CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance trifluralin[1]

(Question No EFSA-Q-2009-588)

Re-Issued on 14 July 2009

EFSA changes as a result of resubmission evaluation highlighted in yellow

SUMMARY

Trifluralin is one of the 52 substances of the second stage covered by Commission Regulation (EC) No 451/2000[2], as amended by Commission Regulation (EC) No 1490/2002[3]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Greece being the designated rapporteur Member State submitted the DAR on trifluralin in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 11 July 2003. Following a quality check on the DAR, the peer review was initiated on 24 July 2003 by dispatching the DAR for consultation of the Member States and the notifier, the European Union Trifluralin Taskforce comprising of Agan Chemical Manufacturers Ltd. and Dintec Agroquímica Produtos Químicos Lda. at the time of finalisation of the conclusion. Subsequently, the comments received were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 15 January 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in April, May and June 2004 (round 1-2 of the EPCO expert meetings).

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 10 February 2005 leading to the conclusions set out in the EFSA Conclusion finalised on 14 March 2005 (EFSA Scientific Report (2005) 28)

Following the Commission Decision of 20 September 2007 (2007/629/EC)[4] concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant, the

[1] For citation purposes: Conclusion on pesticide peer review regarding the risk assessment of the active substance trilfuralin. *EFSA Scientific Report* (2009) 327, 1-111

[2] OJ No L 53, 29.02.2000, p. 25

[3] OJ No L 224, 21.08.2002, p. 25

[4] OJ No L255, 29.9.2007, p. 42

European Union Trifluralin Taskforce made a resubmission application for the inclusion of trifluralin in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the areas of concern identified in the European Commission review report as follows:

- the high toxicity to aquatic organisms, in particular fish
- the high potential for bioaccumulation
- the high persistence in soil
- the potential for long-range transport via air

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Greece, being the designated rapporteur Member State, submitted an evaluation of the additional data on trifluralin in the format of an Additional Report. The Additional Report was received by EFSA on 19 January 2009. In accordance with Article 19, the EFSA distributed the Additional Report to the Member States and the applicant for comments on 22 January 2009. The EFSA collated and forwarded all comments received to the Commission on 3 March 2009. At the same time, the collated comments were forwarded to the rapporteur Member State for compilation in the format of a Reporting Table.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 24 April 2009, the Commission requested the EFSA to arrange a peer review of the Additional Report provided by the rapporteur Member State, and to deliver its conclusion on the risk assessment within 90 days.

The peer review commenced with EFSA's consideration of the Reporting Table containing the applicant's response to the comments and the RMS' evaluation of the comments and response. All points that were identified as unresolved at the end of the comment evaluation phase were further considered in a series of scientific meetings and a telephone conference with Member State experts in May 2009.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in June 2009. The EFSA conclusion has therefore been re-issued to update the risk assessment in the areas of residues, environmental fate and behaviour and ecotoxicology.

The original conclusion from the review was reached on the basis of the evaluation of the representative uses as a herbicide as proposed by the notifier which comprised spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflower, cotton and winter cereals at application rate up to 1.2 kg trifluralin per hectare. The use on winter cereals was no longer supported in the resubmission application, and therefore the conclusion has only been updated in relation to the risk assessment for the representative uses presented in the Additional Report, i.e. use only on oilseed rape, sunflower and cotton at an application rate of up to 1.2 kg trifluralin per hectare. The risk assessment presented for winter cereals has not been updated.

The representative formulated product for the evaluation was 'EF-1521' ('Treflan'), an emulsifiable concentrate (EC), registered under different trade names in Europe. For the uses on oilseed rape, sunflower and cotton, incorporation into soil takes place after the application. Trifluralin can be used only as a pre-sowing/pre-emergence herbicide.

Adequate methods are available to monitor all compounds given in the respective residue definition.

In the mammalian metabolism studies, trifluralin is extensively and rapidly metabolised. Within 48 hours, 82 % is absorbed and more than 90 % is excreted within 168 hours mainly via bile. It has a low acute toxicity, but displayed sensitising properties and should be labelled with **Xi; R43 "May cause sensitisation by skin contact"**. The relevant oral no observed adverse effect level (NOAEL) in the short-term studies was 2.4 mg/kg bw/day in the 1-year dog study, based on increased liver weight and some minor changes in the chemistry. The dermal and inhalation toxicity after subchronic exposure was low.

Regarding genotoxic properties of trifluralin it was concluded that trifluralin induces weak clastogenic and aneugenic effects in a number of *in vivo* and *in vitro* studies, but this was not confirmed in a more reliable micronucleus test. Trifluralin induced neoplastic changes and carcinogenic effects such as Leydig cell tumours, thyroid tumours, urinary bladder tumours and renal carcinoma in rats. Since no NOAEL could be established, the lowest observable adverse effect level (LOAEL) of 30 mg/kg bw/day in the rat is assigned as the most relevant effect level. The following risk phrase is proposed **Xn; R40 "Limited evidence of a carcinogenic effect"**.

There were no direct effects on reproductive performance or fertility observed, and the relevant NOAEL for reproduction was set to 4.5-5.8 mg/kg bw/day in the rat based on haematological changes, decreased maternal body weight during gestation and decreased offspring growth and survival, respectively. Trifluralin did not induce teratogenic or fetotoxic effects at non-maternally toxic doses. The developmental and maternal NOAEL is 50 mg/kg bw/day in the rabbit based on decreased foetal weight, post implantation losses and reduced body weight, food consumption, respectively.

The **proposed acceptable daily intake (ADI) is 0.015 mg/kg bw/day** based on the LOAEL in the rat carcinogenicity study with a margin of safety between LOAEL and ADI of 2000, since the ADI is based on a LOAEL value instead of a NOAEL value and that at this dose level tumour formation was evident.

The **proposed acceptable operator exposure level (AOEL) is 0.026 mg/kg bw/day** based on the NOAEL in the 90-day mechanistic study in rats using a safety factor of 100. No correction for oral absorption is required.

No acute reference dose (ArfD) is allocated.

The outcome of the risk assessment for the plant protection product 'EF-1521' ('Treflan') , an emulsifiable concentrate (EC) containing 480 g trifluralin/L showed that the estimated operator **exposure levels (according to German model) were below the AOEL only if personal protective equipment (PPE) are used both during mixing/loading (gloves) and application (gloves and coverall)**. The calculated exposure levels for bystanders were also below the established AOEL. The value of dermal absorption is 10 % for the concentrate and the diluted formulation. There was no need for estimating the worker exposure, since trifluralin is a pre-emergence herbicide applied directly to soil.

The metabolism of trifluralin was investigated in cereals (maize) and oilseed crops (rapeseed, soybean and cotton). In maize, trifluralin was extensively metabolised and residues were shown to consist of numerous compounds, with few being identified due to their low levels.

The uptake was also limited in rapeseed with low radioactive residues at harvest. No parent trifluralin was detected in mature seeds and mature plant samples; the major compound identified (*ca* 35% of the total radioactive residue) was the metabolite TR-14[5], mainly as conjugate. However, and considering its absolute low level, the PRAPeR 70 meeting of experts on residues agreed not to include this metabolite in the residue definitions. Finally, it was concluded that the residue definitions for risk assessment and monitoring initially proposed by the EPCO 05 meeting of experts for cereals and limited to the parent trifluralin only, are also applicable to the oilseed crops.

No residues of trifluralin above the limit of quantification (LOQ of 0.01 mg/kg) were detected in any of the grain samples collected in the supervised trials conducted on rapeseed, sunflower and cotton according to the critical GAP in Northern and Southern Europe.

Processing studies were not submitted and were considered not necessary. Livestock studies were not assessed in the framework of the resubmission since no significant residues are expected in oilseed commodities at harvest.

The chronic dietary exposure assessment for consumers based on the EFSA PRIMo rev2 and the proposed maximum residue limits (MRLs) of 0.01* mg/kg for rapeseed, sunflower and cotton leads to estimated intakes less than 0.1% of the proposed ADI for all the European diets included in the model. No ARfD was allocated, thus, no acute risk calculation was performed for trifluralin.

In aerobic conditions degradation of trifluralin in soil did not lead to any major metabolite. Under flooded anaerobic conditions a major metabolite TR-4[6] is formed. Furthermore, metabolite TR-14 was formed at amounts above 5 % at the end of the study in all three anaerobic soils tested. Due to its potential degradation under aerobic conditions, TR-4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant. Whereas not discussed in particular during the peer review, it is EFSA's opinion that the same conclusion may be reached for metabolite TR-14.

Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 days at 22 ^{o}C. The degradation under anaerobic conditions was faster than under aerobic conditions. Data indicate that trifluralin is strongly adsorbed to soil and could be classified as immobile. Trifluralin is hydrolytically stable under environmentally relevant conditions. Aqueous photolysis may contribute to the environmental degradation of trifluralin producing metabolites TR-6[7] and TR-15[8]. Trifluralin is not readily biodegradable. During the peer review, it was agreed that worst case DT_{50} = 13 days should be employed for the risk assessment performed in the context of Annex I inclusion, and that a DT_{50} = 2 days could be used to refine the risk assessment when appropriate. Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the fate and behaviour in the environment EPCO 02 expert meeting confirmed the need of a water sediment study, conducted in the presence of light, that could be used by Member States to refine the risk assessment performed in the context of Annex I inclusion. In the resubmission dossier new PEC $_{SW/SED}$ values based on step 3 and step 4 FOCUS SW were provided for trifluralin. In spite of the drawbacks of the calculations available, the PRAPeR TC 10 meeting of experts concluded

[5] TR-14: 2-ethyl-1-propyl-5-(trifluoromethyl)-1*H*-benzimidazol-7-amine
[6] TR-4: 3-nitro-N^2,N^2-dipropyl-5-(trifluoromethyl)benzene-1,2-diamine
[7] TR-6: 3-nitro-5-(trifluoromethyl)benzene-1,2-diamine
[8] TR-15: 2-ethyl-7-nitro-5-(trifluoromethyl)-1*H*-benzimidazole
*: MRL is proposed at LOQ

that the maximum PEC_{SW} and PEC_{SED} at step 3 would result from a loading to the water body driven by drift, and a reliable risk assessment would be obtained if this maximum value is used for the risk assessment. However, if information on the pattern of exposure at step 3 or step 4 calculations are needed for the assessment, then the calculations available would be not acceptable and/or would be insufficient to finalize the risk assessment. The PRAPeR TC 10 meeting of experts identified a data gap for FOCUS SW calculations that provide the information needed to finalize the EU risk assessment. Neither trifluralin nor its anaerobic metabolite TR-4 are expected to contaminate ground water at levels above 0.1 µg/L under the proposed conditions of use.

Trifluralin was designated as a "priority substance" under the water framework directive[9] but has not been identified as a "priority hazardous substance". However, trifluralin was added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002, because it is considered to be a 'PBT' substance fulfilling the criteria for Persistence, Bioaccumulation and Toxicity.

Because of its high volatility, the occurrence of trifluralin in air and transport through air is possible. However, photochemical half-life in air is estimated to be short. A data gap was identified by the PRAPeR TC 10 meeting of experts for the monitoring data in the Arctic regions reported by Canadian researchers and quoted in the report: '*Trifluralin dossier prepared in support of a proposal of trifluralin to be considered as a candidate for inclusion in the Annex I to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (LRTAP Protocol on POPs)'. European Commission, DG, Environment, Brussels, July 2007.*

The risk to insectivorous and fish-eating birds and mammals, bees, ground-dwelling arthropods, soil micro-organisms and earthworms is low with respect to trifluralin and the metabolites as far as investigated.

In the original peer review high risks were identified for aquatic organisms, in particular the chronic risk for fish, which requires consideration of appropriate risk mitigation measures. Using the initial predicted environmental concentrations (PEC's) together with the no observed effect level (NOEC) of 0.3 µg/L leads to a toxicity exposure ratio (TER)-value of 0.38 when a bufferzone of 15 metres is taken into account, which is below the Annex VI trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Further data were considered necessary to address this risk and enable conclusions on the risk assessment to be drawn.

For the resubmission, a new 35-day static early-life-stage (ELS) study was conducted with fathead minnow (*Pimephales promelas*) in a water-sediment system. In addition to the standard observations (i.e. growth and survival), skeletal irregularity was also analysed. The agreed end point from this study was the NOEC of 3.2 µg a.s./L. However, since no data on the exposure pattern were available, it was not possible to conclude on the final fish chronic end point to be used for the risk assessment. Therefore, the chronic risk assessment for fish could not be finalised.

Based on the data gap identified at the PRAPeR TC 10 meeting of experts on environmental fate and behaviour (see section 4.2.1), a data gap was identified to provide a chronic risk

[9] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ No L 327, 22.12.2000, p.1

assessment for fish based on the most relevant end point and on step 3 and step 4 PECsw values.

The EPCO 08 expert meeting (section ecotoxicology, June 2004) considered the risk to earthworm-eating birds and mammals as low, based on the TER value reflecting the soil accumulation plateau. EFSA would like to highlight that the risk to earthworm-eating birds and mammals should be considered further at Member State level when the product is applied after this plateau value is reached. EFSA initially proposed that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached, as the study which is available at present was performed at a lower dose rate. This data requirement was not discussed in an EPCO expert meeting. No new litterbag study was provided with the resubmission dossier. However, the PRAPeR 68 meeting of experts considered this study no longer necessary. The data gap was therefore not confirmed.

The risk to non-target plants could not be calculated with the appropriate end point (median emergence rate (ER_{50}) value) as this value is not reported in the DAR. Based on a conservative no observed effect concentration (NOEC), the risk to non-target plants can be certainly regarded as low if a bufferzone of 5 metres is taken into account.

Regulation (EC) No 850/2004[10] of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC[11] entered into force when the initial peer review of trifluralin was in an advanced stage. For this reason, the original EFSA conclusion finalised on 14 March 2005 (EFSA Scientific Report (2005) 28) did not specifically assess trifluralin against the criteria set in the paragraph 1 of Annex D of the Stockholm Convention[12]. In the framework of the resubmission procedure, it was identified that EFSA should compare the agreed end points against the criteria set in the Stockholm Convention. The result of this assessment is presented under the section Conclusions and Recommendations. EFSA acknowledges that the assessment presented in this conclusion only considers a limited range of representative uses on the basis of the information provided by the notifier in the application dossier and the Member States during the peer review. Therefore, other information may need to be considered by the Commission and the Member States when assessing trifluralin with respect to Regulation (EC) No 850/2004.

Key words: trifluralin, peer review, risk assessment, pesticide, herbicide

[10] OJ No L 158, 30.04.2004, p. 21
[11] OJ No L 33, 08.02.1979, p. 36
[12] http://www.pops.int/default.htm

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Trifluralin is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Greece as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Greece submitted the report of its initial evaluation of the dossier on trifluralin, hereafter referred to as the draft assessment report (Greece, 2003), to the EFSA on 11 July 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 24 July 2003 to the Member States and the main notifier the European Union Trifluralin Taskforce as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 15 January 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the Pesticide Safety Directorate, United Kingdom. The reports of these meetings were made available to the Member States electronically.

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 10 February 2005 leading to the conclusions set out in the EFSA Conclusion finalised on 14 March 2005 (EFSA Scientific Report (2005) 28).

Following the Commission Decision of 20 September 2007 (2007/629/EC)[13] concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant, the European Union Trifluralin Taskforce made a resubmission application for the inclusion of trifluralin in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the areas of concern identified in the European Commission review report (European Commission, 2007a) as follows:

- the high toxicity to aquatic organisms, in particular fish
- the high potential for bioaccumulation
- the high persistence in soil

[13] OJ No L255, 29.9.2007, p. 42

- the potential for long-range transport via air

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Greece, being the designated rapporteur Member State, submitted an evaluation of the additional data on trifluralin in the format of an Additional Report. The Additional Report was received by EFSA on 19 January 2009. In accordance with Article 19, the EFSA distributed the Additional Report to the Member States and the applicant for comments on 22 January 2009. The EFSA collated and forwarded all comments received to the Commission on 3 March 2009. At the same time, the collated comments were forwarded to the rapporteur Member State for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response was evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 24 April 2009, the Commission requested the EFSA to arrange a peer review of the Additional Report provided by the rapporteur Member State, and to deliver its conclusion on the risk assessment within 90 days.

The peer review commenced with EFSA's consideration of the Reporting Table containing the applicant's response to the comments and the RMS' evaluation of the comments and response. All points that were identified as unresolved at the end of the comment evaluation phase were further considered in a series of scientific meetings including a telephone conference with Member State experts in May 2009.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in June 2009. The EFSA conclusion has therefore been re-issued to update the risk assessment in the areas of residues, environmental fate and behaviour and ecotoxicology.

The original conclusion from the review was reached on the basis of the evaluation of the representative uses presented in the DAR, i.e. use as a herbicide which comprised spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflower, cotton and winter cereals at application rate up to 1.2 kg trifluralin per hectare. The use on winter cereals was no longer supported in the resubmission application, and therefore the conclusion has only been updated in relation to the risk assessment of the representative uses presented in the Additional Report, i.e. only the use on oilseed rape, sunflower and cotton, at application rate of up to 1.2 kg trifluralin per hectare. The risk assessment presented for winter cereals has not been updated.

A list of the relevant end points for the active substance as well as the formulation is provided in appendix A.

The documentation developed during the resubmission peer review was compiled as a **peer review report** (EFSA, 2009) comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's Additional Report:

- the comments received
- the resulting reporting table (rev. 1-1 of 8 April 2009)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 9 July 2009)

Given the importance of the Additional Report including its addendum (compiled version of May 2009) and the peer review report with respect to the examination of the active substance, these documents are considered respectively as background documents A and B to this conclusion. The documents of the peer review report and the final addendum developed and prepared during the course of the initial review process are made publicly available as part of the background documentation to the original conclusion, EFSA Scientific Report (2005) 28, finalised on 14 March 2005.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Trifluralin is the ISO common name for α,α,α-trifluoro-2,6-dinitro-*N*,*N*-dipropyl-*p*-toluidine (IUPAC).

Trifluralin, belonging to the class of dinitroaniline herbicides, can be used for the control of grass and broad-leaved weeds with or without incorporation into soil after application. Trifluralin is taken up via roots and shoots and inhibits cell division.

The representative formulated product for the evaluation was 'EF-1521' ('Treflan'), an emulsifiable concentrate (EC), containing 480 g/L trifluralin, registered under different trade names in Europe.

The representative uses evaluated during the original submission comprised spraying to bare soil to control grass and broad-leaved weeds in oilseed rape, sunflower, cotton and winter cereals at application rate up 1.2 kg trifluralin per hectare. For the uses on oilseed rape, sunflower and cotton, incorporation into soil takes place after the application. Trifluralin can be used only as a pre-emergence herbicide.

The representative uses evaluated during the resubmission comprise pre-sowing/pre-emergence applications by broadcast spraying to bare soil followed by incorporation into soil to control grass and broad-leaved weeds in oilseed rape, sunflower and cotton, at maximum application rate of 1.2 kg trifluralin per hectare. Trifluralin can be used only as a pre-sowing/pre-emergence herbicide. The use on winter cereals is no longer supported.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

Trifluralin was discussed at the EPCO experts' meeting on physical/chemical properties and analytical methods (EPCO 06) in June 2004. The resubmission application for trifluralin did not necessitate an additional peer review in this section.

The minimum purity of trifluralin as manufactured should not be less than 950 g/kg, which is higher than the minimum purity given in the FAO specification 183/TC/S (1988) of 930 g/kg. The higher value relates to the submitted results of the batch analysis and not to any toxicological concern to increase the minimum purity. The technical material contains *N*-nitroso-di-*n*-propylamine, which has to be regarded as a relevant impurity. The maximum content in the technical material should not be higher than 1 mg/kg (FAO 183/TC/S).

Beside the emulsion stability in the two-year shelf-life study, the assessment of the data package revealed no particular area of concern in respect of the identity, physical, chemical and technical properties of trifluralin or the respective formulation.

The shelf-life study was evaluated and described by the rapporteur Member State in addendum 4 to Volume 3 (October 2004). The assessment was peer reviewed and confirmed by the experts of the EPCO expert meeting in written form.

Adequate analytical methods are available for the determination of trifluralin in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material and the relevant impurity in the formulation.

Analytical methods for the determination of residues of trifluralin are available for commodities with high fat content (e.g. oilseed rape), cereals, soil, water (incl. drinking and surface water) and air.

An analytical method for food of animal origin is currently not required due to the fact that no residue definition is proposed at the moment (see section 3.2).

Analytical methods for the determination of residues in body fluids and tissues are not required as trifluralin is not classified as toxic or highly toxic.

2. Mammalian toxicity

Trifluralin was discussed at the EPCO expert's meeting on mammalian toxicology (EPCO 04) in May 2004, based on the draft assessment report (Greece, 2003) dated July 2003, as well as on addendum 1 dated December 2003 and addendum 2 dated March 2004 of the final addendum (Greece, 2005). The addendum 4 to the DAR (October 2004) and the EFSA addendum 1 (November 2004) of the final addendum resulted from the outcome of this discussion.

No Additional Report was provided for mammalian toxicology upon resubmission of trifluralin.

There was no change in the assumptions made in this section, however, the list of end points has been revised to reflect the up-to-date format, and additional information was inserted accordingly. For completeness and transparency this information was also included into the conclusion text below. All the information was reported in the draft assessment report and respective addenda and therefore represents no new information relative to the original conclusion (EFSA, 2005a).

2.1. Absorption, distribution, excretion and metabolism (toxicokinetics)

Trifluralin is rapidly and nearly completely absorbed, 82 % within 48 hours. The excretion is also rapid, > 90 % at 168 hours mainly *via* bile, otherwise *via* faeces, regardless of dose level. It is widely distributed and the highest concentration was found in adrenals, fat, kidneys, liver, skin and blood. There was no evidence of accumulation. Trifluralin is extensively metabolised and the major route is conjugation (75 % of the urine residues), reduction of nitro-groups, N-dealkylation, hydroxylation and cyclisation reactions. There were numerous minor metabolites evident, four metabolites identified in the faeces.

A data requirement was stated in the DAR regarding the plant metabolites TR-22[14] and TR-28[15] of the assessment of relevance of the metabolites in groundwater and that *in vitro* tests and acute test should be performed. However, at the EPCO expert meeting on residues (11-12 May 2004) it was concluded that the proposed use in oilseed giving rise to this requirement was not supported by appropriate crop metabolism data. Thus, the toxicological significance of these metabolites was not needed to be considered. This message was forwarded to the expert meeting on toxicology (May 2004) and it was agreed that the data requirement was no longer relevant.

[14] TR-22: 3,5-dinitro-4-(propylamino)-benzoic acid
[15] TR-28: 2,2'-diazene-1,2-diylbis[6-nitro-*N*-propyl-4-(trifluoromethyl)aniline]

2.2. Acute toxicity

The oral and dermal toxicity is low, i.e. oral LD_{50} > 5000 mg/kg bw and dermal LD_{50} > 2000 mg/kg bw. The toxicity during inhalation in rats is also low, LC_{50} > 1.252 mg/L air. The rapporteur Member State concluded that trifluralin was only shown to be mild and reversible irritant in the skin- and eye irritation studies.

Trifluralin was found to have sensitizing properties (Magnuson and Kligman test) and should therefore be labelled as such. The following symbol; risk phrase is proposed on the basis of the outcome of the acute toxicity studies: **Xi; R43 "May cause sensitisation by skin contact"**.

2.3. Short-term toxicity

The short-term effects of trifluralin were studied in a 28-day study in rat, two 90-day studies in rat (one in pregnant rat), and in a 1-year dog study, one 21-day inhalation study in rat and one 21-day dermal study in the rabbit. No 90-day dog study was available. However, at the EPCO expert meeting (May 2004) it was agreed that the 1-year dog study was adequate for the risk assessment and that a 90-day dog study would not be required.

The main effects observed were a decrease in body weight gain, increased alpha-1 globulin and albumin concentration (rat), anaemia (dog), and increased liver weight (rat and dog).

The relevant oral NOAEL is 2.4 mg/kg bw/day, based on abnormal stool, increased liver weight, and some minor changes in chemistry observed at 40 mg/kg bw/day in the 1-year dog study.

In rats, the NOAEL was 5 mg/kg bw/day, based on decreased body weight, increased liver weight and changes in haematological and clinical chemistry parameters at 50 mg/kg bw/day.

Following dermal exposure of trifluralin in the rabbit, local irritation and secondary haematological and histopathological effects but no systemic effects were observed at the tested dose, 1000 mg/kg bw/day (limit test). **The relevant dermal NOAEL is 1000 mg/kg bw/day.**

There were no treatment-related effects observed in male or female rats during inhalation exposure to trifluralin. **The relevant inhalation NOAEL is > 0.09 mg/ kg bw/day (i.e. 22.5 µg/L).**

2.4. Genotoxicity

In the DAR, 11 *in vitro* studies and five *in vivo* studies have been evaluated and presented. There was evidence of aneuploidy induction from an *in vitro* chromosome aberration study, positive effects in a comet tail test, as well as weak positive effects in an *in vivo* micronucleus study. In order to clarify these effects, the need for performing of a new micronucleus study was requested by the rapporteur Member State. This was stated as a data requirement in level 4 of the DAR "An *in vivo* bone marrow micronucleus assay in mice with kinetochore or centromeric staining in order to ascertain the nature of the micronuclei induced". The new study was performed and submitted by the notifier, and the rapporteur Member State has evaluated and presented it in addendum 1. No increase in the incidence of micronuclei formation or the aneuploidy was recorded, when it was administered as a single dose to male and female mice. Hence, trifluralin is considered negative for clastogenic and aneugenic potential in the presented study.

It is summarised in the list of endpoints as follows "Weak clastogenic and aneugenic effects in a limited number of *in vivo* and *in vitro* studies, not confirmed in the most reliable, *in vivo* GLP study (micronucleus study with kinetochore staining)".

2.5. Long-term toxicity and carcinogenicity

Several long-term toxicity studies were performed in the rat, mouse and dog. However, a large number of these were rejected by the rapporteur Member State and defined as unacceptable due to a large number of limitations. Four studies in the rat of which only one is acceptable, two studies in the mouse of which only one is acceptable, and three studies in dog of which none are acceptable but one could be used for supplemental information.

The main effects observed in the Fisher 344 rat study were neoplastic changes i.e. liver hepatic cell adenoma and liver hepatocellular carcinoma that were observed in males from the lowest dose level and from the mid dose level, respectively. Histopathological changes were observed in the kidney. The carcinogenic effects seen were Leydig cell tumours, thyroid tumours and renal carcinoma observed in rats. However, the mechanism of tumour formation was not identified.

Thus, since no NOAEL could be established in the in the two-year study in the Fisher 344 rats, the LOAEL of 30 mg/kg bw/day was agreed on to be used as most relevant effect level (Greece, 2003, Vol.3 B.6.5.1/01). This study is used for the allocation of the ADI, see point 2.10.

In mice, no carcinogenic effect was observed and the NOAEL was 40 mg/kg bw/day, based on decreased body weight, anaemia, and liver and kidney toxicity seen at 180 mg/kg bw/day.

The following symbol; risk phrase is proposed on the basis of the results in the long-term and carcinogenicity studies: **Xn; R40 "Limited evidence of a carcinogenic effect"**.

2.6. Reproductive and developmental toxicity

Four studies were submitted in the dossier on rat and one in the dog in order to determine the reproductive effects of trifluralin (one-, two- and four-generation studies). Two studies were not acceptable according to the rapporteur Member State, these (four-generation in the rat and the dog study) were of very old date (1966), and thus there were many deficiencies and deviations according to test guideline. A summary of the two-generation rat study is also presented in addendum 2.

There were no direct effects on reproductive performance or fertility observed. Whether trifluralin was a possible endocrine disrupter was discussed at the EPCO expert meeting (May 2004). The meeting of experts agreed that there were no clear evidence for endocrine effects, recorded at high dose levels and being hard to distinguish from systemic toxicity.

The relevant NOAEL for reproduction was set to 4.5-5.8 mg/kg bw/day in the rat based on haematological changes, decreased maternal body weight during gestation and decreased offspring growth and survival, respectively at 40.7-50.8 mg/kg bw/day (Greece, 2003, Vol.3 B.6.6.1.1/02).

The reproduction NOAEL to be used within ecotoxicological risk assessments was set to 148 mg/kg bw/day which was the top dose in a two-generation study in the rat (Greece, 2003, Vol.3 B.6.6.1.1/01).

In order to examine teratogenic or developmental effects of trifluralin four studies in rat and rabbit were submitted in the dossier and two (one rat and one rabbit) were not accepted according to the rapporteur Member State, since those were of very old date (1966), and thus, there were many deficiencies and deviation according to test guideline. One dog study was submitted in the dossier but was not considered acceptable according to the same statement as above.

From these studies it is concluded that trifluralin did not induce teratogenic or fetotoxic effects at non-maternally toxic doses.

The relevant developmental NOAEL is 50 mg/kg bw/day in the rabbit based on decreased foetal weight and post implantation losses at 120 mg/kg bw/day, and **the relevant maternal NOAEL is 50 mg/kg bw/day in the rabbit** based on reduced body weight and food consumption at 120 mg/kg bw/day (Greece, 2003, Vol.3 B.6.6.2.2/01).

In the rat, the maternal NOAEL was 100 mg/kg bw/day, based on adrenal enlargement and thickening of the forestomach lining at 300 mg/kg bw/day, and the developmental NOAEL was 300 mg/kg bw/day based on decreased foetal weight and skeletal anomalies at the top dose of 750 mg/kg bw/day (showing marked maternal toxicity).

2.7. Neurotoxicity

No studies were performed.

2.8. Further studies

Urinalysis studies in rats were performed and evaluated in the DAR. An increase in hyaline droplet formation in the renal tubular epithelium was seen at 200 ppm and the NOAEL is 50 ppm, i.e. 2.6 mg/kg bw/day (Greece, 2003, Vol.3 B.6.8.2.1/02). This study is used for the allocation of AOEL, see point 2.10.

Supplemental studies in the rat regarding the mechanism of nephrotoxicity of trifluralin have been evaluated. Trifluralin induced changes in the kidney (mild renal tubular epithelial degeneration) and urine, which may suggest a mechanism for induction of proliferative urinary tract lesions observed in the two-year studies.

2.9. Medical data

Reports from plant employees exposed to trifluralin and trifluralin containing products describe effects such as redness, rash, hives, vesicular change, bullae and pruritis. Epidemiological studies revealed that there was no correlation between increased cancer incidence rate, reproductive effects or asthma following exposure to trifluralin.

2.10. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)

ADI

Initially in the DAR the rapporteur Member State proposed an ADI of 0.024 mg/kg bw/day based on the NOAEL of 2.4 mg/kg bw/day in the 1-year dog study. The rapporteur Member State also made a second proposal of ADI to use the LOAEL of 30 mg/kg bw/day in the rat carcinogenicity study. Since the ADI then would be based on a LOAEL value instead of a

NOAEL value, the rapporteur Member State used a margin of safety between LOAEL and ADI of 1000, and an ADI of 0.03 mg/kg bw/day was set at that time.

The ADI value was discussed at the EPCO expert meeting (May 2004) and it was agreed that it should be based upon the LOAEL in the rat carcinogenicity study (refer to point 2.5 above). However, the meeting of experts agreed that a margin of safety between LOAEL and ADI should be increased to 2000 instead of 1000, since the ADI would be set on a LOAEL value and that at this dose level tumour formation was evident.

The resulting ADI is thus 30 mg/kg bw/day/2000, i.e. 0.015 mg/kg bw/day.

AOEL

The AOEL is based on the NOAEL of 2.6 mg/kg bw/day in the 90-day mechanistic study in rats (refer to point 2.8 above), with a safety factor of 100 and no correction for oral absorption is required.

The AOEL is 0.026 mg/kg bw/day.

ARfD

The allocation of ARfD was discussed at the EPCO expert meeting (May 2004), considering the overall database as well as the results of the rabbit developmental study, and the meeting concluded that the effects were not of concern for acute toxicity. It was agreed that an ARfD was not required for trifluralin.

No ARfD is allocated.

2.11. Dermal absorption

Only one study was submitted in the dossier and it was performed on the Rhesus monkey. Based on the results from this study the rapporteur Member State suggested in the DAR that the dermal absorption should be equal to 1 % for both the undiluted and the diluted formulation.

The study, from a scientific point of view, was discussed at the EPCO expert meeting (May 2004). The meeting concluded that there were some major limitations such as a small number of animals in the group, only 2, and that not all material was accounted for. Therefore, the experts agreed to use 10 % (for both the concentrate as well as the diluted solution) as a default value instead.

2.12. Exposure to operators, workers and bystanders

The representative plant protection product 'EF-1521' ('Treflan') is an emulsifiable concentrate (EC) containing 480 g trifluralin/L. According to the intended uses submitted by the notifier, the applied doses are in the range of 0.48 to 1.2 kg trifluralin/ha while the application volume ranges from 150 to 600 L. The plant protection product is applied using tractor-mounted boom sprayer with hydraulic nozzles and water is the intended dilutent/carrier.

In the DAR the dermal absorption of 1 % was used for both the concentrate and the diluted formulation. However, this value was changed to a default value of 10 % for both the concentrate and the diluted formulation, see point 2.11 above. Thus, the operator risk assessment was revised (see addendum 4).

The risk of exposure for operator and bystander *via* inhalation of the vapour was discussed at the EPCO expert meeting (May 2004). The issue of whether there was a need for the notifier to submit further data on volatility of trifluralin in the spraying solution was also examined. The meeting agreed that the potential for inhalation exposure was low and that no concerns had been identified in the 21-day rat inhalation study. The meeting concluded that no further consideration of inhalation exposure was required for operators and bystanders.

Operator exposure

The estimated operator exposure is below the AOEL of 0.026 mg/kg bw/day for the proposed uses of 'Treflan' (according to the German model) only, if personal protective equipment (PPE) are used both during mixing and loading (i.e. gloves) as well as during application (i.e. gloves and coverall), see table below. According to the UK POEM, operator exposure is above the AOEL, even when the use of gloves during mixing, loading and application is considered.

Estimated exposure, % of AOEL, according to calculations with the German model

Application rate	No PPE	With PPE: gloves (M/L)	With PPE: gloves (M/L + Appl.) and coverall (Appl.)
1.2 kg trifluralin/ha	1469	562	62
0.48 kg trifluralin/ha	588	223	23

M/L= mixing and loading, Appl. = application
PPE: personal protective equipment

Estimated exposure, % of AOEL, according to calculations with the UK POEM

Application rate	No PPE	With PPE: gloves (M/L)	With PPE: gloves (M/L + Appl.)
1.2 kg trifluralin/ha 150 L/ha application volume	6008	-	746
0.48 kg trifluralin/ha 150 L/ha application volume	2404	-	300

M/L= mixing and loading, Appl. = application
PPE: personal protective equipment

Worker exposure

Trifluralin is a pre-emergence herbicide applied directly to soil. Thus, the scenario of re-entry of workers is not applicable and a worker re-entry risk assessment is not considered necessary.

Bystander exposure

Bystanders may be exposed briefly and to relatively low quantities of spray as compared to an operator. No calculations were presented in the DAR. However, since the AOEL is exceeded to a great extent for operators when no PPE is used, some kind of clarification would increase transparency. From calculations, provided by EFSA (November 2004) after the initial peer review process, it is evident that the estimated exposure of bystanders is below the AOEL, see EFSA addendum 1.

3. Residues

The conclusions in this section are based on the DAR (Greece, 2003), the addendum 2 dated March 2004 and addendum 6 dated February 2005 from the final addendum (Greece, 2005), the Additional Report (Greece, 2009a) submitted in the framework of the resubmission, as well as on the outcome of the discussions in the EPCO 05 experts' meeting (May 2004) and the PRAPeR 70 experts' meeting on residues (May 2009).

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

Studies were presented in cotton, soybean and mustard dealing with either translocation or metabolism following pre-planting incorporation of radiolabelled trifluralin to soil at rates comparable to the intended GAP. Radioactivity was translocated to the aerial parts of the plants and the expiration of ^{14}C-carbon dioxide indicated that trifluralin was metabolised. Although not necessarily attributed to trifluralin, the concentration of residues in the seeds of these crops increased with time and metabolites having a similar lipophilic nature as trifluralin may be accumulating in seeds of oilseed crops.

Since no attempts have been made to investigate the nature of the residue in the seeds although significant levels of total radioactivity were detected, the oilseed studies were regarded as inadequate to conclude on a residue definition for oilseeds by the EPCO 05 meeting of experts, and a new metabolism study was requested to support uses on oilseed crops. This new study on oilseed rape was provided in the framework of the resubmission procedure. ^{14}C-trifluralin labelled on the phenyl ring was applied onto the soil prior to planting, at a dose rate of 1800 g a.s./ha (1.5N). At harvest, 197 days after application, the total radioactive residues were low, 0.017 mg/kg in seeds and 0.095 mg/kg in the mature plant samples. No parent trifluralin was detected; the major compound identified, mainly as conjugates, was the metabolite TR-14[16] accounting for 33% of TRR (0.0056 mg equiv./kg) in seeds and 36% of TRR (0.025 mg equiv./kg) in the plant samples. After discussion and considering the absolute low level expected when trifluralin is applied at its normal dose rate, the PRAPeR 70 meeting of experts agreed not to include the metabolite TR-14 in the residue definitions.

In addition, the metabolism of trifluralin was studied in maize following post-emergence spray application. Trifluralin was rapidly metabolized as it was only detected in maize forage within the first four weeks after treatment. Resulting from an extensive metabolism the radioactive residue consisted of a complex mixture of compounds. Only few metabolites were identified due to their occurrence at very low levels. Further on, a large part of the radioactivity was bound to natural plant constituents (lignin and cellulose). Limited translocation of radioactivity to the cobs and grain was observed. Due to the low levels of radioactivity (0.02 mg/kg) in the grain at harvest identification was not possible. In addition, no radioactive residues were found in the oil or flour processed from the grain of treated plants.

[16] TR-14: 2-ethyl-1-propyl-5-(trifluoromethyl)-1*H*-benzimidazol-7-amine (also referenced as TSN 028333)

Finally, the PRAPeR 70 meeting of experts concluded that the residue definitions for risk assessment and monitoring initially proposed by the EPCO 05 meeting on residues for cereals and limited to the parent trifluralin only, are applicable to the oilseed crops.

Supervised residue trials were initially submitted for cereals and oilseed crops. The magnitude of trifluralin residues in grain and straw was determined in a total of 6 cereal field residue trials (2 in barley and 4 in wheat), conducted over two growing seasons in Northern European regions consistent with critical GAP. All residues were analysed using validated methods. Trifluralin was the only residue determined. Grain and straw residues were determined at a limit of quantification (LOQ) of 0.01 mg/kg in all trials. At harvest (>87 days after application), no residues were found in any of the cereal grain or straw samples. In addition, a large number of trials generated in the 1960s and 1970s in Canada and the USA were submitted. It was decided by the EPCO expert meeting on residues that a comparability and acceptability assessment of these trials needed to be made to consider their relevance to the Southern European GAP, which is currently not supported by available data.

A range of supervised residue trials on oilseed crops performed in the EU over several years (1989 to 2001) was submitted. All trials were carried out using a single application, at a rate of 1100 to 1400 g a.s./ha. The samples were analysed for trifluralin only, using methods that were considered as sufficiently validated. In rapeseed (12 north trials), sunflower (4 south trials) and cotton (4 south trials) residues in seeds at harvest were below the LOQ (<0.01 mg/kg). Considering that trifluralin is applied early in the growing season and that no residues above the LOQ were observed in at least 8 residue trials performed on oilseed crops in northern and southern EU, EFSA is of the opinion that no additional trials have to be requested on rapeseed in southern EU and on sunflower in northern EU. As stated in the EU guideline 7525/VI/95 rev.7 (European Commission, 2001), such a database is even sufficient to extrapolate MRLs to the entire oilseed group (peanut excluded).

Moreover, additional trials performed in USA and Brazil confirm that no residues are expected at harvest in oilseed crops, since trifluralin residues in seeds were at or below 0.01 mg/kg in trials, using dose rates up to 4200 g a.s./ha (3.5N) on sunflower and 6720 g a.s./ha (5.6N) on cotton. It must be noted that MRL values for oilseeds were not discussed during the PRAPeR 70 meeting of experts and these proposals have to be considered as not peer reviewed.

Storage stability studies were performed following an initial storage at +4°C or at ambient temperature for 7 to 50 days with a further period at -15°C or -25°C up to *ca* 16 months. The studies were performed on water containing matrices (wheat forage, potato, peas, grapes…), starch containing matrices (wheat grains) and oily matrices (cotton seed, flax seed, sunflower seeds, oil…). Although an initial decline in the residue levels (15% to 30%) was observed in several matrices, including oily matrices during the initial storage period at +4°C or at ambient temperature, no significant additional decrease was observed in the further period when the samples were stored frozen. Based on this observation, it was concluded that trifluralin residues have to be considered stable when stored at -15°C/-25°C up to 12/16 months.

No study on the effects of processing was submitted, having regard to the low residue levels detected in the raw agricultural products (<0.01 mg/kg). However, it was reported in the DAR that in a total of 9 overdosed trials performed on sunflower and cotton (up to 5040 g a.s./ha) no residues above the LOQ (0.01 mg/kg) were observed in the raw commodities (seeds) and their processed fractions (meal, oil…). One residue at 0.03 mg/kg was however recorded in cotton gin by-products in one trial, at an application rate of 2270 g a.s./ha.

3.1.2. Succeeding and rotational crops

In the field, trifluralin degrades slowly (see point 4.1.2). Therefore, three crop rotation studies with radiolabelled trifluralin were presented in order to address the potential incorporation of soil residues into succeeding and rotational crops. A variety of crops was planted in treated soil aged for 30 days up to 395 days. Total radioactive residues were less than 0.08 mg/kg in crop parts relevant for human consumption from trials in line with conditions expected from the representative GAPs. Analyses of these residues indicated that they were comprised of multiple components, none of them exceeding 0.01 mg/kg. Except in turnip roots, the parent trifluralin was generally not detected in any of the other rotational crops. Exceptionally, in one maize grain sample obtained from a trial following a soil application twice the intended rate, a residue of 0.03 mg/kg trifluralin was found.

However, residues in crops grown in rotation in commercial practice are expected to be negligible. Therefore, no concern about exposure to trifluralin residues incorporated into these crops by uptake from soil is raised.

3.2. Nature and magnitude of residues in livestock

It is noted that with regard to its $\log P_{ow}$ trifluralin is characterised as fat-soluble. However, in terms of the representative uses on oilseed crops supported in the framework of the resubmission, no quantifiable trifluralin residues were found in oilseeds grains and no significant residues are expected to occur in potential feeding crops grown in rotation with oilseed crops. Thus, livestock metabolism and feeding studies are not necessary to support the use on oilseeds, and no residue definition or MRLs for food of animal origin are currently proposed. This should be reconsidered if further uses than oilseed crops relevant for animal feeding are envisaged.

3.3. Consumer risk assessment

The chronic consumer risk assessment was performed using the EFSA PRIMo rev2 Model and considering the proposed MRL values of 0.01* mg/kg for rapeseed, sunflower and cotton. No chronic risk was identified since the TMDI was less than 0.1% of the ADI (0.015 mg/kg bw/day) for all the European diets included in the model.

An ARfD was not allocated for trifluralin (see point 2.10), thus trifluralin residues on food do not pose an acute risk to consumers.

3.4. Proposed MRLs

Based on the supervised residue trials the following MRLs are proposed for trifluralin on oilseeds:

- Rape seed: 0.01* mg/kg
- Sunflower: 0.01* mg/kg
- Cotton seed: 0.01* mg/kg

*: MRL is proposed at the limit of quantification (LOQ).

Considering that trifluralin is applied very early in the growing season (pre-sowing or pre-emergence) and that no residues above the LOQ (0.01 mg/kg) were detected in at least 8 trials performed on oilseed crops in southern and northern EU respectively, EFSA is of the opinion

that no additional trials need to be requested. The proposed MRLs are applicable for both the northern and southern EU.

For cereals, in the evaluation meeting, Member States proposed to raise the MRL from 0.01* mg/kg, initially proposed by the rapporteur Member State for cereals, to an LOQ of 0.05* mg/kg to allow a cost effective monitoring, as the dietary exposure assessment does not indicate any of the considered consumer subgroups to be at risk by applying an LOQ of 0.05 mg/kg. This point was not considered for by the PRAPeR 70 meeting of experts in the framework of the resubmission. Nevertheless and having regard to the very low contribution of oilseeds in the consumer exposure, EFSA is of the opinion that such a proposal is also acceptable for rapeseed, sunflower and cotton.

Trifluralin is approved in non-EU countries, however, no Codex MRLs have been established or proposed yet and need to be considered.

4. Environmental fate and behaviour

The conclusion in this section is based on the trifluralin DAR (Greece, 2003), addendum 2 dated March 2004 and addendum 5 dated December 2004 from the final addendum (Greece, 2005). The fate and behaviour of trifluralin in the environment was discussed in the EPCO 02 experts' meeting (April 2004).

The original conclusion on trilfuralin (EFSA, 2005a) has been revisited after resubmission. Two additional study reports, by Reeves (Greece, 2009a, Vol.3 B.8.6.2) and Knowles (Greece, 2009a, Vol.3 B.8.6.1), concerning the environmental fate and behaviour of trifluralin were provided in the resubmission dossier and evaluated by the rapporteur Member State in the Additional Report. These study reports were intended to provide PEC_{GW} values with a second FOCUS model and to provide FOCUS SW calculations for $PEC_{SW/SED}$. The Additional Report was peer reviewed and discussed at the PRAPeR TC 10 expert teleconference meeting (19 May 2009). Prior to the meeting the rapporteur Member State provided a corrigendum and an addendum (addendum 1) to the Additional Report. Taking into account Commission Regulation (EC) No 33/2008, additional information or new (i.e. newly submitted) study reports provided after the submission of the Additional Report to EFSA could not be considered in the peer review. After the experts' meeting, the rapporteur Member State provided addendum 2 to the Additional Report that included further information and clarifications requested by the meeting.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

Information on trifluralin metabolism in soil under dark aerobic conditions at 22°C is provided by one study where three different soils were used. The soils covered a range of pH values (4.9-7.0), clay contents (8.8 % - 36.4 %) and organic matter contents (2.6 - 5.1 %). Volatiles were only trapped and analysed for one soil.

Under aerobic conditions degradation of trifluralin in soil did not lead to any major metabolites but several minor metabolites were formed by oxidative dealkylation of N-propyl, reduction of nitro groups with cyclation and dimerization to form azoxy-benzene compounds. The level of unextractable residues was between 23.3 % and 43.1 % AR after 120 days and reached between 33.5 % and 54.1 % after one year. Most of the non-extractable residues were

in the humin fraction. As measured in one of the soils, CO_2 evolved was 8.4 % AR at 120 days and 18.5 % AR after one year.

An analogous study under flooded anaerobic conditions shows the formation of a major metabolite TR-4[17] (maximum of 13.2 % AR after 60 days). Metabolite TR-14 was formed at amounts above 5 % at the end of the study in all three soils tested (maximum 8.3 % AR after 60 days). The relevance of metabolite TR-4 for the proposed representative uses and the need for further assessment was discussed in the fate and behaviour in the environment expert meeting (EPCO 02, April 2004). Whereas it was not possible to exclude the relevance of anaerobic conditions for the representative uses, it was judged, based on molecular structure, that this metabolite would be degraded under aerobic conditions. However, Member States may need to address further the fate and behaviour and ecotoxicology of this metabolite for specific environmental conditions. The relevance of the other anaerobic metabolite TR-14 was not discussed during the peer review, however, since the levels found are lower than for TR-4 and that under aerobic conditions it may be expected to follow a degradation route analogous to other aerobic metabolites, the same conclusion reached for metabolite TR-4 is applicable to metabolite TR-14.

According to the soil photolysis study, photolysis is not expected to be a significant degradation route of trifluralin in the environment and no major photolysis products were identified.

4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products

The degradation rate of trifluralin at 22°C under aerobic and anaerobic conditions was investigated in the same studies used to establish the trifluralin metabolism and in another study under aerobic conditions with two additional soils. Half-lives were obtained by fitting the degradation curve to first-order kinetics. Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 days at 22°C. The degradation under anaerobic conditions was faster than under aerobic conditions with first-order half-life between 23 to 54 days.

Field dissipation studies are available from the EU (Germany and United Kingdom) and USA (Georgia, Illinois and California). Trifluralin shows to be highly persistent in the EU sites and moderately persistent in the USA sites. Overall mean half-life in field is 170 days confirming the concern for the high persistence of this compound already shown by the laboratory studies.

A field accumulation study is available in a UK site for five years. Under the study conditions, trifluralin residues in soil did not increase after each annual application. However, since field dissipation studies show quite variable results, potential for accumulation has been estimated by calculation with the worst case field DT_{50} of 375 days and given in the end points list.

PEC soil presented in the DAR were calculated taking into account different DT_{50} (mean field, 80th percentile field and worst case). However, only PEC soil calculated using worst case DT_{50} (375 days) are used in the risk assessment for Annex I inclusion and shown in the list of end points. Initial PEC soil are also provided for the anaerobic metabolite TR-4.

[17] TR-4: 3-nitro-N^2,N^2-dipropyl-5-(trifluoromethyl)benzene-1,2-diamine

4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction products

A batch adsorption/desorption study in four soils is available for trifluralin. The data indicate that trifluralin is strongly adsorbed to soil (K_{Foc} = 6414 – 13414 mL/g) and may be classified as immobile. For the anaerobic metabolite TR-4 a Koc = 13600 mL/g was estimated, using the "pckocwin v.1.66 (EPA)" program, indicating also low mobility potential for this metabolite. The PRAPeR TC 10 meeting of experts discussed the acceptability of the Koc value estimated for metabolite TR-4. The experts agreed that the value may be considered reasonable when used together with a 1/n = 1 to model the EU representative uses. However, if an assessment at national level indicates that the exposure approaches a groundwater trigger or surface water tier 1 risk assessment trigger, then measured data on adsorption could be needed to assess uses where anaerobic soil conditions cannot be excluded.

Two aged residue column leaching studies with a total of three experiments are available. Amounts between 0.42 to 2.54 % AR are found in the leachate. However, this radioactivity may not be attributed to the parent compound and was not further identified. More data on the leaching potential of metabolite TR-4 was initially requested by the rapporteur Member State in the DAR pending decision on its relevance. According to the conclusions of the fate and behaviour in the environment EPCO expert meeting no further data for this metabolite are necessary to finalise the assessment made in the context of Annex I inclusion.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Trifluralin is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 52°C with an extrapolated half-life above one year at 20°C.

Aqueous photolysis may contribute to the environmental degradation of trifluralin (DT_{50} irr. = 7 h vs. DT_{50dark} = 480 h). Aqueous photolysis is enhanced in natural water (DT_{50} = 1.1 h). Photodegradation of trifluralin led to the formation of two major photoproducts: TR-6[18] (maximum of 50.4 % AR at the end of the study after 48.5 hours continuous irradiation) and TR-15[19] (maximum of 31.5 % AR at the end of the study after 48.5 hours continuous irradiation). Initial PECsw values have been calculated for these metabolites based on the maximum amounts observed in the photolysis study. These values have been used for the risk assessment. No further data on these metabolites were deemed necessary by the fate and behaviour in the environment EPCO expert meeting to conclude the risk assessment.

Trifluralin is not readily biodegradable.

Two water/sediment studies were available in the original dossier and summarized in the DAR. The first study was performed in two water sediment systems. Trifluralin dissipated from the system mainly by volatilization. Dissipation half-life of trifluralin in the whole system was 4.9- 5.9 days. Half-life for trifluralin in the water phase was estimated to be 13 days based on the worst case system (sandy loam). Volatilization was the major dissipation route identified for trifluralin (50 – 73 % AR) specially produced during the first part of the study where heavy aeration was done. The second study was performed in one water sediment system. In this study trifluralin was applied to the sediment. The water phase was not analysed in this system since radioactivity was below 10 % AR in all samples. Major

[18] TR-6: 3-nitro-5-(trifluoromethyl)benzene-1,2-diamine
[19] TR-15: 2-ethyl-7-nitro-5-(trifluoromethyl)-1*H*-benzimidazole

metabolite TR-4 (max 16 % after 28 days) was identified in the sediment phase. Non-identified substances reached a level of 27 % at the end of the study. Volatilization reached levels of 5 – 7 % AR.

The rapporteur Member State required a third study with direct application of the substance to the sediment, in order to minimize evaporation, to obtain degradation data on the major sediment metabolite TR-4 and to identify non-characterized substances.

Member States decided in the Evaluation meeting (January 2003) that the DT_{50} to be used on the PECsw calculation for the risk assessment should be discussed at an experts' meeting (open point 4.3).

A new water sediment study was submitted by the notifier and summarized by the rapporteur Member State in an addendum (see final addendum, addendum 2). Two water sediment systems were studied where the test substance was applied to the sediment. Three major metabolites were found in the sediment: TR-4 (maximum of 27 % AR after 7 days), TR-7[20] (maximum of 14.2 % AR after 33 days) and TR-14 (maximum of 29.5 % after 54 days). Non-identified compounds (up to 23 % AR) were shown to be the sum of multiple peaks of minor components. Non-extractable residues grow up to a maximum of 77 % AR and are associated with the humin fraction. No volatiles were observed in this study. Dissipation half-lives in the water phase in these systems are one and two days based on the only three data points (0 – 3 days) where trifluralin was observed in the aqueous phase.

The selection of the most appropriate DT_{50} to be used for PECsw calculation and aquatic risk assessment was discussed in two EPCO experts meetings (April 2004 and June 2004). The experts took into account the different factors contributing to the dissipation of trifluralin from the water phase (e.g. volatilization, photolysis, adsorption to sediment). They also took into account the different experimental settings used in the studies reported (e.g. application to water or to sediment). It was agreed that worst case DT_{50} = 13 days from the first study by Yon, 1993 (Greece, 2003, Vol.3 B.8.4.3.2) should be employed for the risk assessment in the context of Annex I inclusion, and that a DT_{50} = 2 days from the third study by Cook and Meitl (Greece, 2005, Addendum2 Vol.3 B.8.4.3.2) could be used to refine the risk assessment when appropriate. The DT_{50} = 6 hours used in the original DAR for ecotoxicological aquatic risk assessment was found not reliable by the experts' meetings. This shorter half-life was claimed to be derived from the low amount of substance found in the water phase at the first sampling point in day 0 with respect to the theoretical application rate in the first water sediment study by Yon (Greece, 2003, Vol.3 B.8.4.3.2 Ref K40) under the Dutch guideline study design. As already shown in the DAR this part of the study suffers of some drawbacks (e.g. volatilization has been artificially and unrealistically enhanced by fast aeration).

In a letter to the evaluation meeting of November 2004 the rapporteur Member State proposed to reconsider dissipation in water column supporting a DT_{50} under six hours. However, no new data were offered for consideration. The evaluation meeting supported EFSA in collecting the values agreed during the peer review in its conclusions. The rapporteur Member State expressed his wish that the particular position in opposition of these values should be quoted in the EFSA conclusions (Ioannou, A., 2004).

PECsed values are calculated for trifluralin metabolites TR-4 and initial PECsed values are also calculated for metabolites TR-7 and TR-14.

Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the fate and behaviour in the environment EPCO expert meeting confirmed the need of a water

[20] TR-7: N^2,N^2-dipropyl-5-(trifluoromethyl)benzene-1,2,3-triamine

sediment study conducted in the presence of light that could be used by Member States to refine the risk assessment performed in the context of Annex I inclusion.

In the resubmission dossier, new PEC $_{SW/SED}$ values based on step 3 and step 4 FOCUS SW were provided for trifluralin. Essential information for the evaluation of the results of this modelling exercise was missing in the report provided in the dossier (e.g. application windows, exposure pattern, run-off mitigation applied, separated effect of spray drift and run-off mitigation measures). Additionally, the experts in the PRAPeR TC10 teleconference meeting noted that the whole system water/sediment decline rates used in this modelling exercise represent dissipation, rather than degradation, due to volatilization occurring in the laboratory water/sediment studies. In spite of the drawbacks of the calculations available, the PRAPeR TC 10 meeting of experts concluded that the maximum PEC_{SW} and PEC_{SED} at step 3 would result in a reasonable worst case risk assessment if this maximum value is used. However, if information on the pattern of exposure at step 3 or step 4 calculations are needed for the assessment, then the calculations in the Additional Report (as amended by the corrigendum) would be not acceptable and/or would be insufficient to finalize the risk assessment. The meeting of experts identified a data gap for FOCUS SW calculations that provide the information needed to finalize the risk assessment.

4.2.2. Potential for ground water contamination of the active substance, their metabolites, degradation or reaction products

PEC_{GW} of trifluralin and the anaerobic metabolite TR-4 were estimated using FOCUS PELMO 1.1.1 for the nine EU scenarios and the representative uses. In the lack of a reliable DT_{50} for TR-4 a worst case of DT_{50} = 1800 days (ten times DT_{50} of trifluralin) was used in the simulation. The calculated concentration in ground water for both compounds was negligible in all nine scenarios. In the resubmission dossier new FOCUS GW calculations using FOCUS PEARL model were provided. An error in the input parameters was identified during the peer review (0.5 cm instead of 5 cm incorporation depth was used in the calculation). The PRAPeR TC10 meeting of experts also noted that a formation fraction of 1 should be used for the anaerobic metabolite TR-4 (instead of 0.5). The rapporteur Member State re-did the calculation with the input parameters agreed by the experts and presented them in addendum 2 to the Additional Report. The calculations were redone with FOCUS PELMO (ver. 3.2.2), and therefore should replace the ones submitted in the original dossier. The results confirmed that 80th percentile annual average concentration over the 20 years simulation period is expected to be below the regulatory limit of 0.1 µg/L. Reliable calculations with a second model are not available.

Monitoring data in the EU, Switzerland and Norway were reviewed. Within this data set, trifluralin occurrence in ground water is rare and extremely rare at levels above 0.1µg/L that were attributed isolated pollution incidents. Trifluralin was more frequently found in surface waters with maximum concentration between 0.2 µg/L and 0.7 µg/L. In the countries where trifluralin is found in surface waters, positive samples range between 4 % and 16.4 % of the analysed samples but only a maximum of 3.2 % of the samples were above 0.1 µg/L. Trifluralin was designated as a "priority substance" under the water framework directive[21] but has not been identified as a "priority hazardous substance". However, trifluralin was added to

[21] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ No L 327, 22.12.2000, p.1

the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002.[22]

4.3. Fate and behaviour in air

Because of its high volatility [vapour pressure= 9.5 x 10-3 Pa (25 °C) and Henry's law constant = 10.2 Pa m^3 mol^{-1} at 20°C], the occurrence of trifluralin in air and transport through air is possible. This was confirmed by the study conducted to assess the volatilisation of trifluralin from the soil surface. However, the photochemical half-life in air, estimated with SAR method (Atkinson), was of 5.3 hours. This value is under the trigger of 2 days established to represent a concern for a potential long-range transport by the Stockholm Convention.

PEC air were not calculated since they are not used in the assessment and no method at EU level is agreed for such calculation.

No further information on volatilization and potential long-range transport of trifluralin has been submitted, neither by the applicant in the resubmission dossier nor by the Member States during the peer review. However, during the PRAPeR TC10 experts' meeting a Member State expert tabled a paper prepared by the European Commission, DG Environment in relation to the examination of trifluralin under the LRTAP Protocol on POPs (European Commission, 2007b). In this document some monitoring data obtained by Canada on measurements of trifluralin in arctic regions are quoted as an indication of potential long-range transport of trifluralin. Since the data were not available in the resubmitted dossier and the document did not contain the raw information, the experts were not able to conclude on the relevance and reliability of this information. A data gap was identified for the applicant to submit the Canadian data quoted in the DG Environment document.

5. Ecotoxicology

The conclusions in this section are based on the DAR (Greece, 2003), the addendum 2 (March 2004), addendum 3 (June 2004), addendum 5 (December 2004) and the EFSA addendum 2 (January 2005) from the final addendum (Greece, 2005), as well as on the outcome of the discussions in the EPCO 03 and 08 experts' meetings (May-June 2004).

Trifluralin resubmission was discussed at the PRAPeR 68 meeting of experts on ecotoxicology (May 2009) on the basis of the Additional Report (Greece, 2009a).

5.1. Risk to terrestrial vertebrates

The risk to birds and mammals is calculated according to the Guidance Document on Birds and Mammals (European Commission, 2002a). The risk was calculated for an insectivorous bird and an insectivorous mammal. This risk assessment is based on the residue values for large insects. It was considered that these residue values were more appropriate, as the product will be applied to bare soil and hence only ground-dwelling species are exposed. This risk assessment was revised by the rapporteur Member State in addendum 3 of June 2004. It was considered not necessary to assess the risk for herbivorous birds and mammals as the product will be applied to bare soil (trifluralin is a pre-emergence herbicide).

[22] Trifluralin, Hazardous substances series. OSPAR Commission, 2004 (ISBN 1-904426-37-9).

All calculated first-tier TER values for insectivorous birds and mammals do not breach the appropriate Annex VI trigger value, and hence the acute, short- and long-term risk to insectivorous birds and the acute and long-term risk to insectivorous mammals can be considered as low for the representative uses.

Also the risk from secondary poisoning was assessed as the logPow exceeds 3. This risk assessment was revised in addendum 3 of June 2004.

The risk to fish-eating birds and mammals can be regarded as low (Annex VI trigger not breached).

The Annex VI trigger value is breached for earthworm-eating birds (TER=2.8) and mammals (TER=3.12), if the risk is calculated with the PEC(twa, 4 weeks) value which takes into account the accumulation plateau (which is reached after 14 years). The risk to earthworm-eating birds and mammals was discussed in the EPCO expert meeting (section ecotoxicology, June 2004). The experts considered this as an extreme worst case situation. The Annex VI trigger value of 5 is respected if the risk is calculated based on the plateau PEC, i.e. the background contamination after 14 years, leading to a TER value of 5.27 for earthworm-eating birds and 5.96 for earthworm-eating mammals. The experts considered the risk to earthworm-eating birds and mammals low based on this calculation. EFSA would like to highlight that the risk to earthworm-eating birds and mammals should be considered further at Member State level when the product is applied after the plateau value is reached.

5.2. Risk to aquatic organisms

Selenastrum capricornutum is the most sensitive aquatic organism on an acute time-scale and fathead minnow is the most sensitive species on a chronic time-scale when tested with trifluralin and the lead formulation. Due to the difference in Annex VI trigger value, the risk assessment is driven by the end points for fish, both on an acute and long term time-scale.

The resulting acute TER-value at 1m from a field (7.9) is below and hence breaches the Annex VI trigger value of 100, so the risk should be considered as high. The rapporteur Member State calculated the risk taking into account buffer zones. This resulted in a TER-value of 110, indicating a low acute risk for fish if a bufferzone of 15 meters is taken into account.

The choice of a relevant end point for the long-term risk for fish was extensively discussed during the EPCO 08 expert meeting (section ecotoxicology, June 2004). Trifluralin induces vertebral lesions in several fish species, and in some instances this effect is induced after short-term exposure (24 hours for brown trout). The EPCO meeting agreed that the risk assessment should be based on initial PEC and on the NOEC of 0.3 µg/L (based on the observed vertebral lesions in the study with fathead minnow), together with an uncertainty factor of 10 to conduct the risk assessment. This would lead to a TER value of 0.38 when a bufferzone of 15 m is taken into account (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Consequently, the risk for aquatic organisms should be regarded as high. Therefore, in the original peer review it was considered necessary to further refine the risk either by higher tier studies or by a refinement of the exposure assessment.

The EPCO meeting agreed that the use of time weighted average PECsw values is a possible approach (i.e. a refinement of the exposure assessment), but in that case more information is needed on the critical exposure period (time to onset of effects) in order to choose the most relevant time weighted average PECsw value. Therefore, the following data requirement was

initially set by the EPCO experts' meeting: 'notifier to submit exposure studies with different exposure times using the fathead minnow as the most sensitive fish species. As an alternative, microcosm tests with a more realistic exposure regime may be run'. For the resubmission, a new 35-day static early-life-stage (ELS) study was conducted with fathead minnow (*Pimephales promelas*) in a water-sediment system. In addition to the standard observations (i.e. growth and survival), skeletal irregularity was also analysed. The radiographs showed minimal to slight thickening of vertebral bone density effects for 12.2% of the fish in the control, and for 6.5% at concentration of 3.2 µg a.s./L. At 10 µg a.s./L, slight to moderate increase in bone density effects were observed for 9.1% of the fish and moderate abnormalities to the shape of occasional vertebrae for 6.8%.

The rapporteur Member State argued that the bone effects can be caused normally by environmental stressors and that effects on survival were seen in the test only at higher concentration. Therefore, the rapporteur Member State proposed the NOAEC of 10 µg a.s./L as the relevant end point for the risk assessment.

However, due to the different classification of the effects at 10 µg a.s./L with respect to the control and the lower concentration, and considering that with the available information it is not possible to exclude that bone effects at 10 µg a.s./L will not occur in field, the PRAPeR 68 meeting of experts agreed to take the NOEC of 3.2 µg a.s./L as relevant end point from this study.

The experts noted that in the Opinion of the EFSA PPR panel for dimoxystrobin (EFSA, 2005c), the use of standard flow-through ELS study *vs.* specifically designed ELS test in the presence of sediment was discussed. According to the recommendations reported in this Opinion, the PRAPeR 68 meeting of experts agreed that more information on the environmental fate and behaviour of trifluralin is necessary to determine if the study fully reflects the fate properties of the active substance (i.e. general exposure pattern in surface water).

Therefore the experts agreed that, pending on the exposure pattern in surface water, the end point to be used for risk assessment could be derived both from flow-through and static studies.

All the available chronic studies on fish were considered during the meeting:

- 48-day flow-trough early life-stage with rainbow trout (NOEC 1.14 µg a.s./L);
- 166-day flow-trough full life-cycle with sheephead minnow (NOEC 1.3 µg a.s./L);
- 35-day flow-trough early life-stage with fathead minnow (NOEC 0.3 µg a.s./L);
- 24-hour exposure test with brown trout for vertebral lesions (NOEC 25 µg a.s./L):
- 35-day static[23] early life-stage with fathead minnow (NOEC 3.2 µg a.s./L);

The PRAPeR 68 meeting of experts concluded that the relevant end point from the static test is the NOEC of 3.2 µg a.s./L. The relevant end point from the flow-through test is the NOEC of 0.3 µg a.s./L.

Since no data on the exposure pattern of the active substance in surface water were available in the Additional Report (see point 4.2.1), the experts agreed that, in case of single exposure peak[24] the relevant end point for TER calculations should be the NOEC of 3.2 µg a.s./L and it

[23] Water-sediment test system
[24] EFSA notes after the resubmission peer review that the duration of a single exposure peak should not exceed the duration of exposure in the static effect test, i.e. 24 hours.

should be compared with the PECmax; in case of repeated exposure the NOEC of 0.3 µg a.s./L should be used. No information was available on how the fish in field may respond to the exposure pattern of trifluralin, therefore the experts considered the use of a twa-PEC approach with this latter end point as not appropriate.

The PRAPeR 68 meeting of experts discussed the safety factor to be applied. With the NOEC of 3.2 µg a.s./L the rapporteur Member State considered appropriate to reduce the standard safety factor of 10, since the end point was based on physiological effects (i.e. more sensitive parameters than growth or survival). However, the experts considered any safety factor reduction not appropriate with this end point, since no comparable tests with other species were available. In case of the use of the NOEC of 0.3 µg/L it is possible to apply a safety factor reduction, as 3 species were tested in comparable flow-through studies with consistent results according to the Opinion of the EFSA PPR panel (EFSA, 2005d).

Overall, it was concluded that no data on the exposure pattern were available allowing for a final decision on which chronic toxicity end point to fish should be used for risk assessment; in addition, only PECsw values calculated with step 3 of FOCUS were peer reviewed (see point 4.2.1). Therefore, the chronic risk assessment for fish cannot be finalised.

Based on the data gap identified at the PRAPeR TC 10 meeting on environmental fate and behaviour (see point 4.2.1), a data gap was identified for the applicant to provide a chronic risk assessment to fish based on the most relevant end point and on step 3 and step 4 PECsw values.

Trifluralin and the metabolites TR-4, TR-7 and TR-14 can be found in concentrations above 10% of the AR in the sediment. Therefore the risk to sediment-dwelling organisms needs to be addressed. This risk assessment is available in addendum 3 of June 2004. The effects of the active substance and the metabolite TR-4 were tested on sediment-dwelling organisms. The resulting TER values do not breach the Annex VI trigger value, and hence the risk from the active substance and the metabolite TR-4 can be regarded as low. No studies with the metabolites TR-7 and TR-14 on sediment-dwelling organisms were in the original peer review available. The rapporteur Member State regarded the risk from these metabolites as addressed based on the similarity with the parent compound. This was not accepted by the EPCO expert meeting (section ecotoxicology, June 2004), because if metabolites have different functional groups than the parent compound then they may act differently. Although the QSAR approach is usually not relevant for major metabolites, it was decided that in this case this tool could be used, as data from other metabolites are available. If the part of the molecule relevant for the pesticide activity has been removed and the QSAR calculations with both metabolites show, confirmed by the project leader of the PSD-project or another independent organization or authority, a lower toxicity than the active substance, then no further testing is required. Alternatively, studies with sediment-dwelling organisms would need to be made available. In the evaluation meeting of November 2004 the rapporteur Member State indicated that these data were already made available to them but were not evaluated.

For the resubmission, new studies on sediment-dwelling organisms were provided with the metabolites TR-4, TR-7 and TR-14. The NOEC for TR-4 was 0.3324 mg/L; for TR-7 and TR-14 the NOEC values corresponded to the higher tested concentration (60 mg/kg and 77 mg/kg, respectively). TER calculations indicated a low risk from these metabolites.

Furthermore, the metabolites TR-6 and TR-15 were tested. These metabolites are less toxic to aquatic organisms than the parent compound. Based on the resulting TER-values the risk from these metabolites can be considered as low (Annex VI trigger not breached).

Studies on bio-accumulation in fish are available as the logPow exceeds 3 and the DT_{50} in water exceeds 10. The steady state bioconcentration factor is found to be 5674, which exceeds the Annex VI trigger value of 100 for not readily biodegradable products.

In the list of end points available at the EPCO expert meeting (section ecotoxicology, June 2004) it was stated that the CT_{50} for bioaccumulation is 6 hours. In a summary of all chronic toxicity studies, which was made available by the rapporteur Member State during the expert meeting, other and longer depuration half-lives were mentioned under remarks, as the main aim of these studies was to look at chronic effects. The EPCO experts concluded that the risk for bioaccumulation was addressed, and hence the risk for bioaccumulation can be regarded as low based on the very fast depuration. After this meeting EFSA noticed that the CT_{50} of 6 hours was erroneous. The rapporteur Member State communicated to EFSA that the correct value is 4.7 days. This was verified by EFSA in the study by Graper and Rainey (Greece, 2003, Vol.3 B.9.2.3/01), on which the BCF is based, and it is indeed stated in this study report that the depuration half-life equals 4.7 days. As this implies that the experts in the EPCO meeting may have based their decision on the wrong CT_{50} value in the list of end points at that time, the risk for bio-accumulation was further worked out by EFSA below in this conclusion.

This BCF-value and the fact that the depuration is less than 95% after 14 days trigger a fish full-life-cycle study which is available with the sheephead minnow. The resulting NOEC from this study is 1.3 µg/L (based on fecundity, no vertebral lesions observed), which is higher than the NOEC which was chosen for the long-term risk assessment in the original peer review. As mentioned above, a high long-term risk to aquatic organisms was identified for which a data requirement was open. Therefore, EFSA initially proposed that Member States may reconsider the risk for bioaccumulation when the long-term assessment is revised. Residues in fish were found during the available field monitoring study. The PRAPeR 68 meeting of experts considered the risk for bioaccumulation addressed by both the fish chronic end points identified to be used for risk assessment.

The secondary poisoning for birds and mammals was assessed (see 5.1) and the risk to fish-eating birds and mammals can be regarded as low (Annex VI trigger not breached).

An assessment of the biomagnification in aquatic food chains is not considered necessary as the DT_{90} for water and sediment is below 100 days.

5.3. Risk to bees

Acute contact and oral toxicity studies, both with trifluralin and the lead formulation, are available. The resulting HQ values do not breach the appropriate Annex VI trigger value indicating a low risk to bees.

5.4. Risk to other arthropod species

Toxicity to non-target arthropods was high in laboratory studies on the two indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Therefore extended laboratory studies with both indicator species were performed, in which the effect on mortality was less than the 50% Escort II trigger value, but the effect on fecundity exceeded this trigger for both species. Effects on fecundity at 60 g a.s./ha (drift rate= 33.24 g as/ha) are below the trigger, indicating a low risk for arthropods off-field.

Besides studies with the two indicator species, 4 acceptable studies with other species were presented of which 2 are ground-dwelling species (*Poecilus cupreus* and *Aleochara bilineata*)

and 2 are foliage-dwelling (*Chrysoperla carnea* and *Phygadeuon trichops*). For none of these species effects were noted above the Escort II trigger value, and hence the risk in-field for these species can be regarded as low. Ground-dwelling species are considered the most relevant in-field for this representative use as the product will be applied to bare soil.

5.5. Risk to earthworms

Studies on the acute toxicity to earthworms from trifluralin, the lead formulation and the metabolite TR-4 are available. The end points were corrected for the high logPow. The TER-values resulting from the end points derived from these studies do not breach the Annex VI trigger value, indicating a low acute risk to earthworms for the representative uses.

Due to its high DT_{90} (DT_{90}field > 365 days), long-term exposure is expected. A study on the effects on reproduction is available. The long-term risk assessment for earthworms was revised. This was during the EPCO expert meeting (section ecotoxicology) not yet available in an addendum but it was made available later by the rapporteur Member State (addendum 3 of June 2004). The resulting NOEC was refined taking into account actual test values (application rate and surface of the test unit, dry soil weight in the test unit), as the first-tier long-term TER value breached the Annex VI trigger value. This refined end point resulted in a TER-value of 4.44, which is slightly below the Annex VI trigger value of 5. It was agreed by the EPCO experts' meeting that the long-term risk to earthworms could be regarded as low in this case, given the worst case assumptions associated with the risk assessment (e.g. maximum soil PEC taking into account 14 years of accumulation and NOEC being at the top dose tested).

5.6. Risk to other soil non-target macro-organisms

Given the persistency in soil (DT_{90}field > 365 days), a litterbag study was conducted for this substance. For the 0.025 mm mesh bags no statistically significant effects were seen after six months when compared with the control. For the 0.5 mm mesh bags statistically significant effects were seen after six months when compared with the control, as the organic breakdown was increased in the treatment group. This was not regarded as an adverse effect.

It was noted by EFSA that the application rate in this study equals a single application, and not a single application including the accumulated concentration in the soil according to the Guidance Document on Terrestrial Ecotoxicology (European Commission, 2002b). Therefore, EFSA initially proposed that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached. The need for this study was not discussed in an EPCO experts' meeting. No new litterbag study was provided with the resubmission. The PRAPeR 68 meeting of experts agreed that no further data were necessary, since the usefulness of a litterbag study was quite often questioned. Therefore, the data gap was not confirmed.

5.7. Risk to soil non-target micro-organisms

The effects of a 480 EC formulation and the soil metabolite TR-4 were tested on soil microbial respiration and nitrogen transformation. No deviations of more than 25 % after 60 days were observed (i.e. no breaching of the Annex VI trigger value), and hence the risk to soil non-target micro-organisms is considered to be low. The tested concentrations cover the maximum PECs taking into account accumulation.

5.8. Risk to other non-target-organisms (flora and fauna)

Studies on the effects of trifluralin on non-target terrestrial plants are available. The rapporteur Member State assessed the risk in the DAR by comparing the NOEC expressed in drift rate with the Ganzelmeier drift rate at 1m without calculating a TER-value. The rapporteur Member State concluded that the risk to non-target plants is low and that risk mitigation measures are not necessary. But this approach does not take into account a safety factor.

Based on a NOEC of 35 g a.s./ha for cereals, the TER-values resulted in 1.05 at 1m and 5.12 at 5 m. According to the Guidance Document on Terrestrial Ecotoxicology (European Commission, 2002b), the TER of the most sensitive species should be compared to a trigger of 5 if at least 6 species have been tested. But this TER is then based on an ER_{50} and not on a more conservative NOEC value. Therefore, the risk to non-target terrestrial plants can certainly be considered as low if a no spray bufferzone of 5 m is taking into account, as it is based on this conservative NOEC value (see addendum made by EFSA).

Also a study on the post-emergence is available. Here cucumber is the most sensitive species with an ER_{25} (again no ER_{50} reported) of 748 g a.s./ha, which resulted in a TER value of 22.5 at 1m (see addendum 2 made by EFSA). The difference in sensitivity between the pre-emergence and post-emergence study can be explained by the fact that trifluralin is a pre-emergence herbicide.

The risk to non-target plants was not discussed in an EPCO expert meeting.

5.9. Risk to biological methods of sewage treatment

No effects were seen at the highest concentration tested (100 mg/L). The risk for biological methods of sewage treatment is considered to be low.

6. Residue definitions

6.1. Soil

Definition for risk assessment:	Trifluralin, TR-4 (anaerobic metabolite), TR-14 (anaerobic metabolite).
Definition for monitoring:	Trifluralin

6.2. Water

6.2.1. Ground water

Definition for exposure assessment:	Trifluralin, TR-4 (anaerobic metabolite), TR-14 (anaerobic metabolite)
Definition for monitoring:	Trifluralin

6.2.2. Surface water

Definition for risk assessment

in surface water:	Trifluralin, TR-6, TR-15
in sediment:	Trifluralin, TR-4, TR-7, TR-14
Definition for monitoring:	Trifluralin

6.3. Air

Definition for risk assessment:	Trifluralin
Definition for monitoring:	Trifluralin

6.4. Food of plant origin

Definition for risk assessment:	Trifluralin (cereals and oilseed/pulse crops)
Definition for monitoring:	Trifluralin (cereals and oilseed/pulse crops)

6.5. Food of animal origin

Definition for risk assessment:	not necessary/not proposed
Definition for monitoring:	not necessary/not proposed

6.6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

6.6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Trifluralin	Medium to highly persistent ($DT_{50\ lab}$ = 81 to 356 d at 22°C)	See points 5.5, 5.6 and 5.7.
TR-4 (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	Anaerobic metabolite. No DT_{50} available, assessed to be degradable under aerobic conditions based on chemical structure. Worst case DT_{50} = 1800 d used for FOCUS gw	Acute risk to earthworms is considered to be low (trigger not breached). The risk to soil non-target micro-organisms is considered to be low.
TR-14 (EFSA concluded that no further assessment is necessary for EU evaluation)	Anaerobic metabolite. No DT_{50} available, assessed to be degradable under aerobic conditions based on chemical structure.	No data with soil organisms available.

6.6.2. 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
Trifluralin	Immobile	No	Yes, to be assessed by Member States	Yes, assessed in the DAR	Yes, assessed in the DAR
TR-4 (anaerobic) (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	Immobile (SAR estimation)	No	-	-	Acute risk to earthworms is considered to be low (trigger not breached). Also the risk to sediment-dwelling organisms and soil non-target micro-organisms is considered to be low (trigger not breached).
TR-14 (anaerobic) (the EPCO expert meeting agreed that no further assessment was necessary for EU evaluation)	No data	Not assessed	-	-	

6.6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Trifluralin (water and sediment)	See point 5.2.
TR-6 (photolysis metabolite, water phase only)	The risk to aquatic organisms is considered low (trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.
TR-15 (photolysis metabolite, water phase only)	The risk to aquatic organisms is considered low (trigger not breached) based on an acute toxicity study with fish, an acute toxicity study with *Daphnia magna* and a toxicity study with algae.
TR-4 (sediment only)	The risk to sediment-dwelling organisms is considered to be low (trigger not breached).
TR-7 (sediment only)	Low risk is expected on sediment-dwelling organisms, since this metabolite is less toxic than the parent compound.
TR-14 (sediment only)	Low risk is expected on sediment-dwelling organisms, since this metabolite is less toxic than the parent compound.

6.6.4. Air

Compound (name and/or code)	Toxicology
Trifluralin	Rats LC_{50} inhalation > 1.252 mg/L air /4 h. head-only, no classification proposed.

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- Further information on conduct and comparability of north American residue trials in cereals is required to support southern European uses (relevant for the uses in cereals; submission date proposed by the notifier: December 2005; refer to point 3.1.1). This data gap is for information only as it refers to the non-supported use; the data gap becomes relevant only should this use be considered again in the future.
- For situations where anaerobic conditions are expected to be relevant, potential ground water contamination by metabolite TR-14 may need to be assessed (not essential to finalize the risk assessment at EU level, refer to point 4.1).
- A water sediment study conducted in the presence of light that could be used by Member States to refine the risk assessment performed in the context of Annex I inclusion (not essential to finalize the risk assessment at EU level, refer to point 4.2.1).
- FOCUS surface water step 3 and 4 calculations are required with PRZM simulations that simulate an even incorporation of trifluralin over the top 5cm. The pesticide properties that should be used are: soil DT_{50} geometric mean normalised to FOCUS reference condition laboratory values (ca. 135 days see open point 4.5); surface water DT_{50} 1000 days; sediment DT_{50}, a geomean of whole system values that represents actual degradation (includes volatile trap mass); K_{Foc} 8765 mL/g; 1/n=0.972; spray drift mitigation alone and spray drift + run-off mitigation at step 4 should be reported separately. For step 3 and 4 the patterns of exposure (e.g. graphical outputs from TOXSWA) that the models produced should be reported. The application window used in simulations should be appropriate and clearly reported (data gap identified at the PRAPeR TC10 meeting of experts, date of submission unknown, refer to point 4.2.1).
- Available monitoring data from the Arctic or other regions remote from agriculture should be provided to enable conclusions on the potential for long-range atmospheric transport to be drawn. In particular, data quoted in Trifluralin Dossier for the LRTAP Protocol on POPs (European Commission 2007b) need to be provided and assessed (data gap identified at the PRAPeR TC10 meeting of experts, date of submission unknown, refer to point 4.3).
- A data gap was identified to provide a chronic risk assessment for fish based on the most relevant end point and on Step 3 and Step 4 PECsw values (data gap identified at the PRAPeR 68 meeting of experts, date of submission unknown, refer to point 5.2).

CONCLUSIONS AND RECOMMENDATIONS

OVERALL CONCLUSIONS

The conclusion of the resubmission was reached on the basis of the evaluation of the representative uses as a herbicide as proposed by the applicant which comprise pre-sowing/ pre-emergence applications by broadcast spraying to bare soil followed by incorporation into soil to control grass and broad-leaved weeds in oilseed rape, sunflower and cotton, at maximum application rate of 1.2 kg trifluralin per hectare. The use on winter cereals was not supported in the resubmission application, and therefore the conclusion has only been updated in relation to the risk assessment for the representative uses presented in the Additional

Report. The risk assessment presented for winter cereals has not been updated. Trifluralin can be used only as a pre-emergence herbicide.

The representative formulated product for the evaluation was 'EF-1521' ('Treflan'), an emulsifiable concentrate (EC), registered under different trade names in Europe.

Analytical methods for the determination of residues of trifluralin are available for commodities with high fat content (e.g. oilseed rape), cereals, soil, water (incl. drinking and surface water) and air.

An analytical method for food of animal origin is currently not required due to the fact that no residue definition is proposed at the moment.

In the mammalian metabolism studies, trifluralin is extensively and rapidly metabolised and absorbed. It has a low acute toxicity, but has sensitising properties (proposed classification: R43 **"May cause sensitisation by skin contact"**). Trifluralin induced neoplastic changes, and carcinogenic effects were seen in rats such as Leydig cell tumours, thyroid tumours and renal carcinoma (proposed classification: R40 **"Limited evidence of a carcinogenic effect"**). A NOAEL could not be established, but the LOAEL of 30 mg/kg bw/day in the rat was assigned as the most relevant effect level. There were no direct effects on reproductive performance or fertility.

The ADI is 0.015 mg/kg bw/day based on the LOAEL in the rat carcinogenicity study with a margin of safety between LOAEL and ADI of 2000.

The AOEL is 0.026 mg/kg bw/day and no ARfD was allocated. According to the German model, the estimated operator exposure was below the AOEL only if personal protective equipment is worn both during mixing/loading and during application.

The metabolism of trifluralin was investigated in cereals (maize) and oilseed crops (rapeseed, soybean and cotton). In maize, trifluralin was extensively metabolised and residues were shown to consist of numerous compounds, with few being identified due to their low levels. The uptake was also limited in rapeseed with low radioactive residues at harvest. No parent trifluralin was detected in mature seeds and mature plant samples; the major compound identified (*ca* 35% TRR) was the metabolite TR-14, mainly as conjugate. However, and considering its absolute low level, the PRAPeR 70 meeting of experts agreed not to include this metabolite in the residue definitions. Finally, it was concluded that the residue definitions for risk assessment and monitoring initially proposed by the EPCO 05 meeting on residues for cereals and limited to the parent trifluralin only, are also applicable to the oilseed crops.

No residues of trifluralin above the LOQ (0.01 mg/kg) were detected in any of the grain samples collected in the supervised trials conducted on rapeseed, sunflower and cotton according to the critical GAP in Northern and Southern Europe.

Processing studies were not submitted and were considered not necessary. Livestock studies were not assessed in the framework of the resubmission, since no significant residues are expected in oilseed commodities at harvest.

The chronic dietary exposure assessment for consumers based on the EFSA PRIMo rev2 and the proposed MRLs of 0.01* mg/kg for rapeseed, sunflower and cotton leads to estimated intakes less than 0.1% of the proposed ADI for all the European diets included in the model. No ARfD was allocated, thus, no acute risk calculation was performed for trifluralin.

Under aerobic conditions degradation of trifluralin in soil did not lead to any major metabolites, but several minor metabolites were formed by oxidative dealkylation of N-propyl, reduction of nitro groups with cyclation and dimerization to form azoxy-benzene compounds. The level of unextractable residues was between 23.3 % and 43.1 % AR after 120 days and reached between 33.5 % and 54.1 % after one year. As measured in one soil, CO_2 evolved was 8.4 % AR at 120 days and 18.5 % AR after one year.

Under flooded anaerobic conditions a major metabolite TR-4 is formed. Furthermore, metabolite TR-14 was formed at amounts above 5 % at the end of the study in all three anaerobic soils tested. The EPCO 02 experts' meeting (section fate and behaviour) agreed that according to the molecular structure it may be expected that this metabolite undergoes degradation under aerobic conditions and that therefore, relevance of metabolite TR-4 may be addressed by Member States where anaerobic conditions are envisaged to be relevant. Whereas not discussed in particular during the peer review, it is the EFSA's opinion that the same conclusion may be reached for metabolite TR-14.

Under aerobic laboratory conditions trifluralin is medium to highly persistent with half-lives between 81 to 356 days at 22°C. The degradation under anaerobic conditions was faster than under aerobic conditions.

Overall mean half-life in field is 170 days confirming the concern for the high persistence of this compound already shown by the laboratory studies. Potential for accumulation has been estimated by calculation with the worst-case field DT_{50}. PEC soil calculated using worst-case DT_{50} are employed in the risk assessment for Annex I inclusion and shown in the list of end points.

Data indicate that trifluralin is strongly adsorbed to soil and could be classified as immobile. For the anaerobic metabolite TR-4 Koc was estimated, using the "pckocwin v.1.66 (EPA)" program, indicating also low mobility potential for this metabolite.

Trifluralin is hydrolytically stable in sterile aqueous buffers between pH 3 and pH 9 at 52°C, with an extrapolated half-life above one year at 20°C. Aqueous photolysis may contribute to the environmental degradation of trifluralin and it is enhanced in natural water. Photodegradation of trifluralin led to the formation of two major photoproducts: TR-6 and TR-15. Initial PECsw values have been calculated for these metabolites based on the maximum amounts observed in the photolysis study. No further data were deemed necessary to conclude the risk assessment for these metabolites.

Trifluralin is not readily biodegradable.

The selection of the most appropriate DT_{50} to be used for PECsw calculation and aquatic risk assessment was discussed in two EPCO experts' meetings (April 2004 and June 2004). It was agreed that worst-case DT_{50} = 13 days from the first study by Yon (Greece, 2003, Vol.3 B.8.4.3.2) should be employed for the risk assessment performed in the context of Annex I inclusion, and that a DT_{50} = 2 days from the third study by Cook and Meitl (Greece, 2005, Addendum2 Vol.3 B.8.4.3.2) could be used to refine the risk assessment when appropriate. PECsed values are calculated for trifluralin metabolites TR-4 and initial PECsed values are also calculated for metabolites TR-7 and TR-14.

Due to the potential contribution of photolysis to the dissipation of trifluralin in water, the EPCO 02 expert meeting (section fate and behaviour) confirmed the need for a water sediment study conducted in the presence of light that could be used by Member States to refine the risk assessment performed in the context of Annex I inclusion.

In the resubmission dossier new PEC $_{SW/SED}$ values based on step 3 and step 4 FOCUS SW were provided for trifluralin. In spite of the drawbacks of the calculations available, the PRAPeR TC 10 meeting of experts concluded that the maximum PEC_{SW} and PEC_{SED} at step 3 would result from a loading to the water body driven by drift, and a reliable risk assessment would be obtained if this maximum value is used for the risk assessment. However, if information on the pattern of exposure at step 3 or step 4 calculations are needed for the assessment, then the calculations available would be not acceptable and/or would be insufficient to finalize the risk assessment. The meeting of experts identified a data gap for FOCUS SW calculations that provide the necessary information needed to finalize the risk assessment.

After the resubmission, PECgw of trifluralin and the anaerobic metabolite TR-4 were estimated by the rapporteur Member State using FOCUS PELMO 3.2.2 for the EU scenarios and the representative uses considered. Calculated concentration in groundwater for both compounds was negligible in all relevant scenarios.

Trifluralin was designated as a "priority substance" under the water framework directive but has not been identified as a "priority hazardous substance". However, trifluralin was added to the OSPAR (Convention for the Protection of the Marine Environment of the North-East Atlantic) List of Chemicals for Priority action in 2002, because it is considered to be a PBT substance.

Because of its high volatility, the occurrence of trifluralin in air and transport through air is possible. However, the photochemical half-life in air is estimated to be short ($DT_{50\ air} << 2$ days). A data gap was identified by the PRAPeR TC 10 meeting of experts for the monitoring data in the Arctic regions reported by Canadian researchers and quoted in the Trifluralin dossier for the LRTAP Protocol on POPs (European Commission, 2007b).

PECair were not calculated since they are not used in the assessment and no method at EU level is agreed for such calculation.

The risk to insectivorous and fish-eating birds and mammals, bees, ground-dwelling arthropods, soil micro-organisms and earthworms is low with respect to trifluralin and the metabolites as far as investigated.

In the original peer review high risks were identified for aquatic organisms, in particular the risk for fish, which requires consideration of appropriate risk mitigation measures. Using the initial PEC value together with the NOEC of 0.3 µg/L leads to a TER-value of 0.38 when a bufferzone of 15 metres is taken into account, which is below the Annex VI trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Further data were considered necessary to address this risk and enable conclusions on the risk assessment to be drawn.

For the resubmission, a new 35-day static early-life-stage (ELS) study was conducted with fathead minnow (*Pimephales promelas*) in a water-sediment system. In addition to the standard observations (i.e. growth and survival), skeletal irregularity was also analysed. The agreed end point from this study was the NOEC of 3.2 µg a.s./L. However, since no data on the exposure pattern were available, it was not possible to assess if it would be appropriate to use the new end point for a refined risk assessment.

Based on the data gap identified at the PRAPeR TC 10 meeting (see point 4.2.1), a data gap was identified to provide a chronic risk assessment for fish based on the most relevant end point and on step 3 and step 4 PECsw values.

The EPCO 08 expert meeting (section ecotoxicology, June 2004) considered the risk to earthworm-eating birds and mammals as low based on the TER value reflecting the soil accumulation plateau. EFSA would like to highlight that the risk to earthworm-eating birds and mammals should be considered further at Member State level, when the product is applied after this plateau value is reached.

EFSA initially proposed that a new litterbag study should be made available in which the tested dose rate reflects the concentration in the soil after a single application when the accumulation plateau has been reached, as the study which is available at present was performed at a lower dose rate. This data requirement was not discussed in an EPCO expert meeting. No new litterbag study was provided with the resubmission dossier. However, the PRAPeR 68 meeting of experts considered this study no longer necessary. The data gap was therefore not confirmed.

The risk to non-target plants could not be calculated with the appropriate end point (an ER_{50}-value) as this value is not reported in the DAR. Based on a conservative NOEC, the risk to non-target plants can be certainly regarded as low if a bufferzone of 5 metres is taken into account.

Regulation (EC) No 850/2004[25] of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC entered into force when the initial peer review of trifluralin was in an advanced stage. For this reason, the original EFSA conclusion (EFSA, 2005a) did not specifically assess trifluralin against the criteria set out in paragraph 1 of Annex D of the Stockholm Convention.

In the framework of the resubmission procedure, it was identified that EFSA should compare the agreed end points against the criteria set in the Stockholm Convention.

Persistence:

- *Stockholm Convention Criteria: evidence that half-life in soil > six months (EFSA interprets 182.5 days)*

  Trifluralin end points:

  DT_{50} soil (laboratory data) = 81 – 356 days (geometric mean: 161 days)

  DT_{50} soil (laboratory data normalized to 20 °C, pF 2) = 66.3 – 279 days (geometric mean: 134 days)

  DT_{50} soil (field studies, un-normalized) = 54 – 375 days.

- *Stockholm Convention Criteria: evidence that half-life in water > 2 months (EFSA interprets 60.8 days)*

  Trifluralin end points:

  Trifluralin is stable to hydrolysis under common environmental conditions (20 °C, pH 4 – 9).

  Trifluralin dissipates from water in dark water/sediment systems in a maximum 13 days due mainly to volatilization and adsorption to the sediment.

  Trifluralin degradation in dark water/sediment systems was not determined due to the dominant contribution of volatilization.

[25] OJ No L 158, 30.04.2004, p. 21

- *Stockholm Convention Criteria: evidence that half-life in sediment > six months (EFSA interprets 182.5 days)*

  Trifluralin end points:

  Trifluralin dissipates from sediment in dark water/sediment systems in a maximum 24.5 days due mainly to partition to water followed by volatilization.

  Trifluralin degradation in dark water/sediment systems was not determined due to the dominant contribution of volatilization.

- *Stockholm Convention Criteria: evidence that the chemical is otherwise sufficiently persistent to justify its consideration within the scope of the Convention*

  Trifluralin assessment:

  A data gap has been identified by the PRAPeR TC 10 meeting of experts for the monitoring data in the Arctic regions reported by Canadian researchers and quoted in the Trifluralin dossier for the LRTAP Protocol on POPs (European Commission, 2007b).

Bioaccumulation:

- *Stockholm Convention Criteria: bio-concentration factor or bio-accumulation factor in aquatic species > 5000 or, in absence of such data, that the log Kow > 5*

  Trifluralin end points:

  BCF in fish: 5674 mL/g

- *Stockholm Convention Criteria: other reasons for concern, such as high bio-accumulation in other species, high toxicity or ecotoxicity*

  No other information is available for ecotoxicology.

- *Stockholm Convention Criteria: monitoring data in biota indicating that the bio-accumulation potential of the chemical is sufficient to justify its consideration within the scope of the Convention*

  A field monitoring study on fish was available in the DAR (Greece, 2003, Vol.3 B9.2.5/01). The study was designed to measure trifluralin residues in fish and benthic invertebrates; to perform radiological examinations on fish and to monitor the concentrations of trifluralin in water, sediment and field run-off. Trifluralin can accumulate to detectable levels in fish inhabiting ponds that receive run-off from fields treated with trifluralin. The half-life of trifluralin in the tissues of several fish species ranged from 15-30 days.

Potential for long-range environmental transport:

- *Stockholm Convention Criteria: measured levels of the chemical in locations distant from the sources of its release that are potential concern*

- *Stockholm Convention Criteria: monitoring data showing that long-range environmental transport of the chemical, with the potential for transfer to a receiving environment, may have occurred via air, water or migratory species*

  Trifluralin assessment:

  A data gap was identified by the PRAPeR TC 10 meeting of experts for the monitoring data in the Arctic regions reported by Canadian researchers and quoted in the Trifluralin dossier for the LRTAP Protocol on POPs (European Commission 2007b).

- *Stockholm Convention Criteria: environmental fate properties and/or model results that demonstrate that the chemical has a potential for long-range environmental transfer through air, water or migratory species, with the potential for transfer to the receiving environment in locations distant from the sources of its release. For a chemical that migrates significantly through the air, its half-life in air should be greater than two days*

  Trifluralin end points:

  Photochemical half-life in air calculated to be 5.3 hours or 0.446 days (using [OH]= 1.5 x 10^6 radicals /cm^3 and assuming 12 hours of sunlight per day; half-life in air << 2 days)

Adverse effects:

- *Stockholm Convention Criteria: evidence of adverse effects to human or the environment that justifies consideration of the chemical within the scope of the Convention*

  Trifluralin end points:

  Trifluralin is classified as 'Very toxic to aquatic organisms/May cause long-term adverse effects in the aquatic environment' (R50/R53).

  Trifluralin is classified as a carcinogenic substance category 3, R40: "Limited evidence of a carcinogenic effect" (for an overview of the toxicological profile of the active substance, please refer to the list of end points in Appendix A).

- *Stockholm Convention Criteria: toxicity or ecotoxicity data that indicate the potential for damage to human health or to the environment*

  Trifluralin end points:

  For ecotoxicology refer to the information reported under the subsections above "Bioaccumulation" and "Adverse effects".

  Evidence of carcinogenic potential was found in Fischer 344 rat (tumour formation in various tissues, i.e. kidney, urinary bladder, thyroid, Leydig cell). The mechanism of tumour formation is not identified (refer to section 2.5 of the conclusion).

EFSA acknowledges that the assessment presented in this conclusion only considers a limited range of representative uses on the basis of the information provided by the notifier in the application dossier and by the Member States during the peer review. Therefore, other information may need to be considered by the Commission and the Member States when assessing trifluralin with respect to Regulation (EC) No 850/2004.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED (for the supported uses in the resubmission)

- The two-year shelf-life study indicates that permanent agitation of the tank mixture during the spraying is appropriate to exclude any problems regarding the emulsion stability.
- The estimated operator exposure was below the AOEL only if PPE (gloves) is used during mixing and loading as well as during application (gloves and coverall) (refer to point 2.12).
- The application of trifluralin on oilseeds used as forage to feed animals has not been considered in the framework of the resubmission. This point should be reconsidered at Member State level if such a use is envisaged (refer to point 3.2).

- The uses supported in the resubmission are only representative of incorporated applications; the PRAPeR TC 10 meeting of experts agreed that it is important to highlight that for this substance incorporation may mitigate the potential volatilization losses and may contribute to the run-off mitigation.
- EFSA would like to highlight that the risk to earthworm-eating birds and mammals should be considered further at Member State level when the product is applied after the plateau value is reached (refer to point 5.1).
- Appropriate risk mitigation measures (e.g. a 5 meter no spray bufferzone) are required with regard to the risk for non-target terrestrial plants (refer to point 5.8).

ISSUES THAT COULD NOT BE FINALIZED

- The surface water exposure assessment is not finalized. A data gap for FOCUS SW calculations was set to provide the information needed to finalize the EU risk assessment.
- The chronic risk for fish is not finalized, since it was not possible to assess if it would be appropriate to use the new chronic fish end point for a refined risk assessment.
- The assessment of the potential for long-range transport was not finalized, since a data gap was identified for available monitoring data from the Arctic or other regions remote from agriculture to enable conclusions to be drawn.

CRITICAL AREAS OF CONCERN (for the supported uses in the resubmission)

- The risk to aquatic organisms was high, in particular the risk for fish. Using the initial PEC value together with the NOEC of 0.3 µg/L leads to a TER-value of 0.38 when a bufferzone of 15 metres is taken into account which is below the trigger value of 10 (without detailed calculations, a bufferzone of 50 m should lead to a TER-value of approximately 1). Following the resubmission, a potential high chronic risk for fish could not be excluded since it was not possible to assess if it would be appropriate to use the new chronic fish end point for a refined risk assessment. (refer to the identified data gaps by PRAPeR TC 10 and PRAPeR 68).
- The potential for long-range transport cannot be concluded without the proper consideration of existing scientific information indicating the detection of trifluralin in the Arctic regions (European Commission 2007b).

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APPENDICES

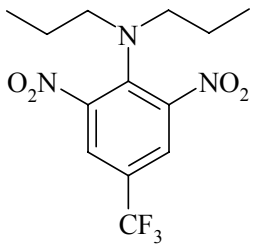
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Changes as a result of the resubmission evaluation highlighted in yellow

Appendix 1.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Trifluralin
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	Greece

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	α,α,α-trifluoro-2,6-dinitro-*N*,*N*-dipropyl-*p*-toluidine
Chemical name (CA) ‡	2,6-dinitro-*N*,*N*-dipropyl-4-(trifluoromethyl) benzenamine
CIPAC No ‡	183
CAS No ‡	1582-09-8
EEC No (EINECS or ELINCS) ‡	EINECS: 216-428-8 ELINCS: not applicable
FAO Specification ‡ (including year of publication)	AGP: CP/235 (1988); 183/TC/S 950 g/kg (±20 g) *N*-nitroso-di-*n*-propylamine: max. 1 mg/kg
Minimum purity of the active substance as manufactured ‡ (g/kg)	950 g/kg, for both companies of the EUTTF
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	*N*-nitroso-di-*n*-propylamine: max.1 mg/kg
Molecular formula ‡	$C_{13}H_{16}F_3N_3O_4$
Molecular mass ‡	335.28
Structural formula ‡	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	47.2 ± 0.1 °C (pure 99.4%)
Boiling point (state purity) ‡	Not determinable due to decomposition
Temperature of decomposition	202 ± 1 °C (pure 99.4%)
Appearance (state purity) ‡	pure a.s. (99.4%): bright orange crystalline solid, with odour vaguely of mothballs tech. a.s. (96.2%): bright orange crystalline solid, with faint aniline odour
Vapour pressure ‡ (state temperature, state purity)	9.5×10^{-3} Pa at 25°C (pure 100%)
Henry's law constant ‡	10.2 $Pa \cdot m^3 \cdot mol^{-1}$ at 20 °C (pure 100%)
Solubility in water ‡ (state temperature, state purity and pH)	At 20 °C (pure 100%): In distilled water: 0.194 mg/L pH 5: 0.184 mg/L pH 7: 0.221 mg/L pH 9: 0.189 mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	>250 g/kg in hexane, toluene, chloroform, methylene chloride, acetone, ethyl acetate and acetonitrile, at 20 °C. 142.0 g/L in methanol at 18 °C.
Surface tension (state concentration and temperature, state purity)	at 24.5° C: 71.4 mN/m (saturated solution) 72.1 mN/m (half-saturated solution) (tech. 96.8%)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{o/w}$ = 5.27 at 20 °C (pure 100%) pH ranged 7.73-8.86 (pH of aqueous phase after partition)
Dissociation constant ‡(state purity)	Not determinable since trifluralin does not contain ionizable functional groups.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	In neutral medium (CH_3OH): pure 99.5% (or 99.9%) λmax (nm) — ε ($M^{-1} \times cm^{-1}$) 209.0 — 19.4×10^3 272.2 (or 273) — 8.46×10^3 (or 7.69×10^3) 385 — 2.44×10^3
Flammability (state purity)‡	Non highly flammable (technical 97.86%)
Explosive properties (state purity)‡	Not explosive (technical 96.8%)
Oxidising properties ‡(state purity)‡	Not oxidising (technical 96.8%)

List of representative uses evaluated*(Trifluralin)

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			PHI (days)	Remarks: (m)
					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 (l) min max	water l/ha min max	kg as/ha (l) min max	(m)	
Oilseed rape	Northern and Southern Zones	Treflan 'EF-1521'	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre A/S	1	NA	0.08-0.8	150-600	0.48-1.2	NA	Low rate in light soils, high rate in heavy soils The dose should not exceed the 1.2 kg a.s./ha [1]
Sunflower	Northern and Southern Zones	Treflan 'EF-1521'	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre S	1	NA	0.08-0.8	150-600	0.48-1.2	NA	
Cotton	Southern Zone	Treflan 'EF-1521'	F	Grass and broad-leaved weeds	EC	480 g/L	BI	Pre Pre S	1	NA	0.08-0.48	200-600	0.48-1.2	NA	

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			PHI (days)	Remarks: (m)
					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 (l) min max	water l/ha min max	kg as/ha (l) min max	(m)	
~~Winter Cereals~~	~~Northern Zone~~	~~EF 1521~~	~~F~~	~~Grass and broad-leaved weeds~~	~~EC~~	~~480 g/L~~	~~BS~~	~~Post Pre A~~	~~1~~	~~NA~~	~~0.096-0.74~~	~~150-600~~	~~0.576-1.2~~	~~NA~~	Non-supported uses.
~~Winter Cereals~~	~~Southern Zone~~	~~EF 1521~~	~~F~~	~~Grass and broad-leaved weeds~~	~~EC~~	~~480 g/L~~	~~BS~~	~~Post Pre A~~	~~1~~	~~NA~~	~~0.096-0.74~~	~~150-600~~	~~0.576-1.2~~	~~NA~~	

[1] Environmental and ecotoxicological risk assessment could not be finalized.

BI = Broadcast spray to bare soil followed by incorporation into soil

BS = Broadcast spray to bare soil without incorporation

Pre Pre= Pre-sowing pre-emergence

Post Pre = Post sowing pre-emergence

A = Autumn , S= Spring, NA = Not applicable

* 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).	(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).

(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	(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

Appendix 1.2: Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (analytical technique)	Dow AgroSciences Certain amounts of trifluralin technical and dimethyl phthalate (IS) are dissolved in acetone and trifluralin content is determined by GC/FID. Makhteshim Agan Certain amounts of trifluralin technical product and dipropylphthalate (internal standard) are dissolved in acetonitrile. The solution is sonicated and filtered through a 0.45µm filter. Analysis is made by GC/FID.
Impurities in technical as (analytical technique)	DowAgroSciences Significant impurities Trifluralin technical is dissolved in acetone. Analysis is made by GC/FID using the external standard technique. *N*-nitrosamines The method is applied for the determination of the volatile nitrosamines NDMA, NDEA, NDPA, NDBA, NPIP, NPYR and NMOR. Certain amounts of trifluralin technical, sodium chloride, ascorbic acid, glycerine are dissolved in water. The mixture is boiled at 35^{o}C under vacuum in a Claisen apparatus and the distillate is collected. The distillate is extracted by SPE (elution with dichloromethane). The determination of the volatile nitrosamines is performed by GC using thermo energy analyzer detector. Quantitation is made by the internal standard technique (N-nitroso-buthyl-propyl-amine). Makhteshim Agan Significant impurities Trifluralin technical is dissolved in acetonitrile. The solution is sonicated and filtrated through a 0.45µm filter. Analysis is made by GC/FID using the external standard technique. *N*-nitrosamines The method is applied for the determination of *N*-

	nitrosodipropylamine (NDPA). A certain amount of trifluralin technical and a certain amount of N-nitrosodiethylamine (NDEA) standard solution (internal standard) are dissolved in n-hexane. The solution is sonicated, cleaned-up through a Bio-Rad chromatographic column and filtered through a 45µm filter paper. Analysis is made by GC using a thermal energy analyzer detector.
Plant protection product (analytical technique)	An aliquot of the sample is diluted with an internal standard solution of dipropyl phthalate in ethyl acetate and analyzed by GC/FID. Quantitation is made by internal standard calculation using peak areas.
Impurities in the plant protection product (analytical technique)	Determination of di-n-propylnitrosoamine in formulation EF-1521: An aliquot of the sample is spiked with an internal standard solution of di-iso-propylnitrosoamine (DiPNA) in 1-chlorobutane. A solid phase extraction technique is performed on an aliquot of sample that has been spiked with internal standard. An aliquot of the extract is analysed by GC/MS. Quantitation is performed at m/z 130 for both DiPNA and DnPNA. Qualitative confirmation is performed at m/z 70 for both DiPNA and DnPNA. External standard calculation using peak areas may also be performed.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		trifluralin
Food of animal origin		not necessary/not proposed
Soil		trifluralin
Water	surface	trifluralin
	drinking/ground	trifluralin
Air		trifluralin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Method GRM 01.29 (Ref. OR43) Substrates: cottonseed, wheat, barley Extraction: Samples are extracted with methanol. Clean up: The extracts are diluted with water and purified using a hydrophilic-lipophilic balanced SPE column. Analysis: Analysis is carried out by GC/NCI-MS. Determined analyte: trifluralin LOQ: 0.01 mg/kg Method ERC 94.13 (Ref. OR03) Substrates: oilseed rape (whole plant, straw, seed) Extraction: Samples are extracted with methanol. After addition of water the methanol extract is partitioned into hexane. Clean up: The hexane extract is purified using a Florisil SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg for oilseed rape seed 0.2 mg/kg for oilseed rape whole plant and straw Method ERC 94.4 (Ref. OR02) Substrates: sunflower seed Extraction: Samples are extracted with methanol. After addition of water the methanol extract is partitioned into hexane. Clean up: The hexane extract is purified using an aminopropyl SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	No method submitted, but not required, since no MRLs have been proposed for products of animal origin.

Soil (analytical technique and LOQ)	1) Method ERC-96.26 (Ref.: OR16) Substrate: sediment Extraction: Residues of trifluralin are extracted from sediment with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg 2) Method ERC 92.41 (Ref.: OR05) Substrate: soil Extraction: Residues of trifluralin are extracted from sediment with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.01 mg/kg 3) Method AM-AA-CA-R116-AA-755 (Ref.: OR04) Substrate: soil Extraction: Residues of trifluralin are extracted from soil with an aqueous acetonitrile mixture. Clean up: The extract is purified using a C18 SPE cartridge. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.022 mg/kg
Water (analytical technique and LOQ)	Method GRM-01.34 (Ref.: OR51) Substrates: drinking water, surface water, ground water Extraction: Samples are extracted with isooctane. Analysis: Analysis is carried out by GC/NCI-MS. Determined analyte: trifluralin LOQ: 0.05 µg/L

Air (analytical technique and LOQ)	Method 295/152-D2149 (Ref.: OR55) Substrates: Air (ambient temperature and humidity and 35°C and >80% humidity) Extraction: The trifluralin residue is extracted from the XAD-4 resin air sampling tubes with hexane. Analysis: Analysis is carried out by GC/ECD. Determined analyte: trifluralin LOQ: 0.72 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	No method submitted, but not required.

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

	RMS/peer review proposal
Active substance	None

Appendix 1.3: 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 nearly complete (82 % at 48 hrs after single oral administration), plasma Cmax at 0.75-4 hrs after both single low and high oral dose administration
Distribution ‡	Widely distributed; highest concentration in adrenals, fat, kidneys, liver, skin and blood
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	Rapid and higher than 90 % at 168 hrs, mainly via bile, otherwise via faeces, regardless of dose level
Metabolism in animals ‡	Extensively metabolized, mainly through conjugation (75 % of the urine residue), reduction of nitro-groups, N-dealkylation, hydroxylation and cyclization reactions. Numerous minor urinary metabolites (< 5 % of the urine residue or < 2 % of the initial dose); four faecal identified metabolites (1-9 % of the dose). No species difference
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 1.252 mg/L/ 4-hour, head only exposure	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitising (M & K)	**R43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Decreased body weight gain, increased alpha-1 globulin and albumin concentrations (rat), anaemia

	(dog), increased liver weight (rat, dog)	
Relevant oral NOAEL ‡	2.4 mg/kg bw/day, 1-year dog study 5 mg/kg bw/day, 90-day rat study	
Relevant dermal NOAEL ‡	1000 mg/kg bw/day, 21-day rabbit	
Relevant inhalation NOAEL ‡	> 0.09 mg/kg bw/day (i.e. 22.5 µg/L), 21-day rat study (limit test)	

Genotoxicity ‡ (Annex IIA, point 5.4)

Weak clastogenic and aneugenic effects in a limited number of *in vivo* and *in vitro* studies, not confirmed in the most reliable, *in vivo* GLP study (micronucleus study with kinetochore staining)	

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

Target/critical effect ‡	Body weight reduction, anaemia, liver & kidney effects (mouse, rat). Tumour formation in kidney, thyroid, urinary bladder, Leydig cells (Fischer 344 rat).	
Relevant NOAEL ‡	Not established LOAEL = 30 mg/kg bw/day, 2-year rat NOAEL = 40 mg/kg bw/day, 2-year mouse	
Carcinogenicity ‡	Evidence of carcinogenic potential in Fischer 344 rat (tumour formation in various tissues, i.e. kidney, urinary bladder, thyroid, Leydig cell). The mechanism of tumour formation is not identified.	**R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Decreased maternal growth, anaemia, uterine atrophy and decreased offspring growth and survival from 40,7-50,8 mg/kg bw/day (rat)	

Relevant parental NOAEL ‡	4.5-5.8 mg/kg bw/day	
Relevant reproductive NOAEL ‡	148 mg/kg bw/day* (overall from two multigeneration studies)	
Relevant offspring NOAEL ‡	4.5-5.8 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	No teratogenic or fetotoxic effects were observed at non-maternally toxic doses (rat, rabbit)	
Relevant maternal NOAEL ‡	Rabbit: 50 mg/kg bw/day Rat: 100 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rabbit: 50 mg/kg bw/day Rat: 300 mg/kg bw/day	

*Agreed at EPCO 04 experts meeting in May 2004 (18002/EPCO/PSD/04)

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data-not required	
Repeated neurotoxicity ‡	No data-not required	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Increase in hyaline droplet formation in the renal cortical tubular epithelium and altered urinalysis. NOAEL = 2.6 mg/kg bw/day (50 ppm), 90-day rat
Studies performed on metabolites or impurities ‡	No data-not required

Medical data ‡ (Annex IIA, point 5.9)

Effects of occupational exposure involve redness, rash, hives, vesicular change, bullae and pruritis. Epidemiological studies revealed that there was no evidence of correlation between increased cancer incidence rate or reproductive effects or asthma and exposure to trifluralin.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.015 mg/kg bw/day	LOAEL of 30 mg/kg bw/day rat carcinogenicity study	2000†
AOEL ‡	0.026 mg/kg bw/day	90-day rat mechanistic urinalysis study	100
ARfD ‡	Not relevant		

† The safety factor was agreed on the EPCO expert meeting in May 2004 (18002/EPCO/PSD/04) to be allocated for trifluralin since the ADI is based on a LOAEL (based on tumour formation) instead of a NOAEL.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (TREFLAN (code EF-1521) EC containing 480 g/L trifluralin)	A default value of 10 % is used for both the concentrate formulation and the in-use field dilution

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Field application with tractor mounted boom sprayer application rate of 1.2 kg trifluralin/ha (high).
	UK POEM: % of AOEL
	Without PPE 6008 %
	PPE gloves (M/L+A) 746 %
	German model: % of AOEL

	Without PPE: 1469 % PPE gloves (M/L): 562 % PPE gloves (M/L+A), coverall (A): 62 % Field application with tractor mounted boom sprayer application rate of 0.48 kg trifluralin/ha (low). UK POEM: % of AOEL Without PPE 2404 % PPE gloves (M/L+A) 300 % German model: % of AOEL Without PPE: 588 % PPE gloves (M/L): 223 % PPE gloves (M/L+ A), coverall (A): 23 %
Workers	Re-entry is not applicable since it is a pre-emergence herbicide applied directly to the soil.
Bystanders	The exposure is below the AOEL.

M/L = Mixing and loading, A = Application

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

	RMS/peer review proposal
Substance classified (trifluralin)	**Xn** "Harmful" **Carc. Cat. 3, R40:** "Limited evidence of a carcinogenic effect" **R43:** "May cause sensitization by skin contact"

Appendix 1.4: Residues

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

Plant groups covered	Cereals (maize), Pulses/Oilseeds (oilseed rape, cotton, soybean)
Rotational crops	Leafy crops (cabbage), Root vegetables (sugar beet, turnip), Cereals (maize and wheat), Pulses/Oilseeds (soybeans) and Fruit crops (tomato)
Plant residue definition for monitoring	Trifluralin (for cereals and pulses/oilseeds)
Plant residue definition for risk assessment	Trifluralin (for cereals and pulses/oilseeds)
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	Not necessary for the supported use
Animal residue definition for monitoring	Not necessary for the supported use
Animal residue definition for risk assessment	Not necessary for the supported use
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not relevant
Fat soluble residue: (yes/no)	Yes (log $P_{O/W}$ >4 at 25 °C)

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

.....	TRR less than 0.15 mg equiv./kg in immature and mature rotational crops (cereals, pulses, leafy, root and fruit crops) planted 30 days or more after applications at rates approximately equal to the GAP, and less than 0.08 mg/kg in crop parts relevant for human consumption. Residues comprised of multiple components, none exceeded 0.01 mg/kg. Metabolism in rotational crops considered similar to primary crops. In several US field studies, trifluralin residues <0.01 mg/kg (3 sites) in wheat grains and <0.01 mg/kg (5 sites) and 0.03 mg/kg (1 site) in maize grains, for crops planted in normal rotation after applications of trifluralin over two or three successive years at 2 or 3 times the normal application rate.

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

..

Studies performed on water containing-, starch- and oily-matrices following an initial storage at +4°C or ambient temperature for 7 to *ca* 50 days with a further period at -15°C or -25°C up to *ca* 16 months. An initial decline (15% to 30%) was observed in several matrices (among which oily matrices), during the initial storage period, but no additional decrease was observed for the storage period at -15 or -25°C. Thus trifluralin residues were considered stable up to 12-16 months when stored frozen.

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

Intakes by livestock ≥ 0.1 mg/kg diet/day:	**Ruminant:** yes/no	**Poultry:** yes/no	**Pig:** yes/no
Muscle	no	no	no
Liver	no	no	no
Kidney	no	no	no
Fat	no	no	no
Milk	no		
Eggs		no	

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern /Southern Region	Trials results relevant to the critical GAP (a)	Recommendation/ comments	MRL (mg/kg)	HR (c)	STMR (b)
Oilseed Rape	NEU	12x <0.01* mg/kg	No additional trials requested since trifluralin is applied early in the growing season (pre-sowing/pre-emergence) and no residues above LOQ (0.01 mg/kg) observed in at least 8 southern and 8 northern trials preformed on oilseed crops.	0.01*	0.01	0.01
Sunflower	SEU	4x <0.01* mg/kg		0.01*	0.01	0.01
Cotton	SEU	4x <0.01* mg/kg		0.01*	0.01	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 critical GAP
(c) Highest residue

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

ADI	0.015 mg/kg b.w./day
TMDI (EFSA PRIMo rev2)	<0.1% ADI for all EU diets included in the EFSA PRIMo Model rev
NEDI (% ADI)	-
Factors included in NEDI	-
ARfD	Not necessary
Acute exposure (% ARfD)	Not applicable

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not relevant (residues in RAC <0.01 mg/kg)			

* Calculated on the basis of distribution in the different portions, parts or products as determined through balance studies

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

Rape seeds	0.01* mg/kg
Sunflower seeds	0.01* mg/kg
Cotton seeds	0.01* mg/kg

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	Measured: 8.4 % (after 120 days) & 18.5 % (after 364 days), (at 22 °C)
Non-extractable residues after 100 days ‡	Measured: 23.3 - 43.1 % (after 120 days) & 33.5 - 54.1 % (after 364 days), (at 22 °C)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	None

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

Anaerobic degradation ‡	Active substance (at 22 °C) : 25.5 - 57.0 % (30th day of flooded conditions) 12.3 - 35.6 % (60th day of flooded conditions) Volatile components: Less significant than under aerobic conditions Non-extractable residues: 23.2 - 42.4 % (30th day of flooded conditions) 35.3 - 60.1 % (60th day of flooded conditions) Major metabolites: TR-4: Range: ND - 11.6%, Max: 13.2% (60th day of flooded conditions)
Soil photolysis ‡	Active substance: 65.2 % after 29.8 days (irradiation) 80.2 % after 29.8 days (dark control) No major metabolites

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

Method of calculation

Active substance:

Solver function in a Microsoft Excel spreadsheet to find the best fit between the observed experimental data and the first order rate equation, as below:

$C_t = C_0 \times e^{-k*t}$

Metabolite TR-4:

Insufficient degradation data to calculate a DT_{50}/DT_{90}.

Laboratory studies ‡ (range or median, with n value, with r^2 value)

DT_{50lab} (aerobic):

Soil type	Moisture (MWHC)	Temp. °C	DT_{50} (days)	DT_{50} (days) @ pF 2	DT_{50} (days) @ pF 2 & @ 20 °C
Speyer 2.1	40%	22	136	116	134.9
Speyer 2.2	40%	22	356	240	279
Sandy loam	75%	22	154	91	105.8
Loam	75%	22	81	57	66.3
Clay loam	75%	22	179	139	161.6
		Geomean	**161**	**115**	**134**

Metabolites: No major metabolites

DT_{90lab} (22°C, aerobic):

Active substance:

- SL: 512 days (r^2= 0.938)
- L: 270 days (r^2= 0.956)
- CL: 593 days (r^2= 0.948)
- Speyer 2.1: 452 days (r^2= 0.930)
- Speyer 2.2: 1181 days (r^2= 0.973)

Mean DT_{90} (22°C, aerobic): 602 days

Metabolites: No major metabolites

DT_{50} (10°C, aerobic)

Active substance:

Based on $DT_{50\ (20°C)}$ = 95 - 418 days & Q_{10} = 2.2,

DT_{50} =209 to 920 days.

	DT_{50lab} (22°C, anaerobic): Active substance: - SL: 54 days (r^2= 0.990) - L: 23 days (r^2= 0.998) - CL: 35 days (r^2= 1.000) Mean DT_{50} (22°C, anaerobic): 37 days DT_{90} (22°C, anaerobic): Active substance: - SL: 181 days (r^2= 0.990) - L: 77 days (r^2= 0.998) - CL: 116 days (r^2= 1.000) Mean DT_{90} (22°C, anaerobic): 125 days DT_{50} (photolysis): Active substance: - SL: 44 days (irrad.) & 68 days (dark control) (r^2= 0.867) DT_{90} (photolysis): Active substance: - SL: 147 days & 225 days (dark control) (r^2= 0.867)
	degradation in the saturated zone ‡: no data
Field studies ‡ (state location, range or median with n value)	DT_{50} (field): Active substance: Germany: 183 days (r^2=0.971), 164 days (r^2=0.963), 200 days (r^2=0.857), 375 days (r^2=0.810) United Kingdom: 177 days (r^2=0.986), 177 days (r^2=0.926), 281 days (r^2=0.854), 255 days (r^2=0.941) USA: 35 days (r^2=0.667) *(Shellman-Georgia)*[26], 54 days (r^2=0.976) *(Mansfield-Illinois)*, 56 days (r^2=0.930) *(Fresno-California)*, 84 days (r^2=0.789) (Marion Junction-Alabama) Mean DT_{50}: 170 days

[26] Value not to be used for risk assessment due to poor fitting.

	DT_{90} (field): Active substance: Germany: 609 days (r^2=0.971), 544 days (r^2=0.963), 664 days (r^2=0.857), 1246 days (r^2=0.810) United Kingdom: 589 days (r^2=0.986), 589 days (r^2=0. 926), 935 days (r^2=0.854), 848 days (r^2=0.941) USA: 116 days (r^2=0.667) *(Shellman-Georgia)*[27], 178 days (r^2=0.976) *(Mansfield-Illinois)*, 186 days (r^2=0.930) *(Fresno-California)*, 278 days (r^2=0.789) *(Marion Junction-Alabama)* Mean DT_{90}: 565 days
Soil accumulation and plateau concentration ‡	Experiment: Accumulation study in UK: five annual applications with trifluralin (Treflan) at a rate of 1.2 kg a.s./ha. Under the study conditions, trifluralin residues in soil one year after each application did not increase over the course of the five-year study. Therefore, it is considered that trifluralin does not accumulate in soil following successive applications. The maximum trifluralin concentrations, with respect to the 0-10 and 0-30 cm horizon were 1.26 mg/kg (following 2nd application) and 0.49 mg/kg (following 2nd application) respectively. Estimation: 1) Application Rate = 1 x 1.2 kg a.s./ha per year 2) Simulation period: 20 years 3) DT_{50SOIL} = 375 days (maximum value) derived from field studies, no process other than degradation considered. 4) Accumulation plateau = 1.661 mg/kg (reached after 14 years) Results and Comments: According to the submitted experimental data, trifluralin does not accumulate in soil following successive applications. However, an accumulation plateau for trifluralin can be observed in the field where the DT_{50} values of trifluralin are quite high. Based on the degradation data submitted for trifluralin ($DT_{50(max)\ FIELD\text{-}SOIL}$= 375 days), the highest predicted accumulation plateau in the soil was estimated to be 1.661 mg/kg after 14 years successive applications (application pattern: 1 x 1.2 kg a.s./ha per year).
Soil residue studies	No data are provided. Not required.

[27] Value not to be used for risk assessment due to poor fitting.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡

Active substance: Adsorption

Soil	pH	Org. C	K_F	K_{oc}	1/n
S	7.7	0.29	18.6	6414	0.962
SL	5.7	0.81	54.6	6741	0.974
L	6.5	1.04	88.3	8490	0.966
CL	6.9	1.16	156	13414	0.986
Mean:			79.4	8764.7	0.972

Metabolite TR-4: Adsorption

No experimental data are provided.

A Koc value of 13600 mL/g was estimated using the "pckocwin v1.66" program (part of the US EPA's Estimated Program Interface (EPI) suite, v3.10).

Active substance: Desorption

Soil	pH	Org. C	K_F	K_{oc}	1/n
S	7.7	0.29	22.4	7724	0.972
SL	5.7	0.81	63.9	7889	0.983
L	6.5	1.04	103	9904	0.965
CL	6.9	1.16	193	16638	0.999
Mean:			95.6	10538.8	0.980

K_d ‡

Active substance:

Adsorption: K_d = 20.9 - 209 ml/g

Desorption: K_d = 24.3 - 218 ml/g

pH dependence ‡
(yes / no) (if yes type of dependence)

No.

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

Column leaching ‡	Not conducted. Not required.
Aged residues leaching ‡	After ageing for 30 days, 89.59 - 91.89 % AR was located in the top 6 cm of the soil columns. The leachate contained 0.7 - 2.5 % AR and consisted of unresolved polar metabolites. In a second study a 0.42 % AR was recovered in the leachate.
Lysimeter/ field leaching studies ‡	Not conducted. Not required.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	Trifluralin is evenly distributed in the top 5 cm soil horizon with a soil bulk density of 1.5 g/mL, 0% crop intercept to represent pre-sowing application, first order kinetic, DT_{50} = 170 days (mean value), 255 days (80^{th}-ile) and 375 days (maximum value) derived from field studies, no process other than degradation considered.
Application rate	1 x 1.2 kg a.s./ha

$PEC_{(s)}$ (mg/kg)		Single application Actual concentration DT_{50}=375 d	Single application Time weighted average concentration DT_{50}=375 d
Initial	0 d	1.600	1.600
Short term	1 d	1.597	1.599
	2 d	1.594	1.597
	4 d	1.588	1.594
Long term	7 d	1.579	1.590
	14 d	1.559	1.579
	21 d	1.539	1.569
	28 d	1.519	1.559
	42 d	1.480	1.539
	50 d	1.459	1.528
	100 d	1.330	1.461

Metabolites

Method of calculation	Trifluralin is evenly distributed in the top 5 cm soil horizon with a soil bulk density of 1.5 g/mL, 0% crop intercept to represent pre-sowing application, first order kinetic, DT_{50} = 375 days (maximum value) derived from field studies, no process other than degradation considered. Simulation period = 20 years
Application rate	1 x 1.2 kg a.s./ha per year

$PEC_{(s)}$ (mg/kg)		Single application Actual (DT_{50}: 375 d)	Single application Time weighted average (DT_{50}: 375 d)	Multiple application Actual	Multiple application Time weighted average
Initial		3.26	3.26		
Short term	24 h [1]	3.25	3.26		
	2 d [1]	3.25	3.25		
	4 d [1]	3.24	3.25		
Long term	7 d [1]	3.22	3.24		
	28 d [1]	3.10	3.18		
	50 d [1]	2.97	3.11		
	100 d [1]	2.71	2.98		
		[1)] Days after the accumulation plateau reached on 14th application. (Accumulation plateau = 1.661 mg/kg (reached after 14 applications with 1 appl./year with 1.2 kg a.s./ha) (see relevant point: Soil accumulation and plateau concentration)			

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH 4: 5% in 5 days at 50°C pH 7: 0% in 5 days at 50°C pH 9: 0% in 5 days at 50°C

Photolytic degradation of active substance and relevant metabolites ‡	Sterile buffer solution: Trifluralin degraded with a DT_{50} of 7 hours in sterile aqueous buffer ($DT_{50\ (dark\ control)}$ = 480 hours). Two significant photolysis products are formed, i.e. TR-6 (maximum 50. 4 % AR) and TR-15 (maximum 31.5 % AR). Natural water: Trifluralin degraded rapidly with a DT_{50} of 1.1 hours ($DT_{50\ (dark\ control)}$ = 47.9 hours). This is likely due to biotic activity and photosensitising compounds found in natural water systems. The degradation profile of the exposed samples was not determined.
Readily biodegradable (yes/no)	No
Dissipation in water/sediment	1st study : application to the water phase
Degradation in water or in the whole system was not determined due to the contribution of volatilization to the dissipation of trifluralin.	13 d (worst-case value)
- DT_{50} water ‡	
- DT_{90} water ‡	not calculated
- DT_{50} whole system ‡	4.9 - 5.9 d (non linear regression)
- DT_{90} whole system ‡	16.3 - 19.6 d (» » »)
Mineralization	Volatile loss: 53- 60% of A.R. (day 60-end of the study). This loss was not characterised
Non-extractable residues	26% of A.R. (day 60 - end of the study).
Distribution in water / sediment systems (active substance) ‡	3-11 % (at 6 hours, water phase) 76-89 % (at 6 hours, sediment)
Distribution in water / sediment systems (metabolites) ‡	Metabolite TR-4 : 4 - 9% (at day14, sediment) in the 1st study; 16 % (at day 28, sediment) in the 2nd study, not detected in water phase Non- identified substances: 12 - 14% of A.R. (after 2 months, in sediment) in the 1st study; 27 % AR (after 100 d, in sediment) in the 2nd study.

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	a) DT_{50} values: 2 and 13 days (worst-case, data from the original water/sediment study) b) A water depth of 30 cm and c) Spray–drifts of 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15 m).
Application rate	One application of 1.2 kg a.s./ha
Main routes of entry	Spray drift

Days After Treatment	PECsw (µg/L)							
	DT_{50} = 2 day							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	11.08	2.28	1.16	0.80	11.08	2.28	1.16	0.80
1	7.83	1.61	0.82	0.57	9.36	1.93	0.98	0.68
2	5.54	1.14	0.58	0.40	7.99	1.64	0.84	0.58
4	2.77	0.57	0.29	0.20	5.99	1.23	0.63	0.43
7	0.98	0.20	0.10	0.07	4.16	0.86	0.44	0.30
14	0.09	0.02	0.01	0.01	2.27	0.47	0.24	0.16
21	0.01	0.00	0.00	0.00	1.52	0.31	0.16	0.11
28	0.00	0.00	0.00	0.00	1.14	0.23	0.12	0.08
42	0.00	0.00	0.00	0.00	0.76	0.16	0.08	0.06
50	0.00	0.00	0.00	0.00	0.64	0.13	0.07	0.05
100	0.00	0.00	0.00	0.00	0.32	0.07	0.03	0.02

Days After Treatment	PECsw (µg/L)							
	DT_{50} = 13 day							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	11.08	2.28	1.16	0.80	11.08	2.28	1.16	0.80
1	10.51	2.16	1.10	0.76	10.79	2.22	1.13	0.78
2	9.96	2.05	1.04	0.72	10.51	2.16	1.10	0.76
4	8.95	1.84	0.94	0.65	9.98	2.05	1.05	0.72
7	7.63	1.57	0.80	0.55	9.25	1.90	0.97	0.67
14	5.25	1.08	0.55	0.38	7.81	1.61	0.82	0.56
21	3.62	0.74	0.38	0.26	6.67	1.37	0.70	0.48
28	2.49	0.51	0.26	0.18	5.75	1.18	0.60	0.42
42	1.18	0.24	0.12	0.09	4.42	0.91	0.46	0.32
50	0.77	0.16	0.08	0.06	3.87	0.80	0.40	0.28
100	0.05	0.01	0.00	0.00	2.07	0.43	0.22	0.15

Metabolite TR-6 and TR-15 (photoproducts)

Method of calculation	a) Maximum exposure levels (from photolysis study) of 50.4% AR for TR-6 and 31.5% AR for TR-15, b) a water depth of 30 cm and c) spray–drifts of 2.77; 0.57 and 0.29 % (buffer zones of 1; 5 and 10m) d) molecular weight adjustment (MW_{TR-6}/ $MW_{Trifluralin}$= 221.2/335.3, MW_{TR-15}/ $MW_{Trifluralin}$ = 259.2/335.3)
Application rate	One application of 1.2 kg a.s./ha
Main routes of entry	Spray drift

Photoproduct	PECsw (µg/L) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-6	3.68	0.76	0.39
TR-15	2.70	0.56	0.28

Trifluralin

Method of calculation

FOCUS Steps 1-3

Input Parameters for Steps 1 and 2

Property	Value
Solubility in	0.194 mg/L
Koc	8765 mL/g **
Half-life soil	181 d (20ºC)
Half-life	13 d (20ºC)
Half-life	17 d (20ºC)

Input Parameters for Step 3 and 4

Property	Value
Molar Mass	335 g/mol
Saturated vapour pressure	9.5 x 10^{-3} Pa (25ºC)
Molar enthalpy of vaporisation	95000 J/mol (*)
Solubility in water	0.194 mg/L (20ºC)
Molar enthalpy of dissolution	27000 J/mol (*)
Diffusion co-efficient in water	4.3 x 10^{-5} m^2/d (*)
Diffusion co-efficient in	0.43 m^2/d (*)
Koc	8765 mL/g
Freundlich exponent	0.972
Ref. concentration in liquid phase	1 g/m^3 (*)
Factor for uptake by plant roots in soil	0.50 (*)
Wash-off factor from crop	0.05 mm^{-1} (MACRO) (*) 0.50 cm^{-1} (PRZM) (*)
Half-life water	13 d (20ºC)
Half-life soil	181 d (20ºC)
Half-life sediment	17 d (20ºC)
Half-life crop	10 d (*)
Activation energy (TOXSWA)	54000 J/mol (*)
Exponent (MACRO)	0.079 K^{-1} (*)

** FOCUS default*

Application rate	Crops: oilseed rape (winter), cotton, sunflowers Number of applications: 1 Application rate: 1200 g as/ha for Northern zone (NZ) and Southern zone (SZ) default buffer
Main routes of entry	

Trifluralin STEP 1 PEC_{SW} and PEC_{SED} Values Following Use of TREFLAN

Concentration	Max. PECSW *(µg/L)*	TWA PECSW 7 day	TWA PECSW 21 day	Max. PECSED *(µg/kg dw)*	TWA PECSED 7 day	TWA PECSED 21 day
wOSR NZ/SZ	42.6	28.9	22.0	2760	2470	1910
Cotton NZ/SZ	42.6	28.9	22.0	2760	2470	1910
Sunflowers NZ/SZ	42.6	28.9	22.0	2760	2470	1910

Trifluralin STEP 2 PEC_{SW} and PEC_{SED} Values Following Use of TREFLAN

Concentration	Max. PECSW *(µg/L)*	TWA PECSW 7 day	TWA PECSW 21 day	Max. PECSED *(µg/kg dw)*	TWA PECSED7 day	TWA PECSED 21 day
wOSR NZ	11.0	5.15	4.77	606	528	406
SZ	11.0	6.62	6.63	878	764	587
Cotton SZ	13.5	11.3	8.67	1150	1000	768
Sunflowers NZ	11.0	5.15	4.77	606	428	406
SZ	13.5	11.3	8.67	1150	1000	768

STEP 3 PEC_{SW} and PEC_{SED} Values Following Application Use of TREFLAN in winter oilseed rape - default buffer

Trifluralin maximum and TWA water concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
D2	ditch	7.646	4.147	2.615	1.401	0.811	0.434	0.295	0.230	0.177	0.161	0.0998
D2	stream	6.803	3.692	2.329	1.247	0.722	0.378	0.258	0.200	0.149	0.133	0.0821
D3	ditch	7.575	3.249	1.806	0.912	0.524	0.265	0.178	0.134	0.0893	0.0750	0.0376
D4	pond	0.260	0.205	0.166	0.116	0.0774	0.0414	0.0279	0.0211	0.0141	0.0119	0.00722
D4	stream	6.529	1.528	0.765	0.383	0.219	0.110	0.0733	0.0550	0.0367	0.0308	0.0181
D5	pond	0.260	0.194	0.151	0.0984	0.0620	0.0322	0.0216	0.0163	0.0109	0.00916	0.00459
D5	stream	7.044	1.848	0.925	0.463	0.265	0.133	0.0888	0.0667	0.0445	0.0374	0.0187
R1	pond	0.260	0.215	0.180	0.144	0.110	0.0686	0.0484	0.0370	0.0310	0.0281	0.0180
R1	stream	4.933	0.888	0.683	0.459	0.263	0.132	0.0891	0.0681	0.0600	0.0556	0.0370
R3	stream	7.013	1.477	1.136	0.821	0.485	0.305	0.274	0.206	0.142	0.133	0.0838

* Maximum Time Weighted Averaged Exposure Concentrations in water layer in µg.L-1

Trifluralin maximum and TWA sediment concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
D2	ditch	3.666	3.650	3.606	3.465	3.210	2.725	2.365	2.104	1.793	1.713	1.346
D2	stream	3.249	3.235	3.196	3.070	2.845	2.398	2.066	1.828	1.533	1.441	1.100
D3	ditch	2.475	2.452	2.395	2.251	2.050	1.692	1.439	1.252	0.994	0.890	0.536
D4	pond	0.300	0.300	0.299	0.295	0.286	0.255	0.224	0.198	0.160	0.144	0.101
D4	stream	1.126	1.098	1.060	0.986	0.891	0.725	0.610	0.526	0.413	0.369	0.250
D5	pond	0.242	0.241	0.240	0.236	0.226	0.197	0.169	0.148	0.116	0.104	0.0615
D5	stream	1.347	1.315	1.267	1.172	1.052	0.845	0.704	0.602	0.466	0.413	0.241
R1	pond	0.522	0.522	0.521	0.518	0.509	0.477	0.439	0.402	0.370	0.360	0.262
R1	stream	1.570	1.532	1.490	1.412	1.308	1.124	0.991	0.889	0.800	0.798	0.616
R3	stream	3.132	3.060	2.975	2.814	2.618	2.206	1.891	1.672	1.464	1.398	1.117

* Maximum Time Weighted Averaged Exposure Concentrations in sediment in µg.kg-1 DW

STEP 3 PEC_{SW} and PEC_{SED} Values Following Application Use of TREFLAN in cotton - default buffer

Trifluralin maximum and TWA water concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
D6	ditch	6.227	2.776	1.480	0.744	0.427	0.215	0.145	0.119	0.0801	0.0676	0.0345

* Maximum Time Weighted Averaged Exposure Concentrations in water layer in µg.L-1

Trifluralin maximum and TWA sediment concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
D6	ditch	2.151	2.127	2.075	1.952	1.777	1.452	1.221	1.051	0.816	0.720	0.421

* Maximum Time Weighted Averaged Exposure Concentrations in sediment in µg.kg-1 DW

STEP 3 PEC_{SW} and PEC_{SED} Values Following Application Use of TREFLAN in sunflowers - default buffer

Trifluralin maximum and TWA water concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
R1	pond	0.252	0.219	0.193	0.152	0.112	0.0652	0.0624	0.0526	0.0375	0.0316	0.0207
R1	stream	4.329	0.849	0.425	0.213	0.156	0.120	0.0908	0.0765	0.0641	0.0585	0.0549
R3	stream	6.070	1.520	0.761	0.381	0.301	0.205	0.196	0.182	0.142	0.128	0.0906
R4	stream	4.307	1.402	1.159	0.588	0.454	0.307	0.259	0.204	0.163	0.137	0.116

* Maximum Time Weighted Averaged Exposure Concentrations in water layer in µg.L-1

Trifluralin maximum and TWA sediment concentrations

Location	Water body	Global Max	TWA 1d	TWA 2d	TWA 4d	TWA 7d	TWA 14d	TWA 21d	TWA 28d	TWA 42d	TWA 50d	TWA 100d
R1	pond	0.548	0.547	0.546	0.541	0.528	0.506	0.479	0.465	0.428	0.400	0.292
R1	stream	2.319	2.291	2.252	2.175	2.090	2.042	2.039	1.949	1.739	1.640	1.387
R3	stream	5.637	5.592	5.508	5.338	5.112	4.984	4.917	4.720	4.234	4.070	2.893
R4	stream	3.007	2.938	2.853	2.695	2.671	2.451	2.158	1.913	1.658	1.593	1.270

* Maximum Time Weighted Averaged Exposure Concentrations in sediment in µg.kg-1 DW

Step 3 calculations were agreed for the current assessment, however, some input parameters were not agreed by PRAPeR TC 10. Step 4 calculations submitted in the resubmission dossier were not agreed by the PRAPeR TC 10 meeting of experts. A data gap was identified for new FOCUS Step 3 and Step 4 calculations using agreed parameters and approaches.

Metabolites TR-4, TR-6, TR-7, TR-14, TR-15

Method of calculation

FOCUS Steps 1-2

Input Parameters for trifluralin metabolites

Property	Value
TR-4	
Solubility in water	1.41 mg/L
Koc	1.36 x 10^4
Half-life soil	1000 d (20ºC)*
Half-life water	1000 d (20ºC)*
Half-life sediment	1000 d (20ºC)*
TR-6	
Solubility in water	586 mg/L
Koc	622 mL/g **
Half-life soil	1000 d (20ºC)*
Half-life water	1000 d (20ºC)*
Half-life sediment	1000 d (20ºC)*
TR-7	
Solubility in water	27.8 mg/L
Koc	1.91 x 10^4
Half-life soil	1000 d (20ºC)*
Half-life water	1000 d (20ºC)*
Half-life sediment	1000 d (20ºC)*
TR-14	
Solubility in water	1.93 mg/L
Koc	2.40 x 10^4
Half-life soil	1000 d (20ºC)*
Half-life water	1000 d (20ºC)*
Half-life sediment	1000 d (20ºC)*
TR-15	
Solubility in water	21.1 mg/L
Koc	2.84 x 10^3
Half-life soil	1000 d (20ºC)*
Half-life water	1000 d (20ºC)*
Half-life sediment	1000 d (20ºC)*

** conservative estimate of 1000 days used*
*** Calculated using EPI Suite*

Application rate	Crops: oilseed rape (winter), cotton, sunflowers Number of applications: 1 Application rate: 1200 g as/ha for Northern zone (NZ) and Southern zone (SZ) default buffer
Main routes of entry	

Metabolites STEP 1 PEC_{SW} and PEC_{SED} Values Following Use of TREFLAN

PECsw

Concentration	**TR-4 Max. PECSW *(µg/L)***	**TR-6 Max. PECSW *(µg/L)***	**TR-7 Max. PECSW *(µg/L)***	**TR-14 Max. PECSW *(µg/L))***	**TR-15 Max. PECSW *(µg/L)***
wOSR NZ/SZ	10.1	7.42	9.06	8.93	8.59
Cotton NZ/SZ	10.1	7.42	9.06	8.93	8.59
SUNFLOWERS NZ/SZ	10.1	7.42	9.06	8.93	8.59

PECsed

Concentration	**TR-4 PECSED *(µg/kg dw)***	**TR-6 PECSED *(µg/kg dw)***	**TR-7 PECSED *(µg/kg dw)***	**TR-14 PECSED *(µg/kg dw)***	**TR-15 PECSED *(µg/kg dw)***
wOSR NZ/SZ	73.9	25.6	67.6	67.2	52.4
Cotton NZ/SZ	73.9	25.6	67.6	67.2	52.4
SUNFLOWERS NZ/SZ	73.9	25.6	67.6	67.2	52.4

Metabolites STEP 2 PEC_{SW} and PEC_{SED} Values Following Use of TREFLAN

PECsw

Concentration	**TR-4 Max. PECSW *(µg/L)***	**TR-6 Max. PECSW *(µg/L)***	**TR-7 Max. PECSW *(µg/L)***	**TR-14 Max. PECSW *(µg/L))***	**TR-15 Max. PECSW *(µg/L)***
wOSR NZ	10.0	7.27	9.05	8.92	8.52
SZ	10.0	7.27	9.05	8.92	8.52

Cotton	SZ	10.0	7.27	9.05	8.92	8.52
Sunflowers	NZ	10.0	7.27	9.05	8.92	8.52
	SZ	10.0	7.27	9.05	8.92	8.52

PECsed

Concentration		**TR-4 PECSED *(µg/kg dw)***	**TR-6 PECSED *(µg/kg dw)***	**TR-7 PECSED *(µg/kg dw)***	**TR-14 PECSED *(µg/kg dw)***	**TR-15 PECSED *(µg/kg dw)***
wOSR	NZ	71.6	24.8	65.6	65.1	50.8
	SZ	71.9	24.9	65.8	65.3	50.9
Cotton	SZ	71.9	25.0	66.0	65.6	51.1
Sunflowers	NZ	71.6	24.8	65.6	65.1	50.8
	SZ	72.1	25.0	66.0	65.6	51.1

PEC (sediment)

Parent

Method of calculation	a) DT_{50} value of trifluralin in sediment = 18.5 days, b) Partition to sediment 100%, c) A sediment layer of 5 cm depth and sediment bulk density of 1.3 g/ml and d) Spray - drifts : 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15m)
Application rate	One application of 1.2 kg a.s./ha

Days After Treatment	PECsediment (µg/kg)							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
0	51.14	10.52	5.35	3.69	51.14	10.52	5.35	3.69
1	49.26	10.14	5.16	3.56	50.19	10.33	5.26	3.62
2	47.45	9.76	4.97	3.43	49.27	10.14	5.16	3.56
4	44.02	9.06	4.61	3.18	47.49	9.77	4.97	3.43

Days After Treatment	PECsediment (µg/kg)							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
7	39.34	8.10	4.12	2.84	44.98	9.26	4.71	3.25
14	30.27	6.23	3.17	2.19	39.79	8.19	4.17	2.87
Days After Treatment	PECsediment (µg/kg)							
	Actual Concentration				Time-weighted Average Conc.			
	Buffer zones				Buffer zones			
	1 m	5 m	10 m	15 m	1 m	5 m	10 m	15 m
21	23.28	4.79	2.44	1.68	35.40	7.29	3.71	2.56
28	17.91	3.69	1.88	1.29	31.67	6.52	3.32	2.29
42	10.60	2.18	1.11	0.77	25.76	5.30	2.70	1.86
50	7.86	1.62	0.82	0.57	23.11	4.75	2.42	1.67
100	1.21	0.25	0.13	0.09	13.33	2.74	1.40	0.96

PEC (sediment) – Metabolite TR-4

Method of calculation	a) DT_{50} value of TR-4 in sediment = 24 days, b) Partition to sediment 100% (worst-case assumption) and 16% (at day 28 from the water/sediment study), c) A sediment layer of 5 cm depth and sediment bulk density of 1.3 g/ml and d) spray - drifts : 2.77, 0.57, 0.29 and 0.20% (buffer zones of 1, 5, 10 and 15 m), d) molecular weight adjustment (MW_{TR-4}/ $MW_{Trifluralin}$= 305.3/335.3)
Application rate	One application of 1.2 kg a.s./ha

Initial PEC (sediment)

Metabolite TR-4

Method of calculation	a) Partition to sediment 26.5% AR, b) A sediment layer of 5 cm depth and sediment bulk density of 0.8 g/ml and c) Spray - drift values: 2,77; 0.57 and 0.29 % (buffer zones of 1, 5 and 10 m) d) molecular weight adjustment (MW_{TR-4}/ $MW_{Trifluralin}$= 305.3/335.3)
Application rate	One application of 1.2 kg a.s./ha

Metabolite	PEC_{SED} (µg/kg) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-4	20.05 (2.673 µg / L)	4.13	2.10

Initial PEC (sediment) - Metabolites TR-7 and TR-14

Method of calculation	a) Partition to sediment 14.2% AR for TR-7 and 29.5% for TR-14, b) A sediment layer of 5 cm depth and sediment bulk density of 0.8 g/ml and c) Spray - drift values: 2,77; 0.57 and 0.29 % (buffer zones of 1, 5 and 10 m) d) molecular weight adjustment (MW_{TR-7}/ $MW_{Trifluralin}$= 275.3/335.3 and MW_{TR-14}/ $MW_{Trifluralin}$= 271.2/335.3)
Application rate	One application of 1.2 kg a.s./ha

Metabolite	PEC_{SED} (µg/kg) - Initial		
	Buffer zone		
	1 m	5 m	10 m
TR-7	9.69	1.99	1.01
TR-14	19.83	4.08	2.08

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)

FOCUS PELMO (ver. 3.2.2)

Active substance input parameters

Parameter	Trifluralin
Molecular weight	335.3 g/mol
$DT_{50(lab)}$	134 days *geomean of five soils at 20°C and pF 2*
Koc	8765 mL/g *mean of four soils*
Freundlich exponent (1/n)	0.972 *mean of four soils*
Water solubility	0.194 mg/L at 20°C *distilled water*
Vapour pressure	9.5×10^{-3} Pa at 25°C

Model inputs for PELMO

Scenario No.	1	2	3
Crop	Cotton	Oilseed rape	Sunflowers
Application mode	Bare soil		
Application depth	5 cm		
Plant uptake factor	0.5 *(default)*		
Air diffusion co-efficient	0.046 cm^2/s *(calculated using diffu.exe)*		
Volatilisation depth	0.1 cm *(default)*		
pH during sorption test	7 *(default)*		
pKa	20 *(default)*		
Limit for Freundlich equation	0.01 µg/L *(default)*		
Sorption annual increase	0% *(default)*		
FOCUS scenario	Sevilla, Thiva	Châteaudun, Hamburg, Kremsmünster,	Piacenza, Sevilla

			Okehampton, Piacenza, Porto		

Application rate

Spring application to cotton: 1.2 kg as/ha (1 March), with soil incorporation to 5 cm.
Autumn application to winter oilseed rape: 1.2 kg as/ha (30 September), with soil incorporation to 5 cm.
Spring application to sunflowers: 1.2 kg as/ha (1 March), with soil incorporation to 5 cm.
Autumn application to winter cereals: 1.2 kg as/ha (30 November), without soil incorporation.

80th percentile Annual Average Leachate Concentrations at 1 m Depth (µg/L)

Scenario/Use	Châteaudun	Hamburg	Jokioinen	Kremsmünster	Okehampton	Piacenza	Porto	Sevilla	Thiva
Cotton (spring appn.)	-	-	-	-	-	-	-	<0.001	<0.001
Oilseed rape (autumn appn.)	<0.001	<0.001	-	<0.001	<0.001	<0.001	<0.001	-	-
Sunflowers (spring appn.)	-	-	-	-	-	<0.001	-	<0.001	-

"-" = no FOCUS location for this crop

Only calculations with a FOCUS GW model (PELMO) are available. In the resubmission dossier the applicant submitted a modelling exercise using a FOCUS PEARL. Some input parameters used in this simulations were slightly different than agreed by the PRAPeR TC 10 meeting and an error on the input parameters was identified (i.e. 0.5 cm was introduced as application depth instead of 5 cm). Therefore, these calculations would need to be repeated and have been removed from the LoEP.

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	No data. Not required.

Quantum yield of direct phototransformation	No data. Not required.
Photochemical oxidative degradation in air ‡	According to Atkinson's method the half-life of trifluralin in air was found to be 5.3 hours or 0.446 days (using [OH]= 1.5 x 10^6 radicals /cm^3 and assuming 12 h of sunlight per day).
Volatilization ‡	from plant surfaces: No data. Not required. from soil: Following spray application to the soil surface, losses of trifluralin due to evaporation were significantly higher and accounted for 41, 58 and 67% AR after 24 hours. When trifluralin is incorporated into the soil, volatilisation is minimal (1.1-1.4% AR after 24 hours).

PEC (air)

Method of calculation	Because of its high volatility [vapour Pressure= 9.5 x 10-3 Pa (25 °C) and Henry's Constant Law = 10.2 Pa m3 mol-1 at 20°C] the occurrence of trifluralin in air is possible. This was confirmed by the study conducted to assess the volatilisation of trifluralin from the soil surface. Therefore PECA calculation in air was required. However, the notifier cannot provide at the present time such calculations since no formal and agreed guidance at EU level is currently available.

$PEC_{(a)}$

Maximum concentration	Such calculations cannot be provided at the present time since no formal and agreed guidance at EU level is currently available.

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	Soil: Definition for risk assessment: Trifluralin, TR-4 (anaerobic metabolite), TR-14 (anaerobic metabolite). Definition for monitoring: Trifluralin. Water: Ground water: Definition for risk assessment: Trifluralin, TR-4, TR-14. Definition for monitoring: Trifluralin. Surface water: Definition for risk assessment: Trifluralin, TR-6, TR-15. Definition for monitoring: Trifluralin. Sediment: Definition for risk assessment: Trifluralin, TR-4, TR-7, TR-14. Air : Definition for risk assessment and monitoring: Trifluralin

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

Soil (indicate location and type of study)	No data.

Surface water (indicate location and type of study)	Trifluralin was more frequently detected in surface waters, particularly in Belgium, France, Greece and the UK. The maximum concentrations reported from these countries were in the range 0.2-0.7 µg/L. Monitoring data on surface water in UK (report from the Department of the Environment) indicated that the maximum concentrations of trifluralin ranged from 0.5 to 0.6 µg/L while the mean values did not exceed 0.1 µg/L (1991-1993). Data gap was identified by the PRAPeR TC 10 meeting of experts for the monitoring data in the Arctic regions reported by Canadian researchers and quoted in the report: *Trifluralin dossier prepared in support of a proposal of trifluralin to be considered as a candidate for inclusion in the Annex I to the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (LRTAP Protocol on POPs). European Commission, DG, Environment, Brussels, July 2007.*
Ground water (indicate location and type of study)	Trifluralin occurrence in groundwater is rare.
Air (indicate location and type of study)	No data.

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	possibly a candidate for R53

Appendix 1.6: Effects on non-target Species

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/day)	End point (mg/kg feed)
Birds ‡				
Colinus virginianus	a.s.	Acute	LD_{50} >2250 mg/kg bw	
	Preparation	Acute		
	Metabolite 1	Acute		
Colinus virginianus	a.s.	Short-term	LC_{50} = 573,9 mg as/kg bw/d	LC_{50} = 2974 mg as/kg diet
Colinus virginianus	a.s.	Long-term	NOEC=102,85 mg as/kg bw/d	NOEC=1000 mg as/kg diet
Mammals ‡				
Rat	a.s.	Acute	LD_{50} >5000 mg as/kg bw	
Rat	Preparation	Acute	LD_{50} >919 mg as/kg bw	
	Metabolite 1	Acute		
Rat	a.s.	Long-term	NOAEL =148 mg/kg bw/d	
Additional higher tier studies ‡				

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

Crop and application rate

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 – uptake via diet (Birds)				
Insectivorous bird	Acute	17.5	>129	10
Insectivorous bird	Short-term	6.36	90	10
Insectivorous bird	Long-term	6.36	16,1	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement – uptake via diet (Birds)				
	Acute			10
	Short-term			10
	Long-term			5
Tier 1– uptake via drinking water (Birds)				
	Acute			10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird	Long-term	19.5 18.415	5.27[5] 5.6[6]	5
Fish-eating bird	Long-term	7.948	13	5
Tier 1– uptake via diet (Mammals)				
Insectivorous mammals	Acute	10.584	>87	10
Insectivorous mammals	Long-term	3.856	38.38	5
Higher tier refinement – uptake via diet (Mammals)				
	Acute			10
	Long-term			5
Tier 1– uptake via drinking water (Mammals)				
	Acute			10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals	Long-term	24.8 23.438	5.96[5] 6.31[6]	5
Fish-eating mammals	Long-term	4.920	30	5

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.
[5] risk assessment based on the PEC initial value taking account soil accumulation over 14 years.
[6] risk assessment based on the PEC (twa, 3weeks) following 1 application (no accumulation);

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	a.s.	96 hr (flowthrough)	Mortality, EC_{50}	0.088
Pimephales promelas	a.s.	35-day juvenile growth test (flow-through)	Growth NOEC	0.0003[2]
Pimephales promelas	a.s.	35-day NOEC with sediment (static)	NOEC	0.0032[3]
Oncorhynchus mykiss	EF-1521	96 hr (flow-through)	Mortality, EC_{50}	0.205
	Preparation	28 d(flow-through)	Growth NOEC	
Oncorhynchis mykiss	Metabolite TR-6	96 hr (static)	Mortality, EC_{50}	1
Oncorhynchis mykiss	Metabolite TR-15	96 hr (static)	Mortality, EC_{50}	5.46
Aquatic invertebrate				
D.magna	a.s.	48 h (static renewal)	Mortality, EC_{50}	0.245
D.magna	a.s.	21 d (static renewal)	Reproduction, NOEC	0.0507
D.magna	Preparation	48 h (static)	Mortality, EC_{50}	0.299
	Preparation	21 d (static)	Reproduction, NOEC	
D.magna	Metabolite TR-6	48 h (static)	Mortality, EC_{50}	3.52
D.magna	Metabolite TR-15	48 h (static)	Mortality, EC_{50}	9.36

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	NOEC	0.25 810 mg/kg
Chironomus riparius	Metabolite TR-4	28 d (static)	NOEC	0.3324
Chironomus riparius	Metabolite TR-7	28 d (static)	NOEC	60 mg/kg
Chironomus riparius	Metabolite TR-14	28 d (static)	NOEC	77 mg/kg
Algae				
Selenastrum capricornutum	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0122
Selenastrum capricornutum	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.178
Selenastrum capricornutum	Metabolite TR-6	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	8.19 >5.56
Selenastrum capricornutum	Metabolite TR-15	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.67 >9.15
Higher plant				
Lemna gibba	a.s.	14 d (static)	Fronds, EC_{50}	0.0435
	Preparation	14 d (static)	Fronds, EC_{50}	
	Metabolite 1	14 d (static)	Fronds, EC_{50}	
Microcosm or mesocosm tests				
Indicate if not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.
[2] Endpoint from a static water-sedimetn test system. How appropriate the exposure modelling in the static study was has to be verified by reliable FOCUSsw modelling, the endpoint should only compared to the PECmax single exposure peak of similar or shorter duration than seen in the effect study.
[3] In case of repeated exposure. It is possible to apply a safety factor reduction (according to the Opinion of the EFSA PPR panel (EFSA, 2005d).

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

Maximum PEC_{sw} values and TER values for [active substance] – application to [intended use] at [application rate] g a.s./ha

Scenario	PEC global max (µg L)	fish acute	fish prolonged	fish prolonged	Daphnia acute	Daphnia prolonged	Algae acute	Higher plant	Sed. dweller prolonged	Microcosm / Mesocosm
		O. mykiss	***fathead minnow***	***fathead minnow***	***Daphnia magna***	***Daphnia magna***	***S. subspicatus***	***Lemna* sp.**	***C. riparius***	
		LC_{50}	$NOEC_{flow-through}$	$NOEC_{static}$ *	EC_{50}	NOEC	ErC_{50}	ErC_{50}	NOEC	NOEC
		88.0 µg/L	0.3 µg/L	3.2 µg/L	245 µg/L	50.7 µg/L	12.2 µg/L	43.5 µg/L	250.0 µg/L	x.xx µg/L
FOCUS Step 1	42.6	**2.07**	**0.01**	**	**5.75**	**1.19**	**0.29**	**1.02**	**5.87**	
FOCUS Step 2										
North Europe	11.0	**8.00**	**0.03**	**	**22.27**	**4.61**	**1.11**	**3.95**	22.73	
South Europe	11.0	**8.00**	**0.03**	**	**22.27**	**4.61**	**1.11**	**3.95**	22.73	
FOCUS Step 3										
D2 / ditch	7.646	**11.51**	**0.04**	**	**32.04**	**6.63**	**1.60**	**5.69**	32.70	
D2 / stream	6.803	**12.94**	**0.04**	**	**36.01**	**7.45**	**1.79**	**6.39**	36.75	
D3 / ditch	7.575	**11.62**	**0.04**	**	**32.34**	**6.69**	**1.61**	**5.74**	33.00	
D4 / pond	0.260	338.46	**1.15**	**	942.31	195.00	46.92	167.31	961.54	
D4 / stream	6.529	**13.48**	**0.05**	**	**37.52**	**7.77**	**1.87**	**6.66**	38.29	

D5 / pond	0.260	338.46	**1.15**	**	942.31	195.00	46.92	167.31	961.54	
D5 / stream	7.044	**12.49**	**0.04**	**	**34.78**	**7.20**	**1.73**	**6.18**	35.49	
R1 / pond	0.260	338.46	**1.15**	**	942.31	195.00	46.92	167.31	961.54	
R1 / stream	4.933	**17.84**	**0.06**	**	**49.67**	**10.28**	**2.47**	**8.82**	50.68	
R3 / stream	7.013	**12.55**	**0.04**	**	**34.94**	**7.23**	**1.74**	**6.20**	35.65	
Annex VI Trigger**		100	10	100	100	10	10	10	10	5

* Endpoint from a static water-sediment test system. How appropriate the exposure modelling in the static study was has to be verified by reliable FOCUSsw modelling, the endpoint should only compared to the PECmax single exposure peak of similar or shorter duration than seen in the effect study.

** As the profile of the surface water exposure could not be assessed, it is not possible to calculate TER values due to the restrictions on the use of the chronic fish toxicity endpoints. See footnote (*).

FOCUS$_{sw}$ step 4

No peer review FOCUS surface water modelling data available - see fate section

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	5.27 at 20 °C			
Bioconcentration factor (BCF)[1] ‡	5674 mL/g			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	4.7 days			
(CT_{90})	15 days			
Level and nature of residues (%) in organisms after the 14 day depuration phase	9.6%			

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	> 100 µg as/bee	> 100 µg as/bee
Preparation[1]	> 80 µg as/bee	> 100 µg as/bee
Metabolite 1		
Field or semi-field tests		
Indicate if not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	<12	50
a.s.	oral	<15	50
Preparation	Contact		50
Preparation	oral		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[1])
Typhlodromus pyri ‡		Mortality	
Aphidius rhopalosiphi ‡		Mortality	

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Crop and application rate

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri				2
	Aphidius rhopalosiphi				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 (gr as/ha)[1,2]	End point	% effect[3]	Trigger value
Laboratory tests ‡						
Typhlodromus pyri	Proto-nymphs	Treflan (EF-1521), glass slides	60 1200	Mortality Fertility Mortality Fertility	10.5 0.0 [a] 58.9 26.3 [a]	50 %
Aphidius rhopalosiphi	Adult	Treflan (EF-1521), glass slides	60 1200	Mortality Fertility Mortality Fertility	60.6 86 [a] 84.8 N/A [b]	50 %
Chrysoperla carnea	Larvae	Treflan (EF-1521), glass slides	60 1200 60 1200	Mortality Fertility	0.0 0.0 No effect	50 %
Phygadeuon trichops	Adult	Triflurex 48 EC, glass slides	1440	Parasitism	34.1 [c]	50 %

Species	Life stage	Test substance, substrate and duration	Dose (gr as/ha)[1,2]	End point	% effect[3]	Trigger value
Poecilus cupreus	Adult	Triflurex 48 EC, glass slides	1440	Mortality Food consumption	6.6 0.0 [d]	50 %
Aleochara bilineata	Adult	Triflurex 48 EC, glass slides	1440	Parasitism	-9[c]	50 %
Extended Laboratory tests						
Typhlodromus pyri	Proto-nymphs	Treflan (EF-1521), leaf of a dwarf seedling	60 1200	Mortality Fertility Mortality Fertility	7.5 24.7 [a] 30 64.9 [a]	50 %
Aphidius rhopalosiphi	Adult	Treflan (EF-1521), glass cylinder with barley seedlings	60 1200	Mortality Fertility Mortality Fertility	0.0 0.0 [a] 16.7 68.7 [a]	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not
[a] Fecundity effect measured
[b] Not assessed, no surviving females
[c] Parasitism effect measured
[d] Food consumption effect measured
- Indicates that the study design does not have a mortality end point

Field or semi-field tests
Indicate if 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 foetida	a.s. ‡	Acute 14 days	LC_{50} >1000 mg as/kg LC_{50corr} >500 mg a.s./kg d.w.soil
Eisenia foetida	a.s. ‡	Chronic 8 weeks	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
Eisenia foetida	EF-1521	Acute	LC_{50} >480, LC_{50corr} >240 mg as/kg
Eisenia foetida	Elancolan	Chronic	NOEC≥ 28.98 mg as/kg $NOEC_{corr}$≥ 14.49 mg as/kg
Eisenia foetida	Metabolite TR-4	Acute	LC50=186, LC_{50corr} =93 mg/kg
	Metabolite 1	Chronic	
Other soil macro-organisms			
Soil mite	a.s. ‡		
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation		
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡		Effects < 25% at 6.37 kg a.s./ha (8.50 mg a.s./kg).
	metabolite TR-4		Effects < 25% at 10xPEC
Carbon mineralisation	a.s. ‡		Effects < 25% at 6.37 kg a.s./ha (8.50 mg a.s./kg)
	metabolite TR-4		Effects < 25% at 10xPEC
Field studies[2]			
Litter bag : no evidence of any adverse effects on organic matter degradation arising from treatment with EF-1521, when applied at the maximum field rate of 2.5 L/ha (1200 g ai/ha).			

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

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute	3.26	>153	10
	a.s. ‡	Chronic			5
	Preparation	Acute	3.26	>74	10
	Preparation	Chronic	3.26	≥ 4.44	5
	Metabolite TR-4	Acute	0.1923	484	10
	Metabolite 1	Chronic			5
Other soil macro-organisms					
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] Based on initial soil residues after 14 years of accumulation + the immediate following application

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Most sensitive species	Test substance	NOEC (g as/ha)[2] vegetative vigour	NOEC (g as/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
	a.s.	125	35	33.2 (1m)	1.05	5
				6.8 (5m)	5.12	5

[1] Based on Ganzelmeier drift data
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

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

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

Test type/organism	end point

Activated sludge	3h EC50 = >100 µg trifluralin/L
Pseudomonas sp	

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

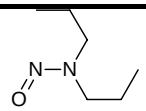
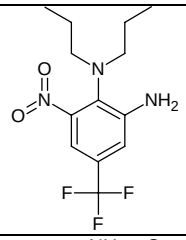
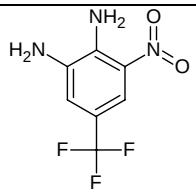
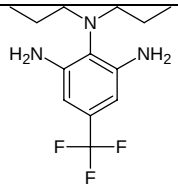
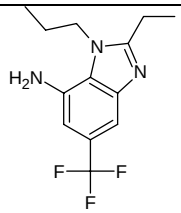
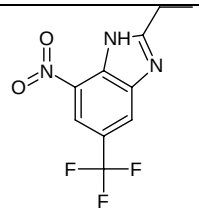
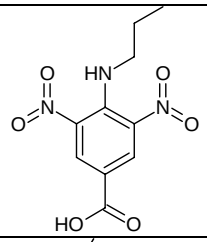
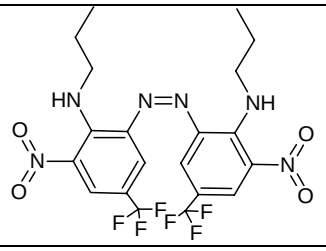
Compartment	
soil	Trifluralin
water	Trifluralin, TR-6, TR-15
sediment	Trifluralin, TR-4, TR-7, TR-14
groundwater	Trifluralin

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
N-nitroso-di-*n*-propylamine	*N*-nitroso-di-*n*-propylamine	
TR-4	3-nitro-N^2,N^2-dipropyl-5-(trifluoromethyl)benzene-1,2-diamine	
TR-6	3-nitro-5-(trifluoromethyl)benzene-1,2-diamine	
TR-7	N^2,N^2-dipropyl-5-(trifluoromethyl)benzene-1,2,3-triamine	
TR-14 (TSN 028333)	2-ethyl-1-propyl-5-(trifluoromethyl)-1*H*-benzimidazol-7-amine	
TR-15	2-ethyl-7-nitro-5-(trifluoromethyl)-1*H*-benzimidazole	
TR-22	3,5-dinitro-4-(propylamino)-benzoic acid	
TR-28	2,2'-diazene-1,2-diylbis[6-nitro-*N*-propyl-4-(trifluoromethyl)aniline]	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
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
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
CT	clearance time
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
EC	emulsifiable concentrate
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
ELS	early-life-stage
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
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
K_{oc}	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)
LRTAP	Long-Range Transboundary Air Pollution
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
NIR	Near-Infrared-(Spectroscopy)
ng	nanogram
nm	nanometer
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PBT	Persistence, Bioaccumulation, Toxicity
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
POP	persistent organic pollutants
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
RMS	rapporteur Member State
RUD	residue per unit dose
SAR	structure/activity relationship
SC	suspension concentrate

SD	standard deviation
SFO	single first-order
SPI	spraying
SRU	low volume spraying
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