Conclusion regarding the peer review of the pesticide risk assessment of the active substance triflumuron

Issued on 30 September 2008

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[1]. 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 as laid down in this report.

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 480g/l triflumuron.

Adequate methods are available to monitor all compounds given in the respective residue definition except for air where a data gap has been identified. Only single methods for the determination of

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

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 some quality control measurements of the plant protection product are possible. Data for the relevant impurities is missing and the specification can not be finalised. A method for the active substance in the plant protection product has been identified as a data gap. Also some physchem properties have been identified as data gaps.

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. According to them, three impurities were considered toxicologically relevant, three plant metabolites were considered covered by the toxicological studies with the parent (use of the same reference value) but new toxicological data were required for the derivation of the acute reference dose for one acutely toxic plant metabolite.
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 the triflumuron, however it was agreed to require further data in order to derive an ARfD for the plant metabolite M07, since this metabolite was shown to be more acutely toxic

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 apples, potatoes and soybean. The study on apples was assessed by the RMS as having several deficiencies, and hence a new fruit metabolism study has been required to support the notified uses in pome fruit and stone fruit crops. The meeting of experts noted deficiencies also in the metabolism studies in potatoes and soybean and agreed that further data is necessary to conclude on a final plant residue definition for risk assessment and monitoring. Though the number and quality of the submitted residue trials was considered sufficient, the conducted trials do not determine all compounds included in the provisionally proposed residue

definition for the risk assessment. In addition, further studies on the level of residues in processed fruit commodities are necessary to allow robust estimates of human and livestock dietary exposure to residues present following the use of triflumuron. Consequently, the assessment in terms of potential residues in food of animal origin including a residue definition for monitoring and risk assessment in animal products could not be finalised, neither could the consumer exposure and risk assessment be concluded. In addition, the need for further data to derive an ARfD was identified for 4-trifluoromethoxyaniline, a metabolite and degradation product of triflumuron that has been considered pertinent for the consumer risk assessment.

At the current stage, with the data available and eligible for evaluation it was only possible to provisionally propose residue definitions and MRLs for the notified uses. However, precise estimates of human and livestock dietary exposure, and finally a robust consumer risk assessment can only be finalised when the outstanding data and information will be evaluated.

Triflumuron is low to moderate persistent in soil ($DT_{50\ lab\ 20\ °C}$ = 6.9 – 52 d) under dark aerobic conditions. Two major metabolites are formed: 2-chlrobenzoic acid (M02, max. 23.5 % TRR; $DT50_{lab\ 20\ °C}$ = 1.2 – 4.2 d) and 4-trifluoromethoxyphenyl urea (M08, TMPU, max. 23.1 % TRR; $DT50_{lab\ 20\ °C}$ = 1.3 – 20.5 d). Trifluoromethoxyphenyl ring was less mineralized and more prone to form unextractable residues than the chlorophenyl ring. The range of pH in the soils investigated was too narrow with respect to the directive requirements. Therefore, a new data gap to address the rate of aerobic degradation of parent and formation and degradation rates of metabolites in alkaline soils was identified.

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 M2 (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.

PEC soil calculations were presented in addendum 2 were accepted by the experts for the parent compound. However, new PEC soil calculations for metabolite M02 and M08 were requested. The new PEC soil have been calculated with the agreed input parameters and EFSA has presented the figures in the list of end points (a mistake was identified in the values calculated in addendum 3).

According 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 = 280 – 113 mL/g) and M02 may be considered very high mobile in soil (Koc = 4.0 – 8.8 mL/g). However, available data may only be considered relevant for acidic soils. Therefore, the experts identified a data gap for batch adsorption / desorption studies with more alkaline soils for parent and metabolite M02. The PRAPeR meeting of experts noted that these studies would eventually influence the results of PEC_{GW} and PEC_{SW} calculations and that these calculations may need to be revised.

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) and M08 (max.

48.8 % AR after 30 d). According the available study, aqueous photolysis is considered to contribute only in a minor extent to the overall degradation of triflumuron. In the lack of the 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 of 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.

The meeting agreed that FOCUS PEC $_{SW / SED}$ presented in the DAR (including the Step 4 approach based on GIS) were not appropriate for the EU risk assessment. New FOCUS PEC_{SW} based on FOCUS kinetics were requested. New calculations provided in addendum 3 are not peer reviewed. 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.

Potential ground water contamination was addressed in the DAR by FOCUS PEC_{GW} calculations (80^{th} percentile at 1 m depth) for triflumuron and its soil metabolites M02 and M08 with the FOCUS model PEARL and the nine FOCUS GW scenarios. Formation fraction of one had been assumed in these calculations for both soil metabolites M02 and M08. During the peer review data gaps have been identified for triflumuron and the metabolite M02 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 M02 and M08. Therefore, results of the available modelling are only relevant for acidic soils. Under these conditions neither the parent triflumuron nor any of the two soil metabolites M02 and M08 are expected to exceed the trigger of 0.1 µg / L.

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) was 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 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. The risk to adult bees was low but bee brood was very sensitive to 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. No long-term studies were conducted with earthworms. 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. 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.
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

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. 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, hereafter referred to as the draft assessment report, 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 draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report 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 draft assessment report 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 as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation

evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 28 January 2008)

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 29 September 2008)

Given the importance of the draft assessment report including its addendum (compiled version of August 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

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. An example 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 attached list of end points.

SPECIFIC 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 548/TC/S/F (2000) of 955 g/kg. The

higher value relates to the submitted results of current 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 548/TC/S/F) and for 4-trifluoro-methoxyaniline it should not be higher than 5 g/kg. The maximum content for toluene has not been concluded on and it is not in the current specification.
As a new specification is needed to include toluene, the specification named 'new proposed specification' in the Addendum to Vol. 4 June 2008 should be regarded as provisional.

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

Beside the specification, 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 were identified:

- Spectra for the relevant impurity N,N'-bis[4-(trifluoromethoxy)phenyl]urea
- Spectra for the relevant impurity 4-trifluoro-methoxyaniline
- 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
- Method of analysis for the active substance in the formulation
- Melting point and temperature of decomposition
- Surface tension of 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 1.

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, as well as for the determination of the respective impurities in the technical material but there is a data gap for the formulation.
Therefore, sufficient data are available to ensure that some 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 origin, and in soil and water. A data gap is identified for a new air method with an appropriate LOQ of at least 0.0012 mg/m^3.

Residues in plants and products of animal origin are analysed by LC-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 LC-MS/MS with a LOQ of 0.01 mg/kg for soil and 0.03 µg/L in water (surface, ground and drinking water). A method for body fluids and tissues is not required as triflumuron is not classified as toxic or very toxic.

2. Mammalian toxicology

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).

Based on the detailed composition of the toxicological batches provided in the addendum 2 to B.6. and in the addendum to Volume 4 (June 2008), the experts agreed that the proposed technical specification was covered by the toxicological batches. 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, not yet specified, a maximum level below 5% w/w in the technical specification would not be of toxicological concern (see also in 2.8).

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 methemoglobin in cats. No methemoglobin 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).

As plant metabolites, **4-trifluoro-methoxyaniline** (M07) and **4-trifluoromethoxyphenylurea** (M08) were discussed by 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), it was agreed to require further data in order to derive an ARfD for the plant metabolite M07.

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.

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 with the parent. Therefore, the reference value (ADI) of the parent could be applied to them as well.

Additional data on several impurities and/or metabolites were provided in the addendum 2. In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review.

Combined toxicity

In acute oral toxicity studies with rats (considered as additional or not acceptable in the DAR), the simultaneous administration of triflumuron and NTN 9306 (sulfopros) didn't show additive effects. A similar administration of triflumuron and FCR 1272 (alpha-cyano-3'phenoxy-4'-fluoro-benzyl-2,2-dimethyl-3-dichlorveny-cis/trans-cyclopropane-carboxylate) indicated a sub-additive toxic effect.

2.9. MEDICAL DATA

There are no indications of any health hazards in employees involved in the manufacture 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 twice 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 fruits, 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 when handling contaminated surfaces.

UK POEM[1] 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[2] with revised parameters according to EUROPOEM and the dermal absorption value of the concentrate. 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.

EFSA note during the written procedure: the agreed dermal absorption value for the concentrate was 1% instead of 2% as used for the calculations in addendum 1. 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.

[2] Krebs B, Maasfeld W, Schrader J, Wolf R, Hoernicke E, Nolting HG, Backhaus GF, Westphal D. 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.

Bystander exposure

Based on the spray drift deposits reported by Ganzelmeier[3], the bystander exposure estimate represents less than 1% of the AOEL.

3. Residues

Triflumuron was discussed in the meeting of experts for residues (PRAPeR 55, round 11) in July 2008 on the basis of the section B.7 of the draft assessment report and the addendum 1 of December 2007. It is noted that the addendum 1 contained the evaluation of several newly submitted studies, however in view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, these new studies could not be considered in the peer review, and therefore a considerable part of the addendum 1 was not discussed in the meeting of experts.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The plant metabolism was investigated in apple, soybean and potatoes using triflumuron ^{14}C labelled in the chlorophenyl ring and the trifluoromethoxy ring, respectively.

In order to support the notified representative uses on apple, pear, peach, and nectarine a metabolism study was required for the fruit crop group.

A study with apples was submitted. The results indicated that triflumuron did not penetrate extensively from the surface into peel and pulp. Apart from triflumuron as the major residue, low levels of metabolites 2-chlorobenzamide (M01), 4-trifluoromethoxyphenyl urea (M08) and 4-trifluoromethoxyphenyl carbamate (M25) were detected in apple matrices. Whether the cleavage of the triflumuron molecule was caused by metabolic activity or by the hydrolytic conditions applied in the analytical procedure could not be clarified. Altogether the study in apples showed several deficiencies and did not allow evaluation of the reliability of the results. The meeting of experts therefore agreed with the RMS proposal to require a new metabolism study in fruit (data gap). A metabolism study in tomato newly submitted by the applicant and evaluated by the RMS in addendum 1 of December 2007 could not be considered in the peer review for reasons already outlined in the introduction to this chapter.

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

Additionally submitted soybean and potato metabolism studies were considered to be of acceptable quality by the RMS. In the potato metabolism study the meeting of experts noted deficiencies in terms of the experimental conditions, which are not clear, and do not allow a conclusion on whether the observed differences in the results for the two radio labels were label specific or for other reasons. The meeting identified the need for further clarification if the study has to be used for the assessment of future uses.

In the soybean and potato matrices investigated, triflumuron was not extensively metabolised. Unchanged triflumuron was always the major component of the total residue.

In soybean foliage and pods between 58% and 99% TRR was identified as triflumuron; in the mature soybean between 20% and 40% TRR. In the beans the metabolites 2-chlorobenzamide (M01) and 2-chlorobenzoic acid (M02) could be detected in low amounts (<1 % TRR). Non-extractable residues were significant in mature beans (71% TRR). Upon acidic treatment of the non-extractable fraction additional amounts of triflumuron (2% TRR) and M02 (30% TRR) could be identified.

A similar picture was seen in the study on potatoes. In potato foliage and tubers, depending on the time of harvest, 64 - 99% TRR and 42 - 49% TRR were identified as triflumuron, respectively. Identified metabolites in the organo-soluble extracts were, depending on the radio label used, M01, M02, M07[4] (<2%TRR each) and M08 (up to 6%TRR) in foliage, and M01 (14% TRR) and M08 (14-19% TRR) in tubers, indicating that cleavage of the parent molecule occurred to some extent. Upon acidic treatment of the non-extractable residues in tubers (40% TRR; chlorophenyl label study) apart from additionally released triflumuron (15% TRR) also M02 (14% TRR) and M01 (about 3% TRR) were found.

The meeting of experts discussed the presumption made by the RMS that M01 and M02 were artefacts generated by acidic hydrolysis of intact triflumuron under the extraction conditions applied, rather than being metabolites that had been linked to plant constituents. This would mean that unchanged triflumuron might also be present to a significant percentage in the non-extractable residue fractions and could be released under certain conditions. However, the meeting agreed it was not possible, on the basis of the available information, to conclude if M01 and M02 are plant metabolites or artefacts, and proposed a data gap for the applicant to demonstrate whether or not M01 and M02 are formed by the extraction procedures used in the plant metabolism studies. In addition, the applicant may consider whether the outcome would possibly have any impact on the results generated by methods used in residue trials.

To investigate the nature of residues upon industrial and household processing, a study simulating processing practices by applying representative hydrolytic conditions was conducted with radiolabelled triflumuron. The results indicated that at temperatures above 90°C triflumuron becomes susceptible to hydrolysis and degrades to M07 and M08 to a significant extent. The meeting of experts did not agree with the applicant's position that temperatures inducing degradation of triflumuron, i.e. higher than 90°C, would not be reached in processes relevant for pome fruit and

[4] 4-trifluoromethoxyaniline (M07)

stone fruit processing. Thus, consumer exposure to these compounds through processed pome fruit and stone fruit products is expected and should be considered.

Despite the fact that all available plant metabolism studies had deficiencies, and a newly submitted study in tomato could not be used for evaluation due to the restrictions laid down in Commission Regulation (EC) No. 1095/2007, the experts agreed that the information available was sufficient to identify triflumuron as a suitable marker compound in crops for monitoring purposes. Therefore it was concluded that a plant residue definition for monitoring and MRL setting could provisionally be proposed as triflumuron.
Prior to the discussion on the residues relevant for consumer risk assessment the meeting of experts sought advice on the toxicity of compounds M01, M02, M07 and M08, which were observed in metabolism and processing studies with triflumuron. The meeting on toxicology PRAPeR 54 concluded that in terms of chronic toxicity the ADI for triflumuron could be applied also to the metabolites. M07 was however shown to be more acutely toxic than triflumuron and would require the setting of an ARfD (for details please refer to chapter 2.8 of this document) which, in contrast, was not necessary for parent triflumuron. Compound M07 is a precursor of M08. The experts took note of the fact that compound M08 is also a plant metabolite of the active substance indoxacarb.
Finally, highlighting again the deficiencies of the available data, the meeting proposed a provisional plant residue definition for risk assessment as the sum of triflumuron and all compounds containing the 3-fluoro methoxy aniline moiety, expressed as triflumuron. It will only be possible to agree on a final residue definition for risk assessment when sufficient data on the nature of residues in food commodities are available.

The magnitude of triflumuron residues was determined in a total of 20 field residue trials in apples and pears conducted in Northern and Southern European regions in three growing seasons, and in 12 trials in peaches and nectarines conducted in Southern Europe in two growing seasons. Field-testing parameters were considered to be consistent with the notified critical GAP. Only 16 of the reported trials in apples and pears were considered by the RMS for further evaluation, no details were given as to why 4 trials carried out in apples (Italy, 1995) were excluded.
Triflumuron was the only residue determined by HPLC-MS/MS (LOQ 0.01 mg/kg) or by HPLC after saponification (MAES) to M08 (LOQ 0.02 mg/kg), respectively. The analytical methods were fully validated as data generation methods, and the determined residue results are supported by acceptable storage stability data.
Provided the residue definition for monitoring will be confirmed as triflumuron alone, the available data would be sufficient to propose MRLs corresponding to the notified representative uses in apples, and pears throughout Europe, and peaches and nectarines in Southern Europe. Based on current

guidance[5] extrapolation from the data on apples and pears to obtain an MRL for the whole group of pome fruit would be possible. Data on peaches and nectarines can be used to extrapolate to apricots, while extrapolation to the whole group of stone fruit, as proposed by the RMS, is not possible.
In terms of risk assessment, the residues determined in the submitted residue trials do not fully correspond to the currently proposed residue definition for risk assessment, since the triflumuron metabolites included in this definition were not analysed. Pending a final conclusion on the relevant residue for risk assessment in terms of the notified uses, further residue trials in apples/pears and peaches/nectarines analysing for the full residue definition for risk assessment may be necessary.

To investigate the residue levels in processed products a study was conducted in apples and peaches, respectively. Triflumuron was the residue determined in apple sauce, juice, pomace and dried apple, and in canned peaches. Except for apple pomace, residue levels of triflumuron were found to be lower in the processed commodities than in the raw commodity. Whether significant amounts of degradation products (M07, M08) had been generated in the processed apple and peach commodities, was not investigated in the studies.
However, altogether the available data were considered not sufficient by the RMS to establish robust residue transfer factors for processed apple and peach commodities. Therefore, a data gap for additional studies, including a balance study and two follow up-studies in apples, as well as three follow up studies for processed peach fruits, was identified.
Newly submitted data on processed apples, peaches and plums, evaluated by the RMS in addendum 1 of December 2007 could not be considered in the peer review for reasons already outlined in the introduction to this chapter. Whether the new data appropriately address the effects of the level of residues as provisionally defined for risk assessment purposes, i.e. including metabolites containing the 3-fluoro methoxy aniline moiety, is not known.

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 is not required. Nevertheless, a rotational crop metabolism study with ^{14}C chlorophenyl ring labelled triflumuron was submitted and evaluated in the DAR in order to further elaborate the picture on the residue behaviour of triflumuron in plants. In all crops and crops 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

[5] Guidance document SANCO 7525/VI/95 rev. 8: Guidelines on comparability, extrapolation, group tolerances and data requirements

crop study with trifluoromethoxy 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. However, the need for further clarification with respect to results in the primary crop metabolism studies is noted (refer to 3.1.1).

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 and laying hens with ^{14}C chlorophenyl labelled and trifluoromethoxyaniline labelled triflumuron, respectively.

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. The 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 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. The 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 2-chlorobenzamide (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, M23).

Provided that exposure in livestock diet is only significant to residues of triflumuron (and no metabolites), the animal residue definition for monitoring is proposed as triflumuron alone (provisional).
The meeting of experts agreed that for risk assessment purposes the residue in livestock matrices should provisionally be defined as sum of triflumuron and all compounds containing the 3-fluoro methoxy aniline moiety, expressed as triflumuron.
Finalisation of the residue definitions is pending availability and assessment of a new fruit metabolism study, apple processing studies, and an accordingly revised livestock exposure assessment.

Considering the notified uses of triflumuron, and based on data from residue and metabolism studies, a feeding study was triggered for ruminants, but not for poultry and pig.
In a study on dairy cattle, triflumuron was administered at levels corresponding to about 5.9 and 11.9 mg per kg feed DM, respectively. 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 0.1 mg/kg for fat. Pending confirmation of the monitoring residue definition for animal products and upon revision of the dietary livestock exposure assessment, the study could be used to derive MRLs for food of animal origin.
For risk assessment purposes it is noted that the study does not analyse for the currently defined residue for risk assessment in animal matrices. The actual residue levels in food of animal origin corresponding to this residue definition (i.e. including compounds containing the 3-fluoro methoxy aniline moiety) will have to be addressed for the consumer exposure and risk assessment.

3.3. CONSUMER RISK ASSESSMENT

Currently the consumer risk assessment **cannot be finalised**. The experts have identified that further data are necessary to conclude on a final residue definition for risk assessment with regard to the notified representative uses. Depending on the outcome, a re-evaluation of livestock exposure and potential residue levels in food of animal origin may be required.

At the current stage, a residue definition for risk assessment has been provisionally proposed for primary fruit crops. This definition includes compounds containing the 3-fluoro methoxy aniline moiety, however occurrence data for these compounds (studies determining their levels in primary crops, processed commodities, and livestock animals) are not available among the data submitted and evaluated in the DAR.
EFAS notes that the proposed residue definition may only be appropriate for a chronic risk assessment, since for all components included the same ADI (i.e. of triflumuron) can be applied. However, an acute risk assessment with the proposed definition will be very difficult. No ARfD has been allocated for triflumuron, while for the included metabolite M07 (which is more acutely toxic), the setting of an ARfD is necessary.
Therefore, for the moment **a robust and reliable acute and chronic risk assessment for consumers cannot be conducted**.

The RMS has carried out a provisional assessment of the chronic dietary risk, considering only residues of parent triflumuron (presented in addendum 1). Consumption data from the WHO GEMS/Food diet, and national consumption data from the UK and Germany (outdated) were used for the intake estimates. The RMS estimated the theoretical maximum daily intake (TMDI) assuming residue of triflumuron in pome fruit and stone fruit at the level of the proposed MRLs for apples/pears and peaches/apricots respectively. Though the meeting of experts agreed with the format of the assessment it highlighted that cherries and plums were also included in the estimates, and that these uses were neither notified for the peer review nor supported by residue data.
The RMS estimated the theoretical maximum daily intake (TMDI) to be at the maximum 75% of the ADI of triflumuron for the consumer group of UK toddlers.

It is highlighted that potential residues in food of animal origin have not been considered, neither was the risk assessment carried out considering in full the residue defined as relevant by the residue definition for risk assessment. If, and to what extent, chronic exposure of consumers may change when, in addition to triflumuron, all compounds containing the 3-fluoro methoxy aniline moiety are considered, can not currently be predicted due to lack of data.
The consumer risk assessment will have to be revised when the outstanding data are available.

The experts proposed that EFSA should review the risk assessment for indoxacarb in terms of the decision to include the common metabolite 4-trifluoromethoxyphenyl urea (M08) in the risk assessment for triflumuron. Indoxacarb is an active substance of the 1st list in the review programme under directive 91/414/EEC. The peer review of indoxacarb was therefore not within the scope of EFSA's remit. However, having regard to article 12(2) of regulation 396/2005/EC, the draft assessment report for indoxacarb will be looked at by EFSA, and a consumer risk assessment will be carried out that may take into account the recent conclusion of the PRAPeR 54 and 55 meetings regarding the common indoxacarb and triflumuron metabolite 4-trifluoromethoxyphenyl urea (M08).

3.4. PROPOSED MRLS

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

Apples, pears	0.5 mg/kg (extrapolation to whole group of pome fruit possible)
Peaches, nectarines	0.3 mg/kg (extrapolation to apricots possible)

It is noted that the group MRL proposed by the RMS for stone fruit is not sufficiently supported by data, since residue trials in cherries and plums would be required.

MRLs can not be proposed for food of animal origin at the moment (refer to chapter 3.2 above).

4. Environmental fate and behaviour

Fate and behaviour of triflumuron was discussed in the meeting of experts PRAPeR 52 (July 2008) on basis of the DAR (May 2005), Addendum 1 (December 2007) and Addendum 2 (June 2008). After the meeting of experts the RMS made available to EFSA Addendum 3 (August 2008).

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 new 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).

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. 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 neither 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 ($DT_{50\ lab\ 20\ ºC}$ = 6.9 – 52 d). RMS presented further details on the half life normalization in addendum 2. The experts agreed with the normalized values proposed by the RMS ($DT_{50\ lab\ 20\ ºC\ Norm\ pF2}$ = 4.6 – 40.8 d) 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 (see above).

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 low persistent in soil under these conditions ($DT50_{lab\ 20\ ºC}$ = 1.2 – 4.2 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 to moderate persistent in soil ($DT50_{lab\ 20\ ºC}$ = 1.3 – 20.5 d). Before the meeting of experts the applicant clarified that a formation fraction of 1 (100 %) had been assumed in the calculation.

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

PECsoil were calculated by the RMS using the standard low tier scenario and 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 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 MS during the written procedure for comments on the conclusion. EFSA recalculated these PECs and the amended values are presented in the list of end points. The PECsoil for this metabolite presented in Addendum 3 should be therefore disregarded.

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 = 280 – 113 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 MS 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 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 (eg. 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.

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 separated 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 100d). Mineralization of the trifluoromethoxyphenyl moiety seems to be practically negligible (CO_2: 2.39 % AR after 100d). 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 systems 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 parent to sink compartment was not considered and all the losses in the water phase were assumed to be due to degradation by setting partition to the sediment 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 have been calculated by the RMS and presented in addendum 3. These calculations have

not been peer reviewed. 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. 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 have not been peer reviewed. 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 (data gap on Koc identified by the meeting). 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 are not peer reviewed. 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.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Potential ground water contamination was addressed in the DAR by FOCUS PEC_{GW} calculations (80^{th} 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, 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 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.

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.

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 fruits 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; Aquatic Ecotoxicology, SANCO/3268/2001 rev.4 final, October 2002; Terrestrial Ecotoxicology, SANCO/10329/2002 rev.2 final, October 2002; Risk Assessment for non-target arthropods, ESCORT 2, March 2000, SETAC.

In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, the new studies could not be considered in the peer review.

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 was considered as the most relevant endpoint for the risk assessment since it was conducted with batches corresponding to the new technical specification (reduction of toxic impurities). 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) was 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 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.

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 to contaminated drinking water. However the risk is assumed to be low considering the low acute toxicity of triflumuron to birds and mammals and that

the morphology of leaves of orchard trees is not conducive for the formation of water reservoirs in leaf axils.

The risk to birds and mammals was assessed as low for the representative uses of triflumuron except the long-term risk to insectivorous birds, which 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 step4 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 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.

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 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 SC480 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 SC480 at rates of 180 g a.s./ha and *C. septemtpunctata*. 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 35d 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.

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 23 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.

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 SC480 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

Ground water

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: **provisional** sum of triflumuron and all compounds containing the 3-fluoro methoxy aniline moiety, expressed as triflumuron.
Definition for monitoring: **provisional** triflumuron

Food of animal origin

Definition for risk assessment: **provisional** sum of triflumuron and all compounds containing the 3-fluoro methoxy aniline moiety, expressed as triflumuron.
Definition for monitoring: **provisional** triflumuron

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
triflumuron	low to moderate persistent in acidic soils ($DT_{50\ lab\ 20\ °C}$ = 6.9 – 52 d) data gap for alkaline soils	The acute toxicity and risk to earthworms is low, however data gaps were identified for a long-term toxicity study with earthworms and a study with collembola. The risk to soil micro-organisms was assessed as low.
2-chlorobenzoic acid	low persistent in acidic soils ($DT50_{lab\ 20\ °C}$ = 1.2 – 4.2 d) data gap for alkaline soils	Low acute toxicity and risk to earthworms, low risk to soil non-target macro- and micro-organisms.
4-trifluoromethoxyphenyl urea	low to moderate persistent in acidic soils ($DT50_{lab\ 20\ °C}$ = 1.3 – 20.5 d) data gap for alkaline soils	Low acute toxicity and risk to earthworms, low risk to soil non-target macro- and micro-organisms.

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
triflumuron	immobile to low mobile in acidic soils (Koc = 1629 – 30006 mL/g) data gap for alkaline soils	FOCUS PEARL: no scenario exceeds 0.1 µg / L in acidic soils Data gaps identified for alkaline soils	Yes	Yes	Yes
2-chlorobenzoic acid	very high mobile in acidic soils (Koc = 4.0 – 8.8 mL/g) data gap for alkaline soils	FOCUS PEARL: no scenario exceeds 0.1 µg / L in acidic soils Data gaps identified for alkaline soils	No data were made available. Assessment needed.	No	No
4-trifluoromethoxyphenyl urea	medium to high mobile (Koc = 280 – 113 mL/g)	FOCUS PEARL: no scenario exceeds 0.1 µg / L in acidic soils Data gaps identified for alkaline soils	No data were made available. Assessment needed.	No	No

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 urea (sediment phase only)	More than 3 orders of magnitude less toxic to aquatic organisms compared to triflumuron. The risk to aquatic organisms was assessed as low.

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

- A specification to include the relevant impurity toluene (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Validated method of analysis for the active substance in the formulation (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Melting point and decomposition point (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Spectra for the relevant impurity *N*,*N'*-bis[4-(trifluoromethoxy)phenyl]urea (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Spectra for the relevant impurity 4-trifluoro-methoxyaniline (relevant for all uses, data gap identified by EFSA September 2008, date of submission unknown, refer to chapter 1)
- 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)
- Surface tension of the formulation (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Method of analysis for air with a LOQ of at least 0.0012 mg/m3 (relevant for all uses, data gap identified by meeting of experts June 2008, date of submission unknown, refer to chapter 1)
- Toxicological data allowing the derivation of an ARfD for the plant metabolite M07 (relevant for all uses, data gap identified by the meeting of experts July 2008, data of submission unknown, refer to chapter 2.8)
- New toxicological data (i.e. newly submitted) for several impurities/metabolites (relevant for all uses, evaluated by the RMS in the addendum 2 to Volume B.6 but not taken into consideration due to Regulation (EC) No. 1095/2007, refer to chapter 2.8)
- A new metabolism study in the category of fruit crops (relevant for all uses, data gap identified by the RMS in the DAR and confirmed by the meeting of experts in July 2008, study in tomatoes submitted and evaluated by the RMS in the addendum 1 to Volume B.7 but not taken into consideration due to Regulation (EC) No. 1095/2007, refer to chapter 3.1)
- A new metabolism study in the category of fruit crops (relevant for all uses, data gap identified by the RMS in the DAR and confirmed by the meeting of experts PRAPeR 55 in July 2008, study in tomatoes submitted and evaluated by the RMS in the addendum 1 to

Volume B.7 but not taken into consideration due to Regulation (EC) No. 1095/2007, refer to chapter 3.1.1)

- The applicant should demonstrate whether or not M01 and M02 are formed by the extraction procedures used in the plant metabolism studies. In addition, the applicant may consider whether the outcome would possibly have any impact on the results generated by methods used in residue trials. (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)
- Pending a conclusion on the residue definition for risk assessment, further residue trials in apples/ pears and peaches/nectarines, which determine all components of the residue definition for risk assessment, may become necessary. (relevant for all uses, data gap identified by EFSA after the meeting of experts PRAPeR 55 in July 2008, no submission date proposed by the applicant, refer to chapter 3.1.1)
- Additional studies on the effects of processing on residue levels including a balance study and two follow up-studies in apples and three follow up studies for processed peach fruits (relevant for all uses, data gap identified by the RMS in the DAR and confirmed by the meeting of experts PRAPeR 55 in July 2008, data on apples, peaches and plums newly submitted and evaluated by the RMS in the addendum 1 to Volume B.7 but not taken into consideration due to Regulation (EC) No. 1095/2007, refer to chapter 3.1.1)
- Data to address the actual residue levels in food of animal origin corresponding to the proposed residue definition (i.e. including compounds containing the 3-fluoro methoxy aniline moiety) will have to be addressed for the consumer exposure and risk assessment (relevant for all uses, data gap identified by EFSA after the meeting of experts PRAPeR 55 in July 2008, no submission date proposed by the applicant, refer to chapter 3.2).
- 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 (approximately pH 8) (relevant for all uses, data of submission not provided, refer to point 4.1.2).
- A data gap was identified for batch soil adsorption / desorption studies for the triflumuron and the soil metabolite 2-chlorobenzoic acid in more alkaline soils (approximately pH 8) (relevant for all uses, data of submission not provided, refer to point 4.1.3).
- A data gap was identified to revise PEC_{GW} and PEC_{SW} on basis of the adsorption / desorption results for triflumuron and metabolite 2-chlorobenzoic acid in alkaline soils and the rate of aerobic degradation of parent and formation and degradation rates of metabolites in alkaline soils (relevant for all uses, data of submission not provided, refer to points 4.2.1 and 4.2.2).
- 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.)
- A long-term study with triflumuron and earthworms (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 5.5.)
- A study with triflumuron and collembola (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 5.5.)
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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 and peaches. 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).

Adequate methods are available to monitor all compounds given in the respective residue definition except for air where a data gap has been identified. 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 some quality control measurements of the plant protection product are possible. Data for the relevant impurities is missing and the specification can not be finalised. A method for the active substance in the plant protection product has been identified as a data gap. Also some physchem properties have been identified as data gaps.

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. According to them, three impurities were considered toxicologically relevant, three plant metabolites were considered covered by the toxicological studies with the parent (use of the same reference value) but new toxicological data were required for the derivation of the acute reference dose for one acutely toxic plant metabolite.
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, however it was agreed to require further data in order to derive an ARfD for the plant metabolite M07, since this metabolite was shown to be more acutely toxic

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 apples, potatoes and soybean. The study on apples was assessed by the RMS as having several deficiencies, and hence a new fruit metabolism study has been required to support the notified uses in pome fruit and stone fruit crops. The PRAPeR meeting of experts noted deficiencies also in the metabolism studies in potatoes and soybean and agreed that further data is necessary to conclude on a final plant residue definition for risk assessment and monitoring. Though the number and quality of the submitted residue trials was considered sufficient, the conducted trials do not determine all compounds included in the provisionally proposed residue definition for risk assessment. In addition, further studies on the level of residues in processed fruit commodities are necessary to allow robust estimates of human and livestock dietary exposure to residues present upon use of triflumuron. Consequently, the assessment in terms of potential residues in food of animal origin including a residue definition for monitoring and risk assessment in animal products could not be finalised, neither could the consumer exposure and risk assessment be concluded. In addition, the need for further data to derive an ARfD was identified for 4-trifluoromethoxyaniline, a metabolite and degradation product of triflumuron that has been considered pertinent for the consumer risk assessment.
At the current stage, with the data available and eligible for evaluation it was only possible to provisionally propose residue definitions and MRLs for the notified uses. However, precise estimates of human and livestock dietary exposure, and finally a robust consumer risk assessment can only be finalised when the outstanding data and information was evaluated.

Triflumuron is low to moderate persistent in soil ($DT_{50\ lab\ 20\ °C}$ = 6.9 – 52 d) under dark aerobic conditions. Two major metabolites are formed: 2-chlrobenzoic acid (M02, max. 23.5 % TRR;

$DT50_{lab\ 20\ °C}$ = 1.2 – 4.2 d) and 4-trifluoromethoxyphenyl urea (M08, TMPU, max. 23.1 % TRR; $DT50_{lab\ 20\ °C}$ = 1.3 – 20.5 d). Trifluoromethoxyphenyl ring was less mineralized and more prone to form unextractable residues than the chlorophenyl ring. The range of pH values in the soils investigated was too narrow with respect to the directive requirements. Therefore, a new data gap to address the rate of aerobic degradation of parent and formation and degradation rates of metabolites in alkaline soils was identified.

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 M2 (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.

PEC soil calculations were presented in addendum 2 were accepted by the experts for the parent compound. However, new PEC soil calculations for metabolite M02 and M08 were requested. The new PEC soil have been calculated with the agreed input parameters and presented in the list of end points by EFSA (a mistake was identified in the values calculated in addendum 3).

According 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 = 280 – 113 mL/g) and M02 may be considered very high mobile in soil (Koc = 4.0 – 8.8 mL/g). However, available data may only be considered relevant for acidic soils. Therefore, the experts identified a data gap for batch adsorption / desorption studies with more alkaline soils for parent and metabolite M02. 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.

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) and M08 (max. 48.8 % AR after 30 d). According the available study, aqueous photolysis is considered to contribute only in a minor extent to the overall degradation of triflumuron. In the lack of the 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 of the trifluoromethoxyphenyl moiety. The pH of the water phase of the systems investigated was in the alkaline range. A data gap, not considered essential to finalize the EU risk assessment, was identified for water / sediment studies within a wider range of pH values.

The meeting agreed that FOCUS PEC $_{SW\ /\ SED}$ presented in the DAR (including the Step 4 approach based on GIS) were not appropriate for the EU risk assessment. New FOCUS PEC_{SW} based on FOCUS kinetics were requested. New calculations provided in addendum 3 are not peer reviewed. 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.

Potential ground water contamination was addressed in the DAR by FOCUS PEC_{GW} calculations (80^{th} percentile at 1 m depth) for triflumuron and its soil metabolites M02 and M08 with the FOCUS model PEARL and the nine FOCUS GW scenarios. Formation fraction of one had been assumed in these calculations for both soil metabolites M02 and M08. During the peer review data gaps have been identified for triflumuron and the metabolite M02 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 M02 and M08. Therefore, results of the available modelling are only relevant for acidic soils. Under these conditions neither the parent triflumuron nor any of the two soil metabolites M02 and M08 are expected to exceed the trigger of 0.1 µg / L.

Based on the physical and chemical properties of triflumuron, 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 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.

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. Bee brood was very sensitive to 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 but no long-term studies were conducted with earthworms. Since triflumuron disturbs 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. 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.

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

- Environmental risk assessment only addresses situations where the soil pH is in the acidic range (refer to chapter 4).
- Flowering weeds should be removed before application of triflumuron to protect bees.

Critical areas of concern

- The specification for the relevant impurity toluene can not be finalised.
- The consumer risk assessment cannot be finalised due to lack of data in terms of nature and level of the relevant residues.
- The long-term risk to birds needs further refinement.
- The high risk to the aquatic environment (acute and chronic risk to aquatic invertebrates).

Appendix 1 – List of endpoints

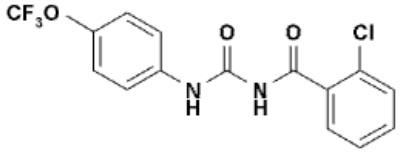
APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Chapter 1: 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] carbamoyl] benzamide
CIPAC N°	584
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)pheny] urea Max. 1 g/kg 4-trifluoro-methoxyaniline Max. 5 g/kg Toluene Max value open
Molecular formula	$C_{15}H_{10}ClF_3N_20_3$
Molecular mass	358.7 g/mol
Structural formula	

Appendix 1 – List of endpoints

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	Open
Boiling point (state purity)	Boiling point cannot be determined due to decomposition
Temperature of decomposition	Open
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 x 10^{-7} Pa at 20 °C (by extrapolation)
Henry's law constant (Pa m3 mol-1)	1.79 x 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)	UV_{max} = 249 nm ε=14.94 x 10^6 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.

Appendix 1 – List of endpoints

Summary of representative uses evaluated (ALSYSTIN SC 480)*

Crop and/or situation	Member State or Country	Product name(s)	F/G or I	Pests or Group of pests controlled	Formulation		Application			Application rate per treatment				PHI (days)	Remarks:
(a)			(b)	(c)	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./hamin max	(l)	(m)
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] [2] [3] [4]
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][2] [3] [4]

[1] The risk assessment could not be concluded due to data gaps in section 6
[2] The consumer risk assessment could not be concluded due to data gaps in the residue section
[3] The specification can not be finalized
[4] Further reifinment is needed for the long-term risk assessment for birds and a high risk to the aquatic environment was identified.

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

Appendix 1 – List of endpoints

Remarks

(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), water dispersible granule (WG)

(e) GCPF Codes - GIFAP Technical Monograph No. 2, 1989

(f) All abbreviations 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 plants 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) The minimum and maximum number of applications possible under practical conditions of use must be provided

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix 1 – List of endpoints

Chapter 2: 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)	Open

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Triflumuron (provisional)
Food of animal origin	Triflumuron (provisional)
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

Appendix 1 – List of endpoints

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)	Open
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/EPCO proposal	ECB decision
Active substance or variant	none	none

Appendix 1 – List of endpoints

Chapter 3: Impact on Human and Animal Health

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

Rate and extent of 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)	Parent compound and metabolites (4-trifluoromethoxyaniline, 4-trifluoromethoxyphenylurea, 2-chlorobenzamide, 2-chlorobenzoic acid)
Toxicologically relevant compounds (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	> 5000 mg/kg bw
Rat LD_{50} dermal	> 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 (test method used and result)	Not sensitiser (Magnusson & Kligman Test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Haematopoietic 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

Appendix 1 – List of endpoints

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	Rat maternal: haemolytic anaemia Rat developmental: delayed skeletal development Rabbit maternal: haemolytic anaemia Rabbit developmental: increased post-implantation loss
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

Appendix 1 – List of endpoints

Other toxicological studies (Annex IIA, point 5.8)

Mode of action of triflumuron	no methaemoglobin formation in cats after single exposure
4-trifluoromethoxyaniline	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 irritant (not classifiable) Ames test negative (other mutagenicity tests not considered acceptable) destruction of haemoglobin with methaemoglobin formation in cats structural alerts for skin sensitisation and carcinogenicity
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 – methemoglobin level: no hemotoxic effect
Combination toxicity	**triflumuron & NTN 9306 (Sulfopros)** rat – acute oral toxicity: no additive effects **triflumuron & FCR 1272 (alpha-cyano-3'phenoxy-4'-fluoro-benzyl-2,2-dimethyl-3-dichlorveny-cis/trans-cyclopropane-carboxylate)** rat – acute oral toxicity: sub-additive toxic 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/day)	0.014	1-yr dog supported by 2-yr rat	100
AOEL (mg/kg bw/day)	0.036	90-d rat	100
ARfD (mg/kg bw)	not necessary		

Dermal absorption (Annex IIIA, point 7.3)

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

Appendix 1 – List of endpoints

Acceptable exposure scenarios (including method of calculation)

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		

*EFSA note following the written procedure: the agreed dermal absorption value for the concentrate was 1% instead of 2% as used for the calculation in addendum 1. However, as a worst case, the higher dermal absorption value for the dilution (5%) should be used.

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

	RMS/peer review proposal	ECB decision
Active substance	Not applicable	None assigned
Preparation	Not applicable	

Appendix 1 – List of endpoints

Chapter 4: Residues

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

Plant groups covered	Study in apples not acceptable – **Data gap** (New study for the fruit crop group presented could not be considered according to Regulation EC/1095/2007) Deficiencies noted in studies in other crop groups, not relevant for representative use: Pulses and oilseeds (soybeans), Root vegetables (potatoes) - Foliar treatment by spray application.
Rotational crops	Not relevant for representive uses in orchards. Additional information available in: Kale / Red beets / Wheat
Metabolism in rotational crops similar to metabolism in primary crops	Not relevant.
Processed commodities	Hydolysis study at representative conditions: 90°C, pH 4 for 20 minutes, 100°C, pH 5 for 60 minutes, and 120°C, pH 6 for 20 minutes. Triflumuron is stable up to 90ºC, but degrades at higher temperatures to 4-trifluoromethoxyphenyl urea (M08)and 4-trifluoromethoxyaniline (M07).
Residue pattern in processed commodities similar to residue pattern in raw commodities	Not enough data – studies required –**data gap** (New studies presented could not be considered according to Regulation EC/1095/2007)
Plant residue definition for monitoring	**provisional:** Triflumuron - pending new fruit metabolism study
Plant residue definition for risk assessment	**provisional:** Triflumuron, including all components containing the 3-fluoro methoxy aniline moiety, expressed as Triflumuron -pending new fruit metabolism study
Conversion factor (monitoring to risk assessment)	**open**

Appendix 1 – List of endpoints

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

Animals covered	Lactating ruminants (goat) Additional information Poultry (laying hens) – only phenyl label
Time needed to reach a plateau concentration in milk and eggs	The plateau was not reached during the duration (3 days) of the study, residues levels in milk increased throughout multiple administration of triflumuron.
Animal residue definition for monitoring	**provisional:** Triflumuron - pending re-evaluation of plant metabolism and livestock exposure
Animal residue definition for risk assessment	**provisional:** Triflumuron, including all components containing the 3-fluoro methoxy aniline moiety, expressed as Triflumuron - pending re-evaluation of plant metabolism and livestock exposure
Conversion factor (monitoring to risk assessment)	**open**
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes (log Pow > 3)

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

Not relevant for representative use

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

Triflumuron: at least 2 years in apple fruit, dried apple fruit, apple sauce, apple pomace, apple juice Results are applicable to stone fruit At least 100 days in liver and meat 89 days in milk.

Appendix 1 – List of endpoints

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

	Ruminant: [1]	Poultry: [1]	Pig: [1]
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 Dairy cattle: 0.77 mg/kg feed (DM) Beef cattle: 2.3 mg/kg feed (DM)	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	**open**	Not relevant	Not relevant
	Residue levels in matrices: Mean = max mg/kg		
Muscle	**open**	[2] Not relevant	[2] Not relevant
Liver	**open**	[2] Not relevant	[2] Not relevant
Kidney	**open**	[2] Not relevant	[2] Not relevant
Fat	**open**	[2] Not relevant	[2] Not relevant
Milk	**open**	[2] Not applicable	[2] Not applicable
Eggs	[2] Not applicable	[2] Not relevant	[2] Not applicable

[1] State whether intake by specified animals is ≥ 0.1 mg/kg diet/day or not, based on a dry weight basis as given in table 1 of Guidance Document Appendix G
[2] Fill in residue levels from appropriate feeding studies at appropriate dose rates according to Guidance Document Appendix G.

Appendix 1 – List of endpoints

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

Crop	Northern or Mediterranean Region	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the intended use	HR (c)	STMR (b)
Apples, pears	N	1 x 0.04; 2 x 0.07; 1 x 0.09; 1 x 0.11; 1 x 0.13; 1 x 0.17; 1 x 0.21	only applicable to triflumuron, **no residue data for metabolites** according to risk assessm. def. available, HR and STMR for risk assessment cannot be derived Extrapolation to whole group pome fruit possible	0.3	open	open
Apples, pears	S	1 x 0.03; 1 x 0.07; 2 x 0.09; 1 x 0.12; 1 x 0.15; 1 x 0.24; 1 x 0.26		0.5	open	open
Peaches, Nectarines	S	1 x 0.02; 1 x 0.04; 1 x 0.05; 1 x 0.06; 1 x 0.07; 2 x 0.09; 1 x 0.11; 2 x 0.13; 1 x 0.14; 1 x 0.24	only applicable to triflumuron, **no residue data for metabolites** according to risk assessm. def. available, HR and STMR for risk assessment cannot be derived Extrapolation to apricots possible	0.3	open	open

(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
I Highest residue

Appendix 1 – List of endpoints

[3] MRL proposal derived from supervised residue trials according to Guidance Document Appendix I. When the MRL is estimated at the LOQ this should be annotated by an asterisk after the number.
[4] STMR value from results of supervised residue trials for MRL setting.
[5] If several representative use or European regions are foreseen for one crop, one row must be used for each specific situation
[6] For some crop/pesticide combination, the residue definition for monitoring and RA may differ. If trials are reported in this table with analysis of the residues accordingly to both definitions, the results are reported in the format x(y), x b eing the result according to the definition for monitoring and y the result according to the definition for RA. The same applies for the HR and the STMR

Appendix 1 – List of endpoints

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

ADI	0.014mg/kg bw/day
TMDI mg/kg (% ADI)	Assessment pending, not finalised due to lack of data (refer to chapter 3.4 of EFSA conlcusion), no robust estimates possible
TMDI mg/kg (% ADI) according to national (to be specified) diets	Assessment pending, not finalised due to lack of data (refer to chapter 3.4 of EFSA conlcusion), no robust estimates possible
IEDI (European Diet) (% ADI)	Not necessary
NEDI microg/kg (specify diet) (% ADI)	Not necessary
Factors included in IEDI and NEDI	Not applied
ArfD	None allocated for triflumuron, required for metabolite M07 but no set due to lack of data
IESTI microg/kg bw/day (% ARfD)	Assessment pending
NESTI microg/kg bw/day (% ARfD)	Assessment pending
Factors included in I(N)ESTI	Assessment pending

[5] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets)

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

Crop/process/processed crop	Number of studies	Transfer factor
apple / washed fruits	1	1 (0.5; 1.5)
apple / dried fruits	1	0.25 (0.1; 0.4)
apple / apple sauce	1	0.35 (0.2; 0.5)
apple / apple juice	1	0.15 (0.1; 0.2)
apple / pomace	1	16.05 (8.3; 23.8)
peach / peel	1	4.9
peach / washed fruit	1	1.15 (1.1; 1.2)
peach / preserve	1	0.1
peach / stoned fruit	1	1.1
peach / peeled fruit	1	0.1

Further processing studies required –**Data gap** (New studies could not be considered according to Regulation EC/1095/2007)

Appendix 1 – List of endpoints

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

Proposed MRLs	Pome fruit 0.5 mg/kg Apricots, peaches, nectarines 0.3 mg/kg MRLs could not be proposed for food of animal origin at the moment with the consequence that the assessment of the use in pome fruit cannot be finalised. (Pending new outstanding metabolism and processing studies; unsure about the presence of metabolites)

When the MRL is proposed at the LOQ this should be annotated by an asterisk after the number.

Appendix 1 – List of endpoints

Chapter 5: Fate and Behaviour in the Environment

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

Mineralization after 100 days	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)	4-trifluoromethoxyphenyl urea (M08), only formed from the trifluoromethoxyphenyl-label: max: 48.5% at anaerobic day 30 2-chlorobenzoic acid (M02) only formed from the chlorophenyl-label: max: 46.7% at anaerobic day 60

Appendix 1 – List of endpoints

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**						
	Data gap has been identified for degradation studies in alcaline soils (approximately pH 8)						
Soil type	X[6]	pH	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	20°C/49 %	18.8 / 62.5	14.6	0.951	SFO
Silt		6.7	20°C/49 %	6.9 / 23	4.6	0.992	SFO
Silt loam		5.5	23°C/75 % of 333 mbar moisture	52 / n.c.	40.8	0.98	SFO
Silt loam		6.7	20°C/50	7.3/24.1	5.2	0.98	SFO
Geometric mean/median					10.9/9.89		

4-trifluoromethoxyphenyl urea (M08)	Aerobic conditions							
Soil type	X	pH	t. °C / % of MWHC	DT_{50}/ DT_{90} (d)	F.F. k_{dp}/k_f (assumed)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt		6.7	20°C/49 %	1.9	1	1.3	0.994	SFO
Sandy loam		6.3	20°C/49 %	4.3	1	3.3	0.916	SFO
Silt loam		5.5	23°C/75 % of 333 mbar moisture	23	1	20.5	0.94	SFO
Silt loam		6.7	20°C/50	3.9/13.1	1	2.80	0.98	SFO
Geometric mean/median						3.96/3.05		

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

Appendix 1 – List of endpoints

2-chlorobenzoic acid (M02)	Aerobic conditions							
Soil type	X	pH	t. °C / % of MWHC	DT_{50}/ DT_{90} (d)	F.F. k_{dp}/k_f (assumed)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Silt		6.3	20°C/49%	0.6/n.c.	1	0.4	0.964	SFO
Sandy loam		6.7	20°C/49%	0.8/n.c.	1	0.6	0.938	SFO
Sandy loam		6.5	20°C/49%	4.2/13.8	1	3.3	0.994	SFO
Loam		7.1	20°C/49%	1.2 /4.0	1	0.6	0.998	SFO
Sandy loam		6.9	20°C/49%	3.4/11.4	1	2.6	0.993	SFO
Geometric mean/median				1.2/1.5	1	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							
Data gap has been identified for studies to be performed under on soils in the alkaline range pH							
Soil Type	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n
Sandy loam	0.3	5.6		90.0		30 006	1.24
Loamy sand	0.6	6.2		9.8		1 629	0.85
Silty clay	0.92	5.4		30.0		3 257	1.03
Loam	0.66	6.2		114.4		17 339	1.21
Silt	2.11	6.7		161.9		7 675	1.00
Slightly humous sand (2.1)	0.95	5.6	33.3		3 510		
Strongly humous loamy sand (2.2)	2.42	5.4	71.1		2 940		
Slightly humous sandy loam (2.3)	1.14	5.8	27.9		2 450		
Aritmetic mean					2 967	11 981	1.07
Aritmetic mean of k_{oc} and K_{foc} (all 8 soils)					8 601		
pH dependence, Yes or No			**Data gap**				

Appendix 1 – List of endpoints

4-trifluoromethoxyphenyl urea (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
Geometric mean/median						163.7 / 154.5	0.78 / 0.78
pH dependence, Yes or No			No				

2-chlorobenzoic acid (M02)							
Data gap has bneen identified for studies to be performed under on soils in the alkaline range pH							
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
Geometric mean/median					6.5 / 7.1		
pH dependence, Yes or No			**Data gap**				

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): 40.8 days. Kinetics: 1st order Worst case normalized 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

Appendix 1 – List of endpoints

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
	PECs only relevant for acidic soils			
Initial	0.0720	0.0720	0.0685	0.124
Short term	0.0708	0.0714		
24h	0.0696	0.0708	0.0674	0.123
2d	0.0673	0.0696	0.0663	0.122
4d			0.0640	0.120
Long term				
7d	0.0639	0.0679	0.0608	0.117
28d	0.0447	0.0573	0.0426	0.0989
50d	0.0308	0.0485	0.0293	0.0837
100d	0.0132	0.0346	0.0125	0.0598
Plateau conc.	-			

Metabolite 4-trifluoromethoxyphenyl urea (TMPU), M08 Method of calculation	Molecular weight: 220.2 g/mol (61.3% parent) DT_{50} (d): 20.5 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	0.0442	0.0442	0.057	0.057
Short term				
24h	0.0427	0.0435	0.055	0.056
2d	0.0413	0.0428	0.053	0.055
4d	0.0386	0.0414	0.050	0.053
Long term				
7d	0.0349	0.0394	0.045	0.051
28d	0.0172	0.0286	0.022	0.037
50d	0.0082	0.0213	0.010	0.027
100d	0.0015	0.0126	0.002	0.016
Plateau concentration	-			

Appendix 1 – List of endpoints

EFSA note: multiple application PEC soil have been recalculated aby EFSA after a comment from a member state. Values in addendum 3 are wrong.

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	0.0315	0.0315	Not relevant due to short DT_{50}	
Short term				
24h	0.0255	0.0285		
2d	0.0207	0.0258		
4d	0.0136	0.0214		
Long term				
7d	0.0072	0.0165		
28d	0.0001	0.0054		
50d	<0.0001	0.0030		
100d	<0.0001	0.0015		
Plateau concentration	-			

Appendix 1 – List of endpoints

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 ☒ > 290 nm	Triflumuron: ϕ =0.0095 mol Einstein $^{-1}$ M01: ϕ = 0.00226
Readily biodegradable (yes/no)	No:

Appendix 1 – List of endpoints

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		

Appendix 1 – List of endpoints

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 day	Max 39.1% after 100 days	39.1% after 100 days
Von Diergardt - Sand	7.3	6.2	2.4% after 100 day	Max 32.8% after 100 days	32.8% 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 day	Max 33.3% after 100%	33.3% after 100%
Von Diergardt - Sand	7.3	6.2	25.4 after 100%	Max 15.0 after 100%	15.0 after 100%

Appendix 1 – List of endpoints

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 DT_{50} soil (d): 19.1 days (SFO 20°C, pF 2). This value is the geometric mean of 5 DT_{50}-values from lab studies calculated by notifier. The recalculated geo-mean DT_{50} is 10.9 days. DT_{50} water/sediment system (d): 6.3 (representative worst case from sediment water studies) DT_{50} water (d): 2.9 DT_{50} sediment (d): 23.9 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 (if performed)	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, Mar. - May
Main routes of entry	15.7 % drift from 3 meter 2-4% runoff/drainage (at $FOCUS_{sw}$ Step 1 and 2)

Appendix 1 – List of endpoints

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	7.36		69.36	
	24	2.30	4.83	67.95	68.65
	2d	1.02	3.24	65.01	67.57
	4d	0.893	2.03	59.49	64.89
	7d	0.586	1.45	52.09	60.96
	14d	0.430	0.975	38.20	52.88
	21d	0.315	0.773	28.01	46.20
	28d	0.231	0.648	20.54	40.67
	42d	0.124	0.490	11.05	32.21
Southern EU	0	7.36		95.86	
	24	2.30	4.83	93.70	94.78
	2d	1.02	3.24	89.64	93.23
	4d	1.20	2.07	82.04	89.51
	7d	0.808	1.57	71.83	84.08
	14d	0.593	1.13	52.67	72.92
	21d	0.435	0.926	38.62	63.71
	28d	0.319	0.788	28.32	56.09
	42d	0.171	0.605	15.23	44.43

FOCUS step 3 and 4 calculations for triflumuron

Data gap

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 DT_{50} soil (d): 4.4 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, Mar. - May
Main routes of entry	drift/runoff/drainage as indicated in $FOCUS_{sw}$ Step 2

Appendix 1 – List of endpoints

PEC_{sw} values (µg/L) and PEC_{sed} values (µg/kg dry sediment) of M08 obtained in FOCUS steps 2 calculations, considering DT_{50} water of 11.7 days (whole system) and DT_{50} sediment of 11.7 days

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	3.02	—	—	—
	1	2.72	n.a	n.a	n.a
	2	2.57	n.a	n.a	n.a
	4	2.28	n.a	n.a	n.a
	7	1.91	n.a	n.a	n.a
	14	1.26	n.a	n.a	n.a
	21	0.83	n.a	n.a	n.a
	28	0.55	n.a	n.a	n.a
	42	0.24	n.a	n.a	n.a
	50	0.15	n.a	n.a	n.a
	100	0.01	n.a	n.a	n.a
Southern EU	0	3.97	—	—	—
	1	3.62	n.a	n.a	n.a
	2	3.41	n.a	n.a	n.a
	4	3.03	n.a	n.a	n.a
	7	2.54	n.a	n.a	n.a
	14	1.68	n.a	n.a	n.a
	21	1.11	n.a	n.a	n.a
	28	0.73	n.a	n.a	n.a
	42	0.32	n.a	n.a	n.a
	50	0.20	n.a	n.a	n.a
	100	0.01	n.a	n.a	n.a

n.a. not available in addendum 3

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 (%): Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 63.6% Soil: 100%
Parameters used in FOCUSsw step 3 (if performed)	not performed

Appendix 1 – List of endpoints

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, Mar. - May
Main routes of entry	drift/runoff/drainage as indicated in $FOCUS_{sw}$ Step 2

PEC_{sw} values (µg/L) and PEC_{sed} values (µg/kg dry sediment) of M02 obtained in FOCUS steps 2 calculations, considering DT_{50} water of 62.9 days (whole system) and DT_{50} sediment of 62.9 days

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	3.32	—	—	—
	1	3.28	n.a	n.a	n.a
	2	3.24	n.a	n.a	n.a
	4	3.30	n.a	n.a	n.a
	7	3.19	n.a	n.a	n.a
	14	2.95	n.a	n.a	n.a
	21	2.74	n.a	n.a	n.a
	28	2.53	n.a	n.a	n.a
	42	2.17	n.a	n.a	n.a
	50	1.99	n.a	n.a	n.a
	100	1.15	n.a	n.a	n.a
Southern EU	0	3.43	—	—	—
	1	3.39	n.a	n.a	n.a
	2	3.35	n.a	n.a	n.a
	4	3.28	n.a	n.a	n.a
	7	3.17	n.a	n.a	n.a
	14	2.94	n.a	n.a	n.a
	21	2.72	n.a	n.a	n.a
	28	2.52	n.a	n.a	n.a
	42	2.16	n.a	n.a	n.a
	50	1.97	n.a	n.a	n.a
	100	1.14	n.a	n.a	n.a

n.a. not available in addendum 3

Appendix 1 – List of endpoints

PEC (ground water) (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 (version 1.3) Scenarios: all nine FOCUS scenarios Crop: stone and pome fruit Crop interception: 70% after 1st application and 80% after 2nd application Triflumuron DT_{50lab}: 19.1 d (regarded as worst case since the consolidated value would be lower: Notifier geometric mean parent normalised to pF2, 20°C; RMS geometric mean: 10.9 days) 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), $^1/_n$= 1.07. Metabolites: The FOCUS GW modelling considered a formation fraction of 1 M08 DT_{50lab}: 4.4 days (geometric mean from 3 lab. studies normalised to pF2, 20°C; overall geometric mean: 3.96 days) Arithmetic mean K_{OM} = 102 mL/g, $^1/_n$ = 0.78 M02 DT_{50lab}: 1.1 days (geometric mean normalised to pF2, 20°C) Worst case value K_{OM} = 0 mL/g, $^1/_n$ = 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.

Appendix 1 – List of endpoints

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

Only relevant for alakline soils, potential effect of pH on degradation rates are not considered.

	Scenario	Parent (µg/L)
Pearl /Pomefruit	Châteaudun	< 0.001
	Hamburg	< 0.001
	Jokioinen	< 0.001
	Kremsmünster	< 0.001
	Okehampton	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001

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

	Scenario	Metabolite M02 (µg/L)
Pearl /Pomefruit	Châteaudun	< 0.001
	Hamburg	0.001
	Jokioinen	0.016
	Kremsmünster	< 0.001
	Okehampton	< 0.001
	Piacenza	< 0.001
	Porto	< 0.001
	Sevilla	< 0.001
	Thiva	< 0.001

Appendix 1 – List of endpoints

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 assessement Enviromental occurring metabolite requiring further assessemtn by other disciplines (toxicology and ecotoxicology).	Soil: active substance, M08, and M02 Surface Water: active substance, M08, and M02 Ground water: 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
Ground water (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 ready biodegradable – candidate for R53

Appendix 1 – List of endpoints

Chapter 6: Effects on Non-target Species

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

Species	Test substance	Time scale	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
Bobwhite quail	a.s.	Long-term	1.65[2]	20
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 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 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[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
Insectivorous	Acute	9.73	58	10
Insectivorous	Short-term	5.43	>148.3	10
Insectivorous	Long-term	5.43	1.22	5
Higher tier refinement (Birds)				
Blue Tit	Long-term	2.5	2.7[1]	5
Tier 1 (Mammals)				
Small herbivorous	Acute	25.6	> 83	10
Small herbivorous	Long-term	6.49	21.95	5

[1] calculating using PT of 0.61 according to Crocker *et al.* (1998) and RUD of 21.9

Appendix 1 – List of endpoints

Secondary poisoning

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Earthworms eating	Long-term	0.51	12.9	5
Fish eating	Long-term	0.928	7.1	5
Tier 1 (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, LC50	> $0.0208_{(mm)}$
Pimephales promelas	a.s.	ELS 36 d (flow-through)	Growth, NOEC	≥ $0.0228_{(mm)}$
Lepomis macrochirus	SC 480	96 hr (static)	Mortality, LC50	$73_{(nom)}$
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (semi static)	Mortality, EC50	$0.0016_{(nom)}$
Daphnia magna	SC 480	48 h (semi static)	Mortality, EC50	$0.00013_{(nom)}$
Daphnia magna	SC 480	21 d (semi static)	Reproduction, NOEC	$0.000032_{(nom)}$
Daphnia magna	M 01	48 h (static)	Mortality, EC50	$>100_{(nom)}$
Daphnia magna	M 02	48 h (static)	Mortality, EC50	$>100_{(nom)}$
Daphnia magna	M 08	48 h (static)	Mortality, EC50	$3.4_{(nom)}$
Sediment dwelling organisms				
Chironomus riparius	a.s.	28 d (static)	EC15	$0.00032_{(nom)}$
Chironomus riparius	M 01	28 d (static)	EC15	> $100_{(nom)}$
Chironomus riparius	M 02	28 d (static)	EC15	> $100_{(nom)}$
Chironomus riparius	M 08	28 d (static)	EC15	$15.6_{(nom)}$
Algae				
Scenedesmus subspicatus.	a.s.	72 h (static)	Biomass: EbC50 Growth rate: ErC50	> $0.025_{(nom)}$ > $0.025_{(nom)}$
Scenedesmus subspicatus..	SC 480	72 h (static)	Biomass: EbC50 Growth rate: ErC50	$157_{(mm)}$ > $179_{(mm)}$
Microcosm or mesocosm tests NOEAEC= 0.1 µg a.s./L $_{(nom)}$				

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

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

Refined aquatic risk assessment using higher tier FOCUS modeling.

Appendix 1 – List of endpoints

FOCUS Step 4

Orchards, 0.18 kg a.s./ha

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg ai/L)	Buffer zone distance	PEC_{sw} (maximum)*	TER	Annex VI trigger
D3	ditch	fish	acute	>20.8	30	0.227	91.630	100
		fish	chronic	>22.8			100.441	10
		daphnids	acute	0.13			0.573	100
		daphnids	chronic	0.032			0.141	10
		algae	acute	>25			110.132	10
D4	pond	fish	acute	>20.8	30	0.036	577.778	100
		fish	chronic	>22.8			633.333	10
		daphnids	acute	0.13			3.611	100
		daphnids	chronic	0.032			0.889	10
		algae	acute	>25			694.444	10
D4	stream	fish	acute	>20.8	30	0.264	78.788	100
		fish	chronic	>22.8			86.364	10
		daphnids	acute	0.13			0.492	100
		daphnids	chronic	0.032			0.121	10
		algae	acute	>25			94.697	10
D5	pond	fish	acute	>20.8	30	0.036	577.778	100
		fish	chronic	>22.8			633.333	10
		daphnids	acute	0.13			3.611	100
		daphnids	chronic	0.032			0.889	10
		algae	acute	>25			694.444	10
D5	stream	fish	acute	>20.8	30	0.285	72.982	100
		fish	chronic	>22.8			80.000	10
		daphnids	acute	0.13			0.456	100
		daphnids	chronic	0.032			0.112	10
		algae	acute	>25			87.719	10
R1	pond	fish	acute	>20.8	30	0.036	577.778	100
		fish	chronic	>22.8			633.333	10
		daphnids	acute	0.13			3.611	100
		daphnids	chronic	0.032			0.889	10
		algae	acute	>25			694.444	10
R1	stream	fish	acute	>20.8	30	0.202	102.970	100
		fish	chronic	>22.8			112.871	10
		daphnids	acute	0.13			0.644	100
		daphnids	chronic	0.032			0.158	10
		algae	acute	>25			123.762	10
R2	stream	fish	acute	>20.8	30	0.270	77.037	100
		fish	chronic	>22.8			84.444	10
		daphnids	acute	0.13			0.481	100
		daphnids	chronic	0.032			0.119	10
		algae	acute	>25			92.593	10

Appendix 1 – List of endpoints

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg ai/L)	Buffer zone distance	PEC_{sw} (maximum)*	TER	Annex VI trigger
R3	stream	fish	acute	>20.8	30	0.351	59.259	100
		fish	chronic	>22.8			64.957	10
		daphnids	acute	0.13			0.370	100
		daphnids	chronic	0.032			0.091	10
		algae	acute	>25			71.225	10
R4	stream	fish	acute	>20.8	30	0.252	82.540	100
		fish	chronic	>22.8			90.476	10
		daphnids	acute	0.13			0.516	100
		daphnids	chronic	0.032			0.127	10
		algae	acute	>25			99.206	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
*PEC values are only indicative and do not necessarily represent a worst case.

Appendix 1 – List of endpoints

FOCUS Step 4

Orchards, 0.18 kg a.s./ha

Scenario[1]	Water body type	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	Buffer zone distance	PEC* (maximum) (µg a.s./L)	TER	Annex VI trigger
D3	ditch	mesocosm	112 d	0.1	30	0.227	0.44	3
D4	pond	mesocosm	112 d	0.1	30	0.036	2.78	3
D4	stream	mesocosm	112 d	0.1	30	0.264	0.38	3
D5	pond	mesocosm	112 d	0.1	30	0.036	2.78	3
D5	stream	mesocosm	112 d	0.1	30	0.285	0.35	3
R1	pond	mesocosm	112 d	0.1	30	0.036	2.78	3
R1	stream	mesocosm	112 d	0.1	30	0.202	0.50	3
R2	stream	mesocosm	112 d	0.1	30	0.270	0.38	3
R3	stream	mesocosm	112 d	0.1	30	0.351	0.28	3
R4	stream	mesocosm	112 d	0.1	30	0.252	0.40	3

[1] drainage (D1-D6) and run-off (R1-R4)
*PEC values are only indicative and do not necessarily represent a worst case.

Metabolites, FOCUS step2 PECsw

Meatbolite	**Test organism[3]**	**Time scale**	**Toxicity endpoint (mg ai/L)**	**PEC_{sw} (maximum) µg/L**	**TER**	**Annex VI trigger**
M02	daphnids	acute	>100	4.1	24390	100
M08	daphnids	acute	15.6	4.96	3145	100

No TER calculation was conducted for M01 since it was regarded as a minor metabolite.

Bioconcentration				
	Active substance	**M 01**	**M 02**	**M 08**
logPow	4.9	0.64	1.98	1.48
Bioconcentration factor (BCF)[1]	612*			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	1.36			
(CT_{90})	3			
Level and nature of residues (%) in organisms after the 14 day depuration phase	negligible			

[1] only required if log Pow >3.
* based on total ^{14}C or on specific compounds

Appendix 1 – List of endpoints

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.i./L test solution. At 7.5 mg a.i./L young bees showed deformations of legs and wings and co-ordination problems, however no behavioural differences were observed at 41.7 mg a.i./L.

Bees Semi field and Field study

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

Two field tests were performed with Triflumuron SC 480 at concentrations of 28.7 g a.i./ha and 48 g a.i./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.i./ha and no effects on mortality, flight intensity or bee brood development were observed, at 54.0 g a.i./ha an effect on bee broad 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

Appendix 1 – List of endpoints

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 $_{\text{In-field}}$ and HQ $_{\text{Off-field}}$, Exposure for parasitoids, predatory mites and foliage dwelling predators

Indicator species	HQ In-field	HQ Off-field
Typhlodromus pyri	0.4	0.10
Aphidius rhopalosiphi	0.5	0.12

Appendix 1 – List of endpoints

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	corr. 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	corr. 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	corr. pre-imaginal mortality	Treated leaves: 100 % Feed: 94% Leaves+feed: 100%	50%

Appendix 1 – List of endpoints

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	Endpoint	% adverse effect	Trigger value
Chrysoperla carnea Steph. IIIA, 10.5.1/ 12		SC 480 Aged residue test, potted apple trees 2 applications (306 g a.i./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.i./ha, 5.421 g a.i./ha, 9.903 g a.i./ha, 21.68 g a.i./ha and 38.61 g a.i./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.i./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 NTA 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	$LC50^1$ > 500 mg a.s./kg d.w.soil
Eisenia foetida	SC 480	Acute 14 days	$LC50^1_{corr}$ > 242.5 mg a.s./kg d.w.soil
	M 02	Acute 14 days	LC50 > 1000 mg p.m./kg d.w.soil
	M 08	Acute 14 days	LC50 562.1 mg p.m./kg d.w.soil

Appendix 1 – List of endpoints

Test organism	Test substance	Time scale	Endpoint
Other soil macro-organisms			
Collembola			
Folsomia candida	M 02	28 d reproduction	NOEC ≥ 100 mg p.m./kg d.w.soil
Folsomia candida	M 08	28 d reproduction	NOEC 31.6 mg p.m./kg d.w.soil
Soil micro-organisms			
Nitrogen mineralisation	a.s.	28 d	14% effect at day 28 at 0.33 mg a.s./kg d.w.soil 25% effect at day 28 at 3.3 mg a.s./kg d.w.soil
	M 02	28 d	No influence at 0.39 mg p.m./kg d.w.soil
	M 08	28 d	No influence at 0.55 mg p.m./kg d.w.soil
Carbon mineralisation	a.s.	28 d	No negative influence at 0.33 and 3.33 mg a.s./kg d.w.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	0.124 mg a.s./kg d.w soil (initial)	> 2016	10
Eisenia foetida	SC 480	Acute	0.124 mg a.s./kg d.w soil (initial)	> 1956	10
Eisenia foetida	M 02	Acute	0.0315 mg./kg d.w soil (initial)	> 31746	10
Eisenia foetida	M 08	Acute	0.057 mg/kg d.w soil (initial)	9861	10
Collembola					
Folsomia candida	M 02	28 d	0.0315 mg./kg d.w soil (initial)	≥ 3174	5
Folsomia candida	M 08	28 d	0.057 mg/kg d.w soil (initial)	543	5

Appendix 1 – List of endpoints

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.

Residues definition (consider all relevant metabolites requiring further assessment from the fate section)

Compartment	Ecotoxicologically relevant residue
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/EPCO proposal	ECB decision
Active substance	R50/R53 N	
Preparation	R50/R53 N	

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

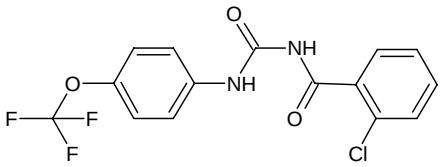
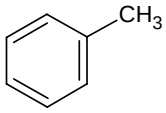
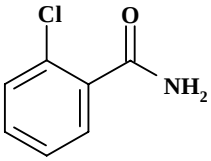
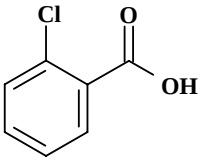
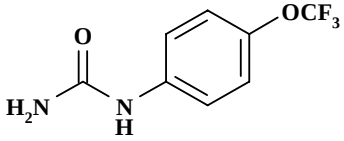
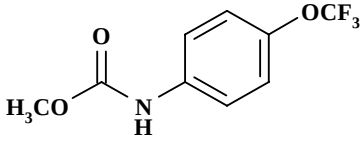
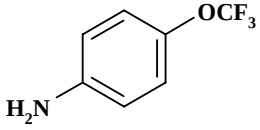
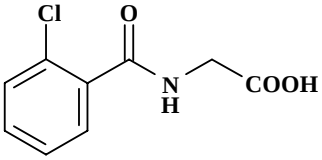
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
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
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
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)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre

Appendix 2 – abbreviations used in the list of endpoints

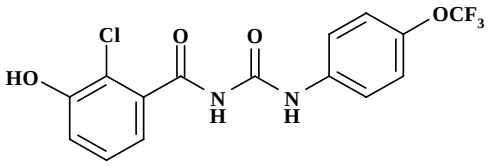
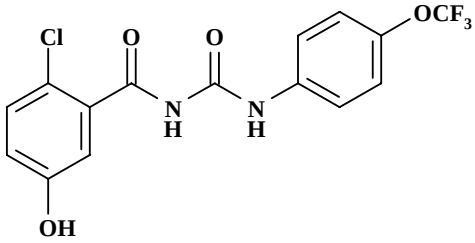
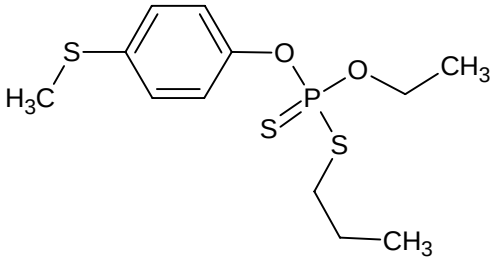
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
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 ground water
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
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
yr	year

Appendix 3 – used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
-	*N,N'*-bis[4-(trifluoromethoxy)phenyl]urea	
-	Toluene	
M01	2-chlorobenzamide	
M02	2-chlorobenzoic acid 2-CBA	
M08	4-trifluoromethoxyphenyl urea TMPU	
M25	4-trifluoromethoxyphenyl carbamate	
M07	4-trifluoromethoxyaniline	
M03	2- chlorohippuric acid	

Appendix 3 – used compound code(s)

M04	SIR 8514-3-hydroxy-2-chlorophenyl acid	
M05	SIR 8514-5-hydroxy-2-chlorophenyl acid	
SIR 8514-3-hydroxy-2-chlorophenyl conjugate (M22)		See structure M04
SIR 8514-3-hydroxy-2-chlorophenyl conjugate (M23)		See structure M05
Sulprofos	*(RS)-O*-ethyl *O*-[4-(methylsulfanyl)phenyl] *S*-propyl phosphorodithioate	
FCR 1272 Cyfluthrin	(RS)-α-cyano-4-fluoro-3-phenoxybenzyl (1*RS*,3*RS*;1*RS*,3*SR*)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate