

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of the active substance triflurosulfuron (considered variant triflurosulfuron-methyl)

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SUMMARY

Triflurosulfuron is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002¹. 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.

France being the designated rapporteur Member State submitted the DAR on triflurosulfuron in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 26 July 2007. The peer review was initiated on 31 August 2007 by dispatching the DAR for consultation of the Member States and the sole applicant Du Pont de Nemours. 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 the 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 May – June 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.

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide on sugar and fodder beet for the control of annual grasses and broad-leaved weeds as proposed by the applicant. Full details of the GAP can be found in the attached list of endpoints.

The representative formulated product for the evaluation was ‘Triflurosulfuron-methyl 50WG’, a water-dispersible granule (WG) containing 500 g/kg of triflurosulfuron-methyl.

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)

Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently be regarded as provisional (September 2008).

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product is possible.

Adequate methods are available to monitor all compounds in the respective residue definitions for monitoring food/feed of plant origin, soil surface water and air, however an analytical method is needed for monitoring metabolites in groundwater.

As for mammalian toxicology, triflurosulfuron-methyl has low acute toxicity via the oral, dermal, or inhalation routes; it is not an eye or skin irritant, nor a skin sensitiser. In repeated dose studies triflurosulfuron-methyl caused decreased body weight gain, food intake and food efficiency, as well as increased liver enzymes and anaemia. The relevant short and long-term No Observed Adverse Effect Levels (NOAELs) are 6.6 mg/kg bw/day and 4.06 mg/kg bw/day, respectively. The weight of evidence from the complete battery of genetic toxicology studies indicates that triflurosulfuron-methyl does not have genotoxic potential. In carcinogenicity tests male rats showed increased incidence of Leydig cell adenomas likely due to an aromatase inhibition mechanism, therefore the compound was proposed for classification as a category 3 carcinogen (**Xn, R40 “Limited evidence of a carcinogenic effect”**). The increase in hepatocellular adenoma in male mice was considered not relevant to human risk assessment. Triflurosulfuron-methyl is not a reproductive toxicant: the reproductive NOAEL is ≥ 89.5 mg/kg bw/day, whereas the maternal and offspring NOAEL is 5.8 mg/kg bw/day based on decreased body weight in parental rats and pups. In developmental toxicity studies in rats, both the maternal and foetal NOAELs are 120 mg/kg bw/day. In rabbits, triflurosulfuron-methyl did not show any teratogenic potential, with the developmental NOAEL ≥ 800 mg/kg bw/day and the maternal NOAEL of 15 mg/kg bw/day. Triflurosulfuron-methyl did not show any neurotoxic potential. The **Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) are 0.04 mg/kg bw/day** (the ADI is based on the NOAEL from the 2-year study in rats with a Safety Factor (SF) of 100; the AOEL is based on the NOAEL from the 90-day study in rats, SF 100 and oral absorption 65%). The **Acute Reference Dose (ARfD) is 1.2 mg/kg bw** based on the NOAEL for maternal body weight loss in the rat developmental study and a SF of 100. The estimated operator, worker and bystander exposure are below the AOEL.

Metabolism of triflurosulfuron-methyl in primary crops was investigated in a sugar beet metabolism study, the results of which showed the only relevant residues at harvest are the metabolites IN-

M7222² and IN-E7710³. Triflurosulfuron-methyl had decreased to <0.01 mg/kg by day 14. The residue definition for risk assessment was therefore set as IN-M7222 and IN-E7710. The residue definition for monitoring is IN-M7222. A confined rotational crop study was conducted, which showed that the only significant residues were the same as those seen in primary crops and this was confirmed by a radiolabelled field study. It was considered by the meeting of experts that the cold rotational crop study was not sufficient to fully quantify residues in rotational crops and a data gap was identified. Sufficient residues data were available for the representative crop sugar beet and it was demonstrated that residues are stable under freezer storage for a period of 12 months. Processing studies are not required as residues are low. In goat metabolism studies conducted at circa 1 and 100 N, four significant metabolites were identified. From this data the meeting of experts appeared to conclude that the residue definition for monitoring and risk assessment should be IN-M7222. However, there is no justification for this in the report of the meeting. The risk assessment can not be conducted as there are no applicable toxicological endpoints available.

Triflurosulfuron-methyl exhibits low to moderate persistence in soil under dark aerobic conditions at 20 °C ($DT_{50 \text{ lab aerobic}} = 5.3 - 15 \text{ d}$). Triflurosulfuron-methyl degrades by cleavage of the sulfonylurea bridge and subsequent cyclisation to yield the two major metabolites methyl saccharin (IN-W6725⁴; $DT_{50} = 13 - 403 \text{ d}$) and triazine amine (IN-D8526⁵; $DT_{50} = 74 - 664 \text{ d}$). Triazine amine is subsequently demethylated to *N*-desmethyl triazine amine (IN-E7710; $DT_{50} = 30 - 393 \text{ d}$) and *N,N*-bis-desmethyl triazine amine (IN-M7222; $DT_{50} = 80 - 486 \text{ d}$). Unextractable radioactivity reached a maximum of 65 % AR after 368 d with triazine labelled compound and a maximum of 48.8 % AR after 90 d with ester carbonyl labelled compound. Mineralization was negligible for the triazine moiety and significant for the ester carbonyl moiety. The meeting of experts agreed that dark aerobic degradation in soil of the metabolites triazine amine (IN-D8526) and *N,N*-bis-desmethyl triazine amine (IN-M7222) show pH dependence.

Under dark anaerobic conditions, degradation of triflurosulfuron-methyl ($DT_{50 \text{ anaerobic}} = 21 \text{ d}$) yields the metabolites methyl saccharin and triazine amine at levels above 10 % AR.

The meeting of experts considered that overall, photolysis will not represent a significant role in the degradation of triflurosulfuron-methyl in soil.

² IN-M7222: *N,N*-bis-desmethyl triazine amine; 6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

³ IN-E7710: *N*-desmethyl triazine amine; *N*-methyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

⁴ IN-W6725: methyl saccharin; 7-methyl-1,2-benzisothiazol-3(2*H*)-one 1,1-dioxide

⁵ IN-D8526: triazine amine; *N,N*-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

Two field studies are available, which were carried out in Northern EU (Colonne and Munich, DE). The aerobic soil metabolites identified in the laboratory studies were also found in the field studies at comparable amounts.

PEC_{soil} were calculated for triflusaluron-methyl and all major aerobic soil metabolites by the rapporteur Member State, based on worst case laboratory DT₅₀ values and the maximum levels formed in the laboratory soil studies, as updated in corrigendum 1.

From the available studies, triflusaluron-methyl may be considered to exhibit high to very high mobility ($K_{foc} = 25 - 52$ mL/g); triazine amine (IN-D8526) medium to high mobility ($K_{foc} = 70 - 374$ mL/g); *N*-desmethyl triazine amine (IN-E7710) medium to very high mobility ($K_{foc} = 41 - 181$ mL/g); *N,N*-bis-desmethyl triazine amine (IN-M7222) high to very high mobility ($K_{foc} = 31 - 127$ mL/g) and methyl saccharin (IN-W6725) very high mobility ($K_{foc} = 6 - 22$ mL/g).

Hydrolysis half-lives for triflusaluron-methyl were DT₅₀ = 3.7 d (pH 5), DT₅₀ = 32 d (pH 7) and DT₅₀ = 36 d (pH 9). The meeting of experts confirmed that photodegradation of triflusaluron-methyl is not expected to play a significant role in the aquatic environment. Triflusaluron-methyl is not readily biodegradable according the available study.

In water / sediment aquatic systems, triflusaluron-methyl partitions to the sediment (max. 22 % AR) and degrades (DT_{50 whole system} = 21 – 39 d) to methyl saccharin (IN-W6725; max. 38.4 % AR in water and 12 % AR in sediment after 100 d) and triazine-amine (IN-D8526; max. 23.2 % AR in water and 18.9 % AR sediment after 61 d) that subsequently degrades to *N*-desmethyl triazine amine (IN-E7710; max. 10.7 % AR in water after 61 d). By an alternative pathway, triflusaluron is formed (JK-555⁶; max. 28.6 % AR in water after 100 d and 19.7 % AR in sediment after 61 d). The meeting of experts agreed that a water sediment study with pH within the acidic range (pH 5 - 6.5) would be needed but this was considered to be not essential to finalise the risk assessment at the EU level. The rapporteur Member State produced new PEC_{SW} using FOCUS up to step 3 for the parent triflusaluron-methyl and up to step 2 for the metabolites that were agreed by the meeting of experts for the EU risk assessment.

Potential ground water contamination was addressed by FOCUS GW modelling.

The meeting of experts agreed on the modelling performed by the rapporteur Member State and summarized in corrigendum 1. Effect of soil pH was considered in the calculations performed by the rapporteur Member State. For the representative use of triflusaluron-methyl in sugar beet every three

⁶ JK-555: triflusaluron; 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbonylsulfamoyl]-m-toluic acid

years, triflurosulfuron-methyl did not exceed the trigger of 0.1 µg/L for any of the scenarios irrespective of the pH. The metabolites triazine amine (IN-D8526) and *N*-desmethyl triazine amine (IN-E7710) exceeded the trigger of 0.1 µg/L for one of the six scenarios modelled (Piacenza) under acidic soil conditions. The metabolite *N,N*-bis-desmethyl triazine amine (IN-M7222) exceeded the trigger of 0.1 µg/L in the six scenarios simulated under acidic soils and in the five scenarios under alkaline soils. Additionally, the trigger of 0.75 µg/L was exceeded for metabolite IN-M7222 in four of the five scenarios with alkaline soils. Degradation of the metabolite methyl saccharin (IN-W6725) is not pH dependent and PEC_{GW} were calculated in a separate simulation. The metabolite methyl saccharin (IN-W6725) exceeded the trigger of 0.1 µg/L in all nine FOCUS GW scenarios and exceeded the trigger of 0.75 µg/L in eight of the scenarios.

Triflurosulfuron-methyl is not expected to volatilize or be prone to long-range transport in the atmosphere.

Triflurosulfuron-methyl is very toxic to algae and higher aquatic plants. The TERs were >10 in two full FOCUS step 3 scenarios (D3, D4) and in the part scenario R1 (pond). The TERs were below the trigger in scenario R3 and the part scenario R1 (stream). Risk mitigation measures and/or a refined aquatic risk assessment is needed in Member States where environmental conditions prevail which are represented by FOCUS scenarios R1 (stream) and R3 (stream).

Non-target plants were more sensitive when technical triflurosulfuron-methyl was applied together with the surfactant X-77. The lower endpoints observed for technical triflurosulfuron-methyl plus X-77 were considered as not being of relevance for the applied for representative use of the formulation 'Triflurosulfuron-methyl 50WG'. The increased toxicity of technical triflurosulfuron-methyl when combined with a surfactant should be considered by Member States in their national registration, if appropriate.

The TERs were 9.4 and 21.5 for the endpoints derived for the formulation with and without surfactant, indicating a low risk to non-target plants in the off-field area.

The risk to birds and mammals, bees, non-target arthropods, soil macro- and soil micro-organisms and biological methods of sewage treatment was assessed as low.

Key words: triflurosulfuron, triflurosulfuron-methyl, peer review, risk assessment, pesticide, herbicide.

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stage of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Triflurosulfuron is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating France as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, France submitted the report of its initial evaluation of the dossier on triflurosulfuron, hereafter referred to as the draft assessment report, received by the EFSA on 26 July 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 31 August 2008 to the Member States and the sole applicant Du Pont de Nemours 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, the EFSA identified and agreed on lacking information to be addressed by the applicant as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the applicant, a scientific discussion took place in experts' meetings in May – June 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 endpoints 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 (revision number 1-1; 12 February 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 (revision 2-1; 29 September 2008).

Given the importance of the draft assessment report including its addendum (compiled version of July 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

Triflurosulfuron is the ISO common name for 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-*m*-toluic acid (IUPAC).

However the data submitted in the dossier relate to the variant triflurosulfuron-methyl, which is methyl 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-*m*-toluate

Triflurosulfuron belongs to the class of triazinylsulfonyleurea herbicides. Triflurosulfuron acts through inhibition of the enzyme acetolactate synthase (ALS) involved in the synthesis of branched-chain amino acids, leading to the cessation of cell division and subsequent growth processes in plants. Triflurosulfuron is primarily adsorbed through the leaves. Triflurosulfuron is used in sugar and fodder beet for the control of annual grasses and broad-leaved weeds.

The representative formulated product for the evaluation was 'Triflurosulfuron-methyl 50WG', a water-dispersible granule (WG) containing 500 g/kg of triflurosulfuron-methyl, registered under different trade names in Europe.

The representative uses evaluated comprise post emergence applications with conventional tractor-mounted spraying devices to control annual grasses and broad-leaved weeds (*Aethusa cynapium*, *Amaranthus retroflexus*, *Brassica napus*, *Galium aparine*, *Lamium purpureum*, *Matricaria sp.*, *Mercurialis annua*, *Polygonum sp.*, *Sinapis arvensis*, *Urtica urens*, *Viola arvensis*) in sugar and fodder

beets, up to growth stage BBCH 39, up to a maximum of four treatments per year, with application rates of maximum 20 g a.s./ha in Northern Europe and up to maximum three treatments per year, with application rates of maximum 30 g a.s./ha in Southern Europe, at a maximum total active substance rate per season of 60 g a.s./ha, with an interval between applications of 7 days.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of triflurosulfuron-methyl is 960 g/kg. No FAO specifications exist.

The applicant was requested to provide a new technical specification based on the five batch analysis for the supported source, or a justification for the levels proposed. The new specification was evaluated in a revised volume 4 (April 2008) of the DAR. The proposed values for some impurities were not acceptable to the meeting PRAPeR 46 (May 2008). Based on the available data, the meeting considered it more appropriate to lower the values for some impurities and to remove some values from the specification. Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently be regarded as provisional (September 2008). New batch analytical data were submitted to the rapporteur Member State, 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, the new studies could not be considered in the peer review.

Experts at the PRAPeR 49 meeting (June 2008) considered the proposed specification adequately covered by the toxicological batches tested. Impurity IN-D8526⁷ (triazine amine), which is more acutely toxic than the parent and considered a relevant groundwater metabolite, is also considered a relevant impurity in the technical material. Consequently the following data gaps were identified by EFSA after the expert meetings:

- spectra for the relevant impurity in the technical material;
- to address the possible formation of the relevant impurity during storage.

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 triflurosulfuron-methyl or the respective formulations. However, the following data gaps were identified:

- a GLP study for the determination of the vapour pressure;
- a new calculation for Henry's law constant based on the vapour pressure.

⁷ IN-D8526: triazine amine; *N,N*-dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

The main data regarding the identity of triflurosulfuron-methyl and its physical and chemical properties are given in appendix 1.

Adequate analytical methods based on HPLC-UV (254 nm) are available for the determination of triflurosulfuron-methyl in the technical material and in the representative formulations as well as for the determination of the respective impurities in the technical material (HPLC-UV and GC-FID).

Sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that quality control measurements of the plant protection product are possible.

The meeting PRAPeR 50 (June 2008) set the metabolite IN-M7222⁸ as the residue definition for monitoring in plants. Metabolites IN-D8526, IN-E7710⁹, IN-M7222 and IN-W6725¹⁰ were set as the residue definition for monitoring drinking and ground water (see sections 2 and 4).

Adequate methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin, soil, surface water and air.

An LC-MS/MS analytical method is available to monitor residues of metabolite IN-M7222 in plant matrices (sugar beet foliage and roots) with LOQ of 0.01 mg/kg. The applicability of a multi-residue method was not tested.

Adequate HPLC-MS/MS methods are available to monitor residues of triflurosulfuron-methyl and metabolites in soil with LOQs of 0.05 µg/kg and 0.2 µg/kg respectively.

An HPLC-MS/MS method is available to monitor triflurosulfuron-methyl in water (drinking water, surface water) with LOQ of 0.05 µg/L, however after the expert meetings a data gap was set for a monitoring method for the metabolites in ground water.

Residues of triflurosulfuron-methyl in air can be determined by a HPLC-UV method with LOQ of 1.2 µg/m³.

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

⁸ IN-M7222: *N,N*-bis-desmethyl triazine amine; 6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

⁹ IN-E7710: *N*-desmethyl triazine amine; *N*-methyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine

¹⁰ IN-W6725: methyl saccharin; 7-methyl-1,2-benzisothiazol-3(2*H*)-one 1,1-dioxide

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

2. Mammalian toxicology

Triflusaluron-methyl was discussed in the PRAPeR 49 meeting of experts in June 2008.

The meeting discussed the level of impurities presented in the updated specification (physical-chemical properties meeting 46) and concluded that this is not of toxicological concern and was adequately covered by the batches tested for mammalian toxicity tests.

EFSA note: the assessment summarised in this section is based only on toxicological studies performed with the variant triflusaluron-methyl. The toxicological profile of different variants might be different, and bridging information could be needed to perform the risk assessment.

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Following oral administration in rats, triflusaluron-methyl is rapidly absorbed and excreted in urine and faeces. In the experts' meeting it was noted that a bile cannulated rat study was not available, however it seemed that at least the oxidized metabolites occurring in faeces could be regarded as having been absorbed. It was agreed to use only the amount in urine and carcass to derive the absorbed dose: 65% in males and 80% in females. Triflusaluron-methyl is extensively metabolised, especially when administered at low doses in the rat. The major biotransformation pathways for triflusaluron-methyl were hydroxylation/demethylation of the triazine ring and cleavage of the sulphonylurea bridge.

2.2. ACUTE TOXICITY

Triflusaluron-methyl has low acute toxicity via the oral, dermal, or inhalation routes; it is not an eye or skin irritant, nor a skin sensitiser.

2.3. SHORT TERM TOXICITY

The short-term toxicity of triflusaluron-methyl was evaluated in rats (90-day), mice (90-day), dogs (90-day and 1-year) and rabbits (21-day), after oral or dermal (rabbits) exposure. Triflusaluron-methyl caused a decrease in body weight gain, food intake and food efficiency, as well as increased liver enzymes and anaemia when administered to rats and dogs. Mice were less sensitive than rats or dogs as effects were limited to the liver. Liver weight was increased in all species, without any histological modification in rats, with centrilobular hypertrophy in mice and with elevated blood enzymes in dogs. Testicular atrophy/degeneration accompanied by oligospermia and thickness of

semiferous tubules was observed in one 90-day rat study and in the 90-day dog study. These findings were not confirmed in a second 90-day rat study and in the 1-year dog study. The relevant short-term NOAEL is 6.6 mg/kg bw/day from the rat studies. Triflusaluron-methyl was not toxic by the dermal route in the rabbits at doses up to 1000 mg/kg bw/day.

2.4. GENOTOXICITY

The weight of evidence from the complete battery of *in vitro* and *in vivo* genetic toxicology studies conducted with triflusaluron-methyl indicates no genotoxic potential.

2.5. LONG TERM TOXICITY

The long-term toxicity and carcinogenicity of triflusaluron-methyl were evaluated in rats and mice.

The NOAEL for triflusaluron-methyl in a long-term feeding study in rats was 4.06 mg/kg bw/day (100 ppm) based on decreases in body weight, food consumption and circulating erythrocyte mass and increased incidences of Leydig cell hyperplasia and adenomas in groups fed at 750 or 1500 ppm.

Male rats showed increased incidence of Leydig cell adenomas at dietary concentrations of 750 ppm and above. Mechanistic studies suggested that triflusaluron-methyl is a weak aromatase inhibitor *in vitro* via a type II binding to cytochrome P450. This mechanism was considered relevant to humans and therefore the compound was proposed for classification as a category 3 carcinogen (**Xn, R40** “**Limited evidence of a carcinogenic effect**”).

In the mouse, the NOAEL for triflusaluron-methyl was 150 ppm (20.9 mg/kg bw/day and 27.7 mg/kg bw/day in males and in females respectively), based on the decreases in mean body weight gain and increased liver weights at the next higher dose. The increase in hepatocellular adenoma at 2500 and 7000 ppm was not considered relevant for human risk assessment as the occurrence of hepatic tumours was predominantly benign and the overall tumour incidence (of any type) was not increased when compared to the control; in addition, triflusaluron-methyl was negative for genotoxic potential and did not induce hepatic tumour formation in rats.

2.6. REPRODUCTIVE TOXICITY

The reproductive and developmental toxicity of triflusaluron-methyl was evaluated in rats and rabbits.

No adverse effects on reproduction were observed in a two-generation study in rats. The reproductive NOAEL for triflusaluron-methyl is ≥ 89.5 mg/kg bw/day, whereas the maternal and offspring NOAEL is 5.8 mg/kg bw/day based on decreases in body weight in parental rats and pups.

Developmental toxicity studies were conducted with triflusaluron-methyl in rats and rabbits.

In the developmental study in rabbits, triflusaluron-methyl did not show any teratogenic potential, with the developmental NOAEL ≥ 800 mg/kg bw/day and the maternal NOAEL of 15 mg/kg bw/day based on decreased body weight. In rats, both the maternal and foetal NOAEL are 120 mg/kg bw/day. The maternal NOAEL was based on body weight effects; the foetal NOAEL was based on a slight increase in the mean percent of foetuses per litter with variations (likely secondary to maternal toxicity noted in early gestation).

2.7. NEUROTOXICITY

Acute and subchronic neurotoxicity studies were conducted in rats with triflusaluron-methyl, showing NOAELs of 2000 mg/kg bw and 186.2 mg/kg bw/day, respectively. In both studies, no clinical or morphological evidence of neurotoxicity was present in male or female rats at any dose tested.

2.8. FURTHER STUDIES

Three metabolites of triflusaluron-methyl (IN-D8526, IN-E7710, and IN-M7222) were investigated for acute oral toxicity (determination of the Approximate Lethal Dose, ALD) and mutagenic potential (Ames test). IN-M7222 was further investigated in the CHO/HGPRT test and in an *in vitro* chromosomal aberration test using human lymphocytes. All these metabolites did not show any genotoxic potential. IN-D8526 and IN-E7710 had an ALD of 670 mg/kg bw and IN-M7222 of 450 mg/kg bw. Metabolite IN-W6725 (methyl saccharin) was investigated for its mutagenic potential in *in vitro* (bacterial and mammalian mutagenicity tests) and *in vivo* (mouse micronucleus test) assays, and showed negative results.

Metabolites IN-D8526, IN-E7710, IN-M7222 and IN-W6725 exceed the trigger of 0.1 $\mu\text{g/L}$ in ground water. Metabolite IN-W6725 also exceeds 0.75 $\mu\text{g/L}$. IN-M7222 also exceeds 0.75 $\mu\text{g/L}$ in alkaline soils. Relevance of these metabolites was discussed in the meeting of experts.

The meeting agreed on the proposed classification as **R40** “**Limited evidence of a carcinogenic effect**” (category 3 carcinogen). Should the proposed classification of the parent triflusaluron-methyl as **R40** category 3 carcinogen be confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC, this would, in line with the guidance document on groundwater metabolites, require that for those metabolites with the potential to contaminate groundwater, convincing evidence must be provided that the metabolites will not lead to the risk of carcinogenicity. Metabolite IN-W6725 gave negative genotoxicity test results, did not show any potential for aromatase inhibition and was negative for herbicidal activity. Given

what is known about saccharin, it was proposed to use the same maximum allowable concentration (MAC; 1.2 mg/l) as for the parent triflusaluron-methyl to perform a risk assessment.

It was noted that IN-M7222 is present in the rat metabolism (<10%), is negative in an *in vitro* test for aromatase inhibition and did not show herbicidal activity. However, it showed higher acute toxicity than triflusaluron-methyl. Metabolites IN-D8526 and IN-E7710 are more acutely toxic than the parent.

In conclusion IN-M7222, IN-D8526 and IN-E7710 should be regarded as relevant groundwater metabolites (it should be noted that IN-D8526 is also a relevant impurity based on its toxicological profile). For IN-M7222 and IN-E7710, the meeting concluded that the limited toxicological database did not allow setting specific reference values.

EFSA note after PRAPeR 49: It is noted that metabolites IN-M7222, IN-D8526 and IN-E7710 are structurally similar to 2-amino-4-methoxy-6-(trifluoromethyl)-1,3,5-triazine (AMTT), a metabolite and an impurity of tritosulfuron¹¹. In December 2007 the EFSA PPR Panel prepared an opinion on metabolite TBSA¹² of tritosulfuron. In the same opinion it is mentioned that a content of AMTT in the technical specification of 2.45% was shown to cause severe effects in long-term studies in rats: neoplastic lesions were found in the mammary glands; non-neoplastic lesions consisted of effects on the testes (degeneration of the germinal epithelium, sperm stasis, focal calcification of seminiferous tubules), the uterus and the mammary gland (diffuse hyperplasia), and increased haematopoiesis in the bone marrow at 3500 ppm tritosulfuron). Furthermore, in a 2-generation reproductive study in rats, there were multiple effects including increased pup mortality in the absence of maternal toxicity and an increase in the number of stillborn pups. Member States might consider this opinion in assessing the toxicological potential of metabolites, if required.

2.9. MEDICAL DATA

No illnesses have been attributed to exposure associated with the handling, testing, or manufacturing of triflusaluron-methyl in US or European plants. There have been no reported accidental poisonings with triflusaluron-methyl and there are no known specific human effects.

¹¹ tritosulfuron: 1-[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]-3-[2-(trifluoromethyl)benzenesulfonyl]urea

¹² TBSA: 2-(trifluoromethyl)benzenesulfonamide

2.10. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARfD)

ADI

The **ADI is 0.04 mg/kg bw/day**, based on the NOAEL of 4.06 mg/kg/day for males from the 2-year study in rat, applying a 100-fold uncertainty factor.

ARfD

During the meeting it was proposed to set an ARfD based on severe effects seen in the rabbit developmental study (i.e. abortions and mortality), but all these effects occurred at the end of the exposure period. Several malformations were found in the rat developmental study spread over several litters, also supporting the setting of an ARfD. The meeting concluded that the malformations possibly related to a single exposure were only at 1000 mg/kg bw/day and at this dose level were not directly relevant to an ARfD. Furthermore the acute toxicological profile of triflurosulfuron-methyl would not trigger setting an ARfD. However, there was a statistically significant reduction in maternal body weight at 350 mg/kg bw/day at days 7-9 (the first 2-3 days of dosing) in the rat developmental study. Therefore, the expert concluded that an **ARfD of 1.2 mg/kg bw** is sufficient due to maternal body weight loss in the rat developmental study (NOAEL for this effect 120 mg/kg bw/day, SF 100).

AOEL

The **AOEL of 0.04 mg/kg bw/day** was based on the NOAEL of 6.6 mg/kg bw/day from the 90-day rat study, applying an SF 100 and considering an oral absorption of 65%.

2.11. DERMAL ABSORPTION

In the *in vitro* dermal penetration study a neat granular formulation was applied to human skin, therefore the experts agreed not to accept the values for the concentrate (<1%) because of the inadequate application. Exposure time in the study was only 6 hours. According to the applicant, 5 tape stripping were performed; as the amount of active substance was a pooled value from each skin sample, it was not possible to exclude the first two skin strips. The experts agreed to include the amount recovered from the 5 tape strips in the calculation of dermal absorption as a worst case. Therefore dermal absorption is 50 % for the dilution and the concentrate.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

‘Triflurosulfuron-methyl 50WG’ is a water dispersible granular formulation containing the active ingredient triflurosulfuron-methyl at 500 g/kg. It is proposed for uses in sugar and fodder beets, at application rates of 0.03 kg/ha of active substance.

During the meeting the rapporteur Member State was asked to provide a new exposure calculation for operators, workers and bystanders using the agreed values for dermal absorption and 50 ha crop treatment for the UK POEM model.

Operator

Model	Application method (crop)	Systemic exposure (mg/kg bw/day)		% of systemic AOEL	
		No PPE	PPE	No PPE	PPE
UK POEM	Field crop	0.182	0.023	455	58
German	Field crop	0.0174	0.0073	43.5	18.2

The estimated exposure levels for operators exposed to triflurosulfuron-methyl for applications on field crops are below the AOEL for both UK POEM (with the use of gloves during mixing/loading and application) and German model (even without PPE).

EFSA note: during the commenting phase of the draft conclusion, the UK stated that the current version of the UK POEM has amended inhalation values for WG formulations (M/L for boom sprayers). Although lower estimates are obtained, the PPE requirements are the same.

Worker

Re-entry exposure might occur as a worst case for crop inspection activities. Assuming a DFR of 3 µg/cm², TC of 5000 cm²/h, 0.5 hour task duration and no coverall or gloves, the absorbed dose was calculated as follows:

$$\text{DFR} \times \text{TC} \times \text{A} \times \text{R} \times \text{DA} \times 0.001 / 60 = 3 \times 5000 \times 0.03 \times 0.5 \times 0.5 \times 0.001 / 60$$

$$= 0.00187 \text{ mg/kg bw/day, which represents 4.6\% of the AOEL.}$$

The estimated exposure for crop inspection activities after treatment is below the AOEL (4.6%).

EFSA note: in line with a comment from the UK, even considering a more protective value of 2 hours for the duration of inspection activities, the predictive exposure would still be below the AOEL (18%).

Bystander

Potential dermal exposure was estimated using drift estimates based on data published by Ganzelmeier *et al.* (1995). Assuming a bystander may be within 10 meters of the spray application, the data shows that for field crops (sugar beets), the drift estimate at 10 meters is 0.3%, with the deposition reaching 0.036 mg/m². Assuming that approximately 1 m² is uncovered, the concentration of triflurosulfuron-methyl in the formulation and 50% absorption through skin, the estimated exposure would be 0.00015 mg/kg (0.37% of the AOEL).

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of ¹⁴C-triflurosulfuron-methyl in sugar beets was studied in a small-scale field plot and in a greenhouse at approximately 100 g a.s./ha, approximately twice the maximum anticipated seasonal use rate. The concentration of total radiolabel, expressed as triflurosulfuron-methyl equivalents, declined rapidly in the sugar beet plants, falling from 4 to 5 mg/kg on day 0 to approximately 0.1 mg/kg 28 days after treatment. By day 14 residues of triflurosulfuron-methyl had declined to <0.01 mg/kg. There were no significant residues of triflurosulfuron-methyl or its transformation products (<0.01 mg/kg) in mature sugar beet roots.

The principal metabolites found in plant samples/tops of ¹⁴C-carbonyl and ¹⁴C-triazine triflurosulfuron-methyl were *N*-desmethyl triazine amine (IN-E7710; <0.022 mg/kg), *N,N*-bis-desmethyl triazine amine (IN-M7222; <0.024 mg/kg), the acid sulfonamide (IN-JJ987¹³; <0.01 mg/kg) and its glucose conjugate (also <0.01 mg/kg).

The metabolic breakdown of triflurosulfuron-methyl involves cleavage of the sulfonylurea bridge that is followed by further metabolism of the initial degradation products.

From this metabolism data it is clear that triflurosulfuron-methyl will not be present at harvest as it is rapidly metabolised therefore it is not in the residue definition. The only compounds that might be present are IN-M7222 and IN-E7710. The meeting of residues experts received the message from the meeting of mammalian toxicology experts that these two metabolites are more toxic than the triflurosulfuron-methyl. On the basis of this information the residue definition for risk assessment is set as IN-M7222 and IN-E7710. The monitoring residue definition is IN-M7222 since this is a good marker compound.

¹³ IN-JJ987: 3-methyl-2-sulfamoylbenzoic acid

A total of nine residue trials were available for the south of Europe and six for the north. The reduced data set for the north is acceptable given the level of the residues. No residues of metabolites IN-M7222 or IN-E7710 were quantifiable at levels greater than 0.01 mg/kg at harvest.

The stability of IN-M7222 and IN-E7710 in a freezer storage stability study was investigated. The study demonstrated that these metabolites are stable for at least 12 months at -20 °C.

Currently processing studies are not necessary as residues are not significant. However, given that there are data gaps identified for a livestock feeding study and further rotational crop data, this requirement could change.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

A confined rotational crop study of ¹⁴C-triflusaluron-methyl was conducted using a sandy loam soil from Somersham, Cambridgeshire under laboratory conditions. The test soil was treated with either ¹⁴C-carbonyl or ¹⁴C-triazine triflusaluron-methyl. The test solutions of both radiolabeled forms were applied to the soil surface of the filled pots at a rate of 100 g a.s./ha (1.7 X). Following application, treated and control pots were maintained under laboratory conditions on a 15-hour light/9-hour dark cycle and a temperature of 16-19°C. Soils were watered at least twice weekly and weeds were uprooted and left on the soil surface. Wheat, lettuce and beetroot were planted at plant back intervals of 30, 120 and 360 days. The carbonyl labelled study resulted in no significant metabolites. In the triazine study, no significant residues were found in lettuce, but significant residues of IN-M7222 (misnamed in the DAR as IN-E7722) were present in straw (0.09-0.23mg/kg) and in beetroot foliage (0.02-0.06 mg/kg). Furthermore, significant residues of IN-E7710 were present in straw at levels of 0.07-0.26 mg/kg and in beet leaves at levels of 0.02-0.06 mg/kg.

In a rotational crop field study, triazine labelled material was applied at a rate of 50 g a.s./ha (0.8X) and 100 g a.s./ha (1.7X). Barley and broccoli were planted at plant back intervals of 120 and 180 days. A root crop was not planted as root crops do not typically follow sugar beet. At harvest, residues of IN-M7222 in straw were 0.013 and 0.129 mg/kg and in broccoli 0.037 and 0.097 mg/kg. The other metabolite found at significant levels was IN-E7710, which was present in straw at 0.013 and 0.016 mg/kg and in broccoli at <0.01 mg/kg. No significant residues were present in grain.

From the two studies presented above it can be concluded the residue definitions for rotational crops are the same as those for primary crops, namely IN-M7222 and IN-E7710 for risk assessment and IN-M7222 for monitoring.

The meeting of experts agreed that the metabolism information was acceptable and sufficient to propose the residue definition for rotational crops but it is clear that there is very limited field trial

data to accurately quantify the residues. The meeting of experts therefore concluded that further rotational crop data are identified as a data gap since the metabolism data indicate that significant residues will be found in following crops.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

In the original DAR the need for animal studies was not triggered as residues of triflurosulfuron-methyl were low. However, as the metabolites IN-M7222 and IN-E7710 are in the residue definition and there are significant residues in rotational crops the need for animal studies is triggered. Intakes are 0.14 mg/kg DM/day for both dairy and beef cattle, which exceeds the trigger of 0.1 mg/kg DM/day.

Two metabolism studies in lactating goat were submitted. In the first study the goats were dosed at a rate of 15 mg/kg DM/day circa 100 N with either triazine or carbonyl labelled triflurosulfuron-methyl. No significant metabolites were found from the carbonyl label. From the triazine label several metabolites were identified: IN-M7222 was present at 0.013 mg/kg in milk; at 0.009 mg/kg in liver and 0.014 mg/kg in kidney. The metabolite IN-E7710 was present at 0.007 mg/kg in milk and 0.007 mg/kg in liver but was not analysed for in kidney. The metabolite IN-D8526 was present at 0.015 mg/kg in milk; 0.027 mg/kg in liver and 0.016 mg/kg in kidney. IN-66036¹⁴ was present at 0.002 mg/kg in milk, 0.005 mg/kg in liver and 0.012 mg/kg in kidney. Triflurosulfuron-methyl was also present but is not of interest since livestock intakes would be of metabolites and not of triflurosulfuron-methyl.

In the second study, goats were dosed with the same material as the first study but at circa 1N. The metabolites identified were the same as in the first study and will not be discussed further.

The main issue with these studies is that animals had been dosed with triflurosulfuron-methyl whereas livestock would not be exposed to this compound but would be exposed to the metabolites IN-M7222 and IN-E7710. However, the meeting of experts concluded from this data that the residue definition for monitoring and risk assessment should be IN-M7222. From the report of the meeting, it is unclear how this decision was reached.

3.3. CONSUMER RISK ASSESSMENT

A consumer risk assessment is not possible at this time for the following reasons:

- There are no toxicological reference values for the metabolites in the residue definition for risk assessment.
- There is a data gap for further rotational crop data.

¹⁴ IN-66036: *N*-desmethyl triflurosulfuron-methyl; methyl 3-methyl-2-({[4-(methylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]carbonyl}sulfamoyl)benzoate

- The level of residues in livestock can not be finalised.
- Risk assessment for IN-W6725 has not been finalised.

3.4. PROPOSED MRLS

It is not possible to propose any MRLs at this time.

4. Environmental fate and behaviour

Fate and behaviour into the environment of triflurosulfuron-methyl was discussed in the PRAPeR 47 meeting of experts on basis of the DAR and the addendum named corrigendum 1 of April 2008.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The route of degradation of triflurosulfuron-methyl (¹⁴C-labelled in either the ester carbonyl moiety or the triazine moiety) under dark aerobic conditions at 25 °C was investigated in a study in one soil (pH 7.8; OC 1.41; clay 15 %). Cleavage of the sulfonylurea bridge and subsequent cyclisation of sulphonamide (transient non detected metabolite) yields the two major metabolites methyl saccharin (IN-W6725; max. 83.7 % AR after 29 d) and triazine amine (IN-D8526; max. 92.3 % AR after 21 d). Triazine amine is subsequently demethylated to *N*-desmethyl triazine amine (IN-E7710; max. 35.9 % AR after 120 d) and *N,N*-bis-desmethyl triazine amine (IN-M7222; max. 12.5 % after 120 d). Unextractable radioactivity reached a maximum of 65 % AR after 368 d in the experiment performed with the triazine labelled triflurosulfuron-methyl and a maximum of 48.8 % AR after 90 d in the experiment performed with triflurosulfuron-methyl labelled at the ester carbonyl moiety. Mineralization was negligible for the triazine moiety (CO₂ = 3.6 % AR) and significant for the ester carbonyl (CO₂ = 37 % AR after 270 d). In an experiment performed in the same soil under sterile conditions, triflurosulfuron-methyl is hydrolysed to the major metabolites methyl saccharin and triazine amine but subsequent degradation was not observed. Route of degradation data was only provided for one soil (pH 7.8). However the compound is ionisable and identification of metabolites for an additional soil with acidic pH would be necessary to ensure that the degradation pathways of the protonated and the ionized forms of the molecule are the same. Rate of degradation in soil under dark aerobic conditions was investigated with ¹⁴C-labelled material. Therefore, the applicant was required to provide any information derived from the rate study that could confirm the route of degradation under acidic soils (Speyer 2.2 [pH 6.1] and Duelman [pH 5.2]). The applicant provided the additional information required that was summarized in an addendum named corrigendum 1 by the rapporteur Member State, which was discussed during the experts meeting. According these data, the soil metabolite triazine amine (IN-D8526) was more persistent under acidic conditions but no new metabolites were observed. Some uncertainties on the level of metabolites *N*-desmethyl triazine amine (IN-E7710) and

N,N-bis-desmethyl triazine amine (IN-M7222) under acidic conditions remain but the experts in the meeting considered that since current risk assessment uses a formation fraction of 1, no further information was required to finalise the risk assessment. However, this uncertainty may need addressing if in the future a formation fraction other than 1 is proposed.

The degradation of triflurosulfuron-methyl was also investigated under dark anaerobic conditions at 25 °C in the same soil used for the aerobic route study. Only the metabolites methyl saccharin (max. 77.4 % AR after 5 d aerobic + 62 d anaerobic) and triazine amine (max. 57.2 % AR after 5 d aerobic + 62 d anaerobic) and unextractable radioactivity were produced at levels above 10 % AR under these conditions.

Photodegradation in soil was investigated in one study with the same soil used in the aerobic route study. Sunlight was simulated with a filtered Xenon lamp of a Suntest apparatus. The experiment extended over a period of 15 d, which was calculated to be equivalent to 75 d (12 h) of natural summer sunlight at 52 °N. Photolysis favours *N*-demethylation of triflurosulfuron-methyl to yield a major photolysis metabolite *N*-desmethyl triflurosulfuron-methyl (IN-66036, max. 12.2 % AR after 2d). Photolysis also favours a different cleavage of the sulfanyl urea bridge that yields the other major photolysis metabolite *N*-desmethyl triazine urea (IN-JM-000¹⁵; max. 13.5 % AR after 15 d). Another photolysis metabolite triazine urea (IN-JL-000¹⁶, max. 7.1 % AR after 15 d) is observed at levels above 5 % from days after treatment 1 to 15. In addition the aerobic/hydrolysis metabolites methyl saccharin (IN-W6725, max. 11.7 % AR after 15d) and triazine amine (IN-D8526, max. 11.8 % AR after 15 d) are formed at major amounts in the photolysis in soil experiment. Additional information on the results of the study was presented by the rapporteur Member State in corrigendum 1. The meeting of experts agreed that photolysis could be relevant for the degradation of triflurosulfuron-methyl for the early applications when no crop cover is present. However, it was considered that overall, photolysis will not represent a significant role in the degradation of triflurosulfuron-methyl in the environment under realistic conditions of use. Risk assessment of the EU representative uses is based on results of laboratory studies and therefore any photolysis during field studies will not have any impact on the risk assessment.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

In addition to the aerobic route of degradation study, the rate of degradation of triflurosulfuron-methyl was investigated in four soils (pH 5.2-8.1; OC 0.72-1.96 %; clay 5-13 %; 40 % MWHC) under dark aerobic conditions at 20 °C using triazine ¹⁴C-labelled triflurosulfuron-methyl. For one of the soils,

¹⁵ IN-JM-000: *N*-desmethyl triazine urea; 1-[4-(methylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea

¹⁶ IN-JL-000: triazine urea; 1-[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea

incubation was carried out at a lower concentration of triflurosulfuron-methyl (one tenth), 10 °C and 21 % MWHC. Triflurosulfuron-methyl exhibits low to moderate persistence in soil under dark aerobic conditions at 20 °C ($DT_{50 \text{ lab aerobic}} = 5.3 - 15 \text{ d}$) or 25 °C ($DT_{50 \text{ lab aerobic}} = 5.7 \text{ d}$ [geomean of the two labels]).

Rate of degradation of methyl saccharin (IN-W6725) was investigated under dark aerobic conditions at 20 °C in two studies with a total of eight soils (pH 5.7 – 7.9; OM 0.5 – 3.2 %; clay 2.0 – 50 %; 45-50 % MWHC). This metabolite exhibits moderate to very high persistence in soil ($DT_{50} = 13 - 403 \text{ d}$).

Rate of degradation of triazine amine (IN-D8526) was investigated under dark aerobic conditions at 20 °C in one study with three soils (pH 5.8 – 7.9; OM 1.8 – 2.7 %; clay 4.4 – 50 %; 45 % MWHC). This metabolite exhibits medium to very high persistence in soil ($DT_{50} = 74 - 664 \text{ d}$).

Rate of degradation of *N*-desmethyl triazine amine (IN-E7710) was investigated under dark aerobic conditions at 20 °C in two studies with a total of eight soils (pH 5.7 – 7.9; OM 0.5 – 3.2 %; clay 2.0 – 50 %; 45 - 50 % MWHC). This metabolite exhibits moderate to very high persistence in soil ($DT_{50} = 30 - 393 \text{ d}$).

Rate of degradation of *N,N*-bis-desmethyl triazine amine (IN-M7222) was investigated under dark aerobic conditions at 20 °C in two studies with a total of eight soils (pH 5.7 – 7.9; OM 0.5 – 3.2 %; clay 2.0 – 50 %; 45 - 50 % MWHC). This metabolite exhibits medium to very high persistence in soil ($DT_{50} = 80 - 486 \text{ d}$).

In the DAR it was unclear which degradation scheme had been assumed in the Model Maker fitting exercise to derive the DT_{50} 's of the metabolites triazine amine (IN-D8526) and methyl saccharin (IN-W6725) from the triflurosulfuron-methyl route study (Singles S.K., 2003a). Information on formation fractions was also missing. The applicant provided the missing information that was summarized by the rapporteur Member State in an addendum. Potential pH dependence of the rate of degradation of triflurosulfuron-methyl and its soil metabolites triazine amine (IN-D8526) and *N,N*-bis-desmethyl triazine amine (IN-M7222) was discussed in the meeting of experts. The meeting of experts agreed that dark aerobic degradation of the two metabolites in soil show pH dependence and agreed to include the longer DT_{50} 's into the list of endpoints. No pH dependence was observed for the degradation rate of parent triflurosulfuron-methyl.

Under dark anaerobic conditions at 25 °C, degradation of triflurosulfuron-methyl is slower than under aerobic conditions ($DT_{50 \text{ anaerobic}} = 21 \text{ d}$).

In the photolysis study, triflurosulfuron-methyl was degraded at the same rate in the irradiated and the dark control ($DT_{50 \text{ light}} = 11.6 \text{ d}$; $DT_{50 \text{ dark}} = 12.6 \text{ d}$). The rapporteur Member State considered that soil photolysis does not play a significant role in the environmental degradation of triflurosulfuron-methyl.

Whereas not actually triggered by laboratory half-lives, two field studies are available which were carried out in Northern EU (Colonne and Munich, DE). The same aerobic soil metabolites identified in the laboratory studies were found in field at comparable amounts.

Since the applicant proposed using the results of the field studies for the EU risk assessment, a data gap for two additional studies was preliminary identified during the peer review. However, the meeting of experts agreed that since the exposure assessment is agreed to be based on laboratory data no additional field studies are necessary and therefore the data gap was considered superseded. Further field studies would be needed in case field endpoints had to be derived for refinement of the risk assessment.

PEC_{soil} for triflurosulfuron-methyl and all major aerobic soil metabolites were calculated by the rapporteur Member State based on worst case laboratory DT_{50} 's and the maximum levels formed in these laboratory soil studies as updated in corrigendum 1.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

From the available studies, triflurosulfuron-methyl may be considered to exhibit high to very high mobility ($K_{\text{foc}} = 25 - 52 \text{ mL/g}$), triazine amine (IN-D8526) medium to high mobility ($K_{\text{foc}} = 70 - 374 \text{ mL/g}$), *N*-desmethyl triazine amine (IN-E7710) medium to very high mobility ($K_{\text{foc}} = 41 - 181 \text{ mL/g}$), *N,N*-bis-desmethyl triazine amine (IN-M7222) high to very high mobility ($K_{\text{foc}} = 31 - 127 \text{ mL/g}$) and methyl saccharin (IN-W6725) very high mobility ($K_{\text{foc}} = 6 - 22 \text{ mL/g}$). The rapporteur Member State proposed to exclude the values obtained in one of the soils investigated (Handford, sandy loam) due to its low organic carbon content. The proposal of the rapporteur Member State was accepted by the meeting of experts.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Hydrolysis of triflurosulfuron-methyl involves the cleavage of the sulfonylurea bridge to produce methyl saccharine (IN-W6725) and triazine amine (IN-D8526). Hydrolysis half-lives for triflurosulfuron-methyl were $DT_{50} = 3.7 \text{ d}$ (pH 5), $DT_{50} = 32 \text{ d}$ (pH 7) and $DT_{50} = 36 \text{ d}$ (pH 9). According the available photolysis study, aqueous photolysis has no effect on the degradation of triflurosulfuron-methyl at pH 5 and would increase the rate of degradation by a factor of 2.2 (pH 7) and 1.4 (pH 9) with respect to aqueous hydrolysis under dark conditions. Based on an aqueous photolysis

study and model calculations photodegradation is not expected to play a significant role in the degradation of triflurosulfuron-methyl in the environment and assessment of exposure to photolysis metabolites was not deemed necessary. This conclusion was confirmed by the meeting of experts. Metabolites methyl saccharine (IN-W6725) and triazine amine (IN-D8526) are stable to hydrolysis and to aqueous photolysis. Triflurosulfuron-methyl is not readily biodegradable according the available study.

In the two water sediment systems available ($\text{pH}_{\text{water}} = 7.5$ both) triflurosulfuron-methyl degrades with a half-life of $\text{DT}_{50 \text{ whole system}} = 22 - 40$ d. In these systems, triflurosulfuron-methyl partition to the sediment (max. 22 % AR) and degrades by cleavage of the sulfonylurea urea bridge to methyl saccharin (IN-W6725, max. 38.4 % AR in water and 12 % AR in sediment after 100 d) and triazine-amine (IN-D8526, max. 23.2 % AR in water and 18.9 % AR sediment after 61 d) which subsequently degrades to *N*-desmethyl triazine amine (max. 10.7 % AR in water after 61 d). In an alternative pathway triflurosulfuron (JK-555¹⁷; max. 28.6 % AR in water after 100 d and 19.7 % AR in sediment after 61 d) is formed. The meeting of experts discussed the fact that degradation/dissipation in water sediment systems has been only investigated in alkaline conditions and agreed that a water sediment study with surface water with pH within the acidic range (pH 5 - 6.5) would be needed to consider the data complete for risk assessment purposes. However, the meeting agreed that since the vast majority of surface water bodies in EU are in the alkaline range, the data gap identified could be considered to be not essential to finalise the risk assessment at EU level. The meeting of experts also discussed the additional information presented by the applicant before the meeting and summarized by the rapporteur Member State in corrigendum 1, related to the kinetic analysis of the water sediment experiments. The experts agreed that the half-life in water may only be considered a dissipation half-life and not a degradation half-life.

PEC_{SW} values originally presented in the dossier were found not acceptable during the peer review. The applicant presented new FOCUS PEC_{SW} before the meeting of experts that were not found to be acceptable by the rapporteur Member State due to the input parameters used. The rapporteur Member State produced new PEC_{SW} using FOCUS up to step 3 for the parent triflurosulfuron-methyl and up to step 2 for the metabolites. The meeting of experts agreed on these PEC_{SW} for the EU risk assessment.

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

Potential ground water contamination was addressed by FOCUS GW modelling by calculating the 80th percentile annual average concentration in the leachate at 1 m deep horizon.

¹⁷ JK-555: triflurosulfuron; 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]-*m*-toluic acid

FOCUS calculations presented in the DAR were not considered acceptable during the peer review. New calculations were presented by the applicant before the meeting of experts, but the input parameters selected by the applicant were not considered fully reliable by the rapporteur Member State. New FOCUS PEC_{GW} calculations with FOCUS PELMO were performed and summarized in corrigendum 1 by the rapporteur Member State. The meeting of experts agreed on the modelling performed by the rapporteur Member State. The effect of soil pH was considered in the calculations by the rapporteur Member State. For the representative use of triflurosulfuron-methyl in sugar beet every three years, triflurosulfuron-methyl did not exceed the trigger of 0.1 µg/L for any of the scenarios irrespective of the pH. Metabolites triazine amine (IN-D8526) and *N*-desmethyl triazine amine (IN-E7710) exceeded the trigger of 0.1 µg/L for one of the six scenarios modelled (Piacenza) under acidic soil conditions and metabolite *N,N*-bis-desmethyl triazine amine (IN-M7222) exceeded the trigger of 0.1 µg/L in the six scenarios simulated under acidic soils and in the five scenarios under alkaline soils. Additionally the trigger of 0.75 µg/L was exceeded for metabolite IN-M7222 in four of the five scenarios with alkaline soils. Degradation of metabolite methyl saccharin (IN-W6725) is not pH dependent and PEC_{GW} were calculated in a separated simulation. Metabolite methyl saccharin (IN-W6725) exceeds the trigger of 0.1 µg/L in all nine FOCUS GW scenarios and the trigger of 0.75 µg/L in eight of them. Simulations with an additional model would be needed in order to complete the risk assessment according to the opinion of the EFSA PPR panel.¹⁸

4.3. FATE AND BEHAVIOUR IN AIR

Based on its physical and chemical properties triflurosulfuron-methyl is not expected to be prone to volatilize. This has been confirmed by the available studies on the volatilization from soil and leaf surfaces. Furthermore, a half-life of 1.4 d in the troposphere was calculated (12 h day, 1.5×10^6 OH·cm⁻³) for triflurosulfuron-methyl based on Atkinson's method. Therefore triflurosulfuron-methyl is not expected to contaminate air or be prone to undergo long-range transport in the atmosphere.

5. Ecotoxicology

Triflurosulfuron-methyl was discussed in the meeting of experts on ecotoxicology, PRAPeR 48 in May 2008 on the basis of the draft assessment report and the addendum named corrigendum 1 (B9) from April 2008. The representative use evaluated is as an herbicide in sugar and fodder beet. The risk assessment was conducted according to the following guidance documents: Risk Assessment for Birds and Mammals SANCO/4145/2000 September 2002; Aquatic Ecotoxicology,

¹⁸ Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (2004) 93, 1-20

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.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Triflurosulfuron-methyl is of low acute and short-term toxicity to birds and of low acute toxicity to mammals. No mortality was observed up to the highest tested doses of 2250 mg/kg bw and 1535 mg/kg bw/d in the acute and short-term studies with birds and at the highest tested dose of 5000 mg/kg bw in the acute toxicity study with mammals. The long-term (reproductive) toxicity endpoint was assessed as 27.6 mg/kg bw/d (birds) and 5.8 mg/kg bw/d (mammals). The first-tier risk assessment resulted in TERs above the Annex VI trigger values of 10 and 5 for insectivorous birds, herbivorous birds and mammals. The risk of plant metabolites was estimated on the assumption of similar toxicity as the parent and the maximum formation rate in the plant metabolism studies. The resulting acute, short-term and long-term TERs were significantly above the trigger values of 10 and 5 suggesting a low risk to herbivorous birds and mammals. The TERs of each of the metabolites would still exceed the trigger values even if their toxicity were to be 10 times greater than that of the parent triflurosulfuron-methyl.

No risk assessment for secondary poisoning was triggered for triflurosulfuron-methyl since the $\log P_{ow}$ is less than 3. The $\log P_{ow}$ values for metabolites in soil (IN-D8526, IN-E7710, IN-W6725, IN-M7222) and in water (IN-D8526, IN-E7710, IN-W6725) were estimated with the US EPA's KowWin model to be below 3, suggesting a low potential for bioaccumulation. Nevertheless, a TER calculation was presented in the DAR for fish-eating and earthworm-eating birds and mammals. The calculations were based on the maximum initial PEC_{soil}/PEC_{sw} values for the parent triflurosulfuron-methyl and it was assumed that the bioconcentration factor would be 100. The resulting TERs were more than 2 orders of magnitude above the trigger of 5.

The $\log P_{ow}$ for the water metabolite IN-JK555 was estimated with the US EPA's KowWin model as 3.1. The TERs for fish-eating birds and mammals were calculated as 1725 and 589 respectively.

It was assumed in the calculations that the long-term toxicity of the metabolites was the same as for the parent triflurosulfuron-methyl. The TERs were more than 2 orders of magnitude above the triggers and would therefore also cover a potential increased long-term toxicity of the metabolites of more than 10 times.

The acute TERs for birds and mammals for the uptake of drinking water from leaf axils were above the trigger of 10.

Overall it is concluded that the risk to birds and mammals is low for the representative uses evaluated.

5.2. RISK TO AQUATIC ORGANISMS

Triflusaluron-methyl was of low toxicity to fish and daphnids in the submitted studies. The lowest endpoints driving the aquatic risk assessment were observed in studies with algae and higher aquatic plants (*Lemna gibba*). The EbC₅₀ for algae and higher aquatic plants were 0.0463 mg a.s./L and 0.00282 mg a.s./L. Studies with 'Triflusaluron-methyl 50WG' and 'Triflusaluron 25SC' suggest a similar toxicity of formulated triflusaluron-methyl to aquatic organisms. The toxicity of the metabolites IN-D8526, IN-W6725, IN-E7710, IN-M7222 and IN-JK555 were tested with representatives of all groups of aquatic organisms and these metabolites were of low toxicity to aquatic organisms. The metabolites IN-E0Q47¹⁹ and IN-66036 were tested with algae and IN-E0Q47 was also tested with aquatic higher plants. IN-E0Q47 was of low toxicity to algae and higher aquatic plants. However a high toxicity to algae and higher aquatic plants was indicated for IN-66036 by the EbC₅₀ value of 0.383 mg/L for algae and 0.0055 mg/L for *Lemna gibba*.

The TER values were calculated on the basis of initial PEC_{SW} values from FOCUS step 1. The TERs for the parent and the metabolites were above the Annex VI trigger values of 100 and 10 except for the TERs for triflusaluron-methyl with algae and higher aquatic plants. The TERs were >10 in two full FOCUS step 3 scenarios (D3, D4) and in the part scenario R1 (pond). The TERs were below the trigger in the scenario R3 and in the part scenario R1 (stream).

A bioconcentration study with fish was not triggered since the log P_{ow} of triflusaluron-methyl is less than 3. The log P_{ow} of the metabolites IN-D8526, IN-E7710, IN-W6725 and IN-M7222 were estimated with the program KowWin to be less than 3. The log P_{ow} of the metabolite IN-JK555 was estimated as 3.1. The BCF for IN-JK555 was calculated as 23.3 according to the formula used in the risk assessment for birds and mammals. An experimental estimation of the BCF was not considered necessary since IN-JK555 is of very low toxicity to fish and other aquatic organisms.

Overall it was concluded that the risk to aquatic organisms is low for environmental conditions represented by FOCUS scenarios D3 and D4. Risk mitigation measures and/or a refined aquatic risk assessment are needed for environmental conditions represented by FOCUS scenarios R1 (stream) and R3 (stream).

5.3. RISK TO BEES

The toxicity of the formulation 'Triflusaluron-methyl 50WG' to bees was studied in limit tests with a concentration of 100 µg a.s./bee. No mortality was observed in the tests. The acute oral and contact

¹⁹ IN-E0Q47: formyl *N*-desmethyl triazine amine; *N*-[4-amino-6-(trifluoromethoxy)-1,3,5-triazin-2-yl]-*N*-methylformamide

HQ value of <0.3 was significantly below the trigger of 50. The risk to bees was considered as low for the representative uses evaluated.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The toxicity of triflurosulfuron-methyl to the tested arthropods was low. Standard laboratory tests of the formulation 'Triflurosulfuron-methyl 50WG' were conducted with *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Poecilus cupreus* and *Chrysoperla carnea*. The LR₅₀ values were estimated as >120 g formulation/ha. The in-field and off-field HQ values were calculated as <0.85 and <0.024, respectively. The risk to non-target arthropods was considered to be low for the representative uses since the HQ values are less than 2.

5.5. RISK TO EARTHWORMS

The acute and chronic (reproductive) toxicities of triflurosulfuron-methyl and the soil metabolites IN-D8526, IN-E7710, IN-M7222 and IN-W6725 to earthworms were low. The formulation 'Triflurosulfuron-methyl 50WG' was tested in an acute toxicity test. The results did not give an indication that the toxicity of triflurosulfuron-methyl would be increased in the formulation. The TERs were calculated with maximum initial PEC_{soil} values. The TERs were more than 2 orders of magnitude above the Annex VI triggers of 10 and 5. TER calculations were also conducted for the photolysis metabolites IN-66036, IN-JM-000 and IN-JL-000. On the basis of structural similarities it was assumed that the toxicity is similar to the parent triflurosulfuron-methyl (for IN-66036) or to the metabolites IN-D8526 and IN-M7222 (for IN-JM-000 and IN-JL-000). The endpoints were compared to maximum PEC_{soil} for the parent triflurosulfuron-methyl multiplied by the maximum formation rate of the metabolites in the photolysis study. The resulting TERs were more than 3 orders of magnitude above the triggers of 10 and 5.

Overall it was concluded that the risk to earthworms is low for the representative uses evaluated.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

The chronic toxicity of each of the soil metabolites IN-D8526, IN-E7710, IN-M7222 and IN-W6725 were tested with collembola. The endpoints were in the range of 10 to 100 mg metabolite/kg soil. The TERs were calculated with initial PEC_{soil} values. The resulting TERs were more than 2 orders of magnitude above the trigger of 5, indicating a low risk.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of greater than 25% on soil respiration and nitrification were observed at rates of up to 7.5 times the recommended application rate of triflurosulfuron-methyl and up to 8.6 to 460 times the maximum PEC_{soil} concentrations of the soil metabolites IN-D8526, IN-E7710, IN-M7222 and IN-

W6725. Overall it was concluded that the risk to soil micro-organisms is low for the representative uses evaluated.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

Sorghum vulgare was the most sensitive plant species out of ten tested crop species (five monocotyledons and five dicotyledons). The results suggest that the plants reacted in a more sensitive manner when technical triflurosulfuron-methyl was applied together with the surfactant X-77 (EC₅₀ = 1.9 g a.s./ha). The endpoints for the formulation 'Triflurosulfuron-methyl 50WG' were 17.8 g a.s./ha (without surfactant) and 7.83 g a.s./ha (with surfactant). The lower endpoints observed for technical triflurosulfuron-methyl plus X-77 were considered to be not of relevance for the applied for representative use of the formulation 'Triflurosulfuron-methyl 50WG'. However, Member States should consider the increased toxicity of technical triflurosulfuron-methyl when combined with a surfactant in their national registration if appropriate.

The TERs were 9.4 and 21.5 for the endpoints derived for triflurosulfuron-methyl with and without surfactant, indicating a low risk to non-target plants in the off-field area.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No adverse effect on respiration of activated sewage sludge was observed up to the highest tested concentration of 1000 mg a.s./L. It is not expected that triflurosulfuron-methyl would reach sewage treatment plants at concentrations exceeding 1000 mg a.s./L if it is applied according to the GAP. The risk to biological methods of sewage treatment plants is considered to be low.

6. Residue definitions

Soil

Definition for risk assessment: triflurosulfuron-methyl, methyl saccharin (IN-W6725), triazine amine (IN-D8526), *N*-desmethyl triazine amine (IN-E7710) and *N,N*-bis-desmethyl triazine amine (IN-M7222).

Definition for monitoring: triflurosulfuron-methyl

Water

Ground water

Definition for exposure assessment: triflurosulfuron-methyl, methyl saccharin (IN-W6725), triazine amine (IN-D8526), *N*-desmethyl triazine amine (IN-E7710) and *N,N*-bis-desmethyl triazine amine (IN-M7222).

Definition for monitoring: triflusaluron-methyl, methyl saccharin (IN-W6725), triazine amine (IN-D8526), *N*-desmethyl triazine amine (IN-E7710) and *N,N*-bis-desmethyl triazine amine (IN-M7222).

Surface water

Definition for risk assessment: triflusaluron-methyl, methyl saccharin (IN-W6725), triazine amine (IN-D8526), *N*-desmethyl triazine amine (IN-E7710), triflusaluron (IN-JK-555) and *N,N*-bis-desmethyl triazine amine (IN-M7222; from soil).

Definition for monitoring: triflusaluron-methyl

Air

Definition for risk assessment: triflusaluron-methyl

Definition for monitoring: triflusaluron-methyl

Food of plant origin

Definition for risk assessment: *N,N*-bis-desmethyl triazine amine (IN-M7222) and *N*-desmethyl triazine amine (IN-E7710)

Definition for monitoring: *N,N*-bis-desmethyl triazine amine (IN-M7222)

The expression of the residue in plants may need to be changed. Depending on the toxicity of this compounds a joint risk assessment or individual risk assessments may be necessary.

Food of animal origin

Definition for risk assessment: *N,N*-bis-desmethyl triazine amine (IN-M7222)

Definition for monitoring: *N,N*-bis-desmethyl triazine amine (IN-M7222)

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
triflusaluron-methyl	low to moderate persistence (DT ₅₀ = 5.3 – 15 d)	The toxicity and risk to earthworms and soil micro-organisms was assessed as low.
methyl saccharin (IN-W6725)	moderate to very high persistence (DT ₅₀ = 13 – 403 d)	The toxicity and risk to earthworms and soil micro-organisms was assessed as low.
triazine amine (IN-D8526)	medium to very high persistence (DT ₅₀ = 74 – 664 d)	The toxicity and risk to earthworms and soil micro-organisms was assessed as low.
<i>N</i> -desmethyl triazine amine (IN-E7710)	moderate to very high persistence (DT ₅₀ = 30 – 393 d)	The toxicity and risk to earthworms and soil micro-organisms was assessed as low.
<i>N,N</i> -bis-desmethyl triazine amine (IN-M7222)	medium to very high persistence (DT ₅₀ = 80 – 486 d)	The toxicity and risk to earthworms and soil micro-organisms was assessed as low.

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
triflurosulfuron-methyl	high to very high mobility (K _{foc} = 25 – 52 mL/g)	FOCUS (PELMO): No	Yes	Yes	Yes
methyl saccharin (IN-W6725)	very high mobility (K _{foc} = 6 - 22 mL/g)	FOCUS (PELMO): Yes, in all nine FOCUS GW scenarios and the trigger of 0.75 µg/L in eight FOCUS scenarios.	No	Negative genotoxicity results; it did not show any potential for aromatase inhibition, negative herbicidal activity. However, due to the amount in groundwater it triggers performing a consumers' risk assessment	No

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
triazine amine (IN-D8526)	medium to high mobility (K _{foc} = 70 - 374 mL/g)	FOCUS (PELMO): Yes, one FOCUS GW scenario under acidic soil.	No data submitted. Data gap.	Yes pending confirmation of classification Carc.cat.3 R40 for triflurosulfuron-methyl in the EChA process under Directive 67/548/EEC	No
N-desmethyl triazine amine (IN-E7710)	medium to very high mobility (K _{foc} = 41 - 181 mL/g)	FOCUS (PELMO): Yes, one FOCUS GW scenario under acidic soil.	No data submitted. Data gap.	Yes pending confirmation of classification Carc.cat.3 R40 for triflurosulfuron-methyl in the EChA process under Directive 67/548/EEC	No
N,N-bis-desmethyl triazine amine (IN-M7222)	high to very high mobility (K _{foc} = 31 - 127 mL/g)	FOCUS (PELMO): Yes, in six FOCUS scenarios under acidic soils and in five scenarios under alkaline soils. Trigger of 0.75 µg/L exceeded in four of the five scenarios with alkaline soils	No	Yes pending confirmation of classification Carc.cat.3 R40 for triflurosulfuron-methyl in the EChA process under Directive 67/548/EEC	No

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
triflurosulfuron-methyl (water and sediment)	Very toxic to aquatic organisms (EbC ₅₀ for algae and aquatic higher plants <1mg/L), Risk mitigation necessary.
methyl saccharin (IN-W6725) (water and sediment)	Low toxicity and low risk to aquatic organisms.
triazine amine (IN-D8526) (water and sediment)	Low toxicity and low risk to aquatic organisms.
<i>N</i> -desmethyl triazine amine (IN-E7710) (only water)	Low toxicity and low risk to aquatic organisms.
<i>N,N</i> -bis-desmethyl triazine amine (IN-M7222) (water and sediment, from soil)	Low toxicity and low risk to aquatic organisms.
triflurosulfuron acid (JK-555) (water and sediment)	Low toxicity and low risk to aquatic organisms.

Air

Compound (name and/or code)	Toxicology
triflusulfuron-methyl	Not acutely toxic via inhalation

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

- A revised specification for the technical material (relevant for all representative uses evaluated, data gap identified by PRAPeR 51 meeting (June 2008), date of submission unknown; refer to chapter 1).
- Spectra for the relevant impurity in the technical material (relevant for all representative uses evaluated, date of submission unknown, data gap identified by EFSA after the expert meetings, refer to chapter 1 and point 2.8).
- GLP study for the determination of the vapour pressure (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- A new calculation for Henry's law constant based on the GLP vapour pressure study (relevant for all representative uses evaluated, date of submission unknown, data gap identified by experts of PRAPeR 46 meeting, May 2008; refer to chapter 1).
- To address the possible formation of the relevant impurity of the technical material during storage (relevant for all representative uses evaluated, date of submission unknown, data gap identified by EFSA after the expert meetings, refer to chapter 1 and point 2.8).
- Monitoring method for the metabolites IN-D8526, IN-E7710, IN-M7222 and IN-W6725 in drinking/ground water (relevant for all representative uses evaluated, date of submission unknown, data gap identified by EFSA after the expert meetings, refer to chapters 1, 2 and 4).
- Should the proposed classification of the parent triflurosulfuron-methyl as carcinogen category 3 **R40** be confirmed in the context of the European Chemicals Agency (ECHA) programme for classification and labelling under Directive 67/548/EEC this would, in line with the guidance document on groundwater metabolites, require that for those metabolites with the potential to contaminate groundwater, convincing evidence must be provided that the metabolites will not lead to the risk of carcinogenicity (relevant for all representative uses evaluated, date of submission unknown, data gap identified by EFSA during the expert meetings, refer to chapters 2 and 4).
- Further data on rotational crops such that a robust risk assessment can be done has been identified as a data gap (relevant for all uses evaluated, data gap identified by meeting of experts May 2008, proposed submission date unknown, refer to chapter 1).
- Data to address the level of residues in livestock has been identified as a data gap (relevant for all uses evaluated, data gap identified by EFSA July 2008, proposed submission date unknown, refer to chapter 1).
- A data gap for a water sediment study with surface water with a pH in the acidic range (pH 5 - 6.5) was identified during the peer review (considered not essential to finalise the risk assessment at EU level; no submission date proposed by the applicant; refer to point 4.2).

- An assessment of the pesticidal activity of the groundwater metabolites triazine amine (IN-D8526) and *N*-desmethyl triazine amine (IN-E7710) is needed (relevant for all uses evaluated, data gap identified after the meeting of experts PRAPeR 48 in May 2008, proposed submission date unknown, refer to chapter 6).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as proposed by the applicant which comprise post emergence foliar spraying to control annual grasses and broad-leaved weeds in sugar and fodder beets (*Aethusa cynapium*, *Amaranthus retroflexus*, *Brassica napus*, *Galium aparine*, *Lamium purpureum*, *Matricaria sp.*, *Mercurialis annua*, *Polygonum sp.*, *Sinapis arvensis*, *Urtica urens*, *Viola arvensis*), up to growth stage of BBCH 39, up to maximum four treatments per year, with application rates of maximum 20 g a.s./ha in Northern Europe and up to maximum three treatments per year, with application rates of maximum 30 g a.s./ha in Southern Europe, at a maximum total active substance rate per season of 60 g a.s./ha, with interval between applications of 7 days.

The data submitted in the dossier relate to the variant triflusaluron-methyl, which is the methyl ester of triflusaluron.

The representative formulated product for the evaluation was ‘Triflusaluron-methyl 50WG’, a water-dispersible granule (WG) containing 500 g/kg of triflusaluron-methyl, registered under different trade names in Europe.

Since clarification is required with respect to the proposed maximum levels of certain impurities in the technical material, the specification as a whole should currently be regarded as provisional (September 2008).

Adequate analytical methods are available to monitor all compounds given in the respective residue definitions in food/feed of plant origin and soil and air, however no analytical method exist for the determination of metabolites included in the residue definition in ground water/drinking water.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product is possible.

As for mammalian toxicology, triflurosulfuron-methyl has low acute toxicity via the oral, dermal, or inhalation routes; it is not an eye or skin irritant, nor a skin sensitiser. In repeated dose studies triflurosulfuron-methyl caused decreases in body weight gain, food intake and food efficiency, as well as increased liver enzymes and anaemia. The relevant short and long-term NOAELs are 6.6 mg/kg bw/day and 4.06 mg/kg bw/day, respectively. The weight of evidence from the complete battery of genetic toxicology studies indicates that triflurosulfuron-methyl does not have genotoxic potential. In carcinogenicity tests, male rats showed increased incidence of Leydig cell adenomas likely due to an aromatase inhibition mechanism, therefore the compound was proposed for classification as a category 3 carcinogen (**Xn, R40 “Limited evidence of a carcinogenic effect”**). The increase in hepatocellular adenoma in mice was not considered relevant for human risk assessment. Triflurosulfuron-methyl is not a reproductive toxicant: the reproductive NOAEL is ≥ 89.5 mg/kg bw/day, whereas the maternal and offspring NOAEL is 5.8 mg/kg bw/day based on decreased body weight in parental rats and pups. In developmental toxicity studies in rats, both the maternal and foetal NOAELs are 120 mg/kg/day. In rabbits, triflurosulfuron-methyl did not show any teratogenic potential, with the developmental NOAEL ≥ 800 mg/kg bw/day and the maternal NOAEL 15 mg/kg/day. Triflurosulfuron-methyl does not show any neurotoxic potential. The **ADI and AOEL are 0.04 mg/kg bw/day**, the **ARfD is 1.2 mg/kg bw**. The estimated operator, worker and bystander exposure is below the AOEL.

Metabolism of triflurosulfuron-methyl in primary crops was investigated in a sugar beet metabolism study, the results of which showed the only relevant residues at harvest are the metabolites IN-M7222 and IN-E7710. Triflurosulfuron-methyl had decreased to <0.01 mg/kg by day 14. The residue definition for risk assessment was therefore set as IN-M7222 and IN-E7710. The residue definition for monitoring is IN-M7222. A confined rotational crop study was conducted which showed that the only significant residues were the same as seen in primary crops and this was confirmed by a radiolabelled field study. It was considered by the meeting of experts that this study was not sufficient to fully quantify residues in rotational crops and a data gap was identified. Sufficient residues data were available for the representative crop sugar beet and it was demonstrated that residues are stable under freezer storage for a period of 12 months. Processing studies are not required as residues are low. In goat metabolism studies conducted at circa 1 and 100 N, four significant metabolites were identified. From this data the meeting of experts appeared to conclude that the residue definition for monitoring and risk assessment should be IN-M7222. However, there is no justification for this in the report of the meeting. A risk assessment can not be conducted as there are no applicable toxicological endpoints available.

Triflurosulfuron-methyl exhibits low to moderate persistence in soil under dark aerobic conditions at 20 °C ($DT_{50 \text{ lab aerobic}} = 5.3 - 15$ d). It degrades by cleavage of the sulfonylurea bridge and subsequent cyclisation to yield the two major metabolites, methyl saccharin (IN-W6725; $DT_{50} = 13 - 403$ d) and

triazine amine (IN-D8526; $DT_{50} = 74 - 664$ d). Triazine amine is subsequently demethylated to *N*-desmethyl triazine amine (IN-E7710; $DT_{50} = 30 - 393$ d) and *N,N*-bis-desmethyl triazine amine (IN-M7222; $DT_{50} = 80 - 486$ d). Unextractable radioactivity reached a maximum of 65 % AR after 368 d with triazine labelled triflurosulfuron-methyl and a maximum of 48.8 % AR after 90 d with ester carbonyl labelled triflurosulfuron-methyl. Mineralization was negligible for the triazine moiety and significant for the ester carbonyl moiety. The meeting of experts agreed that dark aerobic degradation of the metabolites triazine amine (IN-D8526) and *N,N*-bis-desmethyl triazine amine (IN-M7222) in soil show pH dependence.

Under dark anaerobic conditions, degradation of triflurosulfuron-methyl ($DT_{50 \text{ anaerobic}} = 21$ d) yields the metabolites methyl saccharin and triazine amine at levels above 10 % AR.

The meeting of experts considered that overall, photolysis will not represent a significant role in the degradation of triflurosulfuron-methyl in soil.

Two available field studies were carried out in Northern EU (Colonne and Munich, DE). The same aerobic soil metabolites identified in the laboratory studies were found in field studies at comparable amounts.

The PEC_{soil} for triflurosulfuron-methyl and all major aerobic soil metabolites were calculated by the rapporteur Member State based on worst case laboratory DT_{50} 's and maximum formed in these laboratory soil studies as updated in corrigendum 1.

From the available studies triflurosulfuron-methyl may be considered to exhibit high to very high mobility ($K_{\text{foc}} = 25 - 52$ mL/g), triazine amine (IN-D8526) medium to high mobility ($K_{\text{foc}} = 70 - 374$ mL/g), *N*-desmethyl triazine amine (IN-E7710) medium to very high mobility ($K_{\text{foc}} = 41 - 181$ mL/g), *N,N*-bis-desmethyl triazine amine (IN-M7222) high to very high mobility ($K_{\text{foc}} = 31 - 127$ mL/g) and methyl saccharin (IN-W6725) very high mobility ($K_{\text{foc}} = 6 - 22$ mL/g).

Hydrolysis half-lives for triflurosulfuron-methyl were $DT_{50} = 3.7$ d (pH 5), $DT_{50} = 32$ d (pH 7) and $DT_{50} = 36$ d (pH 9). The meeting of experts confirmed that photodegradation of triflurosulfuron-methyl is not expected to play a significant role in the aquatic environment. Triflurosulfuron-methyl is not readily biodegradable according the available study.

In water / sediment aquatic systems, triflurosulfuron-methyl partitions to the sediment (max. 22 % AR) and degrades ($DT_{50 \text{ whole system}} = 21 - 39$ d) to methyl saccharin (IN-W6725; max. 38.4 % AR in water and 12 % AR in sediment after 100 d) and triazine-amine (IN-D8526; max. 23.2 % AR in water and 18.9 % AR sediment after 61 d) that subsequently degrades to *N*-desmethyl triazine amine (max.

10.7 % AR in water after 61 d). By an alternative pathway, triflurosulfuron (JK-555, max. 28.6 % AR in water after 100 d and 19.7 % AR in sediment after 61 d) is formed. The meeting of experts agreed that a water sediment study with a pH in the acidic range (pH 5 - 6.5) would be needed but this was considered not to be essential to finalise the risk assessment at the EU level. The rapporteur Member State produced new PEC_{SW} using FOCUS up to step 3 for the parent triflurosulfuron-methyl and up to step 2 for the metabolites that were agreed by the meeting of experts for the EU risk assessment.

Potential ground water contamination was addressed by FOCUS GW modelling.

The meeting of experts agreed on the modelling performed by the rapporteur Member State and summarized in corrigendum 1. Effect of soil pH was considered in the calculations performed by the rapporteur Member State. For the representative use of triflurosulfuron-methyl in sugar beet every three years, triflurosulfuron-methyl did not exceed the trigger of 0.1 µg/L for any of the scenarios irrespective of the pH. Metabolites triazine amine (IN-D8526) and *N*-desmethyl triazine amine (IN-E7710) exceeded the trigger of 0.1 µg/L for one of the six scenarios modelled (Piacenza) under acidic soil conditions. The metabolite *N,N*-bis-desmethyl triazine amine (IN-M7222) exceeded the trigger of 0.1 µg/L in the six scenarios simulated under acidic soils and in the five scenarios under alkaline soils. Additionally, the trigger of 0.75 µg/L was exceeded for metabolite IN-M7222 in four of the five scenarios with alkaline soils. Degradation of metabolite methyl saccharin (IN-W6725) is not pH dependent and PEC_{GW} were calculated in a separated simulation. The metabolite methyl saccharin (IN-W6725) exceeds the trigger of 0.1 µg/L in all nine FOCUS GW scenarios and the trigger of 0.75 µg/L in eight of them.

Triflurosulfuron-methyl is not expected to volatilize or be prone to long-range transport in the atmosphere.

Triflurosulfuron-methyl is very toxic to algae and higher aquatic plants. The TERs were >10 in two full FOCUS step 3 scenarios (D3, D4) and in the part scenario R1 (pond). The TERs were below the trigger in the scenario R3 and in the part scenario R1 (stream). Risk mitigation measures and/or a refined aquatic risk assessment is needed in Member States where environmental conditions prevail which are represented by FOCUS scenarios R1 (stream) and R3 (stream).

Non-target plants were more sensitive when technical triflurosulfuron-methyl was applied together with the surfactant X-77. The lower endpoints observed for technical triflurosulfuron-methyl plus X-77 were considered as not being of relevance for the applied for representative use of the formulation 'Triflurosulfuron-methyl 50WG'. However Member States should consider the increased toxicity of technical triflurosulfuron-methyl when combined with a surfactant in their national registration if appropriate. The TERs were 9.4 and 21.5 for the endpoints derived for the formulation

‘Triflurosulfuron-methyl 50WG’ with and without surfactant respectively, indicating a low risk to non-target plants in the off-field area.

The risk to birds and mammals, bees, non-target arthropods, soil macro- and soil micro-organisms and biological methods of sewage treatment were assessed as low.

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

- None

Critical areas of concern

- A consumer risk assessment is not possible.
- Metabolites IN-D8526, IN-E7710, IN-M7222 and IN-W6725 exceed the trigger of 0.1 µg/L in ground water. Metabolite IN-W6725 also exceeds 0.75 µg/L (negative genotoxicity and aromatase inhibition potential, negative herbicidal activity; however, due to the concentration in groundwater it triggers a consumers’ risk assessment). The metabolite IN-M7222 also exceeds 0.75 µg/L in alkaline soils. In conclusion, IN-M7222, IN-D8526 and IN-E7710 should be regarded as relevant groundwater metabolites. As for IN-M7222 and IN-E7710, the limited toxicological database did not allow setting specific reference values.

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)

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

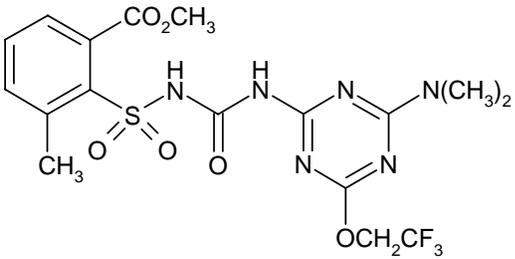
Active substance (ISO Common Name) ‡	triflusulfuron unless otherwise stated the following data relate to the variant triflusulfuron-methyl which is the methyl ester of triflusulfuron.
Function (e.g. fungicide)	Herbicide
Rapporteur Member State	France
Co-rapporteur Member State	/

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]- <i>m</i> -toluic acid (triflusulfuron) methyl 2-[4-dimethylamino-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-ylcarbamoylsulfamoyl]- <i>m</i> -toluate (triflusulfuron-methyl)
Chemical name (CA) ‡	2-[[[[[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]amino]carbonyl]amino]sulfonyl]-3-methylbenzoic acid
CIPAC No ‡	731.201
CAS No ‡	126535-15-7
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	Minimum purity : 96 %
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	<i>N,N</i> -dimethyl-6-(2,2,2-trifluoroethoxy)-1,3,5-triazine-2,4-diamine Max. 6 g/kg

Appendix 1 – List of endpoints

Molecular formula †
Molecular mass †
Structural formula †

C ₁₇ H ₁₉ F ₃ N ₆ O ₆ S
492.43 g/mol


Appendix 1 – List of endpoints

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	159 °C – 162 °C (purity 98.9 %)
Boiling point (state purity) ‡	No boiling was measured (decomposition of active substance occurs at the temperature above melting point)
Temperature of decomposition (state purity)	Decomposition occurs at temperatures above 159°C – 162°C
Appearance (state purity) ‡	White crystalline solid. (a.s 98.9%) and white powdery crystalline solid (technical a.s.)
Vapour pressure (state temperature, state purity) ‡	open
Henry's law constant ‡	open
Solubility in water (state temperature, state purity and pH) ‡	Purity 98.6% PH 3: 0.0011 g/l at 25 °C PH 5: 0.0038 g/l at 25 °C PH 7: 0.26 g/l at 25 C PH 9: 11 g/l at 25 °C
Solubility in organic solvents ‡ (state temperature, state purity)	Purity : 95.6%, at 25 °C Acetone : 120 g/L, Acetonitrile : 80 g/L, Chloroform : 160 g/L, Ethyl acetate : 27 g/L, n-hexane : <0.0016g/L, Methanol 7.0 g/L, Dichloromethane 580 g/L, Octan-1-ol : 0.026 g/L Toluene : 2.0 g/L
Surface tension ‡ (state concentration and temperature, state purity)	67.92 mN/m at 4.465 mg/L at 20°C Purity : 98.9%
Partition co-efficient ‡ (state temperature, pH and purity)	pH 5: 2.3 at 25 °C pH 7: 0.96 at 25 °C pH 9: -0.066 at 25 °C purity : 95.6%
Dissociation constant (state purity) ‡	pKa: 4.4 at 25 °C

Appendix 1 – List of endpoints

UV/VIS absorption (max.) incl. ϵ ‡
 (state purity, pH)

$\lambda = 228 \text{ nm}$ et 291 nm for acidic solution
 $\lambda = 235 \text{ nm}$ et 291 nm for neutral et basic solutions

at 291 nm $\epsilon \text{ mol}^{-1} \cdot \text{cm}^{-1}$ for acidic is $9.81 \cdot 10^2$, for
 neutral is $4.74 \cdot 10^2$, for basic is $4.81 \cdot 10^2$
 purity : 98.9%

Flammability ‡ (state purity)

Not highly flammable (purity 95.6%)

Explosive properties ‡ (state purity)

Not explosive (purity 95.6%)

Oxidising properties ‡ (state purity)

No oxidizing property (statement)

Appendix 1 – List of endpoints

Summary of representative uses evaluated (Triflurosulfuron-methyl)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (min in days) (l)	Remarks (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (days)	g as/hL min max	water L/ha min max	g a.s./ha min max		
Sugar and fodder beet	Austria Belgium Denmark Finland France Germany Ireland Netherlands Sweden UK	Debut, Safari,	F	Broad leaf weeds, various annual grasses	WG	500	Medium-low volume spraying, broadcast or band application	BBCH between 9 and 39	1-4	7	3-20	100 - 500	15-20	None *	60 g a.s. maximum per season; closest cultivation frequency every third year [1]
Sugar and fodder beet	Greece Italy Spain	Debut, Safari,	F	Broad leaf weeds, various annual grasses	WG	500	Medium-low volume spraying, broadcast or band application	BBCH between 9 and 39	1-3	7	4-30	100 - 500	20-30	None	60 g a.s. maximum per season; closest cultivation frequency every third year [1]

Appendix 1 – List of endpoints

* Do not treat later than Growth Stage BBCH 39. PHI is covered by conditions of use and/or growing period between application and harvest.

[1] A consumer risk assessment is not possible.

Remarks :

- | | |
|--|---|
| (a) For crops, the EU and Codex classifications (both) should be used; where equipment used must be indicated. | (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of |
| relevant, the use situation should be described (e.g. fumigation of a structure) | (i) g/kg |
| (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) | (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3-152-4), |
| (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds | including where relevant, information on season at time of application |
| (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) | (k) The minimum and maximum number of application possible under practical conditions of use must be provided |
| (e) GCPF Codes - GIFAP Technical Monograph No. 2, 1989 | (l) PHI - minimum pre-harvest interval |
| (f) All abbreviations must be explained | (m) Remarks may include: Extent of use/economic importance/restrictions |
| (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench | |

Appendix 1 – List of endpoints

Methods of Analysis

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

Technical as (analytical technique)	Carbamate process : HPLC-UV (230 nm) Cyanate process : HPLC-UV (254nm)
Impurities in technical as (analytical technique)	HPLC-UV (220 or 230 nm) GC-FID Karl Fisher
Plant protection product (analytical technique)	HPLC-UV (254 nm)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	IN-M7222
Food of animal origin	-
Soil	Triflurosulfuron-methyl
Water surface	Triflurosulfuron-methyl
drinking/ground	Triflurosulfuron-methyl, IN-M7222, IN-D8526, IN-E7710, IN-W6725
Air	Triflurosulfuron-methyl

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS (sugar beet foliage and roots) LOQ 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	As no MRL established, no method required
Soil (analytical technique and LOQ)	HPLC-MS/MS with LOQ = 0.05 µg/kg (triflurosulfuron-methyl) HPLC-MS/MS with LOQ = 0.2µg/kg (metabolites)
Water (analytical technique and LOQ)	LC-MS/MS with LOQ = 0.05µg/L (drinking and surface water) (triflurosulfuron-methyl) Method required for metabolites (drinking water)
Air (analytical technique and LOQ)	HPLC-UV with LOQ = 1.2 µg/m ³

Appendix 1 – List of endpoints

Body fluids and tissues (analytical technique and LOQ)

No method required as active substance not classified as toxic or highly toxic
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Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

Active substance

RMS/peer review proposal

none

Appendix 1 – List of endpoints

Impact on Human and Animal Health

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

Rate and extent of absorption:	Rapid, 65% in rats at low dose, based on urine and carcass
Distribution:	Well distributed
Potential for accumulation:	No potential for accumulation in organs
Rate and extent of excretion:	Almost complete in 72 hours via the urine and faeces
Metabolism in animals	Extensively metabolised by hydroxylation/demethylation on the triazine ring and cleavage of the sulphonylurea bridge
Toxicologically significant compounds (animals and plants)	Parent compound and metabolites
Toxicologically significant compounds (environment)	Parent compound and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral	> 5000 mg/kg b.w.
Rat LD ₅₀ dermal	> 2000 mg/kg b.w.
Rat LC ₅₀ inhalation	> 5.1 mg/L (4 hours, nose only)
Skin irritation	Non irritant
Eye irritation	Non irritant
Skin sensitization (test method used and result)	Non sensitising (M&K)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Body weight, food intake/decrease; liver: increased weight/elevated blood enzymes;/hypertrophy; erythrocytes: regenerative anaemia
Lowest relevant oral NOAEL / NOEL	6.6 mg/kg bw (90 days rat)
Lowest relevant dermal NOAEL / NOEL	1000 mg/kg bw (21 days in rabbit)
Lowest relevant inhalation NOAEL / NOEL	No data not required

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential

Appendix 1 – List of endpoints

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

Target/critical effect	Decreased body weight, food consumption and RBC (rat); decreased body weight and increased liver weight (mice)	
Lowest relevant NOAEL / NOEL	4.06 mg/kg/d, 2 year feeding study in male rat 20.9 mg/kg bw/day (male) in 18 month study in mice	
Carcinogenicity	Testis/increased incidence of Leydig cell hyperplasia and adenoma in male rat.	R40
	Liver/slight increased adenomas in male mice	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	decreased bw in pups and parents, no reproductive effects	
Relevant parental NOAEL ‡	5.8 mg/kg bw	
Relevant reproductive NOAEL ‡	≥ 89.5 mg/kg bw	
Relevant offspring NOAEL ‡	5.8 mg/kg bw	

Developmental toxicity

Developmental target / critical effect ‡	No teratogenic potential in rabbit Developmental effects in rat at maternotoxic doses.	
Relevant maternal NOAEL ‡	120 mg/kg bw in rat 15 mg/kg bw in rabbit	
Relevant developmental NOAEL ‡	≥ 800 mg/kg bw in rabbit 120 mg/kg bw in rat	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL (acute): 2000 mg/kg bw (for neurotoxicity) NOAEL (90 day): 186.2 mg/kg bw/day	
Repeated neurotoxicity ‡		
Delayed neurotoxicity ‡	No data, not required	

Appendix 1 – List of endpoints

Other toxicological studies (Annex IIA, point 5.8)

IN-D8526	No mutagenic potential (Ames), ALD 670 mg/kg bw, no aromatase inhibition
IN-E7710	No mutagenic potential (Ames), ALD 670 mg/kg bw, no aromatase inhibition
IN-M7222	No mutagenic potential (Ames, CHO/HPRT, chromosome aberration in vitro), ALD 450 mg/kg bw, no aromatase inhibition
IN-W6725	No mutagenic potential (Ames, CHO/HPRT, micronucleus), no aromatase inhibition
Other impurities	Toxicological studies provided for impurities IN-JH152, IN-KE010, IN-KH237, and IN-JK541: ALD > 5000 mg/kg bw; negative in vitro mutagenicity studies for IN-KE010, IN-KH237, and IN-JK541

Medical data (Annex IIA, point 5.9)

No adverse effects related to triflurosulfuron
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Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.04 mg/kg/d	2 year study in rat	100
AOEL (systemic)	0.04 mg/kg bw/d	90 day study in rat	100, corrected for 65% oral absorption
ARfD (acute reference dose)	1.2 mg/kg bw	Rat developmental study	100

Dermal absorption (Annex IIIA, point 7.3)

In vitro dermal absorption in human skin (Triflurosulfuron 50 WG, DEBUT, SAFARI)	50% (concentration and dilution)
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Appendix 1 – List of endpoints

Acceptable exposure scenarios (including method of calculation)

Operator	Model	Internal exposure (mg/kg b.w.)	% AOEL
	POEM	0.1817 (no PPE)	455
		0.02319 (gloves)	58.0
	BBA	0.01739 (no PPE)	43.5
		0.00729 (gloves)	18.2
Workers	4.6 % of AOEL		
Bystanders	0.37 % of AOEL		

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data

Xn R40, Carc. cat. 3

Appendix 1 – List of endpoints

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

Plant groups covered	root vegetables (sugar beets),
Rotational crops	wheat, lettuce, sugar beet, broccoli
Metabolism in rotational crops similar to metabolism in primary crops?	No IN-M7222 and IN-N7710 accumulate in rotational crops.
Processed commodities	No
Residue pattern in processed commodities similar to residue pattern in raw commodities?	-
Plant residue definition for monitoring	IN-M7222
Plant residue definition for risk assessment	IN-M7222 and IN-N7710
Conversion factor (monitoring to risk assessment)	none

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

Animals covered	Goat
Time needed to reach a plateau concentration in milk and eggs	48 h
Animal residue definition for monitoring	IN-M7222
Animal residue definition for risk assessment	IN-M7222
Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

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

Residues of triflurosulfuron methyl below LOQ IN-M7222 and IN-N7710 accumulates in barley and broccoli. Further rotational crop studies are required

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

IN-M7222 and IN-N7710 are stable for up to 18 months at < -18°C

Appendix 1 – List of endpoints

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

Further data are required to address the level of residues in livestock.

Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

Ruminant:	Poultry:	Pig:
Conditions of requirement of feeding studies		
YES	-	-
	-	-
	-	-
-	-	-
-	-	-
-	-	-
-	-	-
-	-	-
-	-	-
-	-	-

Appendix 1 – List of endpoints

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses IN-E7710 and IN-M7222 /kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Sugar beets PHI ≥ 90 days	N (60g s.a./ha) S (60 g s.a./ha)	6 x <0.02 9 x <0.02	Triflurosulfuron methyl is applied at 2 (30 g s.a./ha) to 4 times (15 g s.a./ha) At a PHI of 90 days, all residue levels were below the LOD (0.003 mg/kg in 14 trials or 0.007mg/kg in 1 trial)	0.02	0.02	0.02

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

Appendix 1 – List of endpoints

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

ADI	No definitive tox reference values were established for IN-M7222 and IN-E7710
TMDI (% ADI) according to WHO diet	
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	
ARfD	
IESTI (% ARfD)	
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
N/A				

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

.Sugar beet

Appendix 1 – List of endpoints

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

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

Mineralization after 100 days ‡	17.5 % after 90 d, [¹⁴ C- ester carbonyl]-label (n ²⁰ =1) 3.6 % after 368 d, [¹⁴ C- triazine]-label (n=1)
Non-extractable residues after 100 days ‡	48.8 % after 90 d, [¹⁴ C- ester carbonyl]-label (n=1) 46 % after 90 d, [¹⁴ C- triazine]-label (n=1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	IN-W6725 – max 83.7 % at 29 d, [¹⁴ C- ester carbonyl]-label (n=1) IN-D8526 – max 92.3 % at 21 d, [¹⁴ C- triazine]-label (n=1) IN-E7710 – max 35.9 % at 120 d, [¹⁴ C- triazine]-label (n=1) IN-M7222 – max 12.5 % at 120 d, [¹⁴ C- triazine]-label (n=1)
Anaerobic degradation ‡ (aerobic 5d/anaerobic 62 d)	
Mineralization after 100 days	<0.1 % after 62 d, [¹⁴ C- ester carbonyl]-label (n=1) <0.8 % after 62 d, [¹⁴ C- triazine]-label (n=1)
Non-extractable residues after 100 days	9.6-10.5 % after 62 d, [¹⁴ C- ester carbonyl]-label (n=1) 29.9 % after 62 d, [¹⁴ C- triazine]-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	IN-W6725 - 57.7 % (5 d) / 71.7-77.4 % (62 d), [¹⁴ C- ester carbonyl]-label (n=1) IN-D8526 : 47.4 % (5 d) / 57.2 % (62 d), [¹⁴ C- triazine]-label (n=1)

20
n corresponds to the number of soils.

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)

Continuous artificial light (Xenon) during 15 days (equivalent to 75 d natural summer sunlight at latitude 52° N)

The information obtained from the aerobic laboratory studies clearly indicate that microbial degradation is significantly faster than photolysis at 52°N. Despite the fact that the estimated photolytic DT50 will probably be shorter at latitude of 30-40°N, it is not expected to lead to a significant competitive process in field for the intended use.

- dark conditions:

IN-W6725 : max. 62.4 % after 15 d, [¹⁴C- ester carbonyl]-label (n=1)

IN-D8526 : max. 47.5 % after 15 d, [¹⁴C- triazine]-label (n=1)

- continuous artificial light:

IN-W6725 : max. 11.7 % after 15 d, [¹⁴C- ester carbonyl]-label (n=1)

IN-66036 : max. 12.2 % after 2 d, [¹⁴C- ester carbonyl]-label (n=1)

IN-D8526 : max. 11.8 % after 15 d, [¹⁴C- triazine]-label (n=1)

IN-JM000 : 13.5 % after 15 d, [¹⁴C- triazine]-label (n=1)

IN-JL000: non-transient minor, max 7.1% after 2 days, [¹⁴C- triazine]-label (n=1)

Appendix 1 – List of endpoints

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

Laboratory studies ‡

Triflurosulfuron-methyl	Aerobic conditions – Persistence and modelling endpoints						
Soil type	X ²¹	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Sandy loam (Somersham)		7.8	25 / 75% of pF2.5	5.7/19	✓ 6	9	SFO
Loamy sand (Speyer 2.2)		6.1	20 / 42% MWHC	6.2/21	6	9	SFO
Sandy loam (Alstedgard)		8.1	20 / 42% MWHC	5.3/18	5	6	SFO
Loamy sand (Duelman)		5.2	20 / 42% MWHC	15/48	12	6	SFO
Silt (Soest)		7.3	20 / 42% MWHC	6.4/21	5*	7	SFO
Silt (Soest)		7.3	20 / 42% MWHC (low dose rate: 5g/ha)	8.8/29	7*	5	SFO
Silt (Soest)		7.3	20 / 21% MWHC	7.3/24	3*	4	SFO
Silt (Soest)		7.3	10 / 42% MWHC	21/69	8*	16	SFO
Geometric mean/median DT50				8.4/6.9	6.5/6.0	-	SFO

* The four values for Soest soil were averaged before calculating the mean and median for all soils (then, there is only one value for Soest soil, not 4).

²¹ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Appendix 1 – List of endpoints

IN-W6725	Aerobic conditions – Persistence & modelling endpoints							
Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Silt loam (Mattapex)		5.9	20 / 50% MWHC	107/354	-	✓ 87	5	SFO
Sandy loam (Handorf)		5.8	20 / 50% MWHC	403/1340	-	367	2	SFO
Clay (San Pietro)		7.9	20 / 50% MWHC	124/413	-	104	2	SFO
Sandy clay loam (Hidalgo)		7.8	20 / 50% MWHC	372/1237	-	239	1	SFO
Clay loam (Lleida)		7.5	20 / 50% MWHC	101/337	-	91	3	SFO
Loamy sand (Mattapex)		6.6	20 / 50% MWHC	31/103	-	24	3	SFO
Clay loam (Pesaro)		7.6	20 / 50% MWHC	88/293	-	71	3	SFO
Loamy sand (Speyer)		5.7	20 / 50% MWHC	13/43	-	13	2	SFO
Geometric mean/median			-	-	-	79/89	-	SFO

Appendix 1 – List of endpoints

IN-D8526	Aerobic conditions –Persistence & modelling endpoints							
Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Sandy loam (Handorf)		5.8	20 / 50% MWHC	167/556	-	152	5	SFO
Silt loam (Mattapex)		5.9	20 / 50% MWHC	369/2373 ¹	-	303 586	5	DFOP ² DT90 _{DFOP} /3.3 2
Loamy sand* (Speyer 2.2)		6.1	20 / 42% MWHC	108/359	0.64	108	14	SFO
Clay (San Pietro)		7.9	20 / 50% MWHC	74/246	-	62	4	SFO
Sandy loam* (Somersham)		7.8	25 / 75% of pF2.5	40/134	0.8	**	20	SFO
Loamy sand (Duelman)		5.2	20 / 42% MWHC	664/2207	1	552	15	SFO
Geometric mean for acidic soils (pH<7)				-	-	284	-	SFO
Worst-case for alkaline soils (pH>7)				-	-	62	-	SFO

* study conducted on parent substance

** not reliable for modelling

¹ Persistence endpoint. Kinetic parameters: m₀=103.4% AR, k₁=0.086 day⁻¹, k₂=0.001 day⁻¹, g=0.335

² If the model allows the use of a DFOP kinetics. Otherwise, use DT90/3.32. The DT90/3.32 value is used in the calculation of the geometric mean.

Appendix 1 – List of endpoints

IN-E7710	Aerobic conditions – Persistence & modelling endpoints							
Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Silt loam (Mattapex)		5.9	20 / 45% MWHC	226/1225 ¹ 143/474 ³	-	109 ³	2 5	DFOP SFO
Sandy loam (Handorf)		5.8	20 / 45% MWHC	393/>1000 0 ² 159/527 ³	-	135 ³	2 5	FOMC SFO
Clay (San Pietro)		7.9	20 / 45% MWHC	273/906	-	213	5	SFO
Sandy clay loam (Hidalgo)		7.8	20 / 50% MWHC	241/801	-	155	3	SFO
Clay loam (Lleida)		7.5	20 / 50% MWHC	76/251	-	69	4	SFO
Loamy sand (Mattapex)		6.6	20 / 50% MWHC	30/100	-	23	5	SFO
Clay loam (Pesaro)		7.6	20 / 50% MWHC	87/290	-	70	2	SFO
Loamy sand (Speyer)		5.7	20 / 50% MWHC	42/489 ⁴ 67/222 ³	-	67 ³	1 9	DFOP SFO
Sandy loam* (Somersham)		7.8	25 / 75% of pF2.5	183/608	0.73	209	17	SFO
Geometric mean/median			-	-	-	87/109	-	SFO

* study conducted on parent substance

¹ Persistence endpoint. Kinetic parameters: m₀=100.72% AR, k₁=0.057 day⁻¹, k₂=0.002 day⁻¹, g=0.277

² Persistence endpoint. Kinetic parameters: m₀=103.5% AR, α=0.185, β=9.455

³ SFO for modelling endpoint

⁴ Persistence endpoint. Kinetic parameters: m₀=94.5% AR, k₁=0.055 day⁻¹, k₂=0.003 day⁻¹, g=0.482

Appendix 1 – List of endpoints

IN-M7222	Aerobic conditions – Persistence & modelling endpoints							
Soil type	X ¹	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	f. f. k _{dp} /k _f	DT ₅₀ (d) 20 °C pF2/10kPa	St. (χ ²)	Method of calculation
Silt loam (Mattapex)		5.9	20 / 45% MWHC	182/603	-	✓ 138	4	SFO
Sandy loam (Handorf)		5.8	20 / 45% MWHC	166/550	-	141	3	SFO
Clay (San Pietro)		7.9	20 / 45% MWHC	292/970	-	228	4	SFO
Sandy clay loam (Hidalgo)		7.8	20 / 50% MWHC	486/1614	-	312	3	SFO
Clay loam (Lleida)		7.5	20 / 50% MWHC	242/802	-	219	4	SFO
Loamy sand (Mattapex)		6.6	20 / 50% MWHC	80/266	-	61	5	SFO
Clay loam (Pesaro)		7.6	20 / 50% MWHC	334/1108	-	268	3	SFO
Loamy sand (Speyer)		5.7	20 / 50% MWHC	165/547	-	165	6	SFO
Geometric mean/median for acidic soils (pH<7)						118/140		SFO
Geometric mean/median for alkaline soils (pH>7)					-	254/248		

Appendix 1 – List of endpoints

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	X ¹	pH (CaCl ₂)	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm.	Method of calculatio n
Silt (0-30cm) Silt loam (30-90cm) Bare soil	Northern Germany		7.03- 7.63	90	5	16.5	6	2 (χ ² =6)	SFO
Silt loam (0-30cm) Silty clay loam (30-70cm) Silt loam (70-90cm)	Southern Germany		6.9-7.6	90	5	16.5	5	3 (χ ² =6)	SFO

IN-D8526	Aerobic conditions								
Soil type	Location		pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm.	Method of calculatio n
Silt (0-30cm) Silt loam (30-90cm) Bare soil	Northern Germany		7.03 - 7.63	90	85	282	19	33 (χ ² =20)	SFO

Appendix 1 – List of endpoints

IN-E7710		Aerobic conditions							
Soil type	Location		pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm.	Method of calculation
Silt (0-30cm) Silt loam (30-90cm) Bare soil	Northern Germany		7.03 - 7.63	90	319	1059	26	101 (χ ² =28)	SFO
Silt loam (0-30cm) Silty clay loam (30-70cm) Silt loam (70-90cm)	Southern Germany		6.9-7.6	90	146	485	20	51 (χ ² =19)	SFO

IN-M7222		Aerobic conditions							
Soil type	Location		pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	St. (χ ²)	DT ₅₀ (d) Norm.	Method of calculation
Silt (0-30cm) Silt loam (30-90cm) Bare soil	Northern Germany		7.03 - 7.63	90	>300	-	39	>300 (χ ² =38)	SFO
Silt loam (0-30cm) Silty clay loam (30-70cm) Silt loam (70-90cm)	Southern Germany		6.9-7.6	90	63	210	28	31 (χ ² =30)	SFO

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

Yes for IN-D8526 and IN-M7222

Soil accumulation and plateau concentration ‡

-

Appendix 1 – List of endpoints

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X ²²	pH	t. °C / % MWHC	DT ₅₀ / DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (r ²)	Method of calculation
Sandy loam (Somersham)		7.8	25°C, 75% FC for 5 days, then flooded for up to 62 days	21/-	-		Linear first- order
Geometric mean/median			-	-	-	-	-

Soil adsorption/desorption (Annex II A, point 7.1.2)

Triflurosulfuron-methyl ‡									
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n		
Sandy loam (Somersham)	1.45	7.3	-	-	0.36	25	0.90		
Sandy loam (Hanford)	0.38	6.2	-	-	0.50*	132*	0.94*		
Silty clay (Fargo-Ryan)	2.70	7.4	-	-	1.28	47	0.92		
Silt loam (Portneuf)	0.79	8.2	-	-	0.41	52	0.94		
Loamy sand (Speyer 2.2)	1.93	5.9	-	-	0.67	35	0.92		
Arithmetic mean/median						0.68/0.54	40/41	0.92/0.92	
pH dependence, Yes or No				No					

* Values from this soil are not included in the mean and median. The soil is considered not representative of agricultural soils due to its low organic carbon content.

²² X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Appendix 1 – List of endpoints

IN-D8526 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam (Somersham)	1.45	7.3	-	-	1.05	72	0.91
Sandy loam (Hanford)	0.38	6.2	-	-	5.24*	1379*	0.87*
Silty clay (Fargo-Ryan)	2.70	7.4	-	-	10.1	374	0.88
Silt loam (Portneuf)	0.79	8.2	-	-	1.35	171	0.89
Loamy sand (Speyer 2.2)	1.93	5.9	-	-	1.35	70	0.91
Arithmetic mean/median					3.46/1.35	172/122	0.90/0.90
pH dependence (yes or no)				No			

* Values from this soil are not included in the mean and median. The soil is considered not representative of agricultural soils due to its very organic carbon content.

IN-E7710 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam (Somersham)	1.45	7.3	-	-	0.59	41	0.90
Sandy loam (Hanford)	0.38	6.2	-	-	0.72*	189*	0.89*
Silty clay (Fargo-Ryan)	2.70	7.4	-	-	4.88	181	0.87
Silt loam (Portneuf)	0.79	8.2	-	-	0.87	110	0.85
Loamy sand (Speyer 2.2)	1.93	5.9	-	-	2.43	126	0.80
Arithmetic mean/median					2.19/1.65	115/118	0.86/0.86
pH dependence (yes or no)				No			

* Values from this soil are not included in the mean and median. The soil is considered not representative of agricultural soils due to its low organic carbon content.

Appendix 1 – List of endpoints

IN-M7222 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam (Somersham)	1.45	7.3	-	-	0.61	42	0.95
Sandy loam (Hanford)	0.38	6.2	-	-	0.69*	182*	0.93*
Silty clay (Fargo-Ryan)	2.70	7.4	-	-	3.42	127	0.94
Silt loam (Portneuf)	0.79	8.2	-	-	0.37	47	1.05
Loamy sand (Speyer 2.2)	1.93	5.9	-	-	0.59	31	0.99
Arithmetic mean/median					1.25/0.60	62/45	0.98/0.97
pH dependence (yes or no)				No			

* Values from this soil are not included in the mean and median. The soil is considered not representative of agricultural soils due to its low organic carbon content.

IN-W6725 ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam (Somersham)	1.45	7.3	-	-	0.08	6	0.95
Sandy loam (Hanford)	0.38	6.2	-	-	0.16*	42*	1.03*
Silty clay (Fargo-Ryan)	2.70	7.4	-	-	0.59	22	0.95
Arithmetic mean/median					0.34/0.34	14/14	0.95/0.95
pH dependence (yes or no)				No			

* Values from this soil are not included in the mean and median. The soil is considered not representative of agricultural soils due to its low organic carbon content.

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

Column leaching ‡	No data provided. Not required.
Aged residues leaching ‡	No data provided. Not required.
Lysimeter/ field leaching studies ‡	No data provided. Not required.

Appendix 1 – List of endpoints

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT ₅₀ (d): 15 days, maximal laboratory value
Method of calculation	Kinetics: SFO
Application data	Crop: sugar beet Depth of soil layer: 5cm Soil bulk density: 1.5g/cm ³ No crop interception Number of applications: 2 Interval (d): 7 Application rate(s): 30 g as/ha

PEC _(s) (µg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	40		68.9	
Short term 24h	38.2	39.1	65.8	67.3
2d	36.5	38.2	62.8	65.8
4d	33.3	36.5	57.3	62.9
Long term 7d	28.9	34.2	49.9	58.9
28d	11.0	22.4	18.9	38.6
50d	4.0	15.6	6.8	26.9
100d	0.4	8.6	0.7	14.8
Plateau concentration	-	-		

Appendix 1 – List of endpoints

IN-W6725	Molecular weight relative to the parent: 0.4			
Method of calculation	DT ₅₀ (d): 403 days			
	Kinetics: SFO			
	worst case from lab studies.			
Application data	Application rate assumed: 10.044 g as/ha (assumed IN-W6725 is formed at a maximum of 83.7 % of the applied dose)			
PEC_(s) (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	13.4		26.6	
Short term 24h	13.4	13.4	26.6	26.6
2d	13.4	13.4	26.5	26.6
4d	13.3	13.4	26.4	26.5
Long term 7d	13.2	13.3	26.3	26.4
28d	12.8	13.1	25.3	26.0
50d	12.3	12.8	24.4	25.5
100d	11.3	12.3	22.4	24.4
Plateau concentration	57 µg/kg for 1 application/year 31.4 µg/kg for 1 application every third yer			

Appendix 1 – List of endpoints

IN-D8526	Molecular weight relative to the parent: 0.48			
Method of calculation	DT ₅₀ (d): 369 days			
	Kinetics: DFOP			
	worst case from lab studies.			
Application data	Application rate assumed: 13.29 g as/ha (assumed IN-D8526 is formed at a maximum of 92.3% of the applied dose)			
PEC_(s) (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	17.7		32.7	
Short term 24h	17.2	17.5	31.9	32.3
2d	16.8	17.2	31.2	31.9
4d	15.9	16.8	29.9	31.2
Long term 7d	15.0	16.2	28.4	30.3
28d	12.0	13.9	23.7	26.6
50d	11.3	12.9	22.5	25.0
100d	10.7	11.9	21.3	23.4
Plateau concentration	86.7 µg/kg for 1 application/year 44.5 µg/kg for 1 application every third yer			

Appendix 1 – List of endpoints

IN-E7710	Molecular weight relative to the parent: 0.45			
Method of calculation	DT ₅₀ (d): 393 days			
	Kinetics: FOMC			
	worst case from lab studies.			
Application data	Application rate assumed: 4.6035 g as/ha (assumed IN-E7710 is formed at a maximum of 34.1 % of the applied dose)			
PEC_(s) (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	6.1		11.7	
Short term 24h	6.0	6.1	11.5	11.6
2d	5.9	6.0	11.3	11.5
4d	5.7	5.9	11.1	11.3
Long term 7d	5.5	5.8	10.7	11.1
28d	4.8	5.3	9.4	10.2
50d	4.4	4.9	8.6	9.7
100d	3.9	4.5	7.8	8.9
Plateau concentration*	20.1 µg/kg for 1 application/year 13.0 µg/kg for 1 application every third yer			

*Plateau concentration was calculated with the maximal SFO DT50 value of 273 days as it was not reached with the FOMC value.

Appendix 1 – List of endpoints

IN-M7222	Molecular weight relative to the parent: 0.425			
Method of calculation	DT ₅₀ (d): 485 days			
	Kinetics: SFO			
	worst case from lab studies.			
Application data	Application rate assumed: 1.3898 g as/ha (assumed IN-M7222 is formed at a maximum of 10.9 % of the applied dose)			
PEC_(s) (µg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.85	1.85	3.68	3.68
Short term 24h	1.85	1.85	3.68	3.68
2d	1.84	4.85	3.67	3.68
4d	1.84	1.85	3.66	3.67
Long term 7d	1.83	1.84	3.64	3.66
28d	1.78	1.81	3.54	3.61
50d	1.72	1.79	3.43	3.55
100d	1.60	1.72	3.19	3.43
Plateau concentration	9.1 µg/kg for 1 application/year 4.7 µg/kg for 1 application every third yer			

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 % ‡	<p>pH 5: 3.7d at 25 °C (linear 1st order) IN-W6725: 99.4 % AR (30 d), [¹⁴C- ester carbonyl]-label IN-D8526: 98.4 % AR (30 d), [¹⁴C- triazine]-label</p>
	<p>pH 7: 32 d at 25 °C (linear 1st order) IN-W6725: 46.4 % AR (30 d), [¹⁴C- ester carbonyl]-label IN-D8526: 47.4 % AR (30 d), [¹⁴C- triazine]-label</p>
	<p>pH 9: 36 d at 25 °C (linear 1st order) IN-W6725: 44.1 % AR (30 d), [¹⁴C- ester carbonyl]-label IN-D8526: 43.0 % AR (30 d), [¹⁴C- triazine]-label</p>
Photolytic degradation of active substance and metabolites above 10 % ‡	<p>Artificial light (Xenon) for 15 days at 25°C</p> <p>Considering the DT50 obtained for photolysis, hydrolysis and for dissipation from the water phase in water sediment systems, hydrolysis and dissipation from the water phase are expected to be the major route of degradation of triflurosulfuron-methyl in environmental conditions. Photolysis is not expected to be significant.</p>
	<p>pH 5: 3.8 d (1st order) IN-W6725: 71.2% (15 d), [¹⁴C- triazine]-label IN-D8526: 46.8% (7 d), [¹⁴C- ester carbonyl]-label IN-E0Q47: 20.1% (15 d) , [¹⁴C- ester carbonyl]-label Unknown T9: 24% (15 d) , [¹⁴C- ester carbonyl]-label</p>
	<p>pH 7: 13.9 d (1st order) IN-W6725: 18.1% (15 d), [¹⁴C- triazine]-label IN-66036: 14.7% (15 d), [¹⁴C- triazine]-label IN-D8526: 18.2% (15 d), [¹⁴C- ester carbonyl]-label Unknown T9: 13.5% (7 d) , [¹⁴C- ester carbonyl]-label</p>

Appendix 1 – List of endpoints

	<p>pH 9: 24.6 d (1st order) IN-W6725: 18.9% (15 d), [¹⁴C- triazine]-label IN-66036: 9.1-9.5% (15 d), [¹⁴C- triazine]-label & [¹⁴C- ester carbonyl]-label IN-D8526: 12.1% (15 d), [¹⁴C- ester carbonyl]-label Unknown T9: 16.2% (15 d) , [¹⁴C- ester carbonyl]-label</p>
Quantum yield of direct phototransformation in water at $\lambda > 290$ nm	<p>Parent: $6.85 \cdot 10^{-5} \text{ mol} \cdot \text{Einstein}^{-1}$ at pH 7 (estimated GSSOLAR) IN-D8526: stable at pH 7 IN-W6725: stable at pH 7</p>
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Triflurosulfuron-methyl	Distribution (eg max in water 94.9- 90.8after 0-0.25 d. Max. sed 22.5-13.3 % after 7-14 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT ₅₀ -DT ₉₀ whole sys.	St. (r ²)	DissT ₅₀ -DissT ₉₀ water	St. (r ²)	DT ₅₀ -DT ₉₀ sed	St. (r ²)	Method of calculation
Brown Carrick Hill	7.5	7.2	20	40-133	0.99	31-103	0.99	-	-	SFO
Hinchingbrooke	7.5	7.7	20	22-73	0.99	18-60	0.99	-	-	SFO
Geometric mean/median DT50			-	30/31		24/25		-		SFO

Mineralization and non extractable residues					
Water / sediment system	pH water phase	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)
Brown Carrick Hill	7.5	7.2	1.0-2.8 after 100 d	5.5-16.1 after 100 days	5.5-16.1 after 100 days
Hinchingbrooke	7.5	7.7	1.5-2.1 after 100 d	5.6-9.0 after 100 days	5.6-9.0 after 100 days

Appendix 1 – List of endpoints

IN-W6725	Distribution (eg max in water 38.4 after 100 d. Max. sed 12 % after 100 d)
IN-D8526	Distribution (eg max in water 23.2 after 61 d. Max. sed 18.9 % after 61 d)
IN-E7710	Distribution (eg max in water 10.7 after 61 d. Max. sed <5.3 %)
IN-JK555	Distribution (eg max in water 28.6% after 100 d. Max. sed 19.7 % after 61 days)

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 492.4 Water solubility (mg/L): 260 K _{OC} (L/kg): 40 DT ₅₀ soil (d): 6.5 days (geomean, Lab, SFO) DT ₅₀ water/sediment system (d): 40 (representative worst case from sediment water studies) DT ₅₀ water (d): 1000 DT ₅₀ sediment (d): 40 Crop interception (%): Minimal crop cover
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: 1.1 Vapour pressure: 6 10 ⁻¹⁰ Pa Koc: 40 1/n: 0.92
Application rate	Crop: Sugar beets Number of applications: 2 Interval (d): 7 Application rate(s): 30 g as/ha Application window: D3: 11 April to 11 May D4: 20 April to 20 May R1: 2 April to 2 May R3: 6 March to 5 April

Appendix 1 – List of endpoints

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	19.54		7.59	
	24 h	19.18	19.36	7.67	7.63
	2 d	18.85	19.18	7.54	7.62
	4 d	18.20	18.85	7.28	7.51
	7 d	17.28	18.38	6.91	7.33
	14 d	15.31	17.33	6.12	6.92
	21 d	13.56	16.36	5.42	6.54
	28 d	12.01	15.46	4.80	6.18
	42 d	9.42	13.86	3.77	5.54

FOCUS STEP 2 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.93		0.75	
	24 h	1.92	1.92	0.75	0.75
	2 d	1.92	1.92	0.75	0.75
	4 d	1.91	1.92	0.75	0.75
	7 d	1.90	1.91	0.75	0.75
	14 d	1.88	1.90	0.74	0.75
	21 d	1.86	1.89	0.73	0.74
	28 d	1.84	1.88	0.72	0.74
	42 d	1.80	1.86	0.71	0.73

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
Southern EU March-May	0 h	3.39		1.33	
	24 h	3.38	3.38	1.33	1.33
	2 d	3.37	3.38	1.33	1.33
	4 d	3.36	3.37	1.32	1.33
	7 d	3.35	3.37	1.32	1.32
	14 d	3.31	3.35	1.30	1.32
	21d	3.28	3.33	1.29	1.31
	28 d	3.24	3.31	1.27	1.30
	42 d	3.17	3.28	1.25	1.29
Southern EU June- September	0 h	2.66	---	1.04	---
	24 h	2.65	2.65	1.04	1.04
	2 d	2.65	2.65	1.04	1.04
	4 d	2.64	2.65	1.04	1.04
	7 d	2.62	2.64	1.03	1.04
	14 d	2.60	2.63	1.02	1.03
	21d	2.57	2.61	1.01	1.03
	28 d	2.54	2.60	1.00	1.02
	42 d	2.49	2.57	0.98	1.01

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 ditch		0 h	0.136		0.027	
		24 h	0.068	0.108	0.021	0.026
		2 d	0.009	0.070	0.016	0.023
		4 d	<0.001	0.036	0.012	0.019
		7 d	<0.001	0.021	0.010	0.016
		14 d	<0.001	0.020	0.007	0.013
		21d	<0.001	0.014	0.005	0.012
		28 d	<0.001	0.010	0.004	0.011
		42 d	<0.001	0.007	0.003	0.009

Appendix 1 – List of endpoints

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D4 pond		0 h	0.010		0.013	
		24 h	0.010	0.010	0.013	0.013
		2 d	0.009	0.009	0.013	0.013
		4 d	0.009	0.009	0.013	0.013
		7 d	0.009	0.009	0.012	0.013
		14 d	0.009	0.009	0.012	0.013
		21 d	0.008	0.009	0.012	0.012
		28 d	0.008	0.008	0.012	0.012
		42 d	0.008	0.008	0.011	0.012
D4 stream		0 h	0.112		0.004	
		24 h	<0.001	0.007	0.001	0.002
		2 d	<0.001	0.004	0.001	0.002
		4 d	<0.001	0.003	<0.001	0.002
		7 d	<0.001	0.003	<0.001	0.002
		14 d	<0.001	0.002	<0.001	0.002
		21 d	<0.001	0.002	<0.001	0.002
		28 d	<0.001	0.001	<0.001	0.002
		42 d	<0.001	0.001	<0.001	0.002
R1 pond		0 h	0.012		0.015	
		24 h	0.012	0.012	0.015	0.015
		2 d	0.012	0.012	0.015	0.015
		4 d	0.012	0.012	0.015	0.015
		7 d	0.012	0.012	0.015	0.015
		14 d	0.011	0.011	0.015	0.015
		21 d	0.010	0.011	0.014	0.015
		28 d	0.010	0.011	0.014	0.015
		42 d	0.008	0.011	0.013	0.015
R1 stream		0 h	0.366		0.045	
		24 h	<0.001	0.144	0.017	0.030
		2 d	<0.001	0.072	0.012	0.023
		4 d	<0.001	0.036	0.009	0.017
		7 d	<0.001	0.023	0.008	0.013
		14 d	<0.001	0.013	0.008	0.010
		21 d	<0.001	0.009	0.005	0.009
		28 d	<0.001	0.007	0.004	0.008
		42 d	<0.001	0.005	0.003	0.006

Appendix 1 – List of endpoints

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3 stream		0 h	2.156		0.045	
		24 h	1.044	0.144	0.017	0.030
		2 d	0.002	0.072	0.012	0.023
		4 d	<0.001	0.036	0.009	0.017
		7 d	0.006	0.023	0.008	0.013
		14 d	<0.001	0.013	0.008	0.010
		21 d	<0.001	0.009	0.005	0.009
		28 d	<0.001	0.007	0.004	0.008
		42 d	<0.001	0.005	0.003	0.006

IN-W6725

Parameters used in FOCUS_{sw} step 1 and 2

Molecular weight: 197.2
 Water solubility (mg/L): 260
 Soil or water metabolite: soil and water
 Koc (L/kg): 6
 DT₅₀ soil (d): 89 days (Lab, median, SFO)
 DT₅₀ water/sediment system (d): 1000
 DT₅₀ water (d): 1000
 DT₅₀ sediment (d): 1000
 Crop interception (%): Minimal crop cover
 Maximum occurrence observed:
 Total system: 49.8%
 Soil: 83.7%

Application rate

Crop: sugar beets
 Number of applications: 2
 Interval (d): 7
 Application rate(s): 30 g as/ha
 Application window: March-May & June-September

Appendix 1 – List of endpoints

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	6.76	---	0.40	---
	24 h	6.76	6.76	0.41	0.40
	2 d	6.75	6.76	0.41	0.40
	4 d	6.74	6.75	0.40	0.40
	7 d	6.73	6.74	0.40	0.40
	14 d	6.69	6.73	0.40	0.40
	21 d	6.66	6.71	0.40	0.40
	28 d	6.63	6.70	0.40	0.40
	42 d	6.57	6.66	0.39	0.40

FOCUS STEP 2 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	1.10	---	0.07	---
	24 h	1.10	1.10	0.07	0.07
	2 d	1.10	1.10	0.07	0.07
	4 d	1.10	1.10	0.07	0.07
	7 d	1.09	1.10	0.07	0.07
	14 d	1.09	1.09	0.07	0.07
	21 d	1.08	1.09	0.07	0.07
	28 d	1.08	1.09	0.06	0.07
	42 d	1.07	1.08	0.06	0.07

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
Southern EU March-May	0 h	2.10	---	0.13	---
	24 h	2.10	2.10	0.13	0.13
	2 d	2.10	2.10	0.13	0.13
	4 d	2.10	2.10	0.13	0.13
	7 d	2.09	2.10	0.13	0.13
	14 d	2.08	2.09	0.13	0.13
	21 d	2.07	2.09	0.12	0.13
	28 d	2.06	2.08	0.12	0.13
	42 d	2.04	2.07	0.12	0.12
Southern EU June- September	0 h	1.60	---	0.10	---
	24 h	1.60	1.60	0.10	0.10
	2 d	1.60	1.60	0.10	0.10
	4 d	1.60	1.60	0.10	0.10
	7 d	1.59	1.60	0.10	0.10
	14 d	1.59	1.59	0.10	0.10
	21 d	1.58	1.59	0.09	0.10
	28 d	1.57	1.59	0.09	0.10
	42 d	1.56	1.58	0.09	0.09

Appendix 1 – List of endpoints

IN-D8526
 Parameters used in FOCUS_{sw} step 1 and 2

Molecular weight: 237.2
 Water solubility (mg/L): 260
 Soil or water metabolite: soil and water
 Koc (L/kg): 172
 DT₅₀ soil (d): 152 days* (Lab, max for acidic soils, SFO)
 DT₅₀ water/sediment system (d): 1000
 DT₅₀ water (d): 1000
 DT₅₀ sediment (d): 1000
 Crop interception (%): Minimal crop cover
 Maximum occurrence observed:
 Total system: 42.1%
 Soil: 92.3%

Application rate

Crop: sugar beets
 Number of applications: 2
 Interval (d): 7
 Application rate(s): 30 g as/ha
 Application window: March-May & June-September

* This value was the worst-case before the Peer Review. It was agreed PEC_{gw} do not need to be recalculated to finalise EU risk assessment.

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	7.35	---	12.44	---
	24 h	7.32	7.33	12.59	12.52
	2 d	7.31	7.32	12.58	12.55
	4 d	7.30	7.32	12.56	12.56
	7 d	7.29	7.31	12.54	12.56
	14 d	7.25	7.29	12.48	12.53
	21 d	7.22	7.27	12.42	12.50
	28 d	7.18	7.25	12.36	12.47
	42 d	7.11	7.22	12.24	12.42

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 h	1.20		2.06	
	24 h	1.20	1.20	2.06	2.06
	2 d	1.20	1.20	2.06	2.06
	4 d	1.20	1.20	2.05	2.06
	7 d	1.19	1.20	2.05	2.06
	14 d	1.19	1.19	2.04	2.05
	21 d	1.18	1.19	2.03	2.05
	28 d	1.18	1.19	2.02	2.04
	42 d	1.16	1.18	2.00	2.03
Southern EU March-May	0 h	2.32		3.98	
	24 h	2.32	2.32	3.98	3.98
	2 d	2.31	2.32	3.98	3.98
	4 d	2.31	2.31	3.97	3.98
	7 d	2.31	2.31	3.96	3.97
	14 d	2.29	2.31	3.94	3.96
	21 d	2.28	2.30	3.93	3.95
	28 d	2.27	2.30	3.91	3.94
	42 d	2.25	2.28	3.87	3.93
Southern EU June- September	0 h	1.76		3.02	
	24 h	1.76	1.76	3.02	3.02
	2 d	1.76	1.76	3.02	3.02
	4 d	1.75	1.76	3.01	3.02
	7 d	1.75	1.75	3.01	3.01
	14 d	1.74	1.75	2.99	3.01
	21 d	1.73	1.75	2.98	3.00
	28 d	1.72	1.74	2.96	2.99
	42 d	1.71	1.73	2.93	2.98

Appendix 1 – List of endpoints

IN-E7710 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 223.2 Water solubility (mg/L): 260 Soil or water metabolite: soil and water Koc (L/kg): 115 DT ₅₀ soil (d): 109 days (Lab, median, SFO) DT ₅₀ water/sediment system (d): 1000 DT ₅₀ water (d): 1000 DT ₅₀ sediment (d): 1000 Crop interception (%): Minimal crop cover Maximum occurrence observed: Total system: 15.6% Soil: 34.1%
Application rate	Crop: sugar beets Number of applications: 2 Interval (d): 7 Application rate(s): 30 g as/ha Application window: March-May & June-September

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	2.72		3.08	
	24 h	2.71	2.72	3.12	3.10
	2 d	2.71	2.71	3.12	3.11
	4 d	2.71	2.71	3.11	3.11
	7 d	2.70	2.71	3.11	3.11
	14 d	2.69	2.70	3.09	3.10
	21 d	2.68	2.69	3.08	3.10
	28 d	2.66	2.69	3.06	3.09
	42 d	2.64	2.68	3.03	3.08

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 h	0.44		0.50	
	24 h	0.44	0.44	0.50	0.50
	2 d	0.44	0.44	0.50	0.50
	4 d	0.44	0.44	0.50	0.50
	7 d	0.44	0.44	0.50	0.50
	14 d	0.43	0.44	0.50	0.50
	21 d	0.43	0.44	0.50	0.50
	28 d	0.43	0.43	0.49	0.50
	42 d	0.43	0.43	0.49	0.50
Southern EU March-May	0 h	0.85		0.97	
	24 h	0.85	0.85	0.97	0.97
	2 d	0.85	0.85	0.97	0.97
	4 d	0.85	0.85	0.97	0.97
	7 d	0.84	0.85	0.97	0.97
	14 d	0.84	0.84	0.96	0.97
	21 d	0.84	0.84	0.96	0.97
	28 d	0.83	0.84	0.96	0.96
	42 d	0.82	0.84	0.95	0.96
Southern EU June- September	0 h	0.64		0.74	
	24 h	0.64	0.64	0.74	0.74
	2 d	0.64	0.64	0.74	0.74
	4 d	0.64	0.64	0.74	0.74
	7 d	0.64	0.64	0.74	0.74
	14 d	0.64	0.64	0.73	0.74
	21 d	0.63	0.64	0.73	0.73
	28 d	0.63	0.64	0.73	0.73
	42 d	0.62	0.63	0.72	0.73

Appendix 1 – List of endpoints

<p>IN-M7222 Parameters used in FOCUSsw step 1 and 2</p>	<p>Molecular weight: 209.1 Water solubility (mg/L): 260 Soil or water metabolite: soil Koc (L/kg): 62 DT₅₀ soil (d): 254 days (Lab, mean in alkaline soils, SFO) DT₅₀ water/sediment system (d): 1000 DT₅₀ water (d): 1000 DT₅₀ sediment (d): 1000 Crop interception (%): Minimal crop cover Maximum occurrence observed: Total system: 1 10⁻¹⁰% Soil: 10.9%</p>
<p>Application rate</p>	<p>Crop: sugar beets Number of applications: 2 Interval (d): 7 Application rate(s): 30 g as/ha Application window: March-May & June-September</p>

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{SW} (µg/L)		PEC _{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	0.86		0.53	
	24 h	0.85	0.85	0.53	0.53
	2 d	0.85	0.85	0.53	0.53
	4 d	0.85	0.85	0.53	0.53
	7 d	0.85	0.85	0.53	0.53
	14 d	0.85	0.85	0.53	0.53
	21 d	0.84	0.85	0.52	0.53
	28 d	0.84	0.85	0.52	0.53
	42 d	0.83	0.84	0.51	0.52

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 h	0.13		0.08	
	24 h	0.13	0.13	0.08	0.08
	2 d	0.13	0.13	0.08	0.08
	4 d	0.13	0.13	0.08	0.08
	7 d	0.13	0.13	0.08	0.08
	14 d	0.13	0.13	0.08	0.08
	21 d	0.13	0.13	0.08	0.08
	28 d	0.13	0.13	0.08	0.08
	42 d	0.13	0.13	0.08	0.08
Southern EU March-May	0 h	0.27		0.17	
	24 h	0.27	0.27	0.17	0.17
	2 d	0.27	0.27	0.17	0.17
	4 d	0.27	0.27	0.17	0.17
	7 d	0.27	0.27	0.17	0.17
	14 d	0.27	0.27	0.16	0.17
	21 d	0.26	0.27	0.16	0.17
	28 d	0.26	0.27	0.16	0.16
	42 d	0.26	0.26	0.16	0.16
Southern EU June- September	0 h	0.20		0.12	
	24 h	0.20	0.20	0.12	0.12
	2 d	0.20	0.20	0.12	0.12
	4 d	0.20	0.20	0.12	0.12
	7 d	0.20	0.20	0.12	0.12
	14 d	0.20	0.20	0.12	0.12
	21 d	0.20	0.20	0.12	0.12
	28 d	0.20	0.20	0.12	0.12
	42 d	0.20	0.20	0.12	0.12

Appendix 1 – List of endpoints

IN-JK555 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 487.4 Water solubility (mg/L): 260 Soil or water metabolite: water Koc (L/kg): 20 for PEC _{sw} , 10000 for PEC _{sed} DT ₅₀ soil (d): 1 10 ⁻¹⁰ days DT ₅₀ water/sediment system (d): 1000 DT ₅₀ water (d): 1000 DT ₅₀ sediment (d): 1000 Crop interception (%): Minimal crop cover Maximum occurrence observed: Total system: 45.4% Soil: 1 10 ⁻¹⁰ %
Application rate	Crop: sugar beets Number of applications: 2 Interval (d): 7 Application rate(s): 30 g as/ha Application window: March-May & June-September

FOCUS STEP 1 Scenario	Day after overall maximum	PEC _{sw} (µg/L)		PEC _{sed} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	0.25		0.00	
	24 h	0.24	0.24	1.73	0.86
	2 d	0.24	0.24	1.73	1.30
	4 d	0.24	0.24	1.73	1.51
	7 d	0.24	0.24	1.72	1.60
	14 d	0.24	0.24	1.71	1.66
	21 d	0.24	0.24	1.71	1.68
	28 d	0.24	0.24	1.70	1.68
	42 d	0.23	0.24	1.68	1.68

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 & Southern EU	0 h	0.22		1.47	
	24 h	0.21	0.22	1.47	1.47
	2 d	0.21	0.22	1.47	1.47
	4 d	0.21	0.21	1.46	1.47
	7 d	0.21	0.21	1.46	1.46
	14 d	0.21	0.21	1.45	1.46
	21 d	0.21	0.21	1.45	1.46
	28 d	0.21	0.21	1.44	1.45
	42 d	0.21	0.21	1.43	1.45

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.
 Model(s) used: PELMO 3.3.2
 Scenarios (list of names):
 Hambourg, Jijionen, Kremsmunster, Okehampton, Piacenza, Porto for acidic soils
 Chateaudun, Kremsmunster, Piacenza, Sevilla, Thiva for alkaline soils
 Crop: Sugar beets
 Geometric mean DT_{50lab}: 6.5 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2).
 K_{OC}: arithmetic mean 40 L/kg, ¹/_n = 0.92.
 Molecular weight: 492.5 g/mol
 Solubility: 260 mg/l
 Vapour pressure: 6 10⁻¹⁰ Pa
 Plant uptake: 0

Appendix 1 – List of endpoints

<p>Kinetic pathway: Triflurosulfuron → IN-W6725 And Triflurosulfuron → IN-D8526 → IN-E7710 → IN-M7222</p>
<p>IN-W6725 Median DT_{50lab}: 89 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: worst-case: 6 L/kg, ¹/_n= 0.95. Molecular weight: 197.2 g/mol Plant uptake: 0 Formation fraction: 1</p>
<p>IN-D8526 Worst-case DT_{50lab}: 152 d for acidic soils (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2)*. Worst-case DT_{50lab}: 62 d for alkaline soils (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: arithmetic mean 172 L/kg, ¹/_n= 0.90. Molecular weight: 237.2 g/mol Plant uptake: 0 Formation fraction: 1</p>
<p>IN-E7710 Median DT_{50lab}: 109 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K_{OC}: arithmetic mean 115 L/kg, ¹/_n= 0.86. Molecular weight: 223.2 g/mol Plant uptake: 0.5 Formation fraction: 1</p>

Appendix 1 – List of endpoints

	IN-M7222 Geomean DT _{50lab} : 118 d for acidic soils (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). Geomean DT _{50lab} : 254 d for alkaline soils (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.2). K _{OC} : arithmetic mean 62 L/kg, $1/n = 0.98$. Molecular weight: 209.1 g/mol Plant uptake: 0.5 Formation fraction: 1
Application rate	Application rate: 30 g/ha. No. of applications: 2 applications every third year Interval between applications: 7 days Time of application (month or season): 1 st application 15 days after emergence

* This value was the worst-case before the Peer Review. It was agreed PEC_{gw} do not need to be recalculated to finalise the EU risk assessment.

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

Model /Crop	Scenario – Acidic soils	Parent (µg/L)	Metabolite (µg/L)		
			IN-D8526	IN-E7710	IN-M7222
	Hamburg	✓ <0.0 01	✓ 0.031	✓ 0.057	✓ 0.705
	Jokioinen	✓ <0.0 01	✓ 0.001	✓ 0.003	✓ 0.472
	Kremsmunster	✓ <0.0 01	✓ 0.021	✓ 0.037	✓ 0.537
	Okehampton	✓ <0.0 01	✓ 0.029	✓ 0.052	✓ 0.566
	Piacenza	✓ <0.0 01	✓ 0.114	✓ 0.151	✓ 0.554
	Porto	✓ <0.0 01	✓ <0.001	✓ <0.001	✓ 0.116

Appendix 1 – List of endpoints

Model /Crop	Scenario – Alkaline soils	Parent (µg/L)	Metabolite (µg/L)		
			IN-D8526	IN-E7710	IN-M7222
	Chateaudun	✓ <0.0 01	✓ <0.001	✓ 0.018	✓ 0.939
	Kremsmunster	✓ <0.0 01	✓ <0.001	✓ 0.007	✓ 0.933
	Piacenza	✓ <0.0 01	✓ <0.005*	✓ 0.085*	✓ 0.784*
	Sevilla	✓ <0.0 01	<0.001	<0.001	0.411
	Thiva	✓ <0.0 01	✓ <0.001	✓ <0.001	✓ 0.821

* These values differ from the ones reported in the addendum / corrigendum to the DAR. The RMS identified a typo and the correct values have been reported only in the list of endpoints

Model /Crop	Scenario	Metabolite X (µg/L)	Metabolite (µg/L)		
			IN-W6725	-	-
	Chateaudun	✓ <0.0 01	✓ 1.296	-	-
	Hamburg	✓ <0.0 01	✓ 1.416	-	-
	Jokioinen	✓ <0.0 01	✓ 2.161	-	-
	Kremsmunster	✓ <0.0 01	✓ 1.386	-	-
	Okehampton	✓ <0.0 01	✓ 0.968	-	-
	Piacenza	✓ <0.0 01	✓ 0.774	-	-
	Porto	✓ <0.0 01	✓ 0.564	-	-
	Sevilla	✓ <0.0 01	✓ 0.891	-	-
	Thiva	✓ <0.0 01	✓ 0.963	-	-

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	Parent: $6.85 \cdot 10^{-5} \text{ mol} \cdot \text{Einstein}^{-1}$ at pH 7 (estimated GSSOLAR)
Photochemical oxidative degradation in air ‡	DT ₅₀ of 33.1 hours derived by the Atkinson model. OH (12 h) concentration assumed = $1.5 \cdot 10^6 \text{ per cm}^3$
Volatilisation ‡	from plant surfaces (BBA guideline): 0.8 % within 24 hours
	from soil surfaces (BBA guideline): 6.4% within 24 hours
Metabolites	No data. Not required.

PEC (air)

Method of calculation	Not required. Vapour pressure: $6 \cdot 10^{-10} \text{ Pa}$ at 25°C Henry's law constant : $1.14 \cdot 10^{-9} \text{ Pa} \cdot \text{m}^3 \cdot \text{mol}^{-1}$ at 20°C, pH 7
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PEC_(a)

Maximum concentration	Negligible based on expert judgement
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Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: triflurosulfuron-methyl, IN-W6725, IN-D8526, IN-E7710, IN-M7222 Groundwater: triflurosulfuron-methyl, IN-W6725, IN-D8526, IN-E7710, IN-M7222 Surface water: triflurosulfuron-methyl, IN-W6725, IN-D8526, IN-E7710, IN-JK555, IN-M7222 (from soil) Sediment: triflurosulfuron-methyl, IN-W6725, IN-D8526, IN-JK555, IN-M7222 (from soil) Air: triflurosulfuron-methyl
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Appendix 1 – List of endpoints

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

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

Candidate for R53

Appendix 1 – List of endpoints

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/day)	Endpoint (mg/kg feed)
Birds ‡				
<i>Colinus virginianus</i> <i>Anas platyrhynchos</i>	Triflurosulfuron-methyl	Acute	> 2250	
<i>Colinus virginianus</i>	WG 50	Acute	> 2250 WG 50	
<i>Anas platyrhynchos</i>	Triflurosulfuron-methyl	Short-term	> 1535	> 5620
<i>Colinus virginianus</i>	Triflurosulfuron-methyl	Long-term	27.6	250
Mammals ‡				
rat	Triflurosulfuron-methyl	Acute	> 5000	
rat	WG 50	Acute	> 5000 WG 50	
rat	Triflurosulfuron-methyl	Long-term	5.8	
Additional higher tier studies ‡				
No				

Appendix 1 – List of endpoints

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

Sugarbeet 2x 30 g a.s./ha

Indicator species/Category ²	Time scale	ETE mg/kg bw	TER ¹	Annex VI Trigger ³
Tier 1 (Birds)				
Medium herbivorous	Acute	2.78	810	10
Medium herbivorous	Short-term	1.47	1042	10
Medium herbivorous	Long-term	0.78	35.6	5
Insectivorous	Acute	1.62	1387	10
Insectivorous	Short-term	0.90	1697	10
Insectivorous	Long-term	0.90	30.5	5
Fish eating bird	Long-term	a.s.: 0.0108	2560	5
Fish eating bird	Long-term	IN-JK555: 0.016	1725	5
Earthworm eating bird	Long-term	a.s.: 0.036	767	5
Drinking water (small bird 0.01 kg bw)	Acute	16	> 141	10
Tier 1 (Mammals)				
Medium herbivorous	Acute	1.02	> 4887	10
Medium herbivorous	Long-term	0.29	20.3	5
Fish eating mammal	Long-term	a.s.: 0.0067	870	5
Fish eating mammal	Long-term	IN-JK555: 0.0099	586	5
Earthworm eating mammal	Long-term	a.s.: 0.046	126	5
Drinking water (small mammal, 0.01 kg bw)	Acute	9.6	> 521	10

¹ in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

² for cereals indicate if it is early or late crop stage

³ If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Appendix 1 – List of endpoints

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/L)
Laboratory tests ‡				
Fish				
<i>Oncorhynchus mykiss</i>	Triflurosulfuron-methyl	96 hr (static)	Mortality, EC ₅₀	730
<i>Oncorhynchus mykiss</i>	Triflurosulfuron-methyl	97 d (flow-through)	Growth NOEC	57.7
<i>Oncorhynchus mykiss</i>	WG 50	96 hr (static)	Mortality, EC ₅₀	75 a.s.
<i>Oncorhynchus mykiss</i>	IN-D8526	96 hr (static)	Mortality, EC ₅₀	99
<i>Oncorhynchus mykiss</i>	IN-W6725	96 hr (static)	Mortality, EC ₅₀	> 120
<i>Oncorhynchus mykiss</i>	IN-E7710	96 hr (static)	Mortality, EC ₅₀	> 90.6
<i>Oncorhynchus mykiss</i>	IN-M7222	96 hr (static)	Mortality, EC ₅₀	> 121
<i>Oncorhynchus mykiss</i>	IN-JK555	96 hr (static)	Mortality, EC ₅₀	> 100
Aquatic invertebrate				
<i>Daphnia magna</i>	Triflurosulfuron-methyl	48 h (static)	Mortality, EC ₅₀	> 960
<i>Daphnia magna</i>	Triflurosulfuron-methyl	21 d (static)	Reproduction, NOEC	11
<i>Daphnia magna</i>	WG 50	48 h (static)	Mortality, EC ₅₀	> 600 a.s. (not filtered) > 200 a.s. (filtered)
<i>Daphnia magna</i>	IN-D8526	48 h (static)	Mortality, EC ₅₀	324
<i>Daphnia magna</i>	IN-D8526	21 d (static)	Reproduction, NOEC	1.56
<i>Daphnia magna</i>	IN-W6725	48 h (static)	Mortality, EC ₅₀	> 130
<i>Daphnia magna</i>	IN-W6725	21 d (static)	Reproduction, NOEC	> 50

Appendix 1 – List of endpoints

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity ¹ (mg/L)
<i>Daphnia magna</i>	IN-E7710	48 h (static)	Mortality, EC ₅₀	107
<i>Daphnia magna</i>	IN-M7222	48 h (static)	Mortality, EC ₅₀	> 128
<i>Daphnia magna</i>	IN-JK555	48 h (static)	Mortality, EC ₅₀	> 100
<i>Daphnia magna</i>	IN-JK555	21 d (static)	Reproduction, NOEC	32.8
Algae				
<i>Pseudokirchneriella subcapitata</i>	Triflurosulfuron-methyl	120 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	0.0463 - -
<i>Pseudokirchneriella subcapitata</i>	WG 50	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	0.031 a.s. - -
<i>Pseudokirchneriella subcapitata</i>	IN-D8526	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	130 > 220
<i>Pseudokirchneriella subcapitata</i>	IN-W6725	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	26 28.5 38.9
<i>Pseudokirchneriella subcapitata</i>	IN-E7710	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	86 95.6 > 127
<i>Pseudokirchneriella subcapitata</i>	IN-M7222	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	48.6 54.6 132
<i>Pseudokirchneriella subcapitata</i>	IN-JK555	72 h (static)	Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	> 100 > 100
<i>Pseudokirchneriella subcapitata</i>	IN-E0Q47	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	> 30 > 30 > 30
<i>Pseudokirchneriella subcapitata</i>	IN-66036	72 h (static)	Cell density EC ₅₀ Biomass: E _b C ₅₀ Growth rate: E _r C ₅₀	0.383 0.425 > 1.6

Appendix 1 – List of endpoints

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity ¹ (mg/L)
Higher plant				
<i>Lemna gibba</i>	Triflurosulfuron-methyl	14 d (static)	Fronds, EC ₅₀	0.00282
<i>Lemna gibba</i>	WG 50	14 d (static)	Fronds, EC ₅₀	0.0022 a.s.
<i>Myriophyllum aquaticum</i>	SC 25	14 d (static)	Fronds, EC ₅₀	0.018 a.s.
<i>Lemna gibba</i>	IN-D8526	14 d (static)	Fronds, EC ₅₀	> 117
<i>Lemna gibba</i>	IN-W6725	14 d (static)	Fronds, EC ₅₀	94.3
<i>Lemna gibba</i>	IN-E7710	14 d (static)	Fronds, EC ₅₀	> 119
<i>Lemna gibba</i>	IN-M7222	14 d (static)	Fronds, EC ₅₀	> 100
<i>Lemna gibba</i>	IN-JK555	14 d (static) ²	Fronds, EC ₅₀ NOEC (visual)	not reliable 10
<i>Lemna gibba</i>	IN-E0Q47	14 d (static)	Fronds, EC ₅₀	> 30
<i>Lemna gibba</i>	IN-66036	14 d (static)	Fronds, EC ₅₀	0.0055
Microcosm or mesocosm tests				
not required				

¹ indicate whether based on nominal (_{nom}) or mean measured concentrations (_{mm}). In the case of preparations indicate whether endpoints are presented as units of preparation or a.s.

² Validity of the study is questioned however the visual NOEC is accepted as informative value (PRAPeR 48).

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

FOCUS Step1

Sugarbeet, 2 x 30 g a.s./ha

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PEC _i sw	PEC _{twa}	TER	Annex VI Trigger ¹
a.s.	Fish	730	Acute	19.54		37359	100
a.s.	Fish	57.7	Chronic	19.54		2953	10
a.s.	Aquatic invertebrates	> 960	Acute	19.54		49130	100
a.s.	Aquatic invertebrates	11	Chronic	19.54		563	10
a.s.	Algae	0.0463	Chronic	19.54		2.37	10

Appendix 1 – List of endpoints

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PEC _{i sw}	PEC _{twa}	TER	Annex VI Trigger ¹
a.s.	Higher plants ²	0.00282	Chronic	19.54		0.14	10
IN-D8526	Aquatic invertebrates	1.56	Chronic	7.35		212	10
IN-W6725	Algae	26	Chronic	6.76		3846	10
IN-E7710	Algae	86	Chronic	2.72		31618	10
IN-M7222	Algae	48.6	Chronic	0.86		56512	10
IN-JK555	Higher plants	10	Chronic	0.25		40000	10
WG 50%	Higher plants	0.00215	Chronic	19.54		0.11	10

FOCUS Step 2

Sugarbeet, 2 x 30 g a.s./ha

Test substance	N/S ¹	Organism ²	Toxicity endpoint (mg/L)	Time scale	PEC ³ initial	TER	Annex VI Trigger ⁴
a.s.	N	Algae	0.0463	Chronic	1.93	24	10
a.s.	S spring	Algae	0.0463	Chronic	3.89	12	10
a.s.	S summer	Algae	0.0463	Chronic	2.66	17	10
a.s.	N	Higher plants ²	0.00282	Chronic	1.93	1.46	10
a.s.	S spring	Higher plants ²	0.00282	Chronic	3.89	0.72	10
a.s.	S summer	Higher plants ²	0.00282	Chronic	2.66	1.06	10
WG 50%	N	Higher plants	0.00215	Chronic	1.93	1.11	10
WG 50%	S spring	Higher plants	0.00215	Chronic	3.89	0.55	10
WG 50%	S summer	Higher plants	0.00215	Chronic	2.66	0.81	10

Appendix 1 – List of endpoints

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Only the lowest endpoint will be considered: 0.00215 mg a.s./L (WG 50%).

Sugarbeet, 2 x 30 g a.s./ha

Test substance	Scenario ¹	Water body type ²	Test organism ³	Time scale	Toxicity endpoint (mg/L)	PEC ⁴ _{sw}	TER	Annex VI trigger ⁵
WG 50%	D3	ditch	Higher plants	Chronic	0.00215	0.136	16	10
WG 50%	D4	pond	Higher plants	Chronic	0.00215	0.010	215	10
WG 50%	D4	stream	Higher plants	Chronic	0.00215	0.112	19	10
WG 50%	R1	pond	Higher plants	Chronic	0.00215	0.012	179	10
WG 50%	R1	stream	Higher plants	Chronic	0.00215	0.366	5.9	10
WG 50%	R3	stream	Higher plants	Chronic	0.00215	2.156	1	10

¹ drainage (D1-D6) and run-off (R1-R4)

² ditch/stream/pond

³ include critical groups which fail at Step 2.

⁴ indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used

⁵ If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

FOCUS Step 4

Refined risk assessments and / or mitigation measures should be made at the MS level since since the input in water is mainly driven by the run-off route.

Spray – drift (May 2007)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
2 x 0.030	sugar beet	<i>Lemna gibba</i>	14 d	1	4.19	10
2 x 0.030	sugar beet	<i>Lemna gibba</i>	14 d	5	20.48	10

Appendix 1 – List of endpoints

Bioconcentration				
	Active substance	IN-JK555	Metabolite 2	Metabolite 3
logP _{O/W}	0.96			
Bioconcentration factor (BCF) ¹ ‡	Not required X*	23.3 ^a		
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT ₅₀)				
(CT ₉₀)				
Level and nature of residues (%) in organisms after the 14 day depuration phase				

¹ only required if log P_{O/W} > 3.

* based on total ¹⁴C or on specific compounds

^a value used in the risk assessment of secondary poisoning to birds and mammals

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

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ µg/bee)
Triflusal-methyl ‡	> 100	> 100
Field or semi-field tests		
not required		

‡ for preparations indicate whether endpoint is expressed in units of a.s. or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
Triflusal-methyl	Contact	< 0.3	50
Triflusal-methyl	oral	< 0.3	50

Appendix 1 – List of endpoints

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR ₅₀ g/ha ¹)
<i>Typhlodromus pyri</i> ‡	WG 50	Mortality	> 120 g WG 50/ha
<i>Aphidius rhopalosiphi</i> ‡	WG 50	Mortality	> 120 g WG 50/ha

¹ for preparations indicate whether endpoint is expressed in units of a.s. or preparation

Sugarbeet 2 x 30 g a.s./ha

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
WG 50	<i>Typhlodromus pyri</i>	> 120	< 0.85	< 0.024	2
WG 50	<i>Aphidius rhopalosiphi</i>	> 120	< 0.85	< 0.024	2

¹ indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ^{1,2}	Endpoint	% effect ³	Trigger value
<i>Typhlodromus pyri</i>	protonymphs	WG 50, glass, 7 d	60	Mortality Reproduction	0 -11.6	50 %
<i>Aphidius rhopalosiphi</i>	adults	WG 50, glass, 2 d	60	Mortality Reproduction	-2.6 -44.5	50 %
<i>Poecilus cupreus</i>	adults	WG 50, sand, 14 d	60	Mortality Predation	0 -6.45	50 %
<i>Chrysoperla carnea</i>	larvae	WG 50, glass,	60	Mortality Reproduction	-5 1.28	50 %

¹ indicate whether initial or aged residues

² for preparations indicate whether dose is expressed in units of a.s. or preparation

³ indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
not required

Appendix 1 – List of endpoints

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 ¹
Earthworms			
<i>Eisenia foetida</i>	Triflurosulfuron-methyl ‡	Acute 14 days	LC ₅₀ > 1000 mg a.s./kg d.w.soil
<i>Eisenia foetida</i>	Triflurosulfuron-methyl ‡	Chronic 8 weeks	NOEC = 250 mg a.s./kg d.w.soil
<i>Eisenia foetida</i>	WG 50	Acute	LC ₅₀ > 500 mg a.s./kg d.w.soil
<i>Eisenia foetida</i>	IN-D8526	Acute	320.35 LC _{50corr}
<i>Eisenia foetida</i>	IN-D8526	Chronic	62.5 NOEC _{corr}
<i>Eisenia foetida</i>	IN-E7710	Acute	> 500 LC _{50corr}
<i>Eisenia foetida</i>	IN-E7710	Chronic	31.25 NOEC _{corr}
<i>Eisenia foetida</i>	IN-M7222	Acute	864.7
<i>Eisenia foetida</i>	IN-M7222	Chronic	31
<i>Eisenia foetida</i>	IN-W6725	Acute	> 500 LC _{50corr}
<i>Eisenia foetida</i>	IN-W6725	Chronic	250 NOEC _{corr}
Other soil macro-organisms			
<i>Folsomia candida</i>	IN-D8526	Chronic	70
<i>Folsomia candida</i>	IN-E7710	Chronic	100
<i>Folsomia candida</i>	IN-M7222	Chronic	10
<i>Folsomia candida</i>	IN-W6725	Chronic	20
Soil micro-organisms			
Nitrogen mineralisation	WG 50 + surfactant ‡		< 25% effect at day 56 at 450 g WG50 /ha
Nitrogen mineralisation	IN-D8526		< 25% effect at day 56 at 1.9 mg/kg soil
Nitrogen mineralisation	IN-E7710		< 25% effect at day 56 at 0.18 mg/kg soil
Nitrogen mineralisation	IN-M7222		< 25% effect at day 56 at 1.7 mg/kg soil
Nitrogen mineralisation	IN-W6725		< 25% effect at day 56 at 0.35 mg/kg soil

Appendix 1 – List of endpoints

Test organism	Test substance	Time scale	Endpoint ¹
Carbon mineralisation	WG 50 + surfactant ‡		< 25% effect at day 28 at 450 g WG50 /ha
Carbon mineralisation	IN-D8526		< 25% effect at day 28 at 1.9 mg/kg soil
Carbon mineralisation	IN-E7710		< 25% effect at day 42 at 0.18 mg/kg soil
Carbon mineralisation	IN-M7222		< 25% effect at day 28 at 1.7 mg/kg soil
Carbon mineralisation	IN-W6725		< 25% effect at day 28 at 0.35 mg/kg soil
Field studies ²			
Decomposition of organic material: No effect on wheat straw degradation when applied at 31.4 g triflurosulfuron methyl 50WG/ha directly onto litter bags, followed by an application of either 71.2 or 178.2 g Triflurosulfuron methyl/ha onto soil surface in which the litter bags were buried.			

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

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

For TER calculations:

No correction of toxicity for triflurosulfuron-methyl, IN-M7222 and WG 50 since log Pow < 2 at neutral pH

Correction of toxicity for IN-D8526, IN-E7710 and IN-W6725 since low Pow > 2

Toxicity/exposure ratios for soil organisms

Sugarbeet 2 x 30 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC ²	TER	Trigger
Earthworms					
<i>Eisenia foetida</i>	Triflurosulfuron-methyl ‡	Acute	0.0689	> 14 514	10
<i>Eisenia foetida</i>	Triflurosulfuron-methyl ‡	Chronic	0.0689	3268	5
<i>Eisenia foetida</i>	WG 50	Acute	0.0689	> 7257	10
<i>Eisenia foetida</i>	IN-D8526	Acute	0.0327	9800	10
<i>Eisenia foetida</i>	IN-D8526	Chronic	0.0327	1911	5
<i>Eisenia foetida</i>	IN-E7710	Acute	0.0117	> 42700	10
<i>Eisenia foetida</i>	IN-E7710	Chronic	0.0117	2670	5

Appendix 1 – List of endpoints

Test organism	Test substance	Time scale	Soil PEC ²	TER	Trigger
<i>Eisenia foetida</i>	IN-M7222	Acute	0.00368	2.35 x 10 ⁵	10
<i>Eisenia foetida</i>	IN-M7222	Chronic	0.00368	8424	5
<i>Eisenia foetida</i>	IN-W6725	Acute	0.0266	> 18 797	10
<i>Eisenia foetida</i>	IN-W6725	Chronic	0.0266	9398	5
Other soil macro-organisms					
<i>Folsomia candida</i>	IN-D8526	Chronic	0.0327	306	5
<i>Folsomia candida</i>	IN-E7710	Chronic	0.0117	5980	5
<i>Folsomia candida</i>	IN-M7222	Chronic	0.00368	5435	5
<i>Folsomia candida</i>	IN-W6725	Chronic	0.0266	3759	5

¹ to be completed where first Tier triggers are breached

² indicate which PEC soil was used (e.g. plateau PEC)

Changes brought after the PRAPeR meeting 48 are highlighted in blue.

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

Preliminary screening data

Not required for herbicides as ER ₅₀ tests should be provided
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Laboratory dose response tests

Most sensitive species	Test substance	ER ₅₀ (g/ha) ² vegetative vigour	ER ₅₀ (g/ha) ² emergence	Exposure ¹ (g/ha) ²	TER	Trigger
Grain sorghum	WG 50	17.8 g a.s./ha		0.83 (1 m)	21.5	5
Grain sorghum	WG 50 + IN-KG691	7.83 g a.s./ha		0.83 (1 m)	9.4	5
Grain sorghum	Triflurosulfuron-methyl + X-77	1.9 g a.s./ha		0.83 (1 m) 0.17 (5 m)	2.3 11.2	5
Oilseed rape	Triflurosulfuron-methyl + X-77		23.5 g a.s./ha	0.83 (1 m)	28	5

¹ based on Ganzelmeier drift data

² for preparations indicate whether dose is expressed in units of a.s. or preparation

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

No

Appendix 1 – List of endpoints

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

Test type/organism	endpoint
Activated sludge	EC50 > 1000 mg a.s./L
<i>Pseudomonas sp</i>	-

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

Compartment	
soil	Triflusulfuron-methyl
water	Triflusulfuron-methyl
sediment	Triflusulfuron-methyl
groundwater	Triflusulfuron-methyl

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

Active substance	RMS/peer review proposal
	N, R50/53
Preparation WG 50	RMS/peer review proposal
	N, R50/53

Appendix 2 – abbreviations used in the list of endpoints

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
ALD	approximate lethal dose
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
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

Appendix 2 – abbreviations used in the list of endpoints

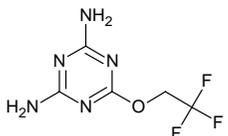
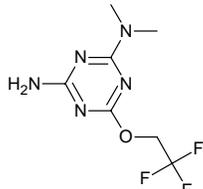
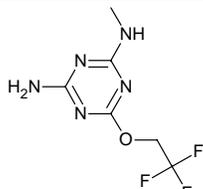
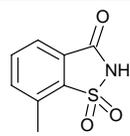
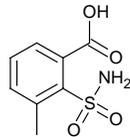
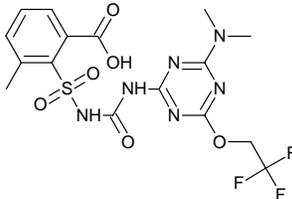
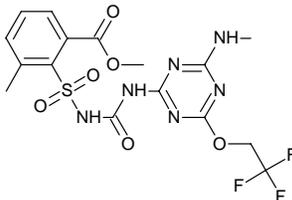
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC ₅₀	lethal concentration, median
LD ₅₀	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _{soil}	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
SF	safety factor
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation

Appendix 2 – abbreviations used in the list of endpoints

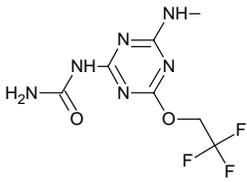
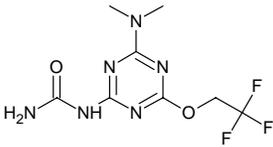
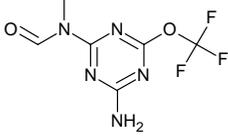
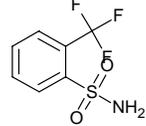
WG	water dispersible granule
yr	year

Appendix 3 – Used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
IN-M7222, <i>N,N</i> -bis-desmethyl triazine amine	6-(2,2,2-trifluoroethoxy)-1,3,5-triazine- 2,4-diamine	
IN-D8526, triazine amine	<i>N,N</i> -dimethyl-6-(2,2,2- trifluoroethoxy)-1,3,5-triazine-2,4- diamine	
IN-E7710, <i>N</i> -desmethyl triazine amine	<i>N</i> -methyl-6-(2,2,2-trifluoroethoxy)- 1,3,5-triazine-2,4-diamine	
IN-W6725, methyl saccharin	7-methyl-1,2-benzisothiazol-3(2 <i>H</i>)-one 1,1-dioxide	
IN-JJ987	3-methyl-2-sulfamoylbenzoic acid	
JK-555, triflurosulfuron	2-[4-dimethylamino-6-(2,2,2- trifluoroethoxy)-1,3,5-triazin-2- yl]carbamoylsulfamoyl]- <i>m</i> -toluic acid	
IN-66036, <i>N</i> -desmethyl triflurosulfuron-methyl	methyl 3-methyl-2-({[4- (methylamino)-6-(2,2,2- trifluoroethoxy)-1,3,5-triazin-2- yl]carbamoyl} sulfamoyl)benzoate	

Appendix 3 – Used compound code(s)

Code/Trivial name	Chemical name	Structural formula
IN-JM-000, <i>N</i> -desmethyl triazine urea	1-[4-(methylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea	
IN-JL-000, triazine urea	1-[4-(dimethylamino)-6-(2,2,2-trifluoroethoxy)-1,3,5-triazin-2-yl]urea	
tritosulfuron	1-[4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-yl]-3-[2-(trifluoromethyl)benzenesulfonyl]urea	
TBSA	2-(trifluoromethyl)benzenesulfonamide	
IN-E0Q47, formyl <i>N</i> -desmethyl triazine amine	<i>N</i> -[4-amino-6-(trifluoromethoxy)-1,3,5-triazin-2-yl]- <i>N</i> -methylformamide	