised field DT50 used as input were normalised using a Q10 of 2.2, exceptionally this was accepted in this case.

separate modelling runs according to the g value of the DFOP kinetics (note, all these parameters are pH dependent and are therefore scenario-specific). After modelling the results (PEC groundwater values) of both runs were summed up and divided by 2. This approach is as outlined in FOCUS (2006) guidance as an appropriate approach for accounting for biphasic kinetics. The experts from the Member States agreed that this modelling approach could be accepted as giving appropriate estimates of the potential groundwater recharge annual average concentrations for the metabolites AE 0456148 (M6) AE 0968400 (M1), AE 1124336 (M7), AE 1392936 (M2), AE 0941989 (M3) as the initial fast phase degradation of tembotrione would maximise the amounts of metabolites formed in the simulations and therefore metabolite mass available for leaching. However they had concerns over using the values from these groundwater simulations for the active substance tembotrione as the initial fast decline estimated from the field dissipation studies may have been the consequence of soil photolysis. If this was the explanation for the initial fast decline, photolysis could not occur deeper in the soil profile and the faster initial decline that had been simulated in all soil layers would not occur. Therefore the RMS carried out further groundwater simulations[10] for just the active substance tembotrione that just utilised the slower second phase first order decline from the field DFOP fits. The potential for groundwater exposure, from the representative uses, by tembotrione, AE 1124336 (M7), AE 0941989 (M3) and AE 0968400 (M1) above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all eight relevant FOCUS groundwater scenarios. However for the metabolites AE 0456148 (M6) and AE 1392936 (M2), contamination of groundwater above the 0.1 µg/L limit cannot be excluded and metabolite non-relevance assessments were triggered for these metabolites. The conclusion of these assessments was that AE 0456148 (M6) and AE 1392936 (M2) were not relevant with respect to groundwater (see sections 2 and 3). Risk managers are reminded that the FOCUS groundwater scenario vulnerability characterisation and selection made by the FOCUS groundwater workgroup did not include the issue of soil pH. As the available modelling approach has matched the pH dependent properties of tembotrione and AE 0968400 (M1) with the pH that are defined for each of the scenarios, the extent and regions of the agricultural area that would be protected by the available simulations will be different to that which results from substances that do not exhibit pH dependent degradation and or adsorption. Vulnerable higher pH soil situations will exist in every geoclimatic zone represented by the FOCUS groundwater scenarios, but the available assessment only considers alkaline conditions in the four scenarios: Châteaudun, Kremsmunster, Sevilla and Thiva.

In dark natural sediment water systems tembotrione degraded exhibiting pH dependent medium to high persistence in both water and sediment (as in soil, degrading faster under alkaline conditions) to the metabolite AE 0456148 (M6) which was persistent. The terminal metabolite, CO_2, accounted for only 0.3 – 1.1 %AR from the phenyl ring but more, 13.3 – 51.9 %AR from the cyclohexyl ring by 102 – 105 days. Residues not extracted (by acetonitrile followed by acetonitrile/water) from sediment were also a sink representing 5 – 16 %AR by 102 – 105 days. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for the metabolites AE 0456148 (M6), AE 0968400 (M1), AE 1392936 (M2) and AE 0941989 (M3), using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1 – 2 in FOCUS calculator). In addition, for the soil photolysis metabolite AE 0941989 (M3), step 3 calculations were completed (FOCUS, 2001). For the active substance tembotrione, appropriate step 3 and step 4 calculations had been completed following the biphasic and pH dependent approach described above for the FOCUS groundwater calculations.[11] The Member State experts discussed and agreed that for the drainage scenarios MACRO should be run with only the second slower phase soil DT_{50} as the more rapid first phase decline from the field studies may have been caused by photolysis and this process would not occur in deeper soil layers. As for groundwater, simulations were also

[10] Simulations utilised PEARL 3.3.3 the Q10 of 2.2 and Walker equation coefficient of 0.7 according to FOCUS (2000), for tembotrione, the FOCUS (2006) time step normalised field DT50 used as input were normalised using a Q10 of 2.2.

[11] Simulations including those for AE 0941989 (M3) correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.

completed following this approach.[12] The step 4 calculations appropriately followed the FOCUS guidance (FOCUS, 2007), with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 57 – 91 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80 % and erosion run-off flux by 95 %) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2000 mL/g (i.e. tembotrione), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. Risk managers are also reminded that the FOCUS surface water scenario vulnerability characterisation and selection made by the FOCUS surface water workgroup did not consider the issue of pH of soils and natural surface water systems. As the available modelling approach matched the pH dependent properties of tembotrione with the soil pH that are defined for each of the scenarios, the extent and regions of the agricultural area that would be protected by the available simulations will be different to that which is outlined in the FOCUS surface water report.

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

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001).

The risk to birds (acute, short-term and long-term) and mammals (acute) was indicated as low based on the first-tier risk assessment while the long-term risk to mammals (herbivorous) was indicated as high. As refinement, the initial measured residue and residue decline on maize plants were considered and on this basis the risk was concluded as low.

Several studies on fish, aquatic invertebrates, sediment-dwelling organisms, algae and higher aquatic plants were available for tembotrione, the formulated product and metabolites except M3. Aquatic plants were the most sensitive species. The risk from exposure to tembotrione was assessed as low for fish, sediment-dwelling organisms and algae with FOCUS step 1 or 2, while the risk to aquatic invertebrates (i.e. *Americamysis bahia*) and to aquatic higher tier plants (i.e. *Lemna gibba*) required the subsequent assessment with FOCUS step 3 and 4. The TERs were above the triggers for aquatic invertebrates providing that mitigation measures, comparable to a no-spray buffer zone of 20 m and in vulnerable run-off situations mitigation such as vegetated run-off buffer strips, for example up to 20 m, will be applied. Such mitigation measures were also sufficient to conclude a low risk for *Lemna*, except for the scenario R4. A risk assessment was performed for the pertinent metabolites (i.e. M6, M1, M2, M3) with endpoints for the active substance divided by 10 being used, to assess the risk from exposure to M3. TERs above the triggers were calculated for invertebrates and *Lemna*, for metabolites M6, M1, and M2 at FOCUS step 1. TERs were above the triggers for these indicator species, for metabolite M3 at FOCUS step 3.

The risk to terrestrial non-target plants was indicated as low based on deterministic risk assessment with one species, providing that the mitigation measured aimed at reducing the drift by the 90 % will be applied. Based on probabilistic risk assessment on nine species, the risk was indicated as low with a drift reduction of 50 %.

The risk to bees, non-target arthropods, earthworms, soil microorganisms and methods for sewage treatment was concluded as low.

[12] Though these simulations that were completed by the RMS utilised the older Q10 of 2.2.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
tembotrione	Low to moderate persistence. Reduced persistence at higher soil pH. Single first order DT_{50} 3.8-49.2 days (20°C, -10kPa soil moisture). Double first order in parallel DT_{50} 1.8-4.1 days (DT_{90} 27.8-105 days field studies).	Low risk
AE 0968400 (M1)	Low to moderate persistence. Single first order DT_{50} 5.8-34.8 days (20°C, -10kPa soil moisture).	Low risk
AE 1392936 (M2)	Low to moderate persistence. Single first order DT_{50} 7.4-15.6 days (20°C, -10kPa soil moisture).	Low risk
AE 0941989 (M3, from soil photolysis)	Low persistence. Single first order DT_{50} 1.1-6.2 days (20°C, -10kPa soil moisture).	Low risk
AE 0456148 (M6)	Low to medium persistence. Single first order DT_{50} 3.4-63.9 days (20°C, -10kPa soil moisture). Single first order DT_{50} 10.2-16.9 days (field studies).	Low risk

6.2. Ground water

Compound (name and/or code)	**Mobility in soil**	**>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
tembotrione	Very high to high mobility K_{Foc} 20-131 mL/g. Increased mobility at higher pH.	No	Yes	Yes	Yes
AE 0968400 (M1)	Very high to high mobility K_{Foc} 18-123 mL/g. Increased mobility at higher pH.	No	No data available, assessment not triggered.	No data available, assessment not triggered.	Low risk indicated from higher exposure expected in surface water.
AE 1392936 (M2)	Very high mobility K_{Foc} 0-0.11 mL/g.	Yes at 3 out of 8 FOCUS scenarios. The range for these 3 scenarios was 0.13 to 0.137 µg/L.	No	No (LD_{50} > 2000 mg/kg bw (rat); no genotoxic potential).	Low risk indicated from higher exposure estimated in surface water at FOCUS step 1.
AE 0941989 (M3, from soil photolysis)	Medium to low mobility K_{Foc} 400-1743 mL/g.	No	Non peer reviewed information available, but assessment not triggered.	No data available, assessment not triggered.	No data available, assessment not triggered.
AE 0456148 (M6)	Very high mobility K_{Foc} or K_{doc} 0-3.7 mL/g.	Yes at 6 out of 8 FOCUS scenarios. The concentration range for these 6 scenarios was 0.309 to 1.49 µg/L. 3 scenarios >0.75 µg/L.	No	No (LD_{50} > 2000 mg(kg bw (rat); no genotoxic potential; NOAEL 162.49 mg/kg bw per d (90-d rat)).	Low risk indicated from higher exposure estimated in surface water at FOCUS step 1.
AE 1124336 (M7)	Medium mobility K_{Foc} 201-332 mL/g.	No	No data available, assessment not triggered.	No data available, assessment not triggered.	No data available, assessment not triggered.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
tembotrione	Low risk indicated at FOCUS step 4 (i.e. mitigation measures needed for higher plants and invertebrates).
AE 0968400 (M1)	Low risk indicated at FOCUS step 1.
AE 1392936 (M2 in water but not sediment)	Low risk indicated at FOCUS step 1.
AE 0941989 (M3, from soil photolysis, input from run-off/drainage)	Low risk indicated at FOCUS step 3 when toxicity endpoints for tembotrione divided by 10 are used.
AE 0456148 (M6, input from run-off/drainage)	Low risk indicated at FOCUS step 1.

6.4. Air

Compound (name and/or code)	Toxicology
tembotrione	Not acutely toxic to rats. LC_{50}> 4.58 mg/L (4h, nose only).

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where 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 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

None.

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

- It should also be noted that the formulation has a pourability issue and appropriate labelling should be considered (see section 1).

- The estimated operator exposure is below the AOEL (35 %) when personal protective equipment (PPE) of gloves during mixing and loading, and gloves and sturdy footwear are used during application according to the German model. Worker exposure was estimated to be below the AOEL (9 %) if gloves are used (see section 2).

- No spray-drift buffer zones and vegetated buffer strips to mitigate spray drift and run-off input are necessary to protect aquatic organisms (plants and invertebrates). Drift needs to be mitigated by up to 91 % in geoclimatic situations represented by all the FOCUS scenarios. In geoclimatic situations represented by the FOCUS run-off scenarios, mitigation of solute run-off by 80 % and erosion run-off by 95 % needs to be achieved.

- Mitigation measures to reduce the drift by 50 % are necessary to protect terrestrial non-target plants.

- Using expert judgement, the occurrence of significant residues at plant back intervals shorter than 90 days was considered unlikely, but confidence is limited due to the lack of experimental data. It may be considered whether or not a plant-back restriction for plant back intervals shorter than 90 days is deemed appropriate.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where 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 of Annex VI to Directive 91/414/EEC and where 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).

No issues that could not be finalised were identified.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude 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 where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude 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.

No critical areas of concern were identified.

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

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

Representative use		Maize	Sweet corn
Operator risk	Risk identified		
	Assessment not finalised		
Worker risk	Risk identified		
	Assessment not finalised		
Bystander risk	Risk identified		
	Assessment not finalised		
Consumer risk	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial vertebrates	Risk identified		
	Assessment not finalised		
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified		
	Assessment not finalised		
Risk to aquatic organisms	Risk identified	1/8 FOCUSsw scenarios	1/8 FOCUSsw scenarios
	Assessment not finalised		
Groundwater exposure active substance	Legal parametric value breached		
	Assessment not finalised		
Groundwater exposure metabolites	Legal parametric value breached		
	Parametric value of 10µg/L[(a)] breached		
	Assessment not finalised		
Comments/Remarks			

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

Austria, 2007. Draft Assessment Report (DAR) on the active substance tembotrione prepared by the rapporteur Member State Austria in the framework of Directive 91/414/EEC, February 2007.

Austria, 2012. Final Addendum to Draft Assessment Report on tembotrione, compiled by EFSA, December 2012.

EFSA (European Food Safety Authority), 2007. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32.

EFSA (European Food Safety Authority), 2013. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance tembotrione.European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10 June 1999.

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

European Commission, 2003. Guidance Document on Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated under Council Directive 91/414/EEC. SANCO/221/2000-rev. 10 - final, 25 February 2003.

European Commission, 2004. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2009. Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC. SANCO/10597/2003 – rev. 8.1, May 2009.

European Commission, 2010. Guidance document on residue analytical methods. SANCO/825/00 rev. 8.1, 16 November 2010.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2000. FOCUS Groundwater Scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000-rev.2. 202 pp, as updated by the Generic Guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp., as updated by the Generic Guidance for FOCUS surface water scenarios, version 1.1 dated March 2012

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2007. Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

FOCUS (Forum for the co-ordination of pesticide fate models and their use), 2009. Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Workgroup, EC Document Reference SANCO/13144/2010-version.1. 604 pp, as outlined in Generic Guidance for Tier 1 FOCUS groundwater Assessment, version 2.0 dated January 2011.

JMPR (Joint Meeting on Pesticide Residues), 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

JMPR (Joint Meeting on Pesticide Residues), 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.

WHO (World Health Organization), 2011.Guidelines for drinking-water quality, fourth edition.

APPENDICES

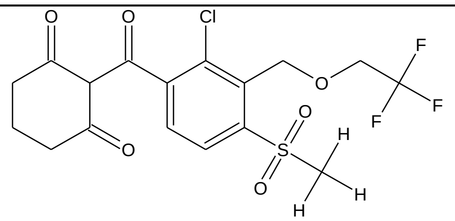
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡[13]	Tembotrione (proposed ISO common name)
Function (*e.g.* fungicide)	Herbicide

Rapporteur Member State	Austria
Co-rapporteur Member State	Not relevant

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-{2-chloro-4-mesyl-3-[(2,2,2-trifluoroethoxy)methyl]benzoyl}cyclohexane-1,3-dione
Chemical name (CA) ‡	1,3-cyclohexanedione, 2-[2-chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy) methyl]benzoyl]-
CIPAC No ‡	790
CAS No ‡	335104-84-2
EC No (EINECS or ELINCS) ‡	not allocated yet
FAO Specification (including year of publication) ‡	no FAO specification is available at the time of evaluation
Minimum purity of the active substance as manufactured ‡	945 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Toluene: max. 10 g/kg HCN: max. 1 g/kg
Molecular formula ‡	$C_{17}H_{16}ClF_3O_6S$
Molecular mass ‡	440.82 u
Structural formula ‡	

13 ‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	123 °C (989 g/kg)
Boiling point (state purity) ‡	no boiling point before decomposition (989 g/kg)
Temperature of decomposition (state purity)	decomposition starts around 150 °C (989 g/kg)
Appearance (state purity) ‡	beige powder (989 g/kg)
	beige powder (947 g/kg)
Vapour pressure (state temperature, state purity) ‡	(989 g/kg) $1.1*10^{-8}$ Pa at 20 °C $2.9*10^{-8}$ Pa at 25 °C $2.6*10^{-6}$ Pa at 50 °C
Henry's law constant ‡	$1.71*10^{-10}$ Pa.m^{3}.mol^{-1} at 20 °C: values used for calculation: vapour pressure at 20 °C: $1.1*10^{-8}$ Pa water solubility at 20 °C: 28.3 g/L
Solubility in water (state temperature, state purity and pH) ‡	all at 20 °C (989 g/kg) 0.22 g/L pH 4 (buffered solution 0.1 mol/L) all at 20 °C (993 g/kg) 71 g/L pH 7 (measured pH: 6.7) 62 g/L pH 9 (measured pH: 8.6)
Solubility in organic solvents ‡ (state temperature, state purity)	all at 20 °C (989 g/kg) Ethanol 8.2 g/L n-Hexane 47.6 mg/L Toluene 75.7 g/L Dichloromethane > 600 g/L Acetone 300 to 600 g/L Ethyl acetate 180.2 g/L DMSO > 600 g/L
Surface tension ‡ (state concentration and temperature, state purity)	(947 g/kg) 64.2 mN/m at 20 °C (90 % saturated solution)
Partition co-efficient ‡ (state temperature, pH and purity)	(989 g/kg) pH = 2 logPow = 2.16 at 23 °C pH = 7 logPow = - 1.09 at 24 °C pH = 9 logPow = - 1.37 at 23 °C
Dissociation constant (state purity) ‡	3.18 (989 g/kg)

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Concentration = 10 mg/L		(989 g/kg)
	Solution	**λmax [nm]**	**ε [L/mol x cm]**
	Neutral	203 232 284 291	31021 14224 13800 12960
	Acidic	205 231 283 291	31015 15370 14303 12937
	Basic	217 258 291	17015 22080 13415
Flammability ‡ (state purity)	Not highly flammable		(956 g/kg)
Explosive properties ‡ (state purity)	Not explosive		(956 g/kg)
Oxidising properties ‡ (state purity)	Not oxidising		(947 g/kg)

Summary of representative uses evaluated (*Tembotrione*)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min – max (l)	water L/ha min – max	kg as/ha min – max (l)		
Maize	EU	Laudis®	F	Grasses and broad leave weeds	OD	44 g/L	broadcast	BBCH 12-18	1-2 (split application)	14	0.03-0.07	150-400	0.1	>90 days	100 g ai/ha max per season; PHI corresponding to harvest at BBCH 89
Sweet Corn	EU	Laudis®	F	Grasses and broad leave weeds	OD	44 g/L	broadcast	BBCH 12-18	1-2 (split application)	14	0.03-0.07	150-400	0.1	>47 days	100 g ai/ha max per season; PHI corresponding to harvest at BBCH 79

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.2)

Technical as (analytical technique)	HPLC - UV
Impurities in technical as (analytical technique)	HPLC - UV GC / FID Karl Fischer titration Photometry
Plant protection product (analytical technique)	HPLC - UV

Analytical methods for residues (Annex IIA, point 4.3)

Residue definitions for monitoring purposes

Food of plant origin		Sum of parent tembotrione (AE 0172747) and metabolite M5 (AE 1417268), expressed as tembotrione.
Food of animal origin		Metabolite M5 (AE 1417268) only
Soil		Tembotrione (AE 0172747)
Water	surface	Tembotrione (AE 0172747)
	drinking/ground	Tembotrione (AE 0172747)
Air		Tembotrione (AE 0172747)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS 0.01 mg/kg (tembotrione) 0.01 mg/kg (M5) for tomato (water containing), maize grain (dry crops, orange (acid material) and oil seed rape (oily material)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS 0.002 mg/kg (tembotrione) for milk 0.002 mg/kg (M5) for milk 0.01 mg/kg (tembotrione) for meat, kidney, liver and egg 0.01 mg/kg (M5) for meat, kidney, liver and egg
Soil (analytical technique and LOQ)	LC-MS/MS 5 µg/kg (tembotrione)
Water (analytical technique and LOQ)	LC-MS/MS 0.05 µg/L (tembotrione)
Air (analytical technique and LOQ)	LC-MS/MS 2.1 µg/m^3 (tembotrione)
Body fluids and tissues (analytical technique and LOQ)	No method required as the active substance is not toxic or highly toxic

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	No classification is justified

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Rapid and almost completely to > 93 % (based on urinary and biliary excretion) after single oral low dose (rat study)
Distribution ‡	Widely distributed (highest residues found in liver and kidneys)
Potential for accumulation ‡	Low potential for accumulation
Rate and extent of excretion ‡	Almost completely excreted (> 93 %) within 96 hours; in males 20-35 % of radioactivity found in urine vs. 59-73 % in faeces; in females radioactivity was preferentially excreted via urine (74-84 % vs. 15-22 % in faeces)
Metabolism in animals ‡	Extensively metabolized mainly via oxidative mechanisms with the formation of hydroxyl groups on either or both rings of the molecule; some sex-related quantitative differences in metabolite profile
Toxicologically relevant compounds ‡ (animals and plants)	Parent
Toxicologically relevant compounds ‡ (environment)	Parent

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 2500 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 4.58 mg/L (4h, nose only)	
Skin irritation ‡	No skin irritation	
Eye irritation ‡	Slight eye irritation; no classification required	
Skin sensitisation ‡	Skin sensitizer (M & K test)	R43

Short term toxicity (Annex IIA, point 5.3)

Target/critical effect ‡	Rats, mice and dogs: Eyes (corneal effects), liver (organ weight, clinical chemistry, histological alterations)	
Relevant oral NOAEL ‡	0.07 mg/kg bw per day (90-day rat) 64 mg/kg bw per day (90-day mouse) 9 mg/kg bw per day (1 year dog)	
Relevant dermal NOAEL ‡	<50 mg/kg bw per day (28-day rat) (LOAEL)	

Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No evidence of a genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat: Eyes (corneal effects), liver (organ weight, clinical chemistry, histological alterations), kidneys and thyroid (histological alterations) Mice: Liver (organ weight, clinical chemistry, histological alterations), gall bladder stones	
Relevant NOAEL ‡	0.04 [♂] mg/kg bw per day (2 year rat) 0.1 [♀] mg/kg bw per day (2 year rat) <4,3 mg/kg bw per day (18 month mice) (LOAEL)	
Carcinogenicity ‡	squamous cell carcinoma of the cornea in male rats at 200 and 800 ppm; likely not relevant for humans	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: eye lesions, organ weight changes (liver, kidney, thymus, testes) Reproductive: no effects Offspring: eye lesions, organ weight changes, dilated renal pelvis	
Relevant parental NOAEL ‡	<1.3 mg/kg bw per day = LOAEL	
Relevant reproductive NOAEL ‡	98.2 mg/kg bw per day	
Relevant offspring NOAEL ‡	<1.3 mg/kg bw per day = LOAEL	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: lower body weight gain, clinical signs Fetal: delayed ossification, increased incidence of anomalies;	
Relevant maternal NOAEL ‡	<25 mg/kg bw per day (rat) = LOAEL 1 mg/kg bw per day (rabbit)	
Relevant developmental NOAEL ‡	<25 mg/kg bw per day (rat) = LOAEL 1 mg/kg bw per day (rabbit) Mortality in the dams at the highest dose level in the rabbit developmental study (100 mg/kg bw per day)	R48 /22

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	acute neurotoxic NOAEL 200 mg/kg bw (rat)	
Repeated neurotoxicity ‡	No signs of neurotoxicity up to 160 mg/kg bw per day (90 day rat). NOAEL established at 16.4 mg/kg bw per day (males) based on reduced bodyweight and food consumption.	
Developmental neurotoxicity ‡	Decrease in acoustic startle response NOAEL 0.8 mg/kg bw per day (parental and developmental)	

Other toxicological studies (Annex IIA, point 5.8 and 5.10)

Mechanism studies ‡	Tembotrione inhibits the enzyme 4-hydroxy-phenylpyruvate dioxygenase (HPPDase) resulting in species-specific tyrosinaemia in rats producing ocular and liver effects
Studies performed on metabolites or impurities‡	M2 (soil and plant metabolite): LD_{50} > 2000 mg/kg bw (rat) no genotoxic potential M5 (plant metabolite): ADME study (5mg/kg bw, rat) LD_{50} > 2000 mg/kg bw (rat) no genotoxic potential NOAEL 12.7 mg/kg bw per day (90 day rat) M6 (soil metabolite): LD50 > 2000 mg(kg bw (rat) no genotoxic potential NOAEL 162.49 mg/kg bw per day (90-day rat) M1 (soil metabolite): no data
	Metabolites M2, M5, and M6 are considered to be of lower toxicity than the parent based on the data available and are thus not of toxicological relevance

Medical data ‡ (Annex IIA, point 5.9)

Limited information – new substance

Summary (Annex IIA, point 5.11)	Value	Study	Safety factor
Parent			
ADI ‡	0.0004 mg/kg bw per day	Chronic toxicity study in rats	100
AOEL ‡	0.0007 mg/kg bw per day	Sub chronic/chronic toxicity study in rats	100
ARfD ‡	0.1 mg/kg bw	Rabbit developmental study (NOAEL for maternal mortality)	100
Metabolites			
ADI ‡	M5: 0.013 mg/kg bw per day	90-day rats	1000
	M6: 0.2 mg/kg bw per day	90-day rats	1000
AOEL ‡	Not required		
ARfD ‡	M5: 0.1 mg/kg bw	Rabbit developmental study of the parent	100

Dermal absorption ‡ (Annex IIIA, point 7.6)

Formulation (AE 0172747 02 OD06 A105)	2 % for the concentrate and 5 % for the spray dilution (based on *in vivo* study in rat and comparative *in vitro* rat skin human skin)

Exposure scenarios (Annex IIIA, point 7.3, 7.4 and 7.5)

Operator	Field application (100 g a.s./ha) POEM (no PPE) 3745 % of AOEL POEM (with PPE) 632 % of AOEL BBA (no PPE) 598 % of AOEL BBA (with PPE) 35 % of AOEL
Workers	Worker: not relevant – no re-entry anticipated Crop inspection: 9 % of the AOEL (with PPE)
Bystanders	17.5 % of the AOEL (according to Lloyd and Bell)

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 9)

Substance classified	Tembotrione

Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	No harmonised classification and labelling
Peer review proposal*	Under Council Directive 67/548/EEC14 Xn; R43, R48/22 Under Regulation (EC) No 1272/2008)15 Skin Sens. 1 (H317) STOT RE 2 (H373)

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

[14] OJ No 196, 16.08.1967, p. 001-0098
[15] OJ No L 353, 31.12.2008, p. 0001-1355

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Cereals (maize)
Rotational crops	Swiss Chard, turnips, wheat, mustard greens, summer squash
Metabolism in rotational crops similar to metabolism in primary crops?	Similar: In **primary crops**, the parent compound was rapidly metabolised via stepwise hydroxylation at the cyclohexane dione ring. The mono-hydroxylated parent compound (M10) was formed initially followed up by a second oxidative step in the 6-position to form the -4,6-dihydroxy metabolite (M5) immediately after treatment. In a next step, the cleavage of the hydroxylated cyclohexane dione ring resulted in the formation of AE 0172747-benzoic acid (M6). As a minor route, the cleavage of the ether bond in M6 was observed to result in the AE 0172747-carboxy benzylic alcohol (M2). This minor route is similar to metabolism in **rotational crops**: The metabolic profile of [U-14C-phenyl]-AE 0172747 in confined rotational crops involved cleavage of the complete cyclohexyl moiety from the parent compound leaving the benzoic acid moiety of the molecule AE 0456148 (M6) and to a lesser extent subsequent cleavage of the ether bond to form AE 1392936 (M2).
Processed commodities	Field corn was processed to: flour, grits, meal, starch and oil, silage
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Similar.
Plant residue definition for monitoring	Sum of parent tembotrione (AE 0172747) and metabolite M5 (AE 1417268), expressed as tembotrione.
Plant residue definition for risk assessment	Sum of parent tembotrione (AE 0172747) and metabolite M5 (AE 1417268), expressed as tembotrione. Toxicity equivalence factor 0.0308 for residues of M5 (AE 1417268) to be applied in chronic risk assessment
Conversion factor (monitoring to risk assessment)	None.

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Laying hen, lactating cow

Time needed to reach a plateau concentration in milk and eggs	**Milk**: In the [Phenyl UL-14C-]-label dosed cows the concentrations of radioactive residues in the milk were below the LOQ at all collections. In the [Cyclohexyl UL-14C-]-label dosed cows negligible concentrations of radioactivity were detected in milk and steady state conditions were achieved within 48 h. **Eggs**: The concentration of radioactivity in egg yolks was above the limit of quantification at all time points after day 2 and started to plateau by day 7.
Animal residue definition for monitoring	M5 (AE 1417268), only.
Animal residue definition for risk assessment	M5 (AE 1417268), only.
Conversion factor (monitoring to risk assessment)	None.
Metabolism in rat and ruminant similar (yes/no)	Yes.
Fat soluble residue: (yes/no)	No. ($logP_{ow}$ = - 1.09 at pH =7)

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	Field tests in succeeding crops: Following one foliar spray and one directed application (7±2 day interval) of AE 0172747 to corn at a mean total rate 0.185 kg ai/ha, the total residue [sum of tembotrione (AE 0172747) plus metabolites AE 1417268 (M5), AE 0456148 (M6) and AE 1392936 (M2)] was <0.010 mg/kg (LOQ) in the RACs of mustard greens, turnips, summer squash and wheat grown as rotational crops at a plant back interval (PBI) of 90 to 120-days. These data support a 90-day plant-back interval for leafy vegetable crops, root crops, cucurbit crops, and cereal grain crops after the use of AE 0172747 on corn. Using expert judgement, as for the representative uses in maize and sweet corn, significant residue levels in succeeding crops were considered unlikely at a shorter PBI of 30 days, however experimental data are not available for plant back intervals shorter than 90 days.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

	Residues of AE 0172747 (**tembotrione**), AE 0456148 (**M6**) and AE 1392936 (**M2**) in corn grain, forage and fodder were stable during frozen storage at ≤-10 °C for at least **28 months** (861days). Metabolite AE 1417268 (M5) is stable in corn grain and corn forage for at least 16 months. Residues of AE 0172747, AE 0456148 (M6), AE 1392936 (M2) and AE 1417268 (M5) in turnip roots, yellow squash and mustard greens were stable during frozen storage at ≤-10 °C for at least 12 months (350 days).

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes; for metabolite M5 (AE 1417268): 1.1 mg M5/kg diet	No.	Yes; for metabolite M5 (AE 1417268): 0.17 mg M5/kg diet
Potential for accumulation (yes/no):	No.	No.	---
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No.	No.	---
	Feeding studies with M5 at the dose rate of 0.5 mg a.i./kg dry feed (corresponding to 10 mg M5/550 kg/day) ** Residue levels in matrices : Mean (max)[mg/kg]		
Muscle	Not detected (<0.001)	---	---
Liver	0.015 (0.017)	---	---
Kidney	0.032 (0.036)	---	---
Fat	Not detected (<0.001)	---	---
Milk	Not detected (<0.001)		
Eggs		---	

** In addendum 3 to B.7 the dietary burden calculations were based on the HR of 0.26 mg M5/kg found in a field trial for silage processing. This value was reliable regarding the storage period. A processing factor of 0.85 could be estimated for silage.

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Maize/corn	N, field use	9 x <0.02	According to proposed residue definition; parent tembotrione and metabolite M5 below their LOQs of <0.01 mg/kg each.	0.02*	<0.02	<0.02
Maize/corn	S, field use	9 x <0.02		0.02*	<0.02	<0.02
Sweet corn	N, field use	4 x <0.02		0.02*	<0.02	<0.02
Sweet corn	S, field use	4 x <0.02		0.02*	<0.02	<0.02
With respect to animal intake						
Maize/corn	N, field use, fodder: 78-90 days after application	Metabolite M5: 4 x <0.01; 1 x 0.01; 1 x 0.02; 1 x 0.06, 1 x 0.26 Parent tembotrione: 7 x <0.01	Results given separately with respect to the feeding study which was conducted by dosing the metabolite M5 to lactating cows.	---	Metabolite M5: 0.26 Parent tembotrione: <0.01	Metabolite M5: <0.01 Parent tembotrione: <0.01
Maize/corn	S, field use, fodder: 80-90 days after application	Metabolite M5: 5 x <0.01; 1 x 0.02; Parent tembotrione: 6 x <0.01		---	Metabolite M5: 0.02 Parent tembotrione: <0.01	Metabolite M5: <0.01 Parent tembotrione: <0.01

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.0004 mg/kg bw per day	
TMDI (% ADI) according Primo, rev.2	6.9%(WHO Cluster Diet B)	
TMDI (% ADI) according to Primo, rev.2	6.4% (IE adult), 3.4% (UK infant)	
IEDI (WHO European Diet) (% ADI)		
NEDI (specify diet) (% ADI)		
Factors included in IEDI and NEDI		
ARfD	0.1 mg/kg bw	
IESTI (% ARfD): According to Primo, rev.2	1.5	Sweet corn
	1.2	Bovine liver
	0.2	Milk and milk products, cattle
	0.2	Bovine kidney
	0.1	Maize
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not relevant. See IESTI.	
Factors included in IESTI and NESTI	Not relevant.	

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) *)
		Transfer factor	Yield factor	
Whole corn grain/milling/grits (large)	1	0.98	Not necessary	16.72
Whole corn grain/milling/meal	1	1.12	Not necessary	3.29
Whole corn grain/milling/flour	1	0.87	Not necessary	3.85
Whole corn grain/dry milling/refined oil	1	0.01	Not necessary	0.01
Whole corn grain/wet milling/starch	1	0.05	Not necessary	1.13
Whole corn grain/wet milling/refined oil	1	0.01	Not necessary	0.01
Green plant material/silage	1	0.85	Not necessary	83.5

*) Total transference does not result in 100%. Sub-specimens of intermediate fractions were not analysed for tembotrione residues (steepwater, hull, germ presscake, soapstock, etc.)

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Maize/Corn *	0.02
Sweet Corn *	0.02
Bovine Liver **	0.15
Bovine Kidney **	0.04
Swine liver, kidney **	0.02
Milk **	0.002*
Bovine meat, fat; Swine meat, fat **	0.01*

*Residues expressed in mg tembotrione /kg according to the residue definition
** Residues expressed in mg M5 /kg according to the residue definition
When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	20.1 – 55.2 % AR after 120 d [^{14}C-phenyl]-label (n = 4) 13.2 – 50.8 % AR after 91 d [^{14}C-phenyl]-label (n = 2) 77.3 % AR after 120 d [^{14}C-cyclohexyl]-label (n = 1) 37.4 % AR after 91 d [^{14}C-cyclohexyl]-label (n = 1)
Non-extractable residues after 100 days ‡	17.6 – 39.4 % AR after 120 d [^{14}C-phenyl]-label (n = 4) 16.6 – 28.3 % AR after 91 d [^{14}C-phenyl]-label (n = 2) 18.9 % AR after 120 d [^{14}C-cyclohexyl]-label (n = 1) 16.7 % AR after 91 d [^{14}C-cyclohexyl]-label (n = 1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	**Note:** Minimum/maximum values are given as arithmetic mean values of replicates and/or labels **Soil risk assessment:** M6 (AE 0456148): 19.7 – 72.4 % AR (n = 6); maximum by 7, 14, 21, 30 or 270 days M1 (AE 0968400): 1.4 – 14.9 % AR (n = 6); maximum by 4, 30, 35, 120 or 179 days **Groundwater risk assessment:** M6 (AE 0456148): 19.7 – 72.4 % AR (n = 6); maximum by 7, 14, 21, 30 or 270 days M1 (AE 0968400): 1.4 – 14.9 % AR (n = 6); maximum by 4, 30, 35, 120 or 179 days M7 (AE 1124336): 0.3 –7.1 % of AR (n = 6); maximum by 30, 35, 42, 56 or 120 days M2 (AE 1392936): 3.5 – 4.2 % AR (n = 2); maximum by 14 or 179 days **Note:** Metabolite M2 (AE 1392936) was found > 10 % of AR in one soil only towards study end (from 270 DAT onwards, maximum 17.1 % of AR) when the microbial activity of this soil had almost ceased. M2 (AE 1392936) was not observed > 5 % of AR in any other laboratory degradation study and was not detected in the field > LOD.

Route of degradation in soil – Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	
Mineralization after 100 days	Negligible after 120 d [^{14}C-phenyl]-label (n = 1) Negligible after 120 d [^{14}C-cyclohexyl]-label (n = 1) Sterile conditions: No degradation
Non-extractable residues after 100 days	12.6 % after 120 d [^{14}C-phenyl]-label (n = 1) 22.9 % after 120 d [^{14}C-cyclohexyl]-label (n = 1) **Note:** Amount of NER at onset of the anaerobic phase (by 5 DAT) 3.5 and 16.1 % of AR, respectively
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	None (no further metabolite formation after ‘aging’ period)
Soil photolysis ‡	
Metabolites that may require further consideration	**Note:** Minimum/maximum values are given as arithmetic

for risk assessment – name and/or code, % of applied (range and maximum)	mean values of replicates and/or labels M6 (AE 0456148): 22.0 % AR (n = 1) M3 (AE 0941989): 15.9 % AR (n = 1)

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Tembotrione (AE 0172747)	Aerobic conditions						
Soil type (in order of increasing pH)	Label[a]	pH (H_2O)	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[c]	Chi[2] error (%)	Method of calculation
Loamy sand	Ph	5.9	20 °C, 45 % MWHC	49.2 / 163	49.2	9.5	SFO
Loamy sand	Ph, Cy-He	6.3	25 °C, 75 % pF2.5	30 / 262 -	- 87.2	2.4	DFOP SFO (DFOP, k_2)[b]
Sandy loam	Ph	7.4	20 °C, 45 % MWHC	14.8 / 49.0	12.9	9.1	SFO
Silt loam	Ph	7.6	25 °C, 75 % pF2.5	6.6 / 21.9	7.1	11.0	SFO
Silt loam	Ph, Cy-He	7.7	20 °C, 45 % MWHC	4.3 / 14.2	4.2	4.5	SFO
Clay	Ph	8.2	20 °C, 45 % MWHC	5.7 / 18.9	3.8	12.4	SFO
Geometric mean				na (15.2) / na (50.2)	6)	-	-
Silt loam	Ph	7.7	10 °C, 45 % MWHC	14.5 / 48.2	-	-	SFO

na denotes not applicable owing to pH dependence (number in brackets indicate geometric mean if pH dependence is not taken into account)

[a] Labels used as replicates in case of two labels,

[b] Degradation rate of slower DFOP compartment (k_2) used as conservative approach

[c] Q_{10} = 2.58, Walker equation coefficient 0.7

M6 (AE 0456148)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from parent)	DT_{50} (d) 20 °C pF2/ 10kPa[c]	Chi[2] error (%)	Method of calculation
Loamy sand	Ph	5.9	20 °C, 45 % MWHC	11.5 / 38.3	1.000	11.5	24.4	SFO (MCM)[b]
Sandy loam	Ph	7.4	20 °C, 45 % MWHC	73.0 / 242	1.000	63.9	8.3	SFO (MCM)[b]
Silt loam	Ph	7.6	25 °C, 75 % pF2.5	6.0 / 19.8	0.741	6.5	32.2	SFO (MCM)[b]
Silt loam	Ph	7.7	20 °C, 45 % MWHC	14.5 / 48.1	1.000	14.1	20.7	SFO (MCM)[b]
Clay	Ph	8.2	20 °C, 45 % MWHC	5.1 / 17.1	1.000	3.4	24.3	SFO (MCM)[b]
Geometric mean **Arithmetic mean**				**13.0 / 43.2** **- / -**	**-** **0.851**	**11.8** **-**	**-**	**-**

[a] Parent label

[b] Multi-compartment model (all SFO)

[c] Q_{10} = 2.58, Walker equation coefficient 0.7

M1 (AE 0968400)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from M6)	DT_{50} (d) 20 °C pF2/10kPa[e]	Chi[2] error (%)	Method of calculation
Sandy loam	Ph	7.4	20 °C, 45 % MWHC	39.8 / 132	0.310	34.8	10.2	SFO (MCM)[b]
Silt loam	Ph	7.7	20 °C, 45 % MWHC	11.9 / 39.6	0.362	11.6	39.1	SFO (MCM)[b]

M1 (AE 0968400)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from M6)	DT_{50} (d) 20 °C pF2/10kPa[e]	Chi^2 error (%)	Method of calculation
Clay	Ph	8.2	20 °C, 45 % MWHC	38.1 / 127	0.178	25.5	28.4	SFO (MCM)[b]
Sand	Ph	6.6	20 °C, 55 % MWHC	9.1 / 30.2	na[d]	9.1	4.7	SFO[c]
Silt loam	Ph	6.6	20 °C, 55 % MWHC	5.8 / 19.3	na[d]	5.8	5.2	SFO[c]
Loam	Ph	5.7	20 °C, 55 % MWHC	6.8 / 22.6	na[d]	6.8	5.9	SFO[c]
Loam	Ph	7.4	20 °C, 55 % MWHC	5.9 / 19.6	na[d]	5.9	5.4	SFO[c]
Geometric mean Arithmetic mean				**12.1 / 40.3** - / -	**-** **0.283**	**11.2** -		

[a] L denotes parent label

[b] MCM denotes multi-compartment model (all SFO), tembotrione applied as parent

[c] metabolite M1 (AE 0968400) applied as parent

[d] na denotes not applicable (metabolite applied as parent)

[e] Walker equation coefficient 0.7

M2 (AE 1392936)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from M6)	DT_{50} (d) 20 °C pF2/ 10kPa[c]	Chi^2 error (%)	Method of calculation
Sandy loam	-	7.5	20 °C, 50 % MWHC	15.6 / 51.9	-	15.6	7.0	SFO
Clay loam	-	7.9	20 °C, 55 % MWHC	11.7 / 38.7	-	10.6	5.3	SFO
Silt loam	Ph	8.2	25 °C, 75 % pF2.5	- / -	0.147	-	18.0	SFO (MCM)[b]
Clay loam	-	8.3	20 °C, 50 % MWHC	7.9 / 26.2	-	7.4	5.7	SFO
Geometric mean **Arithmetic mean**				**11.3 / 37.5** **- / -**	**-** **0.147**	**10.7** **-**		

[a] L denotes parent label

[b] MCM denotes multi-compartment model (all SFO)

[c]Walker equation coefficient 0.7

M7 (AE 1124336)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from M1)	DT_{50} (d) 20 °C pF2/10kPa[d]	Chi² error (%)	Method of calculation
Clay	Ph	8.2	20 °C, 45 % MWHC	26.2 / 86.9	1.000	17.5	16.6	SFO (MCM)[b]
Sand	Ph	6.6	20 °C, 55 % MWHC	23.7 / 78.7	0.36	23.7	11.0	SFO (MCM)[c]
Silt loam	Ph	6.6	20 °C, 55 % MWHC	9.2 / 30.5	0.35	9.2	18.5	SFO (MCM)[c]
Loam	Ph	5.7	20 °C, 55 % MWHC	19.1 / 63.4	0.21	19.1	16.2	SFO (MCM)[c]
Loam	Ph	7.4	20 °C, 55 % MWHC	4.0 / 13.3	0.35	4.0	35.0	SFO (MCM)[c]
Geometric mean **Arithmetic mean**				**13.4 / 44.6** **-**	**-** **0.46**	**12.4** **-**	**-** **-**	**-** **-**

[a] L denotes parent label

[b] MCM denotes multi-compartment model (all SFO), tembotrione as parent

[c] MCM denotes multi-compartment model (all SFO), metabolite M1 (AE 0968400) applied as parent

[d] Walker equation coefficient 0.7

M3 (AE 0941989)	Aerobic conditions							
Soil type (in order of increasing pH)	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. (from P)	DT_{50} (d) 20 °C pF2/ 10kPa[e]	Chi² error (%)	Method of calculation
Loamy sand[b]	Ph	5.3	20 °C, 75 % 1/3 bar	5.2 / 17.3	0.535	3.3	5.5	SFO (MCM)[c]
Loamy sand[b]	Cy-He	5.3	20 °C, 75 % 1/3 bar	9.8 / 32.5	0.507	6.2	11.3	SFO (MCM)[c]
Sandy loam	-	7.3	20 °C, 40 % MWHC	1.1 / 3.6	-	1.1	11.5	SFO
Clay loam	-	7.5	20 °C, 53 % MWHC	1.3 / 4.3	-	1.3	8.3	SFO
Clay loam	-	7.9	20 °C, 45 % MWHC	1.1 / 3.5	-	1.1	19.0	SFO
Overall geometric mean[d] **Arithmetic mean**				**1.8 / 6.0** **- / -**	**-** **0.521**	**1.6** **-**		

[a] L denotes parent label

[b] Additional degradation data from soil photolysis (irradiated samples)

[c] MCM denotes multi-compartment model (parent FOMC, metabolite SFO)

[d] Results of the two labels of the Pikeville soil (loamy sand, pH 5.3) were averaged by geometric mean before averaging all soils

[e] Walker equation coefficient 0.7

Field studies ‡

Tembotrione (AE 0172747)	Aerobic conditions (non-normalized)							
Soil type (crop) (in order of increasing pH)	Location	pH (H_2O)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Chi^2 error (%)	DT_{50} (d) norm.	Method of calculation
Loam (grass)	Germany	5.6	0 – 30	2.9	57.0	7.7	ns	DFOP
Loam (grass)	Spain	6.4	0 – 30	4.1	105	8.7	ns	DFOP
Sandy loam (grass)	Germany	6.9	0 – 30	1.8	27.8	4.7	ns	DFOP
Silt loam (grass)	Northern France	7.1	0 – 30	2.0	47.2	5.5	ns	DFOP
Silty clay (grass)	Italy	8.1	0 – 30	2.4	32.0	5.2	ns	DFOP
Sandy loam (grass)	Great Britain	8.1	0 – 30	3.1	32.4	12.1	ns	DFOP

Tembotrione (AE 0172747)	Aerobic conditions (non-normalized) – cont'd								
Soil type (crop) (in order of increasing pH)	Location	pH (H_2O)	Depth (cm)	DT_{50} (d) k_1	DT_{50} (d) k_2	k_1 (d^{-1})	k_2 (d^{-1})	$g(k_1)$ (-)	Method of calculation
Loam (grass)	Germany	5.6	0 – 30	1.5	32.4	0.45	0.021	0.664	DFOP
Loam (grass)	Spain	6.4	0 – 30	2.1	58.3	0.32	0.012	0.653	DFOP
Sandy loam (grass)	Germany	6.9	0 – 30	0.6	12.4	1.1	0.056	0.526	DFOP
Silt loam (grass)	Northern France	7.1	0 – 30	1.0	25.3	0.70	0.027	0.634	DFOP
Silty clay (grass)	Italy	8.1	0 – 30	0.4	12.9	1.60	0.054	0.444	DFOP
Sandy loam (grass)	Great Britain	8.1	0 – 30	0.9	13.3	0.80	0.052	0.459	DFOP
Worst case	**Spain**			**2.1**	**58.3**	**0.32**	**0.012**	**0.653**	**DFOP**

Tembotrione (AE 0172747)	Aerobic conditions (normalized to 20 °C and pF2, time-step normalization, $\mathbf{Q_{10} = 2.58}$, Walker equation coefficient 0.7)								
Soil type (crop) (in order of increasing pH)	Loc.	pH (H_2O)	Depth (cm)	DFOP-DT_{50}/DT_{90} (d) norm.	SFO-DT_{50} (d) norm., **rapid** DFOP compart-ment	SFO-DT_{50} (d) norm., **slow** DFOP compart-ment	$g(k_1)$ (0 .. 1)	Chi^2 error (%)	Method of calcu-lation
Loam (grass)	DE	5.6	0 – 30	2.0 / 36.4	1.2	23.8	0.71	9.5	DFOP
Loam (grass)	SP	6.4	0 – 30	2.8 / 71.4	1.2	37.1	0.62	9.6	DFOP
Sandy loam (grass)	DE	6.9	0 – 30	1.2 / 14.4	0.2	5.7	0.43	7.3	DFOP
Silt loam (grass)	FR	7.1	0 – 30	1.3 / 21.5	0.6	10.4	0.58	9.2	DFOP
Silty clay (grass)	I	8.1	0 – 30	3.3 / 26.8	0.1	10.2	0.38	10.9	DFOP

Tembotrione (AE 0172747)	Aerobic conditions (normalized to 20 °C and pF2, time-step normalization, **Q_{10} = 2.58**, Walker equation coefficient 0.7)								
Soil type (crop) (in order of increasing pH)	Loc.	pH (H_2O)	Depth (cm)	DFOP-DT_{50}/DT_{90} (d) norm.	SFO-DT_{50} (d) norm., **rapid** DFOP compart-ment	SFO-DT_{50} (d) norm., **slow** DFOP compart-ment	g(k_1) (0 .. 1)	Chi^2 error (%)	Method of calcu-lation
Sandy loam (grass)	UK	8.1	0 – 30	2.6 / 16.7	0.2	6.1	0.33	12.5	DFOP
Geometric mean					**na** (0.4)	**na** (12.2)	-	-	-
Arithmetic mean					-	-	**na** (0.51)	-	-

na denotes not applicable owing to pH dependence (number in brackets indicate geometric/arithmetic mean if pH dependence is not taken into account), the following linear regressions were used to derive FOCUS scenario specific endpoints for PEC_{GW} and PEC_{SW}:

- Rapid DFOP compartment: Norm. SFO-$DegT_{50}$ (d) = -0.433 · pH(H_2O) + 3.64, min/max: 0.11/1.23
- Slow DFOP compartment: Norm. SFO-$DegT_{50}$ (d) = -8.27 · pH(H_2O) + 73.7, min/max: 6.4/27.8
- g(k_1) (0 .. 1) = -0.140 · pH(H_2O) + 1.49, min/max: 0.35/0.71

M6 (AE 0456148)	Aerobic conditions (non-normalized)								
Soil type (crop) (in order of increasing pH)	Loc.	pH (H_2O)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Chi^2 error (%)	DT_{50} (d) norm.	f. f. (from parent)	Method of calculation
Loam (grass)	DE	5.6	0 – 30	10.2	34.0	13.0	ns	na	SFO[a]
Loam (grass)	SP	6.4	0 – 30	98.8[b]	328[b]	27.6	ns	na	SFO[a]
Sandy loam (grass)	DE	6.9	0 – 30	13.9	46.3	8.4	ns	na	SFO[a]
Silt loam (grass)	FR	7.1	0 – 30	15.8	52.6	23.1	ns	na	SFO[a]
Silty clay (grass)	I	8.1	0 – 30	14.0	46.6	26.8	ns	na	SFO[a]
Sandy loam (grass)	UK	8.1	0 – 30	16.9	56.2	10.7	ns	na	SFO[a]
Worst case				**16.9**	**56.2**	-	**ns**	-	-

na denotes not applicable
ns denoted not shown here, refer to table below
[a] SFO starting from maximum occurrence
[b] Not reliable owing to low statistical significance (t-test)

M6 (AE 0456148)	Aerobic conditions (normalized to 20 °C and pF2, time step normalization, **Q_{10} = 2.58**, Walker equation coefficient 0.7)								
Soil type (crop) (in order of increasing pH)	Location	pH (H_2O)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	DT_{50} (d) norm.	Chi^2 error (%)	f. f. (from parent)	Method of calculation
Loam (grass)	DE	5.6	0 – 30	nc	nc	14.7[a]	62.3	0.13	$P_{DFOP} \rightarrow M_{SFO}$
Sandy loam (grass)	SP	6.4	0 – 30	nc	nc	69.8	30.5	0.37	$P_{DFOP} \rightarrow M_{SFO}$
Loam (grass)	DE	6.9	0 – 30	nc	nc	12.3	23.7	0.50	$P_{DFOP} \rightarrow M_{SFO}$
Silty clay (grass)	FR	7.1	0 – 30	nc	nc	13.0	21.1	0.71	$P_{DFOP} \rightarrow M_{SFO}$

M6 (AE 0456148)	Aerobic conditions (normalized to 20 °C and pF2, time step normalization, Q_{10} **= 2.58**, Walker equation coefficient 0.7)								
Soil type (crop) (in order of increasing pH)	Location	pH (H_2O)	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	DT_{50} (d) norm.	Chi^2 error (%)	f. f. (from parent)	Method of calculation
Silt loam (grass)	I	8.1	0 – 30	nc	nc	17.7	24.4	1.00	P_{DFOP} → M_{SFO}
Sandy loam (grass)	UK	8.1	0 – 30	nc	nc	9.2	24.1	0.79	P_{DFOP} → M_{SFO}
Geometric mean **Arithmetic mean**				- -	- -	**17.9** -	- -	- **na** (0.58)	

na denotes not applicable owing to pH dependence (number in brackets indicates arithmetic mean if pH dependence is not taken into account), the following linear regression was used to derive FOCUS scenario specific endpoints for PEC_{GW} and PEC_{SW}:

ff (0 .. 1) = 0.303 · pH(H_2O) – 1.55, min/max: 0.14/0.91

[a] Not reliable owing to low statistical significance (t-test), not included into geometric mean

pH dependence ‡ (yes / no) (if yes type of dependence)	Tembotrione (AE 0172747): Slower degradation in acidic soils (lab and field) M6 (AE 0456148): Lower formation fraction observed in acidic soils in the field
Soil accumulation and plateau concentration ‡	Not expected to occur

Laboratory studies ‡

Tembotrione (AE 0172747)	Anaerobic conditions						
Soil type	L[a]	pH (H_2O)	t. °C / % MWHC	$DegT_{50}$ / $DegT_{90}$ (d)	$DegT_{50}$ (d) 20 °C pF2/ 10kPa	Chi^2 error (%)	Method of calculation
Silt loam	Ph	8.3	20 °C / water logged	257 / 853	-	5.8	SFO
Silt loam	Cy-He	8.3	20 °C / water logged	301 / 1000	-	3.1	SFO
Geometric mean				**278 / 924**	**-**		
Tembotrione (AE 017274)	Soil photolysis (net, converted to environmental midsummer days, Athens, Greece, EU, 38 °N)						
Soil type	L[a]	pH (H_2O)	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/ 10kPa	Chi^2 error (%)	Method of calculation
Loamy sand	Ph	5.3	20 °C / 75 % 1/3 bar	4.1 / 13.4	-	3.0	SFO (DFOP, k_1)[b]
Loamy sand	Cy-He	5.3	20 °C / 75 % 1/3 bar	3.5 / 11.8	-	2.8	SFO (DFOP, k_1)[b]
Geometric mean				**3.8 / 12.6**	**-**		

[a] L denotes parent label

[b] Rapidly dissipating compartment (k_1) of DFOP kinetics considered to represent fraction of test item exposed to irradiation

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Tembotrione ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.8	5.6	-	-	3.62	131	0.899
Loamy sand	1.6	6.3	-	-	2.09	130	0.922
Sandy loam	1.3	7.4	-	-	0.35	27	0.892
Silt loam	4.5	7.6	-	-	2.40	53	0.977
Silt loam	1.7	7.7	-	-	0.54	32	0.882
Clay	2.5	7.8	-	-	0.51	20	0.871
Arithmetic mean						**na** (66)	**0.907**
pH dependence, Yes or No			Yes				

na denotes not applicable owing to pH dependence (the number in brackets indicates arithmetic mean if pH dependence is not taken into account), the following linear regression was used to derive FOCUS scenario specific endpoints for PEC_{GW} and PEC_{SW}: Kfoc (mL/g) = -53.7 · pH(H_2O) + 445, min/max: 26.2/144

M6 (AE 0456148) ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd[a] (mL/g)	Koc[a] (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.5	6.6	0.006	0.4	0.01	0.7	0.985
Sandy loam	1.0	6.7	0.043	4.3	0.04	3.6	0.963
Sandy loam	1.1	6.9	0.043	3.9	0.04	3.7	0.944
Silt loam	4.0	7.4	0.063	1.6	-[b]	1.6[c]	1.000[d]
Silt loam	1.5	7.4	0.000	0.0	-[b]	0.0[c]	1.000[d]
Arithmetic mean			**-**	**2.0**	**-**	**1.9**	**0.978**
pH dependence (yes or no)			No				

[a] Based on highest test item concentration (1 mg L^{-1})

[b] Not reliable

[c] Koc value based on highest test item concentration used together with a PRAPeR 32 agreed 1/n default value of 1.0

[d] PRAReR 32 agreed default value

M1 (AE 0968400) ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.5	6.6	-	-	1.03	69	0.787
Sandy loam	1.0	6.7	-	-	1.23	123	0.787
Sandy loam	1.1	6.9	-	-	1.04	94	0.823
Silt loam	4.0	7.4	-	-	1.00	25	0.708
Silt loam	1.5	7.4	-	-	0.27	18	0.728

Arithmetic mean	-	**na** (66)	**0.767**
pH dependence (yes or no)	Yes		

na denotes not applicable owing to pH dependence (the number in brackets indicates arithmetic mean if pH dependence is not taken into account), the following linear regression was used to derive FOCUS scenario specific endpoints for PEC_{GW} and PEC_{SW}: Kfoc (mL/g) = -97.6 · pH(H_2O) + 749, min/max: 26.8/105

M2 (AE 1392936) ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.6	6.6	-	-	0.002	0.11	0.953
Sand loam	1.7	7.5	-	-	0.000	0.00	1.000[a]
Clay loam	2.1	7.9	-	-	0.000	0.00	1.000[a]
Clay loam	2.5	8.3	-	-	0.000	0.00	1.000[a]
Arithmetic mean					**-**	**0.03**	**0.988**
pH dependence (yes or no)			No				

[a] PRAPeR 32 agreed default value

M7 (AE 1124336) ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.5	6.6	-	-	3.4	227	0.873
Sandy loam	1.0	6.7	-	-	3.1	310	0.834
Sandy loam	1.1	6.9	-	-	3.5	317	0.804
Silt loam	4.0	7.4	-	-	13.3	332	0.886
Silt loam	1.5	7.4	-	-	3.0	201	0.903
Arithmetic mean					**-**	**278**	**0.860**
pH dependence (yes or no)			No				

M3 (AE 0941989) ‡							
Soil Type (in order of increasing pH)	OC %	Soil pH (H_2O)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.6	6.6	-	-	6.8	423	1.002
Sandy loam	1.7	7.5	-	-	6.8	400	0.933
Clay loam	2.1	7.9	-	-	36.6	1743	1.020
Clay loam	2.5	8.3	-	-	23.6	944	1.032
Arithmetic mean					**-**	**878**	**0.997**
pH dependence (yes or no)			No				

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	Not studied - no data requested
Aged residues leaching ‡	Not studied - no data requested
Lysimeter/ field leaching studies ‡	Not studied - no data requested

PEC (soil) (Annex IIIA, point 9.1.3)

Tembotrione Method of calculation	DT_{50} (d): 4.2 DT_{90} (d): 105 Kinetics: DFOP (k_1 = 0.324 d^{-1}, k_2 = 0.0119 d^{-1}, g(k_1) = 0.65) Representative worst case from non-normalized field studies
M6 (AE 0456148) Method of calculation	DT_{50} (d): 69.8 Kinetics: SFO Worst case of valid normalized field data (note: valid non-normalized worst case DT_{50} would be 16.9 d) Max. occurrence: 62.3 % (field) Molar ratio: 346.7 / 440.8 = 0.787 Apparent application rate: 49.0 g/ha or 2 x 24.5 g/ha
M1 (AE 0968400) Method of calculation	DT_{50} (d): 39.8 Kinetics: SFO Representative worst case from non-normalized lab studies Max. occurrence: 14.9 % (lab) Molar ratio: 318.7 / 440.8 = 0.723 Apparent application rate: 10.8 g/ha or 2 x 5.4 g/ha
M2 (AE 1392936) Method of calculation	DT_{50} (d): 15.6 Kinetics: SFO Representative worst case from non-normalized lab studies Max. occurrence: 17.1 % (lab) Molar ratio: 264.7 / 440.8 = 0.600 Apparent application rate: 10.3 g/ha or 2 x 5.1 g/ha
M7 (AE 1124336) Method of calculation	DT_{50} (d): 26.2 Kinetics: SFO Representative worst case from non-normalized lab studies Max. occurrence: 8.7 % (lab) Molar ratio: 332.7 / 440.8 = 0.755 Apparent application rate: 6.6 g/ha or 2 x 3.3 g/ha
M3 (AE 0941989) Method of calculation	DT_{50} (d): 9.8 Kinetics: SFO Representative worst case from non-normalized lab studies Max. occurrence: 15.9 % (soil photolysis) Molar ratio: 404.4 / 440.8 = 0.917 Apparent application rate: 14.6 g/ha or 2 x 7.3 g/ha

Application data	**Maize (single):** Application rate(s): 100 g ai/ha Number of applications: 1 Interval (d): - % plant interception: 25 Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 **Maize (split):** Application rate(s): 50 g ai/ha Number of applications: 2 Interval (d): 14 % plant interception: 25 Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3

PEC$_{(s)}$ (mg/kg)	**Tembotrione (AE 0172747)**			
	Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial	0.100		0.065	
Short term				
24 h	0.082	0.091	0.053	0.059
2 d	0.068	0.083	0.044	0.054
4 d	0.051	0.072	0.033	0.047
Long term				
7 d	0.039	0.061	0.025	0.040
14 d	0.030	0.048	0.020	0.031
21 d	0.027	0.042	0.018	0.027
28 d	0.025	0.038	0.016	0.025
50 d	0.019	0.031	0.013	0.020
100 d	0.011	0.023	0.007	0.015
Plateau concentration	No expected to occur		No expected to occur	

PEC(s) (mg/kg)		**M6 (AE 0456148)**			
		Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial		0.049		0.046	
Short term	24 h	0.048	0.049	0.045	0.046
	2 d	0.048	0.048	0.045	0.045
	4 d	0.047	0.048	0.044	0.045
Long term	7 d	0.046	0.047	0.043	0.044
	14 d	0.043	0.046	0.040	0.043
	21 d	0.040	0.044	0.037	0.041
	28 d	0.037	0.043	0.035	0.040
	50 d	0.030	0.039	0.028	0.036
	100 d	0.018	0.031	0.017	0.029
Plateau concentration		No expected to occur		No expected to occur	

PEC(s) (mg/kg)		**M1 (AE 0968400)**			
		Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial		0.011		0.010	
Short term	24 h	0.011	0.011	0.009	0.010
	2 d	0.010	0.011	0.009	0.009
	4 d	0.010	0.010	0.009	0.009
Long term	7 d	0.010	0.010	0.009	0.009
	14 d	0.008	0.010	0.008	0.009
	21 d	0.007	0.009	0.007	0.008
	28 d	0.007	0.009	0.006	0.008
	50 d	0.005	0.007	0.004	0.006
	100 d	0.002	0.005	0.002	0.005
Plateau concentration		No expected to occur		No expected to occur	

PEC(s) (mg/kg)	M2 (AE 1392936)			
	Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial	0.010		0.008	
Short term 24 h	0.010	0.010	0.008	0.008
2 d	0.009	0.010	0.007	0.008
4 d	0.009	0.009	0.007	0.007
Long term 7 d	0.008	0.009	0.006	0.007
14 d	0.006	0.008	0.004	0.006
21 d	0.004	0.007	0.003	0.005
28 d	0.003	0.006	0.002	0.005
50 d	0.001	0.004	0.001	0.003
100 d	0.000	0.002	0.000	0.002
Plateau concentration	No expected to occur		No expected to occur	

PEC(s) (mg/kg)	M7 (AE 1124336)			
	Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial	0.007		0.006	
Short term 24 h	0.006	0.007	0.005	0.006
2 d	0.006	0.006	0.005	0.005
4 d	0.006	0.006	0.005	0.005
Long term 7 d	0.005	0.006	0.005	0.005
14 d	0.005	0.005	0.004	0.005
21 d	0.004	0.005	0.003	0.004
28 d	0.003	0.005	0.003	0.004
50 d	0.002	0.004	0.001	0.003
100 d	0.000	0.002	0.000	0.002
Plateau concentration	No expected to occur		No expected to occur	

$PEC_{(s)}$ (mg/kg)	**M3 (AE 0941989)**			
	Single application Actual	Single application Time weighted average	Split application Actual	Split application Time weighted average
Initial	0.015		0.010	
Short term 24 h	0.014	0.014	0.009	0.010
2 d	0.013	0.014	0.009	0.009
4 d	0.011	0.013	0.008	0.009
Long term 7 d	0.009	0.012	0.006	0.008
14 d	0.005	0.009	0.004	0.006
21 d	0.003	0.008	0.002	0.005
28 d	0.002	0.006	0.001	0.004
50 d	0.000	0.004	0.000	0.003
100 d	0.000	0.002	0.000	0.001
Plateau concentration	No expected to occur		No expected to occur	

Route and rate of degradation in water (Annex IIA. point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4, 7 and 9: stable No metabolites > 10 %
Photolytic degradation of active substance and metabolites above 10 % ‡	Sterilized buffer solution, pH 7.0 DT_{50} = 56.3 days [Ph and Cy-He label used as replicates) Converted to natural summer light, Athens, Greece, EU: DT_{50} = 269 days No metabolites > 10 % AR
Quantum yield of direct photo-transformation in water at Σ > 290 nm	$\Phi = 8.91 \times 10^{-5}$ GC-SOLAR (pure water, close to the surface): DT_{50} under natural summer light, 40 °N: 1.2 days
Readily biodegradable ‡ (yes/no)	No (based on data)

Degradation in water / sediment

Tembotrione (AE 0172747)	Distribution (max. in sed 67.7 % AR after 61 d)									
Water / sediment system (aerobic)	pH water phase	pH sed (Ca)	t. °C	$DegT_{50}$ / $DegT_{90}$ (d) whole sys.	Chi^2 error (%)	$DegT_{50}$ / $DegT_{90}$ (d) water	Chi^2 error (%)	$DegT_{50}$ / $DegT_{90}$ (d) sed	Chi^2 error (%)	Method of calculation

Silt loam	7.5	5.9	20 °C	176 / 584	4.8	Stable[a]	18.7	153 / 509	8.7	All SFO[b]
Sand	8.1	7.1	20 °C	65.9 / 219	11.0	Stable[a]	16.4	17.0 / 56.4	21.2	All SFO[b]
Geometric mean				**108 / 358**		**Stable**		**51.0 / 149**		

[a] Worst case assumption used for inverse modelling ($DegT_{50}$ set to 1000 days)

[b] Degradation data obtained by inverse modelling (all compartments SFO)

M6 (AE 0456148)	Distribution (max. in water 76.0 % AR after 141 d, max. in sed. 22.1 % AR after 365 d)									
Water / sediment system (aerobic)	pH water phase	pH sed (Ca)	t. °C	$DegT_{50}$ / $DegT_{90}$ (d) whole sys.	Chi[2] error (%)	$DegT_{50}$ / $DegT_{90}$ (d) water	Chi[2] error (%)	$DegT_{50}$ / $DegT_{90}$ (d) sed	Chi[2] error (%)	Method of calculation
Silt loam	7.5	5.9	20 °C	Stable	28.7	-	-	-	-	P_{SFO} → M_{SFO}
Sand	8.1	7.1	20 °C	Stable	33.3	-	-	-	-	P_{SFO} → M_{SFO}
Geometric mean				**Stable**		**-**		**-**		

Mineralization and non extractable residues					
Water / sediment system (aerobic)	pH water phase	pH sed	Mineralization (end of study)	Non-extractable residues in sed.	Non-extractable residues in sed. (end of the study)
Silt loam	7.5	5.9	63.0 % after 365 d (Cy-He label) 1.7 % after 365 d (Ph label)	22.2 % after 365 d (Cy-He label) 18.9 % after 222 d (Ph label)	22.2 % after 365 d (Cy-He label) 13.4 % after 365 d (Ph label)
Sand	8.1	7.1	67.2 % after 175 d (Cy-He label) 1.5 % after 175 d (Ph label)	16.8 % after 141 d (Cy-He label) 9.4 % after 42 d (Ph label)	16.1 % after 175 d (Cy-He label) 5.6 % after 175 d (Ph label)

PEC (surface water) and PEC sediment (Annex IIIA. point 9.2.3)

Tembotrione Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 440.8 Water solubility (mg/L): 28300 K_{FOC} (L/kg): 66 *(arithmetic mean, pH dependence not taken into account at FOCUSsw STEP 1 and 2)* DT_{50} soil (d): 12.3[a] *(geometric mean, field, normalized, Q_{10} = 2.2, SFO-DT_{50} based on DFOP rate k_2, pH dependence not taken into account at FOCUSsw STEP 1 and 2)* DT_{50} water/sediment system (d): 108 *(geometric mean from 2 water/sediment studies)* DT_{50} water (d): 1000 DT_{50} sediment (d): 51.0 (*degradation rates for water and sediment from inverse modelling*) [a] **Note:** 12.2 days based on Q_{10} value of 2.58 (to be used in further assessments)

Tembotrione Parameters used in FOCUSsw step 3 and 4	Version control no. of FOCUS software: SWASH 1.1 Vapour pressure (Pa): 0 (*field data*) Water solubility (mg/L): 28300 K_{FOC} (L/kg) (***pH dependence***) = -53.7 · pH(H_2O) + 445 L/kg; min/max = 26.2/144 L/kg $^1/_n$ = 0.907 (*arithmetic mean, n = 6*) DT_{50} soil (d): Rapid DFOP compartment (***pH dependence***): SFO-$DT_{50field.\ norm.}$ = -0.434 · pH(H_2O) + 3.64 d; min/max = 0.11/1.23 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) Slow DFOP compartment (***pH dependence***): SFO-$DT_{50field.\ norm.}$ = -8.27 · pH(H_2O) + 73.7 d; min/max = 6.4/27.8 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) g(k_1) (***pH dependence***) = -0.140 · pH(H_2O) + 1.49; min/max = 0.35/0.71 (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) DT_{50} water (d): 1000 (*default value*) DT_{50} sediment (d): 51 (*geometric mean, inverse modelling*) Plant uptake: 0.0 (*field data*) DT_{50} soil (d) drainage scenarios, for simulations excluding possible influence of photolysis causing the fast phase degradation: Slow DFOP compartment (***pH dependence***): SFO-$DT_{50field.\ norm.}$ = -8.34 · pH(H2O) + 74.1 d; min/max = 6.6 / 27.8 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.2*) **Note:** For future assessments the worst case $DegT_{50}$ in sediment (153 days) is recommended at STEP 3 (PRAPeR 67).

	Molecular weight (g/mol): 346.7 Water solubility (mg/L): 386 Soil or water metabolite: Soil/water K_{FOC} (L/kg): 1.9 DT_{50} soil (d): 18.1[a] *(geometric mean of normalized field data, Q_{10} = 2.2)* DT_{50} water/sediment system (d): 1000 *(no degradation observed)* DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 62.3 *(max. occurrence in field studies)* Water: 76.0 Sediment: 22.1 Total system: 95.2 [a] **Note:** 17.9 days based on Q_{10} value of 2.58 (to be used in further assessments)
M6 (AE 0456148) Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 318.7 Water solubility (mg/L): 2240 Soil or water metabolite: Soil K_{FOC} (L/kg): 65.8 *(arithmetic mean, pH dependence not taken into account at FOCUSsw STEP 1 and 2)* DT_{50} soil (d): 11.2 *(geometric mean of normalized lab data, Q_{10} = 2.58)* DT_{50} water/sediment system (d): 1000 *(degradation in water/sediment unknown)* DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 14.9 Water: 3.0 Sediment: 1.4 Total System: 4.4
M1 (AE 0968400) Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 264.7 Water solubility (mg/L): 27420 Soil or water metabolite: Soil K_{FOC} (L/kg): 0.03 DT_{50} soil (d): 10.7 *(geometric mean of normalized lab data, Q_{10} = 2.58)* DT_{50} water/sediment system (d): 1000 *(degradation in water/sediment unknown)* DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 17.1 Water: 0.0 Sediment: 0.0 Total System: 0.0

M2 (AE 1392936) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 332.7 Water solubility (mg/L): 161.3 Soil or water metabolite: Soil K_{FOC} (L/kg): 278 DT_{50} soil (d): 12.4 *(geometric mean of normalized lab data, Q_{10} = 2.58)* DT_{50} water/sediment system (d): 1000 *(degradation in water/sediment unknown)* DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 8.7 Water: 0.0 Sediment: 0.0 Total System: 0.0
M7 (AE 1124336) Parameters used in FOCUSsw step 1 and 2	Molecular weight: 404.4 Water solubility (mg/L): 526.5 Soil or water metabolite: Soil K_{FOC} (L/kg): 878 DT_{50} soil (d): 1.6 *(geometric mean of normalized lab data, Q_{10} = 2.58)* DT_{50} water/sediment system (d): 1000 *(degradation in water/sediment unknown)* DT_{50} water (d): 1000 DT_{50} sediment (d): 1000 Maximum occurrence observed (% molar basis with respect to the parent): Soil: 15.9 *(Soil photolysis)* Water: 0.0 Sediment: 0.0 Total System: 0.0
M3 (AE 0941989) Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS software: SWASH 3.1, MACRO 4.4.2, PRZM 3.1.1 & TOXSWA 3.3.1, Vapour pressure (Pa): 0.000000001 low but not measure value Water solubility (mg/L): 526 K_{FOC} (L/kg) = 878 L/kg $^{1}/_{n}$ = 0.997 DT_{50} soil (d):= 1.6 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) DT_{50} water (d): 1000 (*default value*) DT_{50} sediment (d): 1000 (*default value*) Plant uptake: 0.5

M3 (AE 0941989) Parameters used in FOCUSsw step 3	*Tembotrione: All FOCUSsw steps:* Crop: **Maize (single appl.)** Application rate(s): 100 g as/ha Number of applications: 1 Interval (d): - Crop: **Maize (split appl.)** Application rate(s): 50 g as/ha Number of applications: 2 Interval (d): 14 *FOCUSsw step 1 and 2:* Crop interception: 25 % (minimum) Application window: March – May Scenarios: South/North EU *FOCUSsw step 3:* Foliar application, crop interception modelled by FOCUS SWASH, application window 1 – 31 days (single) and 1 – 45 days (split) after emergence, application handled by PAT *FOCUSsw step 4 (SWAN 1.1.4):* Foliar application, crop interception modelled by FOCUS SWASH, application window 1 – 31 days and 1 – 45 days (split) after emergence, application handled by PAT **20 m buffer zone** (vegetated filter strip, Sanco/10422/2005, version 2.0, September 2007): Reduction of volume of run off (%): 80 Reduction of mass of pesticide transported in the aqueous phase (%): 80 Reduction of eroded sediment (%): 95 Reduction of mass of pesticide transported in the sediment phase (%): 95
Application rate	**Note:** In order to account for the biphasic degradation (DFOP) of tembotrione, two separate modelling runs were performed at STEP 3 and 4 for each scenario and each intended use with tembotrione following SFO kinetics based on the **rapid** DFOP and on the **slow** DFOP compartment, respectively. The application rate was multiplied by 2 and partitioned into the two separate modelling runs according the g(k_1) value of the DFOP kinetics (note, all these parameters are pH dependent and are therefore scenario specific). After modelling, results (global $PEC_{SW/SED}$ values) of both runs were summed up and divided by 2. The multiplication/division procedure with a factor of 2 ensures a conservative assessment in case that the 1/n value is not exactly 1.0 (FOCUS groundwater report). – For application details refer to the revised DAR version 01 (April 2009).

	Note: For tembotrione (AE 0172747) an additional, more conservative surface water risk assessment was calculated for the drainage scenarios (MACRO) based on the SFO DT_{50} of the slower DFOP compartment (k_2), only
	M3 (AE 0941989) FOCUSsw step 3 Single application at 15.9g/ha (based on max formation of 15.9% and tembotrione application rate of 100g/ha), application date 1-31 days after emergence. In SWASH soil incorporation was selected, so spray drift entry was precluded (as this metabolite was only a soil photolysis product). I.e. simulation was as if M3 was applied to soil as parent.

FOCUS STEP 1 Scenario	Substance	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
-	Tembotrione (AE 0172747)	31.6	20.7
	M6 (AE 0456148)	16.9	0.32
	M1 (AE 0968400)	3.33	2.19
	M2 (AE 1392936)	3.42	0.00
	M7 (AE1124336)	1.60	4.44
	M3 (AE 0941989)	2.24	19.7

FOCUS STEP 2 Scenario	Substance	**Single application**		**Split application**			
				Single application		Multiple application	
		PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
North EU	Tembotrione (AE 0172747)	4.53	2.94	2.27	1.47	3.42	2.22
	M6 (AE 0456148)	2.78	0.05	1.39	0.03	2.26	0.04
	M1 (AE 0968400)	0.41	0.27	0.23	0.15	0.30	0.20
	M2 (AE 1392936)	0.40	0.00	0.20	0.00	0.29	0.00
	M7 (AE1124336)	0.19	0.53	0.11	0.32	0.14	0.39
	M3 (AE 0941989)	0.06	0.52	0.03	0.26	0.03	0.26
South EU	Tembotrione (AE 0172747)	8.20	5.32	4.10	2.66	6.09	3.95
	M6 (AE 0456148)	4.88	0.09	2.44	0.05	3.93	0.07
	M1 (AE 0968400)	0.80	0.53	0.45	0.30	0.57	0.38
	M2 (AE 1392936)	0.79	0.00	0.40	0.00	0.56	0.00
	M7 (AE1124336)	0.38	1.06	0.23	0.63	0.28	0.78
	M3 (AE 0941989)	0.12	1.04	0.06	0.52	0.06	0.52

FOCUS STEP 3 Scenario	Tembotrione (AE 0172747)					
	Single application		**Split application**			
			Single application		Multiple application	
	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum
D3 – ditch	0.524	0.145	0.262	0.075	0.228	0.078
D4 – pond	0.022	0.047	0.011	0.024	0.019	0.046
D4 – stream	0.453	-	0.226	0.013	0.198	-
D5 – pond	-	-	0.013	0.028	-	-
D5 – stream	-	-	0.210	0.008	-	-
D6 – ditch	-	-	0.265	0.051	-	-
R1 – pond	0.026	0.037	0.013	0.019	0.030	0.042
R1 – stream	1.034	0.135	0.517	0.069	0.528	0.075
R2 – stream	0.653	0.095	0.320	0.047	0.409	0.099
R3 - stream	0.513	0.044	0.257	0.023	1.199	0.130
R4 - stream	**2.277**	**0.303**	0.871	0.123	**1.345**	**0.209**

- indicates higher values from the following tables when only slow phase DT50 was used for drainage simulations should be taken forward for use in risk assessment

FOCUS STEP 4 (20 m buffer zone) Scenario	Tembotrione (AE 0172747)					
	Single application		**Split application**			
			Single application		Multiple application	
	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum	PEC$_{SW}$ (µg/L) – global maximum	PEC$_{SED}$ (µg/kg) – global maximum
D3 – ditch	0.047	0.014	nc	nc	0.019	0.007
D4 – pond	0.013	0.031	nc	nc	0.013	0.033
D4 – stream	0.053	-	nc	nc	0.022	-
D5 – pond	-	-	nc	nc	-	-
D5 – stream	-	-	nc	nc	-	-
D6 – ditch	-	-	nc	nc	0.061	-
R1 – pond	0.009	0.015	nc	nc	0.009	0.014
R1 – stream	0.208	0.029	nc	nc	0.114	0.017
R2 – stream	0.112	0.020	nc	nc	0.075	0.022
R3 - stream	0.059	0.006	nc	nc	0.267	0.031

R4 - stream	**0.527**	**0.074**	nc	nc	**0.313**	**0.051**

nc denotes not calculated (only worst case situation at STEP 3 considered)

- indicates higher values from the following tables when only slow phase DT50 was used for drainage simulations should be taken forward for use in risk assessment

Conservative surface water risk assessment based on the SFO DT_{50} of the slower DFOP compartment (k_2), only, to ensure that soil photolysis that could not occur in deeper soil layers is excluded in simulations of the drainage scenarios:

FOCUS STEP 3 Scenario	Tembotrione (AE 0172747)					
	Single application		**Split application**			
			Single application		Multiple application	
	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
D3 – ditch	0.524	0.145	nc	nc	nc	nc
D4 – pond	0.022	0.046	nc	nc	nc	nc
D4 – stream	0.453	0.027	nc	nc	nc	nc
D5 – pond	0.031	0.068	nc	nc	nc	nc
D5 – stream	0.420	0.022	nc	nc	nc	nc
D6 – ditch	0.534	0.108	nc	nc	nc	nc

FOCUS STEP 3 Scenario	M3 (AE 0941989)			
	Single application			
	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum		
D3 – ditch	<0.001	<0.001		
D4 – pond	<0.001	<0.001		
D4 – stream	<0.001	<0.001		
D5 – pond	<0.001	<0.001		
D5 – stream	<0.001	<0.001		
D6 – ditch	<0.001	<0.001		
R1 – pond	0.000134	0.000587		
R1 – stream	0.0117	0.00333		
R2 – stream	0.00149	0.000736		
R3 - stream	0.000067	0.000024		
R4 - stream	0.0425	0.032		

FOCUS STEP 4	Tembotrione (AE 0172747)	
	Single application	**Split application**

(20 m buffer zone) Scenario			Single application		Multiple application	
	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
D3 – ditch	0.047	0.014	nc	nc	nc	nc
D4 – pond	0.012	0.034	nc	nc	nc	nc
D4 – stream	0.053	0.010	nc	nc	nc	nc
D5 – pond	0.019	0.047	nc	nc	nc	nc
D5 – stream	0.052	0.014	nc	nc	nc	nc
D6 – ditch	0.057	0.033	nc	nc	nc	nc

PEC (ground water) (Annex IIIA. point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model, with appropriate FOCUSgw scenarios, according to FOCUS guidance Model(s) used: PEARL 4.4.4 Scenarios (list of names): All if appropriate Crops: Maize All input data not mentioned in this section are set to FOCUS default values **Tembotrione (AE 0172747):** Rapid DFOP compartment (***pH dependence***): $SFO\text{-}DT_{50field.\ norm.}$ = -0.438 · pH(H_2O) + 3.68 d; min/max = 0.14 / 1.25 d (*normalisation to 10kPa or pF2,* *20 °C with* Q_{10} *of 2.2, refer to note below*) Slow DFOP compartment (***pH dependence***): $SFO\text{-}DT_{50field.\ norm.}$ = -8.34 · pH(H2O) + 74.1 d; min/max = 6.6 / 27.8 d (*normalisation to 10kPa or pF2,* *20 °C with* Q_{10} *of 2.2, refer to note below*) g(k_1) value (***pH dependence***) = -0.139 · pH(H_2O) + 1.48; min/max = 0.35 / 0.71 (*normalisation to 10kPa or pF2,* *20 °C with* Q_{10} *of 2.2, refer to note below*) K_{FOC} (***pH dependence***) = -53.7 · pH(H_2O) + 445 L/kg; min/max = 26.2 / 144 L/kg $^1/_n$ = 0.907 (*arithmetic mean, n = 6*) Plant uptake: 0.0 (*field data*) Vapour pressure: 0 Pa (*field data*) **M6 (AE 0456148):** Arithmetic mean $DT_{50field.\ norm.}$: 18.1 d (*geometric mean, normalisation to 10kPa*

	or pF2, 20 °C with Q_{10} of 2.2) K_{FOC}: 1.9 L/kg (*arithmetic mean, n = 5*) $^{1}/_{n}$ = 0.978 (*arithmetic mean, n = 5*) Formation fraction (*from parent,* ***pH dependence***) = 0.303 · pH(H_2O) - 1.54; min/max 0.14 / 0.91 *(refer to note below)* Plant uptake: 0.0 (*field data*) Vapour pressure: 0 Pa (*field data*) **M1 (AE 0968400):** Arithmetic mean $DT_{50lab.\ norm.}$: 11.2 d (*geometric mean, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58)* K_{FOC} (***pH dependence***) = -97.6 · pH(H_2O) + 749 L/kg; min/max: 26.8 / 105 L/kg $^{1}/_{n}$ = 0.767 (*arithmetic mean, n = 5*) Formation fraction (*from M6 (AE 0456148)*): 0.283 (*arithmetic mean, n = 3*) Plant uptake: 0.5 **M2 (AE 1392936):** Arithmetic mean $DT_{50lab.\ norm.}$: 10.7 d (*geometric mean, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58)* K_{FOC}: 0.03 L/kg (*arithmetic mean, n = 4*) $^{1}/_{n}$ = 0.988 (*arithmetic mean, n = 4*) Formation fraction (*from M6 (AE 0456148)*): 0.147 (*only one value available*) Plant uptake: 0.5 **M7 (AE 1124336):** Arithmetic mean $DT_{50lab.\ norm.}$: 12.4 d (*geometric mean, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) K_{FOC}: 278 L/kg (*arithmetic mean, n = 5*) $^{1}/_{n}$ = 0.860 (*arithmetic mean, n = 5*) Formation fraction (*from M1 (AE 0968400)*): 0.46 (*arithmetic mean, n = 5*) Plant uptake: 0.5 **M3 (AE 0941989):** Arithmetic mean $DT_{50lab.\ norm.}$: 1.6 d (*arithmetic mean, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) K_{FOC}: 878 L/kg (*arithmetic mean, n = 4*) $^{1}/_{n}$ = 0.997 (*arithmetic mean, n = 4*) Formation fraction (*from parent*): 0.521 (*arithmetic mean, n = 2*) Plant uptake: 0.5
	Note: $DegT_{50}$ values used for tembotrione (AE 0172747) and M6 (AE 0456148) for PECgw calculation were temperature normalized using a **Q_{10} value of 2.2**. The correct input data for tembotrione (AE 0172747) and M6 (AE 0456148) based on a **Q_{10} value of 2.58** are slightly different and should be used in case of further assessments:

	Tembotrione (AE 012747): Rapid DFOP compartment (***pH dependence***): SFO-$DT_{50field.\ norm.}$ = -0.433 · $pH(H_2O)$ + 3.64 d; min/max = 0.11 / 1.23 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) Slow DFOP compartment (***pH dependence***): SFO-$DT_{50field.\ norm.}$ = -8.27 · pH(H2O) + 73.7 d; min/max = 6.4 / 27.8 d (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) g(k_1) value (***pH dependence***) = -0.140 · $pH(H_2O)$ + 1.49; min/max = 0.35 / 0.71 (*normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) **M6 (AE 0456148):** Arithmetic mean $DT_{50field.\ norm.}$: 17.9 d (*geometric mean, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) Formation fraction (*from parent,* ***pH dependence***) = 0.303 · $pH(H_2O)$ - 1.55; min/max 0.14 / 0.91 In case of the metabolites **M1 (AE 0968400)**, **M2 (AE 1392936)**, **M3 (AE 0941989)** und **M7 (AE 1124336)**, all studies considered relevant were conducted at 20 °C, therefore no change in $DegT_{50}$ values occurs if a Q_{10} value of 2.58 would have been applied instead of the old Q_{10} value of 2.2.
Application rate	Crop: **Maize (single application)** Application rate: 100 g/ha Number of applications: 1 Interval (d): - % crop interception: 25 Time of application: 5 days after emergence
	Crop: **Maize (split application)** Application rate: 50 g/ha Number of applications: 2 Interval (d): 14 % crop interception: 25 Time of application: 5 and 19 days after emergence
	Note: In order to account for the biphasic degradation (DFOP) of tembotrione, two separate modelling runs (including the entire degradation pathway) were performed for each scenario and each intended use with tembotrione following SFO kinetics based on the **rapid** DFOP and on the **slow** DFOP compartment, respectively. The application rate was multiplied by 2 and partitioned

	into the two separate modelling runs according the g value of the DFOP kinetics (note, all these parameters are pH dependent and are therefore scenario specific). After modelling, results (PEC_{GW} values) of both runs were summed up and divided by 2. The multiplication/division procedure with a factor of 2 ensures a conservative assessment in case that the 1/n value is not exactly 1.0 (FOCUS groundwater report). – For application details refer to the revised DAR version 01 (April 2009).
	Note: For tembotrione (AE 0172747) an additional, more conservative groundwater exposure assessment was calculated based on the SFO DT_{50} of the slower DFOP compartment (k_2), only

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1 m)

FOCUS PEARL 4.4.4	Scenario	Tembotrione (AE 0172747) (µg/L)	Metabolite (µg/L)				
			M6 (AE 0456148)	M1 (AE 0968400)	M2 (AE 1392936)	M7 (AE 1124336)	M3 (AE 0941989)
Single appl.	Chateaudun (C)	< 0.001	0.974	0.035	0.116	0.004	< 0.001
	Hamburg (H)	< 0.001	**1.391**	**0.043**	**0.135**	**0.007**	< 0.001
	Jokioinen (J)	No maize					
	Kremsmünster (K)	**0.001**	1.124	0.028	0.130	0.006	< 0.001
	Okehampton (N)	< 0.001	0.374	0.005	0.038	0.002	< 0.001
	Piacenza (P)	**0.001**	0.309	0.012	0.036	0.003	< 0.001
	Porto (O)	< 0.001	0.048	< 0.001	0.006	< 0.001	< 0.001
	Sevilla (S)	< 0.001	0.028	< 0.001	0.004	< 0.001	< 0.001
	Thiva (T)	< 0.001	0.295	0.011	0.039	0.001	< 0.001
Split appl.	Chateaudun (C)	< 0.001	1.032	0.036	0.123	0.004	< 0.001
	Hamburg (H)	< 0.001	**1.490**	**0.047**	**0.144**	**0.007**	< 0.001
	Jokioinen (J)	No maize					
	Kremsmünster (K)	0.001	1.180	0.029	0.137	0.007	< 0.001
	Okehampton (N)	< 0.001	0.397	0.005	0.040	0.002	< 0.001
	Piacenza (P)	**0.002**	0.345	0.013	0.039	0.003	< 0.001
	Porto (O)	< 0.001	0.052	< 0.001	0.006	< 0.001	< 0.001
	Sevilla (S)	< 0.001	0.030	< 0.001	0.005	< 0.001	< 0.001
	Thiva (T)	< 0.001	0.328	0.013	0.043	0.001	< 0.001

Additional conservative groundwater exposure assessment based on the SFO DT_{50} of the slower DFOP compartment (k_2), only:

FOCUS PEARL 3.3.3	Scenario	Tembotrione (AE 0172747) (µg/L)	Metabolite (µg/L)				
			M6 (AE 0456148)	M1 (AE 0968400)	M2 (AE 1392936)	M7 (AE 1124336)	M3 (AE 0941989)
Single appl.	Chateaudun (C)	< 0.001	nc	nc	nc	nc	nc
	Hamburg (H)[a]	< 0.001	nc	nc	nc	nc	nc
	Jokioinen (J)	No maize					
	Kremsmünster (K)	0.001	nc	nc	nc	nc	nc
	Okehampton (N)	< 0.001	nc	nc	nc	nc	nc
	Piacenza (P)	**0.007**	nc	nc	nc	nc	nc
	Porto (O)	< 0.001	nc	nc	nc	nc	nc
	Sevilla (S)	< 0.001	nc	nc	nc	nc	nc
	Thiva (T)	< 0.001	nc	nc	nc	nc	nc
Split appl.	Chateaudun (C)	< 0.001	nc	nc	nc	nc	nc
	Hamburg (H)[a]	< 0.001	nc	nc	nc	nc	nc
	Jokioinen (J)	No maize					
	Kremsmünster (K)	0.001	nc	nc	nc	nc	nc
	Okehampton (N)	< 0.001	nc	nc	nc	nc	nc
	Piacenza (P)	**0.009**	nc	nc	nc	nc	nc
	Porto (O)	< 0.001	nc	nc	nc	nc	nc
	Sevilla (S)	< 0.001	nc	nc	nc	nc	nc
	Thiva (T)	0.001	nc	nc	nc	nc	nc

Fate and behaviour in air (Annex IIA. point 7.2.2. Anne*x* III. point 9.3)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct photo-transformation	$\Phi = 8.91 \times 10^{-5}$
Photochemical oxidative degradation in air ‡	DT_{50} of 2.93 hrs derived by the Atkinson model (version 1.90), OH^- concentration (12 h) assumed = 1.5×10^6 cm^{-3}
Volatilisation ‡	Not studied – no data requested
	Not studied – no data requested
Metabolites	None

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure and dimensionless Henry's Law Constant

PEC$_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (e.g. toxicology and ecotoxicology) and/or requiring consideration for groundwater exposure.	Soil:	Tembotrione (AE 0172747), M6 (AE 0456148), M1 (AE 0968400), M2 (AE 1392936), M3 (AE 0941989) (the latter from soil photolysis)
	Surface Water:	Tembotrione (AE 0172747), M6 (AE 0456148), input from
	run-off/drainage:	M1 (AE 0968400), M2 (AE 1392936), M3 (AE 0941989) (the latter from soil photolysis)
	Sediment:	Tembotrione (AE 0172747), M6 (AE 0456148), input from
	run-off/drainage:	M1 (AE 0968400), M3 (AE 0941989) (the latter from soil photolysis)
	Ground water:	Tembotrione (AE 0172747), M6 (AE 0456148), M1 (AE 0968400), M7 (AE 1124336), M2 (AE 1392936), M3 (AE 0941989) (the latter from soil photolysis)
	Air:	Tembotrione (AE 0172747)

Monitoring data. if available (Annex IIA. point 7.4)

Soil (indicate location and type of study)	No monitoring data, new active substance
Surface water (indicate location and type of study)	No monitoring data, new active substance
Ground water (indicate location and type of study)	No monitoring data, new active substance
Air (indicate location and type of study)	No monitoring data, new active substance

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

R53, Not readily biodegradable

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw per day)	End point (mg/kg feed)
Birds ‡				
Colinus virginianus	a.s.	Acute	>2250	/
Colinus virginianus	a.s.	Short-term	> 1788	> 5620
Colinus virginianus	a.s.	Long-term	22.2	250
Mammals ‡				
Rattus norvegicus	a.s.	Acute	> 2000	/
Rattus norvegicus	Preparation	Acute	> 2000	/
	Metabolite M5	Acute	> 2000	/
	Metabolite M6	Acute	> 2000	/
Rattus norvegicus	a.s.	Long-term	0.8	10
Additional higher tier studies ‡				
Not required				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Maize / sweet corn 100 g a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivorous bird	Acute	6.6	> 341	10
Insectivorous bird		5.4	> 417	10
Medium herbivorous bird	Short-term	3	> 588	10
Insectivorous bird		3	> 593	10
Medium herbivorous bird	Long-term	1.6	13.8	5
Insectivorous bird		3	7.4	5
Higher tier refinement (Birds)				
Not required				
Tier 1 (Mammals)				
Medium herbivorous mammal	Acute	2.4	> 821	10
Medium herbivorous mammal	Acute (form.)	2.4	> 36	10
Medium herbivorous mammal	Long-term	0.59	**1.35**	5
Higher tier refinement (Mammals): measured residues and decline on maize plants considered				
Medium herbivorous mammal	Long-term	0.12	6.72	5

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Test substance	Test organism	Time scale (test type)	Endpoint	NOEC [mg/L]	LC_{50} / EC_{50} [mg/L]	Nominal / mean measured
Tembotrione	*Oncorhynchus mykiss*	96 h (s)	Mortality	100	> 100	n L
	Pimephales promelas	34 d (f)	Fry survival	0.604	-	mm
AE 0456148 (M6)	*Oncorhynchus mykiss*	96 h (s)	Mortality	Not derived	> 100	n L
Laudis	*Oncorhynchus mykiss*	96 h (s)	Mortality	a.s.: 0.197 Prod.: 4.6	a.s. 1.37 Prod.: 32	n
Tembotrione	*Americamysis bahia*	96 h (f)	Mortality Subl. effects	0.046	0.1	mm
	Daphnia magna	21 d (ss)	Reproduc. Growth	5	-	n
	Chironomus riparius [a]	28 d (s)	Emergence Develo. rate	2 32	12.5 > 32	n
AE 0456148 (M6)	*Daphnia magna*	48 h (s)	Immobility	Not derived	> 115	mm
	Daphnia magna	21 d (ss)	Reproduc. Growth	113	-	mm
Laudis	*Americamysis bahia*	96 h(s)	Mortality Subl. effects	0.055 (Prod.: 1.3)	0.15 (Prod.: 3.8)	n
Tembotrione	*Pseudokirch. subcapitata*	96 h (s)	Biomass Growth rate	0.2 0.2	0.38 0.75	mm
AE 0456148 (M 6)	*Pseudokirch. subcapitata*	72 h (s)	Biomass Growth rate	100 100	> 100 > 100	nL
AE 0968400 (M1)	*Pseudokirch. subcapitata*	72 h (s)	Yield [b] Growth rate	12.3 12.3	28.2 133	gmm
AE 1392936 (M2)	*Pseudokirch. subcapitata*	72 h (s)	Biomass Growth rate	100 100	> 100 > 100	nL
Laudis	*Pseudokirch. subcapitata*	72 h (s)	Biomass Growth rate	a.s.: 0.054 Prod.: 1.25 a.s.: 0.027 Prod.: 0.63	a.s.: 0.082 Prod.: 1.9 a.s.: 0.154 Prod.: 3.6	n
Tembotrione	*Lemna gibba*	7 d (ss)	Biomass Growth rate	0.0032 0.0032	0.00599 0.00848	n
AE 0456148 (M 6)	*Lemna gibba*	7 d (s)	Biomass Growth rate	Not derived 100	> 100 > 100	n
AE 0968400 (M1)	*Lemna gibba*	7 d (s)	Yield [b] Growth rate	32 32	84 127	n
AE 1392936 (M2)	*Lemna gibba*	7 d (s)	Biomass Growth rate	Not derived 100	> 100 > 100	n
Laudis	*Lemna gibba*	7 d (s)	Yield Growth rate	a.s.: < 0.0027 Prod: <0.063 a.s.: 0.0027 Prod.: 0.063	a.s.: 0.0037 Prod: 0.085 a.s.: 0.006 Prod.: 0.140	n

f…flow-through, gmm…geometric mean measured, mm…mean measured, n…nominal, nL…nominal Limit test, Prod…Product, s…static, ss…semi-static

[a] Water spiked study

[b] Yield endpoint according to OECD 201 and 221 (adopted 2006) is considered as surrogate for the biomass endpoint by the RMS

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Toxicity exposure ratios for the active substance and the formulation AE 0172747 02 OD06A101

GAP: Maize, single application of 0.1 kg a.s./ha or a split application of 2 x 0.05 kg a.s./ha.

FOCUS step 1 and step 2

At FOCUS step 1 single and split application result in the same PECsw values. At FOCUS step 2 the single application yielded higher PEC_{sw} values for the active substance and metabolites. Additionally PEC_{sw} values for southern EU were higher than for northern EU. TER values were only calculated for southern EU at FOCUS step 2 (worst case compared to northern EU).

Focus step 1 and step 2 (South EU), single application of 0.1 kg a.s/ha in maize

Test substance	Test organism	Time scale (test type)	Toxicity [mg a.s./L]	PEC [mg a.s./L]		TER		Annex VI trigger
				Step 1	Step 2	Step 1	Step 2	
Tembotrione	*Oncorhynchus mykiss*	LC_{50} (96 h)	> 100	0.0316	0.00820	>3165	>12195	100
	Pimephales promelas	NOEC (34 d)	0.604	0.0316	0.00820	19	74	10
Laudis	*Oncorhynchus mykiss*	LC_{50} (96 h)	1.37	0.0316	0.00820	**43**	167	100
Tembotrione	*Americamysis bahia*	LC_{50} (96 h)	0.1	0.0316	0.00820	**3.2**	**12**	100
	Daphnia magna	NOEC (21 d)	5	0.0316	0.00820	158	610	10
	Chironomus riparius	NOEC (28 d)	2	0.0316	0.00820	63	244	10
Laudis	*Americamysis bahia*	LC_{50} (96 h)	0.15	0.0316	0.00820	**4.7**	**18**	100
Tembotrione	*Pseudokirch. subcapitata*	E_bC_{50} (96 h) E_rC_{50} (96 h)	0.38 0.75	0.0316	0.00820	12 24	46 91	10
Laudis	*Pseudokirch. subcapitata*	E_bC_{50} (72 h) E_rC_{50} (72 h)	0.082 0.154	0.0316	0.00820	**2.6** **4.9**	10 19	10
Tembotrione	*Lemna gibba*	E_bC_{50} (7 d) E_rC_{50} (7 d)	0.00599 0.00848	0.0316	0.00820	**0.2** **0.3**	**0.7** **1.0**	10
Laudis	*Lemna gibba*	E_yC_{50} (7 d) E_rC_{50} (7 d)	0.0037 0.006	0.0316	0.00820	**0.1** **0.2**	**0.5** **0.7**	10

FOCUS step 3 and step 4

At FOCUS step 3 and step 4 some scenarios yielded higher PEC_{sw} values for single application and some scenarios for split application. The higher PEC_{sw} value (from single or split application) for the respectiv FOCUS scenario was used for TER calculations.

FOCUS step 3 and step 4, single application of 0.1 kg a.s/ha or split application of 2 x 0.05 kg a.s./ha (whichever application scenario yielded the higher PEC_{sw} value for the respective scenario)

FOCUS scenario		Maximum PEC_{SW} [mg a.s./L]	TERacute *Americamysis bahia* LC_{50}: 0.1 mg a.s./L	TER acute Formulation *Americamysis bahia* EC_{50}: 0.15 mg a.s./L
Focus step 3	D3 ditch [a]	0.000524	191	286
	D4 pond [a]	0.000022	4545	6818
	D4 stream [a]	0.000453	221	331
	D5 pond [a]	0.000031	3226	4839

FOCUS scenario		Maximum PEC_{SW} [mg a.s./L]	TERacute *Americamysis bahia* LC_{50}: 0.1 mg a.s./L	TER acute Formulation *Americamysis bahia* EC_{50}: 0.15 mg a.s./L
	D5 stream [a]	0.000420	238	357
	D6 ditch [a]	0.000534	187	281
	R1 pond	0.000026	3846	5769
	R1 stream	0.001034	**97**	145
	R2 stream	0.000653	153	230
	R3 stream	0.000513	195	292
	R4 stream	0.002277	**44**	**66**
Focus step 4 20 m buffer zone	R1 pond	0.000009	11111	16667
	R1 stream	0.000208	481	721
	R2 stream	0.000112	893	1339
	R3 stream	0.000059	1695	2542
	R4 stream	0.000527	190	269
Annex VI trigger			100	100

[a] For drainage scenarios in PRAPeR 67 (fate and behaviour) additional FOCUS step 3 PECsw calculations were demanded taking into account the SFO-DT_{50} of the slower DFOP compartment (k_2) only (additional conservative RMS assessment). For the scenarios D3 ditch, D4 pond and D4 stream the resulting PECsw values from the additional assessment were identical to the original values and hence no additional TERs were calculated. For the D5 pond, D5 stream and D6 ditch scenarios the additonal PECsw values differed slightly from the original ones and respective TER values are presented in the table.

FOCUS step 3 and step 4, single application of 0.1 kg a.s/ha or split application of 2 x 0.05 kg a.s./ha (whichever application scenario yielded the higher PEC_{sw} value for the respective scenario)

Focus scenario [1]		Maximum PEC_{SW} [mg a.s./L]	Active substance (*Lemna gibba*)		Formulation (*Lemna gibba*)	
			E_bC_{50}: 0.00599 mg a.s./L	E_rC_{50}: 0.00848 mg a.s./L	E_yC_{50}: 0.0037 mg a.s./L	E_rC_{50} 0.006 mg a.s./L
Step 3	D3 ditch [a]	0.000524	11	16	**7.1**	11
	D4 pond [a]	0.000022	272	385	168	273
	D4 stream [a]	0.000453	13	19	**8.2**	13
	D5 pond [a]	0.000031	193	274	119	194
	D5 stream [a]	0.000420	14	20	**8.8**	14
	D6 ditch [a]	0.000534	11	16	**6.9**	11
	R1 pond	0.000026	230	236	142	231
	R1 stream	0.001034	**5.8**	**8.2**	**3.6**	**5.8**
	R2 stream	0.000653	**9.2**	13	**5.7**	**9.2**
	R3 stream	0.000513	12	17	**7.2**	**12**
	R4 stream	0.002277	**2.6**	**3.7**	**1.6**	**2.6**
Step 4 20 m no spray buffer zone	D3 ditch [a]	0.000047			78.7	
	D4 stream [a]	0.000053			69.8	
	D5 stream [a]	0.000052			71.1	
	D6 ditch [a]	0.000057			64.9	
Step 4 20 m buffer zone no spray and run-off	R1 stream	0.000208	29	41	18	29
	R2 stream	0.000112	53	76	33	54
	R3 stream	0.000059	102	144	63	102
	R4 stream	0.000527	11	16	**7.0**	11
Annex VI trigger			10	10	10	10

[a] For drainage scenarios in PRAPeR 67 (fate and behaviour) additional FOCUS step 3 PECsw calculations were demanded taking into account the SFO-DT_{50} of the slower DFOP compartment (k_2) only (additional conservative RMS assessment). For the scenarios D3 ditch, D4 pond and D4 stream the resulting PECsw values from the additional assessment were identical to the original values and hence no additional TERs were calculated. For the D5 pond, D5 stream and D6 ditch scenarios the additonal PECsw values differed slightly from the original ones and respective TER values are presented in the table.

Toxicity exposure ratios for metabolites

Focus step 1

Test substance	Test organism	Toxicity estimate	Toxicity [mg/L]	PEC [mg/L]	TER	Annex VI trigger
				Step 1	Step 1	
AE 0456148 (M 6)	*Oncorhynchus mykiss*	LC_{50} (96 h)	> 100	0.0169	> 5917	100
	Daphnia magna	EC_{50} (48 h)	> 115	0.0169	> 6805	100
	Daphnia magna	NOEC (21d)	113	0.0169	6686	10
	Pseudokirchneriella subcapitata	E_bC_{50} (72 h) E_rC_{50} (72 h)	> 100 > 100	0.0169	> 5917 > 5917	10

Test substance	Test organism	Toxicity estimate	Toxicity [mg/L]	PEC [mg/L]	TER	Annex VI trigger
				Step 1	Step 1	
	Lemna gibba	E_bC_{50} (7 d) E_rC_{50} (7 d)	> 100 > 100	0.0169	> 5917 > 5917	10
AE 0968400 (M1)	*Pseudokirchneriella subcapitata*	E_bC_{50} (72 h) E_rC_{50} (72 h)	28.2 133	0.00333	8468 39940	10
	Lemna gibba	E_bC_{50} (7 d) E_rC_{50} (7 d)	84 127	0.00333	25225 38138	10
AE 1392936 (M2)	*Pseudokirchneriella subcapitata*	E_bC_{50} (72 h) E_rC_{50} (72 h)	> 100 > 100	0.00342	> 29240 > 29240	10
	Lemna gibba	E_bC_{50} (7 d) E_rC_{50} (7 d)	> 100 > 100	0.00342	> 29240 > 29240	10
AE 0941989 (M3) [a]	*Oncorhynchus mykiss*	LC_{50} (96 h)	> 10	0.00224	4464	100
	Pimephales promelas	NOEC (28 d)	0.0604	0.00224	27	10
	Americamysis bahia	LC_{50} (96 h)	0.01	0.00224	**4.5**	100
	Daphnia magna	NOEC (21d)	0.5	0.00224	223	10
	Chironomus riparius	NOEC (28 d)	0.2	0.00224	89	10
	Pseudokirchneriella subcapitata	E_bC_{50} (72 h)	0.038	0.00224	17	10
	Lemna gibba	E_bC_{50} (7 d)	0.000599	0.00224	**0.3**	10

[a] Toxicity values are not measured. It was assumed that the metabolite M3 is ten times more toxic than the active substance for fish, invertebrates, algae, aquatic macrophytes and sediment dwelling organisms. TER calculations with these hypothetical toxicity values were performed to get some indication on the risk to aquatic organisms from exposure to the metabolite M3.

Focus step 2

AE 0941989 (M3)	*Americamysis bahia*	LC_{50} (96 h)	0.01	0.00012	**83**	100
	Lemna gibba	E_bC_{50} (7 d)	0.000599	0.00012	**5**	10

Focus step 3, (R1 stream highest value)

AE 0941989 (M3)	*Americamysis bahia*	LC_{50} (96 h)	0.01	0.000043	235	100
	Lemna gibba	E_bC_{50} (7 d)	0.000599	0.000043	14.1	10

Bioconcentration					
	Active substance	AE 0968400 (M1)	AE 1392936 (M2)	AE 0941989 (M3)	AE 0456148 (M6)
$logP_{O/W}$	pH 7: -1 pH 9: -1.4	1.42	-0.17	1.44	1.43
Bioconcentration factor (BCF) ‡	No study required				
Annex VI Trigger for the bioconcentration factor					
Clearance time (days) (CT_{50})					
(CT_{90})					
Level and nature of residues (%) in organisms after the 14 day depuration phase					

[1] Values calculated with KOWWIN v1.67

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
a.s. ‡	> 92.8	> 100
Preparation	14	> 17
Field or semi-field tests		
not required		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

maize / sweet corn 100 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 1	50
a.s.	oral	< 1.1	50
Formulation AE 0172747 02 OD06 A101	Contact	< 5.8	50
Formulation AE 0172747 02 OD06 A101	oral	7.1	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡	AE 0172747 02 OD06 A101	Mortality	1.301 L prod./ha
Aphidius rhopalosiphi ‡	AE 0172747 02 OD06 A101	Mortality	0.256 L prod./ha

maize / sweet corn 100 g a.s./ha

Test substance	Species	Effect (LR_{50} L/ha)	HQ in-field	HQ off-field[1]	Trigger
Formulation AE 0172747 02 OD06 A101	*Typhlodromus pyri*	1.301	1.73	0.05	2
	Aphidius rhopalosiphi	0.256	8.79	0.24	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (L prod./ha)[1]	End point	% Effect[3]	Trigger value
Aphidius rhopalosiphi	adults	AE 0172747 02 OD06 A101, barley plants, 48 h	0.107 0.229 0.491 1.051 2.25	Corrected mortality / reproduction	3.7 / n.d. 7.4 / n.d. 7.4 / -23.8 11.1 / 37.6 11.1 / 5.9	50 %
Typhlodromus pyri	proto-nymphs	AE 0172747 02 OD06 A101, maize leaves, 14 d	0.218 0.474 1.033 2.25	Corrected mortality / reproduction	- 2.6 / 21.4 9.2 / 16.1 5.3 / 21.5 10.5 / 40	50 %
Chrysoperla carnea	larvae	AE 0172747 02 OD06 A101, maize leaves, until pupation	0.107 0.229 0.491 1.051 2.25	Corrected mortality	0 2.6 0 -2.6 7.7 no effect on reproduction	50 %

[1] initial residues
[3] positive percentages relate to adverse effects

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	a.s. ‡	Acute 14 days	LC_{50} 1000 mg a.s./kg d.w.soil (mg a.s/ha)
Eisenia fetida	a.s. ‡	Sub-chronic 28 d	$NOEC_{repro}$ 1.25 mg a.s./kg d.w.soil (mg a.s/ha)
Eisenia fetida	Preparation AE 0172 747 02 OD06 A101	Acute	LC_{50} 562-1000 mg form./kg d.w.soil
Eisenia fetida	Metabolite M6	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Metabolite M1	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Metabolite M2	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Metabolite M3	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Metabolite M7	Acute	LC_{50} > 1000 mg a.s./kg d.w.soil
Other soil macro-organisms: Collembola			

Test organism	Test substance	Time scale	End point[1]
Folsomia candida	AE 0172747 02 OD06 A101 (formulation)	Chronic	NOEC 2.68 mg a.s./kg d.w.soil (mg a.s/ha)
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	Sub-chronic	0.69 % effect at day 28 at 1.053 mg a.s./kg d.w.soil (790 g a.s/ha)
	AE 0172747 02 OD06 A101 (formulation)	Sub-chronic	-2.33 % effect at day 28 at 1.6 µL form./kg d.w.soil (500 g a.s/ha)
Carbon mineralisation	a.s. ‡	Sub-chronic	-7.1 % effect at day 28 at 1.053 mg a.s./kg d.w.soil (790 g a.s/ha)
	AE 0172747 02 OD06 A101 (formulation)	Sub-chronic	3 % effect at day 28 at 1.6 µL form./kg d.w.soil (500 g a.s/ha)
Field studies			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

Toxicity/exposure ratios for soil organisms

maize / sweet corn 100 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia fetida	a.s. ‡	Acute	0.1	> 10000	10
Eisenia fetida	a.s. ‡	Chronic	0.1	12.5	5
Eisenia fetida	Preparation	Acute	0.1	> 241	10
Eisenia fetida	Metabolite M6	Acute	0.049	> 20408	10
Eisenia fetida	Metabolite M1	Acute	0.01*	> 100000	10
Eisenia fetida	Metabolite M2	Acute	0.015*	> 66667	10
Eisenia fetida	Metabolite M3	Acute	0.017	> 58824	10
Eisenia fetida	Metabolite M7	Acute	0.007	> 142857	10
Other soil macro-organisms					
Folsomia candida	a.s. ‡	Chronic	0.1	27	5

* new PEC`s April 2009

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} or HC_5 (mL prod./ha) vegetative vigour	ER_{50} (mL prod./ha) emergence	Exposure (mL prod./ha)	TER	Trigger
Deterministic risk assessment						
Brassica oleracea	AE 0172747 02 OD06 A101	61.2	76.8	62.3[1]	0.98 9.82[2]	5
Probabilistic risk assessment						
9 species	AE 0172747 02 OD06 A101	43.0	/	62.3[1]	0.7 1.4[3]	1

[1] based on Ganzelmeier drift data: 2.77 % drift at 1 m distance
[2] with 90 % drift reduction
[3] with 50 % drift reduction

Additional studies (e.g. semi-field or field studies)

Tests on biological activity (pre- and post-emergence herbicide screening): Metabolite M6, M5, M2: not biologically active
Semi-field or field studies not required

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	Endpoint
Activated sludge	EC_{50} > 1000 mg a.s./L

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

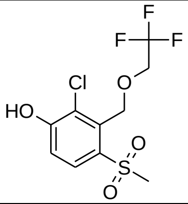
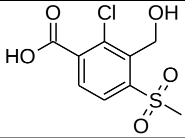
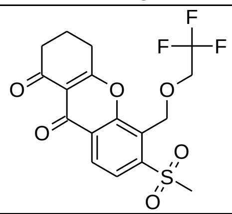
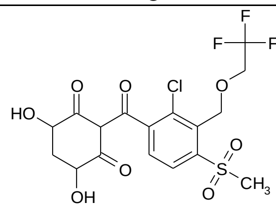
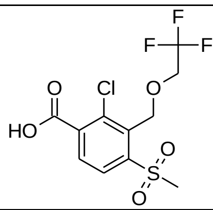
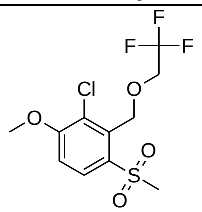
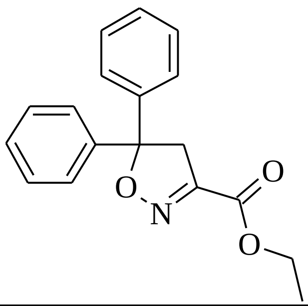
Compartment	
Soil	Parent
Water	Parent
Sediment	Parent
Groundwater	Parent

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	N, R50/53

	RMS/peer review proposal
Preparation	N, R50/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
AE 0968400 (M1)	2-Chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy) methyl]phenol	
AE 1392936 (M2)	2-Chloro-3-(hydroxymethyl)-4-(methylsulfonyl)benzoic acid	
AE 0941989 (M3)	6-(Methylsulfonyl)-5-[(2,2,2-trifluoroethoxy)methyl]-3,4-dihydro-1H-xanthene-1,9(2H)-dione	
AE 1417268 (M5)	2-{2-Chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy) methyl]benzoyl}-4,6-dihydroxycyclohexane-1,3-dione	
AE 0456148 (M6)	2-Chloro-4-(methylsulfonyl)-3-[(2,2,2-trifluoroethoxy)methyl]benzoic acid	
AE 1124336 (M7)	2-Chloro-1-methoxy-4-(methyl sulfonyl)-3-[(2,2,2-trifluoroethoxy) methyl]benzene	
Isoxadifen-ethyl		

* The metabolite name in bold is the name used in the conclusion.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice

GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPPD	4-hydroxyphenylpyruvate dioxygenase
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on 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)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year