CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Triflumuron is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission 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 six months a conclusion on the risk assessment to the EU-Commission.

Italy being the designated rapporteur Member State submitted the DAR on triflumuron in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 15 July 2005. The peer review was initiated on 28 February 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Bayer CropScience AG. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in June – July 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in August 2008 leading to the conclusions set out in the EFSA Conclusion finalised on 30 September 2008 (EFSA Scientific Report (2008) 194).

Following the Commission Decision of 16 March 2009 (2009/241/EC)[5] concerning the non-inclusion of triflumuron in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Bayer CropScience AG made a resubmission application for the inclusion of triflumuron in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues and concerns identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (SANCO/146/08) as follows:

- The risk to consumers

1 On request from the European Commission, Question No EFSA-Q-2010-00855, issued on 9 December 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L 224, 21.08.2002, p. 25
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 71, 17.3.2009, p.59
6 OJ L 15, 18.01.2008, p.5

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance triflumuron. EFSA Journal 2011;9(1):1941. [81 pp.] doi:10.2903/j.efsa.2011.1941. Available online: www.efsa.europa.eu/efsajournal.htm

- The risk to aquatic organisms
- The acute toxicity of metabolite M07
- The lack of data to determine an appropriate residue definition
- The lack of data on the levels of residues in processed commodities
- The high risk to the aquatic environment

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Italy, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 5 March 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 March 2010 and 11 March 2010 respectively. The EFSA collated and forwarded all comments received to the Commission on 26 April 2010.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the Commission requested the EFSA to deliver its conclusions on triflumuron.

The conclusion from the original review was reached on the basis of the evaluation of the representative uses as an insecticide on apples, pears, peaches and nectarines. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the same representative uses. Full details of the GAP can be found in the attached list of end points.

The representative formulated product for the evaluation was "Alsystin SC 480", a suspension concentrate (SC), containing 480 g/l triflumuron.

Adequate methods are available to monitor all compounds given in the respective residue definition. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. Data for the relevant impurity 4-trifluoro-methoxyaniline are missing.

With regard to its toxicological properties, triflumuron is extensively absorbed after oral administration and has a low acute toxicity. The main adverse effect after repeated administration is haemolytic anaemia with compensative responses and secondary effects in different organs. No mutagenic or carcinogenic potential has been demonstrated in the available tests. In the reproductive toxicity testing, no specific effects on the fertility parameters, on the growth of the offspring or on the foetal development were observed in the absence of maternal toxicity. It was agreed that triflumuron has no specific neurotoxic potential.

Several tests were performed on metabolites and/or impurities. The plant metabolites M01, M02, M07 and M08 were considered as covered by the toxicological studies with the parent (use of the same acceptable daily intake). Since it was shown to be acutely more toxic than triflumuron, new toxicological data were provided for the plant metabolite M07 during the resubmission, allowing the derivation of a specific acute reference dose.

The agreed Acceptable Daily Intake (**ADI**) for triflumuron is 0.014 mg/kg bw/day, based on the 1-year dog study supported by the 2-year rat study and with the use of a safety factor of 100. The agreed Acceptable Operator Exposure Level (**AOEL**) is 0.036 mg/kg bw/day, based on the overall NOAEL

of the 90-day rat studies and applying a safety factor of 100. The derivation of an Acute Reference Dose (**ARfD**) was not considered needed for triflumuron.

The agreed dermal absorption values resulting from *in vivo* and *in vitro* testing are 1% for the concentrate (mixing/loading) and 5% for the dilution (application). The estimated operator exposure levels according to the models are below the AOEL without the use of personal protective equipment, and the estimated exposure values for the workers and bystanders are even lower.

The plant metabolism of triflumuron was investigated in apple, tomato, potato and soya bean. Triflumuron was seen to be the major component of the residues in all plant groups investigated. Therefore, the residue definition for monitoring was proposed as triflumuron alone. For the fruit crop group, since no metabolite was detected in significant levels in the metabolism studies conducted on apple and tomato, triflumuron alone was also proposed to define the residue for risk assessment. For the oilseed and root crop groups, metabolites M07 and M08 were, in addition to the parent, included in the definition for risk assessment. Sufficient supervised residue trials were submitted to derive MRL on pome fruit, peaches and nectarines. Processing factors were calculated for processed fruit commodities, and additional studies on apples and peaches confirmed that metabolites M07 and M08 are not expected to be present above the LOQ in processed fractions. However a data gap was identified for peaches, asking for supplementary information on the initial residue levels in the raw products, prior processing. It was concluded that, based on the representative uses, no MRLs are necessary for products of animal origin. No chronic risk was identified for the consumers, the highest TMDI being 46% of the ADI. The acute risk was not considered since no ARfD was allocated to triflumuron.

Triflumuron is low to moderate persistent in soil under dark aerobic conditions. Two major metabolites are formed: 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea. The trifluoromethoxyphenyl ring was less mineralized and more prone to form unextractable residues than the chlorophenyl ring.

From the data available it was not possible to derive reliable half-lives either for parent or for major soil metabolites under anaerobic conditions. Metabolites M02 (max 46.7 % AR) and M08 (max. 48.5 % AR) were the only major metabolites identified under dark anaerobic conditions. According the study available, triflumuron may be considered stable to photolysis in soil.

PECs soil have been updated in the Additional Report.

According to the available adsorption / desorption studies triflumuron may be considered immobile to low mobile in soil (Koc = 1629 – 30006 mL/g), metabolite M08 may be considered medium to high mobile in soil (Koc = 113 - 280 mL/g) and M02 may be considered very high mobile in soil (Koc = 4.0 – 8.8 mL/g).

Triflumuron was stable to hydrolysis at pH 5 and 7 and degrades with a half-life between 29 and 57 d at pH 9. Main hydrolysis metabolites at this pH were M02 (max. 28.9 % AR after 30 d) and M08 (max. 48.8 % AR after 30 d). According to the available study, aqueous photolysis is considered to contribute only in a minor extent to the overall degradation of triflumuron. In the absence of a corresponding study, it is proposed to classify triflumuron as not readily biodegradable.

In water sediment systems triflumuron partitioned to the sediment and degraded (DT_{50} = 4.1 – 7.1 d) to major metabolites M08 (max in water: 47.8 % AR after 14 d, max. in sed.: 20.4 % AR after 7 d; DT_{50} = 11.4 – 11.7 d) and M02 (max in water: 60.4 % AR after 14 d, max. in sed.: 7.9 % AR after 14 d; DT_{50} = 17.6 – 62.9 d). Mineralization was more important for the chlorophenyl ring than for the trifluoromethoxyphenyl moiety. The pH of the water phase of the systems investigated was in the

alkaline range. A data gap, which was not considered essential to finalize the EU risk assessment, was identified for water / sediment studies within a wider range of pH values.

Updated PEC $_{SW/SED}$ were presented in the resubmission dossier following the FOCUS SW scheme. New calculations have been presented in the Addendum to the Additional Report. Only the Step 4 calculations taking into account 95% mitigation for spray drift have been retained for the assessment.

PEC GW calculations have been updated with FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 to the current GAP and with the new degradation data available. Neither the parent triflumuron nor the two soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea are expected to exceed the trigger of 0.1 µg/L for any of the relevant scenarios.

Based on the physical and chemical properties of triflumuron, the volatilization study available and the calculated photochemical half-life for triflumuron, it is expected that it will not be transported over long range distances and will not accumulate in air.

The first-tier risk assessment for birds resulted in acute and short-term TERs above the Annex VI trigger of 10 but the long-term TER was below the trigger of 5. The refined long-term risk assessment was based on blue tit (*Cyanistes caeruleus*) as a focal species. A PT of 0.61 and a RUD of 5.1 (birds feeding only on large insects) were suggested to refine the risk assessment. The experts rejected the RUD refinement since no data supported the assumption that blue tits would feed only on large insects. The long-term TER was below the trigger of 5 on the basis of the agreed refinement steps and the revised long-term NOEC of 20 ppm. Therefore a data gap was identified in the expert meeting. The refinements suggested by the applicant and evaluated by the RMS in the Additional Report were not accepted and therefore the data gap remains.

The acute and long-term trigger values for mammals were exceeded in the first-tier risk assessment indicating a low risk. The risk from secondary poisoning of earthworm- and fish-eating birds and mammals was assessed as low.

Triflumuron was very toxic to aquatic invertebrates. The acute and chronic TERs for daphnids were significantly below the Annex VI triggers of 100 and 10 for all FOCUS step 4 scenarios with a no-spray buffer zone of 30 m. A mesocosm study was submitted. The experts agreed on a regulatory endpoint of 0.1 µg a.s./L in combination with an assessment factor of 3. A no-spray buffer zone of 30 m would not be sufficient to achieve TERs >3. Further refinement of the aquatic risk assessment is needed. New FOCUS step 4 calculations including the maximum spray drift reduction of 95% did not result in a FOCUS scenario where all TERs exceeded the trigger of 3 (applied to a mesocosm NOAEC of 0.1 µg a.s./L). A high risk to the aquatic environment is indicated.

The risk to adult bees was low but bee brood was very sensitive for exposure to triflumuron (insect growth regulator). Exposure of bees was considered to take place via flowering weeds in the orchards. Increased mortality of pupae was observed at an application rate relevant for exposure on weeds. It was further noted that the second application was not covered by the field studies. It was not sufficiently demonstrated that the risk to bee brood development was low and risk mitigation measures such as cutting flowering weeds in the treated field were suggested to protect bees. *Chrysoperla carnea* was the most sensitive non-target arthropod species tested. This observation was confirmed in a field study in an apple orchard. Full recovery of affected arthropod populations (including the most sensitive species *C. carnea*) was observed. The study provided some evidence that a sufficiently high number of *Chrysoperla* larvae could survive in the untreated area to allow recolonisation of the treated in-field area. Overall it was concluded that the risk to non-target arthropods was sufficiently addressed for the representative uses evaluated. The acute risk to earthworms was assessed as low. Since triflumuron inhibits the chitin synthesis the experts considered the potential adverse long-term effects

on earthworms necessary to be investigated and therefore a data gap was identified under the first review. For the resubmission, a long-term (reproduction) study with earthworms was submitted and the long-term risk to earthworms was evaluated as low. No studies with other soil non-target macro-organisms were made available for triflumuron under the first review. The experts agreed in the meeting that studies with collembola should be conducted considering the high toxicity to arthropods and that the DT_{90} can be longer than 100 days under some soil conditions. For the resubmission, new soil degradation studies were made available which indicated that the DT_{90} is less than 100 days and therefore a study with collembola was not triggered any longer.

The risk to soil micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

KEY WORDS

triflumuron, peer review, risk assessment, pesticide, insecticide

TABLE OF CONTENTS

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, and by Commission Regulation (EC) No 1095/2007[7], regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State (RMS). Triflumuron is one of the 79 substances of the third stage Part A covered by the amended Regulation (EC) No 1490/2002 designating Italy as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Italy submitted the report of its initial evaluation of the dossier on triflumuron (Italy, 2005), hereafter referred to as the draft assessment report (DAR), to the EFSA on 15 July 2005. 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 DAR. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the DAR was distributed for consultation on 28 February 2007 to the Member States and the main applicant Bayer CropScience AG as identified by the rapporteur Member State.

The comments received on the DAR were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier a scientific discussion took place in expert meetings in June – July 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in August 2008 leading to the conclusions set out in the EFSA Conclusion finalised on 30 September 2008 (EFSA, 2008).

Following the Commission Decision of 16 March 2009 (2009/241/EC)[8] concerning the non-inclusion of triflumuron in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Bayer CropScience AG made a resubmission application for the inclusion of triflumuron in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[9]. The resubmission dossier included further data in response to the issues and concerns identified in the conclusions leading to the Decision on non-inclusion, as set out in the Review Report (European Commission, 2009) as follows:

- The risk to consumers
- The risk to aquatic organisms
- The acute toxicity of metabolite M07
- The lack of data to determine an appropriate residue definition
- The lack of data on the levels of residues in processed commodities
- The high risk to the aquatic environment

[7] OJ L 246, 21.9.2007, p.19
[8] OJ L 71, 17.3.2009, p. 59
[9] OJ L 15, 18.01.2008, p. 5

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Italy, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Italy, 2010a). The Additional Report was received by the EFSA on 5 March 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 March 2010 and 11 March 2010 respectively. The EFSA collated and forwarded all comments received to the Commission on 26 April 2010. The collated comments were also forwarded to the RMS 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 were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 25 May 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on triflumuron within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 26 May 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that there was no need for EFSA to organise a consultation with Member State experts, however, it was agreed that further information should be requested from the applicant in the area of fate and behaviour in the environment.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in September 2010.

The conclusion from the original review was reached on the basis of the evaluation of the representative uses as presented in the DAR, i.e. use as an insecticide on apples, pears, peaches and nectarines. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the same representative uses. 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, 2010) 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 reporting table (rev. 1-1 of 31 May 2010)

- the evaluation table (14 October 2010)

Given the importance of the Additional Report including its addendum (compiled version of August 2010 containing all individually submitted addenda) (Italy, 2010b) and the Peer Review Report, both 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, finalised on 30 September 2008 (EFSA, 2008).

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Triflumuron is the ISO common name for 1-(2-chlorobenzoyl)-3-(4-trifluoromethoxyphenyl)urea (IUPAC).

Triflumuron belongs to the class of chitin synthesis inhibitors. Examples of other members of this class are novaluron and lufenuron.

The representative formulated product for the evaluation was "Alsystin SC 480", a suspension concentrate (SC).

The evaluated representative uses are as an insecticide on apples, pears, peaches and nectarines. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of triflumuron as manufactured should not be less than 980 g/kg, which is higher than the minimum purity given in the FAO specification (FAO, 2000) of 955 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*,*N*'-bis[4-(trifluoromethoxy)phenyl]urea, 4-trifluoro-methoxyaniline and toluene, which have to be regarded as relevant impurities. The maximum content in the technical material for *N*,*N*'-bis[4-(trifluoromethoxy)phenyl]urea should not be higher than 1 g/kg (FAO, 2000) and for 4-trifluoro-methoxyaniline it should not be higher than 5 g/kg. The maximum content for toluene has been agreed by mammalian toxicology to be 50 g/kg. The new specification provided in the resubmission was not accepted by the rapporteur as for resubmissions the specification should not be changed unless it is necessary for Annex I inclusion.

Therefore the specification as given in the original submission called the 'new proposed specification' in the Addendum to Vol. 4 of June 2008 should be regarded as the accepted specification with the addition of the 50 g/kg specification for toluene.

The content of triflumuron in the representative formulation is 480 g/l (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of triflumuron or the respective formulation. However, the following data gaps remain after the resubmission:

– Storage stability where the relevant impurity 4-trifluoro-methoxyaniline is analysed before and after storage

– Method of analysis for 4-trifluoro-methoxyaniline in the formulation

A data gap for spectra for toluene is not required as it is a well characterized compound. Also data gaps for methods and storage stability for toluene and *N*,*N*'-bis[4-(trifluoromethoxy)phenyl]urea are not triggered as, according to their structures, neither of these substances can be formed on storage.

The main data regarding the identity of triflumuron and its physical and chemical properties are given in Appendix A.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of triflumuron in the technical material, the formulated product, as well as for the determination of the respective impurities in the technical material.

Therefore, sufficient data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. triflumuron in food of plant and animal origin, and in soil, water and air.

Residues in plants and products of animal origin are analysed by HPLC-MS/MS with a LOQ of 0.01 mg/kg for plants and 0.005 mg/kg for milk, liver, kidney, fat and muscle. Residues in soil and water are analysed by HPLC-MS/MS with a LOQ of 0.01 mg/kg for soil and 0.03 µg/L in water (surface, ground and drinking water). Residues in air are analysed by HPLC-UV with a LOQ of 0.0012 mg/m^3. A method for body fluids and tissues is not required as triflumuron is not classified as toxic or very toxic.

2. Mammalian toxicity

Triflumuron was discussed by the experts in mammalian toxicology in July 2008 (PRAPeR meeting 54, round 11) on the basis of the section B.6. of the draft assessment report (amended version provided in July 2006) and its addenda (addendum 1 of December 2007 and addendum 2 of June 2008). New data for the plant metabolite M07 were evaluated in the Additional Report for the resubmission (March 2010).

Based on the detailed composition of the toxicological batches provided in the addendum 2 to B.6 and in the addendum to Volume 4 (J une 2008), the experts agreed that the proposed technical specification was covered by the toxicological data. The identified relevant impurities were 4-trifluoro-methoxyaniline (impurity 2), N,N'-bis[4-(trifluoromethoxy)phenyl]urea) (impurity 5 or bisarylurea) and toluene. For this last one, a maximum level below 5% w/w in the technical specification is not of toxicological concern.

2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics)

The extent of oral absorption was shown to be between 78 and 96% based on measurements in bile-cannulated animals. Therefore the experts agreed that no correction for oral absorption was needed. Distributed preferably in fatty tissues, the maximum concentration in most organs and tissues was reached between 8 and 24 hours after administration, up to 72h for the blood values indicating a possible binding of the parent compound and/or its metabolites. However, the low amount of residues and the rapid excretion (89-95% within 48h via urine and faeces) suggested that there is no bioaccumulation in the body. The main metabolic pathways included hydrolysis, conjugation and/or hydroxylation, with up to 26 components identified in bile.

2.2. Acute toxicity

Triflumuron exhibits very low acute toxicity following oral (LD_{50} >5000 mg/kg bw), dermal (LD_{50} >5000 mg/kg bw), inhalative (LC_{50} >5 mg/L air/4 hours, aerosol, nose-only), intraperitoneal and subcutaneous administration. No irritating properties to skin or eyes were demonstrated, and no skin sensitisation was induced in a maximisation test. Based on these results, no classification is proposed for the acute toxicity.

Note: In the initial DAR, a new skin irritation test was required by the RMS. However, during the peer-review, it was agreed that the negative results of the available test could be taken into account.

2.3. Short-term toxicity

The short-term toxicity of triflumuron has been investigated after oral administration in rats (28 and 90 days of exposure) and dogs (90 days and 1 year of exposure), after dermal administration in rabbits (3 weeks) and after inhalative administration in rats (3 weeks).

The main adverse effect observed after repeated administration of triflumuron is erythrocyte damage (with haematological changes), with compensative responses (extramedullary hematopoiesis in the spleen, immature erythrocytes in the peripheral blood) and secondary effects (in spleen, liver and kidneys). Considering further detailed results for the studies summarised in the DAR (see addendum 2), the experts agreed that the overall short-term NOAEL for rats was 3.6 mg/kg bw/day based on effects of haemolytic anaemia. Further details were also provided for the dog studies and discussed by the experts. In the presence of equivocal haematological effects, accompanied by histopathological findings (indications of increased erythropoiesis) at the mid dose in the 1-year dog study, the experts agreed that the low dose was the overall short-term NOAEL for dogs i.e. 1.42 mg/kg bw/day (as a conservative approach).

With regard to dermal administration, the NOAEL in rabbits was 100 mg/kg bw/day based on effects in the spleen. And with regard to the exposure by inhalation, the agreed short-term NOAEC was 0.0045 mg a.s./L in rats.

2.4. Genotoxicity

The mutagenic potential of triflumuron was tested in several *in vitro* studies (gene mutations in yeast, bacterial and mammalian cells, unscheduled DNA synthesis and chromosome aberrations tests) and two *in vivo* tests (micronucleus assay and dominant lethal test in mice). Even with some deficiencies, the micronucleus test was considered by the experts as acceptable for the risk assessment.

Considering a more detailed summary table provided in the addendum 3, the experts agreed that triflumuron has no potential for genotoxicity based on the negative results of the available studies.

2.5. Long-term toxicity

The long-term toxicity and carcinogenicity of triflumuron has been investigated in rats and mice.

In both species, indications of haemolytic anaemia were found in haematology, necropsy and histopathology. Elevated fluoride levels were determined in the bones and teeth of rats and mice without macroscopic or microscopic alterations, and were not considered adverse. Further details were provided for both studies in the addendum 2 and discussed by the experts. As a conservative approach for the 2-year rat study, the equivocal haematological changes observed at the mid dose and accompanied by an increased spleen weight and pigment deposits were considered as adverse, resulting in an agreed NOAEL of 0.82 mg/kg bw/day. Similarly in mice, the agreed NOAEL was 5.19 mg/kg bw/day based on haematological effects (in both sexes) and increased bilirubin (males).

Considering that the extent of haemolytic anaemia after the administration of triflumuron was not representing a severe functional disorder, the experts agreed that the classification with R48/22 was not justified. With regard to the carcinogenic properties of the compound, there was no indication of an oncogenic potential.

2.6. Reproductive toxicity

In the rat multigeneration study, several limitations were discussed by the experts (no haematological analysis, few histopathological examinations). Nevertheless, it was concluded that the potential for reproductive toxicity was sufficiently assessed and the agreed NOAEL for the reproductive parameters and for the offspring was 133 mg/kg bw/day (the highest dose, with the use of a conversion factor of 15). No parental NOAEL was derived since the critical effect of haemolytic anaemia had not been measured and was presumed to occur in dams at the high dose.

In order to examine teratogenic or developmental effects of triflumuron, two studies with rats and two with rabbits were evaluated in the DAR. In both species, there was no evidence of teratogenic activity. The relevant maternal NOAEL for both species was 300 mg/kg bw/day based on effects of haemolytic anaemia, whereas the foetal/developmental NOAEL was 300 mg/kg bw/day in rats based on delayed skeletal development and 300 mg/kg bw/day in rabbits based on increased post-implantation loss.

2.7. Neurotoxicity

Triflumuron has not a structure related to those capable of inducing neurotoxicity. The severe spasms observed in one 90-day rat study at the high dose level (360 mg/kg bw/day) were considered to be related to general toxicity and not to a specific neurotoxic potential. Therefore, no specific neurotoxicity studies were considered necessary.

2.8. Further studies

Mode of action

Triflumuron was tested for its ability to induce methaemoglobin in cats. No methaemoglobin formation was found after a single oral administration of 500 mg/kg bw (*study not acceptable).*

Metabolites and impurities

The compound **4-trifluoro-methoxyaniline** (impurity 2 and metabolite M07) has been tested for acute toxicity and genotoxicity. It was shown to be toxic after oral or inhalative administration (25 < oral LD_{50} ≤ 200 mg/kg bw, 0.5 < inhalative LC_{50} ≤ 2 mg/L) and very toxic after dermal exposure (LD_{50} <50 mg/kg bw). It was not irritant to the skin, but moderately irritant to the eyes. For the mutagenicity testing, it was negative in an Ames test (and results of further tests for DNA modification in bacteria and induction of micronuclei *in vivo* were not considered acceptable in the DAR). Additionally, destruction of haemoglobin and formation of methaemoglobin was demonstrated in cats, and structural alerts for skin sensitisation and carcinogenicity were identified (see addendum 2). In a 6-day single dose toxicity study with rats provided for the resubmission, a NOAEL of 0.5 mg/kg bw/day was identified.

The plant metabolites, **4-trifluoro-methoxyaniline** (M07) and **1-[4-(trifluoromethoxy)phenyl]urea** (M08) were discussed in the meeting. Both were proposed in the early steps of the rat metabolism (M08 being a precursor of M07), but only found in traces in faeces or up to 3% in bile (for M08). Considering that triflumuron has a very low ADI for a compound that is not very toxic, the experts agreed that the reference value of the parent could be used for the metabolites M07 and M08. However, since M07 was shown to be more acutely toxic than the parent (for which an acute reference

dose was not considered needed), the derivation of an ARfD for this metabolite was considered needed. Based on the 6-day single dose toxicity study with rats, the agreed ARfD is 0.005 mg/kg bw for M07.

The plant metabolites M01 (**2-chlorobenzamide**) and M02 (**2-chlorobenzoic acid**), being rat metabolites, were considered by the experts to be sufficiently covered by the toxicity data of the parent. Therefore, the reference value (ADI) of the parent could be applied to them as well.

The compound **N,N'-bis-(trifluoromethoxyphenyl) urea** (impurity 5) has been investigated for acute oral toxicity in rats and haemotoxicity in cats. It was shown to be toxic in male rats (LD_{50} 133 mg/kg bw) and harmful in females (LD_{50} 277 mg/kg bw). In cats, it did not produce mortality or methaemoglobin formation up to 1000 mg/kg bw.

2.9. Medical data

There are no indications of any health hazards in employees involved in the manufacturing or formulation of triflumuron. No clinical cases or poisoning incidents with triflumuron were reported in the DAR.

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

ADI

Considering that rats (2-year study) and dogs (1-year study) had shown a similar sensitivity to triflumuron, the meeting agreed on the proposed **ADI** of **0.014 mg/kg bw/day**, derived by using a safety factor of 100, based on the 1-year dog study supported by the 2-year rat study.

AOEL

Taking into account that the maximum number of applications of triflumuron does not exceed two applications a year, the experts agreed that the use of a 90-day study to derive the AOEL was a conservative approach. Therefore the proposed value by the RMS was accepted by the meeting, resulting in an **AOEL** of **0.036 mg/kg bw/day**, with the use of a safety factor of 100, based on the overall NOAEL of the 90-day rat studies.

ARfD

As proposed by the RMS in the addendum 1, and considering the toxicological profile of triflumuron, it was agreed by the meeting that no acute reference dose was needed.

2.11. Dermal absorption

An *in vivo* and an *in vitro* study have been performed with the formulation Triflumuron SC 480. EFSA notes that this formulation has not been certified as similar to the representative formulation 'Alsystin SC 480' (with regard to co-formulants and solvents), but it is not expected that the differences would influence significantly the dermal absorption results.

Even though it was noted that the tape strips should have been included in the dermal absorption value in the *in vitro* study, the experts agreed that this would not lead to a significant change of the values proposed by the RMS. Therefore, the dermal absorption values of 1% for the concentrate and 5% for the dilution were considered as acceptable to perform the risk assessment.

2.12. Exposure to operators, workers and bystanders

The representative plant protection product 'Alsystin SC 480' is a suspension concentrate containing 480 g triflumuron/L for use in orchards (on pome fruit, peaches and nectarines).

Operator exposure

According to the intended uses submitted by the applicant the maximum applied dose is 180 g triflumuron/ha. The maximum volume is 1500 L water/ha. The product is applied using tractor mounted air blast sprayers and hand held devices. Revised exposure estimates with the German and UK models were provided in the addendum 1, agreed during the meeting and are summarised in the table below.

Estimated exposure presented as % of AOEL (0.036 mg/kg bw/day), according to calculations with the German and UK POEM model. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Application	Model	Without PPE:	With PPE:
Tractor-mounted	German BBA**	35	8
	UK POEM*	42	26
Hand-held	German BBA**	32	9
	UK POEM[1]	-	-

*PPE (personal protective equipment): gloves during mixing/loading and application, standard protective garment and sturdy footwear during application.
**PPE: gloves during mixing/loading and application.
[1]UK POEM does not contain data for high crops and therefore could not be used for hand-held exposure assessment to Alsystin SC 480 used in orchards.

According to these results, it was agreed that the use of PPE was not necessary to have exposure levels below the AOEL.

During the meeting, a field study was also presented where the application in orchards was performed with a SC formulation containing bitertanol. The experts agreed not to use this study for the risk assessment because of some weaknesses (e.g. low number of operators).

Worker exposure

Revised calculations were provided in the addendum 1, using assumptions from Krebs (Krebs *et al.*, 2000) with revised parameters according to EUROPOEM and the dermal absorption value of the concentrate. It was noted that the dermal absorption value of 1% for the concentrate was used in the revised calculations. The resulting exposure estimate was 18% of the AOEL for workers not wearing protective equipment and re-entering the field when the spray has dried. However, as a worst case, the higher dermal absorption value for the dilution (5%) should be used, leading to an exposure estimate of 45% of the AOEL.

Bystander exposure

Based on the spray drift deposits reported by Ganzelmeier (Ganzelmeier *et al.*, 1995), the bystander exposure estimate represents less than 1% of the AOEL.

3. Residues

In the course of the first peer review, triflumuron was discussed in the meeting of experts for residues in July 2008 (PRAPeR 55) on the basis of the draft assessment report of May 2005. Following the non-inclusion decision, new metabolism and processing studies were provided and evaluated in the Additional Report of March 2010, in order to support the resubmission of the active substance according to the Commission Regulation (EC) No 33/2008. It must be noted, that most of the studies presented in the Additional Report of March 2010 had already been submitted in the addendum 1 to the DAR of December 2007, but they were not considered during the first peer review, on account of the restrictions as laid down in Commission Regulation (EC) No 1095/2007.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The plant metabolism was investigated in apple, soya and potatoes using ^{14}C-triflumuron labelled in the chlorophenyl and the trifluoromethoxy ring. In addition and as requested following the first peer review, a new metabolism study conducted on tomato was provided and evaluated in the Additional Report of March 2010.

In apples, the results indicated that triflumuron did not penetrate from the surface into peel and pulp and, at harvest 31 days after application, *c.a.* 90% of the TRR was recovered in the surface washes. Apart from triflumuron as the major residue (98% TRR at PHI 35 days), traces of metabolites M01, M08 and M25 were detected in apple matrices. However, and having regard to some deficiencies, the PRAPeR 55 meeting of experts was of the opinion to request a new metabolism study on fruits crops. This new study, conducted on tomato, was evaluated in the course of the resubmission process. A similar profile was observed on tomato. One week after the second application, almost the whole radioactivity was recovered in the surface washes (>97% TRR) and was exclusively composed of unchanged triflumuron. No metabolites were identified either in the surface washes or in the peel or fruit extracts, confirming that the cleavage of the parent compound is not expected in fruit crops.

As in fruit crops, triflumuron was not extensively metabolised in the soya bean and potato and unchanged triflumuron was always detected as the major component of the total residues. In potato, depending on the time of harvest, 64-99% TRR and 42-49% TRR were identified as triflumuron in foliage and tubers respectively. A similar picture was seen in soya where total triflumuron accounted for 58% and 99% TRR in the foliage and pods and for 20-40% TRR in bean. Part of triflumuron was present as conjugates and released after acid hydrolysis (up to 26% in soya bean and 23% in potato tuber).

Beside triflumuron, metabolites M01, M02 and M07, M08 resulting from the cleavage of the parent molecule at the urea bond were identified in the soya and potato extracts (up to 14% TRR for metabolites M02 and M08 in potato tuber). In addition, upon acidic hydrolysis of the non-extractable fractions, a further release of these metabolites was observed in potato tuber (M01 and M02, 3% and 14%TRR) and in soya bean (M02 and M07, *c.a.* 30% TRR). It was suggested that this supplementary amounts of metabolites M01, M02 and M07 could be an artefact resulting from the acidic hydrolysis of intact triflumuron incorporated to plant constituents. This point was discussed during the PRAPeR 55 meeting, but the experts were unable to conclude on the basis of the available information. Therefore, a data gap was proposed for the applicant to demonstrate whether or not M01, M02 and M07 are formed by the extraction procedures used in the plant metabolism studies. This data gap remains since no additional explanations were provided by the applicant to solve this issue in the

course of the resubmission process. Nevertheless, the presence of the metabolites M01, M02 and M07, M08 in the organic fractions before acid hydrolysis, indicates that triflumuron is effectively metabolised to some extent in soya and potato. Therefore these metabolites cannot be considered as artefacts of the workup procedure only.

To investigate the nature of residues upon industrial processing, a study simulating processing practices by applying representative hydrolytic conditions was conducted with radiolabelled triflumuron. The results indicated that under conditions simulating sterilisation, triflumuron becomes susceptible to hydrolysis and is degraded to M07 and M08 to a significant extent (17 and 16% TRR respectively). However, this study was performed with the ^{14}C labelling on the phenoxy moiety only and it is highly probable that a labelling on the chlorophenyl ring would have shown the counter part metabolites, M01 and M02, to be also significant metabolites produced under sterilisation conditions. Therefore it must be considered that M01, M02 and their counter part metabolites M07 and M08 resulting from the cleavage of the parent molecule are significant metabolites in processed commodities. Therefore, consumer exposure to these compounds through processed products is expected and should be considered.

Based on these studies and considering that free triflumuron represents in plants and processed commodities a significant part of the radioactivity, it is concluded that triflumuron alone is a suitable marker for monitoring purposes.

For risk assessment and for the fruit crops group, the residue definition can be limited to triflumuron alone, since the metabolism studies conducted on apple and tomato have shown the residues almost totally composed of the parent compound alone. For the other crop groups, metabolites M01, M02 and M07, M08 which were observed in significant proportions in the soya and potato metabolism, have to be taken into account. The PRAPeR 54 meeting on toxicology concluded that in terms of chronic toxicity, the ADI set for triflumuron could be applied also to the metabolites. However M07 was shown to be more acutely toxic than triflumuron and an ARfD of 0.005 mg/kg bw was proposed for this metabolite (see section 2.8), whereas no ARfD is necessary for the parent.

Provisionally and having regard to the highest acute toxicity allocated to the metabolite M07, it is proposed to define the residue for risk assessment for the oilseeds/pulses and root/tuber crops as the sum of triflumuron and metabolites M07 and M08 expressed as triflumuron, pending the additional information requested above, in order to confirm if M01, M02 and M07, M08 have to be considered mainly as plant metabolites or as artefacts resulting from the analytical procedures. It must be noted that the counter part metabolites M01 and M02 are automatically taken into account in the consumer risk assessment when the residue is expressed as “parent compound”. This residue definition is also applicable to processed commodities and probably to rotational crops (see section 3.1.2). It must be noted that M08 is also a plant metabolite of the active substance indoxacarb.

The magnitude of triflumuron residues was determined in a total of 16 field trials conducted on apples and pears in Northern and Southern European regions over three growing seasons, and in 12 trials on peaches and nectarines conducted in Southern Europe over two growing seasons. Experimental designs were considered to be consistent with the notified critical GAP. Samples were analysed for triflumuron only, by HPLC-MS/MS (LOQ 0.01 mg/kg) or by HPLC after saponification to M08 (LOQ 0.02 mg/kg). Residue results are supported by acceptable storage stability data, showing triflumuron residues to be stable up to 2 years in apple matrices when stored frozen at -18°C.

To investigate the residue levels in processed products, a study was conducted in apples and peaches, respectively. Processing factors for the parent triflumuron were determined for washed fruits, apple sauce and juice, pomace, canned peaches and prunes. Processing factors were found to be less than 1, except in apple pomace, apple and peach peel and in prune. Additional processing studies on apple

were evaluated in the Additional Report of March 2010, where samples were analysed for the parent and the metabolites M07 and M08. Neither of these two metabolites was detected in any processed fractions above the LOQ of 0.005 mg/kg. For peaches similar information was provided and metabolites M07 and M08 were never detected above the LOQ in the different processed fractions investigated. However, the data concerning the residue levels of the parent triflumuron in the raw and processed commodities were not provided. A data gap is proposed since the absence of the metabolites M07 and M08 can only be confirmed if triflumuron was present in sufficient levels in the raw peaches, before processing.

3.1.2. Succeeding and rotational crops

Since there is usually no crop rotation in orchards, data on potential uptake of triflumuron residues by succeeding crops are not required. Nevertheless, a rotational crop metabolism study with ^{14}C chlorophenyl ring labelled triflumuron was submitted and evaluated in the DAR. In all crops and crop parts, triflumuron could be identified (5-11% TRR), though in lower amounts than metabolites M01 and M02. Metabolite M01 was present at 1% to 20% TRR in different crops, while metabolite M02 was by far the major component of the total residue (37-64% TRR). The findings correspond with the observation that M02 was a major soil metabolite, besides M08 (refer to chapter 4.1.1). A rotational crop study with the trifluoromethoxyphenyl ring label was not available for evaluation, however the presence of M08 in rotated crops can be assumed. These additional data indicate that the identity of metabolites in rotational crops might be very similar to that found in the primary crops studied. If further uses on crops usually rotated are envisaged, the need for a rotational crop study conducted with a labelling on the trifluoromethoxyphenyl ring should be reconsidered, in order to confirm that the residue definition for risk assessment proposed for primary crops and including the metabolites M07 and M08 is also applicable to rotational crops.

3.2. Nature and magnitude of residues in livestock

Livestock, mainly ruminants, can be exposed to residues of triflumuron when fruit pomace is used in animal diet. Triflumuron is considered a fat-soluble compound and therefore accumulation of residues in the body tissue of livestock animals may occur. The biokinetic behaviour and metabolism of triflumuron was investigated in lactating goat with ^{14}C-triflumuron labelled on the chlorophenyl and 4-trifluoro-methoxyaniline moieties and in laying hens using the chlorophenyl label only.

After oral administration to goats, excretion via faeces and urine was the major excretory pathway. Only low amounts were excreted in the milk. In accordance with the high rate of excretion, the radioactive residues found in organs and tissues at sacrifice were low. The highest concentrations were detected in liver and in fatty tissues. The results did not indicate essential differences between the two radiolabels with respect to the distribution pattern of the administered radioactivity. Metabolism of triflumuron was not extensive in goats. Upon analysis, triflumuron was the major residue in all matrices and unchanged triflumuron was predominantly present in fat (96% TRR), milk (60-75% TRR) and muscle (58-80% TRR). Lower triflumuron levels were found in liver (15-20% TRR) and kidney (20-27% TRR). A major metabolite in muscle was 2-chlorobenzamide (M01) (20% TRR) and in kidney 2-chlorohippuric acid in free and conjugated form (36%). Though liver contained the highest total residues, the identification rate was low, as attempts for further extraction of residues were unsuccessful. The meeting of experts concluded that the study was old and therefore additional information is unlikely to be obtained, however the applicant should clarify the presence of 7 compounds in the TLC analysis and whether they were of a polar or non-polar nature.

The hen study is not required to support the notified representative uses, but was assessed in the DAR and is briefly summarised below to complete the picture on metabolism of triflumuron in livestock animals. Laying hens excreted about 94% of the administered radioactivity over the test period of

4 days. Eggs contained only 0.2% of the administered radioactivity. The highest concentrations of radioactivity were found in fat, skin and liver of laying hens. Triflumuron was the major residue in all hen matrices. Unchanged triflumuron was present in amounts above 90% TRR in muscle, heart, fat and skin, about 85% in liver and eggs and 59% TRR in kidney. Upon analysis only low amounts (<7% TRR) of metabolites M01 and M02 were identified in hen matrices.

Based on the findings from livestock metabolism studies, the main metabolic reactions were the cleavage of triflumuron between the urea carbon and the urea nitrogen to form the metabolite M01, and the cleavage between the benzoyl carbon and the urea nitrogen to form 2-chlorobenzoic acid (M02) and 4-trifluoromethoxyphenyl urea (M08). Conjugation of the latter two metabolites was found. Hydroxylation of the chlorophenyl ring of triflumuron was observed as a further detoxification pathway in the lactating goat study. The isomeric metabolites SIR 8514-3-hydroxy-2-chlorophenyl and SIR 8514-5-hydroxy-2-chlorophenyl were detected as free acids (M04, M05) and as conjugates (M22 (M04 conjugates), M23 (M05 conjugates)).

Considering the representative uses on fruit crops and the processing studies showing metabolites M07 and M08 not to be present in processed commodities (apple pomace), livestock is only exposed to residues of triflumuron and the animal residue definition for monitoring and risk assessment can be limited to triflumuron alone. However this residue definition should be reconsidered if additional uses lead to significantly increased intakes of the metabolites M07 and M08 by livestock.

Considering the representative uses of triflumuron, a feeding study was triggered for ruminants, but not for poultry and pig. In a study on dairy cattle, triflumuron was administered at levels of *c.a.* 5.9 and 11.9 mg per kg feed DM, corresponding to a 15N and 30N dose rate respectively, for beef cattle. Milk, muscle, fat and liver were analysed for triflumuron. In milk, residues of triflumuron were generally below the LOQ of 0.01 mg/kg regardless of the feeding level tested. In tissues, residues of triflumuron were generally below the LOQ of 0.05 mg/kg for liver, kidney and muscle and the LOQ of 0.1 mg/kg for fat. Having regard to the absence of detectable residues in the feeding study conducted with exaggerated residue intakes, no MRLs are proposed for ruminant products.

3.3. Consumer risk assessment

The consumer risk assessment was performed using the EFSA PRIMo model rev.2 and considering the ADI of 0.014 mg/kg bw/d and the MRLs proposed for pome fruit and peaches/nectarines. No chronic concern was identified for the consumers, the highest TMDI being 46% of the ADI (DE Child). No ARfD was allocated to triflumuron and therefore, no acute risk assessment was conducted.

An ARfD of 0.005 mg/kg bw was allocated to the metabolite M07 detected in the metabolism studies conducted on soya and potato and in the standard hydrolysis study. However, no acute risk assessment was conducted, since M07 is not a relevant metabolite in the fruit crop group and is not present in the processed commodities. However, additional information is required to confirm that M07 is effectively not present in the processed peach commodities (see point 3.1.1).

3.4. Proposed MRLs

In accordance with the residue definition for monitoring (triflumuron alone) the following MRLs are proposed:

- Pome fruit 0.5 mg/kg
- Peaches/nectarines 0.3 mg/kg

4. Environmental fate and behaviour

Fate and behaviour of triflumuron was discussed in the meeting of experts PRAPeR 52 (July 2008) on the basis of the DAR (May 2005), Addendum 1 (December 2007) and Addendum 2 (June 2008). After the meeting of experts the RMS prepared an Addendum 3 (August 2008). The conclusion has been updated with the information provided in the resubmission dossier, summarised and assessed by the RMS in the Additional Report (March 2010) and the Addendum to the Additional Report (June 2010).

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

Route of degradation of triflumuron (^{14}C labelled either at the trifluoromethoxyphenyl or at the chlorophenyl ring) was investigated in soil under dark aerobic conditions at 20 ºC in two studies with a total of three soils (pH ($CaCl_2$) 5.5 – 6.7; OC 1.02 – 2.11 %; clay 5 – 20 %). Two major metabolites are formed as a result of the molecule break at the urea bridge: **2-chlorobenzoic acid** (M02, 2-CBA. max. 23.5 % TRR) and **4-trifluoromethoxyphenyl urea** (M08, TMPU, max. 23.1 % TRR). The chlorophenyl ring was more easily mineralized (CO_2: 64.6 – 65.9 % AR after 120 d) than the trifluoromethoxyphenyl ring (CO_2: 12.8 – 18.1 % AR after 120 d). Correspondingly, unextractable residue was higher in the experiments performed with triflumuron labelled in the trifluoromethoxyphenyl ring (max. 76.8 % AR after 91 d) than in the experiments performed with triflumuron labelled in the chlorophenyl ring (max. 35.1 % AR after 16 d). However, the meeting noted that the extraction procedure employed in one of the studies was rather weak and that the amount of unextracted residues may have been overestimated.

During the peer review it was noted that the range of pH in the soils investigated was too narrow and did not fulfil the Directive requirement to address a sufficiently wide range of soil conditions. Hydrolysis of parent triflumuron is pH dependent, being more stable at acidic pHs (see section 4.2.1). The experts in the meeting agreed that the soils tested would represent a worst case with respect to the persistence of parent compound but may underestimate the amount of metabolites formed under more alkaline situations. In fact, the data suggest shorter half-lives in the less acidic soils in agreement with the hydrolysis results. Therefore, the meeting of experts identified a data gap for data to address the rate of aerobic degradation of parent and formation and degradation rates of metabolites in alkaline soils (approximately pH 8). Under the resubmission, a new study has been provided to investigate the rate of degradation in three soils (two of them with slightly alkaline pH). From the data in the new study, there is no evidence of a pH dependency of triflumuron degradation. The new values have been incorporated in the list of endpoints. Additionally, data presented in the DAR have been re-evaluated and the results from the study Whitfield and Clay, 1983 (Italy, 2005) have been excluded from the assessment.

Degradation in soil under dark anaerobic conditions was not reported in the DAR but had been investigated in one of the studies available in the dossier. The RMS summarized the information found in this study in addendum 2. Metabolites 2-chlorobenzoic acid (max 46.7 % AR) and 4-trifluoromethoxyphenyl urea (max. 48.5 % AR) were the only major metabolites identified under these conditions.

Photolysis of triflumuron in soil was investigated at 25 ºC in a study with artificial light simulating sun irradiation during 41 d. No degradation occurred either in the irradiated or the dark control samples. Triflumuron may be considered photochemically stable in soil.

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

In addition to the studies presented in section 4.1.1, the rate of degradation of triflumuron (^{14}C labelled at the trifluoromethoxyphenyl ring) in soil under dark aerobic conditions at 20 ºC was investigated in one additional soil (pH 6.7, OC 0.94 %, clay 15.9 %).

Under dark aerobic conditions in soil, triflumuron is low to moderate persistent. The RMS presented further details on the half-life normalization in addendum 2. The experts agreed with the normalized values proposed by the RMS for its use in environmental modelling for acidic soils. A data gap was identified for data to address the rate of aerobic degradation of parent and formation and degradation rates of metabolites in alkaline soils. This data gap has been fulfilled in the resubmission dossier. New data and assessment confirm that triflumuron is low to moderate persistent in soil ($DT_{50\ lab\ 20\ ºC\ Norm\ pF2}$ = 1.2 – 14.6 d).

An additional study was performed to investigate the rate of degradation of triflumuron metabolite 2-chlorobenzoic acid in three soils (pH 6.5 – 7.1; OC 1.3 – 3.1 %; clay 7.7 – 16.9 %) under dark aerobic conditions at 20 ºC. This metabolite is very low to low persistent in soil under these conditions ($DT_{50\ lab\ 20\ ºC\ Norm\ pF2}$ = 0.4 – 3.3 d).

Half-life of metabolite 4-trifluoromethoxyphenyl urea was calculated with the studies performed with the parent labelled at the trifluoromethoxyphenyl ring. According to this calculation metabolite 4-trifluoromethoxyphenyl urea was low persistent in soil ($DT_{50\ lab\ 20\ ºC\ Norm\ pF2}$ = 1.3 – 3.3 d). Before the meeting of experts the applicant clarified that a formation fraction of 1 (100 %) had been assumed in the calculation. The new assessment indicates that this metabolite is low persistent in soil.

From the data available it was not possible to derive reliable half-lives either for the parent or for the major soil metabolites under anaerobic conditions.

PECsoil were calculated by the RMS using the standard low tier scenario presented in the DAR. The 90th percentile DT_{50} was used instead of the absolute worst case. New calculations were presented in addendum 2 with worst case normalized DT_{50} = 40.8 d and interception by crop coverage according to FOCUS. These new calculations were accepted by the experts for the parent compound. The meeting of experts noted that the maximum observed values for 4-trifluoromethoxyphenyl urea (28.1 %) and 2-chlorobenzoic acid (23.5 %) had been used together with the degradation rate calculated with the formation fraction of 1. This was considered an inappropriate combination and new PEC soil calculations for metabolite 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea were requested. New PECsoil were calculated by the RMS after the meeting of experts. The new PECsoil were calculated with the agreed input parameters. For both metabolites, worst case laboratory DT_{50} assuming 100 % formation from triflumuron has been used in the calculation. However, an error in the calculation of the 4-trifluoromethoxyphenyl urea PEC soil was identified by a Member State during the written procedure for comments on the conclusion. EFSA recalculated these PECsoil and the amended values are presented in the list of end points. The PEC soil for this metabolite presented in Addendum 3 should be therefore disregarded. PECsoil have been updated in the Additional Report.

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

Adsorption / desorption of triflumuron in soil was investigated in three batch equilibrium studies with a total of eight soils (pH 5.4 – 6.7). Triflumuron may be considered immobile to low mobile in soil (Kfoc = 1629 – 30006 mL/g).

Adsorption / desorption of metabolite 4-trifluoromethoxyphenyl urea in soil was investigated in one batch equilibrium study with four soils (pH 5.1 – 6.7). Metabolite 4-trifluoromethoxyphenyl urea may be considered medium to high mobile in soil (Kfoc = 113 – 280 mL/g).

Adsorption / desorption of metabolite 2-chlorobenzoic acid in soil was investigated in one batch equilibrium study with four soils (pH 5.1 – 6.7). Metabolite 2-chlorobenzoic acid may be considered very highly mobile in soil (Koc/foc = 4.0 – 8.8 mL/g).

The Member State experts discussed in the experts' meeting the narrow pH range investigated in these experiments. The pKa of triflumuron is not available and the influence of the pH on the leaching potential of parent and metabolites is not known. Experts also noted that the adsorption study for 2-chlorobenzoic acid had some deficiencies (e.g. degradation took place within the equilibrium time). In the narrow pH range investigated, some pH dependence was already observed. Therefore, the experts agreed that batch adsorption / desorption studies with more alkaline soils (approximately pH 8) for parent and metabolite 2-chlorobenzoic acid are needed and a new data gap was identified. The meeting of experts noted that these studies would eventually influence the results of PEC_{GW} and PEC_{SW} calculations and that the calculations may need to be revised. No additional information has been presented in the resubmission dossier. The RMS re-evaluated available data and indicated that for triflumuron, the pH of two soils measured in water was already alkaline (pH 7.2-7.6). For 2-chlorobenzoic acid, a Koc = 0 was used in the exposure assessment. Therefore, the potential pH dependence would be irrelevant. Hence, the data gap is considered superseded by this assessment.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Hydrolysis of triflumuron (^{14}C labelled at the chlorophenyl ring) was investigated in one study in buffered aqueous solutions (pH 5, 7 and 9) at 25 ºC. Triflumuron was stable at pH 5 and 7 and degrades with a half-life of 57 d at pH 9. In a separate study, hydrolysis of triflumuron (^{14}C labelled at the trifluoromethoxyphenyl ring) was investigated at pH 9 (DT_{50} = 28.6 d). Main hydrolysis metabolites were 2-chlorobenzoic acid (max. 28.9 % AR after 30 d at pH 9) and 4-trifluoromethoxyphenyl urea (max. 48.8 % AR after 30 d at pH 9).

Aqueous photolysis of triflumuron (^{14}C labelled either at the chlorophenyl or the trifluoromethoxyphenyl ring) was investigated in one study at pH 7. No degradation was observed in the dark controls whereas an average DT_{50} = 32. 8 d was calculated for the irradiated samples (continuous irradiation). The main aqueous photolysis metabolite was **2-chlorobenzamide** (M01, max. 19.4 % AR after 10 d). Aqueous photolysis is considered to contribute only to a low extent to the overall degradation of triflumuron. Metabolite 2-chlorobenzamide is deemed to be stable to direct photolysis on the basis of the quantum yield calculated from its UV absorption spectra.

No experimental study on the ready biodegradability of triflumuron has been provided. It is proposed to classify triflumuron as not readily biodegradable.

A study to investigate dissipation and degradation of triflumuron in water sediment systems is available. Triflumuron (^{14}C labelled either at the chlorophenyl or the trifluoromethoxyphenyl ring) was applied to two different systems (pH_{water} = 7.3 – 7.6; pH_{sed} = 5.9 -6.2; OC 0.26 – 3.5 %; clay 0.1 – 13 %). Triflumuron partitioned to the sediment and degraded to major metabolites **4-trifluoromethoxyphenyl urea** (max in water: 47.8 % AR after 14 d, max. in sed.: 20.4 % AR after 7 d) and **2-chlorobenzoic acid** (max in water: 60.4 % AR after 14 d, max. in sed.: 7.9 % AR after 14 d). After 14 d less than 2 % AR could be identified as the parent compound in the water phase. The metabolite 2-chlorobenzamide was only observed as a transient transformation product (max 6.4 %

AR after 7 d). Unextracted residues in the sediment were higher in the experiments with triflumuron labelled at the trifluoromethoxyphenyl ring (max. 66 % after 100 d) than in the experiments with triflumuron labelled at the chlorophenyl ring (max. 33.28 % AR after 100 d). In contrast, mineralization was more important in the experiments performed with triflumuron labelled in the chlorophenyl ring (CO_2: 35.7 % AR after 100 d). Mineralization of the trifluoromethoxyphenyl moiety seems to be practically negligible (CO_2: 2.39 % AR after 100 d). The pH of the water phase of the systems investigated was in the alkaline range. A data gap was identified by the meeting of experts for water / sediment studies with a wide range of pHs. This data gap was not considered essential to finalize the EU risk assessment. Degradation of triflumuron in the whole system was relatively rapid (DT_{50} = 4.1 – 7.1 d). Also degradation of metabolites 4-trifluoromethoxyphenyl urea (DT_{50} = 11.4 – 11.7 d) and 2-chlorobenzoic acid (DT_{50} = 17.6 – 62.9 d) were estimated by a non-linear multicompartmental fitting of data. A more detailed description of the multicompartmental model used to fit data was provided by the RMS in addendum 2. The experts noted that there were some shortcomings in the assumptions used in this modelling exercise. In particular, degradation of the parent to the sink compartment was not considered. Furthermore, all the losses in the water phase were assumed to be due to degradation and the partition to the sediment was set as zero. The meeting of experts agreed that new FOCUS PEC_{SW} were necessary based on FOCUS kinetics P1 approach (DT_{50} = 1000 d for one compartment and DT_{50} = whole system for the other). New FOCUS Step 3 PEC $_{SW / SED}$ for the parent triflumuron had been calculated by the RMS and presented in addendum 3. These calculations had not been peer reviewed under the first review. Reporting in addendum 3 does not indicate which input parameters have actually been used. In a clarification during the written procedure the RMS clarified that 1000 d has been used as half-life for the parent in the sediment phase. EFSA also noted that the calculations were only performed for multiple applications when single applications are expected to give the worst case results. The RMS confirms that, when using the input parameters originally proposed by the applicant, single application calculation results in PEC_{SW} 10 to 30 % higher than with the multiple application. Single application calculations with the parameters agreed by the meeting are not available. Higher PECsed are expected to be obtained when these calculations are available.

PEC $_{SW / SED}$ according FOCUS SW STEP 1 and 2 were calculated for metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea. However, the meeting of experts noted that the observed values for 4-trifluoromethoxyphenyl urea (15.5 %) and 2-chlorobenzoic acid (5.9 %) in soil had been used together with a half-life in soil kinetically derived assuming a formation fraction of 1 (100 %). This combination of input parameters was considered inappropriate by the meeting of experts. Furthermore, the meeting noted that the maximum values used were below the maximum values actually observed in the studies. Therefore, new PEC $_{SW / SED}$ calculations for metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea were deemed necessary. New Step 2 FOCUS PEC $_{SW / SED}$ calculations based on the different worst case combinations of input parameters have been calculated by the RMS in addendum 3. These calculations had not been peer reviewed under the first review. EFSA considers that for metabolite 2-chlorobenzoic acid parameter combination B1 best represents the meeting outcome and FOCUS SW guidance for acidic soils and parameter combination C1 for alkaline soils. Since the calculated values are practically identical, slightly worst case C1 are retained for the EU risk assessment. With respect to metabolite 4-trifluoromethoxyphenyl urea, EFSA considers that parameter combination B2 best represents the meeting outcome. Therefore, B2 Step 2 PEC SW values are retained for EU risk assessment of 4-trifluoromethoxyphenyl urea.

As an overall conclusion, the meeting agreed that the FOCUS PEC $_{SW / SED}$ presented in the DAR (including the Step 4 approach based on GIS) were not considered appropriate for the EU risk assessment. New calculations provided in addendum 3 were not peer reviewed under the first review. EFSA considers that Step 2 calculations for metabolites are adequate for risk assessment. However, Step 3 and Step 4 calculations do not necessary represent worst case estimations. Step 3 single

application calculations are still missing for the combination of input parameters agreed by the meeting.

Updated PEC $_{SW/SED}$ were presented in the resubmission dossier following FOCUS SW scheme (FOCUS, 2001). Clarifications were required from the applicant on the application of the mitigation measures considered at Step 4 calculations. New calculations have been presented in the Addendum to the Additional Report. Only the Step 4 calculations taking into account 95% mitigation for spray drift have been retained for the assessment. The applicant proposed to increase the mitigation above 99% by combination of different mitigation measures. This approach was considered not to reflect realistic mitigation by the EFSA PPR Panel (FOCUS, 2007) and has not been considered further in this assessment.

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

Potential groundwater contamination was addressed in the DAR by FOCUS PEC_{GW} calculations (80th percentile at 1 m depth) for triflumuron and its soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea with the FOCUS model PEARL and the nine FOCUS GW scenarios. For soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea it was not clear which formation fractions had been assumed in the calculations and the meeting agreed that new calculations would be needed if a different formation fraction had been used. After the experts' meeting, the RMS confirmed in the addendum 3 that a formation fraction = 1 had been assumed for the metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea in the calculations presented in the DAR.

Additionally, during the first peer review data gaps had been identified for triflumuron and the metabolite 2-chlorobenzoic acid adsorption / desorption studies on more alkaline soils. Furthermore, rate of formation / degradation on alkaline soils needs to be investigated for triflumuron and both soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea. Therefore, results of the available modelling are only relevant for acidic soils. Under this situation neither the parent triflumuron nor the two soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea are expected to exceed the trigger of 0.1 μg / L. After the meeting, the RMS presented in addendum 3 a new calculation with a worst case assumption for metabolite 2-chlorobenzoic acid (K_{OM} = 0 L/kg). However, this simulation does not consider the possible effect of alkaline pH on the degradation rates.

PEC GW calculations have been updated with FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 to the current GAP and with the new degradation data available[10]. Neither the parent triflumuron nor the two soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea are expected to exceed the trigger of 0.1 μg/L for any of the relevant scenarios.

4.3. Fate and behaviour in air

Based on the physical and chemical properties, triflumuron is not expected to significantly volatilize under normal environmental conditions. In the available volatilisation field trial, negligible volatilization is observed from soil surface. However, significant volatilization is observed from plant surface (17 % AR after 24 h). The photochemical half-life of triflumuron in air was calculated to be 1.2 d (based on 1.5 x 10^6 OH· / cm^3 and 12 h/d). As a result it is expected that triflumuron will not be transported over long range distances and will not accumulate in air.

[10] Simulations utilised the agreed Q10 of 2.58 (EFSA 2007) and Walker equation coefficient of 0.7.

5. Ecotoxicology

Triflumuron was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 52) in July 2008 on the basis of the draft assessment report (DAR), addendum 1 from December 2007 and addendum 2 from June 2008. The representative uses evaluated are uses as an insecticide in orchards (pome fruit in northern and southern Europe and peaches and nectarines in southern Europe) at application rates of 2 x 0.18 kg a.s./ha. The risk assessment was conducted according to the following guidance documents: Risk Assessment for Birds and Mammals. SANCO/4145/2000 September 2002 (European Commission, 2002c); Aquatic Ecotoxicology, SANCO/3268/2001 rev.4 final, October 2002 (European Commission, 2002b); Terrestrial Ecotoxicology, SANCO/10329/2002 rev.2 final, October 2002 (European Commission, 2002a); Risk Assessment for non-target arthropods, ESCORT 2, March 2000, SETAC. The conclusion has been updated with the information provided in the resubmission dossier, summarised and assessed by the RMS in the Additional Report (March 2010) and the Addendum to the Additional Report (June 2010).

5.1. Risk to terrestrial vertebrates

The validity of the acute oral toxicity study with birds was questioned during the peer-review. The experts agreed that the study was not fully in compliance with current validity criteria. However the experts were of the opinion that the study is scientifically robust enough to be used in the risk assessment. Three short-term (dietary) studies were submitted. The higher endpoint from the latest study with bobwhite quail was considered as the most relevant endpoint for the risk assessment since it was conducted with batches corresponding to the new technical specification (given in the Addendum to Vol. 4 of June 2008). A NOEC of 80 mg a.s./kg feed was used for the long-term risk assessment for birds. It was noted that biologically (but not statistically) significant effects of up to 25% on the number of hatchlings and the 14 day old survivors were observed at the concentration of 80 mg a.s./kg diet. The experts agreed on a NOEC of 20 mg a.s./kg diet corresponding to 1.65 mg a.s./kg bw/d.

The first-tier risk assessment for insectivorous birds resulted in acute and short-term TERs above the Annex VI trigger of 10 but the long-term TER was below the trigger of 5. The refined long-term risk assessment was based on blue tit (*Cyanistes caeruleus*) as a focal species. A PT of 0.61 and a RUD of 5.1 (birds feeding only on large insects) were suggested by the RMS to refine the risk assessment. The experts rejected the RUD refinement since no data supported the assumption that blue tits would feed only on large insects. It was proposed that a realistic dietary composition of blue tits could be 70% small insects and 30% large insects leading to a RUD value of 21.9. The PT value of 0.61 was discussed. Some experts were of the opinion that this value should be applied since it is the mean 90th percentile. However in most recent decisions in experts' meetings it was agreed that the upper 95th percentile confidence interval of 0.79 should be used to capture the uncertainty in the PT value. Nevertheless, also with the PT of 0.61 and the agreed PD refinement the long-term TER was below the trigger of 5 and the experts proposed a data gap for further refinement of the risk assessment.

In the additional report the applicant suggested the following refinements of the long-term risk assessment: Using the geometric mean NOEL from the studies with bobwhite quail (*Colinus virginianus*) and mallard duck (*Anas platyrhynchos*), a generic residue decline in arthropods with a DT_{50} of 10 days and a PT (proportion of time spent feeding in the treated area) of 0.27. The suggested refinements were not accepted by the RMS. EFSA agrees to use the RUD value of 21 as suggested in the new Guidance Document (EFSA, 2009). However, assuming a generic DT_{50} of 10 days for residue decline in insects and using the geometric mean value from the studies with bobwhite quail and mallard duck are not suggested in the new Guidance Document and hence are not agreed by EFSA. The PT refinement of 0.27 (mean value) is also not agreed by EFSA. The RMS suggested using the 95th upper confidence interval of the 90th percentile PT. This would be a conservative approach taking

into consideration variability in the underlying dataset. A high long-term risk to birds is indicated on the basis of the available data and the data gap to address the long-term risk to birds remains.

The TERs for earthworm- and fish-eating birds were above the trigger of 5 indicating a low risk.

The log P_{ow} of the metabolites M01, M02 and M08 were <3 and therefore no risk assessment for secondary poisoning of fish- and earthworm-eating birds and mammals was required.

Triflumuron was of low acute oral toxicity to mammals. The endpoints of LC_{50} >2123 mg a.s./kg bw and NOEL of 142.5 mg a.s./kg bw/d were used in the acute and long-term risk assessment. The first-tier TERs were calculated as >83 and 22 indicating a low risk to herbivorous mammals. The TERs for earthworm- and fish-eating mammals were well above the trigger of 5. The risk from plant metabolites to herbivorous mammals was assessed as low.

No risk assessment was provided for exposure in relation to drinking contaminated water. However, the risk is assumed to be low considering the low acute toxicity of triflumuron to birds and mammals. Furthermore, the morphology of leaves of orchard trees is not conducive to the formation of water reservoirs in leaf axils.

The risk to birds and mammals was assessed as low for the representative uses of triflumuron. Only the long-term risk to insectivorous birds needs further refinement.

5.2. Risk to aquatic organisms

Triflumuron was very toxic to aquatic invertebrates. The toxicity to fish and algae was low. The risk assessment was driven by the toxicity to daphnids. The acute and chronic TERs for daphnids were significantly below the Annex VI triggers of 100 and 10 for all FOCUS step 4 scenarios with a no-spray buffer zone of 30 m. Acute TERs <100 were observed also for fish in some of the scenarios.

A mesocosm study was conducted. Copepods and daphnids were the most sensitive organisms investigated in the mesocosm study. Sediment dwelling organisms (Chironomids) were also investigated in the mesocosm and hence are covered by the mesocosm endpoint. The RMS suggested a NOAEC of 0.1 µg a.s./L together with an assessment factor of 1. The experts noted that effects on cladocera were observed until day 43 after the last treatment at the concentration of 0.1 µg a.s./L. Recovery was shown 56 days after the last treatment. The experts rejected the proposed factor of 1 and suggested an assessment factor of at least 3. A no-spray buffer zone of 30 m would not be sufficient to achieve TERs >3 in a full FOCUS step 4 scenario with the available PECsw values calculated for 2 applications. It should be noted that the PECsw values are only indicative and do not necessarily represent a worst case (see also point 4.2.1).

The metabolites M01, M02 and M08 were more than 3 orders of magnitude less toxic to fish and invertebrates compared to triflumuron. The risk to aquatic organisms of the metabolites was assessed as low.

Overall it is concluded that a high risk to the aquatic environment cannot be excluded on the basis of the submitted data.

New calculations have been presented in the addendum to the Additional Report. Only the Step 4 calculations taking into account 95% mitigation for spray drift have been retained for the assessment. No full FOCUS step 4 scenario including 95% spray drift mitigation exceeded the TER of 3 based on the mesocosm endpoint (NOAEC of 0.1 µg a.s./L). Therefore a high risk to the aquatic environment is indicated and the conclusion on the risk to aquatic organisms remains unchanged.

5.3. Risk to bees

The acute oral and contact toxicity to adult bees was low. The oral and contact HQ values were <1.6 and <1.8 respectively, indicating a low risk. In order to take into account the mode of action (insect growth regulator) also bee brood feeding studies and field studies were conducted.

Increased mortality of bee brood was observed after feeding on 41.7 mg a.s./L feeding solution. The experts concluded that it was not possible to derive a clear NOEC from the available feeding study. No effects on bee-brood development were observed in the field studies at application rates of up to 48 g/ha. Increased mortality of pupae was observed at 54 g a.s./ha. The tested rates were too low to cover the application rate of 2 x 180 g a.s./ha. However the product is applied after flowering (BBCH 71) and therefore exposure concentrations in flowering weeds growing in the field were considered relevant for the bee risk assessment. The application rate for weeds growing in-field would be 54 g a.s./ha assuming 70% interception. The experts noted that the second application was not covered by the field studies and that in reality the bees would be exposed for a longer period of time. The experts agreed that it was not sufficiently demonstrated on the basis of the submitted data that the risk to bee brood development is low. Risk mitigation measures such as cutting flowering weeds in the treated field were suggested to protect bees.

5.4. Risk to other arthropod species

The in-field and off-field exposure of leaf dwelling non-target arthropod species was calculated as 306 g a.s./ha and 37.12 g .a.s./ha (not including the vegetation distribution factor of 10 for off-field). No mortality or reproductive effects of >50 % were observed in standard glass plate tests with the formulation Triflumuron SC 480 and the indicator species *Typhlodromus pyri* and *Aphidius rhopalosiphi* at treatment rates of 384 and 300 g a.s./ha. However, other leaf dwelling insects *Coccinella septempunctata* and *Chrysoperla carnea* reacted very sensitive. Effects (mortality and reproduction) of >50% were observed in glass plate tests with Triflumuron SC 480 at rates of 180 g a.s./ha and *C. septempunctata*. The lowest concentration of 8 g a.s./ha led to 100% mortality in an extended lab study with *C. carnea*. Mortality of >50% was observed in a semi-field test with *C. carnea* on bean plants at an application rate of 9.9 g a.s./ha. All animals died in an aged residues test even after 112 d of ageing. However, the plants were treated with 2 x 306 g a.s./ha and the high mortality rate may be due to the higher application rates.

A field test was made available where an apple orchard was treated with 180 g a.s./ha and after 35 d with 6 g a.s./ha. Based on bioassays and field inventory, the RMS concluded on a low risk to non-target arthropods. It was noted by the experts that the second application was not according to the proposed GAP (2 x 180 g a.s./ha). The RMS explained that the second application should mimic the off-field exposure. Full recovery of affected arthropod populations (including the most sensitive species *C. carnea*) was observed in the field study. This was in contradiction with the aged residues test where 100% mortality of *Chrysoperla* larvae was observed even after 112 days of ageing. This was explained by the fact that the larvae were found on the newly grown parts of the trees (grown after the treatment) where aphids were abundant. The experts concluded that the submitted information provides enough evidence that a sufficiently high number of *Chrysoperla* larvae can survive in the untreated area to allow recolonisation of the treated in-field area.

Overall it was concluded that the risk to non-target arthropods was sufficiently addressed for the representative use evaluated.

5.5. Risk to earthworms

The acute toxicity of technical and formulated triflumuron was low (LC_{50} >1000 mg triflumuron/kg soil). No long-term studies were conducted with earthworms. The RMS argued that the DT_{50} in the

laboratory studies were less than 60 days and the number of applications is < 3 and therefore no long-term study is triggered. It was confirmed by the experts on fate and behaviour that the 4 soil degradation studies give some indication that the field DT_{90} can be longer than 100 days. Since triflumuron disturbs the chitin synthesis it was considered necessary to investigate potential adverse long-term effects on earthworms. A data gap was identified by the experts for a long-term (reproduction) study with earthworms.

A new long-term (reproduction) study with earthworms was evaluated in the Additional Report. A NOEC of ≥ 378 mg a.s./kg soil was observed in the study. The long-term risk was assessed as low and the data gap was closed.

The acute toxicity of the major soil metabolites M02 and M08 to earthworms was low (LC_{50} >1000 mg M02/kg soil, LC_{50} = 562.1 mg M08/kg soil). The acute TERs for triflumuron, 2-chlorobenzoic acid and M08 were 2 - 3 orders of magnitude above the Annex VI trigger of 10 indicating a low acute risk. The longest lab DT_{50} for M08 was 4.3 days and the longest DT_{90} for 2-chlorobenzoic acid was 13.8 days. Therefore a long-term risk assessment is not triggered for the soil metabolites.

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

Studies with collembola and the soil metabolites 2-chlorobenzoic acid and M08 were submitted. The NOECs for reproduction were 100 mg M02/kg soil and 31.6 mg M08/kg soil. The NOECs were about 4 orders of magnitude higher then the calculated maximum PECsoil suggesting a low risk to collembola.

No studies with other soil non-target macro-organisms were made available for triflumuron. The experts agreed in the meeting that studies with collembola should be conducted considering the high toxicity to arthropods and that the DT_{90} can be longer than 100 days under some soil conditions. A data gap was identified for a study with collembola and triflumuron.

New soil degradation studies were submitted and evaluated in the Additional Report. The results indicate that the field DT_{90} would be less than 100 days. Therefore EFSA agrees that no long-term studies with collembola are triggered and that the risk to soil non-target macro-organisms is assumed to be low.

5.7. Risk to soil non-target micro-organisms

No effects of >25% on soil respiration and nitrification were observed in studies with technical and formulated triflumuron up to the highest tested concentration of 5.33 mg a.s./kg soil. Only nitrogen turnover was tested with the major soil metabolites 2-chlorobenzoic acid and M08. No effects >25% were observed at concentrations of 0.53 mg M02/kg soil and 0.75 mg M08/kg soil. The tested concentrations were more than 5 times higher than the maximum PECsoil values indicating a low risk to soil micro-organisms.

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

No adverse effects were detected in pre- and post-emergence tests with Triflumuron SC 480 and 5 monocotyledon and 6 dicotyledon plant species up to the highest tested application rate of 1.08 kg triflumuron/ha. The applied rate was about 10 times higher than the application rate suggested in the GAP. Therefore the risk to non-target plant species was considered to be low for the representative uses evaluated.

5.9. Risk to biological methods of sewage treatment

Respiration of activated sludge was inhibited by 44.3 % at the highest tested concentration of 10 g triflumuron/L. It was not expected that triflumuron would reach sewage treatment plants in higher concentrations if applied according to the GAP. Therefore the risk to biological methods of sewage treatment was considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: triflumuron, 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea.

Definition for monitoring: triflumuron

Water

Groundwater

Definition for exposure assessment: triflumuron, 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea.

Definition for monitoring: triflumuron

Surface water

Definition for risk assessment: triflumuron, 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea.

Definition for monitoring: triflumuron

Air

Definition for risk assessment: triflumuron

Definition for monitoring: triflumuron

Food of plant origin

Definition for risk assessment: Fruit crops: triflumuron
Oilseed and tuber crops: sum triflumuron, M07 and M08 expressed as triflumuron (provisional)

Definition for monitoring: triflumuron

Food of animal origin

Definition for risk assessment: triflumuron (provisional)

Definition for monitoring: triflumuron

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

7.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
triflumuron	low persistent to moderate persistent in soils ($DT_{50\ lab\ 20\ °C}$ = 1.2 – 14.6 d)	The acute toxicity and long-term risk to earthworms and soil non-target macro-organisms are low. The risk to soil micro-organisms was assessed as low.
2-chlorobenzoic acid	very low to low persistent ($DT_{50\ lab\ 20\ °C}$ = 0.4 – 3.3 d)	Low acute toxicity and risk to earthworms, low risk to soil non-target macro- and micro-organisms.
4-trifluoromethoxyphenyl urea	low persistent ($DT_{50\ lab\ 20\ °C}$ = 1.3 – 3.3 d)	Low acute toxicity and risk to earthworms, low risk to soil non-target macro- and micro-organisms.

7.2. Groundwater

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
triflumuron	immobile to low mobile in acidic soils (Koc = 1629 – 30006	FOCUS PEARL: no scenario exceeds 0.1 µg / L	Yes	Yes	Yes

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
	mL/g)				
2-chlorobenzoic acid	very high mobile in acidic soils (Koc = 4.0 – 8.8 mL/g) Koc = 0 for modelling	FOCUS PEARL: no scenario exceeds 0.1 µg / L	No data were made available. Assessment not needed.	No	No
4-trifluoromethoxyphenyl urea	medium to high mobile (Koc = 113 – 280 mL/g)	FOCUS PEARL: no scenario exceeds 0.1 µg / L	No data were made available. Assessment not needed.	No	No

7.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Triflumuron (water and sediment)	Very toxic to aquatic organisms. A high risk was observed and a data gap remains for further refinement of the risk assessment.
2-chlorobenzoic acid (water phase only)	More than 3 orders of magnitude less toxic to aquatic organisms compared to triflumuron. The risk to aquatic organism was assessed as low.
4-trifluoromethoxyphenyl	More than 3 orders of magnitude less toxic to aquatic organisms compared to triflumuron. The risk to aquatic organisms was assessed as low.

urea (sediment phase only)	

7.4. Air

Compound (name and/or code)	Toxicology
triflumuron	low acute toxicity by inhalation (rat LC_{50} >5 mg/L air/4h) 3-week NOAEC in rats 0.0045 mg a.s./L

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

- Storage stability where the relevant impurity 4-trifluoro-methoxyaniline is analysed before and after storage (relevant for all uses, data gap identified by EFSA September 2008, date of submission unknown, refer to chapter 1)

- Method of analysis for 4-trifluoro-methoxyaniline in the formulation (relevant for all uses, data gap identified by EFSA September 2008, date of submission unknown, refer to chapter 1)

- The applicant should demonstrate whether or not M01, M02 and M07, M08 are formed by the extraction procedures used in the plant metabolism studies (relevant for all uses, data gap identified by the meeting of experts PRAPeR 55 in July 2008, no submission date proposed by the applicant, refer to chapter 3.1.1)

- The processing study conducted on peaches, referenced "*Kuppels, U.; Billian, P.; Schmeer, K. (2009)"* and providing information on the residue levels of triflumuron in the raw and processed commodities is required (relevant for the representative use on peach/nectarine, no submission date proposed by the applicant, refer to chapter 3.1.1)

- A data gap was identified by the meeting of experts for water / sediment studies with a wide range of pHs (data gap considered not essential to finalize the EU risk assessment, data of submission not available, refer to point 4.2.1).

- A new long-term risk assessment for insectivorous birds (relevant for all uses; data gap identified in the meeting of experts on ecotoxicology, PRAPeR 53 in July 2008; no submission date proposed by the applicant, refer to point 5.1.)

- The aquatic risk assessment needs further refinement. (relevant for all uses; data gap identified in the meeting of experts on ecotoxicology, PRAPeR 53 in July 2008; no submission date proposed by the applicant, refer to point 5.2.).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide on apples, pears, peaches and nectarines. Full details of the GAP can be found in the attached list of end points.

The representative formulated product for the evaluation was "Alsystin SC 480", a suspension concentrate (SC), containing 480 g/l triflumuron.

Adequate methods are available to monitor all compounds given in the respective residue definition. Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. Data for the relevant impurity 4-trifluoro-methoxyaniline are missing.

With regard to its toxicological properties, triflumuron is extensively absorbed after oral administration and has a low acute toxicity. The main adverse effect after repeated administration is haemolytic anaemia with compensative responses and secondary effects in different organs. No mutagenic or carcinogenic potential has been demonstrated in the available tests. In the reproductive

toxicity testing, no specific effects on the fertility parameters, on the growth of the offspring or on the foetal development were observed in the absence of maternal toxicity. It was agreed that triflumuron has no specific neurotoxic potential.

Several tests were performed on metabolites and/or impurities. The plant metabolites M01, M02, M07 and M08 were considered as covered by the toxicological studies with the parent (use of the same acceptable daily intake). Since it was shown to be acutely more toxic than triflumuron, new toxicological data were provided for the plant metabolite M07 during the resubmission, allowing the derivation of a specific acute reference dose.

The agreed Acceptable Daily Intake (**ADI**) for triflumuron is 0.014 mg/kg bw/day, based on the 1-year dog study supported by the 2-year rat study and with the use of a safety factor of 100. The agreed Acceptable Operator Exposure Level (**AOEL**) is 0.036 mg/kg bw/day, based on the overall NOAEL of the 90-day rat studies and applying a safety factor of 100. The derivation of an Acute Reference Dose (**ARfD**) was not considered needed for triflumuron.

The agreed dermal absorption values resulting from *in vivo* and *in vitro* testing are 1% for the concentrate (mixing/loading) and 5% for the dilution (application). The estimated operator exposure levels according to the models are below the AOEL without the use of personal protective equipment, and the estimated exposure values for the workers and bystanders are even lower.

The plant metabolism of triflumuron was investigated in apple, tomato, potato and soybean. Triflumuron was seen to be the major component of the residues in all plant groups investigated. Therefore, the residue definition for monitoring was proposed as triflumuron alone. For the fruit crop group, since no metabolite was detected in significant levels in the metabolism studies conducted on apple and tomato, triflumuron alone was also proposed to define the residue for risk assessment. For the oilseed and root crop groups, metabolites M07 and M08 were, in addition to the parent, included in the definition for risk assessment. Sufficient supervised residue trials were submitted to derive MRLs on pome fruit, peaches and nectarines. Processing factors were calculated for processed fruit commodities, and additional studies on apples and peaches confirmed that metabolites M07 and M08 are not expected to be present above the LOQ in processed fractions. However a data gap was identified for peaches, asking for supplementary information on the initial residue levels in the raw products, prior processing. It was concluded that, based on the representative uses, no MRLs are necessary for products of animal origin. No chronic risk was identified for the consumers, the highest TMDI being 46% of the ADI. The acute risk was not considered since no ARfD was allocated to triflumuron.

Triflumuron is low to moderate persistent in soil under dark aerobic conditions. Two major metabolites are formed: 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea. The trifluoromethoxyphenyl ring was less mineralized and more prone to form unextractable residues than the chlorophenyl ring.

From the data available it was not possible to derive reliable half-lives neither for the parent nor for the major soil metabolites under anaerobic conditions. Metabolites M2 (max 46.7 % AR) and M08 (max. 48.5 % AR) were the only major metabolites identified under dark anaerobic conditions. According to the study available, triflumuron may be considered stable to photolysis in soil.

PECs soil have been updated in the Additional Report.

According to the available adsorption / desorption studies triflumuron may be considered immobile to low mobile in soil (Koc = 1629 – 30006 mL/g), metabolite M08 may be considered medium to high mobile in soil (Koc = 113 - 280 mL/g) and M02 may be considered very high mobile in soil (Koc = 4.0 – 8.8 mL/g).

Triflumuron was stable to hydrolysis at pH 5 and 7 and degrades with a half-life between 29 and 57 d at pH 9. Main hydrolysis metabolites at this pH were M02 (max. 28.9 % AR after 30 d) and M08

(max. 48.8 % AR after 30 d). According to the available study, aqueous photolysis is considered to contribute only in a minor extent to the overall degradation of triflumuron. In the absence of a corresponding study, it is proposed to classify triflumuron as not readily biodegradable.

In water sediment systems triflumuron partitioned to the sediment and degraded (DT_{50} = 4.1 – 7.1 d) to major metabolites M08 (max in water: 47.8 % AR after 14 d, max. in sed.: 20.4 % AR after 7 d; DT_{50} = 11.4 – 11.7 d) and M02 (max in water: 60.4 % AR after 14 d, max. in sed.: 7.9 % AR after 14 d; DT_{50} = 17.6 – 62.9 d). Mineralization was more important for the chlorophenyl ring than for the trifluoromethoxyphenyl moiety. The pH of the water phase of the systems investigated was in the alkaline range. A data gap, which was not considered essential to finalize the EU risk assessment, was identified for water / sediment studies within a wider range of pH values.

Updated PEC $_{SW/SED}$ were presented in the resubmission dossier following the FOCUS SW scheme. New calculations have been presented in the Addendum to the Additional Report. Only the Step 4 calculations taking into account 95% mitigation for spray drift have been retained for the assessment.

PEC GW calculations have been updated with FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3 to the current GAP and with the new degradation data available. Neither the parent triflumuron nor the two soil metabolites 2-chlorobenzoic acid and 4-trifluoromethoxyphenyl urea are expected to exceed the trigger of 0.1 µg/L for any of the relevant scenarios.

Based on the physical and chemical properties of triflumuron, the volatilization study available and the calculated photochemical half-life for triflumuron, it is expected that it will not be transported over long range distances and will not accumulate in air.

The first-tier risk assessment for birds resulted in acute and short-term TERs above the Annex VI trigger of 10. However, the long-term TER was below the trigger of 5 on the basis of the agreed refinement steps and a data gap was identified for a new refined long-term risk assessment. The acute and long-term trigger values for mammals were exceeded in the first-tier risk assessment indicating a low risk. The risk from secondary poisoning of earthworm- and fish-eating birds and mammals was assessed as low. The refinements suggested by the applicant and evaluated by the RMS in the Additional Report were not accepted and therefore the data gap remains.

Triflumuron was very toxic to aquatic invertebrates. A mesocosm study was submitted. The experts agreed on a regulatory endpoint of 0.1 µg a.s./L in combination with an assessment factor of 3. A no-spray buffer zone of 30 m would not be sufficient to achieve TERs >3 and further refinement of the aquatic risk assessment is needed. New FOCUS step 4 calculations including the maximum spray drift reduction of 95% did not result in a FOCUS scenario where all TERs exceeded the trigger of 3 (applied to a mesocosm NOAEC of 0.1µg a.s./L). A high risk to the aquatic environment is indicated.

Bee brood was very sensitive for exposure to triflumuron. It was not sufficiently demonstrated that the risk to bee brood development is low and risk mitigation measures such as cutting flowering weeds in the treated field were suggested to protect bees. *Chrysoperla carnea* was the most sensitive non-target arthropod species tested. This observation was confirmed in a field study in an apple orchard. Full recovery of affected arthropod populations (including the most sensitive species *C. carnea*) was observed. The study provided some evidence that a sufficiently high number of *Chrysoperla* larvae can survive in the untreated area to allow recolonisation of the treated in-field area. Overall it was concluded that the risk to non-target arthropods was sufficiently addressed for the representative uses evaluated. The acute risk to earthworms was assessed as low. Since triflumuron inhibits the chitin synthesis, the experts considered the potential adverse long-term effects on earthworms necessary to be investigated and therefore a data gap was identified under the first review. For the resubmission, a long-term (reproduction) study with earthworms was submitted and the long-term risk to earthworms was evaluated as low. No studies with other soil non-target macro-organisms were made available for triflumuron under the first review. The experts agreed in the meeting that studies with collembola should be conducted considering the high toxicity to arthropods and that the DT_{90} can be longer than

100 days under some soil conditions. For the resubmission, new soil degradation studies were made available which indicated that the DT_{90} is less than 100 days and therefore a study with collembola was not triggered any longer.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- Flowering weeds should be removed before application of triflumuron to protect bees.

ISSUES THAT COULD NOT BE FINALISED

None.

CRITICAL AREAS OF CONCERN

- The long-term risk to birds needs further refinement.
- The high risk to the aquatic environment (acute and chronic risk to aquatic invertebrates).

REFERENCES

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance triflumuron EFSA Scientific Report (2008) 194.

EFSA (European Food Safety Authority), 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance triflumuron.

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

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

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

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

European Commission, 2009. Review Report for the active substance triflumuron finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 2 December 2008 in support of a decision concerning the non-inclusion of triflumuron in Annex I of Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. SANCO/146/08-final, 17 March 2009.

FOCUS, 2001. "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

FOCUS, 2007. "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

Ganzelmeier H, Rautmann D, Spangenberg R, Streloke M, Herrmann M, Wenzelburger H-J, Walter HF, 1995. Studies on the spray drift of plant protection products. Mitteilungen aus der Biologischen Bundensanstalt für Land- und Forstwirtschaft Berlin-Dahlem. Heft 305, 1995.

Italy, 2005. Draft Assessment Report (DAR) on the active substance triflumuron prepared by the rapporteur Member State Italy in the framework of Directive 91/414/EEC, May 2005.

Italy, 2008. Final Addendum to Draft Assessment Report on triflumuron, compiled by EFSA, August 2008.

Italy, 2010a. Additional Report to the Draft Assessment Report on the active substance triflumuron prepared by the rapporteur Member State Italy in the framework of Commission Regulation (EC) No 33/2008, March 2010.

Italy, 2010b. Final Addendum to the Additional Report on triflumuron, compiled by EFSA, August 2010.

Krebs B, Maasfeld W, Schrader J, Wolf R, Hoernicke E, Nolting HG, Backhaus GF, Westphal D, 2000. Uniform Principles for Safeguarding the Health of Worker Re-entering Crop Growing Areas after Application of Plant Protection Products. Bulletin of the German Plant Protection Service, 2000, 52(1) 5-9.

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

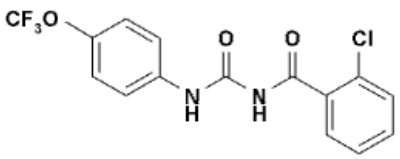
APPENDICES

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

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

Active substance (ISO Common Name)	Triflumuron
Function (e.g. fungicide)	Insecticide
Rapporteur Member State	Italy

Identity (Annex IIA, Point 1)

Chemical name (IUPAC)	1-(2-chlorobenzoyl)-3-[4-trifluoromethoxyphenyl] urea
Chemical name (CA)	2-chloro-*N*-[[[4-(trifluoromethoxy)phenyl]amino]carbonyl]benzamide
CIPAC N°	548
CAS N°	64628-44-0
EEC N° (EINECS or ELINCS)	264-980-3
FAO Specification (including year of publication)	AGP:CP/370 (2000) Triflumuron minimum purity: 955 g/kg Impurities: *N*,*N*'-bis[4-(trifluoromethoxy)phenyl]urea Maximum: 1.0 g/kg Water Maximum: 1.0 g/kg
Minimum purity of the active substance as manufactured (g/kg)	980 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	*N*,*N*'-bis-[4-(trifluoromethoxy)phenyl] urea Max. 1 g/kg 4-trifluoro-methoxyaniline Max. 5 g/kg Toluene Max. 50 g/kg
Molecular formula	$C_{15}H_{10}ClF_3N_20_3$
Molecular mass	358.7 g/mol
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	194°C (purity 99.6)
Boiling point (state purity)	Boiling point cannot be determined due to decomposition
Temperature of decomposition	>360°C (purity 99.6)
Appearance (state purity)	Colourless to white crystalline powder (purity: 99.8%)
Surface tension	Not applicable (water solubility < 1mg/L)
Vapour pressure (in Pa, state temperature)	2×10^{-7} Pa at 20 °C (by extrapolation)
Henry's law constant (Pa m3 mol-1)	1.79×10^{-3} Pa x m^3/mol at 20 °C
Solubility in water (state temperature, state purity and pH)	0.04 mg/l at 20 °C in un-buffered water (purity 99.8 %)
Solubility in organic solvents (g/l or mg/l, state temperature)	At 20 °C (purity 99.8 %) acetone: 26.6 g/l acetonitrile: 4.5 g/l dichloromethane: 11.7 g/l dimethylsulfoxide: 127.4 g/l ethylacetate: 23.3 g/l n-heptane: < 0.1 g/l 1-octanol: 1.2 g/l polyethyeneglycol: 9.6 g/l 2-propanol: 1.3 g/l xylene: 1.7 g/l
Partition co-efficient (log Pow) (state temperature, pH and purity)	log P_{OW} = 4.90 at 22 °C (purity 99.9%)
Dissociation constant (state purity)	Due to poor water solubility (≤ 0.04 mg/l), it is not possible to specify a pK value of Triflumuron. Triflumuron exhibits no basic properties in aqueous solution.
UV/VIS absorption (max.) incl. ε (state purity, pH)	UVmax = 249 nm ε=14.94 x 106 cm^2/mol (purity 99.8 %) results were determined using a solution of the a.s. in acetonitrile.
Flammability (state purity)	The a.s. (purity 99.6%) is not highly flammable in the sense of EC guideline A.10. It does not liberate gases in hazardous amounts as defined in EC guideline A.12.
Explosive properties (state purity)	The a.s. (purity 99.6%) is not explosive in the sense of EC guideline A.14.
Oxidizing properties (state purity)	The a.s. (purity 99.6%) has no oxidising properties in the sense of EC guideline A.17.

Summary of representative uses evaluated (triflumuron)*

Crop and/ or situation (a)	Member State or Country	Product name(s)	F/G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application			Application rate per treatment				PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	Method kind (f-h)	growth stage & season (j)	# min max (k)	Interval between applications (min)	kg a.s./hl min max	water L/hamin max	kg a.s./hami n max		
pome fruit, (apples/ pears)	*Northern and Southern Europe*	Als. SC	*F*	Lithocolletis blancardella Lithocolletis coryfoliella Lyonetia clerkella Cydia pomonella Cydia molesta Plesiocoris rugicollis Hoplocampa testudinea Leucoptera scitella Orgia antiqua Zeuzera pyrina Psylla piri	SC	480g/l	SPI	71 (post blossom)	2	40	0.012	Max .1500	max. 0.18 per appl.	28	*[1]*
Peaches/ nectarines	*Southern Europe*	Als. SC	*F*	Cydia molesta Anarsia lineatella Phyllonorrycter cerasicolella Zeuzera pyrina	SC	480g/l	SPI	71 (post blossom)	2	40	0.012	Max. 1500	max. 0.18 per appl.	14	*[1]*

[1] Further refinement is needed for the long-term risk assessment for birds and a high risk to the aquatic environment was identified.

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(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) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

* Uses for which the risk assessment can not be concluded are marked grey.

Methods of Analysis

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

Technical as (principle of method)	The principle is RP-HPLC of sample solutions with an isocratic eluent and UV-detection using certified reference substance as external standard. No CIPAC method available
Impurities in technical as (principle of method)	The method (RP-HPLC and UV detection) does not differ substantially from the method for technical as
Plant protection product (principle of method)	The principle is RP-HPLC of sample solutions with an isocratic eluent and UV-detection using certified reference substance as external standard (validated 2009). Open No method provided for the analysis of 4-trifluoro-methoxyaniline (relevant impurity)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Triflumuron
Food of animal origin		Triflumuron
Soil		Triflumuron
Water	surface	Triflumuron
	drinking/ground	Triflumuron
Air		Triflumuron

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Primary, confirmatory and enforcement methods are based on RP-HPLC-ESI-MS/MS ILV: yes Quantitative MRM: m/z = 357 → m/z = 154 Confirmatory MRM: m/z = 357 → m/z = 176 LOQ Olive (fruit), Orange (fruit), Tomato (fruit), Wheat (grain): 0.01 mg/kg

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Based on RP-HPLC-ESI-MS/MS ILV: yes Quantitative MRM: m/z = 357 → m/z = 154 Confirmatory MRM: m/z = 357 → m/z = 176 LOQ Bovine Milk, bovine Liver, Bovine Kidney, Bovine Fat, Bovine Meat: 0.005 mg/kg
Soil (principle of method and LOQ)	Based on RP-HPLC-ESI-MS/MS Quantitative MRM: m/z = 357 → m/z = 154 LOQ soil: 0.01 mg/kg
Water (principle of method and LOQ)	Based on RP-HPLC-ESI-MS/MS Quantitative MRM: m/z = 357 → m/z = 154 LOQ surface, ground and drinking water: 0.03 µg/L
Air (principle of method and LOQ)	RP-HPLC-UV(DAD) LOQ air: 0.0012 mg/m3 (validated 2009)
Body fluids and tissues (principle of method and LOQ)	No method available; triflumuron is not considered toxic or highly toxic.

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

	RMS proposal	ECB decision
Active substance or variant	none	none

Impact on Human and Animal Health

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

Rate and extent of oral absorption	≥80% within 72h (based on urine, bile and carcass)
Distribution	Preferably distributed in fatty tissues, also found in blood, liver, kidney, lung and spleen.
Potential for accumulation	No potential for accumulation.
Rate and extent of excretion	Almost completely excreted via urine and faeces within 48h (with ~40 to 50% by biliary excretion).
Metabolism in animals	In rats, metabolites were formed through hydrolysis followed by subsequent conjugation, or by hydroxylation of the parent compound followed by hydrolysis and/or conjugation.
Toxicologically relevant compounds (animals and plants)	Triflumuron and metabolites (4-trifluoro-methoxyaniline, 1-[4-(trifluoromethoxy)phenyl]urea, 2-chlorobenzamide, 2-chlorobenzoic acid)
Toxicologically relevant compounds (environment)	Triflumuron

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw	-
Rat LD_{50} dermal	> 5000 mg/kg bw	-
Rat LC_{50} inhalation	> 5 mg/L air 4h (aerosol, nose-only)	-
Skin irritation	Not irritant	-
Eye irritation	Not irritant	-
Skin sensitisation	Non sensitiser (Magnusson & Kligman Test)	-

Short-term toxicity (Annex IIA, point 5.3)

Target / critical effect	Hematopoietic system (haemolytic anaemia)	
Relevant oral NOAEL	3.6 mg/kg bw/d (rat, 90-day study) 1.42 mg/kg bw/d (dog, 12-month study)	-
Relevant dermal NOAEL	100 mg/kg bw/d (rabbit, 3-week study)	-
Relevant inhalation NOAEC	0.0045 mg a.s./L (rat, 3-week study)	-

Genotoxicity (Annex IIA, point 5.4)

No genotoxic properties	-

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

Target/critical effect	Haematopoietic system (haemolytic anaemia)	
Relevant NOAEL	0.82 mg/kg bw/d (rat) 5.19 mg/kg bw/d (mouse)	
Carcinogenicity	No carcinogenic potential	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental: not determined (no assessment of haematological parameters) Offspring: no adverse effect Reproductive: no adverse effect	-
Relevant parental NOAEL	not determined	-
Relevant reproductive NOAEL	133 mg/kg bw/d	-
Relevant offspring NOAEL	133 mg/kg bw/d	-

Developmental toxicity

Developmental target / critical effect	Maternal: haemolytic anaemia (rat, rabbit) Developmental: delayed skeletal development (rat); increased post-implantation loss (rabbit)	-
Relevant maternal NOAEL	Rat: 300 mg/kg bw/d Rabbit: 300 mg/kg bw/d	-
Relevant developmental NOAEL	Rat: 300 mg/kg bw/d Rabbit: 300 mg/kg bw/d	-

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)

Mode of action of triflumuron	No methaemoglobin formation in cats after single exposure

4-trifluoro-methoxyaniline (M07)	25< rat oral LD_{50} ≤200 mg/kg bw 0.5 < rat inhalative LC_{50} ≤2 mg/L air Rat dermal LD_{50} <50 mg/kg bw Not skin irritant, moderate eye irritation (not classifiable) Ames test negative (other mutagenicity tests not considered accepatble) Destruction of haemoglobin with methaemoglobin formation in cats Structural alerts for skin sensitisation and carcinogenicity 6-day single dose toxicity in rat: NOAEL= 0.5 mg/kg/bw/d
N,N'-bis-(trifluoromethoxyphenyl) urea	Rat oral LD_{50}: 133 (M)-277 (F) mg/kg bw cat – acute oral toxicity: > 1000 mg/kg bw cat – methaemoglobin level: no haemotoxic effect

Medical data (Annex IIA, point 5.9)

No detrimental effects on health in manufacturing personnel. No cases of poisoning.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI (mg/kg bw/d)	0.014	1-yr dog supported by 2-yr rat	100
AOEL (mg/kg bw/d)	0.036	90-d rat	100
ARfD (mg/kg bw) for triflumuron	Not necessary	-	-
ARfD (mg/kg bw) for metabolite M07	0.005	6-day single dose toxicity in rat	100

Dermal absorption (Annex IIIA, point 7.3)

Triflumuron SC 480	Human/rat *in vitro* and rat *in vivo*: 1 % (concentrate) and 5% (dilution)

Exposure scenarios (Annex IIIA, point 7.2)

Operator (exposure levels in % of AOEL)	**Model**	**No PPE**	**With PPE**
	UK POEM-tractor	42	26*
	German BBA- tractor	35	8**
	German BBA- hand held	32	9**
	Field study: measured exposure just above the AOEL without the use of PPE.		
Workers	Estimated exposure is 45 % of AOEL (without PPE)		

Bystanders	Estimated exposure is 0.47 % of AOEL

* PPE (personal protective equipment): gloves during M/L (mixing/loading) and A (application), standard protective garment and sturdy footwear during A.
** PPE: gloves during M/L and A

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

	RMS/peer review proposal	ECB decision
Active substance(Triflumuron)	Not applicable	None assigned
Preparation(Alsystin 480 SC)	Not applicable	

Residues

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

Plant groups covered	Fruit crops: (tomato, apple), Pulses/Oilseeds: (soya bean) Root vegetables: (potato) Foliar treatment by spray application.
Rotational crops	Not relevant for the representative uses. However, study available on leafy crop (kale), root crop (red beet) and cereal (wheat), but with the chlorophenyl label only.
Metabolism in rotational crops similar to metabolism in primary crops	Not relevant for the representative uses. Parent, M01 and M02 seen to be the major components in rotational crops (and probably the counter part metabolites M07 and M08, but not confirmed since no study available with the trifluoromethoxyphenyl label).
Processed commodities	Triflumuron degraded to M08 (16% TRR) and M07 (17% TRR) under sterilisation conditions (and probaly to M01 and M02 but not confirmed since no study available with the chlorophenyl label).
Residue pattern in processed commodities similar to residue pattern in raw commodities	Triflumuron does not concentrate in processed fruit commodities, except peel, dry apple, pomace and prune. No residues of M07 and M08 were found in the processed matrices above the LOQ of 0.005 mg/kg (to be confirmed for peach).
Plant residue definition for monitoring	Triflumuron
Plant residue definition for risk assessment	Fruit crops: Triflumuron Oilseeds/pulses and tuber crops: sum triflumuron, M07 and M08 expressed as triflumuron (provisional)
Conversion factor (monitoring to risk assessment)	Not necessary for fruit crops Open for other plant groups

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

Animals covered	Goat and Poultry (chlorophenyl label only)
Time needed to reach a plateau concentration in milk and eggs	Plateau not reached during the duration of the study (3 days) .
Animal residue definition for monitoring	Triflumuron
Animal residue definition for risk assessment	Triflumuron (to be reconsidered if further uses are envisaged on additional plant groups)
Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Not concluded, since no residues above the LOQ are observed in the different matrices in the cattle feeding study.

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

Not relevant for representative uses. To be reconsidered if further uses on crops usually rotated are envisaged. (additionnal study with a ^{14}C trifluoromethoxyphenyl label should be considered)

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

Triflumuron residues stable when stored at *c.a.* -18°C: - 2 years in high water containing matrices (apple fruit, apple sauce, pomace, juice) - 100 days in bovine liver and meat and 89 days in milk.

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

	Ruminant:	**Poultry:**	**Pig:**
Note: Intakes not finalised, indicative, unable to conclude on residues in livestock	Conditions of requirement of feeding studies		
Intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 0.14/0.41 mg/kg DM (dairy/beef cattle)	Not relevant	Not relevant
Potential for accumulation (yes/no):	Yes	Not relevant	Not relevant
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues	No	Not relevant	Not relevant
	Dairy cattle fed at 5.9 and 11.9 mg/kg DM of triflumuron and sacrificed on day 29 of the study Residue levels in matrices: Mean = max mg/kg		
Muscle	<0.05	Not relevant	Not relevant
Liver	<0.05	Not relevant	Not relevant
Kidney	<0.05	Not relevant	Not relevant
Fat	<0.10	Not relevant	Not relevant
Milk	<0.01		
Eggs		Not relevant	

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

Crop	Northern Southern Region	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the intended use	HR (c)	STMR (b)
Apple and Pear	N	0.04; 0.07; 0.07; 0.09; 0.11; 0.13; 0.17; 0.21	Values underlined: trials on pear. North trials: R_{max}: 0.29; R_{ber}: 0.32 South trials: R_{max}: 0.39; R_{ber}: 0.44 Extrapolation to pome fruit group possible	0.5 (based on southern data)	0.21	0.10
	S	0.03; 0.07; 2x 0.09; 0.12; 0.15; 0.24; 0.26			0.26	0.11
Peach and Nectarine	S	0.02; 0.04; 0.05; 0.06; 0.07; 2x 0.09; 0.11; 2x 0.13; 0.14; 0.24	R_{max}: 0.27 R_{ber}: 0.26	0.3	0.24	0.09

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

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[5]

ADI	0.014 mg/kg bw/day
TMDI mg/kg (% ADI) according to EFSA PRIMo model	Highest TMDI: 46% ADI (DE Child)
TMDI mg/kg (% ADI) according to national (to be specified) diets	-
IEDI (European Diet) (% ADI)	Not necessary
NEDI microg/kg (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applied
ARfD	Not required and not allocated for triflumuron, Metabolite M07 = 0.005 mg/kg bw
IESTI mg/kg bw/day (% ARfD)	Not necessary since M07 not found in fruit crop metabolism and processed commodities.
NESTI microg/kg bw/day (% ARfD)	-
Factors included in I(N)ESTI	-

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

Crop/process/processed crop	Number of studies	Transfer factor Mean (individual values)
Apple / washed fruits	5	0.87 (0.42, 0.46, 0.73, 1.25, 1.50)
Apple / dried fruits	4	0.20 (0.10, 0.13, 0.19, 0.38)
Apple / apple sauce (pasteurised)	5	0.36 (0.15, 0.21, 0.31, 0.50, 0.65)
Apple / apple juice (pasteurised)	5	0.08 (<0.04;<0.04, <0.05, 0.13, 0.17)
Apple / pomace dried	5	11.2 (7.5, 8.3, 8.1, 8.5, 23.8)
Apple / peel	2	10.1 (9.6, 10.5)
Apple / peeled fruit	2	0.08 (0.05, 0.12)
Peach / peel	1	5.25
Peach / washed fruit	1	1.15
Peach / preserve	1	<0.1
Peach / stoned fruit	1	1.1
Peach / peeled fruit	1	<0.1
Plum / washed fruit	1	0.75
Plum / preserve	1	<0.5
Plum / depitted fruit	1	1
Plum / dried fruit	1	2.5

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

Plant products

Pome fruit	0.5 mg/kg
Peaches/Nectarines	0.3 mg/kg

Animal products

MRL proposals not necessary according to the representative uses on pome fruit and peach/nectarine

When the MRL is proposed at the LOQ this should be annotate by an asterisk (*) after the figure

Fate and Behaviour in the Environment

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

Mineralization after 100 days	Trifluoromethoxyphenyl-label 12.8 - 18.1% at day 120 (n=2) *8.0% at day 112 d (23°C, n=1) Chlorophenyl-label: 64.6 - 65.9% at day 120 (n=2) *52.5% at day 112 (23°C, n=1)
Non-extractable residues after 100 days	Trifluoromethoxyphenyl -label 68.7 - 70.9% at day 120 (n=2) *54.0% at day 112 (23°C, n=1) Chlorophenyl-label 24.0 - 30.0% at day 120 (n=2) *18.9% at day 112 (23°C, n=1)

Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	4-trifluoromethoxyphenyl urea (M08), only formed from the trifluoromethoxyphenyl -label max: 13.5% and 12.3% after 3 and 7 days; 0.3% and 2.8% day 120 (n=2) max: 23.1% after 84 days; 15.6% at day 112 (23°C, n=1) 2-chlorobenzoic acid (M02) only formed from the chlorophenyl-label max 5.9% and 3.9% after 3 and 7 days; n.d. at 120 days (n=2) max: 23.5% after 7 days; 0.3% after 112 days (23°C, n=1)

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

Anaerobic degradation Non-extractable residues after 60 anaerobic days post 30 days of aerobic incubation	Trifluoromethoxyphenyl-label (n =1): 53.3% Chlorophenyl-label (n =1): 16.1%
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	(M08), only formed from the trifluoromethoxyphenyl-label: max: 48.5% at anaerobic day 30 (M02) only formed from the chlorophenyl-label: max: 46.7% at anaerobic day 60
Soil photolysis Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	chlorophenyl-labelled: 2-chlorobenzamide (M01): maximum 3% at day 22 2-chlorobenzoic acid (M02): ≤ 1% 41 days of illumination: average light intensity measured 1062±54 μW/cm^2 mineralisation: 0.1% non-extractable residues: 2.3%

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

Laboratory studies

Parent	Aerobic conditions						
Soil type	X[11]	pH ($CaCl_2$) / pH (H_2O)	t. °C / % of MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		6.3 / 7.2	20°C/49 %	18.8 / 62.5	14.6	0.951	SFO
Silt		6.7 / 7.6	20°C/49 %	6.9 / 23	4.6	0.992	SFO
Silt loam		6.7 / 7.5	20°C/50 %	7.3/24.1	5.2	0.98	SFO
Loam		5.6 / 5.8	20°C/ 54.6 %	3.5 / 11.6	2.7	0.988	SFO
Clay loam		7.3 / 7.4	20°C/ 94.8%	1.7 / 5.7	1.2	0.994	SFO
Clay loam		7.6 / 8.0	20°C/ 43.1%	7.3 / 24.4	5.3	0.986	SFO
Geometric mean/median					4.3 / 4.9		

M08	Aerobic conditions						
Soil type	X	pH	t. °C / % of MWHC	DT_{50}/ DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt		6.7	20°C/49 %	1.9	1.3	0.994	SFO
Sandy loam		6.3	20°C/49 %	4.3	3.3	0.916	SFO
Silt loam		6.7	20°C/50	3.9/13.1	2.80	0.98	SFO
Geometric mean/median					2.29 / 2.8		

M02	Aerobic conditions						
Soil type	X	pH	t. °C / % of MWHC	DT_{50}/ DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt		6.3	20°C/49%	0.6/n.c.	0.4	0.964	SFO
Sandy loam		6.7	20°C/49%	0.8/n.c.	0.6	0.938	SFO
Sandy loam		6.5	20°C/49%	4.2/13.8	3.3	0.994	SFO
Loam		7.1	20°C/49%	1.2 /4.0	0.6	0.998	SFO
Sandy loam		6.9	20°C/49%	3.4/11.4	2.6	0.993	SFO
Geometric mean/median				1.2/1.5	1.1/0.6		

Field studies

	Not required

pH dependence (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration	Not applicable

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent							
Soil Type	OC %	Soil pH ($CaCl_2$)	Kd	Kf	Koc	Kfoc	1/n
Sandy loam	0.3	5.6		90.0		30006	1.24
Loamy sand	0.6	6.2		9.8		1629	0.85
Silty clay	0.92	5.4		30.0		3257	1.03

[11] X This column is reserved for any other property that is considered and may have a particular impact on the degradation rate.

Loam	0.66	6.2		114.4		17339	1.21
Silt	2.11	6.7 ($CaCl_2$)/ 7.6 (H_2O)		161.9		7675	1.00
Slightly humous sand (2.1)	0.95	5.6	33.3		3510		
Strongly humous loamy sand (2.2)	2.42	5.4	71.1		2940		
Slightly humous sandy loam (2.3)	1.14	5.8	27.9		2450		
Geometric mean/median					2935 / 2940	7331 / 7675	1.06 / 1.03
Arithmetic mean					2967	11981	1.07
Arithmetic mean of k_{oc} and K_{foc} (all 8 soils)					8601		
pH dependence, Yes or No			No				

M08							
Soil Type	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n
Sandy loam	1.02	6.3		2.86		280	0.8158
Silt loam	0.83	6.5		1.57		189	0.7524
Silt	2.11	6.7		2.53		120	0.7333
Silt clay	1.05	5.1		1.19		113	0.8123
Arithmetic mean /median						175.5 / 154.5	0.78 / 0.78
pH dependence, Yes or No			No				

M02							
Soil Type	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n
Sandy loam	1.02	6.3			7.61		n.a.
Silt loam	0.83	6.5			6.54		n.a.
Silt	2.11	6.7			3.97		n.a.
Silt clay	1.05	5.1	0.093			8.82	0.8841
Arithmetic mean /median					6.04 / 7.1		
pH dependence, Yes or No			No				

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

Column leaching	Not provided. Not required
Aged residues leaching	Not provided. Not required
Lysimeter/ field leaching studies	Not provided. Not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 14.6 days. Kinetics: SFO Worst case DT_{50} from laboratory studies
Application data	Crop: pome and stone fruit Depth of soil layer: 5 cm. % plant interception: 70% of plant interception after the first application and 80% after the second application (flowering, BBCH code 71) Number of applications: 2 Interval (d): 40 Application rate(s): 180 g as/ha

PEC(s) (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.072	-	0.072	-
Short-term	24h	0.069	0.070	0.069	0.070
2d		0.065	0.069	0.065	0.069
4d		0.060	0.066	0.060	0.066
Long-term					
7d		0.052	0.061	0.052	0.061
28d		0.019	0.040	0.019	0.040
50d				0.037	0.035
100d				0.003	0.025
Plateau conc.		-			

Metabolite 4-trifluoromethoxyphenyl urea (TMPU) Method of calculation	Molecular weight: 220.2 g/mol (61.3% parent) DT_{50} (d): 21.5 days Kinetics: SFO Wost case DT_{50} from laboratory studies..
Application data	Application rate assumed: 100% maximum formation from the applied dose

PEC(s) (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum predicted		0.044	-	0.044	-
Short-term	24h	0.043	0.044	0.043	0.044
2d		0.041	0.043	0.041	0.043
4d		0.039	0.042	0.039	0.042
Long-term	7d	0.035	0.040	0.035	0.040
28d		0.018	0.029	0.018	0.029
50d				0.030	0.027
100d				0.006	0.021
Plateau concentration		-			

Metabolite 2-chlorobenzoic acid (2-CBA) Method of calculation	Molecular weight 2-CBA: 156.6 g/mol (43.7% parent) DT_{50} (d): 3.3 days Kinetics: SFO Worst case DT_{50} from laboratory studies.
Application data	Application rate assumed: 100% maximum formation from the applied dose.

PEC(s) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum predicted	0.031		0.031	-
Short-term 24h	0.025	0.029	0.025	0.029
2d	0.021	0.026	0.021	0.026
4d	0.014	0.021	0.014	0.021
Long-term 7d	0.007	0.017	0.007	0.017
28d	<0.001	0.005	<0.001	0.005
50d			0.003	0.005
100d			<0.001	0.003
Plateau concentration	-			

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

Hydrolytic degradation of the active substance and metabolites > 10%.	pH 5 Chlorophenyl-label Triflumuron is stable No major metabolites
	pH 7 Chlorophenyl-label Triflumuron is stable (extrapolated DT_{50}: 465 d) No major metabolites
	pH 9 Chlorophenyl-label Triflumuron DT_{50} at 25°C: 57 days (1^{st} order, r^2=0.99) Major degradation product: M02 (max 28.9 % at day 30) Trifluoromethoxyphenyl-label Triflumuron DT_{50} at 25°C: 28.6 days (1^{st} order, r^2=0.991) Major degradation product: M08 (max 48.8% at day 30)
Photolytic degradation of active substance and metabolites above 10%	Triflumuron DT_{50} (mean of two tests using both labels): 32.8 days (r^2 = 0.965, SFO); corresponding predicted environmental half-lives under solar summer conditions (June) are 119.2 days at Phoenix, US, and 184.8 days at Athens, Greece Major metabolite: 2-chlorobenzamide (M01) max 19.4% day 10 M01 The environmental half-life was assessed by means of two different arithmetic models (GC-SOLAR and Frank&Klöpffer). An environmental direct photolysis half-life between 95 days and > 1 year was calculated, indicating that direct photodegradation in water does not significantly contribute to the elimination of 2-chlorobenzamide *(M01)* in the environment
Quantum yield of direct phototransformation in water at Σ > 290 nm	Triflumuron: ϕ =0.0095 mol Einstein $^{-1}$ M01: ϕ = 0.00226
Readily biodegradable (yes/no)	No

Degradation in water / sediment

Parent	Chlorophenyl-label (max in water 47.1 – 50.7% at day 0. Max. sed 46.9 - 48.0% after 1 d)									
Water / sediment system	pH w	pH sed	t.°C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Hoenniger - Loamy silt	7.6	5.9	20°	7.1		2.3		19.9	0.96	SFO
Von Diergardt - Sand	7.3	6.2	20°	5.7		2.9		14.9	0.97	SFO
Geometric mean/median				6.36/6.4		2.58/2.6		17.2/17.4		
Parent	Trifluoromethoxyphenyl-label (max in water 57.0 – 69.3% at day 0. Max. sed 48.7 - 35.1% after 1-3 d)									
Water / sediment system	pH w	pH sed	t.°C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Hoenniger - Loamy silt	7.6	5.9	20°	5.5		3.0		27.9	0.96	SFO
Von Diergardt - Sand	7.3	6.2	20°	4.1		2.8		8.8	0.98	SFO
Geometric mean/median				4.7/4.8		2.9/2.9		15.7/18.4		

Metabolite **M08**	Distribution (max in water 24.6% and 47.8% after 14 d. Max. sed. 20.4% and 14.1% after 7 and 14 d)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Hoenniger - Loamy silt	7.6	5.9	20°	11.4		11.4		11.4	0.96	SFO
Von Diergardt - Sand	7.3	6.2	20°	11.7		11.7		11.7	0.98	SFO
Geometric mean/median				11.5/11.6		11.5/11.6		11.5/11.6		
Metabolite **M02**	Distribution (max in water 44.8% and 60.4% after 14 d. Max. sed. 4.1% and 7.9% after 7 and 14 d)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Hoenniger - Loamy silt	7.6	5.9	20°	17.6		17.6		17.6	0.96	SFO
Von Diergardt - Sand	7.3	6.2	20°	62.9		62.9		62.9	0.97	SFO
Geometric mean/median				33.3/40.3		33.3/40.3		33.3/40.3		

Mineralization and non extractable residues: Trifluoromethoxyphenyl-label					
Water / sediment system	pH w	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
Hoenniger - Loamy silt	7.6	5.9	2.4% after 100 days	Max 66% after 100 days	66% after 100 days
Von Diergardt - Sand	7.3	6.2	2.4% after 100 days	Max 57.5% after 100 days	57.5% after 100 days

Mineralization and non extractable residues: Chlorophenyl-label					
Water / sediment system	pH w	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
Hoenniger - Loamy silt	7.6	5.9	35.7% after 100 days	Max 33.3% after 100 days	33.3% after 100 days
Von Diergardt - Sand	7.3	6.2	25.4 % after 100 days	Max 15.0 % after 100 days	15.0 % after 100 days

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

Triflumuron Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 358.7 Water solubility (mg/L): 0.04 Kom (L/kg): 4989, 1/n= 1.07 (Arithmetic mean) DT_{50} soil (d): 4.3 days (SFO 20°C, pF 2). This value is the geometric mean of 6 DT_{50}-values from lab studies. DT_{50} water/sediment system (d): 6.4 (representative worst case from sediment water studies) DT_{50} water (d): 6.4 (whole system) DT_{50} sediment (d): 1000 (worst case) Crop interception (%): 70 92% partitioning to top 1cm layer of sediment, entry route as for surface water, pattern of decline reflecting that measured in the sediment/water study
Parameters used in FOCUSsw step 3 -4	Version control no. of FOCUS calculator: SWASH 2.1, including MACRO 4.3b, PRZM 3.21b connected to PRZM in FOCUS 1.5.6, and TOXSWA 2.1.2 K_{om}: 4989 mL/g arithmetic mean (regarded as worst case since the consolidated value would be slighly higher, i.e. 5000 mL/g based on the Koc given earlier (see soil adsorption/desorption) 1/n: 1.07 arithmetic mean
Application rate	Crop: pome and stone fruit Crop interception: Number of application: 2 Interval (d): 40 Application rate(s): 180 g as/ha Depth of water body: 30 cm Application window: late application, March - May
Main routes of entry	15.7 % drift from 3 meter 2-4% runoff/drainage (at $FOCUS_{sw}$ Step 1 and 2)

FOCUS STEP 2 Scenario **two applications**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.71	---	87.26	---
	24 h	2.96	5.33	86.48	86.87
	2 d	1.62	3.81	85.71	86.48
	4 d	1.28	2.58	84.20	85.72
	7 d	0.90	1.89	81.98	84.59
	14 d	0.84	1.38	77.02	82.03
	21 d	0.79	1.19	72.37	79.58
	28 d	0.74	1.08	67.99	77.22

FOCUS STEP 2 Scenario **two applications**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	42 d	0.66	0.96	60.02	72.79
Southern EU	0 h	7.71	---	100.30	---
	24 h	2.96	5.33	99.41	99.85
	2 d	1.62	3.81	98.53	99.41
	4 d	1.43	2.60	96.79	98.53
	7 d	1.03	1.96	94.23	97.24
	14 d	0.97	1.48	88.54	94.30
	21 d	0.91	1.30	83.18	91.48
	28 d	0.85	1.19	78.15	88.77
	42 d	0.75	1.06	68.99	83.67

FOCUS STEP 2 Scenario **single application**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	9.44	---	72.55	---
	24 h	3.28	6.36	71.91	72.23
	2 d	1.55	4.38	71.27	71.91
	4 d	1.07	2.79	70.01	71.28
	7 d	0.74	1.94	68.17	70.34
	14 d	0.70	1.33	64.05	68.21
	21 d	0.66	1.11	60.17	66.17
	28 d	0.62	0.99	56.54	64.21
	42 d	0.55	0.86	49.91	60.53
Southern EU	0 h	9.44	---	85.58	---
	24 h	3.28	6.36	84.82	85.20
	2 d	1.55	4.38	84.07	84.82
	4 d	1.23	2.81	82.58	84.07
	7 d	0.88	2.01	80.40	82.96
	14 d	0.83	1.43	75.54	80.46
	21 d	0.78	1.22	70.98	78.05
	28 d	0.73	1.10	66.68	75.74
	42 d	0.64	0.96	58.86	71.39

FOCUS STEP 3: two applications

FOCUS STEP 3 Scenario **two applications**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D 3 ditch		0 h	5.22	-	5.13	-
		24 h	3.38	4.29	4.90	5.10
		2 d	1.22	3.28	4.53	5.02
		4 d	0.11	1.86	3.87	4.77
		7 d	0.04	1.09	3.19	4.38
		14 d	0.02	0.56	2.37	3.66
		21d	0.01	0.38	1.98	3.20
		28 d	0.01	0.29	1.74	2.88
		42 d	0.00	0.19	1.45	2.46

FOCUS STEP 3 Scenario **two applications**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D 4 pond		0 h	0.26	-	1.05	-
		24 h	0.23	0.25	1.05	1.05
		2 d	0.21	0.24	1.05	1.05
		4 d	0.17	0.21	1.03	1.05
		7 d	0.13	0.19	1.00	1.05
		14 d	0.07	0.15	0.90	1.02
		21 d	0.04	0.12	0.82	0.99
		28 d	0.03	0.10	0.74	0.96
		42 d	0.01	0.08	0.63	0.89
D 4 stream		0 h	5.287	-	1.104	-
		24 h	0.004	1.455	0.977	1.062
		2 d	0.003	0.729	0.860	1.004
		4 d	0.002	0.366	0.689	0.900
		7 d	0.001	0.210	0.528	0.780
		14 d	< 0.001	0.105	0.359	0.610
		21 d	< 0.001	0.070	0.289	0.515
		28 d	< 0.001	0.053	0.249	0.453
		42 d	< 0.001	0.035	0.202	0.377

FOCUS STEP 3 Scenario **two applications**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D 5 pond		0 h	0.25	-	0.95	-
		24 h	0.23	0.24	0.95	0.95
		2 d	0.20	0.23	0.94	0.95
		4 d	0.16	0.21	0.93	0.95
		7 d	0.12	0.19	0.90	0.94
		14 d	0.07	0.15	0.81	0.92
		21d	0.04	0.12	0.74	0.90
		28 d	0.02	0.10	0.67	0.86
		42 d	0.01	0.07	0.57	0.80
D 5 stream		0 h	5.712	-	1.595	-
		24 h	0.029	2.147	1.424	1.546
		2 d	0.006	1.079	1.26	1.468
		4 d	0.004	0.542	1.014	1.323
		7 d	0.002	0.311	0.781	1.152
		14 d	0.001	0.156	0.532	0.904
		21 d	< 0.001	0.104	0.427	0.763
		28 d	< 0.001	0.078	0.368	0.673
		42 d	< 0.001	0.052	0.299	0.559
R 1 pond		0 h	0.255	-	0.928	-
		24 h	0.226	0.24	0.926	0.928
		2 d	0.201	0.226	0.92	0.927
		4 d	0.161	0.203	0.901	0.925
		7 d	0.116	0.178	0.863	0.919
		14 d	0.058	0.138	0.765	0.894
		21 d	0.031	0.111	0.68	0.86
		28 d	0.018	0.092	0.613	0.824
		42 d	0.008	0.066	0.524	0.756

FOCUS STEP 3 Scenario **two applications**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R 1 stream		0 h	4.05	-	0.76	-
		24 h	0.001	0.86	0.68	0.73
		2 d	0.001	0.43	0.60	0.69
		4 d	0.001	0.22	0.50	0.63
		7 d	< 0.001	0.12	0.40	0.55
		14 d	< 0.001	0.07	0.30	0.45
		21d	< 0.001	0.04	0.25	0.39
		28 d	< 0.001	0.03	0.23	0.35
		42 d	< 0.001	0.02	0.19	0.30
R 2 stream		0 h	5.42	-	0.60	-
		24 h	< 0.001	0.58	0.58	0.59
		2 d	< 0.001	0.29	0.55	0.58
		4 d	< 0.001	0.15	0.52	0.56
		7 d	< 0.001	0.10	0.48	0.54
		14 d	< 0.001	0.05	0.43	0.49
		21 d	< 0.001	0.03	0.40	0.47
		28 d	< 0.001	0.02	0.37	0.45
		42 d	< 0.001	0.02	0.34	0.42
R 3 stream		0 h	5.71	-	1.79	-
		24 h	0.02	2.09	1.62	1.74
		2 d	0.005	1.05	1.46	1.67
		4 d	0.004	0.53	1.22	1.52
		7 d	0.002	0.30	0.99	1.36
		14 d	0.001	0.15	0.73	1.11
		21 d	< 0.001	0.10	0.62	0.96
		28 d	< 0.001	0.08	0.55	0.87
		42 d	< 0.001	0.05	0.47	0.75

FOCUS STEP 3 Scenario **two applications**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R 4 stream		0 h	4.04	-	0.59	-
		24 h	0.001	0.81	0.51	0.56
		2 d	0.001	0.41	0.44	0.53
		4 d	< 0.001	0.20	0.35	0.47
		7 d	< 0.001	0.12	0.26	0.40
		14 d	< 0.001	0.06	0.21	0.32
		21d	< 0.001	0.04	0.16	0.28
		28 d	< 0.001	0.03	0.15	0.26
		42 d	< 0.001	0.02	0.50	0.23

FOCUS STEP 3: single application

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D 3 ditch		0 h	6.57	-	4.80	-
		24 h	3.72	5.22	4.51	4.75
		2 d	0.84	3.68	4.08	4.65
		4 d	0.07	1.97	3.37	4.35

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.04	1.15	2.65	3.90
		14 d	0.01	0.59	1.81	3.13
		21d	0.006	0.39	1.43	2.66
		28 d	0.004	0.30	1.22	2.33
		42 d	0.002	0.20	0.96	1.93
D 4 pond		0 h	0.30	-	0.85	-
		24 h	0.27	0.28	0.85	0.85
		2 d	0.25	0.27	0.84	0.85
		4 d	0.21	0.25	0.83	0.85
		7 d	0.17	0.23	0.81	0.84
		14 d	0.10	0.18	0.74	0.83
		21 d	0.06	0.15	0.67	0.81
		28 d	0.04	0.12	0.60	0.78
		42 d	0.02	0.09	0.49	0.73
D 4 stream		0 h	6.36	-	0.55	-
		24 h	0.001	0.76	0.48	0.52
		2 d	0.001	0.38	0.41	0.49
		4 d	< 0.001	0.19	0.32	0.43
		7 d	< 0.001	0.11	0.24	0.36
		14 d	< 0.001	0.05	0.15	0.28
		21 d	< 0.001	0.04	0.12	0.23
		28 d	< 0.001	0.03	0.10	0.20
		42 d	< 0.001	0.02	0.08	0.16

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D 5 pond		0 h	0.30	-	0.82	-
		24 h	0.27	0.28	0.82	0.82
		2 d	0.25	0.27	0.82	0.82
		4 d	0.21	0.25	0.81	0.82
		7 d	0.16	0.22	0.78	0.82
		14 d	0.09	0.17	0.70	0.80
		21d	0.06	0.14	0.63	0.78
		28 d	0.04	0.12	0.56	0.75
		42 d	0.02	0.09	0.46	0.69
D 5 stream		0 h	6.91	-	0.79	-
		24 h	0.001	1.08	0.68	0.75
		2 d	0.001	0.54	0.59	0.70
		4 d	0.001	0.27	0.46	0.62
		7 d	0.001	0.16	0.35	0.53
		14 d	< 0.001	0.08	0.22	0.40
		21 d	< 0.001	0.05	0.17	0.34
		28 d	< 0.001	0.04	0.15	0.29
		42 d	< 0.001	0.03	0.12	0.24
R 1 pond		0 h	0.30	-	0.78	-
		24 h	0.27	0.28	0.78	0.78
		2 d	0.24	0.27	0.78	0.78
		4 d	0.20	0.24	0.77	0.78
		7 d	0.15	0.21	0.74	0.78
		14 d	0.09	0.17	0.65	0.76

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		21 d	0.05	0.13	0.57	0.73
		28 d	0.03	0.11	0.50	0.70
		42 d	0.01	0.08	0.41	0.64

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R 1 stream		0 h	5.05	-	0.74	-
		24 h	0.001	1.02	0.64	0.71
		2 d	0.001	0.51	0.56	0.66
		4 d	0.001	0.26	0.44	0.59
		7 d	< 0.001	0.15	0.33	0.50
		14 d	< 0.001	0.08	0.29	0.43
		21d	< 0.001	0.05	0.23	0.37
		28 d	< 0.001	0.04	0.20	0.33
		42 d	< 0.001	0.03	0.16	0.28
R 2 stream		0 h	6.66	-	0.42	-
		24 h	< 0.001	0.58	0.36	0.39
		2 d	< 0.001	0.29	0.31	0.36
		4 d	< 0.001	0.14	0.24	0.32
		7 d	< 0.001	0.08	0.18	0.27
		14 d	< 0.001	0.04	0.11	0.21
		21 d	< 0.001	0.03	0.09	0.17
		28 d	< 0.001	0.02	0.07	0.15
		42 d	< 0.001	0.01	0.06	0.12
R 3 stream		0 h	7.10	-	1.61	-
		24 h	0.01	2.27	1.43	1.56
		2 d	0.005	1.14	1.25	1.47
		4 d	0.003	0.57	0.99	1.32
		7 d	0.003	0.36	1.01	1.22
		14 d	0.001	0.18	0.68	1.03
		21 d	< 0.001	0.12	0.54	0.89
		28 d	< 0.001	0.09	0.47	0.79
		42 d	< 0.001	0.06	0.39	0.67

FOCUS STEP 3 Scenario **single application**	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R 4 stream		0 h	5.05	-	0.74	-
		24 h	0.001	1.02	0.64	0.70
		2 d	0.001	0.51	0.56	0.66
		4 d	0.001	0.26	0.44	0.58
		7 d	< 0.001	0.15	0.32	0.50
		14 d	< 0.001	0.08	0.25	0.39
		21d	< 0.001	0.05	0.19	0.33
		28 d	< 0.001	0.04	0.18	0.30
		42 d	< 0.001	0.03	0.17	0.26

FOCUS STEP 4: 95% drift reduction

FOCUS Scenario	Triflumuron			
	two applications		one application	
	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
D3, ditch	0.261	0.245	0.329	0.232
D4, pond	0.013	0.048	0.015	0.039
D4, stream	0.265	0.054	0.318	0.028
D5, pond	0.013	0.043	0.015	0.038
D5, stream	0.286	0.078	0.346	0.039
R1, pond	0.013	0.045	0.015	0.040
R1, stream	0.203	0.131	0.253	0.134
R2, stream	0.271	0.383	0.333	0.021
R3, stream	0.286	0.332	0.355	0.340
R4, stream	0.202	0.097	0.253	0.098

Metabolite 4-Trifluoromethoxyphenyl urea (M08) Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight: 220.2 Water solubility (mg/l): 13630 Soil or water metabolite: K_{OM} (L/kg): 102, 1/n=0.78 (Aritmetic mean) DT_{50} soil (d): 4 days (geometric mean from 3 lab. studies normalised to pF2, 20°C; overall geometric mean: 3.96 days) DT_{50} whole system (d): 11.7 DT_{50} other compartment (d): 11.7 Crop interception (%): 70 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 61.9% Soil: 100%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Crop: pomefruit Number of applications: 2 Interval (d): 40 Application rate(s): 180 g as/ha Depth of water body: 30 cm Application window: late application, March - May
Main routes of entry	drift/runoff/drainage as indicated in $FOCUS_{sw}$ Step 2

FOCUS STEP 2 Scenario **two applications**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	2.99	---	4.69	---
	24 h	2.49	2.74	4.42	4.55
	2 d	2.32	2.57	4.16	4.42
	4 d	2.96	2.49	3.70	4.18
	7 d	2.37	2.55	3.10	3.84
	14 d	1.56	2.24	2.05	3.19
	21 d	1.03	1.92	1.35	2.68
	28 d	0.68	1.65	0.89	2.29
	42 d	0.30	1.26	0.39	1.73
Southern EU	0 h	3.86	---	6.17	---
	24 h	3.51	3.68	5.82	6.00
	2 d	3.31	3.55	5.48	5.82
	4 d	2.94	3.33	4.87	5.50
	7 d	2.46	3.06	4.08	5.05
	14 d	1.63	2.54	2.69	4.20
	21 d	1.07	2.13	1.78	3.53
	28 d	0.71	1.82	1.18	3.01
	42 d	0.31	1.37	0.51	2.28

FOCUS STEP 2 Scenario **single application**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	4.69	---	5.28	---
	24 h	2.95	3.27	4.98	5.13
	2 d	2.76	3.06	4.69	4.98
	4 d	3.34	2.94	4.17	4.70
	7 d	2.67	2.94	3.49	4.32
	14 d	1.76	2.56	2.30	3.59
	21 d	1.16	2.19	1.52	3.02
	28 d	0.77	1.88	1.01	2.58
	42 d	0.34	1.43	0.44	1.95
Southern EU	0 h	4.24	---	6.76	---
	24 h	3.85	4.04	6.38	6.57
	2 d	3.63	3.89	6.01	6.38
	4 d	3.22	3.65	5.34	6.02
	7 d	2.70	3.35	4.47	5.54
	14 d	1.78	2.78	2.95	4.60
	21 d	1.18	2.34	1.95	3.87
	28 d	0.78	2.00	1.29	3.30
	42 d	0.34	1.51	0.56	2.49

Metabolite 2-Chlorobenzoic acid (M02)
Parameters used in FOCUSsw step 1 and 2

Molecular weight: 156.6
Water solubility (mg/l): 3723
Soil or water metabolite: -
Kom (L/kg): 0
1/n=0.9 (default)
DT_{50} soil (d): 1.1 days (geomean, pF2, 20°C)
DT_{50} whole system (d): 62.9
DT_{50} other compartment (d): 62.9

	Crop interception (%): 70% Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 63.9% Soil: 100%
Parameters used in FOCUSsw step 3 (if performed)	not performed
Application rate	Crop: pomefruit Number of applications: 2 Interval (d): 40 Application rate(s): 180 g as/ha Depth of water body: 30 cm Application window: late application, March - May
Main routes of entry	drift/runoff/drainage as indicated in $FOCUS_{sw}$ Step 2

FOCUS STEP 2 Scenario **two applications**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	3.34	---	< 0.001	---
	24 h	3.30	3.32	< 0.001	< 0.001
	2 d	3.26	3.30	< 0.001	< 0.001
	4 d	3.32	3.28	< 0.001	< 0.001
	7 d	3.21	3.27	< 0.001	< 0.001
	14 d	2.97	3.18	< 0.001	< 0.001
	21 d	2.75	3.08	< 0.001	< 0.001
	28 d	2.55	2.97	< 0.001	< 0.001
	42 d	2.18	2.77	< 0.001	< 0.001
Southern EU	0 h	3.45	---	< 0.001	---
	24 h	3.41	3.43	< 0.001	< 0.001
	2 d	3.37	3.41	< 0.001	< 0.001
	4 d	3.30	3.37	< 0.001	< 0.001
	7 d	3.19	3.32	< 0.001	< 0.001
	14 d	2.95	3.19	< 0.001	< 0.001
	21 d	2.73	3.08	< 0.001	< 0.001
	28 d	2.53	2.96	< 0.001	< 0.001
	42 d	2.17	2.76	< 0.001	< 0.001

FOCUS STEP 2 Scenario **single application**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	2.64	---	< 0.001	---
	24 h	2.61	2.63	< 0.001	< 0.001
	2 d	2.59	2.62	< 0.001	< 0.001
	4 d	2.53	2.59	< 0.001	< 0.001
	7 d	2.45	2.55	< 0.001	< 0.001
	14 d	2.27	2.45	< 0.001	< 0.001
	21 d	2.10	2.36	< 0.001	< 0.001
	28 d	1.94	2.28	< 0.001	< 0.001
	42 d	1.67	2.12	< 0.001	< 0.001
Southern EU	0 h	2.77	---	< 0.001	---
	24 h	2.74	2.76	< 0.001	< 0.001
	2 d	2.71	2.74	< 0.001	< 0.001
	4 d	2.65	2.71	< 0.001	< 0.001
	7 d	2.57	2.67	< 0.001	< 0.001

FOCUS STEP 2 Scenario **single application**	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	14 d	2.38	2.57	< 0.001	< 0.001
	21 d	2.20	2.47	< 0.001	< 0.001
	28 d	2.04	2.38	< 0.001	< 0.001
	42 d	1.74	2.22	< 0.001	< 0.001

PEC (groundwater) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Model(s) used: FOCUS-PEARL 3.3.3 and FOCUS-PELMO 3.3.2 Scenarios: all nine FOCUS scenarios Crop: stone and pome fruit Crop interception: 70% after 1st application and 80% after 2nd application **Triflumuron** DT_{50lab}: 4.3 d (geometric mean) K_{fOM}: parent, arithmetic mean 4989 mL/g (regarded as worst case since the consolidated value would be slighly higher, i.e. 5000 mL/g based on the Koc given earlier (see soil adsorption/desorption), K_{OC} = 8601 $^1/_n$= 1.07. **Metabolites**: The FOCUS GW modelling considered a formation fraction of 1 **M08** DT_{50lab}: 4.0 days (geometric mean lab. studies normalised to pF2, 20°C; overall geometric mean: 3.96 days) K_{OM} = 102 mL/g, Arithmetic mean K_{OC} = 178 $^1/_n$ = 0.78 **M02** DT_{50lab}: 1.1 days (geometric mean normalised to pF2, 20°C) K_{OM} = 0 mL/g, Worst case value $^1/_n$ = 0.9 (default)
Application rate	Application rate: 180 g./ha, No. of applications: 2, with a spray interval of 40 days Time of application (month or season): first application after flowering of pome and stone fruit (BBCH code 71); second application 40 days later.

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

Pearl 3.3.3 /Pomefruit	Scenario	Parent (µg/L)	PELMO 3.3.2 /Pomefruit	Scenario	Parent (µg/L)
	Châteaudun	< 0.001		Châteaudun	< 0.001
	Hamburg	< 0.001		Hamburg	< 0.001
	Jokioinen	< 0.001		Jokioinen	< 0.001
	Kremsmünster	< 0.001		Kremsmünster	< 0.001
	Okehampton	< 0.001		Okehampton	< 0.001
	Piacenza	< 0.001		Piacenza	< 0.001
	Porto	< 0.001		Porto	< 0.001

	Sevilla	< 0.001		Sevilla	< 0.001
	Thiva	< 0.001		Thiva	< 0.001

	Scenario	Metabolite M08 (µg/L)		Scenario	Metabolite M08 (µg/L)
Pearl 3.3.3 /Pomefruit	Châteaudun	< 0.001	PELMO 3.3.2 /Pomefruit	Châteaudun	< 0.001
	Hamburg	< 0.001		Hamburg	< 0.001
	Jokioinen	< 0.001		Jokioinen	< 0.001
	Kremsmünster	< 0.001		Kremsmünster	< 0.001
	Okehampton	< 0.001		Okehampton	< 0.001
	Piacenza	< 0.001		Piacenza	< 0.001
	Porto	< 0.001		Porto	< 0.001
	Sevilla	< 0.001		Sevilla	< 0.001
	Thiva	< 0.001		Thiva	< 0.001

	Scenario	Metabolite M02 (µg/L)		Scenario	Metabolite M02 (µg/L)
Pearl 3.3.3 /Pomefruit	Châteaudun	< 0.001	PELMO 3.3.2 /Pomefruit	Châteaudun	< 0.001
	Hamburg	< 0.001		Hamburg	0.003
	Jokioinen	< 0.001		Jokioinen	0.026
	Kremsmünster	< 0.001		Kremsmünster	< 0.001
	Okehampton	< 0.001		Okehampton	< 0.001
	Piacenza	< 0.001		Piacenza	< 0.001
	Porto	< 0.001		Porto	< 0.001
	Sevilla	< 0.001		Sevilla	< 0.001
	Thiva	< 0.001		Thiva	< 0.001

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

Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	DT_{50} of 0.421 days, corresponding to a chemical lifetime of 0.61 days hours derived by the Atkinson method of calculation Maximum chemical lifetime of triflumuron in air: 1.2 d
Volatilisation	from plant surfaces (BBA guideline): 17% after 24 hours
	from soil (BBA guideline): 1% after 24 hours
Metabolites	-

PEC (air)

Method of calculation	-

$PEC_{(a)}$

Maximum concentration	-

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: active substance, M08 and M02 Surface Water: active substance, M08 and M02 Groundwater: active substance, M08 and M02

Air:	active substance

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

Soil (indicate location and type of study)	Not applicable
Surface water (indicate location and type of study)	Not applicable
Groundwater (indicate location and type of study)	Not applicable
Air (indicate location and type of study)	Not applicable

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

Not readily biodegradable – candidate for R53

Ecotoxicology

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds				
Bobwhite quail	a.s.	Acute	561	
Bobwhite quail	a.s.	Short-term	>805.1[1]	>5626
Mallard duck	a.s.	Short-term	179.5	2018
Bobwhite quail	a.s.	Long-term	1.65[2]	20
Mallard duck	a.s.	Long-term	6.9	80
Mammals				
Rat	a.s.	Acute	>5000	
Rat	SC 480	Acute	>2123	>5000
Rat	a.s.	Long-term (2-generation)	142.5	

[1] calculated according to SANCO/4145/2000 (European Commission, 2002c) and considering the mean body weight of 58 g and the daily food consumption of 8.3 g per bird per day, derived from Bowers and Banman, 2002 (IIA, 8.1.2/03)

[2] calculated according to SANCO/4145/2000 (European Commission, 2002c) and considering the mean body weight of 206.6 g and the daily food consumption of 17 g per bird per day, derived from Carlisle and Carsel, 1983 (IIA, 8.1.3/01)

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

Orchards, 0.18 kg a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 – uptake via diet (Birds)				
Insectivorous	Acute	9.73	58	10
Insectivorous	Short-term	5.43	>148.3	10
Insectivorous	Long-term	5.43	0.3	5
Higher tier refinement – uptake via diet (Birds)				
Tier 1 – secondary poisoning (Birds)				
Earthworms eating	Long-term	0.51	12.9	5
Fish eating	Long-term	0.928	7.1	5
Tier 1– uptake via diet (Mammals)				
Small herbivorous	Acute	25.6	> 83	10
Small herbivorous	Long-term	6.49	21.95	5
Tier 1 – secondary poisoning (Mammals)				
Earthworms eating	Long-term	0.632	225.4	5
Fish eating	Long-term	585	243	5

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)	Endpoint	Toxicity[1] (mg a.s./L)
Laboratory tests				
Fish				
Lepomis macrochirus	a.s.	96 hr (flow-through)	Mortality, LC_{50}	> 0.0208 (mm)
Oncorhynchus mykiss	a.s.	96 hr (flow-through)	Mortality, LC_{50}	> 0.0242
Pimephales promelas	a.s.	ELS 36 d (flow-through)	Growth, NOEC	≥ 0.0228 (mm)
Lepomis macrochirus	SC 480	96 hr (static)	Mortality, LC_{50}	73 (nom)

Oncorhynchus mykiss	SC 480	96 hr (static)	Mortality, LC_{50}	168.7
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (semi static)	Mortality, EC_{50}	$0.0016_{(nom)}$
Daphnia magna	SC 480	48 h (semi static)	Mortality, EC_{50}	$0.00013_{(nom)}$
Daphnia magna	SC 480	21 d (semi static)	Reproduction, NOEC	$0.000032_{(nom)}$
Daphnia magna	M 01	48 h (static)	Mortality, EC_{50}	$>100_{(nom)}$
Daphnia magna	M 02	48 h (static)	Mortality, EC_{50}	$>100_{(nom)}$
Daphnia magna	M 08	48 h (static)	Mortality, EC_{50}	$3.4_{(nom)}$
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	EC_{15}	$0.00032_{(nom)}$
Chironomus riparius	M 01	28 d (static)	EC_{15}	$> 100_{(nom)}$
Chironomus riparius	M 02	28 d (static)	EC_{15}	$> 100_{(nom)}$
Chironomus riparius	M 08	28 d (static)	EC_{15}	$15.6_{(nom)}$
Other crustaceans				
Orconectes immunis	a.s.	96 hr (static)	Mortality, LC50	> 0.0998 [2]
Mysidopsis bahia	a.s.	96 hr (static)	Mortality, LC50	0.0039
Algae				
Scenedesmus subspicatus.	a.s.	72 h (static)	Biomass: E_bC_{50} Growth rate: Er C_{50}	$> 0.025_{(nom)}$ $> 0.025_{(nom)}$
Scenedesmus subspicatus..	SC 480	72 h (static)	Biomass: Eb C_{50} Growth rate: Er C_{50}	$157_{(mm)}$ $> 179_{(mm)}$
Microcosm or mesocosm tests NOAEC= 0.1 µg a.s./L $_{(nom)}$				

1 (nom): nominal concentration; (mm): mean measured concentration

2 The LC50 was corrected by the control mortality of 20% and was 42% at the given concentration. Although not a standard species and tested above the limit of the water solubility, a significantly lower sensitivity than to Daphnia is evidenced

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

Refined aquatic risk assessment using higher Tier FOCUS modelling

FOCUS Step 4

Pome and Stone fruits, 1 application	**Triflumuron PEC/STEP 4***	**Fish**		**Daphnia**		**Chiron.**	**Algae**
		TER_A	**TER_{LT}**	**TER_A**	**TER_{LT}**	**TER_{LT}**	**TER_{LT}**
Endpoint		73 mg/L	≥ 22.8 µg/L	0.13 µg/L	0.032 µg/L	0.32 µg /L	157 mg/L
FOCUS Scenario	**Water (µg/L)**						
D3, ditch	0.329	221884.50	69.30	0.40	0.10	0.97	477203.65
D4, pond	0.015	4866666.67	1520.00	8.67	2.13	21.33	10466666.67
D4, stream	0.318	229559.75	71.70	0.41	0.10	1.01	493710.69
D5, pond	0.015	4866666.67	1520.00	8.67	2.13	21.33	10466666.67
D5, stream	0.346	210982.66	65.90	0.38	0.09	0.92	453757.23
R1, pond	0.015	4866666.67	1520.00	8.67	2.13	21.33	10466666.67
R1, stream	0.253	288537.55	90.12	0.51	0.13	1.26	620553.36
R2, stream	0.333	219219.22	68.47	0.39	0.10	0.96	471471.47
R3, stream	0.355	205633.80	64.23	0.37	0.09	0.90	442253.52
R4, stream	0.253	288537.55	90.12	0.51	0.13	1.26	620553.36

* considering spray drift reducing measures of 95% (nozzles only)

FOCUS Step 4

Pome and Stone fruits, 1 application	Triflumuron PEC/STEP 4*	Margin of Safety (TER) for Mesocosm Endpoint
FOCUS Scenario	**Water (µg/L)**	**NOEAEC 0.1 µg a.s./L**
D3, ditch	0.329	0.30
D4, pond	0.015	6.67
D4, stream	0.318	0.31
D5, pond	0.015	6.67
D5, stream	0.346	0.29
R1, pond	0.015	6.67
R1, stream	0.253	0.40
R2, stream	0.333	0.30
R3, stream	0.355	0.28
R4, stream	0.253	0.40

* considering spray drift reducing measures of 95% (nozzles only)

Metabolites, FOCUS step 2 PECsw

Metabolite	Test organism	Time scale	Toxicity endpoint (µg product metabolite/L)	PEC_{sw} (maximum) µg/L	TER	Annex VI trigger
M01	daphnids	acute	EC_{50} >100000	9.44	>10593	100
	chironomus	chronic	EC_{15} >100000	9.44	>10593	10
M02	daphnids	acute	EC_{50} >100000	3.43	>29155	100
	chironomus	chronic	EC_{15} >100000	3.43	>29155	10
M08	daphnids	acute	EC_{50} 3400	4.24	802	100
	chironomus	chronic	EC_{15} 15600	4.24	3679	10

Bioconcentration				
	Active substance	**M01**	**M02**	**M08**
Log Pow	4.9	0.64	1.98	1.48
Bioconcentration factor (BCF)	612*			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	1.36			
Clearance time (days) (CT_{90})	3			
Level and nature of residues (%) in organisms after the 14 day depuration phase	negligible			

* based on total ^{14}C or on specific compounds

Effects of Triflumuron SC 480 on Bees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD 50 µg a.s./bee)	Acute contact toxicity (LD50 µg a.s./bee)
a.s.	> 226	> 200
SC 480	> 228.6	> 200

Field or semi-field tests
Feeding test: bees did not show effects at a concentration of 2.5 mg a.s./L test solution. At 7.5 mg a.s./L young bees showed deformations of legs and wings and coordination problems, however no behavioural differences were observed at 41.7 mg a.s./L.

Bees: Semi-field and Field study

Study	Application rate		N°. application	Application after flowering
Semi-field	1st trial	28.7 g a.s./ha	2	1st application at BBCH 71, interval period 40 days
		48 g a.s./ha		
	2nd trial	28.7 g a.s./ha		
		48 g a.s./ha		
Tunnel test	1st trial	28.3 g a.s./ha		
	2nd trial	54 g a.s./ha		

Two field tests were performed with Triflumuron SC 480 at concentrations of 28.7 g a.s./ha and 48 g a.s./ha, corresponding to the off-crop and in-crop PEC respectively. No effects on mortality, population density, bee brood development or behaviour were observed in the treatment groups.
A tunnel test was performed with Triflumuron SC 480 at concentrations of 28.3 g a.s./ha and no effects on mortality, flight intensity or bee brood development were observed. At 54.0 g a.s./ha an effect on bee brood can not be excluded.

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

Orchards, 360 (180 x 2) g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 1.8	50
a.s.	oral	< 1.6	50
SC 480	Contact	< 1.8	50
SC 480	oral	< 1.6	50

Effects of Triflumuron SC 480 on Non-target Arthropods exposed to Triflumuron (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	% Effect
Typhlodromus pyri	SC 480	Mortality Reproduction	14% at 384 g as/ha 7.3% at 384 g as/ha
Aphidius rhopalosiphi	SC 480	Mortality Reproduction	13% at 300 g as/ha 16% at 300 g as/ha

Tier 1 $HQ_{In\text{-}field}$ and $HQ_{Off\text{-}field}$, Exposure for parasitoids, predatory mites and foliage dwelling predators

Indicator species	$HQ_{In\text{-}field}$	$HQ_{Off\text{-}field}$
Typhlodromus pyri	0.4	0.10
Aphidius rhopalosiphi	0.5	0.12

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% adverse effect	Trigger value
Trichogramma cacoeciae	Adults pupae in host eggs	SC 480, glass plates 56 d	51.2 g a.s./ha	effect on parasitation efficiency [%]	37%	50%
Trichogramma cacoeciae	Adults pupae in host eggs	WP 25, glass plates 53 d	20.8 g a.s./ha	effect on parasitation efficiency [%]	7 % 77 %	50%
Orius insidiosus	Second instar nymphs	WP 25, coffin cells, 32 d	300 g a.s./ha	corrected mortality [%] (juvenile mortality)	90 %	50%
Coccinella septempunctata	3-4 d old larvae	SC 480, glass plates, 46 d	360 g a.s./ha	mortality	60 %	50%
Coccinella septempunctata	3 d old larvae	WP 25, coffin cells, 15 d	242 g a.s./ha	corrected mortality [%]	100 %	50%
Coccinella septempunctata	3-5 d old larvae	SC 480, apple leaves, treated aphids	from 8 g a.s./ha to 270 g a.s./ha ext. lab	mortality reproduction	No effects on mortality nor effects on reproduction in the tested concentrations	50%
Chrysoperla carnea Steph.	2-3 d old larvae	SC 480, bean leaves, treated feed	from 8 to 270 g a.s/ha	mortality	100% at all concentrations	50%
Chrysoperla carnea Steph.	2-3 d old larvae	SC 480, bean leaves, partially treated feed		LR_{50}	0.3 g a.s./ha	50%
Chrysoperla carnea Steph.	2-3 d old larvae	SC 480, bean leaves (treated leaves, treated feed , treated feed + treated leaves)	135 g a.s./ha	corrected pre-imaginal mortality	Treated leaves: 100 % Feed: 94% Leaves+feed: 100%	50%
Chrysoperla carnea Steph. IIIA, 10.5.1/ 12		SC 480 Aged residue test, potted apple trees 2 applications (306 g a.s./ha each), spray interval 40 days		Mortality	100% (all assays)	

*negative value indicates increased parasitation efficiency compared to control

Field or semi-field tests

Chrysoperla carnea Steph, semi-field test, 43 d. Triflumuron SC 480 was applied to bean plants at five different rates corresponding to 2.475 g a.s./ha, 5.421 g a.s./ha, 9.903 g a.s./ha, 21.68 g a.s./ha and 38.61 g a.s./ha. The LR_{50} (95 % confidence limits) of Triflumuron SC 480 was calculated as 10.35 (6.95 – 15.42) mL product/ha, which is similar to 5.08 (3.41 – 7.57) g a.s./ha.
Typhlodromus pyri, field test (vine), 78 d. Triflumuron WP 25 was applied twice (79 g a.s./ha and 184 g a.s./ha respectively). Related to control the effects of Triflumuron WP 25 were 12% one week and 35% four weeks after the second treatment.
Chrysoperla carnea, field test, (orchard), 6 months. Triflumuron SC 480 was applied twice (180 g a.s./ha and 6 g a.s./ha respectively). In this study Triflumuron SC 480 resulted harmful and with long-lived residual effects. However considering the adaptive dispersal strategy of adult green lacewings the recolonisation of the crop is not affected. Moreover the abundance of lacewing larvae in both the treated and control plots was constant in all sampling dates throughout the full growing season. Therefore it is possible to conclude that the impact on the non-target arthropod fauna (including lacewing population) was not significant (Forster *et al*., 2005).

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	Endpoint
Earthworms			
Eisenia foetida	a.s.	Acute 14 days	LC_{50} [1] > 500 mg a.s./kg dw soil
Eisenia foetida	SC 480	Acute 14 days	$LC_{50\ corr}$ [1] > 242.5 mg a.s./kg dw soil
Eisenia foetida	SC 480	Reproduction, 56 days	NOEC ≥ 378 mg a.s./kg dw soil
Eisenia andrei	M 02	Acute 14 days	LC_{50} > 1000 mg parent metabolite/kg dw soil
Eisenia andrei	M 08	Acute 14 days	LC_{50} 562.1 mg parent metabolite/kg dw soil
Other soil macro-organisms			
Collembola			
Folsomia candida	M 02	28 d reproduction	NOEC ≥ 100 mg parent metabolite/kg dw soil
Folsomia candida	M 08	28 d reproduction	NOEC 31 mg parent metabolite/kg dw soil
Soil micro-organisms			
Nitrogen mineralisation	a.s.	28 d	14% effect at day 28 at 0.33 mg a.s./kg dw soil 25% effect at day 28 at 3.3 mg a.s./kg dw soil
	M 02	28 d	No influence at 0.39 mg parent metabolite/kg dw soil
	M 08	28 d	No influence at 0.55 mg parent metabolite/kg dw soil
Carbon mineralisation	a.s.	28 d	No negative influence at 0.33 and 3.33 mg a.s./kg dw soil during the 28 d experiments
Field studies: not required			

[1] endpoint has been corrected due to log Pow >2.0

Toxicity/exposure ratios for soil organisms

Orchards 360 (180 x 2) g a.s./ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia foetida	a.s.	Acute	0.072 mg a.s./kg dw soil (maximum)	>6944	10
Eisenia foetida	SC 480	Acute	0.072 mg a.s./kg dw soil (maximum)	3368	10
Eisenia foetida	SC 480	Reproduction, 56 days	0.072 mg a.s./kg dw soil (maximum)	>5250	10
Eisenia andrei	M 02	Acute	0.031 mg parent metabolite/kg dw soil	>32258	10
Eisenia andrei	M 08	Acute	0.044 mg parent metabolite/kg dw soil	12775	10
Collembola					
Folsomia candida	M 02	28 d	0.031 mg parent metabolite/kg dw soil	≥ 3225	5
Folsomia candida	M 08	28 d	0.044 mg parent metabolite/kg dw soil	705	5

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

Preliminary screening data

In the pre-emergence and post-emergence-test all tested plants showed no phytotoxic effects up to the highest application rate of 1080 g a.s./ha.

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

Test type/organism	endpoint
Activated sludge	Based on the results that the maximum effect of triflumuron on activated sludge, corresponding to 44.3 % inhibition of the respiration, occurs at the tested concentrations of 10000 mg/L, the risk for the biological methods of sewage treatment is considered to be low.

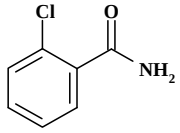
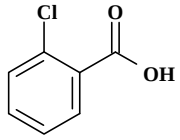
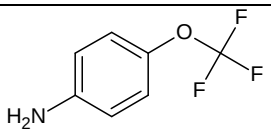
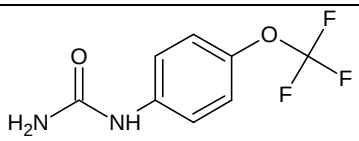
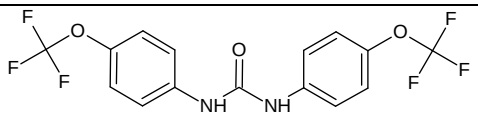
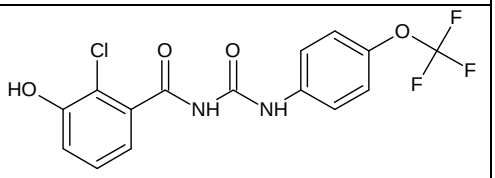
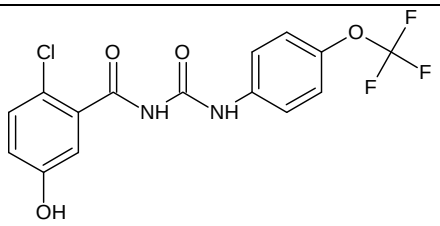
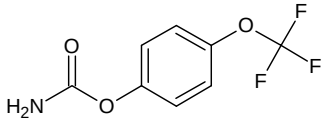
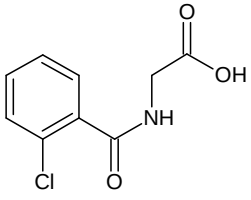
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	a.s.
water	a.s.
sediment	a.s.
groundwater	a.s.

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

RMS proposal	ECB decision
Active substance	R50/R53 N
Preparation	R50/R53 N

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
M01	2-chlorobenzamide	
M02 or 2-CBA	2-chlorobenzoic acid	
M07 or impurity 2	4-trifluoro-methoxyaniline	
M08 or TMPU	1-[4-(trifluoromethoxy)phenyl]urea	
impurity 5	1,3-bis[4-(trifluoromethoxy)phenyl]urea *N*,*N*'-bis[4-(trifluoromethoxy)phenyl]urea	
M04	2-chloro-3-hydroxy-*N*-{[4-(trifluoromethoxy)phenyl]carbamoyl}benzamide	
M05	2-chloro-5-hydroxy-*N*-{[4-(trifluoromethoxy)phenyl]carbamoyl}benzamide	
M25	4-(trifluoromethoxy)phenyl carbamate	
-	2-chlorohippuric acid	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

.

ABBREVIATIONS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
CT	clearance time
d	day
dw	dry weight
DAD	diode array detector
DAR	draft assessment report
DM	dry matter
DNA	deoxyribonucleic acid
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
ELS	early life stage
EMDI	estimated maximum daily intake
ER50	emergence rate, median
ESI	electrospray ionisation
ETE	estimated theoretical exposure
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GIS	geographic information system
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HQ	hazard quotient
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MRM	multiple reaction monitoring
MS	mass spectrometry
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEC	no observed adverse effect concentration

NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in groundwater
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RP	reversed phase
RMS	rapporteur Member State
RPE	respiratory protective equipment
SC	suspension concentrate
SFO	single first order
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
yr	year