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

nicosulfuron

finalised: 29 November 2007

SUMMARY

Nicosulfuron is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

United Kingdom being the designated rapporteur Member State submitted the DAR on nicosulfuron in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 7 December 2005. The peer review was initiated on 12 May 2006 by dispatching the DAR for consultation of the Member States and the sole applicant ISK Biosciences Europe S.A. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in February – March 2007. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in May – June 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 26 September 2007 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 as proposed by the notifier which comprises foliar spraying to control perennial grass weed species and a range of annual grass weed and broad-leaved weed species in grain and fodder maize up to the BBCH 12-18 leaf stage, in Northern and Southern Europe, at a single application at a maximum rate of 60 g as/ha.

The representative formulated product for the evaluation was "SL-950 4% SC", an oil dispersion (OD), registered under different trade names in Europe.

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

Adequate methods are available to monitor nicosulfuron residues in grain and fodder maize, soil water and air. Only single methods for the determination of residues are available.
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 are possible.

Nicosulfuron is absorbed rapidly but only to a limited extent (about 40%) in the rat following oral administration. It is widely and uniformly distributed in the body and is excreted largely unchanged via bile and urine. The compound is of low acute toxicity by the oral, dermal, inhalational and intraperitoneal route. It is non-irritant to skin, slightly irritant to the eye and showed weak sensitisation potential in a Guinea pig maximisation test. Nicosulfuron was of low toxicity also in the short term studies in rat, mouse and dog, showing mild hepatotoxicity in the rat at very high dose levels. No genotoxicity was observed *in vitro* and *in vivo*, and no evidence of carcinogenicity was seen in the rat. Increased incidences of hepatocellular adenoma and carcinoma were seen in male mice at the top dose level but not considered to be of relevance to the risk assessment. No effects on reproduction were seen in a two-generation study with rats. No evidence of teratogenicity was seen in developmental toxicity studies in the rat and rabbit. There is no proposal for a classification for effects on human health. None of the groundwater metabolites (ASDM, ADMP, AUSN, UCSN, MU-466, HMUD) was considered to be relevant according to the current EU guidance document on relevance of metabolites.

The acceptable daily intake (ADI) is 2 mg/kg bw/day, derived from a chronic rat study, and applying a safety factor of 100. Subchronic dog studies (28-day, 90-day and 1-year) support this value. Due to the low acute toxicity of nicosulfuron, it was agreed that an acute reference dose (ARfD) is not required. The acceptable operator exposure level (AOEL) was set at 0.8 mg/kg bw/day, based on the subchronic dog studies applying a safety factor of 100 and correcting for oral absorption of 40%. The exposure estimates for operators were 4% and 27% of the AOEL wearing PPE (personal protective equipment) with the German model, and with the UK POEM respectively. When no PPE is worn values rise to 10% and 39% respectively. Estimated exposures both for bystanders and re-entry workers were estimated to be well below the AOEL.

Metabolism of nicosulfuron was studied in maize. A few hours after application to the plants, a considerable amount of metabolism had already occurred. Nevertheless, 60 days after application nicosulfuron was still the most significant residue (41-52% TRR). Major metabolites identified were AUSN and ASDM (individually around 20% TRR), indicating that a cleavage of the ring structures had occurred. At harvest (102 days after application) the residue profile was very similar to that observed at the 60 days interval. The total residue upon application according to the notified GAP was very low and no significant residues of nicosulfuron or its metabolites are expected in maize at harvest. This was confirmed by the results of supervised residue trials. Also in following crops no significant residue levels are expected, since due to phytotoxic effects other crops than cereals could not be grown until nicosulfuron and metabolites have decreased to <0.001 mg/kg in the soil. No

significant uptake of residues from soil was found in the cereal crops analysed for total residues in lysimeter studies. Therefore it was concluded that based on the data submitted to support the use in maize, the residue definition in this crop could be limited to nicosulfuron for risk assessment and monitoring purposes.

Intakes of nicosulfuron by domestic animals will not be significant and livestock studies were not necessary. Some data is available for future reference, however at this time it is not possible to propose residue definitions in animal products.

In a chronic consumer risk assessment all residue intakes from maize were significantly less than 1 % of the ADI and it can therefore be concluded that the chronic risk to the consumer is low. The consumer may be also exposed to soil metabolites leaching into ground water used as drinking water but the additional exposure from this source does most likely not exceed 0.05% of the ADI of nicosulfuron.

An acute risk assessment was not necessary as nicosulfuron has been shown to have a very low acute toxicity profile and no ARfD was allocated to this substance.

In soil under aerobic conditions nicosulfuron exhibits very low to low persistence. Degradation produced five metabolites, the maximum amounts seen in the route of degradation studies were: 14.4% AR for HMUD, 7.2% AR for ADMP, 21.5% AR for ASDM, 26.8% AR for AUSN and 11% AR for UCSN. Mineralisation to carbon dioxide accounted for a maximum of 16.8 % AR after 112 days. The formation of unextractable residues was a significant sink accounting for 35.2-45.9 % AR after 112 days. Under anaerobic soil conditions degradation was slower than under aerobic conditions but no novel breakdown products were identified. Aerobic degradation studies with metabolites indicated that ADMP is low to moderate persistent, HMUD is moderate persistent, AUSN and ASDM are medium to high persistent and UCSN is high persistent in soil. Degradation of nicosulfuron is not considered dependent on the pH conditions of the soil. Nicosulfuron and ADMP exhibit high to very high mobility in soil, HMUD, AUSN, UCSN, ASDM and MU-466 (a metabolite identified in the lysimeter studies) exhibit very high mobility.

Chemical hydrolysis may contribute to the overall degradation of nicosulfuron in acidic water, but it is unlikely to be a significant route of degradation under neutral or alkaline conditions. Aqueous photolysis is not expected to be a major route of dissipation in surface water. In a dark sediment/water study, nicosulfuron was predominantly found in the water phase, with partitioning to sediment being relatively low (maximum 18-24% AR at 14d). One major metabolite (HMUD) and three minor metabolites (AUSN, UCSN and ASDM) were present in both the water and sediment phases, although their concentrations were generally lower in the sediment phase. Mineralisation reached a maximum of 1.4% AR.

The PEC for surface water and sediment for nicosulfuron used a FOCUS Step 4 assessment with a 5 metre buffer zone. Step 1 and Step 2 calculations were performed for metabolites HMUD, AUSN, UCSN and ASDM.

The PEC groundwater used FOCUS PELMO and this model produced one scenario where nicosulfuron is predicted to be above 0.1 µg/L. ADMP and MU-466 were not predicted to be exceed the trigger of 0.1 µg/L in any scenario. AUSN, UCSN and ASDM are predicted to be above 0.75

µg/L in 6 out of 8 scenarios, but less than 2.5 µg/L and HMUD is predicted to be above 0.1 µg/L in five scenarios but all are less than 0.75 µg/L. On the basis of the available mammalian toxicology data, it was concluded that none of the groundwater metabolites was considered to be relevant according to the current EU guidance document on relevance of metabolites.
Nicosulfuron is not expected to be transferred to the atmospheric compartment and potential for long range transport may be considered negligible.

The risk to all groups of non-target organisms was assessed as low for the representative use of nicosulfuron in maize except for aquatic macrophytes and terrestrial non-target plants. *Lemna gibba* was the most sensitive aquatic organism tested. A no-spray buffer zone of 5 metres is required achieve a TER of >10 in the 4 FOCUS step4 drainage scenarios (D3, D4, D5, D6) but only in one run-off part scenario (R1 pond) out of 4 run-off scenarios the TER was >10. No-spray buffer zones are not sufficient as a risk mitigation measure under geoclimatic conditions where run-off is the dominant route of entry into surface water and further risk mitigation measures have to be considered at Member States level. 23 different plant species (predominantly dicotyl and monocotyl crop species) was tested. In the original risk assessment it was suggested to use the lowest endpoint and to reduce the safety factor from 5 to 1. The trigger of 1 was exceeded if an in-field no-spray buffer zone of 5 metres is applied. The original risk assessment was not accepted in the peer-review and it was suggested to use an HC5 approach as outlined in the terrestrial guidance document. Such a risk assessment was submitted by the applicant and assessed by the RMS in a not peer-reviewed addendum 4 from July 2007. The HC_5 is similar to the lowest endpoint and hence also requiring a 5 meter in-field no-spray buffer zone to mitigate the risk to non-target plants in the off-field area.

Key words: nicosulfuron, 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 stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Nicosulfuron is one of the 79 substances of the third stage, part A, covered by the Regulation (EC) No 1490/2002 designating United Kingdom as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, United Kingdom submitted the report of its initial evaluation of the dossier on nicosulfuron, hereafter referred to as the draft assessment report, to the EFSA on 7 December 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 11(2) of the Regulation (EC) No 1490/2002 the revised version of the draft assessment report was distributed for consultation on 12 May 2006 to the Member States and the main applicant ISK Biosciences Europe S.A. as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in February – March 2007 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings in May – June 2007. 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 with representatives from Member States on 26 September 2007 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 Health, Plant Protection Products and their Residues (PPR).

In accordance with Article 11(4) of the Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

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

- the comments received
- the resulting reporting table (rev. 1-1 of 13 March 2007)
- the consultation report

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

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 27 September 2007)

Given the importance of the draft assessment report including its addendum (compiled version of July 2007 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.

By the time of the presentation of this conclusion to the EU-Commission, the rapporteur Member State has made available amended parts of the draft assessment report (Vol 4). Since this revised document contains confidential information, the document cannot be made publicly available.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Nicosulfuron is the ISO common name for 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea (IUPAC).

Nicosulfuron belongs to the class of pyrimidinylsulfonylurea herbicides. It is a systemic herbicide acting by absorption by foliage and uptake over the roots. It is used for the control of perennial grass weed species and a range of annual grass weed and broad-leaved weed species in grain and fodder maize.

The representative formulated product for the evaluation was "SL-950 4% SC", an oil dispersion (OD), registered under different trade names in Europe.

The representative uses evaluated comprise spraying with conventional ground spraying equipment to control perennial grass weed species (*Elymus repens, Sorghum halepense)* and a range of annual grass weed (*Alopecurus myosuroides, Poa annua, Lolium spp., Setaria spp., Digitaria spp., Echinchloa crus galli*) and broad-leaved weed species (*Chenopodium album, Matricaria chamomilla, Stellaria media, Solanum nigrum, Amaranthus spp., Galium aparine, Polygonum spp., Sinapis*

arvensis) in grain and fodder maize up to the BBCH 12-18 leaf stage, in Northern and Southern Europe, at a single application at a maximum rate of 60 g as/ha.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of nicosulfuron is 930 g/kg. The minimum purity in the FAO specification 709/TC (May 2006) is 910 g/kg. The higher value relates to the fact that the FAO specification was developed based on data submitted by another manufacturer.

Besides the storage stability at high temperatures, 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 nicosulfuron or the respective formulation. Storage of the formulations at higher temperatures is not recommended. However, the experts of the PRAPeR 21 meeting required additional validation data for the method of analysis for all impurities in accordance with SANCO 3030/99 and a study for log P_{ow} at neutral and alkaline pH.

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

Adequate analytical methods are available for the determination of nicosulfuron in the technical material and in the representative formulation. However additional validation data are needed for the determination of the respective impurities in the technical material.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.
Adequate analytical methods are available for the determination of nicosulfuron residues in food of plant origin (in grain and fodder maize), soil, water and air. As the residue definition for all matrices is nicosulfuron, further methods of analysis and validation data for impurities and metabolites are not required.
For the determination of residues of nicosulfuron in maize shoots (sprouts), grain and whole plants, a series of multistage methods based on extraction, partition and clean-up were used. Either HPLC or GC determination methods were used, with either LC/MS or GC/MS being used for confirmatory determination. Acceptable validation data were submitted for analysis of active substance, the validation data submitted for metabolite analysis were less satisfactory, however the residue definition for plant and products is ‘parent nicosulfuron’, therefore the lack of validation data in these cases is not a critical issue. Recovery data were obtained for nicosulfuron at levels between 0.01 and 0.10 mg/kg with acceptable mean recoveries and RSD values. Only single methods for the determination of residues are available.

An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed. Analytical methods for the determination of residues in body fluids and tissues are not required.

The employed methods for nicosulfuron in soil water and air are largely based on those used for crop residues, with HPLC/UV detection but employing specific extraction conditions. In some cases, more specific GC/MS or LC/MS is used for confirmation.
Acceptable methods are also available for metabolites in soil and water, however the residue definition is the parent nicosulfuron in the case of these matrices, too.

2. Mammalian toxicology

The active substance was discussed at the PRAPeR experts meeting for mammalian toxicology (PRAPeR 24, round 5) in June 2007.

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

Nicosulfuron is rapidly but incompletely (about to 40%) absorbed and widely and evenly distributed. Maximum plasma concentrations were attained at 1-2 hours following oral administration of a low dose while there are indications of a reduced absorption at higher dose levels. No indications for accumulation potential were observed. Nicosulfuron is mainly excreted via faeces (63 -73%) and urine (23 -28%) and is also largely excreted unchanged (70 -86 %).

2.2. Acute toxicity

Nicosulfuron was found to be of low acute toxicity by the oral, dermal, inhalation and intraperitoneal routes. There are indications, however, that alcohol may potentiate its toxicity. Nicosulfuron was not irritant to rabbit skin, was a slight eye irritant and was found to be a weak skin sensitiser in a Guinea Pig Maximisation Test. No classification was warranted based on the effects observed in these studies.

2.3. Short term toxicity

Nicosulfuron was found to be of low toxicity in short-term studies in the rat, mouse and dog. Treatment-related findings in the rat (a 28-day study and a 90-day study) were limited to slightly reduced weight gain and elevated serum enzyme activities indicating mild hepatotoxicity in both tests at very high dose levels leading to NOAELs of 358- and 499 mg/kg bw/day respectively. Findings in a 6-weeks study in mice were limited to minor effects on bodyweight and food consumption in males at the highest dose leading to a NOAEL 782 mg/kg bw/day. The dog was identified as being slightly more sensitive. In all three dog studies (a 28-day, a 90-day and a 1- year study) NOAELs were set at 200 mg/kg bw/day based on reduced body weight gain, increased liver weights and elevated serum enzyme activities.

2.4. GENOTOXICITY

No evidence of genotoxicity was found in an appropriate battery of studies *in vitro* and *in vivo*.

2.5. LONG TERM TOXICITY

In 24-month studies with rat and mouse Nicosulfuron was found to be of low toxicity following chronic administration. In the rat minor effects on bodyweight, food consumption, clinical chemistry parameters and haematological parameters (consistent with mild anaemia) and a slightly increased incidence of interstitial cell adenoma and thyroid follicular cell carcinoma (only in males) were seen at the top dose level. Incidences of both tumour types were within the historical control range and not considered to be treatment-related. Red blood cells were identified as target of toxicity and the NOAELs set were 199.3- and 254.4 mg/kg bw/day for males and females respectively. In the mouse study the liver was identified as target of toxicity based on increased incidences of hepatocellular adenoma and carcinoma in males at the top dose level. NOAELs were set at 562- and 544 mg/kg bw/day for males and females respectively. In the absence of genotoxicity and considering the occurrence of the liver tumours at high doses in one sex (males) and one (relatively susceptible) species only, they were not considered relevant for humans.

2.6. REPRODUCTIVE TOXICITY

Following a preliminary reproductive toxicity study a multi-generation study in the rat has been carried out. While no effects on reproduction and offspring have been observed leading to NOAELs of 3302- and 3719 mg/kg bw/day respectively the parental NOAEL was lower (379 mg/kg bw/d) based on effects observed on bodyweight. A preliminary and a full developmental study have been carried out in both rat and rabbit with top dose levels being 1000- and 600 mg/kg bw/day respectively. For the rat both the maternal and developmental NOAEL toxicity was set at 1000 mg/kg bw/day while for the rabbit the respective NOAELs were set at 300 mg/kg bw/day based on mortality and clinical signs in mothers and effects on skeletal development of foetuses at the top dose.

2.7. NEUROTOXICITY

Nicosulfuron has not a structure similar or related to those capable of inducing neurotoxicity. In all studies provided, nicosulfuron exhibited no signs of neurotoxicity or histopathological changes with respect to brain, spinal cord or peripheral nerves. Therefore, no specific neurotoxicity studies were considered necessary.

2.8. FURTHER STUDIES

It was shown that the metabolites ASDM, AUSN, HMUD, MU-466 and UCSN have the potential to exceed a concentration of 0.1 µg/L in groundwater while that was not case for ADMP (see section 4.2.2). In addition these metabolites were also detected in plants, as impurities increasing during storage and in the rat metabolism.

Additional studies addressing the toxicological properties of the metabolites ASDM[2], ADMP[3] , AUSN[4], UCSN[5], HMUD, the breakdown product MU-466[6] and the mixed soil leachates from one lysimeter study [7] were carried out.

ASDM was found to be of low acute oral toxicity in the rat and mouse (LD50 >2000 and >5000 mg/kg bw respectively) and of low dermal toxicity (LD50 >2000 mg/kg bw) in the rat. It is not a skin- or eye irritant but was found to be a skin sensitiser in a Guinea pig maximisation test. No treatment-related adverse effects were seen in a 28- day and a 90-day study in the rat at dose levels of up to 1000 mg/kg bw/day. No genotoxic effects were observed in *in vitro* bacterial- and mammalian cell mutation and mammalian clastogenicity tests and in an *in vivo* mouse micronucleus test. No effects on reproduction were seen in a one-generation study in the rat at dose levels up to 1000 mg/kg bw/day. No evidence of maternal toxicity was seen in a rat developmental study at dose levels of up to 1000 mg/kg bw/day while at the top dose in pups an increased incidence of dilated ureters were observed.
ADMP was found to be of moderate acute oral toxicity in the mouse (LD50 is 737- and 1073 mg/kg bw in males and females respectively). In an *in vitro* bacterial mutagenicity assay it was found not to be mutagenic. ADMP is a common metabolite to amidosulfuron, for which it was shown to be of low acute oral toxicity in rats (LD50 >2000 mg/kg bw).

The experts concluded that the ADI of nicosulfuron would cover any concern in regard to toxcicological properties of ASDM and ADMP and could therefore be applied also for these two metabolites.

AUSN was found to be of low acute toxicity in rats (LD50 >2000 mg/kg bw). It yielded negative results in a bacterial mutagenicity assay and in an *in vitro* clastogenicity and an *in vitro* cell mutation test with mammalian cells. The experts concluded that AUSN was a non-relevant groundwater metabolite for which the ADI of nicosulfuron can be applied.

UCSN and **MU-466** were both found to be of low acute oral toxicity in the rat (LD50 >2000 mg/kg) and for both substances no evidence of genotoxicity could be found in an *in vitro* test battery (bacterial mutation-, mammalian cell mutation and clastogenicity in mammalian cells). While MU-466 did not reach a level in groundwater for which a refinement of its toxicological significance was necessary, it was concluded that for UCSN the ADI of nicosulfuron would cover any concern in regard to toxicological properties.

[2] ASDM: *N*,*N*-dimethyl-2-sulfamoylpyridine-3-carboxamide
[3] ADMP: 4,6-dimethoxypyrimidin-2-amine
[4] AUSN: 2-[(carbamimidoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide
[5] UCSN: 2-[(carbamoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide
[6] MU-466: *N*-methyl-2-sulfamoylpyridine-3-carboxamide
[7] The test material was mixed soil leachates (containing parent nicosulfuron and metabolites ASDM, AUSN, UCSN and MU-466) of the first and second year of one lysimeter of the lysimeter study conducted in Switzerland with radiolabelled nicosulfuron (see section 4.1.3).

HMUD was not evaluated initially since it is a minor rat metabolite that has a structure very similar to the parent compound. Additional *in vitro* studies provided by the applicant showed that the metabolite was negative in a bacterial mutagenicity assay and did not induce mutations or chromosomal aberrations in mammalian cells.
Overall, none of the groundwater metabolites (see table Ground water, chapter 6) was considered to be relevant according to the current EU guideline Sanco/221/2000-rev.10.

The soil leachate of the lysimeter study was found to be of low acute oral toxicity (LD50 >2000 mg/kg) and was negative in a bacterial mutagenicity test.

2.9. MEDICAL DATA

Medical screening did neither reveal abnormalities attributable to chemical exposure in nicosulfuron formulators (n=4) nor in workers involved in the manufacture of technical nicosulfuron (n=35).

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

ADI

The ADI is set at 2 mg/kg bw/day, derived from the chronic rat study, and applying a safety factor of 100. Subchronic dog studies (28-day, 90-day and 1-year) support this value.

AOEL

The AOEL was set at 0.8 mg/kg bw/day, based on the subchronic dog studies applying a safety factor of 100 and correcting for oral absorption of 40%.

ARfD

Due to the low acute toxicity of nicosulfuron to the fact that no relevant effects were observed at early time-points in short term studies, an ARfD is not considered necessary.

2.11. DERMAL ABSORPTION

In the absence of any specific data on dermal absorption or any appropriate data on the comparative dermal toxicity of nicosulfuron and considering the physicochemical properties of the substance the default (worst case) absorption value of 100% was used.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product “SL-950 4% SC” is a soluble concentrate formulation containing 40 g nicosulfuron/L for use as a post emergence herbicide on fodder and grain maize.

Operator exposure

According to the intended use submitted by the applicant the maximum applied dose is 60 g nicosulfuron/ha. The minimum volume is 200 L water/ha. The only supported use is tractor mounted field crop sprayer (FCS) with hydraulic boom and nozzles. The estimated exposures are provided in the table below.

The estimated exposure presented as % of AOEL (0.8 mg/kg bw/day), according to calculations with the German and UK POEM model.

Use/Method	Model	Without PPE	With PPE:
Maize/FCS	**German BBA**	10	4
	UK POEM	39	27

*PPE (personal protective equipment): gloves during mixing/loading

Based on the results of the operator exposure models used, the operator exposure estimates are below the AOEL with both models, namely 10- and 39 % of the AOEL without the use of PPE and 4- and 27% with the use of PPE in the POEM and BBA model respectively. However, in view of the classification of "SL-950 4% SC" as skin irritant, protective gloves should be worn by operators when handling the product concentrate.

Worker exposure

No minimum re-entry period is recommended on the product label since it is not expected that workers would re-enter treated crops after spraying to perform crop inspection tasks until spray deposits are dry. Estimates of exposure to nicosulfuron for workers re-entering maize crops treated with applications of 'SL-950 4% SC' did not exceed the systemic AOEL of 0.8 mg/kg bw/d. The predicted exposure based on the German re-entry model[8] for re-entry workers is less than 2 % of the AOEL of 0.8 mg/kg bw/d.

Bystander exposure

Predicted exposure for a bystander[9] from application of 'SL-950 4% SC' is less than 1% of the short term systemic AOEL of 0.8 mg/kg bw/d.

3. Residues

Nicosulfuron was discussed in the meeting of experts in residues PRAPeR 25 in Parma (Round 5, June 2007).

[8]Hoernicke *et al.*, 1998. Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflantzenschutzmitteln behandelten Kulturen. Nachrichtenbl. Deut. Pflantzenschutzd. 50 (10), p 267.
[9]Lloyd and Bell, 1983. Hydraulic nozzles: comparative spray drift study.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

Metabolism of nicosulfuron was studied in maize. Two studies, one for pyridyl- and one for pyrimidinyl- labelled nicosulfuron are available for maize grown in soil. The field rate (N) and 5N application rates were used, with a 4% SC formulation and direct foliar application.

In the pyrimidinyl study, a few hours after application a considerable amount of metabolism had already occurred. Nicosulfuron was present at 24 % TRR (0.69 mg/kg) and metabolite HMUD 4 % TRR (0.11 mg/kg). At the 60 day time interval the TRR was low with only 0.06 mg/kg in the straw and only 0.003 mg/kg in the grain and the metabolite profile has changed considerably. The metabolites identified were not present initially. Nicosulfuron was still the most significant residue at 52 % TRR (0.029 mg/kg), and metabolites identified were DMPU 5.9 % TRR (0.003 mg/kg) and ADMP 5.5 % TRR (0.003 mg/kg). The other two metabolites were M1 and M5, with M1 being the most significant at 13% TRR (0.007 mg/kg). At the 102 day harvest point the residue profile was very similar to the 60 day harvest; however some slight increases in metabolite levels were noted which is deemed a result of a decrease in water content.
In the pyridyl labelled study, immediately after application nicosulfuron was the predominant residue at 51 % TRR (0.79 mg/kg). Six metabolite fractions were characterised and three identified as AUSN 20.4 % TRR (0.32 mg/kg), HMUD 3.6 % TRR (0.056 mg/kg) and ASDM 17.3 % TRR (0.27 mg/kg). AUSN and ASDM were not identified in the pyrimidinyl study since cleavage of the ring structures has occurred. The only other significant metabolite fraction present was M1 at 1.6 % TRR (0.025 mg/kg). At day 60 the TRR had decreased to 0.05 mg/kg in the straw and 0.001 mg/kg in the grain, and the same fractions and compounds were characterised as at the 0 day sampling interval. Nicosulfuron was still present at 41% TRR (0.024 mg/kg), AUSN 13.5 % TRR (0.008 mg/kg), ASDM 16.7 % TRR (0.01 mg/kg.) and HMUD 0.1 % TRR (0.001 mg/kg). No other metabolites were present at significant levels. At the 102 day interval it would appear that the M1 metabolite fraction had increased from 0.1 % TRR to 29 % TRR. Further work was undertaken to clarify how metabolite M1 was formed, the reason for the significant difference in levels of M1 found between the day 60 and day 102 interval is still unknown. However, M1 was shown to be a fraction of metabolites (partially conjugates of parent and ASDM) rather than one single metabolite and individual residues are generally low.

The experts in toxicology concluded that the ADI of the nicosulfuron can also be applied to the two metabolites ADMP and ASDM (refer to paragraph 2.8 above). Their inclusion in the residue definition for risk assessment was considered by the meeting of experts in residues. In the maize study ASDM appeared at similar amounts as nicosulfuron. ASDM was also found in ruminant metabolism study as a significant part of the total residue. Considering that residue levels of nicosulfuron in the residue trials are below the limit of quantification (LOQ), exposure of consumer and livestock to residues is expected to be very low. It is therefore not considered necessary to include ASDM in the residue definition for risk assessment or enforcement. The experts concluded

that based on the metabolism and residue data submitted for maize, residues in this crop should be defined as nicosulfuron.

There were a total of 20 Northern Europe residues trials conducted in accordance with the representative GAP, the majority of which had analysis of both grain and whole plant (silage). No residues were quantified in grain above the LOQ of 0.01 mg/kg. For Southern Europe there were a total of 14 trials conducted in accordance with the representative GAP, again the majority of which had analysis of both grain and whole plant (silage). No residues were quantified in grain above the LOQ of 0.01 mg/kg. One positive residue was detected in whole plant at 0.013 mg/kg. Given the results of the other trials this positive residue is likely to be as a result of contamination however as there is no decline data it was taken into consideration in the risk assessment.
The data supplied in the storage stability study demonstrated that residues of nicosulfuron are stable for at least 9 months which is sufficient to cover the storage period of the residue trials.
No data on processing data are required as residues are below the LOQ.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

The DT_{50} in soil from field studies is 63 days (refer to 4.2.1); therefore at 100 days there will be greater than 10 % of substance remaining in the soil. However, the main concern was that metabolites ADMP and ASDM have a similar toxicity to nicosulfuron, and that at least ASDM is medium to high persistent in soil (refer to paragraph 4.1.2). Nevertheless, lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg). Moreover the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period. So were after a plant back interval of 27 to 30 days marked phytotoxic effects observed in following crops while residues of nicosulfuron, ADMP and ASDM in the soil were found to be below the LOQ (0.01 mg/kg). Thus other crops than cereals could not be grown until the following spring at which time residues in soil of nicosulfuron and relevant metabolites have decreased to <0.001 mg/kg. It can be concluded that at this level in soil no significant residues will occur in rotational crops. The meeting agreed that no further data would be necessary.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Intakes of nicosulfuron by domestic animals will not be significant and these metabolism studies were not necessary as detailed in Directive 96/68/EC. However, livestock metabolism data with lactating goats were evaluated and reported by RMS in the DAR for future reference.
The majority of radioactivity was rapidly excreted and identifiable residues were produced in the high dose level studies. In the more appropriate dose level study no significant residues were detected in edible tissues and organs (<0.001 mg/kg).
The toxicity of some of the metabolites found in significant levels in the metabolism studies is not known and any requirement for further investigation is currently not triggered. It is therefore not possible to propose residue definitions in animal products at this time.

3.3. CONSUMER RISK ASSESSMENT

Chronic intakes were assessed using the UK and the WHO/ GEMS Food consumption data for maize. All intakes were significantly below 1 % of the ADI of 2 mg/kg bw/day and it can therefore be concluded that the chronic risk to the consumer is low. An acute risk assessment was not necessary as nicosulfuron has been shown to have a very low acute toxicity profile and no ARfD was allocated to this substance.

The level of 0.1 µg /L is exceeded by nicosulfuron metabolites HMUD, AUSN, UCSN and ASDM in groundwater. Moreover, also the level of 0.75 µg /L is exceeded by metabolites ASDM, AUSN and UCSN. As consumers may be exposed to metabolites through groundwater used as drinking water, a consumer exposure/ risk assessment was performed as required in the Guidance document.[10] From a risk management point of view the exposure of consumers to metabolites 'non-relevant' in the hazard assessment at levels less than 0.75 µg/L is considered acceptable (threshold of concern approach) and therefore, for metabolite HMUD no further assessment was conducted. For ASDM, AUSN and UCSN the PRAPeR 24 meeting agreed that the ADI for nicosulfuron can be applied to the metabolites (refer to paragraph 2.8). The presented assessment by EFSA (not peer reviewed) considers the sum of possible intakes of the metabolites from drinking water in addition to the intake through diet. Intake estimates for adults, children and bottle-fed infants are based on the default assumptions laid down in the WHO Guidelines of drinking water quality. For the exposure estimates the results of the FOCUS gw modelling were used that are in good agreement with the highest annual average concentration found in the submitted lysimeter studies, and therefore are considered to reflect a 'realistic worst case'. For an adult consumer of 60 kg bw consuming 2L/day, a 10-kg child consuming 1L/ day and a 5-kg bottle-fed infant consuming 0.75 L/day the following daily intakes of metabolite were estimated:

Met.	Av'ge conc. [µg/L]	Intake in µg/day			Intake in mg/ kg bw / day			% ADI of nicosulfuron		
		Adult	Toddler	Infant	Adult	Toddler	Infant	Adult	Toddler	Infant
ASDM	1.239	2.48	1.24	0.93	0.00004	0.00012	0.00019	<0.01	<0.01	0.01
UCSN	1.195	2.39	1.20	0.90	0.00004	0.00012	0.00018	<0.01	<0.01	0.01
AUSN	2.063	4.13	2.06	1.55	0.00007	0.00021	0.00031	<0.01	0.01	0.02

The intakes were compared to the ADI of nicosulfuron and lead to an additional contribution to the intakes through food items which corresponds to less than 0.05% of the ADI of nicosulfuron at the maximum.

[10] Guidance document SANCO/221/2000 rev.20 on the assessment of the relevance of metabolites in ground water of substances regulated under council directive 91/414/EEC

3.4. PROPOSED MRLS

Based on the available information that support the representative use on maize an MRL for maize grain at the LOQ (0.01* mg/kg) was proposed.

4. Environmental fate and behaviour

Nicosulfuron was discussed at the PRAPeR experts' meeting on fate and behaviour in the environment (PRAPeR 22) in May 2007.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

The aerobic route of degradation of nicosulfuron was studied in a silt loam soil in the dark (20 ºC and 75% of the field capacity for soil moisture) using two different radio-labels: pyridine and pyrimidine labelled nicosulfuron. Mineralisation was low using the pyridine label, 1.3% AR at day 112, compared to the pyrimidine label (16.8% AR at day 112). Unextracted radioactivity at day 112 ranged between 35.2 and 45.9% AR in the two studies. Degradation produced five metabolites: **HMUD**[11] (max. 14.4% AR at 28d), **AUSN**[12] (max. 19.5% AR at 112d), **ASDM**[13] (max. 21.5% AR at 85d), **UCSN**[14] (6.5-8.5% AR, with max. at 85d) and **ADMP**[15] (1.9-7.2% AR, max. 31d).

The sequence of metabolite accumulation is consistent with an initial demethylation of a pyrimidinyl methyoxy group to form HMUD, followed by cleavage of the pyrimidinyl ring to produce AUSN and UCSN. Additionally, ASDM and ADMP are produced by cleavage of the sulfonylurea bridge.

Anaerobic degradation of nicosulfuron was investigated in two studies. Results indicated that anaerobic conditions prevented further degradation of either nicosulfuron or its metabolites (mineralisation max. 0.5% AR at 90d).

Photodegradation was investigated in two studies. Results showed that photolysis may have some effect (DT_{50}light = 36-35.9 days and DT_{50}dark = 97-111 days, with DT_{50} values extrapolated beyond the experimental period and assuming a 12 hour photoperiod), although it is unlikely to have a significant influence on dissipation in the field as there will be reduced levels of light reaching cropped areas. In the ^{14}C-pyridine labelled study, metabolite ASDM had accumulated to 23% AR and 17% AR by day 30 in irradiated soil and dark control, respectively. A new metabolite, DMPU[16], was formed in the irradiated samples at a maximum amount of 2.6% AR (day 30) in the study with [^{14}C-pyrimidine] nicosulfuron.

[11] HMUD: 2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-*N*,*N*-dimethylpyridine-3-carboxamide
[12] AUSN: 2-[(carbamimidoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide
[13] ASDM: *N*,*N*-dimethyl-2-sulfamoylpyridine-3-carboxamide
[14] UCSN: 2-[(carbamoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide
[15] ADMP: 4,6-dimethoxypyrimidin-2-amine
[16] DMPU: (4,6-dimethoxypyrimidin-2-yl)urea

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

In the original DAR, four soil types were used to investigate the rate of degradation of nicosulfuron. However, as the soils covered a limited pH range (5.3 – 6.6) and concerns raised on the pH dependency of nicosulfuron dissipation, the applicant submitted a new laboratory aerobic soil degradation study with three soils at pH 7.0-7.2 using nicosulfuron labelled in the pyrimidine position. The study was summarised and evaluated by RMS in addendum 3 to Annex B.8, dated 2 May 2007 (together with Corrigendum to addendum 3). The experts of PRAPeR 22 agreed that based on the current data from seven soils, no pH effect on the rate of degradation of nicosulfuron has been demonstrated. Nicosulfuron can be classified as low to moderate persistent in soil (1^{st} order DT_{50} = 7-46.3 days). For modelling purposes, the geometric mean of soil DT_{50} values normalised to reference conditions (20ºC and pF2) was 16.4 days.

The aerobic degradation of soil metabolites ADMP, ASDM, AUSN and UCSN was investigated in three soils (pH 6.0-7.3, organic carbon content 0.98-2.29%, clay content 1.1-9.3%) where each metabolite was used as the starting material. ADMP was rapidly degraded and therefore can be classified as low to moderate persistent (1^{st} order DT_{50} = 2.9-11.3 days). Results indicated that the other 3 metabolites were medium to high (AUSN and ASDM) or high (UCSN) persistent (1^{st} order DT_{50}s calculated at 20ºC and 40% MWHC were in the range of 90.5-268.5 days, 73.8-218.2 days and 126.2-307.5 days for ASDM; AUSN and UCSN respectively). The DT_{50} of HMUD was calculated using ModelMaker based on data from the two routes of degradation studies on one soil with the parent compound; this produced DT_{50} values of 27.4 and 30.8 days.

Although no field dissipation studies are required to be conducted, the applicant submitted four bare soil field dissipation studies conducted in northern and southern Europe, together with four studies conducted on cropped trial sites. In some of these studies the claimed LOQ was lower than the fortified concentrations used in procedural recovery tests; and therefore the LOQ was not validated for these studies. A position paper on the relevance of the field studies conducted in France was provided by the applicant, but considered unacceptable by RMS and the PRAPeR meeting experts on fate and behaviour. Under field conditions 1^{st} order DT_{50}s of nicosulfuron ranged from 8.9 to 63.3 days (reliable trials on bare soil: 2 in Germany and 2 in France). It was not possible to calculate field dissipation rates for the metabolites ASDM and ADMP. During the peer review it was also agreed that field dissipation of nicosulfuron is not soil pH dependent.

Predicted environmental concentrations (PEC) in soil for nicosulfuron were calculated assuming a worst case first order DT_{50} of 63 days from field studies. PECsoil calculations for metabolites ADMP, ASDM, AUSN, UCSN and HMUD have been performed based on the longest DT_{50} values from laboratory studies. Further information on the method of calculation used by RMS to calculate the plateau level in soil for the metabolites was provided in addendum 3 and considered acceptable.

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

The adsorption and desorption behaviour of nicosulfuron was investigated in ten soils using either the pyridine and pyrimidine radiolabels. Only the pyrimidine studies with four soils were considered

acceptable and the Kfoc values ranged from 7.9 to 51.3 mL/g (mean 20.73 mL/g) and 1/n ranged between 0.9-1.01 (mean = 0.94). In the DAR the RMS indicated that the adsorption of nicosulfuron is pH dependant (with greater adsorption under alkaline conditions), whilst the applicant considered the adsorption to be clay dependent. To address the issue, further analysis of the correlation between nicosulfuron adsorption and soil properties was reported in addendum 3 and discussed by the experts of PRAPeR 22. In conclusion, the experts agreed that the relation of adsorption with clay content is more convincing and should be considered in the groundwater modelling (see section 4.2.2).

The six metabolites ADMP, ASDM, AUSN, UCSN, HMUD and **MU-466**[17] (metabolite identified in the lysimeter studies, see below) were also investigated in adsorption/desorption studies in 4 or 5 soils. Metabolite ADMP may be classified as high to very high mobile (K_{foc} = 42.0-60.4 mL/g), and all the other metabolites exhibit very high mobility in soil (ASDM: K_{foc} = 2.3-7.7 mL/g; AUSN: K_{foc} = 13.0-39.0 mL/g; UCSN: K_{oc} = 1.1-5.6 mL/g; HMUD: K_{oc} = 0.88-10.75 mL/g; MU-466: K_{oc} = 1.32-16.08 mL/g).

Following initial review of the laboratory and field studies the RMS asked the applicant to consider the concern on pH dependent adsorption of metabolites. A simple regression analysis indicated the possibility for weak positive correlations between soil pH and the adsorption of metabolites ASDM, AUSN and MU-466, with higher K_{foc}/K_{oc} values under alkaline conditions. As a consequence a new FOCUS groundwater modelling (see section 4.2.2) was performed by RMS using scenario specific adsorption values. Thus, further information regarding pH dependency of nicosulfuron and its metabolites was submitted and evaluated in addendum 3. The experts considered that due to the limited range of soil pH values tested, a clear correlation could not be determined. However, it was agreed that, in this particular case where metabolites exhibit very low K_{foc}/K_{oc} values, the introduction of the scenario specific adsorption values for ASDM, AUSN and MU-466 in FOCUSgw modelling is not expected to affect the results.

Four column leaching studies were conducted on three soils using ^{14}C-pyrimidine nicosulfuron. Three studies used an exaggerated field rate of 300 g a.s./ha and the fourth used the proposed dose of 60 g a.s./ha. The percentage of the applied radioactivity in the leachate varied between 48-92% with the vast majority of the leachate corresponding to unchanged nicosulfuron with very low doses (2.2-11.1% AR) of metabolites ADMP and DMPU.

In a second study, aged soil column leaching was investigated using ^{14}C-pyrimidine nicosulfuron which was aged for 28 days. The results showed that 55% of the applied radioactivity was found in the leachate (50% AR was nicosulfuron), confirming the mobility of nicosulfuron in soil.

Three sets of lysimeter studies were conducted in Germany and Switzerland with pyridine and pyrimidine radiolabelled nicosulfuron. All the lysimeter were cropped with maize in the first and second years and wheat rye on the final year. Applications were made at 40 or 60 g a.s./ha at the 3-4 leaf stage. Analysis of the leachate in the first lysimeter study showed that the level of nicosulfuron reached a maximum of 0.07 µg/L with a mean of 0.04-0.06 µg/L over the two years, although this was from an application rate of 40 g a.s./ha instead the proposed 60 g a.s./ha. Three metabolites were

[17] MU-466: *N*-methyl-2-sulfamoylpyridine-3-carboxamide

found in significant quantities, with the following annual average concentrations: ASDM 0.18-0.99 µg/L, AUSN 0.24-0.59 µg/L, and UCSN 0.03-0.22 µg/L. In the second study analysis of the leachate showed that nicosulfuron reached a maximum annual average concentration of 0.15 µg/L following a single application of 60 g a.s./ha. Four metabolites produced significant annual average concentrations: ASDM (0.34-2.70 µg/L), AUSN (0.68-1.62 µg/L), UCSN (0.06-0.94 µg/L) and MU-466 (0.07-0.14 µg/L). Overall these results indicated that nicosulfuron and the metabolites ASDM, AUSN, UCSN and MU-466 all have the potential to leach into groundwater at annual average concentrations above 0.1 µg/L.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

Two studies on the aqueous hydrolysis of nicosulfuron were conducted using buffer solutions at pH 5, 7 and 9 using pyridine and pyrimidine labelled nicosulfuron. In both studies, significant hydrolysis of nicosulfuron was observed at pH 5 only, with the DT_{50} value for nicosulfuron being 15-16 days. At the final assessment on day 32 in the pH 7 buffer solution nicosulfuron had only degraded to 87.1% and 94.7% and at pH 9 to 83.2% and 95.8%. Major hydrolysis degradation products at pH 5 were ASDM, ADMP and the new metabolite **DUDN**[18] (max 13.9% AR at day 32). Thus, chemical hydrolysis may contribute to the overall degradation of nicosulfuron in acidic water, but it is unlikely to be a significant route of degradation under neutral or alkaline conditions.

Two additional studies were submitted investigating the hydrolysis of ASDM (pH 4, 7 and 9) and ADMP (pH 5). Half lives of ASDM at 3 pH values calculated at 25ºC were in the range 48-272 days. It was estimated that ADMP is hydrolytically stable for more than one year at 25ºC.

Although some photodegradation may be seen under environmental conditions, it is not expected to be a major route of dissipation in surface water. A phototransformation study was conducted which showed the DT_{50} (first order kinetic) to be 18.7 hours; from these data the quantum yield was determined to be 1.99×10^{-3} mol $Einstein^{-1}$. The estimated half-lives at latitude 30ºN ranged between 3.1 days (summer) and 7.1 days (winter), and at 50ºN between 3.4 days (summer) and 24.3 days (winter).

In the absence of a specific study on ready biodegradation, nicosulfuron can be classified as not ready biodegradable.

A dark sediment/water study was conducted on two natural aquatic systems using ^{14}C-pyridine nicosulfuron. The need for a corresponding study to be carried out using ^{14}C-pyrimidine nicosulfuron was discussed at the meeting of experts. The peer review had questions over the major metabolite ADMP, the only metabolite which will not be found with the pyridine-label. Following the confirmation by the experts of the ecotoxicology section that this metabolite is not relevant to aquatic species (see section 5.2), it was agreed that no further assessment on ADMP is required.

[18] DUDN: 2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-*N*,*N*-dimethylpyridine-3-carboxamide

Nicosulfuron was predominantly found in the water phase of both systems, although it partitioned into the sediment and reached a maximum (on day 14) of 24% and 18% in the river and pond systems respectively. Unextractable radioactivity increased to 42% AR in the river and 58% AR in the pond system by day 177. Four metabolites (HMUD, AUSN, UCSN and ASDM) were identified in both the water and sediment phases, although their concentrations were generally lower in the sediment phase (maximum formation < 5.7% AR). Except HMUD (max 14.1% AR at day 62 in the water phase) concentrations of metabolites were < 10% AR. Mineralisation to CO_2 reached a maximum of 1.4%.
Nicosulfuron dissipates from the water phase in 25 and 32 days according to first order non-linear kinetics. Rate of degradation of nicosulfuron from water and sediment were calculated using a multi-compartment model kinetics. DT_{50}water were 63.9-66.2 days and DT_{50}sediment were 8.8-21.9 days. No information on the degradation of the metabolites was available and a worst-case DT_{50} of 300 days was assumed for all metabolites for use in FOCUS surface water modelling as recommended by the Guidance Document on Aquatic Ecotoxicology.
The water pH of the systems was pH 6.9 for both the river and pond systems. Thus, taking into consideration the hydrolysis studies, it is not known whether the degradation under a different pH, particularly under more acid conditions, would give rise to different metabolite formation or greater concentration of metabolites. Therefore, Member States should be aware that for acidic water bodies the available assessment does not cover the potential aquatic exposure to metabolite DUDN (the major hydrolysis degradation product at pH 5).

Predicted Environmental Concentrations in surface water (PECsw) and sediment (PECsed) were re-calculated by the applicant (see addendum 3) and evaluated by the experts of PRAPeR 22. With respect to the original calculations reported in the DAR, the new geometric mean soil DT_{50} of 16.4 days (derived from the dataset with the 3 additional soils provided by the applicant) for nicosulfuron was considered. It was noted that the DT_{50} values for water and sediment were referred to dissipation rates and not to degradation rates as recommended by the FOCUSsw group. However, as the final version of the FOCUS Guidance on degradation kinetics was not available at the time of submission of the dossier, the experts concluded that the approach taken to calculate the rate of degradation was adequate and that the surface water exposure is acceptable.
Step 1, Step 2 and Step 3 calculations were performed for nicosulfuron and Step 1 and Step 2 calculations (maximum concentrations only) for major metabolites HMUD, AUSN, UCSN and ASDM. Since for some of the metabolites a clear pH dependence of adsorption could not be established (see section 4.1.3), a worst case approach was used for all metabolites (i.e. lowest Koc values and worst-case laboratory DT_{50} values normalised to 20ºC and pF2, except for HMUD, for which the geometric mean of two values from 2 parent labels with 1 soil was considered). The RMS re-ran the modelling for Step 3 calculations for nicosulfuron using revised application windows based on the FOCUS recommended emergence date + 7 days. Results showed that the R4 stream scenario gives the highest PEC for both surface water and sediment. A Step 4 assessment was not submitted by the applicant but one was undertaken by the RMS implementing a 5 m no spray buffer zone (see addendum 3). The refined modelling indicated that the inclusion of a 5 m no spray buffer zone has no,

or minimal impact on the PEC values for the R scenarios, where the peak exposures are largely due to run off.

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

During the peer review process, concerns raised on the appropriate modelling to be perform to assess the potential for groundwater contamination from nicosulfuron. In particular, pH dependent degradation for the parent and pH dependence of adsorption for the parent and the metabolites were questioned (see sections 4.1.2 and 4.1.3). As a consequence, two different approaches for FOCUS groundwater modelling were performed by the applicant (with clay dependant sorption) and the RMS (with pH dependant sorption) and included in addendum 3. The modelling was based on the proposed GAP (60 g nicosulfuron/ha, applied once per year between BBCH growth stages 12-18) using the PELMO model and the eight FOCUS groundwater scenarios that are considered relevant for maize production. The experts accepted the modelling approach using K_{fclay} dependency for the parent as provided by the applicant. The revised geometric mean normalised DT_{50} of 16.4 days for nicosulfuron was used for all scenarios (no pH dependency for soil degradation). For metabolites modelling, worst case degradation rates were considered (except for HMUD). Scenario specific adsorption values were developed to take into account the pH dependency on adsorption for metabolites AUSN, ASDM and MU-466. The results of the simulations indicated that the 80th percentile annual average concentrations in leachate at 1 m depth (PECgw) for nicosulfuron is below 0.1 µg/L in 7 out of the 8 FOCUS scenarios (0.132 µg/L in Hamburg scenario). PECgw values for ADMP and MU-466 are below 0.1 µg/L, for HMUD are between 0.1 µg/L and 0.65 µg/L in 5 scenarios and for AUSN, UCSN and ASDM are in the range 0.059-2.063 µg/L, 0.137-1.195 µg/L and 0.097-1.239 µg/L, respectively. An assessment of the relevance of AUSN, ASDM, ADMP, UCSN, HMUD and MU-466 has been provided in line with the steps laid out in the EU guidance document Sanco/221/2000-rev.10 on relevance of metabolites. These data are considered sufficient to support the conclusion that all metabolites identified as having the potential to occur in groundwater at levels above 0.1 µg/L are "non-relevant".

4.3. FATE AND BEHAVIOUR IN AIR

Nicosulfuron has a vapour pressure of < 8 X 10^{-10} Pa at 25ºC and the Henry's Law constant is 1.48 x 10^{-11} Pa m^3 mol^{-1}. The vapour pressure indicates that nicosulfuron is not volatile. In addition, submitted studies which considered the volatilisation from soil and plants produced losses of 6.2% and 8.3% respectively, in 24 hours. A calculated half-life for photochemical oxidative degradation in the atmosphere by the method of Atkinson was 0.587 hours. This suggests that even if nicosulfuron were to enter the atmosphere, it would degrade quickly and would not be subject to long range transport.

5. Ecotoxicology

Nicosulfuron was discussed at the PRAPeR experts' meeting on ecotoxicology (PRAPeR 23) in May 2007. Following a comment from the section on physical-chemical properties the relevance of impurities 1-4 was discussed. Impurities 1 and 3 are considered to be covered by the risk assessment for the metabolites where the risk was assessed as low. For impurities 2 and 4 an open point was set to address the ecotoxicological relevance since no information was made available. In addendum 4 (not peer-reviewed) from July 2007 the RMS confirmed that the majority of the ecotox studies were conducted with batch 801 which contains impurities 2 and 4 at levels equivalent to that from exposure to commercially manufactured nicosulfuron. Hence the risk from the two impurities is accounted for in the risk assessment for nicosulfuron.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The acute, short-term and long-term toxicity of nicosulfuron to birds and the acute and long-term toxicity to mammals are low. The acute, short-term and long-term TER calculations for medium herbivorous and for insectivorous birds resulted in values greater than the Annex VI trigger values of 10 and 5. Also the acute and long-term TER values for mammals were 2-3 orders of magnitude above the trigger of 10 and 5, respectively.

The avian toxicity of the two major plant metabolites ASDM and AUSN was not tested. The toxicity of ASDM and AUSN to mammals is low (LD50 >2000) and also in the tests with earthworms and aquatic organisms no indication was found that the metabolites would have a higher toxicity than nicosulfuron. Given that exposure levels for herbivorous birds and mammals to these metabolites will be lower than that from nicosulfuron (the maximum residue level of the metabolites is not exceeding one quarter of the maximum level of nicosulfuron) and that their avian toxicity is not likely to be greater than that of nicosulfuron, the risk to birds and mammals from exposure to these metabolites is assumed to be covered by the risk assessment for the parent.

The risk of secondary poisoning of earthworm- and fish-eating birds and mammals is considered to be low because the of the low log P_{ow} of <1 of nicosulfuron and its metabolites

The risk to birds and mammals from uptake of contaminated drinking water was assessed as low by the RMS. Overall it is concluded that the risk to birds and mammals is low from the representative use in maize.

5.2. RISK TO AQUATIC ORGANISMS

Lemna gibba was the most sensitive aquatic organism tested (EC_{50} based on frond number of 0.0017 mg a.s./L). The TER values calculated with FOCUS step1 PECsw exceeded the Annex VI trigger for all groups of aquatic organisms except for *Lemna gibba*. The applicant suggested to use time weighted average PECsw values. This was not agreed by the RMS since no information on the time to onset of effects was available. New studies were provided by the applicant and a new risk

assessment was presented in addendum 3 (May 2007). Three out of eleven FOCUS step 3 part scenarios achieved initial PECsw values resulting in TERvalues greater than the Annex VI trigger of 10. Taking a no-spray buffer zone of 5 metres into account then the 4 FOCUS step4 drainage scenarios (D3, D4, D5, D6) and one run-off part scenario (R1 pond) would result in initial PECsw with a TER of >10. New studies with *Lemna gibba* investigating the potential of recovery were also submitted for risk refinement. However regeneration in Lemna is by division of fronds and can occur relatively quickly compared to other macrophytes with other modes of reproduction. It was considered therefore as not appropriate to use theses data in refinement of a risk assessment in which they would be pivotal.

A study with sediment dwelling organisms (*Chironomus riparius*) was submitted but assessed as not valid. However, nicosulfuron and its metabolites have a low affinity to the sediment phase and the toxicity of nicosulfuron and its metabolites to *Daphnia magna* is low. The chronic NOEC for daphnids is 5.2 mg nicosulfuron/L and thus greater than the trigger of 0.1 mg/L. Therefore a study with sediment dwelling organisms is not triggered and the risk is considered to be low.

The metabolites HMUD, ASDM and AUSN were identified as major metabolites in the water phase. In addition the minor metabolites MU-466 and UCSN were tested. The metabolite DUDN was formed in amounts of >10% in a hydrolysis study at a pH of 5 but was not found at a pH of 7 and higher. DUDN was not found in the water sediment study and it is not expected that surface waters with such a low pH (pH of 5) occur frequently in agricultural landscapes. Therefore it was considered not necessary to conduct studies with aquatic organisms and the metabolite DUDN. No information is available on amounts of DUDN formed by hydrolysis in the pH range of 5-7 and uncertainty remains with regard to the risk to aquatic organisms from the metabolite DUDN under acidic water conditions.
The TER values for the metabolites HMUD, ASDM and AUSN based on PECsw from FOCUS step1 were markedly above the Annex VI trigger values indicating a low risk to aquatic organisms from the metabolites. No chronic testing was conducted with the metabolites. The acute toxicity of the metabolites was lower than that of nicosulfuron and it is expected that the long-term toxicity will also be low and no chronic testing with the metabolites is required.

The PEC values for the metabolites HMUD, AUSN, UCSN and ASDM were above 0.1 µg/L and therefore the TER values for the most sensitive organism (*Lemna gibba*) and the maximum PECs for the metabolites were calculated. The TERs were in the range of >1538 to >60976 indicating a large margin of safety in situations when ground water emerges to become surface water.

No bioconcentration study with fish is required since the log Pow for nicosulfuron and its metabolites is <1.

Overall it is concluded that the risk to aquatic organisms is low for most groups of organisms except for aquatic macrophytes. Risk mitigation measures such as a no spray buffer zone of 5 metres is

required. No-spray buffer zones are not sufficient under geoclimatic conditions where run-off is the dominant route of entry into surface water and further risk mitigation measures have to be considered at Member States level.

5.3. RISK TO BEES

The acute oral and contact toxicity of technical and formulated nicosulfuron was tested. The RMS considered that bees could be exposed in maize fields when they forage on weeds or on aphid honey dew. The acute oral and contact HQ values were below the trigger of 50 indicating a low risk to bees from the representative use of nicosulfuron.

5.4. RISK TO OTHER ARTHROPOD SPECIES

No statistical significant effects were observed in standard laboratory tests with *Typhlodromus pyri*, *Poecilus cupreus*, *Coccinella septembpunctata* and *Aleochara bilineata* at an application rate of 1.5 litre formulation/ha (60 g nicosulfuron/ha). The parasitation rate of *Aphidius rhopalosiphi* was reduced by 50% at the tested application rate of 1.5 L formulation/ha. The test was repeated as an extended lab test where the wasps were exposed to freshly treated seedlings. The observed parasitation rate of 17.6 parasitised aphids/female was lower than the parasitation rate in the control with 21.1 parasitised aphids/female but this difference was not statistically significant. The in-field and off-field HQ values based on LR_{50} values for *A. rhopalosiphi* and *T. pyri* were below the trigger of 2.

Overall it is concluded that the risk to non-target arthropods is low for the representative use of nicosulfuron in maize.

5.5. RISK TO EARTHWORMS

The acute toxicity to earthworms of technical and formulated nicosulfuron and its soil metabolite ADMP is low. The TER values for nicosulfuron and the metabolite ADMP based on maximum initial PECs (of 0.06 mg nicosulfuron/kg soil and 0.038 mg ASDM/kg soil) are markedly above the trigger values and indicate a large margin of safety. The tests with the metabolites ADMP, AUSN, HMUD, UCSN and MU-466 are non-standard and not GLP with only 2 replicates and a duration of exposure of 7 days instead of 14 days. However the studies provide an indication that the toxicity to earthworms is low and the approximate TER values with maximum PEC values would be in the range of 20000 – 208000. No test on the chronic toxicity of nicosulfuron to earthworms has been submitted. The DT_{90} is in the range of 30 – 210 days. According to the terrestrial guidance document a case by case decision should be made on the necessity of chronic testing when the field DT_{90} is in the range of 100 to 365 days. The RMS decided that no chronic testing with nicosulfuron is required since the acute toxicity to earthworms is very low and the acute TERs are more than 3 orders of magnitude above the trigger of 10.

Because of their persistence (DT_{90} of >365 days) the metabolites ASDM, AUSN, UCSN were tested in long-term studies with earthworms. The long-term TERs ranged from 1.2 to 1.6 indicating a

potential long-term risk to earthworms. A new long-term (reproduction) test with a mixture of the three metabolites was submitted and evaluated in addendum 3 (May 2007). No effects were observed at the concentrations tested (0.35 mg ASDM/kg soil, 0.1 mg AUSN/kg soil and 0.05 mg UCSN/kg soil). The corresponding TERs were calculated as 5.6 for each of the metabolites.

Overall it is concluded that the acute and long-term risk of nicosulfuron and its soil metabolites to earthworms is low for the representative use evaluated...

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

The DT_{90} field is 100-365 days but because the standard in-field HQ values for non-target arthropods were <2 and no effects of >25% were observed in tests with soil non-target micro-organisms the RMS considered that no further studies with nicosulfuron are required. The DT_{90} (lab) for ADMP is 9.5-38 days and therefore no further study with soil macro-organisms/litter bag test is triggered. The DT_{90} (lab) for the metabolite HMUD is 102 days but due to its structural similarity to nicosulfuron and the low toxicity of nicosulfuron to earthworms, non-target arthropods and soil micro-organisms adverse effects on organic matter breakdown are considered unlikely.

The metabolites ASDM, AUSN, UCSN have DT_{90}s of >365 days and hence the risk to soil non-target macro-organisms needs to be assessed. Since the long-term TER for earthworms was >5 and no effects of >25% were observed in the tests with soil micro-organisms no test with collembola or litterbag test is triggered. However the applicant submitted a study with *Folsomia candida*. No effects were observed at the concentrations tested (0.35 mg ASDM/kg soil, 0.1 mg AUSN/kg soil and 0.05 mg UCSN/kg soil). The corresponding TERs were calculated as 5.6 for each of the metabolites.

Overall it is concluded that the risk of nicosulfuron and its soil metabolites to other soil non-target macro-organisms is low for the representative use evaluated...

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of >25% on soil respiration or nitrification were observed in test with technical nicosulfuron and formulated as SL-950 4% SC at application rates of up to 600 g nicosulfuron/ha, equivalent to a 0.8 mg nicosufuron/kg soil. The maximum initial PECsoil of 0.06 mg is about 13 times less then the tested concentration. Therefore the risk to soil micro-organism from nicosulfuron is considered as low. The major metabolites AUSN, UCSN and ASDM were tested as a mixture. No effects of >25% were observed at test concentrations of 0.082 mg AUSN/kg soil, 0.034 mg UCSN/kg soil and 0.191 mg ASDM/kg soil. The tested concentrations were more than 3 times higher than the maximum PECsoil for the metabolites indicating a low risk to soil micro-organisms.

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

Herbicidal effects of SL-950 4% SC were tested in glasshouse grown plants and in one field trial. A total of 23 different plant species (predominantly dicotyl and monocotyl crop species) was tested.

Generally the plants tolerated a relatively high dose of nicosulfuron when applied pre-emergence but reacted very sensitive when the application was post emergence. The lowest endpoint was observed for rice (EC_{50} = 0.47 g nicosulfuron/ha). If the endpoint is compared to the PECs of 1.662 g nicosulfuron/ha and 0.342 g nicosulfuron/ha from spray drift at 1 and 5 metres distance from the field the resulting TERs are 0.28 and 1.37 indicating a potential high risk to non-target plants. The RMS suggested to reduce the trigger value from 5 to 1 based on the argument that the differences in species sensitivity are sufficiently addressed by the high number of species tested and proposed a 5 m no spray buffer zone as a risk mitigation measure. The reduction of the safety factor from 5 to 1 was questioned during the peer-review and not agreed by the experts. In the experts´ meeting it was concluded that it would be possible to use an HC_5 value without a safety factor (trigger of 1) as suggested in the guidance document on terrestrial ecotoxicology and a data gap was set for the applicant to calculate the HC_5 and to revise the risk assessment for terrestrial plants. The applicant submitted a new risk assessment according to the approach suggested by the experts. The new risk assessment was evaluated by the RMS in a not peer-reviewed addendum 4 from July 2007. It was concluded by the RMS that no details have been provided for the calculations used to derive the SSD curve but that visual inspection gives the impression of a reasonably good fit of the plotted data to derived curve. The HC_5 value of 0.464 g a.s./ha is similar to the lowest endpoint (rice EC_{50} = 0.47 g nicosulfuron/ha) leading to the conclusion that risk mitigation such as a 5 meter in-field no-spray buffer zone would be required to mitigate the risk to non-target plants in the off-field area.

No herbicidal effects were observed in a test with 5 plant species (maize and two other monocotyl and dicotyl species) and the metabolites ASDM, ADMP, AUSN, MU-466, HMUD and UCSN up to an application rate of 100 g/ha. The soil concentration of the metabolites is considered to be lower than that of nicosulfuron and given the lower toxicity of the metabolites the risk posed to non-target plants is considered to be covered by the risk assessment for nicosulfuron.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No effects on cell multiplication of the bacterium *Pseudomonas putida* was observed when exposed to a concentration of up to 250 mg nicosulfuron/L. No significant inhibition of respiration of activated sewage sludge was observed in tests with lysimeter leachate (5.35 µg/L of parent equivalents) and with the soil metabolites ASDM, AUSN, UCSN, MU-466 and HMUD at a concentration of 100 mg/L. It is unlikely that nicosulfuron will reach waste water treatment plants but based on a worst case scenario of direct overspray a PEC of 0.02 mg nicosulfuron can be calculated based on a water depth of 30 cm. Although nicosulfuron was not directly tested with activated sewage sludge the tests with *Pseudomonas putida* and the tests with soil metabolites and activated sewage sludge suggest that the risk to biological methods of sewage treatment is low for the representative use in maize.

6. Residue definitions

Soil

Definitions for risk assessment: nicosulfuron, HMUD[19], AUSN[20], UCSN[21], ASDM[22], ADMP[23]

Definitions for monitoring: nicosulfuron

Water

Ground water

Definitions for exposure assessment: nicosulfuron, HMUD, AUSN, UCSN, ASDM, ADMP, MU-466[24]

Definitions for monitoring: nicosulfuron

Surface water

Definitions for risk assessment (water): nicosulfuron, HMUD, AUSN, UCSN, ASDM, ADMP (all metabolites except HMUD only via soil)

Definitions for risk assessment (sediment): nicosulfuron

Definitions for monitoring: nicosulfuron

Air

Definitions for risk assessment: nicosulfuron

Definitions for monitoring: nicosulfuron

Food of plant origin

Definitions for risk assessment: nicosulfuron

Definitions for monitoring: nicosulfuron

Food of animal origin

Definitions for risk assessment: unable to propose, however not required for representative use

Definitions for monitoring: unable to propose, however not required for representative use

[19] HMUD = 2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-*N*,*N*-dimethylpyridine-3-carboxamide

[20] AUSN = 2-[(carbamimidoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide

[21] UCSN = 2-[(carbamoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide

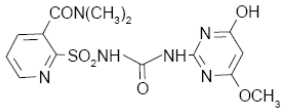
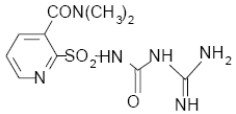
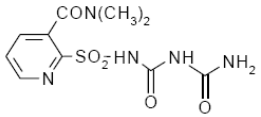
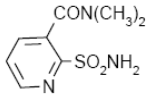
[22] ASDM = *N*,*N*-dimethyl-2-sulfamoylpyridine-3-carboxamide

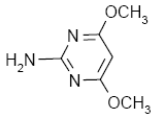
[23] ADMP = 4,6-dimethoxypyrimidin-2-amine

[24] MU-466 = *N*-methyl-2-sulfamoylpyridine-3-carboxamide

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
nicosulfuron	Low to moderate persistence ($DT_{50\ lab}$ = 7-46.3 d, 20°C and different soil moisture)	The toxicity and the risk to earthworms, other soil macro-and soil micro-organisms are low.
HMUD 	Moderate persistence ($DT_{50\ lab}$ = 27.4-30.8 d, 20°C and 55% MWHC)	Indication of low toxicity to earthworms. The risk to earthworms was assessed as low, the risk to other soil macro- organisms is considered to be low due to its structural similarity to nicosulfuron.
AUSN 	Medium to high persistence ($DT_{50\ lab}$ = 73.8-218.2 d, 20°C and 40% MWHC)	The toxicity to earthworms is low. The risk to earthworms, other soil macro-organisms and soil micro-organisms was assessed as low.
UCSN 	High persistence ($DT_{50\ lab}$ = 126.2-307.5 d, 20°C and 40% MWHC)	The toxicity to earthworms is low. The risk to earthworms, other soil macro-organisms and soil micro-organisms was assessed as low.
ASDM 	Medium to high persistence ($DT_{50\ lab}$ = 90.5-268.5 d, 20°C and 40% MWHC)	The toxicity to earthworms is low. The risk to earthworms, other soil macro-organisms and soil micro-organisms was assessed as low.

Compound (name and/or code)	Persistence	Ecotoxicology
ADMP 	Low to moderate persistence ($DT_{50\ lab}$ = 2.9-11.3 d, 20°C and 40% MWHC)	The toxicity and the risk to earthworms are 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 relevance
nicosulfuron	High to very high mobility (K_{foc} = 7.9-51.3 mL/g)	FOCUS PELMO 3.3.2: yes, trigger exceeded in 1 out of 8 scenarios (0.132 µg/L for Hamburg scenario) Lysimeter: yes, annual average concentration max 0.17 µg/L	Yes	Relevant	The risk to aquatic organisms in surface water was assessed as low when groundwater becomes surface water due to the low concentration of nicosulfuron in groundwater.
HMUD	Very high mobility ($K_d$oc = 0.88-10.75 mL/g)	FOCUS PELMO 3.3.2: yes, trigger exceeded in 5 out of 8 scenarios (max 0.65 µg/L for Hamburg scenario) Lysimeter: no	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms. The risk to aquatic organisms in surface water was assessed as low when groundwater becomes surface 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 relevance
AUSN	Very high mobility (K_{foc} = 13.0-39.0 mL/g)	FOCUS PELMO 3.3.2: yes, trigger exceeded in 7 out of 8 scenarios (max 2.063 µg/L for Hamburg scenario); trigger 0.75 µg/L exceeded for 6 scenarios Lysimeter: yes, annual average concentration max 1.62 µg/L	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms. The risk to aquatic organisms in surface water was assessed as low when groundwater becomes surface water.
UCSN	Very high mobility ($K_d$oc = 1.1-5.6 mL/g)	FOCUS PELMO 3.3.2: yes, trigger exceeded in all 8 scenarios (max 1.195 µg/L for Kremsmunster scenario) ; trigger 0.75 µg/L exceeded for 6 scenarios Lysimeter: yes, annual average concentration max 0.94 µg/L	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms. The risk to aquatic organisms in surface water was assessed as low when groundwater becomes surface water.
ASDM	Very high mobility (K_{foc} = 2.3-7.7 mL/g)	FOCUS PELMO 3.3.2: yes, trigger exceeded in 7 out of 8 scenarios (max 1.239 µg/L for Kremsmunster scenario) ; trigger 0.75 µg/L exceeded for 4 scenarios Lysimeter: yes, annual average concentration max 2.70 µg/L	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms. The risk to aquatic organisms in surface water was assessed as low when groundwater becomes surface 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 relevance
ADMP	High to very high mobility (K_{foc} =42.0-60.4 mL/g)	FOCUS PELMO 3.3.2: no Lysimeter: no	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms
MU-466	Very high mobility ($K_d$oc = 1.32-16.08 mL/g)	FOCUS PELMO 3.3.2: no Lysimeter: yes, annual average concentration max 0.14 µg/L	No No herbicidal effects detected at rates of up to 100 g/ha. The lowest EC_{50} for nicosulfuron was 0.47 g/ha	Not relevant	Low toxicity to aquatic organisms

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Nicosulfuron (water and sediment)	The risk to aquatic organisms is low except for aquatic macrophytes.
HMUD (water only)	Less toxic to aquatic organisms compared to nicosulfuron. The risk was assessed as low for all groups of aquatic organisms.

Compound (name and/or code)	Ecotoxicology
AUSN (water only originating from soil)	Less toxic to aquatic organisms compared to nicosulfuron. The risk was assessed as low for all groups of aquatic organisms.
UCSN (water only originating from soil)	Less toxic to aquatic organisms compared to nicosulfuron. The risk was assessed as low for all groups of aquatic organisms.
ASDM (water only originating from soil)	Less toxic to aquatic organisms compared to nicosulfuron. The risk was assessed as low for all groups of aquatic organisms.
ADMP (water only originating from soil)	Less toxic to aquatic organisms compared to nicosulfuron. The risk was assessed as low for all groups of aquatic organisms.

Air

Compound (name and/or code)	Toxicology
nicosulfuron	Not acutely toxic by inhalation (Rat LC_{50} > 5.47 mg/L)

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

- Additional validation data for the method of analysis for impurities, as the linearity range covered must include the specification limits in accordance with SANCO 3030/99. (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown, refer to point 1)
- A study for log P_{ow} at neutral and alkaline pH is required (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown, refer to point 1)
- A risk assessment for terrestrial plants based on HC_5 (relevant for all representative uses evaluated; data gap identified in the experts´ meeting PRAPeR 23 (May 2007); submitted by the applicant and evaluated by the RMS in a not peer-reviewed addendum 4 from July 2007; refer to point 5.8.

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 spraying with conventional ground spraying equipment to control perennial grass weed species (*Elymus repens, Sorghum halepense)* and a range of annual grass weed (*Alopecurus myosuroides, Poa annua, Lolium spp., Setaria spp., Digitaria spp., Echinchloa crus galli*) and broad-leaved weed species (*Chenopodium album, Matricaria chamomilla, Stellaria media, Solanum nigrum, Amaranthus spp., Galium aparine, Polygonum spp., Sinapis arvensis*) in grain and fodder maize up to the BBCH 12-18 leaf stage, in Northern and Southern Europe, at a single application at a maximum rate of 60 g as/ha.

The representative formulated product for the evaluation was "SL-950 4% SC", an oil dispersion (OD), registered under different trade names in Europe.

Adequate analytical methods are available for the determination of nicosulfuron residues in food of plant origin (in grain and fodder maize), soil, water and air.
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 products are possible.

Nicosulfuron is absorbed rapidly but only to a limited extent (about 40%) in the rat following oral administration. It is widely and uniformly distributed in the body and is excreted mainly via faeces (63 - 73%) and urine (23 - 28%). It is largely excreted unchanged (70 - 86%). The compound is of low acute toxicity by the oral, dermal, inhalational and intraperitoneal route. It is non-irritant to skin, slightly irritant to the eye and showed weak sensitisation potential in a Guinea pig maximisation test.

Nicosulfuron was of low toxicity also in the short term studies in rat, mouse and dog, showing mild hepatotoxicity in the rat at very high dose levels. No genotoxicity was observed *in vitro* and *in vivo*, and no evidence of carcinogenicity was seen in the rat. Increased incidences of hepatocellular adenoma and carcinoma were seen in male mice at the top dose level but not considered to be of relevance to the risk assessment. No effects on reproduction were seen in a two-generation study with rats. No evidence of teratogenicity was seen in developmental toxicity studies in the rat and rabbit.

The acceptable daily intake (ADI) is 2 mg/kg bw/day, derived from the chronic rat study, and applying a safety factor of 100. Subchronic dog studies (28-day, 90-day and 1-year) support this value. Due to the low acute toxicity of nicosulfuron, it was agreed that an acute reference dose (ARfD) is not required. The acceptable operator exposure level (AOEL) was set at 0.8 mg/kg bw/day, based on the subchronic dog studies applying a safety factor of 100 and correcting for oral absorption of 40%. The exposure estimates for operators were 4% and 27% of the AOEL wearing PPE (personal protective equipment) with the German model, and with the UK POEM respectively. When no PPE is worn values rise to 10% and 39% respectively. Estimated exposures both for bystanders and re-entry workers were estimated to be well below the AOEL.

Metabolism of nicosulfuron was studied in maize. A few hours after application to the plants, a considerable amount of metabolism had already occurred. Nevertheless, 60 days after application nicosulfuron was still the most significant residue (41-52% TRR). Major metabolites identified were AUSN and ASDM (individually around 20% TRR), indicating that a cleavage of the ring structures had occurred. At harvest (102 days after application) the residue profile was very similar to that observed at the 60 days interval. The total residue upon application according to the notified GAP was very low and no significant residues of nicosulfuron or its metabolites are expected in maize at harvest. This was confirmed by the results of supervised residue trials. Also in following crops no significant residue levels are expected, since due to phytotoxic effects other crops than cereals could not be grown until nicosulfuron and metabolites have decreased to <0.001 mg/kg in the soil. No significant uptake of residues from soil was found in the cereal crops analysed for total residues in lysimeter studies. Therefore it was concluded that based on the data submitted to support the use in maize, the residue definition in this crop could be limited to nicosulfuron for risk assessment and monitoring purposes.

Intakes of nicosulfuron by domestic animals will not be significant and livestock studies were not necessary. Some data is available for future reference, however at this time it is not possible to propose residue definitions in animal products.

In a chronic consumer risk assessment all residue intakes from maize were significantly less than 1 % of the ADI and it can therefore be concluded that the chronic risk to the consumer is low. The consumer may be also exposed to soil metabolites leaching into ground water used as drinking water but the additional exposure from this source does most likely not exceed 0.05% of the ADI of nicosulfuron.

An acute risk assessment was not necessary as nicosulfuron has been shown to have a very low acute toxicity profile and no ARfD was allocated to this substance.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level with the exception that for acidic water bodies the available assessment does not cover the potential aquatic exposure to metabolite DUDN. For the applied for intended uses, the potential for groundwater exposure by just the active substance nicosulfuron above the parametric drinking water limit of 0.1 µg/L, is low. The available information (FOCUS groundwater modelling and lysimeter studies) indicates that the metabolites AUSN, UCSN and ASDM have the potential to contaminate groundwater at concentrations >0.75 µg/L. Metabolite HMUD is predicted to be above 0.1 µg/L in five FOCUS scenarios but all are less than 0.75 µg/L. The toxicological assessment was able to conclude that all the metabolites AUSN, ASDM, ADMP, UCSN, HMUD and MU-466 are not relevant regarding groundwater at the expected concentrations.

The risk to all groups of non-target organisms was assessed as low for the representative use of nicosulfuron in maize except for aquatic macrophytes and terrestrial non-target plants. A no-spray buffer zone of 5 metres is required achieve a TER of >10 in the 4 FOCUS step4 drainage scenarios (D3, D4, D5, D6) but only in one run-off part scenario (R1 pond) out of 4 run-off scenarios the TER was >10. No-spray buffer zones are not sufficient as a risk mitigation measure under geoclimatic conditions where run-off is the dominant route of entry into surface water and further risk mitigation measures have to be considered at Member States level. 23 different plant species (predominantly dicotyl and monocotyl crop species) was tested. In the original risk assessment it was suggested to use the lowest endpoint and to reduce the safety factor from 5 to 1. The trigger of 1 was exceeded if an in-field no-spray buffer zone of 5 metres is applied. The original risk assessment was not accepted in the peer-review and it was suggested to use an HC5 approach as outlined in the terrestrial guidance document. Such a risk assessment was submitted by the applicant and assessed by the RMS in a not peer-reviewed addendum 4 from July 2007. The HC_5 is similar to the lowest endpoint and hence also requiring a 5 meter in-field no-spray buffer zone to mitigate the risk to non-target plants in the off-field area.

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

- The available risk assessment does not cover the potential aquatic exposure to metabolite DUDN for acidic water bodies.
- Risk mitigation measures such as a no-spray buffer zone of 5 metres is required to mitigate the risk to aquatic macrophytes. However no-spray buffer zones are not sufficient under geoclimatic conditions where run-off is the dominant route of entry into surface water and further risk mitigation measures have to be considered at Member State level.
- Risk mitigation measures such as an in-field no-spray buffer zone of 5 metres is necessary to protect non-target plants in the off-field area.

Critical areas of concern

- None

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

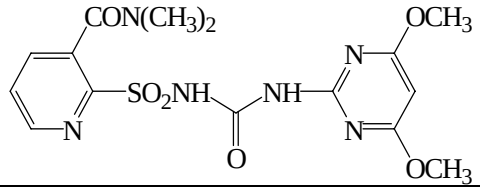
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Nicosulfuron
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	United Kingdom
Co-rapporteur Member State	None

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylnicotinamide or 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-dimethylcarbamoyl-2-pyridylsulfonyl)urea
Chemical name (CA) ‡	2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino] carbonyl]amino]sulfonyl]-*N*,*N*-dimethyl-3-pyridinecarboxamide
CIPAC No ‡	709
CAS No ‡	111991-09-4
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	709/TC (2006) min 910 g/kg
Minimum purity of the active substance as manufactured ‡	930 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula ‡	$C_{15}H_{18}N_6O_6S$
Molecular mass ‡	410.4 g/mol
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	145 - 170°C (98.4% pure nicosulfuron) accompanied by decomposition 140-161 °C (99-99.8%, nicosulfuron monohydrate form)
Boiling point (state purity) ‡	Not determined – substance decomposes before boiling point is reached
Temperature of decomposition (state purity)	150 - 180°C (99.8%)
Appearance (state purity) ‡	White powder solid (96.18-99.77%)
Vapour pressure (state temperature, state purity) ‡	< 8 x 10^{-10} Pa at 25°C (99.8%)
Henry's law constant ‡	1.48 x 10^{-11} Pa m^3 mol^{-1} at 20°C
Solubility in water (state temperature, state purity and pH) ‡	0.25 g/L at 20 ± 1.0°C (pH 5) (99.8%) 7.5 g/L at 20 ± 1.0°C (pH 6.5) (99.8%) 76.4 g/L at 20 ± 1.0°C (pH 9.0) (95.8%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (99.8%) n-hexane: ≤ 2x10^{-5}g/L toluene: 3 x 10^{-2}g/L - 8 x 10^{-2}g/L dichloromethane: 21.3g/L methanol: 0.40g/L isopropanol: 0.94g/L acetone: 8.9g/L ethylacetate: 2.4g/L
Surface tension ‡ (state concentration and temperature, state purity)	71 mN/m at 20°C (90 % saturated solution) (93.8%)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 0.61 at 20-21 °C (pH 2.3-2.4) (99.8%)
Dissociation constant (state purity) ‡	pKa_1 = 4.78 ± 0.05(99.8%) pKa_2 = 7.58 ± 0.05(99.8%)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	λ_{max} (nm); ε ($L.mol^{-1}.cm^{-1}$) basic 244 nm 2.38 x 10^4 neutral 241 nm 1.92 x 10^4 acidic 241 nm 1.82 x 10^4 (95.3%) No absorbance at λ > 290 nm.
Flammability ‡ (state purity)	Not highly flammable. (93.8%)
Explosive properties ‡ (state purity)	The substance shows no explosive properties. (91.9%)
Oxidising properties ‡ (state purity)	The substance is non–oxidising (93.8%)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Maize	various	SL-950 4% SC	F	weeds	OD	40 g/L	spray application	BBCH 12-18	1	n.a.	15-30	200-400	60	n.r.	-

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).
(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Nicosulfuron
Food of animal origin		Not proposed
Soil		Nicosulfuron
Water	surface	Nicosulfuron
	drinking/ground	Nicosulfuron
Air		Nicosulfuron

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	HPLC-MS/MS. LOQ = 0.01 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Soil (analytical technique and LOQ)	Nicosulfuron: LC/MS. LOQ = 0.05 µg/kg.
Water (analytical technique and LOQ)	Nicosulfuron: HPLC/UV. LOQ = 0.05µg/L Confirmatory method: LC-DAD. LOQ = 0.05µg/L
Air (analytical technique and LOQ)	Nicosulfuron: HPLC/UV. LOQ = 1.2µg/m^3
Body fluids and tissues (analytical technique and LOQ)	Not required

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

	RMS/peer review proposal
Active substance	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapidly absorbed, but only to a limited extent: ~40%, based on urinary and biliary excretion
Distribution ‡	Widely and uniformly distributed
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid and extensive. Predominantly in the faeces (63-73%), of which 15-18% via the bile within 48h. 23-28% in the urine.
Metabolism in animals ‡	Excreted largely (69.5-86.3%) unchanged in the faeces and urine.
Toxicologically relevant compounds ‡ (animals and plants)	Parent compound
Toxicologically relevant compounds ‡ (environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	-
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	-
Rat LC_{50} inhalation ‡	> 5.47 mg/L (4h, whole body)	-
Skin irritation ‡	Non-irritant	-
Eye irritation ‡	Slight irritant (no classification required)	-
Skin sensitisation ‡	Weak sensitiser (M&K): no classification required	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Decreased body weight and liver (increased weight and clinical chemistry)	
Relevant oral NOAEL ‡	200 mg/kg bw/d (dog 28-day, 90-day and 1-year studies)	-
Relevant dermal NOAEL ‡	No data - not required	-
Relevant inhalation NOAEL ‡	No data - not required	-

Genotoxicity ‡ (Annex IIA, point 5.4)

……	No genotoxic potential	-

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

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

Target/critical effect ‡	Red blood cell (rat), liver (mouse)	
Relevant NOAEL ‡	2-year rat: 199 mg/kg bw/d 2-year mouse: 544 mg/kg bw/d	
Carcinogenicity ‡	Increased incidences of hepatocellular tumours at top dose (50000 ppm) in male mice which are not considered as being relevant. Overall, no evidence of carcinogenic potential relevant to human risk assessment.	-

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reproduction: no toxicity at highest dose Parental: body weight effects Offspring: no toxicity at highest dose	-
Relevant parental NOAEL ‡	379 mg/kg bw/d	-
Relevant reproductive NOAEL ‡	3302 mg/kg bw/d	-
Relevant offspring NOAEL ‡	3719 mg/kg bw/d	-

Developmental toxicity

Developmental target / critical effect ‡	Maternal: rat: no findings up to top dose Rabbit: mortality an clinical signs Foetal: increased variations at maternally toxic doses in the rabbit. No adverse findings in the rat	-
Relevant maternal NOAEL ‡	Rat: 1000 mg/kg bw/d Rabbit: 300 mg/kg bw/d	-
Relevant developmental NOAEL ‡	Rat: 1000 mg/kg bw/d Rabbit: 300 mg/kg bw/d	-

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data, none required	-
Repeated neurotoxicity ‡	No data, none required	-
Delayed neurotoxicity ‡	No data, none required	-

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

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	No data, none required
Studies performed on metabolites or impurities ‡	**ASDM**: Rat oral LD50 >2000 mg/kg bw Mouse oral LD50 >5000 mg/kg bw Rat dermal LD50 >2000 mg/kg bw Non-irritating to skin Slight eye irritant Skin sensitiser 28-day and 90-day NOAELS >1000 mg/kg bw/d Not mutagenic in vitro or in vivo Reproductive NOAEL >1000 mg/kg bw/d Developmental NOAEL = 200 mg/kg bw/d **ADMP**: Rat oral LD50 737-1073 mg/kg bw Negative Ames test **AUSN**: Rat oral LD50 >2000 mg/kg bw Not genotoxic in vitro **UCSN**: Rat oral LD50 >2000 mg/kg bw Not genotoxic in vitro **MU-466**: Rat oral LD50 >2000 mg/kg bw Not genotoxic in vitro **HMUD**: Not genotoxic in vitro

Medical data ‡ (Annex IIA, point 5.9)

……..	Limited data; no detrimental effects on health in manufacturing personnel

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

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	2 mg/kg bw/d	Chronic rat supported by subchronic dog	100
AOEL ‡	0.8 mg/kg bw/d	Subchronic dog	100 x 40%
ARfD ‡	Not necessary- not allocated	-	-

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation	100% default value

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Application to maize : POEM % of AOEL (tractor, 60 g a.s./ha, without PPE) 39% (tractor, 60 g.a.s./ha, PPE = gloves during mixing/loading) 27% BBA (tractor, 60 g a.s./ha, without PPE) 10% (tractor, 60 g a.s./ha, PPE = gloves during mixing/loading) 4%
Workers	According to Hoernicke et al. 1998: <2% of AOEL (no PPE)
Bystanders	According to Lloyd and Bell, 1983: <1% of AOEL

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

	RMS/peer review proposal
Substance (name)	None

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

Appendix 1.4: Residues

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

Plant groups covered	Cereals (maize)
Rotational crops	Not required. Lysimeter studies indicated low uptake by cereal plants (TRR <0.01 mg/kg) and the phytotoxic effect of nicosulfuron and its soil metabolites on dicot plants leads to a self-limitation in the re-planting period
Metabolism in rotational crops similar to metabolism in primary crops?	Not applicable
Processed commodities	No data supplied or required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Nicosulfuron
Plant residue definition for risk assessment	Nicosulfuron
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	Ruminants
Time needed to reach a plateau concentration in milk and eggs	Unable to assess due to low total radioactive residues.
Animal residue definition for monitoring	Unable to propose, however intakes are not significant (<0.1 mg/kg diet).
Animal residue definition for risk assessment	Unable to propose, however intakes are not significant (<0.1 mg/kg diet).
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)

……..	No data supplied or required

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

……..	Stable in maize for 9 months.

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

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies Residue levels in matrices : Mean (max) mg/kg		
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-		
Eggs		-	

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Maize	Northern Region	18 x <0.01 mg/kg in grain 17 x <0.01 mg/kg in forage and 1 x 0.015 mg/kg in forage.	The one positive residue in forage was probably due to contamination as samples taken two months earlier showed no quantifiable residues; this result was therefore not taken into consideration in the risk assessment.	0.01* mg/kg	0.01 mg/kg	0.01 mg/kg
Maize	Mediterranean Region	15 x <0.01 mg/kg in grain 14 x <0.01 mg/kg forage and 1 x 0.013 mg/kg forage	As there is no decline data the one positive residue in forage was taken into consideration in the risk assessment.	0.01* mg/kg	0.01 mg/kg	0.01 mg/kg

(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

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

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

ADI	2 mg/kg
TMDI (% ADI) according to WHO European diet	0.0000028 mg/kg bw/day (<1 %) [25]
TMDI (% ADI) according to national (to be specified) diets	0.000001 mg/kg bw/day (<1%), UK diet
IEDI (WHO European Diet) (% ADI)	0.0000028 mg/kg bw/day (<1 %)
NEDI (specify diet) (% ADI)	0.000001 mg/kg bw/day (<1%), UK diet
Factors included in IEDI and NEDI	STMR
ARfD	Not required
IESTI (% ARfD)	Not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required
Factors included in IESTI and NESTI	Not required

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	
Not required	-	-	-	-

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

Maize grain	0.01* mg/kg

* LOQ

[25] Exposure from ground water used as drinking water contributes in addition to the estimated exposure through food with less than 0.05% ADI. For details refer to paragraph 3.4 of the EFSA scientific report.

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

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	*1.3* % AR after *112* d, [^{14}C-pyridine]-label (n[26]= *1*) *16.8* % AR after *112* d, [^{14}C-pyrimidine]-label (n= 1)
Non-extractable residues after 100 days ‡	*35.2* % AR after *112* d, [^{14}C-pyridine]-label (n= *1*) *45.9* % AR after *112* d, [^{14}C-pyrimidine]-label (n= *1*)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	[^{14}C-pyidine] & [^{14}C-pyrimidine] labels HMUD: 4.2-14.4% AR (max day 28 of 112) (n= *2*) [^{14}C-pyridine] label AUSN: 1.5-19.5% AR at 112 d (n= 1) UCSN: 6.5-8.5% AR (max day 85 of 112) n=1 ASDM: 6.6-21.5% AR (max day 85 of 112) n=1 [^{14}C-pyrimidine] label ADMP: 1.9-7.2 % AR (max day 31 of 112) n=1

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

Anaerobic degradation ‡

Mineralization after 100 days	Two studies conducted using radio labeled nicosulfuron, day 0-25 aerobic conditions, day 25-90 anaerobic conditions. *0.1-0.4*% AR, 0-25 d; 0.4-0.5% AR 32-90 d [^{14}C-Pyridine]-label (n= *1*) *5.8-9.6% AR, 0-25* d; 0.4-0.5% AR 32-90 d, [^{14}C-Pyrimidine]-label (n= *1*)
Non-extractable residues after 100 days	*Study duration 90 d* *23.7-15.3* % after *41-90* d, [^{14}C-Pyridine]-label (n= *1*) *16.9* % after *90* d, [^{14}C-Pyrimidine]-label (n= *1*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	HMUD - 8.8-17.2 % AR (max day 41) n=2, (7.2% in soil, 10% in water) [^{14}C-pyridine] & [^{14}C-pyrimidine] labels AUSN - 10.9-19 % AR (max day 70) n=1 UCSN - 1.4-6.1 % AR (max day 90) n=1 ASDM - 1.4-3.3 %AR (max day 70) n=1 [^{14}C-pyridine] label ADMP - *1.0-4.8 %AR (max day 70) n=1* [^{14}C-pyrimidine] label

[26] n corresponds to the number of soils.

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

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	ASDM - 6.2-22.9 % 0-30 d (n= 1) [^{14}C-pyridine] label

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	Label	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Le Noron, loam	pyridine	5.3	20°C, 46.3% MWHC	20.0 / 66.4*	13.3	0.986	1st order non-linear
Le Noron, loam	pyrimi-dine	5.3	20°C, 46.3% MWHC	26.3 / 87.4*	17.4	0.901	1st order non-linear
Mean					**15.3**		
Les Evouettes, silt loam	pyridine	6.1	20 °C, 54.6% MWHC	40.5 / 134.4*	33.2	0.981	1st order non-linear
Les Evouettes, silt loam	pyrimi-dine	6.1	20 °C, 54.6% MWHC	33.1 / 110.1*	27.1	0.993	1st order non-linear
Mean					**30.1**		
Speyer 2.1, sand	pyridine	6.0	20°C, 21.1% MWHC	35.1 / 116.6*	30.6	0.989	1st order non-linear
Speyer 2.1, sand	pyrimi-dine	6.0	20°C, 21.1% MWHC	46.3 / 154.0*	40.4	0.974	1st order non-linear
Mean					**35.5**		
Speyer 2.3, sandy loam	pyridine	6.6	20°C, 31.4% MWHC	26.7 / 88.8*	20.3	0.985	1st order non-linear
Speyer 2.3, sandy loam	pyrimi-dine	6.6	20°C, 31.4% MWHC	23.2 / 77.2*	17.7	0.992	1st order non-linear
Mean					**19.0**		
Pappelacker, loamy sand	pyrimi-dine	7.0	20°C, 40% MWHC	7.0 / 23.4**	**5.7**	0.960	SFO
Karolinenhof, sand	pyrimi-dine	7.2	20°C, 40% MWHC	13.2 / 43.9**	**12.6**	0.992	SFO
Otzberg, silt loam	pyrimi-dine	7.2	20°C, 40% MWHC	18.9 / 62.8**	**14.3**	0.991	SFO
Geometric mean/median					**16.4**		

Values in bold used to calculate geometric mean DT_{50}
* values from DAR (UK, 2005)

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

** values form report A39791 (Mamouni, 2006).

HMUD	Aerobic conditions							
Soil type	Label	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Les Evouettes, silt loam	Pyridine	6.1	20 °C, 54.6% MWHC	30.8 / 102.2	0.00752	25.2	0.983	ModelMaker based on SFO formation and decline from parent
Les Evouettes, silt loam	Pyrimi-dine	6.1	20 °C, 54.6% MWHC	27.4 / 90.0	0.00786	22.4	0.930	ModelMaker based on SFO formation and decline from parent
Mean						23.8		
The DT_{50} for HMUD are 2 values from 2 parent labels for 1 soil. Whereas for the other metabolites more than 1 soil was tested. The notifer calculated these using first-order kinetics in Modelmaker based on formation of HMUD and its subsequent degradation (HMUD formation fraction used was 0.00752 and 0.00786 respectively).								

ADMP	Aerobic conditions							
Soil type	X[27]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	2.9 / 9.5		2.4	0.995	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	6.1 / 20.4		5.4	0.980	1st order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	11.3 / 37.7		7.3	0.970	1st order non-linear
Geometric mean						4.5		

ASDM	Aerobic conditions							
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. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	90.5 / 300.8		73.6	0.995	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	268.5 / 892.1		236.6	0.933	1st order non-linear

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

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

ASDM	Aerobic conditions							
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. (r^2)	Method of calculation
Les Evouettes, loam		7.3	20°C, 40% MWHC	114.8 / 381.4		73.8	0.992	1st order non-linear
Worst-case						236.6		

AUSN	Aerobic conditions							
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. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	73.8/245.1		60.0	0.894	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	218.2/724.8		192.3	0.907	1st order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	101.4/336.9		65.2	0.856	1st order non-linear
Worst-case						192.3		

UCSN	Aerobic conditions							
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. (r^2)	Method of calculation
Collombey, loamy sand		7.6	20°C, 40% MWHC	126.2/419.3		102.6	0.993	1st order non-linear
Speyer 2.2, loamy sand		6.0	20°C, 40% MWHC	307.5/1021.7		271.0.	0.962	1st order non-linear
Les Evouettes, loam		7.3	20°C, 40% MWHC	229.3/761.7		147.5	0.942	1st order non-linear
Worst-case						271.0		

MU-466	Aerobic conditions							
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. (r^2)	Method of calculation
Uffholtz		5.74	20°C, 40% MWHC	89.5 / 297		66.3	0.943	1st order non-linear
Speyer 2.1		6.2	20°C, 40% MWHC	84 / 279		75.5	0.975	1st order non-linear

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

MU-466	Aerobic conditions							
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. (r^2)	Method of calculation
3A		7.1	20°C, 40% MWHC	67.9 / 225.5		59.1	1.000	1st order non-linear
Worst-case						75.5		

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	% OC	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of calculation
Sand (bare soil)	Flackenhorst, Germany	0.8	5.7	0-10	20.7	68.8	0.869	N/A	1st order non-linear
Silty clay loam (bare soil)	Hünfelden, Germany	0.8	7.1	0-10	63.3	210	0.919	N/A	1st order non-linear
Loam (bare soil)	St. Claire, N. France	1.5	5.3	0-5	12	40	0.949	N/A	1st order non-linear
Clay loam, (bare soil)	Lanta, S. France	0.88	6.0	0-5	8.9	29.7	0.964	N/A	1st order non-linear
Geometric mean/median					19.3/16.4				
Cropped soil (maize): Niederhofen and Schifferstadt (Germany), <0.01 mg/kg after 27/28 days, Emilia Romagna (Italy) calculation of DT_{50} not possible; Lombardia and Veneto, (Italy), DT_{50s} uncertain due to non-validated LOQ.									

pH dependence ‡ (yes / no) (if yes type of dependence)	No (based on current data from 7 soils, pH range 5.3-7.2)
Soil accumulation and plateau concentration ‡	No studies provided or required.

Laboratory studies ‡

Parent	Anaerobic conditions
Due to limited degradation observed under anaerobic conditions it was not possible to derive a DT_{50}/DT_{90} for this phase of the study. (Aerobic phase: 21.8, 24.4; r^2 0.909-0.998; n=2)	

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

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent Nicosulfuron (pyrimidine label) ‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.1, (loamy) sand	7.2	0.48	6.0	-	-	0.05	10.0	0.90
Speyer 2.2, loamy sand	8.8	2.55	6.0	-	-	0.20	7.9	0.92
Itingen II, silt loam	23.4	1.42	7.7	-	-	0.73	51.3	0.94
Les Evouettes, loam	11.3	1.40	6.1	-	-	0.19	13.7	1.01
Arithmetic mean/median						0.29	20.7	0.93
pH dependence, Yes or No			No. Clay dependence: Yes, see PECgw section for further details.					

Metabolite ADMP (pyrimidine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	1.17	50.9	0.84
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.71	60.4	0.82
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.83	52.8	0.92
Vetroz, silt loam	19.4	4.05	7.3	-	-	1.70	42.0	0.91
Arithmetic mean/median						1.10	51.5	0.87
pH dependence, Yes or No			No.					

Metabolite ASDM (pyridine label)‡‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	0.05	2.3	0.82
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.08	6.7	0.81
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.12	7.7	1.07
Vetroz, silt loam	19.4	4.05	7.3	-	-	0.24	6.0	0.94
Arithmetic mean/median						0.12	5.7	0.91
pH dependence, Yes or No			Could not be clearly established					

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

Metabolite AUSN (pyridine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	-	-	0.30	13.0	0.98
Collombey, loamy sand	6.7	1.17	7.7	-	-	0.42	35.6	0.92
Sisseln, sandy loam	15.9	1.557	7.8	-	-	0.61	39.0	0.98
Vetroz, silt loam	19.4	4.05	7.3	-	-	0.90	22.3	0.96
Arithmetic mean/median						0.56	27.5	0.96
pH dependence, Yes or No			Could not be clearly established					

Metabolite UCSN (pyridine label)‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, loamy sand	5.1	2.29	7.0	0.02	1.1	-	-	-
Collombey, loamy sand	6.7	1.17	7.7	0.07	5.6	-	-	-
Sisseln, sandy loam	15.9	1.557	7.8	0.06	3.5	-	-	-
Vetroz, silt loam	19.4	4.05	7.3	0.09	2.1	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			No.					

Metabolite HMUD (non-radiolabelled) ‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, sandy loam	8.1	2.3	5.6^{Ca}	0.12	5.07	-	-	-
Mechtildshausen, loam	17.57	1.28	7.37^{Ca}	0.14	10.75	-	-	-
Uffholtz, silt clay loam	34.04	2.67	5.42^{Ca}	0.02	0.88	-	-	-
Sawtry, clay	49.19	2.94	7.23^{Ca}	0.19	6.98	-	-	-
Bretagne 1, Silt loam	17.40	2.11	5.7^{Ca}	0.08	2.83	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			No.					

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

Metabolite MU-466 (non-radiolabelled) ‡								
Soil Type	Clay %	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Speyer 2.2, sandy loam	8.1	2.3	5.6[Ca]	0.07	3.05	-	-	-
Mechtildshausen, loam	17.57	1.28	7.37[Ca]	0.14	10.73	-	-	-
Uffholtz, silt clay loam	34.04	2.67	5.42[Ca]	0.04	1.32	-	-	-
Sawtry, clay	49.19	2.94	7.23[Ca]	0.43	16.08	-	-	-
Bretagne 1, Silt loam	17.40	2.11	5.7[Ca]	0.17	6.50	-	-	-
Arithmetic mean/median						-	-	-
pH dependence, Yes or No			Could not be clearly established					

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

Column leaching ‡	Eluation (mm): 508 mm Time period (d): 4 d
	Leachate: 62.9 – 92.2 % total residues/radioactivity in leachate 41.2-58.6 % active substance, < 0.5 % ADMP, ≤ 1 % DMPU 1.4-5.7 % total residues/radioactivity retained in top 6 cm
Aged residues leaching ‡	Aged for (d): 28 d Time period (d): 8 d Eluation (mm): 480 mm
	Analysis of soil residues post ageing (soil residues pre-leaching): 43.2 % active substance, 9.0 % HMUD, 3.2 % DMPU, 2.4% ADMP
	Leachate: 54.8 % total residues/radioactivity in leachate 49.6 % nicosulfuron, 5.2 % others 28.5 % AR retained in soil column (8.8 % identified as nicosulfuron) 3.5% AR as nicosulfuron in the top 0 - 16.5 cm, and 5.3% AR in the bottom 16.5 - 34.5 cm of column
Lysimeter/ field leaching studies ‡	3 Lysimeter studies, each with two lysimeters, 1 in Germany (Schmallenberg) and 2 in Switzerland (Itingen), each run for: (i) 2 years, (ii) 3 years, (iii) 3 years. Maize was sown in the first two years and then wheat in the final year (ii & iii) Application rates of: (i) pyridine labelled nicosulfuron: year 1 only – 1 x 40 g a.s./ha; (ii) pyridine labelled

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

	nicosulfuron: 1st lysimeter 1 x 60 g a.s/ha/ in year 1 only, 2nd lysimeter 1 x 60 g a.s/ha/ in year 1&2 only (iii) pyrimidine labelled nicosulfuron: 1st lysimeter 1 x 60 g a.s/ha/ in year 1 only, 2nd lysimeter 1 x 60 g a.s/ha/ in year 1&2 only. Average annual rainfall: (i) 600, 1039 mm; (ii & iii) 832, 1136, 1118 mm Average annual leachate volume: (i) 401 -456 and 675-700 L; (ii) 334-335, 515-529, 522-538 L, (iii) 303-346, 485-543, 434-546 L. Annual average concentrations (µg/L) (i) nicosulfuron 0.03-0.07; ASDM 0.18-0.99; AUSN 0.24-0.59; UCSN 0.03-0.22; MU-466 0.02-0.04. (ii) (2nd lysimeter with 2 applications) nicosulfuron 0.03-0.13, ASDM 0.34-2.70, AUSN 0.68-1.62, UCSN 0.06-0.94, MU-466 0.07-0.14. (iii) (2nd lysimeter with 2 applications) nicosulfuron 0.01-0.17, HMUD 0.01-0.03.

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	
Method of calculation	DT_{50} (d): 63 days longest value from field study Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Single application of 60 g a.s/ha to maize, 25% interception

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.060		-	
Short term 24h	0.059	0.060	-	-
2d	0.059	0.059	-	-
4d	0.057	0.059	-	-

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

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term	7d	0.056	0.058	-	-
	28d	0.044	0.052	-	-
	50d	0.035	0.046	-	-
	100d	0.020	0.036	-	-
Plateau concentration		Not calculated			

Metabolite ADMP Method of calculation	DT_{50} (d): 11.3 days longest value from laboratory study. Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Maximum percentage formation (9.8 %) compared to day 0 nicosulfuron (Lanta, France): 0.0102 mg/kg

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.006		-	
Short term	24h	0.006	0.006	-	-
	2d	0.005	0.006	-	-
	4d	0.005	0.005	-	-
Long term	7d	0.004	0.005	-	-
	28d	0.001	0.003	-	-
	50d	0.000	0.002	-	-
	100d	0.000	0.001	-	-
Plateau concentration		Not calculated			

Metabolite ASDM Method of calculation	DT_{50} (d): 268.5 days longest value from laboratory study. Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Maximum percentage formation (63.4 %) compared to day 0 nicosulfuron (St. Claire): 0.0230 mg/kg

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

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.038		-	
Short term	24h	0.038	0.038	-	-
	2d	0.038	0.038	-	-
	4d	0.038	0.038	-	-
Long term	7d	0.037	0.038	-	-
	28d	0.035	0.037	-	-
	50d	0.033	0.036	-	-
	100d	0.029	0.034	-	-
Plateau concentration		Not calculated			

Metabolite AUSN	
Method of calculation	DT_{50} (d): 218.2 days longest value from laboratory study. Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Maximum percentage formation (26.8 %) compared to day 0 nicosulfuron in laboratory studies and compared with its molecular weight.

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.012		-	
Short term	24h	0.012	0.012	-	-
	2d	0.012	0.012	-	-
	4d	0.012	0.012	-	-
Long term	7d	0.012	0.012	-	-
	28d	0.011	0.012	-	-
	50d	0.011	0.011	-	-
	100d	0.009	0.011	-	-
Plateau concentration		Not calculated			

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

Metabolite UCSN Method of calculation	DT_{50} (d): 307.5 days longest value from laboratory study. Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Maximum percentage formation (11 %) compared to day 0 nicosulfuron in laboratory studies and compared with its molecular weight.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.005		-	
Short term 24h	0.005	0.005	-	-
2d	0.005	0.005	-	-
4d	0.005	0.005	-	-
Long term 7d	0.005	0.005	-	-
28d	0.005	0.005	-	-
50d	0.005	0.005	-	-
100d	0.004	0.005	-	-
Plateau concentration	Not calculated			

Metabolite HMUD Method of calculation	DT_{50} (d): 30.8 days longest value from laboratory study. Kinetics: First order. Soil bulk density: 1.5 g/cm³, equal distribution in top 5 cm.
Application data	Maximum percentage formation (14.4 %) compared to day 0 nicosulfuron in laboratory studies and consideration for formation as well as degradation.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.008		-	
Short term 24h	0.008	0.008	-	-
2d	0.008	0.008	-	-
4d	0.008	0.008	-	-

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

PEC(s) (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Long term	7d	0.007	0.008	-	-
	28d	0.006	0.007	-	-
	50d	0.005	0.007	-	-
	100d	0.004	0.006	-	-
Plateau concentration		Not calculated			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: pH 5 at 25°C : Pyridine label DT_{50}15 days, Pyrimidine radio label DT_{50} 16 days. Metabolites formed: ASDM (max 52.8 % at day 32), ADMP (max 65.4 % at day 32), DUDN (max 13.9 % at day 32).
	pH 7: pH 7 at 25°C : DT50 not calculated as hydrolysis slow <15 % at end of study (day 32).
	pH 9: pH 7 at 25°C : DT50 not calculated as hydrolysis slow <15 % at end of study (day 32).
Photolytic degradation of active substance and metabolites above 10 % ‡	Xenon arc lamp, equivalent to summer sunlight at latitude 50°N. 12 hour light/dark cycle, study length 30 days. Two studies using the pyridine label and pyrimidine label. DT_{50} pH Light Dark 5 10-13 15-18 7 51-105 282-368 9 59-77 178-243 Metabolite formation <10 % at pH 7 and 9. At pH 5 ASDM (max 61% at day 30), DUDN (max 22.3% at day 21), ADMP (max 23.1 % at day 8). Estimated DT_{50} at 50°N in winter: 24.3 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	1.99×10^{-3} mol · Einstein $^{-1}$

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

Readily biodegradable ‡ (yes/no)	No
Degradation in water/sediment (pyridine label)	
Degradation - DT_{50} water ‡	63.9-66.2 days, geomean 65.0 days
Degradation - DT_{90} water ‡	212.4-219.9 (calculated with Modelmaker, r^2=0.90-0.97)
Degradation - DT_{50} sediment	8.8-21.9 days, geomean 13.9 days
Degradation - DT_{90} sediment	29.3-72.7 days (calculated with Modelmaker)
Dissipation - DT_{50} water ‡	24.9-32.0 days
Dissipation - DT_{90} water ‡	82.9-106.2 days (1^{st} order non-linear, r^2= 0.922-993, n=2)]
- DT_{50} whole system ‡	33.2-49.8 days
- DT_{90} whole system ‡	110.2-165.4 days (1^{st} order non-linear, r^2= 0.978-994, n=2)
Mineralization	1.1-1.4 % AR at end of study (day 177, n=2)
Non-extractable residues	42.2-57.6 %AR at end of study (day 177, n=2)
Distribution in water / sediment systems (active substance) ‡	Maximum of 24% AR in sediment after 14 days DT_{50} 8.8-21.9 days (calculated with Modelmaker r^2=0.90-0.97)

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

Distribution in water / sediment systems (metabolites) ‡	Water: Maximum formation: HMUD: 14.1 %AR at day 62, AUSN: 9.1 %AR at day 177 (study end), UCSN 5.4 %AR at day 177, ASDM 6.9 %AR day at 177. Sediment: Maximum formation: HMUD: 5.7 %AR at day 30, AUSN: 2.4 %AR at day 105, UCSN 1.4 %AR at day 105, ASDM: 4.4 %AR day at 62.

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: Molecular weight (g/mol):410.4 Water solubility (g/L):9.5 (pH 6.7) at 19.7°C K_{OC} (L/kg): 20.7 DT_{50} soil (d): 16.4 days (In accordance with FOCUS SFO) Geometric mean of laboratory DT_{50} normalised to 20°C and pF2. DT_{50} water/sediment system (d): 42.3 (representative worst case from sediment water studies) DT_{50} water (d): 65.0 DT_{50} sediment (d): 13.9
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: Vapour pressure: <8E-10 at 25°C K_{OC}: 20.7 1/n: 0.94 (Freundlich exponent general or for soil, susp. solids or sediment respectively)
Application rate	Crop: Maize Number of applications: 1 Application rate(s): 60 g as/ha
	Runoff gives the highest PECsw values. Worst case scenario R4 stream.

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

PEC (surface water)

Step 3 maximum PECsw for nicosulfuron

FOCUS STEP 3 Scenario	D3 ditch	D4 pond	D4 stream	D5 pond	D5 stream	D6 ditch
Max PECsw day 0	0.317	0.027	0.277	0.022	0.272	0.317
PECsw day 7	0.003	0.025	0.005	0.020	0.003	0.005
TWA day 1	0.252	0.027	0.033	0.022	0.016	0.185
TWA day 7	0.050	0.026	0.018	0.021	0.010	0.033
Date of application	14 May	30 May	30 May	27 May	27 May	23 Apr
Date of max PEC	14 May	30 May	30 May	27 May	27 May	23 Apr

FOCUS STEP 3 Scenario	R1 pond	R1 stream	R2 stream	R3 stream	R4 stream
Max PECsw day 0	0.023	0.766	1.852	2.329	**2.891**
PECsw day 7	0.021	>0.001	>0.001	>0.001	>0.001
TWA day 1	0.023	0.215	1.119	1.302	2.177
TWA day 7	0.022	0.048	0.164	0.214	0.318
Date of application	10 May	10 May	08 May	18 May	14 Apr
Date of max PEC	20 May	14 May	13 May	23 May	18 Apr

Highest concentration in bold

Step 4 PECsw - R4 stream including a 5 m no spray buffer zone (nicosulfuron)

FOCUS STEP 4 Scenario	Day after overall maximum	PEC_{SW} (µg/L)	
		Actual	TWA
R4 stream	0 h	2.891	
	24 h	0.016	2.177
	2 d	0.001	1.091
	4 d	0.000	0.546
	7 d	0.000	0.314
	14 d	0.000	0.170
	21 d	0.006	0.113
	28 d	0.000	0.085
	42 d	0.000	0.057

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

Summary of values for metabolites used in PECsw modelling

Compound	DT_{50} soil (days)	Peak occurrence in soil	Molecular weight	Koc	1/n	DT_{50} water (days)	DT_{50} sediment (days)	DT_{50} whole system (days)
HMUD	25.2	14.4	396.4	0.88	0.90*	300*	300*	300*
AUSN	192.3	26.8	314.3	13.0	0.96	300*	300*	300*
UCSN	271.0	11.0	315.3	1.1	0.90*	300*	300*	300*
ASDM	236.6	63.4**	**	2.3	0.91	300*	300*	300*

* FOCUS default value. No information on the degradation times for the metabolites in water or sediment are available, therefore the FOCUS default value was used (The RMS notes in line with FOCUS guidance, 1000 days is the appropriate default for sediment and water DT_{50} values; but considers that this would have little effect on the resulting PEC values in this case and so considers 300 days to be acceptable).
The Koc and 1/n are the arithmetic mean values. Since some of the metabolites show pH dependency, a worst case approach was used for all metabolites (i.e. worst-case DT_{50} normalised to 20°C and pF2, see Table 8.7) and the lowest Koc values.
** Since the highest conc. was found in a field dissipation study, the molecular weight ratio does not need to be considered (the same value as for nicosulfuron was input into the model).

Metabolite: HMUD

Method of calculation	Maximum concentrations calculated only. Using FOCUS Step 2.
Application rate	Crop: Maize Number of applications: 1 Application rate(s): 60 g as/ha, assumes a formation of 19.3 % in water. Default degradation values used in water and sediment (300 day). Depth of water body 30 cm.
Main routes of entry	Drift at 1 meter: 2.76 %
PECsw (maximum)	1.049 µg/l

Metabolite: AUSN

Method of calculation	Maximum concentrations calculated only. Using FOCUS Step 2.
Application rate	Crop: Maize Number of applications: 1 Application rate(s): 60 g as/ha, assumes a formation of 11.1 % in water. Default degradation values used in water and sediment (300 day). Depth of water body 30 cm.
Main routes of entry	Drift at 1 meter: 2.76 %
PECsw (maximum)	1.239 µg/l

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

Metabolite: UCSN

Method of calculation	Maximum concentrations calculated only. Using FOCUS Step 2.
Application rate	Crop: Maize Number of applications: 1 Application rate(s): 60 g as/ha, assumes a formation of 6.5 % in water. Default degradation values used in water and sediment (300 day). Depth of water body 30 cm.
Main routes of entry	Drift at 1 meter: 2.76 %
PECsw (maximum)	0.529 µg/l

Metabolite: ASDM

Method of calculation	Maximum concentrations calculated only. Using FOCUS Step 2.
Application rate	Crop: Maize Number of applications: 1 Application rate(s): 60 g as/ha, assumes a formation of 9.4 % in water. Default degradation values used in water and sediment (300 day). Depth of water body 30 cm.
Main routes of entry	Drift at 1 metre: 2.76 %
PECsw (maximum)	2.843 µg/l

PEC (sediment)

Parent

FOCUS STEP 4 Scenario	Day after overall maximum	PEC_{sed} (µg/kg)	
		Actual	TWA
R4 stream	Initial	0.343	0.268 (day 1)
	Short term	0.053 (day 7)	0.117 (day 7)
	Long term	0.005 (day 50)	0.035 (day 50)

Metabolites

Method of calculation	Maximum concentrations calculated only. Using FOCUS Step 2.
Application rate	Same values used for PEDsed as for PECsw.

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

PEC$_{(sed)}$ (µg / kg)	**HMUD** Single application Maximum PECsed	**AUSN** Single application Maximum PECsed	**UCSN** Single application Maximum PECsed	**ASDM** Single application Maximum PECsed
Initial	0.0555 µg/l	0.161 µg/l	0.006 µg/l	0.065 µg/l
Short term	-	-	-	-
Long term	-	-	-	-

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.2 Scenarios (list of names): Chateaudun, Hamburg, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: Maize Clay dependence issues with the parent and pH dependence issues with some metabolites resulted in use of scenario specific adsorption values. Geometric mean parent $DT_{50lab/field}$ 16.4 d (normalisation to pF2, 20 °C with Q10 of 2.2). Revised ground water modelling was included in an addendum. Input values used for FOCUSgw modelling based on the Kf-soil clay content correlation for the parent and scenario specific adsorption values for the metabolites are detailed in the Table below*. No volatilisation assumed. Standard FOCUS scenario 26 year run KOC: parent, arithmetic mean or median: see table below. Metabolites: input data required for each metabolite is detailed in the Table below**.
Application rate	Application rate: 60 g/ha. No. of applications: 1 Time of application (month or season): Spring

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

*Adsorption data for nicosulfuron used in the FOCUS modelling					
Scenario	Horizon	Depth (cm)	Clay content* (%)	Calculated KF CLAY+ (ml/g)	Degradation transformation factor
Châteaudun	1	0-25	30	0.78	1.0
	2	25-50	31	0.81	0.5
	3	50-60	25	0.65	0.5
	4	60-100	26	0.68	0.3
	5	100-120	26	0.68	0.0
	6	120-190	24	0.62	0.0
	7	190-260	31	0.81	0.0
Hamburg	1	0-30	7.2	0.19	1.0
	2	30-60	6.7	0.17	0.5
	3	60-75	0.9	0.02	0.3
	4	75-90	0	0.00	0.3
	5	90-100	0	0.00	0.3
	6	100-200	0	0.00	0.0
Kremsmünster	1	0-30	14	0.36	1.0
	2	30-50	25	0.65	0.5
	3	50-60	27	0.70	0.5
	4	60-100	27	0.70	0.3
	5	100-200	27	0.70	0.0
Okehampton	1	0-25	18	0.47	1.0
	2	25-55	17	0.44	0.5
	3	55-85	14	0.36	0.3
	4	85-100	9	0.23	0.3
	5	100-150	9	0.23	0.0
Piacenza	1	0-30	15	0.39	1.0
	2	30-40	15	0.39	0.5
	3	40-60	7	0.18	0.5
	4	60-80	7	0.18	0.3
	5	80-100	0	0.00	0.3
	6	100-170	0	0.00	0.0

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

*Adsorption data for nicosulfuron used in the FOCUS modelling					
Scenario	Horizon	Depth (cm)	Clay content* (%)	Calculated KF CLAY+ (ml/g)	Degradation transformation factor
Porto	1	0-35	10	0.26	1.0
	2	35-60	8	0.21	0.5
	3	60-100	8	0.21	0.3
	4	100-120	8	0.21	0.0
Sevilla	1	0-10	14	0.36	1.0
	2	10-30	13	0.34	1.0
	3	30-60	15	0.39	0.5
	4	60-100	16	042	0.3
	5	100-120	16	0.42	0.0
	6	120-180	22	0.57	0.0

*fraction < 2 µm
+calculated using the equation $K_{F\ CLAY} = 0.026 \times \%clay$

Scenario specific adsorption values for PECgw modelling for metabolites							
Compound	DT_{50} (days)	pH ≤ 6 Hamburg, Okehampton, Porto		6< pH <7 Piacenza, Sevilla		pH ≥ 7 Chateaudun, Kremsmünster, Thiva	
		Koc	1/n	Koc	1/n	Koc	1/n
HMUD	23.8[a]	5.3	0.9*	5.3	0.9*	5.3	0.9*
AUSN	192.3[b]	13	0.98	P=13 S=22.3	P=0.98 S=0.96	37.3	0.95
ADMP	4.5 [a]	51.5	0.87	51.5	0.87	51.5	0.87
UCSN	271.0[b]	3.1	0.9*	3.1	0.9*	3.1	0.9*
ASDM	236.6[b]	2.3	0.82	P=2.3 S=6.0	P=0.82 S=0.94	7.2	0.94
MU-466	75.5[b]	3.62	0.9*	7.5	0.9*	13.41	0.9*

* FOCUS default value
Koc (lab) values for HMUD and UCSN are pH independent and arithmetic mean values are selected. ASDM and AUSN have pH dependant adsorption and tests were conducted at the same pH as the topsoil in these two scenarios: P= Piacenza, S= Sevilla. Although pH dependency on adsorption can not be clearly established, the introduction of the scenario specific adsorption values for AUSN, ASDM and MU-466 in FOCUSgw modelling will not affect the results.
[a] Geometric mean DT_{50} values, normalised to 20°C and pF2 (lab).
[b] Worst case DT_{50} values, normalised to 20°C and pF2 (lab).
Formation fractions, HMUD, 0.442; ADMP, 0.214; ASDM, 0.214 from parent;
AUSN, 0.687 from HMUD; UCSN, 0.313 from HMUD; MU-466, 0.282 from ASDM.

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

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

Revised PECgw model using clay dependant sorption values								
Scenario	pH [KCl]	Calculated PEC_{gw} [µg/l]						
		Parent	HMUD	AUSN	ADMP	UCSN	ASDM	MU-466
Chateaudun	7.3	<0.001	**0.148**	**1.193**	<0.001	**0.959**	**0.942**	0.053
Hamburg	5.7	**0.132**	**0.650**	**2.063**	0.002	**1.030**	**1.164**	0.055
Kremsmunster	7.0	<0.001	**0.435**	**1.590**	<0.001	**1.195**	**1.239**	0.064
Okehampton	5.1	0.002	**0.547**	**1.762**	<0.001	**0.878**	**1.011**	0.049
Piacenza	6.3	0.027	**0.326**	**1.149**	<0.001	**0.550**	**0.624**	0.030
Porto	4.2	0.004	0.063	**1.124**	<0.001	**0.792**	**0.737**	0.055
Sevilla	6.6	<0.001	<0.001	0.059*	<0.001	**0.137**	0.097	0.008
Thiva	7.0	<0.001	0.003	**0.524**	<0.001	**0.473**	**0.446**	0.033

Scenario failures (values >0.1 µg/l) highlighted in bold text
*this value is an order of magnitude different to the DAR calculations, all other scenarios showed less difference between the RMS and Notifier calculations. The RMS was unable to check the value as no output files were included. As this is not the highest PEC value the RMS considers it to be acceptable.

$PEC_{(gw)}$ From lysimeter / field studies

Parent /metabolite	1st year	2nd year	3rd year
No data, no data required			

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	No data submitted – nor required.
Photochemical oxidative degradation in air ‡	The notifier provided the following information: Atkinson (1988) method used, assuming a rate constant of 1.5 x 10^6 OH radicals/cm³ photochemical produced during a 12 hour-photo phase day with temperature and solar light intensity typically found at sea level gave an atmospheric DT_{50} of 0.587 hours
Volatilisation ‡	From plant surfaces: ‡ 8.3 % over 24 hours
	from soil: ‡ 6.2 % over 24 hours
Metabolites	None

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

PEC (air)

Method of calculation	Expert judgment, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

$PEC_{(a)}$

Maximum concentration	Not calculated but results indicate that it is unlikely to be significant.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: nicosulfuron, HMUD, AUSN, UCSN, ASDM, ADMP Surface Water: nicosulfuron, HMUD, AUSN, UCSN, ASDM, ADMP (all metabolites except HMUD only via soil) Sediment: nicosulfuron Ground water: nicosulfuron, HMUD, AUSN, UCSN, ASDM, ADMP, MU-466 Air: nicosulfuron Residue definitions relevant for monitoring: Taking into account the consideration of occurrence and toxicological /ecotoxicological relevance the environmental definitions for monitoring can be set as **parent nicosulfuron only** for the environmental compartments above.

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

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

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

Candidate for R53

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

Appendix 1.6: Effects on non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail (*Colinus virginianus*)	Technical nicosulfuron	Acute	LD_{50} >2000 NOEL 2000	-
Mallard duck (*Anas platyrhynchos*)	Technical nicosulfuron	Acute	LD_{50} >2000 NOEL 2000	-
Bobwhite quail (*Colinus virginianus*)	'SL-950 4% SC'	Acute	LD_{50} >2000 NOEL 2000	-
Mallard duck (*Anas platyrhynchos*)	'SL-950 4% SC'	Acute	LD_{50} >2000 NOEL 2000	-
Bobwhite quail (*Colinus virginianus*)	Technical nicosulfuron	Short-term (5 day)	LD_{50} >1603 NOEL 1603	LD50 >5000 NOEL 5000
Mallard duck (*Anas platyrhynchos*)	Technical nicosulfuron	Short-term (5 day)	LD_{50} >911 NOEL 911	LD50 >5000 NOEL 5000
Japanese quail (*Coturnix japonica*)	Technical nicosulfuron	Long-term	NOEC 171	NOEC 1000
Mammals ‡				
Rat	Technical nicosulfuron	Acute	LD_{50} >5000	-
Mouse	Technical nicosulfuron	Acute	LD_{50} >5000	-
Rat	ASDM (metabolite)	Acute	LD_{50} >5000	-
Rat	AUSN (metabolite)	Acute	LD_{50} >2000	-
Rat	Technical nicosulfuron	Long-term	NOAEL = 3861 (male)# & 4404 (female)#	-
Additional higher tier studies ‡				
None				

Based on highest treatment dose – no significant adverse effects in study.

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

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

Maize (N. & S. Europe) - one application at 60 g a.s. /ha.

Indicator species	Water uptake [L/day]	ETE [mg/kg bw/d]	Acute TER	Short-term TER (birds only)	Long-term TER
Maximum Step 1 PEC_{sw} 0.02 mg a.s. /L[1]; spray puddle PEC 60mg a.s./l #					
Small insectivorous bird (10 g)	0.002697	0.005394 (surface water) 16.18 (spray puddles)	>370782 >124	>297182 >99	31702 11##
Medium herbivorous bird (300 g)	0.026334	0.00176 (surface water) 5.27 (spray puddles)	>1136782 >380	>910795 >304	97159 32##
Medium herbivorous mammal (3000g)	0.266100	0.00174 (surface water) 5.32 (spray puddles)	>2873563 >376	Not applicable Not applicable	98276 726##

[1] PEC in surface water based on FOCUS surface water scenario step 1
Includes leaf axil water and assumes 5 fold dilution of spray by rainfall as per SANCO/4145 (2002) guidance
Given the likely evaporation of any puddles within a few hours or at most days of formation, long-term exposure from contaminated puddles is considered unlikely.

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

Maize (N. & S. Europe) - one application at 60 g a.s. /ha.

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivore	Acute	3.97	>504	10
Small insectivore	Acute	3.24	>617	10
Medium herbivore	Short-term	1.82	>501	10
Small insectivore	Short-term	1.81	>503	10
Medium herbivore	Long-term	0.97	175	5
Small insectivore	Long-term	1.81	94	5
Higher tier refinement (Birds)				
No data, not required				

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Mammals)				
Medium herbivore	Acute	1.46	3425	10
Medium herbivore	Long-term	0.36	10725	5
Higher tier refinement (Mammals)				
No data, not required				

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
Oncorhyncus mykiss	a.s.	Acute	96h LC50	65.7 mg a.s./L
Oncorhyncus mykiss	a.s.	Chronic (28 day juvenile growth)	28 day NOEC	**10** mg a.s./L
Oncorhyncus mykiss	Formulation[1]	Acute	96h LC50	55.6-100 mg formulation /L (≡ **2.2**-4.0 mg a.s./L)#
Lepomis macrochirus	ASDM[###] (metabolite)	Acute	96h LC50	>100 mg met./L
Brachydanio rerio (zebra fish)	AUSN (metabolite)	Acute	96h LC50	> 100 mg met./L
Oncorhyncus mykiss	MU-466 (metabolite)	Acute	96h LC50	> 100 mg met./L
Oncorhyncus mykiss	HMUD (metabolite)	Acute	96h LC50	> 100 mg met./L
Oncorhyncus mykiss	ADMP (metabolite)	Acute	96h LC50	> 100 mg met./L
Aquatic invertebrate				
Daphnia magna	a.s.	Acute	48h EC50	90 mg a.s./L
Daphnia magna	a.s.	Chronic (21 day repro. toxicity)	21 day NOEC	**5.2** mg a.s./L
Daphnia magna	Formulation[1]	Acute	48h EC50	82.3 mg formulation /L (≡ **3.3** mg a.s./L)
Daphnia magna	ASDM[###] (metabolite)	Acute	48h EC50	>954 mg met./L

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Daphnia magna	AUSN (metabolite)	Acute	48h EC50	> 100 mg met./L
Daphnia magna	MU-466 (metabolite)	Acute	48h EC50	> 100 mg met./L
Daphnia magna	HMUD (metabolite)	Acute	48h EC50	> 100 mg met./L
Daphnia magna	UCSN (metabolite)	Acute	48h EC50	> 100 mg met./L
Daphnia magna	ADMP (metabolite)	Acute	48h EC50	> 100 mg met./L
Sediment dwelling organisms: No data				
Algae				
Anabaena flos-aquae	a.s.	Acute	72h EbC50	7.8 mg a.s./L
Scenedesmus subspicatus	Formulation[1]	Acute	72h ErC50 & EbC50	>100 mg formulation /L (≡ **>4.0** mg a.s./L)
Pseudo-kirchneriella subcapitata	ASDM[###] (metabolite)	Acute	72h ErC50 72h EbC50	>336 mg met./L >54 mg met./L
Scenedesmus subspicatus	AUSN (metabolite)	Acute	72h ErC50 & EbC50	> 100 mg met./L
Scenedesmus subspicatus	MU-466 (metabolite)	Acute	72h ErC50 72h EbC50	> 100 mg met./L 84.4 mg met./L
Scenedesmus subspicatus	HMUD (metabolite)	Acute	72h ErC50 & EbC50	> 100 mg met./L
Scenedesmus subspicatus	UCSN (metabolite)	Acute	72h ErC50 & EbC50	> 100 mg met./L
Scenedesmus subspicatus	ADMP (metabolite)	Acute	72h ErC50 & EbC50	> 100 mg met./L
Higher plant				
Lemna gibba	a.s.	Acute	7 day frond count EC50 Spec. growth rate ErC50	**0.0017 mg a.s./l** **0.0027 mg a.s./l**
Lemna gibba	Formulation[1]	Acute	7 day frond count EC50 Spec. growth rate ErC50 Biomass (dry wt.) EbC50	0.06 mg form./l 0.105 mg form./l >0.229 mg form./l (≡ 0.0024, 0.0042 & >0.0092 mg a.s./l respectively)

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Lemna gibba	ASDM[###] (metabolite)	Acute	7 day frond count EC50, spec. growth rate ErC50 & biomass EbC50	all >100 mg met./l
Lemna gibba	AUSN	Acute	7 day frond count EC50, spec. growth rate ErC50 & biomass EbC50	all > 100 mg met./l
Lemna gibba	HMUD	Acute	7 day frond count EC50, spec. growth rate ErC50 & biomass (dry wt.) EbC50	all > 1 mg met./l
Lemna gibba	UCSN	Acute	7 day frond count EC50, spec. growth rate ErC50 & biomass (dry wt.) EbC50	all > 100 mg met./l
Microcosm or mesocosm tests				
No data (not required)				

[1] 'SL-950 4% SC' (40 g a.s. /L suspension concentrate formulation)
[#] Mortality 0% at 55.6 mg a.s. /L & 100% at 100 mg a.s. /L
[##] Toxicity endpoints in bold represent the lowest endpoints for each test group (fish, aquatic invertebrate, algae and higher aquatic plants) used in the risk assessment.
[###] ASDM is code named 'DAM 520' in some of the submitted toxicity reports.

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

TERs for aquatic organisms based on a comparison of the most sensitive toxicity endpoints with the FOCUS Step 1 maximum PECsw value of 0.02 mg a.s. /l:

Application rate (kg as/ha)	Crop	Most sensitive test organism	Time-scale	Distance (m)	TER#	Annex VI Trigger
1 x 0.06	Maize (N. & S. Europe):	Fish *(Oncorhyncus mykiss)*	Acute	1 metre	110	100
		Aquatic invertebrate. (Daphnia magna)	Acute	1 metre	165	100
		Algae (Scenedesmus subspicatus)	Acute	1 metre	>200	10
		Aquatic plant (Lemna gibba) Based on EC50 frond no.	Acute	1 metre	0.08	10
		Aquatic plant (Lemna gibba) Based on E_rC50	Acute	1 metre	1.35	10

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

Application rate (kg as/ha)	Crop	Most sensitive test organism	Time-scale	Distance (m)	TER#	Annex VI Trigger
		Fish *(Oncorhyncus mykiss)*	Chronic	1 metre	500	10
		Aquatic invertebrate. (Daphnia magna)	Chronic	1 metre	260	10

Figures in bold indicates an area of potential concern requiring a refined risk assessment
Note: Sediment dwelling organisms are not considered to be at risk due to low levels of active / metabolite in sediment (less than 10% AR).

Refined TERs for the most sensitive aquatic organism to nicosulfuron: calculated using *Lemna gibba* 7 day frond count EC50 (0.0017 mg a.s. /L) and FOCUS Step 3 and 4 maximum PECsw values for the relevant scenarios.

Maize (N. & S. Europe) - one application at 60 g a.s. /ha.

Scenario	FOCUS Step 3 (1 metre#) TERs	FOCUS Step 4 (5 metre) TERs
D3 ditch	**5.4**	16.2
D4 pond	63.0	70.8
D4 stream	**6.1**	16.7
D5 pond	77.3	89.5
D5 stream	**6.3**	17.2
D6 ditch	**5.4**	15.9
R1 pond	56.7	85.0
R1 stream	**2.2**	**2.2**
R2 stream	**0.9**	**0.9**
R3 stream	**0.7**	**0.7**
R4 stream	**0.6**	**0.6**

Note: Figures in bold indicate an area of concern.

Refined TERs for the most sensitive aquatic organism to nicosulfuron: calculated using *Lemna gibba* 7 day growth rate ErC50 (0.0027 mg a.s. /L) and FOCUS Step 3 and 4 maximum PECsw values for the relevant scenarios.

Maize (N. & S. Europe) - one application at 60 g a.s. /ha.

Scenario	FOCUS Step 3 (1metre#) TERs	FOCUS Step 4 (5 metre) TERs
D3 ditch	**8.5**	25.1
D4 pond	100	112.5
D4 stream	**9.75**	26.47

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

Scenario	FOCUS Step 3 (1metre#) TERs	FOCUS Step 4 (5 metre) TERs
D5 pond	122.73	142.1
D5 stream	**9.90**	27.3
D6 ditch	**8.52**	25.2
R1 pond	117.39	135.0
R1 stream	**3.52**	**3.5**
R2 stream	**1.46**	**1.5**
R3 stream	**1.16**	**1.2**
R4 stream	**0.93**	**0.9**

Note: Figures in bold indicate an area of concern.

Aquatic TER from exposure to nicosulfuron's major aquatic metabolites based on use of FOCUS Step 1 (1 metre) maximum PECsw values.

Metabolite	Most sensitive test organism	Time-scale	Distance (m)	TER#	Annex VI Trigger
HMUD	Fish *(Oncorhyncus mykiss)*	Acute	1 metre	>27382	100
	Aquatic invertebrate. (Daphnia magna)	Acute	1 metre	>27382	100
	Algae (Scenedesmus subspicatus)	Acute	1 metre	>27382	10
	Aquatic plant (Lemna gibba)	Acute	1 metre	>274	10
AUSN	Fish *(Brachydanio rerio)*	Acute	1 metre	>24498	100
	Aquatic invertebrate. (Daphnia magna)	Acute	1 metre	>24498	100
	Algae (Scenedesmus subspicatus)	Acute	1 metre	>24498	10
	Aquatic plant (Lemna gibba)	Acute	1 metre	>24498	10
ASDM	Fish *(Lepomis macrochirus)*	Acute	1 metre	>10508	100
	Aquatic invertebrate. (Daphnia magna)	Acute	1 metre	>100242	100
	Algae (Pseudo-kerchneriella subcapitata)	Acute	1 metre	5674	10
	Aquatic plant (Lemna gibba)	Acute	1 metre	>10508	10

Note: The aquatic toxicity data for the minor aquatic metabolites UCSN, MU-466 and ADMP indicates a similarly low toxicity to aquatic life as the above major aquatic metabolites. Given that these minor metabolites will be present at lower concentrations, the risk from them to aquatic life is also deemed acceptable.

Bioconcentration				
	Active substance	Metab. 1	Metab. 2	Metab. 3
$logP_{O/W}$	The log Pow for nicosulfuron is 0.61 and that for its principle aquatic metabolites are all less than 1.0.			

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

Bioconcentration	
Bioconcentration factor (BCF) ‡	There is not a potential risk of bioconcentration and no study is required
Annex VI Trigger for the bioconcentration factor	The trigger is log Pow $\geq$ 3
Clearance time (days) (CT_{50})	Not applicable (no study submitted or required).
(CT_{90})	Not applicable (no study submitted or required).
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not applicable (no study submitted or required).

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)
Technical nicosulfuron ‡	Study details did not allow calculation of oral LD_{50} in terms of µg a.s./bee [LC_{50} > 1000 mg a.s. /litre in diet]	LD_{50} 76 µg a.s./bee
Formulation: 'SL-950 4% SC'	>131 µg product/bee – equivalent to 5.24 µg a.s./bee	-
Field or semi-field tests No bee field studies were conducted and none are required.		

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

Crop and application rate: Maize (N. & S. Europe) - one application at 60 g a.s. /ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
Technical nicosulfuron	Contact	0.8	50
Technical nicosulfuron	Oral	-	50
Formulation: 'SL-950 4% SC'	Contact	-	50
Formulation: 'SL-950 4% SC'	Oral	< 11.5	50

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

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

Laboratory tests with standard sensitive species

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Aphidius rhopalosiphi (aphid parasitoid)	Adult (48 hour exposure to glass plate deposit)	'SL-950 4% SC'	60g a.s. /ha	% mortality Water control: 0% 60g a.s./ha: 15% (not significant) Parasitism (no. aphid mummies /female) Water control: 33.3 60g a.s./ha: 16.6 – reduction of 50% (sig. at P=0.05)	50% effects at proposed maximum individual dose	*Aphidius rhopalo-siphi* (aphid parasitoid)
Aphidius rhopalosiphi (aphid parasitoid)	Adult (48 h exposure to deposit on freshly sprayed barley seedlings)	'SL-950 4% SC'	60g a.s. /ha	% mortality Water control: 0% 60g a.s./ha: 5% (not significant) Parasitism (no. aphid mummies /female) Water control: 21.1 60g a.s./ha: 17.6 (not significant)	50% effects at proposed maximum individual dose	*Aphidius rhopalo-siphi* (aphid parasitoid)
Typhlodro-mus pyri (predatory mite)	Proto-nymph through to adult stage (14 day exposure to glass plate residue)	'SL-950 4% SC'	60g a.s. /ha	% mortality (after 7 days exposure) Water control: 17% 1.5 litre product /ha: 41% - control corrected 29% (not sig.) Fecundity (no. of eggs per female during days 7-14) Control: 9.0 1.5 litre product/ha: 9.1 (not sig.)	50% effects at proposed maximum individual dose	*Typhlodro-mus pyri* (predatory mite)

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

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Poecilus cupreus (carabid beetle)	Adult (28 day exposure to initial spray & residues in moist sand substrate)	'SL-950 4% SC'	60g a.s. /ha	% mortality (after 28 day exposure) Water control: 33% 1.5 litre product /ha: 40% -control corrected 10% (not sig.) Mean prey consumption per beetle over study period: Water control: 8.6 1.5 litre product /ha: 8.4 (not sig.)	50% effects at proposed maximum individual dose	*Poecilus cupreus* (carabid beetle)
Coccinella septem-punctata (lady bird)	3 day old larvae through to pupae stage (15-20 day exposure to glass plate residue)	'SL-950 4% SC'	60 & 120g a.s. /ha	% mortality during exposure phase (based on numbers of emerging adults): Water control: 18% 1.5 litre product /ha: 16% -control corrected -6% (not sig.) 3.0 litre product /ha: 40% -control corrected 19% (not sig.) Fecundity (no. of eggs per female during 8-9 week post-exposure phase) & % hatch Control: 137.7 & 60.4% hatch 1.5 litre product/ha: 91.5 & 84.6% hatch (not sig.) 3.0 litre product /ha: 123.4 & 91.2% hatch (not sig.)	50% effects at proposed maximum individual dose	*Coccinella septem-punctata* (lady bird)

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

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	Trigger value
Aloechara bilineata (rove beetle)	Adult plus developing F1 beetles present in treated substrate (28 day exposure to residues in moist sand substrate)	'SL-950 4% SC'	60 g a.s. /ha	% mortality (after 28 day exposure) Water control: 0% 1.5 litre product /ha: 0% Parasitism rate (mean number per treatment group of F1 beetles emerging from Delia pupae) Water control: 356 1.5 litre product /ha: 284 – equivalent to 20% reduction (not sig.)	50% effects at proposed maximum individual dose	*Aloechara bilineata* (rove beetle)

Further laboratory and extended laboratory studies ‡

First tier risk assessment (use on maize - one application at 60 g a.s. /ha):

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field	Trigger
	Typhlodromus pyri	LR_{50} >1.5 litres product /ha (≡ 60g a.s. /ha)	1.0	0.0277 (at 1 metre)	2
	Aphidius rhopalosiphi	LR_{50} >1.5 litres product /ha (≡ 60g a.s. /ha)	1.0	0.0277 (at 1 metre)	2

Field or semi-field tests
No non-target arthropod field studies were conducted and none are required.

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

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	Technical nicosulfuron ‡	Acute, 14 days	LC_{50} > 1000 mg a.s. /kg d.w. soil (highest test dose, no affects reported)

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

Test organism	Test substance	Time scale	End point
Eisenia fetida	ASDM ‡	Acute, 14 days	LC_{50} > 1000 mg ASDM /kg d.w. soil (highest test dose, no affects reported)
Eisenia fetida	ADMP, AUSN, HMUD, MU-466 & UCSN ‡	Acute, 14 days	LC_{50} > 1250 mg metabolite /kg d.w. soil (highest test dose, no affects reported)
Eisenia fetida	'SL-950 4% SC' ‡	Acute, 14 days	LC_{50} > 1000 mg formulation /kg d.w. soil (highest test dose, no affects reported)
Eisenia fetida	AUSN ‡	Chronic, 8 weeks (reproductive toxicity study)	NOEC 0.100 mg AUSN /kg d.w. soil (highest test dose)
Eisenia fetida	UCSN ‡	Chronic, 8 weeks (reproductive toxicity study)	NOEC 0.050 mg UCSN /kg d.w. soil (highest test dose)
Eisenia fetida	ASDM ‡	Chronic, 8 weeks (reproductive toxicity study)	NOEC 0.350 mg ASDM /kg d.w. soil (highest test dose)
Other soil macro-organisms			
Folsomia candida, (Collembola)	AUSN ‡	Chronic, 28 days (reproductive toxicity study)	NOEC 0.100 mg AUSN /kg d.w. soil (highest test dose)
Folsomia candida, (Collembola)	UCSN ‡	Chronic, 28 days (reproductive toxicity study)	NOEC 0.050 mg UCSN /kg d.w. soil (highest test dose)
Folsomia candida, (Collembola)	AUSN ‡	Chronic, 28 days (reproductive toxicity study)	NOEC 0.100 mg AUSN /kg d.w. soil (highest test dose)
Soil micro-organisms			
Nitrogen mineralisation			
Nitrogen transformation and carbon mineralization (respiration)	Technical nicosulfuron ‡	29 day study	At 0.08 & 0.8 mg a.s. /kg soil d.wt. < 25% deviation from control by study end (day 28)
Nitrogen transformation and carbon mineralization (respiration)	''SL-950 4% SC' ‡	28 day study	At doses equivalent to 0.08 & 0.8 mg a.s. /kg soil d.wt. < 25% deviation from control by study end (day 29)
Nitrogen transformation and carbon mineralization (respiration)	AUSN, UCSN & ASDM‡	28 day study	0.082mg AUSN + 0.034mg UCSN + 0.191mg ASDM /kg dry soil:. < 25% deviation from control by study end (day 28)

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

Test organism	Test substance	Time scale	End point
Field studies			
Not conducted and not required.			

Toxicity/exposure ratios for soil organisms

Maize (N. & S. Europe) - one application at 60 g a.s. /ha

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia foetida	Technical nicosulfuron	Acute LC_{50}	0.06	>16667	10
Eisenia foetida	'SL-95- 4% SC'	Acute LC_{50}	1.5 mg product/kg dw soil#	>667	10
Eisenia foetida	ASDM	Acute LC_{50}	0.062	>26316	10
Eisenia foetida	AUSN, HMUD, MU-466, UCSN & ADMP	Acute LC_{50}	0.006-0.062	>20000 - >208000	10
Eisenia foetida	ASDM	Chronic NOEC	0.062	5.6	5
Eisenia foetida	AUSN	Chronic NOEC	0.018	5.6	5
Eisenia foetida	UCSN	Chronic NOEC	0.009	5.6	5
Other soil macro-organisms					
Collembola					
Folsomia candida	ASDM	Chronic NOEC	0.062	5.6	5
Folsomia candida	AUSN	Chronic NOEC	0.018	5.6	5
Folsomia candida	UCSN	Chronic NOEC	0.009	5.6	5

Initial soil PEC for the formulation from one application in maize crops at the proposed dose of 1.5 litres product/ha, assuming 25% crop interception, equal distribution in the top 5 cm of soil and a soil density of 1.5 g/cm^3.

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

Preliminary screening data

Not required for herbicides

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha) vegetative vigour	ER_{50} (g/ha) emergence	Exposure $(g/ha)^2$	TER	Trigger
Post-emergence exposure: rice ‡	'SL-950 4% SC'	0.47 g a.s. /ha (based on % of plants showing visible adverse effects in glasshouse test)	-	1.662 g a.s. /ha (at 1 metre) # 0.342 g a.s. /ha (at 5 metres) # (Post-emergence exposure)	0.28 1.37	5 5
Pre-emergence exposure: Most sensitive species not ascertained (equivalent endpoint for six tested dicot / monocot crop species) ‡	'SL-950 4% SC'	-	>20 g a.s./ha (no adverse effects at 20 g a.s./ha)	1.662 g a.s. /ha (at 1 metre) # 0.342 g a.s. /ha (at 5 metres) # (Pre-emergence exposure)	12.0 58.5	5 5

Assumes 2.77% and 0.57% spray drift exposure at 1 and 5 metres respectively from a single application at the maximum dose of 60 g a.s./ha (90^{th} percentile spray drift values for a single application, ref: Rautmann et al 2001)

Estimated of post-emergence HC5 & refined (probabilistic) risk assessment:

Based on the species sensitivity distribution indicated by the reported post-emergence lab EC50s (relating to a total of 23 crop species), the HC5 is 0.464 g a.s. /ha. If this value is compared to spray drift exposure (see above Table), the TER is 0.28 at 1 metre and 1.4 at 5 metres. Under current SANCO guidance, the risk is acceptable at 5 metres but not at 1 metre. Risk mitigation measures are therefore required.

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

Post-emergence field study – EC_{50} (based on effects on vegetative vigour in young plants) for the most sensitive of six tested dicot / monocot crop species (oilseed rape) was 6.6 g a.s./ha

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

Test type/organism	End point
Activated sludge	--
Pseudomonas putida	Nicosulfuron EC_{50}: > 250 mg a.s. /liter (no reported effects) ASDM, AUSN, UCSN, MU-466, HMUD: > 100 mg metabolite / litre (no significant inhibition)

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

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

Compartment	
soil	Nicosulfuron, AUSN, UCSN, ASDM.
water	Nicosulfuron
sediment	Nicosulfuron
groundwater	Nicosulfuron

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	
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment
S60	This material and its container must be disposed of as hazardous waste.
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

Preparation

RMS/peer review proposal	
R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment
S35	This material and its container must be disposed in a safe way
or	
S60	This material and its container must be disposed of as hazardous waste.
S57	Use appropriate container to avoid environmental contamination
or	
S61	Avoid release to the environment. Refer to special instructions/safety data sheets.

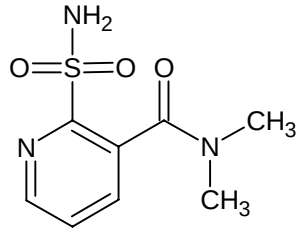
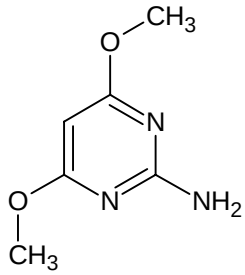
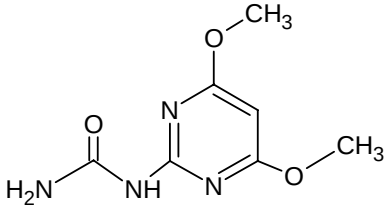
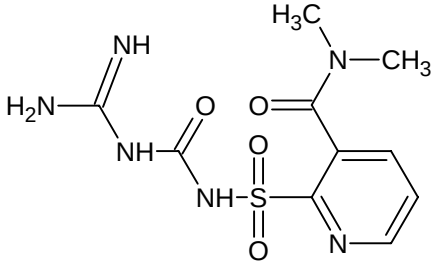
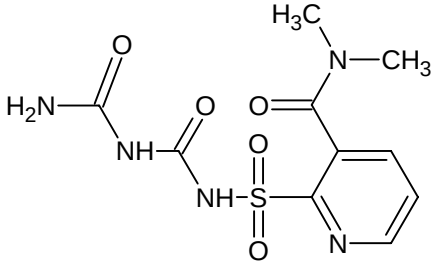
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

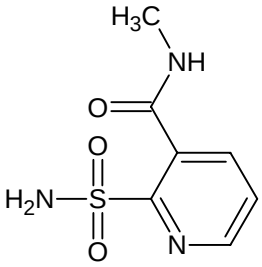
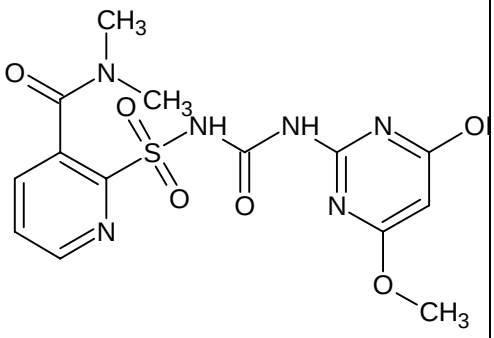
APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
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_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
ASDM	*N*,*N*-dimethyl-2-sulfamoylpyridine-3-carboxamide	
ADMP	4,6-dimethoxypyrimidin-2-amine	
DMPU	(4,6-dimethoxypyrimidin-2-yl)urea	
AUSN	2-[(carbamimidoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide	
UCSN	2-[(carbamoylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylpyridine-3-carboxamide	

Code/Trivial name	Chemical name	Structural formula
MU-466	*N*-methyl-2-sulfamoylpyridine-3-carboxamide	
HMUD	2-{[(4-hydroxy-6-methoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-*N*,*N*-dimethylpyridine-3-carboxamide	
DUDN	2-{[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]amino}-N,N-dimethylpyridine-3-carboxamide