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

rimsulfuron

finalised: 10 August 2005

SUMMARY

Rimsulfuron is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[1], as amended by Commission Regulation (EC) No 1490/2002[2]. 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.

Germany being the designated rapporteur Member State submitted the DAR on rimsulfuron in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 6 August 2003. Following a quality check on the DAR, the peer review was initiated on 14 August 2003 by dispatching the DAR for consultation of the Member States and the sole notifier DuPont de Nemours. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 12 March 2004. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September and October 2004.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 19 July 2005 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 spraying to control broad-leaved and grass weeds at application rates up 20 g rimsulfuron per hectare in maize and potatoes and up to 27.5 g rimsulfuron per hectare in tomatoes. Rimsulfuron can be used only as herbicide.
The representative formulated product for the evaluation was "Rimsulfuron 25 WG", water dispersible granules (WG), registered under different trade names in Europe.

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

[1] OJ No L 53, 29.02.2000, p. 25
[2] OJ No L 224, 21.08.2002, p. 25

Sufficient analytical method 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.

In mammals, rimsulfuron has a low acute toxicity and is not a skin or eye irritant, nor a skin sensitiser.
Main target organs are liver (increase of weight, minor histopathological changes) and kidney (increased weight). In dogs, testes, epidydimes and trachea are also target organs. There is no evidence of a mutagenic, genotoxic and carcinogenic potential of rimsulfuron. Rimsulfuron does not show any adverse effects on reproductive and developmental parameters. The two major metabolites IN-70941[3]and IN-E9260[4] show low acute toxicity. None of them has a genotoxic potential.
The acceptable daily intake (ADI) is 0.1 mg/kg bw/day and the acceptable operator exposure level (AOEL) is 0.07 mg/kg bw/day, with a safety factor of 100 and 143 (the oral absorption was moderate), respectively. No acute reference dose (ARfD) is needed.
The estimated operator exposure is below the AOEL without PPE, according to German model. According to calculations with UK POEM, gloves have to be used during mixing and loading (M/L) in order to be below the AOEL. The estimated worker and bystander exposure is below the systemic AOEL.

Rimsulfuron is rapidly metabolised in maize, potatoes and tomatoes through two degradation pathways starting with either cleavage or contraction of the sulfonylurea bridge of the molecule. Its metabolism is similar to that found in rat and none of its metabolites is of any concern. The residue definition for plant products should be rimsulfuron for monitoring and risk assessment purposes. Supervised residue trials according to the recommended use demonstrate that residues are below the limit of quantification (LOQ) in maize grains and forage, potatoes as well as in tomatoes. No residue is to be expected in rotational and succeeding crops.
Human and animal exposures to residues of rimsulfuron are therefore minimal, and no risk for consumers has been identified

Soil degradation of rimsulfuron yields IN-70941, IN-70942[5] and IN-E9260 as major metabolites. Mineralization of the rings is very low but occurs, non extractable residues are relatively low (*ca.*21% applied radioactivity (AR) at 90 days). Rimsulfuron is of moderate persistence in soil, a major soil metabolite IN 70942 exhibits high persistence in soil, the remaining major soil metabolites are moderately to very highly persistent in soil. Under worst case conditions all these major soil metabolites have the potential to accumulate in soil when rimsulfuron is applied to the same area of land in consecutive years. The resulting accumulated plateau and maximum soil concentrations have been calculated for the intended uses notified. However the accumulated value calculated for IN-70941 may not represent the very worst case situation in colder climatic regions, so the risk to soil

[3] IN-70941: *N*-(4,6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsulfonyl)-2-pyridinyl]urea
[4] IN-E9260: 3-(ethylsulfonyl)-2-pyridinesulfonamide
[5] IN-70942: *N*-[3-(ethylsulfonyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimidinamine

dwelling organisms from exposure to this metabolite should be considered further at MS level. Rimsulfuron and its major soil metabolites except IN-70942 exhibit very high to high mobility in soil. IN-70942 exhibits medium mobility. In the sediment water environment rimsulfuron degrades relatively rapidly through a combination of hydrolysis and microbial degradation to the major water metabolites IN-70941 and IN-70942. These metabolites and the additional metabolite IN-JF999[6] are also major residues in sediment. In the natural sediment water system experiments the metabolite IN-70941 also degrades relatively rapidly, IN-70942 dissipates from the water phase relatively rapidly but is more persistent in sediment. In a laboratory aqueous photolysis study IN-70942 degraded rapidly. Rimsulfuron is classified as not readily biodegradeable. PEC surface water and PEC sediment (initial) values (for parent and metabolites) to be used in the risk assessment for the representative uses from the spray drift route of exposure have been calculated, however the drainage and runoff routes of exposure to surface water bodies have not been assessed. These routes of entry to surface water should be taken into account by MS when these routes of surface water exposure are relevant and the pertinent risk assessments to aquatic organisms should be completed by MS. For the notified intended uses rimsulfuron would not be expected to contaminate shallow vulnerable groundwater at annual average concentrations > 0.1µg/l based on the results of FOCUS groundwater modelling. The concentrations for metabolite IN-70941 are >0.75µg/L but <10µg/l (up to 0.85µg/l) and for IN-E9260 are >0.1µg/L but <0.75µg/l (up to 0.48µg/l). However effects assessments have confirmed that these metabolites are considered not relevant.

The risk to terrestrial vertebrates, aquatic organisms, bees, non-target arthropods, soil macro-organisms including earthworms and springtails and soil micro-organisms is low with respect to rimsulfuron and the metabolites IN-70941, IN-70 942, IN-E9260 and IN-JF 999 occurring in soil and surface water following application according to the proposed GAP. For the metabolite IN 70941 the calculated long-term TER value for earthworms was 4.5 and hence did not meet the Annex VI trigger of 5. No adverse effects were observed in the study and calculations were based on 10-yr accumulated PEC for soil using worst case laboratory data on formation fraction and DT_{50}. The risk is therefore considered low. However Northern Member States may consider to conduct a risk assessment based on the longer DT_{50} obtained in a Danish field study. The metabolites IN-70941 and IN-E9260 have the potential to contaminate vulnerable shallow groundwater that may become surface water, at concentrations above those calculated for rimsulfuron in surface water. A risk assessment for aquatic plants should therefore be considered in MS with shallow ground water. Data from screening studies indicate however that these metabolites are not herbicidally active.

A risk was identified for non-target terrestrial plants exposed to rimsulfuron via spray drift and risk mitigation measures need to be considered. A 5 m buffer zone or drift reducing measures are needed.

[6] IN-JF999: 2-[[3-ethylsulfonyl)-2-pyridinyl]amino]-6-methoxy-4(1*H*)-pyrimidinone

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

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BACKGROUND

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

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Germany submitted the report of its initial evaluation of the dossier on rimsulfuron, hereafter referred to as the draft assessment report, to the EFSA on 6 August 2003. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the draft assessment report was distributed for consultation on 14 August 2003 to the Member States and the main applicant DuPont de Nemours as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 12 March 2004 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in experts' meetings organised on behalf of the EFSA by the EPCO-Team at the Federal Office for Consumer Protection and Food Safety (BVL) in Braunschweig in September and October 2004. 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 19 July 2005 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 8(7) of the amended Regulation (EC) No 451/2000, 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. 1-2 of 26 March 2004)
- 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. 1-2 of 9 August 2005)

Given the importance of the draft assessment report including its addendum (compiled version of April 2005 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Rimsulfuron is the ISO common name for 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea (IUPAC).

Rimsulfuron belongs to the class of pyrimidinylsulfonylurea herbicides such as amidosulfuron, flazasulfuron and imazosulfuron. Rimsulfuron is taken up via leaves and act as an effective inhibitor of plant root and shoot growth by blocking the enzyme *acetolactate synthase* (ALS).

The representative formulated product for the evaluation was "Rimsulfuron 25 WG", water dispersible granules (WG), registered under different trade names in Europe.

The evaluated representative uses as post-emergent herbicide comprise spraying to control a range of broad-leaved and grass weeds in maize, potatoes and tomatoes at application rate up to 20 g rimsulfuron per hectare in maize and potatoes and up to 27.5 g rimsulfuron per hectare in tomatoes. Rimsulfuron can be used only as herbicide.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of rimsulfuron as manufactured should not be less than 960 g/kg. At the moment no FAO specification exists.
The technical material contains no relevant impurities.

The assessment of the data package revealed no particular area of concern.
The main data regarding the identity of rimsulfuron and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of rimsulfuron in the technical material and in the representative formulation.
Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Adequate methods are available to monitor all compounds given in the respective residue definition, i.e. rimsulfuron in food of plant origin, soil, water and air.
The methodology used is HPLC with UV or MS/MS detection. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues.
An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

The discussion in the EPCO experts' meeting on identity, physical and chemical properties and analytical methods (EPCO 11) was limited to the specification of the technical material and a confirmatory method for the determination of impurities in the technical material.

2. Mammalian toxicology

Rimsulfuron was discussed at the EPCO experts' meeting for mammalian toxicology (EPCO 14) in October 2004.

2.1 ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Rimsulfuron is moderately orally adsorbed (approximately 70%) and quickly excreted. Approximately 92-95% is excreted within 72 hours. Most of the dose is excreted via urine (65%), the remaining by faeces. There is no potential for accumulation.
The metabolic degradation of rimsulfuron in rat occurs primarily via contraction of the sulfonylurea bridge.

2.2 ACUTE TOXICITY

Rimsulfuron has a low acute toxicity: the oral and dermal LD_{50} are greater than 5000 and 2000 mg/kg bw, respectively; LC_{50} is greater than 5.4 mg/L.

Rimsulfuron is not a skin or eye irritant, nor a skin sensitiser, even if it has to be noted that the EPCO experts' meeting concluded that the skin sensitisation study (Armondi, 1990) reported in the DAR is not optimal: the test has been performed in a "practical" dosing range instead of an irritating dose (>25% in this case) for the topical induction, as indicated in the Guidelines. Nevertheless, the study has been considered acceptable.

No classification for acute toxicity is needed.

2.3 SHORT TERM TOXICITY

The short term toxicity of rimsulfuron was studied in dietary 90-d studies in rats and mice and in 90-d and 1-yr studies in dog. No major differences among species were evident.

Main target organs were liver (increase of weight, minor histopathological changes) and kidney (increased weight).

In dogs, testes, epidydimes and trachea are also target organs. In light of the effect on testes, the applicant was asked to submit existing historical control data. They were summarised in the 3rd addendum to the DAR; the meeting concluded that this had no impact on the overall risk assessment.

No studies on dermal or inhalation exposure were submitted or required.

The lowest NOAEL is 1.6 mg/kg bw/d in the 1-year dog study. However, this low value may be due to the large distance between the both lowest dose groups (1.6 and 81.8 mg/kg bw/day) in this study. Considering that the NOAEL from the 90-day study is 9.6 mg/kg bw/day, with a LOAEL of 189 mg/kg bw/day, the "true" NOAEL lies between 9.6 and 81.8 mg/kg bw/day.

Thus, the relevant oral NOAEL is 9.63 mg/kg bw/d (90-d dog study).

2.4 GENOTOXICITY

In *in vitro* investigations, rimsulfuron was evaluated using bacterial and mammalian cell mutagenicity tests, a clastogenicity test and an unscheduled DNA synthesis test. The results do not show any evidence of genotoxic effect.

In vivo, rimsulfuron was assessed for the induction of micronuclei in the mouse, giving negative results.

In conclusion, there is no evidence from the available studies of a mutagenic or genotoxic potential of rimsulfuron.

2.5 LONG TERM TOXICITY

A combined chronic toxicity/carcinogenicity 2-year study was conducted in rats and a carcinogenicity 18-month study in mice.

The NOAEL for chronic toxicity in rats is based on reduced body weight and body weight gain, increased absolute-relative liver weight, hepatocellular hypertrophy and changes of relative kidney weight.

Effects in mice consisted in reduced body weight and body weight gain, increased incidence of cataracts in females, increased frequency and severity of testicular artery and tunica lesions, decrease of absolute kidney weight.
Based on the results of the chronic feeding studies in rats and mice, it can be concluded that rimsulfuron does not possess a carcinogenic potential.
The relevant NOAEL is 11.8 mg/kg bw/d from the rat study.

2.6 REPRODUCTIVE TOXICITY

In the two-generation toxicity study with rimsulfuron, the NOAEL for systemic parental toxicity is 3000 ppm (165-217 mg/kg bw/day in males and 204-264 mg/kg bw/day in females), based on effects on body weight, body weight gain and food efficiency in males and slight effects on body weight gain in females. There were no adverse effects on reproductive parameters of the parental animals at any dose level. Body weight was reduced and the incidence of small pups increased in F2 litters at 830 mg/kg bw/day. Therefore, the NOAEL for reproductive toxicity is 165 mg/kg bw/day.
Rimsulfuron was not teratogenic in the developmental studies with rats and rabbits. In the developmental toxicity study in rats, the NOAEL for maternal effects was 2000 mg/kg bw/d based on reduced maternal body weight gain and food consumption and NOAEL for foetal effects was 6000 mg/kg bw/d.
In the developmental study conducted in rabbits, the maternal NOAEL was 170 mg/kg bw/day based on increased maternal mortality at 500 mg/kg bw/day and above. The developmental NOAEL was 500 mg/kg bw/day. Because of high maternal mortality, foetal effects could not be evaluated at the highest dose, 1500 mg/kg bw/day.

2.7 NEUROTOXICITY

None of the subchronic and chronic studies conducted with rimsulfuron in rats, mice or dogs demonstrate any effect that would suggest a neurotoxic potential.

2.8 FURTHER STUDIES

Supplementary studies were conducted with two major metabolites: IN-70941[7] and IN-E9260[8]. The toxicity of both metabolites was studied in acute and subacute oral tests.

<u>Acute and short term toxicity studies on metabolites</u>
Studies on acute dermal toxicity, acute skin irritation, acute eye irritation and skin sensitisation were conducted with metabolites IN-E9260 and IN-70941.

[7] IN-70941: (N-4,6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsulfonyl)-2-pyridinyl]urea
[8] IN-E9260: (3-(ethylsulfonyl)-2-pyridinesulfonamide

Type of study	**Test animals**	**Test material**	**Dose /Concentration**	**Result**
Acute oral	Rat	IN-E9260	2000 mg/kg bw	LD_{50}: ≥2000 mg/kg bw
Acute oral	Rat (male)	IN-70941	670, 2300, 3400, 5000, 7500, 11000 mg/kg	LD_{50}: ≥ 11000 mg/kg bw
Oral subacute (10 days)	Rat (male)	IN-70941	2200 mg/kg bw/d	NOAEL: <2200 mg/kg bw/d
Oral subacute (4 week)	Rat	IN-E9260	0, 50, 150, 450, 1000 mg/kg bw/d	NOAEL: <50 mg/kg bw/d
Acute Percutaneous	Rat	IN- E9260	2000 mg/kg bw	LD_{50}: ≥ 2000 mg/kg bw
Skin irritation	Rabbit	IN- E9260	0.5 g	Non irritant
Eye irritation	Rabbit	IN- E9260	100 mg (0.1 mL)	Non irritant
Skin sensitisation (Maximisation test)	Rabbit	IN- E9260	0.1; 0.5 mL	Not sensitising

Genotoxicity studies

An *in vitro* gene mutation tests in bacteria and an *in vitro* chromosome aberration test in human lymphocytes were conducted with metabolite IN-E9260. *In vitro* gene mutation tests in bacteria and in mammalian cells and an *in vitro* chromosome aberration test in human lymphocytes were conducted with metabolite IN-70941.

None of them was found to have a genotoxic potential.

Summary of metabolites of possible toxicological relevance

The EPCO experts' meeting considered the data on metabolites IN-E9260 and IN-70941 and agreed that the two metabolites are not relevant.

2.9 MEDICAL DATA

The medical records of 10 randomly selected employees from the applicant's French production unit were evaluated. Evaluation of the medical records indicated the clinical biochemistry, urinalysis, haematology, chest X-rays and EKGs were generally within the normal published ranges or were normal in the opinion of the examining physician. So far, no illnesses have been associated with those involved in initial field testing or current uses of rimsulfuron products.

There have been no reported accidental poisonings with rimsulfuron and there have been no epidemiological studies conducted with rimsulfuron. This product has been used commercially in Europe since 1991 and in the United States since 1994. There have been no reports of adverse health effects associated with the manufacture or labelled uses of rimsulfuron.

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

ADI

The chronic studies in rats and mice are considered the appropriate studies to use as a basis for the ADI.

The relevant NOAEL in the chronic studies is 11.8 mg/kg bw/d from the chronic rat study.

Rimsulfuron has no genotoxic, reproduction toxicity and carcinogenic potential. Therefore, the standard assessment factor of 100 is considered appropriate.

The proposed ADI is 0.1 mg/kg bw.

AOEL

For the definition of the AOEL and the risk assessment to be made thereof, usually the results of the short-term toxicity and reproduction/developmental toxicity studies are considered to be of relevance. The lowest NOAEL is 1.6 mg/kg bw/d in the 1-year dog study. However, this low value may be due to the large distance between the both lowest dose groups (1.6 and 81.8 mg/kg bw/day) in this study. Considering that the NOAEL from the 90-day study is 9.6 mg/kg bw/day, with a LOAEL of 189 mg/kg bw/day, the "true" NOAEL lies between 9.6 and 81.8 mg/kg bw/day.

Thus, the systemic AOEL is derived from the NOAEL of the 90-day dog and supported by the 1-year dog study by applying a standard safety factor of 100. Since gastrointestinal absorption was estimated to be approximately 70% based on toxicokinetic investigations with rats, an additional correction factor was employed for calculation of the systemic AOEL.

The proposed AOEL is 0.07 mg/kg bw/d.

ARfD

From the evaluation of the available toxicological database of rimsulfuron, it was agreed there is no need to establish an ARfD. Acute oral studies demonstrate the low toxicity of rimsulfuron. No adverse effects were observed early in repeated-dose studies at dose levels that were relevant for human exposure. No developmental toxicity was induced by rimsulfuron treatment at dose levels below maternal toxicity. In conclusion, there are no toxicological alerts and, therefore, **it is not necessary to derive an ARfD**.

2.11 DERMAL ABSORPTION

No studies on dermal absorption are available for rimsulfuron. On the basis of the physico-chemical properties, the default value should be 100%. However, it is also supposed that dermal absorption would not exceed the oral absorption amount, which is approximately 70%. Thus, the RMS proposed to reduce the default value to 70% which was agreed at the EPCO experts' meeting.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product rimsulfuron 25 WG is a water-dispersible granular formulation (WG) which is packaged in jars ranging in size from 40 – 500 grams. This product is

diluted with water and applied once or twice during a growing season. Only application to field crops (maize, potatoes, tomatoes) is intended.
The estimated operator exposures to rimsulfuron were determined with the German model and the UK Pesticide Operator Exposure Model (POEM).

Operator exposure
According to the intended uses submitted by the applicant the maximum applied dose is 20 g rimsulfuron/ha (80 g formulation/ha) and the minimum volumes 150 L/ha.
Rimsulfuron 25 WG is applied using tractor mounted field crop sprayers, with hydraulic boom.

The estimated operator exposure is below the AOEL without PPE, according to German model (work rate 20 ha/day). According to calculations with UK POEM, (work rate 50 ha/day) gloves have to be used during mixing and loading (M/L) in order to be below the AOEL, (see table below).

Estimated exposure as % of AOEL (0.07 mg/kg bw/day)		
Model	**No PPE**	**With PPE*:**
German	23.2%	-
UK POEM	425.6%	95.6%

*PPE (personal protective equipment): gloves during mixing/loading
The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

Worker exposure
Rimsulfuron 25 WG herbicide may be used on maize, potatoes or tomatoes during the growing season. To assess cases where re-entry is not avoidable, the worker exposure has been calculated using a model proposed by the German BBA (Hoernicke et al., 1998).
The estimated worker exposure is below the proposed systemic AOEL (0.07 mg/kg bw/d), even when PPE is not worn (68.6 %). With the use of PPE the exposure can be further lowered to 3.4 % of the AOEL.

Bystander exposure
Rimsulfuron has a low use rate, low vapour pressure and is applied by ground-directed equipment that produces large non-respirable spray droplets. These factors demonstrate that inhalation exposure to bystanders will be negligible. Potential dermal exposure is estimated using drift estimates based on data published by EPPO (Ganzelmeier et al., 1995). Assuming a bystander (60 kg body weight) may be within 10 meters of the spray application, the data shows that the exposure would be 0.07 µg/kg of rimsulfuron. This may be compared with the systemic AOEL of 70 µg/kg bw for rimsulfuron, to show that this gives an additional margin of safety of 1000.

3. Residues

Rimsulfuron was discussed at the EPCO experts' meeting for residues (EPCO 15) in October 2004.

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

The metabolism of rimsulfuron has been studied in maize, potatoes and tomatoes, using 2 radiolabelled forms (pyridine and pyrimidine rings) in order to investigate the fate of the 2 moieties of the compound. Although plants were treated at approximately 3 times the maximum total annual use rate, total radioactive residues in edible plant parts (maize grains, potato tubers and tomatoes) as well as in fractions intended for animal consumption (maize silage and fodder) were always < 0.02 mg parent equivalent/kg. The metabolic pathway was therefore established by characterization of residues in immature foliage. Two primary degradation pathways were identified. A first mechanism is contraction of the sulfonylurea bridge to form IN-70941, leading further to IN-70942 from loss of $CONH_2$. The second pathway is cleavage of the sulfonylurea bridge to produce IN-E9260 and IN-J290. These first degradation products were further metabolized to a number of minor, polar compounds. None of the metabolites formed is found to be of particular concern. The metabolism of rimsulfuron in plants is similar to that found in rats.

Due to rapid and extensive metabolism in the tested crops, only parent rimsulfuron should be considered in the residue definition for both monitoring and risk assessment.

The magnitude of rimsulfuron residues was monitored in a total of 51 field residue trials (24 in maize, 17 in potatoes, 10 in tomatoes) identified as reflecting the representative uses and covering European regions of crop production. All these trials lead to residues below the LOQ of 0.05 mg/kg in maize forage and grains, potatoes and tomatoes. The reliability of these results is supported by storage stability studies demonstrating the stability at -20°C of residues of rimsulfuron in maize forage, maize grains and potatoes for at least 2 years as well as in tomatoes for at least 6 months.

Due to the very low residue level in the raw agricultural commodities when rimsulfuron is used according to the GAP supported as representative use, no residues are expected in processed products.

3.1.2. Succeeding and rotational crops

Total radioactive residues in food items from lettuce, sugarbeet, sunflower, soybeans, sorghum and wheat, grown in soil treated with ^{14}C-rimsulfuron at 2 times the application rate of representative uses and aged for either 30 days, 120 days or 10 months prior to planting, were below the LOQ of 0.05 mg parent equivalent/kg. Only in wheat straw, total radioactive residues were amounting to 0.38-0.46 mg parent equivalent/kg when the crop was sown after 30 days ageing, with metabolite IN-70941 present at 0.07 mg/kg as main compound identified.

Therefore there is no reasonable expectation of concentration of rimsulfuron or its metabolites/degradation products in the succeeding crop food and feed items after application of rimsulfuron under the normal agricultural practices. No residue definition is needed and no restriction for cultivation of rotational crops needs to be applied.

3.2. Nature and magnitude of residues in livestock

As no significant residues are expected to be present in maize or potato products intended for livestock consumption, metabolism studies are not in principle required. These studies have however been submitted and were evaluated, but no residue definition for animal products needs to be proposed.

Metabolism studies were conducted in lactating goat and laying hens with orally administered rimsulfuron radiolabelled either in the pyridine or pyrimidine ring. Daily dose were approximately 10 mg/kg feed, representing exaggerated dose levels (200-400 x) in respect of the anticipated practical dietary burden. In both animals, minimal transfer of rimsulfuron and its metabolites was observed to the edible animal matrices and tissues. Identification of residues was carried out on the excreta. Two metabolic pathways were identified, based on contraction or cleavage of the sulfonylurea bridge, leading to metabolite patterns which are qualitatively similar to rats and plants.

As mentioned above, given the very low potential exposure of animal to rimsulfuron, no livestock feeding studies were required.

3.3. Consumer risk assessment

The chronic dietary risk assessment has been based on the Theoretical Maximum Daily Intake (TMDI) calculation model of WHO using the WHO European typical diet and the national German diet (4 to 6 year old girl). Residues in maize grains, potatoes and tomatoes were considered to be 0.05 mg/kg, being the level of the LOQ. The calculations made for both diets indicated very low TMDI values (less than 1% of the ADI).

As no ARfD is necessary for rimsulfuron, acute intake calculations were not carried out.

3.4. Proposed MRLs

Based on the available data base, a MRL of 0.05* mg/kg is proposed for maize grains, potatoes and tomatoes to cover the representative uses supported by the applicant on these crops.

4. Environmental fate and behaviour

Rimsulfuron was discussed at the EPCO experts' meeting for fate and behaviour (EPCO 12) in September 2004.

4.1. Fate and behaviour in soil

4.1.1. Route of degradation in soil

A laboratory study (dark aerobic conditions at 25°C and 75% of 1/3 bar water holding capacity (WHC)) on a single sandy loam soil (organic carbon (OC) 0.6%, pH 6.7) dosed with ^{14}C-rimsulfuron demonstrated limited mineralization to CO_2 (0.1% AR pyridine label and 0.3% AR pyrimidine label both at 90 days, by 360 days 1% AR and 6.3% AR mineralization was measured for each label respectively) and non-extractable residue following acetonitrile/water extractions of 21.3% AR (pyridine label) and 22.1 % AR (pyrimidine label) both at 90 days. The following metabolites were detected in amounts > 10 % AR: IN-70941 was present at up to 54 % after 60 days, IN-70942 at up to 23 % after 12 months (study end), and IN-E9260 with maximum amounts of 19 % AR after 6 months.

A study on photolysis in soil demonstrated that the rate of rimsulfuron breakdown in the sandy loam soil as described above was the same in 25°C air dried irradiated soil samples as in non-irradiated air dried samples and the major (>10% AR) metabolites formed in soil under light conditions were the same as in the dark controls and the dark aerobic study on moist soil (described above).

The degradation of rimsulfuron was also studied in this sandy loam soil in the laboratory under flooded anaerobic conditions (25°C), the route and rate of degradation observed was comparable to that observed under aerobic conditions.

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

Aerobic dark laboratory studies on 4 different soils were available, (3 at 20°C and 40% maximum water holding capacity (MWHC) one at 25°C and 75% of 1/3 bar WHC). After normalising using FOCUS guidance (Arrhenius activation energy 54.1kJ/mol) to a common temperature of 20°C, rimsulfuron was degraded with single first order DT_{50}'s in the range 25 to 40 days. In European field studies (2 northern trial sites and 1 southern site) rimsulfuron was degraded with single first order DT_{50}'s ranging from 6 to 14 days and in US field studies (3 sites), single first order DT_{50} values from 8 to 18 days were determined. Rimsulfuron is considered to exhibit moderate persistence.

The single first order DT_{50} values for the soil metabolites, IN-70941, IN-70942, and IN-E9260, were determined in 3 different soils in laboratory studies (20°C, 40% MWHC) where the metabolites were applied as test substance. They ranged from 38 to 615 days, 101 to 214 days, and 252 to 969 days, respectively. The study durations were *ca.*120 days so nearly all the DT_{50} quoted above are extrapolated values.

In the 3 field studies conducted in Europe where rimsulfuron was the applied test substance, single first order DT_{50} values for IN-70941 were 62 to 1100 days and for IN-E9620 were 25 to 294 days (calculated using a 2 compartment kinetic model, parent to metabolite, using the residues detected in all soil layers. This DT_{50} is therefore analogous to a degradation rate and does not represent the rate of the observed decline after the peak formation). As IN-70942 was not detected at levels greater than 10 % of the parent molar equivalence in any of the European field studies, it was not possible to estimate field DT_{50} for this metabolite. These data indicate that in the field, the metabolites IN-70941 and IN-E9620 have the potential to accumulate in soil when rimsulfuron applications are made every year. Because of the potential for these soil metabolites to accumulate, the EPCO experts' meeting requested that Predicted Environmental Concentrations in soil (PEC_s) were calculated taking into account the potential for accumulation of the soil metabolites. Calculations were made using the formation fractions and longest first order DT_{50} from the available database of laboratory studies. The detail of the approach taken is contained in addendum 4 to the draft assessment report dated 20 April 2005.

EFSA considers this approach to represent a worst case for use in risk assessment for the metabolites IN-70942 and IN-E9260. Whilst the use of laboratory values has uncertainty as DT_{50} were extrapolated beyond the study durations, the use of formation fractions and DT_{50} values from the laboratory studies for these 2 metabolites clearly results in more conservative PEC_s being calculated than would result if the data from the field studies had been used as the basis for the calculations. However for the metabolite IN-70941 this is less clear. The kinetic formation fraction and worst case single first order DT_{50} from the laboratory data set are 57% and 615 days respectively. These values from the worst case Danish field study are 49% and 1100 days respectively. These different sets of combinations of input values for accumulation calculations are likely to result in the calculation of a similar accumulated maximum PEC_s for IN-70941. Therefore the PEC_s calculation for IN-70941 contained in the end points (based on the worst case laboratory data) may well represent a realistic worst case and would certainly be expected to cover the situation in many agricultural regions of the EU. However Northern European Member States may wish to confirm this is the case for their territory by recalculating the maximum accumulated PEC_s for IN-70941 using the combination of: parent DT_{50} of 24 days, IN-70941 kinetic formation fraction of 49% and DT_{50} of 1100 days (worst case field data from a Danish trial site).

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

K_{OC}-values of rimsulfuron were determined in a batch adsorption study. The values determined were 19 to 63 L/kg, the Freundlich exponent 1/n was between 0.90 and 1.22. The Freundlich adsorption coefficients of the main metabolites in soil were: IN-70941 (K_{OC}: 34 – 116 L/kg, 1/n: 0.92-0.96), IN-70942 (K_{OC}: 145 – 223 L/kg, 1/n: 0.84-0.85) and IN-E9620 (K_{OC}: 16 – 86 L/kg, 1/n: 0.93-1.08). Column leaching studies showed a high leaching potential of rimsulfuron with 47 - 93 % TAR in the leachate (mainly rimsulfuron and metabolites IN-70941 and IN-70942). Aged residue column leaching studies showed a reduction of the leaching of rimsulfuron and the metabolites with amounts between 23 and 36% AR. Lysimeter studies were not conducted.

4.2. Fate and behaviour in water

4.2.1. Surface water and sediment

Rimsulfuron degrades relatively rapidly in aquatic systems. Hydrolysis single first order DT_{50} values were *ca.* 7 days at pH 7 and 25°C. Contraction of the sulfonylurea bridge leads to the formation of the major (>10% AR) hydrolysis products IN-70941 and IN-70942. Cleavage of the sulfonylurea bridge to form IN-E9260 and IN-J290 was also observed but the amounts formed accounted for <10% AR.

IN-70941 hydrolysed readily in water at pH 7 and 25°C (single first order DT_{50} 8 days). Metabolites IN-70942 and IN-E9260 were stable to hydrolysis.

There was no evidence that rimsulfuron degraded photochemically at environmentally relevant pH. The photochemical degradation of the hydrolysis product IN-70942 was relatively rapid with a calculated single first order DT_{50} value of 3.3 days natural summer sunlight (39°N latitude) at pH 7 and 25°C.

The results of an OECD 301B ready biodegradability test indicated rimsulfuron should be classified as ‘not readily biodegradable’.

In the two aerobic water/sediment systems studied in the laboratory at 20°C (contrasting water pH of 4.3 and 6.7 with sediments, a clay loam OC 1.6% and a sand OC 3.4% respectively), rimsulfuron degraded relatively rapidly in both water and sediment. The single first order degradation DT_{50} of rimsulfuron in these systems was 1 and 7 days in the water-phase and 7 and 12 days in the sediment, respectively. In the water phase, only IN-70941 (75% AR) and IN-70942 (33% AR) were considered to be major (>10% AR) metabolites. The single first order degradation DT_{50} values were 9 and 31 days (IN-70941) and 27 and 22 days (IN-70942), respectively, in the water phase of the two systems. In the sediment phase, IN-70941, IN-70942 and IN-JF999 were the major metabolites with maximum amounts up to 18 % (IN 70941), 78 % (IN 70942), and 24 % (IN-JF999). The single first order degradation DT_{50} values determined for the metabolites in sediment were 19 and 45 days for IN-70941, 128 days for IN-70942 and 86 days for IN-JF999. The maximum amount of sediment residue that was not extracted by acetonitrile/aqueous ammonium acetate was up to 42 % AR in the 3.4% OC system and up to 10 % AR in the 1.6% OC system at the end of the study. IN-E9260 is considered to be only a minor metabolite in water sediment systems, with maximum rates of formation < 4.5 % and < 2.0 % AR in the water and sediment compartments, respectively. Volatiles were formed in small amounts up to 1 % AR at study termination *ca.* 100 days, indicating mineralization of the pyridine and pyrimidine radiolabels was negligible. Rimsulfuron PEC surface water and PEC sediment (initial) values to be used in the risk assessment of the representative uses were calculated and are contained in the endpoints (agreed by the EPCO experts’ meeting). This assessment only considered spray drift to a static 30cm deep water body. The drainage and runoff routes of exposure to surface water bodies have not been assessed. These routes of entry to surface water should be taken into account by MS when these routes of surface water exposure are relevant and the pertinent risk assessments to aquatic organisms should be completed.

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

Standard FOCUS groundwater modelling using FOCUS guidance for substance property input parameters assuming there was no correlation between soil adsorption and soil properties was presented in the addendum 3 to the draft assessment report of July 2003. (The modelling in the original draft assessment report was disregarded as FOCUS recommendations for normalising soil degradation rates to reference conditions had not been followed). The EPCO experts' meeting discussed the modelling presented in addendum 3 and the appropriate adsorption values to be used in leaching modelling. They concluded that there appeared for the metabolites IN-70941 and IN-E9260 to be a correlation between clay content and adsorption. As the FOCUS groundwater scenarios have soil profiles with low clay contents experts agreed that to represent a realistic worst case the mean adsorption value used as input to modelling should exclude the values from the clay soil. Therefore it was agreed that the arithmetic mean Kfoc values of 42L/kg (IN-70941) and 24L/kg (IN-E9260) were the most appropriate values to use as input to modelling. Consequently new FOCUS groundwater simulations were carried out and were assessed by the rapporteur in addendum 4 to the draft assessment report dated 20 April 2005. EFSA and the rapporteur Member State considers that the results of this modelling are appropriate for assessing the potential for shallow vulnerable groundwater exposure to rimsulfuron and its soil breakdown products resulting from the notified intended uses. When used in accordance with the notified GAP on maize, potato and tomato crops FOCUS PELMO 3.3.2 predicts that parent rimsulfuron, IN-70942 and IN-J290 will not leach from the top 1m of vulnerable soil profiles with annual average / biannual average concentrations as defined by FOCUS above 0.1µg/L (up to 0.069µg/L rimsulfuron, 0.063µg/L IN-J290 and 0.096µg/L IN-70942). These concentrations for IN-70941 are >0.75µg/L but <10µg/L (up to 0.85µg/L) and for IN-E9260 are >0.1µg/L but <0.75µg/L (up to 0.48µg/L). Consequently non relevance assessments were required for IN-70941 and IN-E9260 which confirmed that these metabolites are considered not relevant.

4.3. Fate and behaviour in air

The vapour pressure of rimsulfuron was 8.9 x 10^{-7} Pa (20 °C) and the calculated Henry's law constant was between 8.3 x 10^{-8} Pa m^3 mol^{-1} (pH 7, 25 °C) and 4.6 x 10^{-6} Pa m^3 mol^{-1} (pH 5, 25 °C). Due to the low vapour pressure a significant volatilisation of rimsulfuron is not expected. Volatilisation studies conducted with soil and bean leaves showed 0-2.2 % loss of the test substance from the soil system within 24 hours. A loss of 0.3 - 3.5 % could be observed from the bean leaves within 24 hours. The photo-oxidative degradation of rimsulfuron was calculated according to the Atkinson method to be 0.6 hours for reactions with average daily air concentrations of hydroxyl radicals (12 h day; 1.5 x 10^6 hydroxyl radicals per cm^3).

5. Ecotoxicology

Rimsulfuron was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 13) in September 2004.

5.1. Risk to terrestrial vertebrates

The risk to birds and mammals was calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). A medium herbivorous bird, a small insectivorous bird and a medium herbivorous mammal foraging in leafy crops were considered for the calculations. Secondary poisoning is not considered to be of concern for rimsulfuron since the potential for bioaccumulation is low (log Pow < 3).

All calculated first tier TER values for birds and mammals are well above the Annex VI trigger values and hence the acute, short and long term risk to birds as well as the acute and long term risk to other terrestrial vertebrates is considered as low.

5.2. RISK TO AQUATIC ORGANISMS

The aquatic macrophyte *Lemna gibba* was the most sensitive of the species tested with rimsulfuron (EC_{50} = 0.0046 mg/L for the active substance). Green and blue-green algae are less sensitive. The acute toxicity towards fish and daphnids is low. A chronic toxicity study with juvenile fish and an early life stage study with fish indicate that the long-term toxicity towards fish is low. The NOEC (reproduction) obtained in a chronic study with *Daphnia magna* is 1 mg/L. Rimsulfuron is not expected to partition into sediment and therefore no studies with sediment-dwelling organisms were required.

The predicted environmental concentration in surface water was calculated based on 2.77% spray drift to a 30 cm static water body at 1 m distance and 2 applications of 13.75 g a.s./ha (total 27.5 g/ha). All first tier TER values were calculated based on initial concentrations and found to be well above the relevant Annex VI trigger for fish, aquatic invertebrates and algae, hence indicating a low risk. Also for *Lemna gibba* the calculated TER was above the trigger (TER= 18.1). Calculations should have been based on 2.38 % drift per application, but since the presented PEC value is slightly more conservative and all TER values are above the trigger this has no impact on the conclusion.

Studies on *Lemna gibba* with the lead formulation Rimsulfuron 25 WG and Rimsulfuron 25 WG + IN-KG691 (surfactant) indicates that the formulation is not more toxic than the active substance alone.

Toxicity studies with fish, daphnids and algae are available for the metabolites IN-70941, IN-70942 and IN-E9260 (hydrolysis, photolysis and ground water metabolite) which indicate that these metabolites are not more acutely toxic than the parent substance. A study on *Lemna gibba* with the metabolite IN-70942 indicates that this metabolite is less toxic to aquatic plants than the parent substance. No studies with *Lemna* are available for the metabolites IN-70941 and IN-E9260. Since these two metabolites have the potential to contaminate vulnerable shallow ground water that may become surface water, at concentrations above those calculated for rimsulfuron in surface water, a risk assessment should be considered in MS with shallow ground water. However, data from screening studies indicate that these metabolites are not herbicidally active.

The metabolites IN-70942 and IN-JF 999 were detected in amounts >10% of applied radioactivity in the water/sediment studies and thus considered as major metabolites. Although not a formal data requirement, since the acute toxicity to *Daphnia* is > 0.1 mg/L (EC50 = 178 mg/L) for IN-70942, a data requirement was set for a study with sediment dwelling organisms at the Evaluation Meeting (12 March 2004). The metabolite IN-JF 999 is regarded as a degradation product of IN-70942 and therefore the toxicity of this metabolite is assessed in the study with IN-70942. A sediment spiked test with IN-70942 and *Chironomus riparius* was available for national authorisation. This study was evaluated by the RMS and the result and subsequent risk assessment shows that the risk to sediment dwelling organisms is low (TER > 300). Since only spray drift was considered for the exposure of surface water, the risk assessment should be completed taking into account other routes of exposure, such as drainage and run-off, at MS level if relevant.

5.3. RISK TO BEES

The available studies with rimsulfuron and the formulated products Rimsulfuron 25 WG and Rimsulfuron 25 WG + IN-KG691 surfactant indicate a low oral and contact toxicity to honeybees and the calculated HQ values were well below the Annex VI trigger. However due to incomplete dose consumption in the oral tests and uncoordinated movement seen in the contact test a semi-field test was proposed. A study was available for national authorisation and it was decided in the Evaluation Meeting that this study should be evaluated by the RMS. The results from a cage test where Rimsulfuron 25 WG (80 g/ha) and Rimsulfuron 25 WG + IN-KG691 surfactant (60 g/ha) were applied to flowering *Phacelia tanacetifolia* demonstrated that these products had no significant effects on honeybees.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Toxicity to non-target arthropods was low in glass plate studies with the two standard indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri*. Tests with the plant dwelling species *Chrysoperla carnea* (37.5 g a.s./ha) and the soil dwelling species *Aleochara bilineata* (1.1 and 27.5 g a.s./ha) showed no or low effects on mortality and fertility or parasitizing capacity. Hence the risk to non-target arthropods is considered low.

5.5. RISK TO EARTHWORMS

Acute toxicity studies with technical rimsulfuron and the formulated product Rimsulfuron 25 WG are available. The results indicate a low toxicity. The risk assessment was based on calculations of TER values using a maximum soil PEC of 0.03 mg a.s./kg. The resulting TER values are well above the Annex VI trigger indicating a low risk. Since rimsulfuron is not persistent in soil and the number of applications is less than 3 no studies on sublethal effects are required.

Three metabolites were detected at >10% of applied radioactivity in the aerobic soil degradation studies, IN-70941, IN-70942 and IN-E9260. The acute and reproductive effects of these three metabolites were tested in limit-tests at a concentration of 0.18 mg/kg soil, representing the maximum soil PEC for the main metabolite IN-70941. In the tests no effects were observed. In addendum 4 (20 April 2005) a revised long-term risk assessment for earthworms is presented. TER values were calculated using a 10-yr PEC for soil based on worst-case DT_{50} values and formation fractions. For

IN-70941 and IN-E9260 the resulting TER values are 13.2 and 9.2 respectively, indicating a low risk. For IN-70941 the TER is 4.5 and hence does not meet the Annex VI trigger value of 5. Due to the late submission of this addendum it was not peer reviewed by MS or discussed in an EPCO experts' meeting. The rapporteur MS considers the TER of 4.5 acceptable since no adverse effects were seen and the calculation is based on a 10-yr accumulated maximum PEC for soil based on worst-case DT_{50} values and formation fractions. However as discussed in section 4.1.2, whilst the PEC calculation is based on a worst case formation fraction it is not based on the worst case DT_{50} (it was the worst case laboratory DT_{50} but in a Danish field study a longer DT_{50} was calculated). The EFSA agrees with the conclusion that there is likely to be a low risk for earthworms in large areas of the EU. However Northern Member States may consider a risk assessment based on the DT_{50} and kinetic formation fraction calculated from the Danish field trial.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

Studies on reproduction effects with *Folsomia candida* (Collembola) are available for the soil metabolites IN-70941, IN-70942 and IN-E9260 at a maximum soil concentration of 0.183 mg/kg soil, and the results indicate a low risk. No litter bag test is available. The risk to soil macro-organisms was discussed at an EPCO experts' meeting and the meeting agreed that the risk is low based on a weight of evidence approach. No effects were observed in the studies on Collembola or earthworms with the three metabolites, and no significant effects were observed for soil microbial processes, hence indicating a low risk to different groups of soil organism.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of rimsulfuron in a 25% WG formulation, and the metabolites IN-70941 and IN-E9260 on soil carbon and nitrogen conversion were tested. No deviations of more than 25% after 28 days were observed. Hence the Annex VI trigger was met indicating a low risk.

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

The effect on seedling emergence was tested with technical rimsulfuron on eight species (*A. cepa, B. vulgaris, B.napus, C. sativus, G. max, P. sativum, S. bicolor and T. aestivum*) and vegetative vigour was tested with rimsulfuron plus a surfactant on the same species plus *L. esculentum* and *Z. mays*. The most sensitive species for emergence was *Brassica napus* (ER_{50} plant height = 0.69 g/ha) and the most sensitive species for vegetative vigour was *Sorghum bicolor* (ER_{50} total weight = 0.17 g/ha). Vegetative vigour was also assessed for *S. bicolor* with the 25 WG formulation. The ER_{50} for shoot weight was 4.89 g product/ha (1.22 g a.s./ha). In the DAR, TER values were calculated based on the lowest endpoints for the active substance and the formulation. PEC values were calculated from 2.77 and 0.57 % drift for 1 and 5 m respectively and a maximum application rate of 20 g a.s./ha in a single application. A high risk for non-target plants was identified. In an addendum of 20 April 2005 a revised risk assessment is presented taking into account two applications. Drift calculations for each single application was based on 82nd percentiles for 1 and 5 m respectively assuming no degradation between applications. The resulting TER values for both 1 and 5 m are below the trigger value of 5 mentioned in the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) for all representative uses if the endpoint for the active substance is used. For a buffer zone of 5 m the TER values based on the endpoint for the formulation are above the trigger.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

Data from a test with activated sludge are available and indicate that the risk to biological methods of sewage treatment plants is low.

6. Residue definitions

Soil

Definitions for risk assessment: rimsulfuron, IN-70941[9];IN-70942[10]; IN-E9260[11]

Definitions for monitoring: rimsulfuron

Water

Ground water

Definitions for exposure assessment: rimsulfuron, IN-70941, IN-E9260, IN-70942, INJ-290[12]

Definitions for monitoring: rimsulfuron

Surface water

Definitions for risk assessment:

surface water and sediment: rimsulfuron, IN-70941, IN-70942

surface water only: IN-E9260 (where surface water is fed by groundwater)

sediment only: IN-JF999[13]

Definitions for monitoring: rimsulfuron

Air

Definitions for risk assessment: rimsulfuron

Definitions for monitoring: rimsulfuron

Food of plant origin

Definitions for risk assessment: rimsulfuron

Definitions for monitoring: rimsulfuron

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[9] **IN-70941**: *N*-(4,6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsulfonyl)-2-pyridinyl]urea

[10] **IN-70942**: *N*-[3-(ethylsulfonyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimidinamine

[11] **IN-E9260**: 3-(ethylsulfonyl)-2-pyridinesulfonamide

[12] **INJ-290**: 4,6-dimethoxy-2-pyrimidinamine

[13] **IN-JF999**: 2-[[3-ethylsulfonyl)-2-pyridinyl]amino]-6-methoxy-4(1*H*)-pyrimidinone

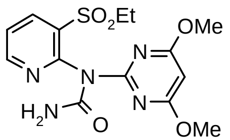
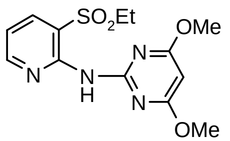
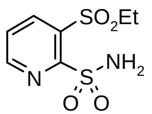
Food of animal origin

Definitions for risk assessment: no residue definition needed

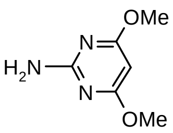
Definitions for monitoring: no residue definition needed

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
rimsulfuron	Moderately persistent ($DT_{50\ lab}$ = 25-40 d, 20°C, 40% MWHC); ($DT_{50\ field}$ = 6-18 d)	The risk to terrestrial vertebrates, earthworms, other soil macro-organisms and soil micro-organisms is low (see sections 5.1, 5.5, 5.6 and 5.7).
IN-70941 	Moderately to very highly persistent ($DT_{50\ lab}$ = 38-615 d, 20°C, 40% MWHC); ($DT_{50\ field}$ = 62-1100 d)	Less toxic than parent compound. The long-term risks to earthworms, *Collembola* and soil micro-organisms are considered low.
IN-70942 	High persistence ($DT_{50\ lab}$ = 101-214 d, 20°C, 40-50% MWHC); ($DT_{50\ field}$ = not possible to calculate due to low levels present)	Less toxic than parent compound. The long-term risks to earthworms, *Collembola* and soil micro-organisms are considered low.
IN-E9260 	Moderately to very highly persistent ($DT_{50\ lab}$ = 252-969 d, 20°C, 40-50% MWHC); ($DT_{50\ field}$ = 25-294 d)	Less toxic than parent compound. The long-term risks to earthworms, *Collembola* and soil micro-organisms are considered low.

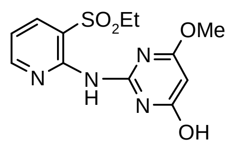
Ground water

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**
rimsulfuron	Very high to high mobility (Koc = 19-63L/kg)	FOCUS modelling: No	yes	yes	yes
IN-70942	medium mobility (Koc = 145-223L/kg)	FOCUS modelling: No	Against target plants, clearly less than 50% of the activity of the parent compound assessment not triggered	No data available assessment not triggered	Less toxic than parent compound assessment not triggered
IN-J290 	Very high mobility (Koc = [14]34L/kg)	FOCUS modelling: No, for maize and tomato, (less critical use on potato not assessed)	No data available assessment not triggered	No data available assessment not triggered	No data available assessment not triggered

[14] Estimated value calculated from log Kow.

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
IN-70941	Very high to high mobility (Koc = 34-116L/kg)	FOCUS modelling: yes. Maize and tomato all scenarios except 1, potato all scenarios except 3 >0.1 µg/l at 1st tier of assessment. Concentrations >0.75µg/L at 1 and 2 scenarios maize and tomato respectively.	Against target plants, clearly less than 50% of the activity of the parent compound	Not relevant; LD_{50}: ≥ 11000 mg/kg bw	Less toxic than parent compound, not considered relevant
IN-E9260	Very high to high mobility (Koc = 16-86L/kg)	FOCUS modelling: yes. Maize and tomato all scenarios except 1, potato all scenarios except 2 >0.1 µg/l at 1st tier of assessment. Concentrations<0.75µg/L at all scenarios.	Against target plants, clearly less than 50% of the activity of the parent compound	Not relevant; LD_{50}: ≥ 2000 mg/kg bw	Less toxic than parent compound, not considered relevant

Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
rimsulfuron	Risks to aquatic organisms are low (see section 5.2).
IN-70941	Less toxic than parent compound. Risk is low.
IN-70942	Less toxic than parent compound. Risk is low.
IN-JF999 	Less toxic than parent compound. Risk is low.
IN-E9260 (groundwater becoming surface water)	Less toxic than parent compound. Risk is low. No data on toxicity to aquatic macrophytes are available but screening data indicates no herbicidal activity.

Air

Compound (name and/or code)	**Toxicology**
rimsulfuron	Not acutely toxic via inhalation (see section 2.2). No data available for short term toxicity.

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

- None

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as herbicide as proposed by the notifier which comprises spraying to control broad-leaved and grass weeds at application rates up 20 g rimsulfuron per hectare in maize and potatoes and up to 27.5 g per hectare in tomatoes. Rimsulfuron can be used only as herbicide.
The representative formulated product for the evaluation was "Rimsulfuron 25 WG", water dispersible granules (WG), registered under different trade names in Europe.

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

Rimsulfuron is moderately orally adsorbed (and quickly excreted). There is no potential for accumulation.
The metabolic degradation of rimsulfuron in rat occurs primarily via contraction of the sulfonylurea bridge:
Rimsulfuron has a low acute toxicity and is not a skin or eye irritant, nor a skin sensitiser, even if it has to be noted that the EPCO experts' meeting concluded that the skin sensitisation study (Armondi, 1990) reported in the DAR is not optimal even if acceptable. **No classification for acute toxicity is needed.**
Main target organs were liver (increase of weight, minor histopathological changes) and kidney (increased weight). In dogs, testes, epidydimes and trachea are also target organs. The relevant oral NOAEL for short term toxicity is 9.63 mg/kg bw/d (90-d dog study).
There is no evidence from the available studies of a mutagenic, genotoxic and carcinogenic potential of rimsulfuron.
The relevant NOAEL for long term toxicity is 11.8 mg/kg bw/d from the 2-year rat study.
Rimsulfuron did not show any adverse effects on reproductive parameters. The NOAEL for reproductive toxicity is 165 mg/kg bw/day.
Rimsulfuron was not teratogenic in the developmental studies with rats and rabbits. The relevant maternal NOAEL is 170 mg/kg bw/day and the developmental NOAEL is 500 mg/kg bw/day.

No sign of neurotoxicity was observed in any test.

Supplementary studies were conducted with two major metabolites: IN-70941 and IN-E9260. They showed low acute toxicity. None of them was found to have a genotoxic potential. In the EPCO experts' meeting it was agreed that the two metabolites are not relevant.

The proposed ADI is 0.1 mg/kg bw/day based on the NOAEL from the 2-year study in rat of 11.8 mg/kg bw/d with a safety factor of 100.

The proposed AOEL is 0.07 mg/kg bw/day based on the NOAEL of the 90-day dog and supported by the 1-year dog study by applying a standard safety factor of 100. An additional correction factor of 0.7 was applied due to the oral absorption of 70%.

From the evaluation of the available toxicological database of rimsulfuron, it was agreed there is no need to establish an ARfD.

No studies on dermal absorption are available for rimsulfuron. A default value of 70% was agreed based on physical-chemical properties and accounting for oral absorption.

The estimated operator exposure is below the AOEL without PPE, according to German model. According to calculations with UK POEM, gloves have to be used during mixing and loading (M/L) in order to be below the AOEL.

The estimated worker and bystander exposure is below the proposed systemic AOEL

Rimsulfuron is rapidly metabolised in maize, potatoes and tomatoes through two degradation pathways starting with either cleavage or contraction of the sulfonylurea bridge of the molecule. Its metabolism is similar to that found in rat and none of its metabolites is of any concern. The residue definition for plant products should be rimsulfuron for monitoring and risk assessment purposes. Supervised residue trials according to the recommended use demonstrate that residues are below the LOQ in maize grains and forage, potatoes as well as in tomatoes. No residue is to be expected in rotational and succeeding crops.

Human and animal exposures to residues of rimsulfuron are therefore minimal, and no risk for consumers has been identified.

The information on fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment. The major soil metabolites IN-70941 and IN-E9260 are persistent, were detected in field studies and have the potential to accumulate in soil is situations like maize cropping when applications can be made in consecutive seasons. Accumulated maximum exposure concentrations have been calculated. FOCUS groundwater modelling identified that these 2 metabolites have the potential to contaminate vulnerable shallow groundwater at annual average concentrations >0.1µg/L, (maize 7 out of 8, potato 7 out of 9 and tomato 4 out of 5 FOCUS scenarios) with these concentrations for IN-70941 potentially being > 0.75µg/L (maize 1 scenario, tomato 2 scenarios).

The risk to terrestrial vertebrates, aquatic organisms, bees, non-target arthropods, soil macro-organisms including earthworms and springtails and soil micro-organisms is low with respect to rimsulfuron and the metabolites IN 70941, IN 70 942, IN E9260 and JF 999. A risk was identified for non-target terrestrial plants and risk mitigation measures need to be considered.

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

- Possible classification of the PPP can be taken into consideration at MS level, based on the skin sensitisation issue
- Appropriate risk mitigation measures are required with regard to the risk to terrestrial plants. A 5 m buffer zone or drift reducing measures are needed.

Critical areas of concern

- A high risk to non-target plants outside the field was identified. A 5 m buffer zone or drift reducing measures are comparable to this is needed.

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

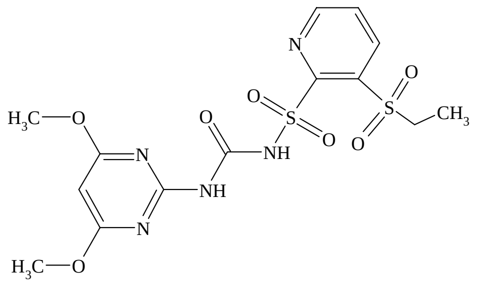
(Abbreviations used in this list are explained in appendix 2)

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

Active substance (ISO Common Name) ‡	Rimsulfuron (ISO, approved)
Function (e.g. fungicide)	herbicide

Rapporteur Member State	Germany
Co-rapporteur Member State	--

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
Chemical name (CA) ‡	N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide
CIPAC No ‡	716
CAS No ‡	122931-48-0
EEC No (EINECS or ELINCS) ‡	none
FAO Specification ‡ (including year of publication)	–
Minimum purity of the active substance as manufactured ‡ (g/kg)	960
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	–
Molecular formula ‡	C14H17N5O7S2
Molecular mass ‡	431.45 g/mol
Structural formula ‡	

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

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	172-173 °C (98.8 %)
Boiling point (state purity) ‡	–
Temperature of decomposition	> 174 °C (DSC)
Appearance (state purity) ‡	white crystalline solid (98 and 98.8%)
Relative density (state purity) ‡	1.5032 ± 0.0016 (20.3 ± 0.1 °C) (98.8 %)
Surface tension	72.1 ± 0.2 mN/m (20.1 ± 0.1 °C) (0.987 g/L, pH 7)
Vapour pressure (in Pa, state temperature) ‡	8.9 x 10^{-7} Pa (20 °C)
Henry's law constant (Pa m^3 mol^{-1}) ‡	4.6 x 10^{-6} Pa m^3 mol^{-1} (pH 5, 25 °C) 8,3 x 10^{-8} Pa m^3 mol^{-1} (pH 7, 25 °C) 1.1 x 10^{-7} Pa m^3 mol^{-1} (pH 9, 25 °C)
Solubility in water ‡ (g/l or mg/l, state temperature)	pH 5: 0.135 g/L pH 7: 7.3 g/L
	pH 9: 5.56 g/L (all at 25 °C) (99.0 %) 23.5 mg/L (20 °C) (98.9 %) (non buffered HPLC grade water)
Solubility in organic solvents ‡ (in g/l or mg/l, state temperature)	Acetone 14.8 g/L Acetonitrile 17.2 g/L Dichloromethane 35.5 g/L N,N-Dimethylformamide 241 g/L Dimethylsulfoxide 113 g/L Ethylacetate 2.85 g/L *n*-Hexane < 0.01 g/L Methanol 1.55 g/L Toluene 0.363 g/L *o*-Xylene 0.093 g/L
Partition co-efficient (log POW) ‡ (state pH and temperature)	pH 5: 0.288 pH 7: - 1.46 (all at 25 °C)
Hydrolytic stability (DT50) ‡ (state pH and temperature)	pH 5 (25 °C): rimsulfuron: 4.7 d (Pyridine), 4.5 d (Pyrimidine) IN-70941: 144 d, IN-70942: stable, IN-E9260: stable
	pH 7 (25 °C): rimsulfuron: 7.3 d (Pyridine), 7.1 d (Pyrimidine) IN-70941: 8 d, IN-70942: stable, IN-E9260: stable

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

	pH 9 (25 °C): rimsulfuron: 4.2 h (Pyridine), 10.9 h (Pyrimidine) IN-70941: 2 h, IN-70942: stable, IN-E9260: stable
Dissociation constant ‡	pK_a: 4.0
UV/VIS absorption (max.) ‡ (if absorption > 290 nm state ε at wavelength)	λ_{max} [nm] ε pH 1.8 230 $1.78 \cdot 10^4$ 290 $1.81 \cdot 10^2$ pH 2.1 290 $2.03 \cdot 10^2$ pH 5.0 240 $2.24 \cdot 10^4$ 290 $4.81 \cdot 10^2$
Photostability (DT50) ‡ (aqueous, sunlight, state pH)	Rimsulfuron (25 °C, natural sunlight: 39° 40’ N): pH 5: 1.1 d, pH 7: 11.7 d, pH 9: 11.1 h IN-70942: 1.1 d (pH 7, xenon lamp > 290 nm), IN-E9260: stable (estimated from studies with as)
Quantum yield of direct phototransformation in water at Σ > 290 nm ‡	Rimsulfuron: Φ = 0.0047 IN-70942: Φ = 0.00072
Flammability ‡	None
Explosive properties ‡	None

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

List 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)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of g as/kg (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	g as/ha min max		
Maize	Northern Europe Southern Europe	Rimsulfuron 25 WG	F	Broadleaved weeds (BLW), grasses	WG	250	Hydraulic sprayer overall	Up to GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	150-500	5.0 –20.0 (total 20.0)	None	+ non-ionic surfactant at 0.1 % Application information covers worst case use in EU. Max rate and latest timing vary between countries
Potato	Northern Europe Southern Europe	Rimsulfuron 25 WG	F	Broadleaved weeds (BLW), grasses	WG	250	Hydraulic sprayer overall	GS 30 (before closing of the rows) Spring	1-2 splitting	4-5 days	N/A	150-400	5.0 –20.0 (total 20.0)	None	
Tomato	Southern Europe	Rimsulfuron 25 WG	F	Broadleaved weeds (BLW), grasses	WG	250	Hydraulic sprayer overall	GS 18 (8 leaves) Spring	1-2 splitting	7 days	N/A	200-500	7.5 – 15 (total 27.5)	None	

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/L
			(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)		
	(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

‡ 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 (principle of method)	HPLC-UV
Impurities in technical as (principle of method)	HPLC-UV; GC-FID
Plant protection product (principle of method)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-UV 0.05 mg/kg (maize, potato, tomato) LC-MS/MS 0.01 mg/kg (maize, potato, tomato)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant, no residue definition is proposed
Soil (principle of method and LOQ)	LC-MS/MS 0.2 µg/kg
Water (principle of method and LOQ)	HPLC-UV 0.1 µg/L LC-MS/MS 0.05 µg/L (drinking- and surface water)
Air (principle of method and LOQ)	LC-MS/MS 3 µg/m^3
Body fluids and tissues (principle of method and LOQ)	Not relevant, the active substance is not classified as toxic or very toxic

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical/chemical data	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 in mammals (Annex IIA, point 5.1)

Rate and extent of absorption ‡	Approximately 70 %, based on urinary excretion
Distribution ‡	Widely distributed, highest residues in blood, skin, liver and kidneys
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	92 - 95 % within 72 hours, approximately two third of the dose in urine and one third in faeces
Metabolism in animals ‡	More than 50 % of residues in urine and faeces were unmetabolised parent substance, 5 metabolites identified
Toxicologically significant compounds ‡ (animals, plants and environment)	Rimsulfuron. The metabolites IN-E9260 and IN-70941 are not considered toxicologically relevant.

Acute toxicity (Annex IIA, point 5.2)

Rat LD50 oral ‡	> 5000 mg/kg bw
Rat LD50 dermal ‡	> 2000 mg/kg bw
Rat LC50 inhalation ‡	> 5.4 mg/L (nose only, 4 h)
Skin irritation ‡	Non irritant
Eye irritation ‡	Non irritant
Skin sensitization ‡ (test method used and result)	Not a skin sensitiser (M & K test*)

* According to the EPCO 14 meeting the study was "not optimal" (25 % concentration during induction phase). However, to repeat the study was not necessary

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Body weight gain, liver, kidney
Lowest relevant oral NOAEL / NOEL ‡	Dog, combined 90-day and 1-year: 9.63 mg/kg bw/d
Lowest relevant dermal NOAEL / NOEL ‡	No studies submitted
Lowest relevant inhalation NOAEL / NOEL ‡	No studies submitted, not required

Genotoxicity ‡ (Annex IIA, point 5.4)

....	No evidence of genotoxicity

‡ 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 ‡	Body weight gain, liver
Lowest relevant NOAEL / NOEL ‡	Rat, 2-yr: 11.8 mg/kg bw/d
Carcinogenicity ‡	No evidence of carcinogenicity

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	No reproduction effects, NOAEL is based on reduced body weight of F2 pups at parental toxic dose
Lowest relevant reproductive NOAEL / NOEL ‡	165 mg/kg bw/d
Developmental target / critical effect ‡	No developmental effects observed
Lowest relevant developmental NOAEL / NOEL ‡	Maternal (rabbit): 170 mg/kg bw/day Developmental (rabbit): 500 mg/kg bw/d

Neurotoxicity / Delayed neurotoxicity ‡ (Annex IIA, point 5.7)

....	No evidence of neurotoxic effects in subchronic and chronic studies, no study on delayed neurotoxicity required

Other toxicological studies ‡ (Annex IIA, point 5.8)

Studies on metabolites IN-E9260 and IN-70941	**IN-E9260**: LD_{50}, rat, oral: ≥ 2000 mg/kg bw/d LD_{50}, rat, dermal: ≥ 2000 mg/kg bw/d Skin and eye irritation: non irritant Skin sensitisation (M&K): not sensitising NOAEL 4-week rat, oral: < 50 mg/kg bw/d Genotoxicity: In vitro gene mutation (S. typh.): negative In vitro chromosome aberration: negative **IN-70941**: Approximate Lethal Dose, male rat, oral: ≥ 11000 mg/kg bw/d 10-day oral test, rats; NOEL < 2200 mg/kg bw/d (the only tested dose) Genotoxicity: In vitro gene mutation: (S. typh.): negative

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

	In vitro gene mutation: (mammalian cells): negative In-vitro chromosome aberration: negative

Medical data ‡ (Annex IIA, point 5.9)

....	No reported accidental poisonings with rimsulfuron. Clinical studies with employees of the chemical production did not show toxic effects.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.1 mg/kg bw	Rat 2-year oral	100
AOEL ‡	0.07 mg/kg bw	Dog 90-day combined 90-day and 1-year oral feed, corrected for 70 % oral absorption	143*
ARfD ‡ (acute reference dose)	Not allocated	Not necessary, no acute toxic alerts	

* Correction for low oral absorption (70%)

Dermal absorption (Annex IIIA, point 7.3)

Rimsulfuron 25 WG	70 % default value

Acceptable exposure scenarios (including method of calculation)

Operator	Operator exposure below systemic AOEL; German model without PPE (23%), UK-POEM with gloves during M/L (95.6%)
Workers	Worker exposure below the AOEL, even with no PPE
Bystanders	Bystander exposure negligible

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	No classification and labelling required.

‡ 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), root vegetables (potato), fruits (tomato)
Rotational crops	Lettuce, soybeans, sugarbeets, sunflower, sorghum, and wheat
Plant residue definition for monitoring	Rimsulfuron
Plant residue definition for risk assessment	Rimsulfuron
Conversion factor (monitoring to risk assessment)	No

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

Animals covered	Goat, hen
Animal residue definition for monitoring	None (study not required)
Animal residue definition for risk assessment	None (study not required)
Conversion factor (monitoring to risk assessment)	None (study not required)
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)

....	Total [14C] residues in food items from lettuce, sugarbeets, sunflower, soybeans, sorghum and wheat, grown in soil treated with [^{14}C] rimsulfuron at the rate of 52 g as/ha (~2X the maximum recommended label use rate) and aged for either 30 days, 120 days or 10 months prior to the planting, were below the LOQ of 0.05 mg/kg.

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

....	Rimsulfuron is stable in maize forage and grain, potato, and tomato for 24, 24, and 6 months, respectively, when stored frozen at approximately –20 °C.

‡ 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)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle Liver Kidney Fat Milk Eggs	No studies conducted / required since no residues (<0.05 mg/kg) were detected in any crops of concern intended for feeding of domestic animals.		

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

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP [mg/kg] (a)	Recommendation/ comments	MRL [mg/kg]	STMR (b)
Maize grain	N-EU	14 x < 0.05		< 0.05	0
	S-EU	10 x < 0.05		< 0.05	0
Maize forage	N-EU	14 x < 0.05			
	S-EU	6 x < 0.05			
Potato tuber	N-EU	12 x < 0.05		< 0.05	0
	S-EU	5 x < 0.05		< 0.05	0
Tomato fruit	S-EU	10 x < 0.05		< 0.05	0

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

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

ADI	0.1 mg/kg bw/d
TMDI (European Diet) (% ADI)	< 0.001 mg/kg bw (< 1.0 %)
TMDI (German Diet, 4-6 year old girl) (% ADI)	< 0.001 mg/kg bw (< 1.0 %)
NEDI (% ADI)	Not calculated
Factors included in NEDI	Not applicable
ARfD	Not allocated
Acute exposure (% ARfD)	Not applicable

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

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

Crop/processed crop	Number of studies	Transfer factor	% Transference *
No study conducted / required since residue levels are < 0.1 mg/kg			

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

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

Tomato	0.05* mg/kg
Potato	0.05* mg/kg
Maize	0.05* mg/kg

*) LOQ

‡ 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 ‡	0.1 % 90 d (Pyridine), n=1 0.3 % 90 d (Pyrimidine)
Non-extractable residues after 100 days ‡	21.3 % after 90 d (Pyridine), n=1 22.1 % after 90 d (Pyrimidine)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum)	**IN-70941**: 53.7 % (60 d, Pyridine), 54.5 % (60 d, Pyrimidine) n=1 **IN-70942**: 20.2 % (360 d, Pyridine), 23.5 % (360 d, Pyrimidine) n=1 **IN-E9260**: 18.9 % (180 d, Pyridine) n=1

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

Anaerobic degradation ‡	CO_2: < 0.1 % 60 d (Pyridine), 0.3 - 1.5 % (Pyrimidine) NER: 17.6 % 60 d (Pyridine), 25.2 % 60 d (Pyrimidine) Min. / max. / 360 d **IN-70941**: 2.5 % / 53.7 % / 31.9 % (Pyridine), 7.1 % / 54.5 % / 30.2 % (Pyrimidine) **IN-70942**: 0.7 % / 20.2 % / 47.0 % (Pyridine) 0.6 % / 23.5 % / 55.9 % (Pyrimidine) **IN-E9260**: 6.8 % / 18.9 % / 22.7 % (Pyridine)
Soil photolysis ‡	CO_2: < 0.6 % 27 d (Pyridine), 0.3 % 27 d (Pyrimidine) NER: 6.1 % 27 d (Pyridine), 7.2 % 27 d (Pyrimidine) **IN-70941**: 42.4 % (Pyridine), 34.4 % (Pyrimidine) dark control: 63.2 % (Pyridine), 73.6 % (Pyrimidine) **IN-70942**: 3.2 % (Pyridine), 5.1 % (Pyrimidine) dark control: 10.6 % (Pyridine), 8.6 % (Pyrimidine) **IN-E9260**: 16.1 % (Pyridine) dark control: 12.6 % (Pyridine) **IN-J290**: 12.7 % (Pyrimidine) dark control: 4.0 % (Pyrimidine)

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

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

Method of calculation	Rimsulfuron: linear first-order regression, metabolites: non-linear first-order regression
Laboratory studies ‡ (range or median, with n value, with r^2 value)	**Rimsulfuron** MWHC % OC pH DT_{50}(d) r^2 DT_{50lab} (25 °C, aerobic): sandy loam 75 % 0.6 6.7 21.3 0.87[1]/ 0.94[2] DT_{50lab} (20 °C, aerobic): loamy sand 40 % 2.3 5.6 30 0.977 sandy loam 40 % 5.4 6.7 40 0.927 loamy sand 40 % 2.4 7.0 25 0.977 " 60 % " " 5 0.982 **IN-70941** MWHC % OC pH DT_{50}(d) r^2 sandy loam 40-50 % 1.2 5.4 359 0.913 clay 40-50 % 1.6 7.9 38 0.982 sandy loam 40-50 % 1.1 5.8 615 0.722 **IN-70942** MWHC % OC pH DT_{50}(d) r^2 sandy loam 40-50 % 1.2 5.4 214 0.928 clay 40-50 % 1.6 7.9 101 0.831 sandy loam 40-50 % 1.1 5.8 116 0.956 **IN-E9260** MWHC % OC pH DT_{50}(d) r^2 sandy loam 40-50 % 1.2 5.4 744 0.814 clay 40-50 % 1.6 7.9 252 0.710 sandy loam 40-50 % 1.1 5.8 969 0.337
	DT_{90lab} (20 °C, 40 % MWHC, aerobic): **rimsulfuron:** 71-134 d, mean: 97 d , r^2: 0.87-0.98
	DT_{50lab} (10 °C, aerobic): **rimsulfuron** MWHC % OC pH DT_{50}(d) r^2 loamy sand 40 % 2.3 5.6 77 0.865

[1] Pyridine
[2] Pyrimidine

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

	DT_{50lab} (25 °C, anaerobic): **rimsulfuron** % OC / pH / DT_{50} (d) / r^2 sandy loam: 0.6 / 6.7 / 18.1[1]/17.9[2] / 0.99[1]/0.91[2] DT_{50lab} (25 °C, soil photolysis): **rimsulfuron** % OC / pH / DT_{50} (d) / r^2 sandy loam (irrad.): 0.6 / 6.7 / 12[1]/11[2] / 0.95[1]/0.93[2] sandy loam (dark): 0.6 / 6.7 / 11[1]/12[2] / 0.95[1]/0.93[2]
	degradation in the saturated zone: not required
Field studies ‡ (state location, range or median with n value)	DT_{50f}:

Rimsulfuron	% OC	pH	DT_{50} (d)	r^2
Greenv. (MS, USA)	0.75	7.0	7.9[1]-9.6[2]	0.88[2]/0.96[1]
Madera (CA, USA)	0.70	7.7	8.0[1]-8.2[2]	0.99[1]/0.99[2]
Rochelle (IL, USA)	2.61	7.8	15.9[2]-17.7[1]	0.94[2]/0.95[1]
Palafolls (ES)	0.8	6.7	5.6	0.95
Lindenh. (DE)	1.1	6.5	10	0.94
Middelf. (DK)	1.1	6.6	14	0.95

IN-70941	% OC	pH	DT_{50} (d)	r^2
Palafolls (Spain)	0.8	6.7	435	0.95
Lindenh. (DE)	1.1	6.5	62	0.94
Middelf. (DK)	1.1	6.6	1100	0.95

IN-E9260	% OC	pH	DT_{50} (d)	r^2
Palafolls (ES)	0.8	6.7	294	0.96
Lindenh. (DE)	1.1	6.5	25	0.97
Middelf. (DK)	1.1	6.6	82	0.98

[1] Pyridine
[2] Pyrimidine

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

	$DT_{90f.}$: **Rimsulfuron** US field studies: range: 26.2-58.8 d, r^2: 0.88-0.99 (n = 3) S-Europe: 19 d, r^2: 0.95 (n = 1) N-Europe: 33 and 46 d, r^2: 0.94 and 0.96 (n = 2)
Soil accumulation and plateau concentration ‡	Calculation of maximum accumulated PEC_{soil} according to the principles of FOCUS Kinetics with mass kinetic formation fractions (from parent to IN-70941=0.485, from IN-70941 to IN-70942=0.883 and parent to IN-E9260=0.104) calculated from the single radiolabelled parent laboratory route of degradation study (parent degradation rate normalised to 20°C from this study) and metabolite DT_{50} used in calculations being the longest lab DT_{50} from lab studies where the metabolite was dosed, 15% crop interception assumed.

		maize (1 × 20 g as/ha)	tomato (2x13.75 g as/ha)
IN-70941	10 yr	0.0341mg/kg	0.0404mg/kg
IN-70942	10 yr	0.0111mg/kg	0.0136mg/kg
IN-E9260	30 yr	0.0160mg/kg	0.0196mg/kg

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡

Rimsulfuron	% OC	pH	K_f	K_{foc}	1/n
Sandy loam	1.2	6.5	0.23	18.9	0.90
Clay loam	2.5	7.7	1.40	54.4	0.97
Sandy loam	0.6	6.3	0.35	50.1	1.22
Silt loam	2.5	5.4	1.58	62.8	0.99

IN-70941	% OC	pH	K_f	K_{foc}	1/n
Sandy loam	1.2	5.4	0.47	39	0.96
Clay	1.6	7.9	1.85	116	0.94
Sandy loam	1.1	5.8	0.37	34	0.92
Sandy loam	0.5	6.3	0.27	54	0.92

IN-70942	% OC	pH	K_f	K_{foc}	1/n
Sandy loam	1.2	5.4	2.68	223	0.84
Clay	1.6	7.9	3.12	195	0.85
Sandy loam	1.1	5.8	1.59	145	0.84
Sandy loam	0.5	6.3	1.07	214	0.85

IN-E9260	% OC	pH	K_f	K_{foc}	1/n
Sandy loam	1.2	5.4	0.27	23	1.08
Clay	1.6	7.9	1.37	86	0.96
Sandy loam	1.1	5.8	0.18	16	0.99
Sandy loam	0.5	6.3	0.17	34	0.93

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

K_d ‡	not required, see Freundlich coefficients above
pH dependence ‡ (yes / no) (if yes type of dependence)	Rimsulfuron: no IN-70941, IN-70942, IN-E9260: no

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

Column leaching ‡	Radioactivity in leachate [%]: ^{14}C rimsulfuron IN-70942 IN-70941 soil 1 97.9[1]/70.7[2] 50.7[1]/60.4[2] 27.5[1]/6.4[2] 5.7[1]/0.9[2] soil 2 89.6[1]/57.3[2] 49.9[1]/45.1[2] 6.9[1]/6.1[2] 2.8[1]/2.6[2] soil 3 76.0[1]/62.0[2] 5.8[1]/ n.d.[2] 3.0[1]/n.d.[2] 60.8[1]/59.8[2] soil 4 89.5[1]/79.5[2] 61.3[1]/54.0[2] 11.8[1]/10.3[2] 11.4[1]/14.1[2] **IN-9260**: 1.6 – 3.5 % in leachate (Pyridine) soil 1 (Speyer 2.1): Sand, 0.7 % C_{org}, pH 6.1 soil 2 (Speyer 2.2): Loamy Sand, 2.3 % C_{org}, pH 6.3 soil 3 (Speyer 2.3): Sandy Loam, 1.3 % C_{org}, pH 6.7 soil 4 (Sassafras): Sandy Loam, 1.3 % C_{org}, pH 6.2
Aged residues leaching ‡	30 days ageing (20 °C, 40 % MWHC, dark), radio-activity in leachate in soil 1 [%]: ^{14}C rimsulfuron IN-70942 IN-70941 IN-E9260 41.7[1]/29.1[2] 5.7[1]/3.0[2] 16.2[1]/ 7.4[2] 11.6[1]/18.7[2] 7.2[1]/n.d.
Lysimeter/ field leaching studies ‡	No data provided, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	1[st] order calculation, $DT_{50,field}$: rimsulfuron: 9.8 d, metabolites calculated accumulated values from laboratory studies (see Soil accumulation and plateau concentration above) 5 cm soil layer, 1.5 kg/L bulk density
Application rate	2 x 13.75 g as/ha with a 7-day interval (parent no interception, metabolites 15% crop interception)

[1] Pyridine
[2] Pyrimidine

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

PEC(s)		**rimsulfuron**: Multiple application Actual (µg/kg)	**rimsulfuron**: Multiple application Time weighted average (µg/kg)
Initial		29.5	29.5
Short term	24 h	27.5	28.5
	2 d	25.6	27.5
	4 d	22.2	25.7
Long term	7 d	18.0	23.3
	28 d	4.1	12.8
	50 d	0.9	8.1
	100 d	< 0.001	4.2

PEC(s)	**IN-70941**: Multiple application Actual (µg/kg)	**IN-70942**: Multiple application Actual (µg/kg)	**IN-E9260**: Multiple application Actual (µg/kg)
Maximum accumulated	40.4	13.6	19.6

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	pH 5 (25 °C): DT_{50}: **rimsulfuron**: 4.7 d (Pyridine), 4.5 d (Pyrimidine) IN-70941: 144 d, IN-70942: stable, IN-E9260: stable **IN-70941**: max. 74.4 % (Pyridine & Pyrimidine) **IN-70942**: max. 12.5 %(Pyridine), 13.0 % (Pyrimidine) **IN-E9260**: 9.3 % (Pyridine)
	pH 7: **rimsulfuron**: 7.3 d (Pyridine), 7.1 d (Pyrimidine) **IN-70941**: 8 d, IN-70942: stable, IN-E9260: stable **IN-70941**: max. 13.3 % (Pyridine), 16.9 % (Pyrimidine) **IN-70942**: max. 81.2 %(Pyridine), 83.8 % (Pyrimidine) **IN-E9260**: 9.9 % (Pyridine)

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

	pH 9: rimsulfuron: 4.2 h (Pyridine), 10.9 h (Pyrimidine) **IN-70941**: 2 h, IN-70942: stable, IN-E9260: stable **IN-70941**: max. 12.5 % (Pyridine), 12.8 % (Pyrimidine) **IN-70942**: max. 90.7 %(Pyridine), 59.8 % (Pyrimidine) **IN-E9260**: < 2.8 % (Pyridine)
Photolytic degradation of active substance and relevant metabolites ‡	**Rimsulfuron** (25 °C, natural sunlight: 39° 40' N): pH 5: 1.1 d, pH 7: 11.7 d, pH 9: 11.1 h **IN-70942**: 1.1 d* (pH 7, xenon lamp > 290 nm), *equivalent to 3.3 d natural sunlight (39° 40' N) **IN-E9260**: stable (estimated from studies with as) **IN-70941**: 25.5 % (Pyridine), 23.6 % (Pyrimidine) **IN-70942**: 9.8 % (Pyridine), 6.9 % (Pyrimidine) **IN-E9260**: 16.2 % (Pyridine) **IN-J290**: 19.1 % (Pyrimidine)
Readily biodegradable (yes/no)	No
Degradation in water/sediment - DT_{50} water ‡	Blackiston / Mills Lawn **rimsulfuron** 1 d / 7 d (1st order) **IN-70941** 9 d / 31 d (1st order) **IN-70942** 27 d / 22 d (1st order)
- DT_{90} water ‡	Blackiston / Mills Lawn **rimsulfuron** 3 d / 26 d (1st order)
- DT_{50} whole system ‡	Blackiston / Mills Lawn **rimsulfuron** 1 d / 11 d (1st order) **IN-70941** 12 d / 28 d (1st order) **IN-70942** n. c. / 107 d (1st order)
- DT_{90} whole system ‡	Blackiston / Mills Lawn **rimsulfuron** 3 d / 35 d (1st order)
Mineralization	0.3 % - 1 % after 100 days
Non-extractable residues	Maximum amounts: Blackiston: 9.8 %/63 d (Pyrid.), 13.5 %/28 d (Pyrim.) Mills Lawn: 33.8 %/99 d (Pyrid.), 42.3 %/99 d (Pyrim.)

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

Distribution in water / sediment systems (active substance) ‡	Pyridine	Blackiston	Mills Lawn
	Total	90.8 - 1.4 %	90.9 - 0.6 %
	Water	88.4 - 0.1 %	86.7 - < 0.1%
	Sediment	2.4–0.9 % (0/63 d)	12.6-0.5 % (14/65 d)
	Pyrimidine	Blackiston	Mills Lawn
	Total	86.2 – 1.8 %	82.3 – 0.5 %
	Water	82.0 – 0.1 %	78.1 – < 0.1 %
	Sediment	4.2-0.5 % (0/7 d)	10.6-0.5 % (7/99 d)
Distribution in water / sediment systems (metabolites) ‡	Maximum amounts:		
	IN-70941	Blackiston	Mills Lawn
	Total	87.2[1]/85.7[2] %	18.8[1]/30.2[2] %
	Water	69.6[1]/74.9[2] % (7/3 d)	11.7[1]/17.2[2] % (7/28 d)
	Sediment	17.5[1]/12.8[2] % (7 d)	7.6[1]/13.0[2] % (14/28 d)
	IN-70942	Blackiston	Mills Lawn
	Total	79.1[1]/77.9[2] %	36.4[1]/32.4[2] %
	Water	29.5[1]/33.5[2] % (14 d)	12.8[1]/16.6[2] % (14 d)
	Sediment	78.0[1]/68.1[2] % (100 d)	25.3[1]/18.7[2] % (42/65 d)
	IN-JF999	Blackiston	Mills Lawn
	Total	3.5[1]/6.2[2] %	20.0[1]/24.5[2] %
	Water	0.1[1]/0.8[2] % (100/28 d)	1.2[1]/0.8[2] % (28/7 d)
	Sediment	3.5[1]/5.6[2]% (63 d)	19.5[1]/24.1[2] % (65 d)
	IN-E9260 was < 6 % in both whole test systems		

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

Parent

Method of calculation	30 cm static water body initial PECsw only Maximum fraction of metabolites formed in water: IN-70941: 75 %, IN-70942: 33.5 %, IN-JF999: 1 %
Application rate	two applications of 13.75 g as/ha (sum 27.5 g as/ha)
Main routes of entry	2.77 % drift (1 m buffer), 90th percentile

$PEC_{(sw)}$	**rimsulfuron**: Multiple application (µg/L)	**IN-70941**: Multiple application (µg/L)	**IN-70942**: Multiple application (µg/L)	**IN-JF999**: Multiple application (µg/L)
Initial	0.254	0.162	0.064	0.002

[1] Pyridine
[2] Pyrimidine

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

PEC (sediment)

Method of calculation	Maximum fraction of metabolites formed in sediment: rimsulfuron: 13 %, IN-70941: 13 %, IN-70942: 78 %, IN-JF999: 24 %, DT_{50} values of total system: rimsulfuron: 6 d, IN-70941: 19.5 d, IN-70942: 102 d, IN-JF999: 86 d 5 cm sediment layer, 1.5 kg/L dry bulk density, 1 % C_{org} 2.77 % drift (1 m buffer), 90th percentile
Application rate	two applications of 13.75 g as/ha (sum of 27.5 g as/ha was used for the calculation)

PEC$_{(sed)}$	rimsulfuron Multiple application Actual (sum of applied) (µg/kg)	IN-70941 Multiple application Actual (sum of applied) (µg/kg)	IN-70942 Multiple application Actual (sum of applied) (µg/kg)	IN-JF999 Multiple application Actual (sum of applied) (µg/kg)
Initial (maximum)	0.107	0.112	0.597	0.176
Short term (4 d)	0.067	0.098	0.581	0.170
Long term (42 d)	0.001	0.025	0.449	0.125

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

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS-PELMO(3.3.2), modelling DT_{50} (d) KOC (L/kg) 1/n **rimsulfuron**: 22 47 1.02 **IN-70941**: 140 42$^{@}$ 0.94 **IN-70942**: 94 194 0.85 **IN-E9260**: 390 24$^{@}$ 0.99 **IN-J290**: 1000 34* 1.0 $^{@}$ mean of adsorption values for 3 different sandy loam soils, excludes a higher adsorption value measured in a clay soil *calculated from log kOW = 0.9514 due to SRC LOGKOW v.1.66 for chemical class 4
Application rate	N-Europe: 20 g as/ha (maize), 15 % interception N-Europe: 20 g as/ha (potato), 15 % interception, 2-yr crop rotation S-Europe: 15 + 12.5 g as/ha (tomato), 20 + 30 % interception

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

PEC$_{(gw)}$

Maximum concentration	Not available, not required
Average annual concentration (Results quoted for modelling with FOCUSgw scenarios, according to FOCUS guidance)	Annual average concentrations (80th percentile) according to FOCUS guidance: active substance: < 0.001 - 0.069 µg/L, **IN-70941**: 0.001 - 0.854 µg/L, **IN-70942**: < 0.001 - 0.096 µg/L, **IN- E9260**: 0.063 - 0.477µg/L, **IN- J290**: 0.000 - 0.064 µg/L, (see detailed results in table below)

PEC(gw) – FOCUS-PELMO modelling results at at 1 m depth for rimsulfuron and major soil metabolites under single application on maize (20 g as/ha)

	Scenario	rimsulfuron (µg/L)	Metabolites [µg/L]			
			IN-70941	IN-70942	IN-E9260	IN-J290
FOCUS-PELMO / maize	Chateaudun	0.009	0.502	0.051	0.348	0.046
	Hamburg	0.052	0.812	0.065	0.470	0.064
	Kremsmünster	0.017	0.638	0.058	0.459	0.062
	Okehampton	0.034	0.664	0.058	0.354	0.048
	Piacenza	0.046	0.612	0.060	0.234	0.020
	Porto	< 0.001	0.107	0.005	0.224	0.025
	Sevilla	< 0.001	0.002	< 0.001	0.063	0.008
	Thiva	< 0.001	0.170	0.017	0.209	0.030

PEC(gw) - FOCUS-PELMO modelling results at 1 m depth for rimsulfuron and major soil metabolites under single application on potato (20 g as/ha, 2-yr crop rotation)

	Scenario	rimsulfuron (µg/L)	Metabolites [µg/L]			
			IN-70941	IN-70942	IN-E9260	IN-J290
FOCUS-PELMO / potato	Chateaudun	0.005	0.255	0.024	0.192	n.c.
	Hamburg	0.014	0.359	0.031	0.218	n.c.
	Jokioinen	0.007	0.255	0.013	0.245	n.c.
	Kremsmünster	0.006	0.255	0.024	0.208	n.c.
	Okehampton	0.011	0.282	0.024	0.169	n.c.
	Piacenza	0.019	0.273	0.023	0.105	n.c.
	Porto	< 0.001	0.053	0.002	0.106	n.c.
	Sevilla	< 0.001	0.010	0.001	0.087	n.c.
	Thiva	< 0.001	0.063	0.007	0.098	n.c.

n.c. = not calculated

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

PEC(gw) - FOCUS-PELMO modelling results at 1 m depth for rimsulfuron and major soil metabolites under single application of 27.5 g as/ha (15 + 12.5 g as/ha) on tomato

	Scenario	rimsulfuron (µg/L)	Metabolites [µg/L]			
			IN-70941	IN-70942	IN-E9260	IN-J290
FOCUS-PELMO / tomato	Chateaudun	0.028	0.761	0.081	0.477	0.063
	Piacenza	0.069	0.854	0.096	0.362	0.036
	Porto	0.001	0.160	0.006	0.235	0.037
	Sevilla	< 0.001	0.001	< 0.001	0.088	0.000
	Thiva	< 0.001	0.242	0.025	0.293	0.045

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

Direct photolysis in air ‡	No data, not required
Quantum yield of direct phototransformation	Rimsulfuron: Φ = 0.0047 IN-70942: Φ = 0.00072
Photochemical oxidative degradation in air ‡	DT_{50}: 0.611 h (12 hr day, Atkinson calculation)
Volatilization ‡	From plant surfaces: 0.3 - 3.5 % in 24 h, from soil: 0 - 2.2 % in 24 h

PEC (air)

Method of calculation	Not required

PEC$_{(a)}$

Maximum concentration	Not required

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

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment	**Soil:** above trigger values: rimsulfuron, IN-70941, IN-70942, IN-E9260 residue definition: rimsulfuron **Water** **Surface water:** above trigger values: rimsulfuron, IN-70941, IN-70942, IN-E9260 for surface water fed by groundwater residue definition: rimsulfuron **Sediment:** above trigger values: IN-70941, IN-70942, IN-JF999 residue definition: none **Groundwater:** above trigger value: IN-70941, IN-E9260 residue definition: rimsulfuron **Air:** residue definition: rimsulfuron

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

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Classification and proposed labelling (Annex IIA, point 10)

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)

Acute toxicity to mammals ‡	LD_{50} 5000 mg as/kg bw (rat)
Long-term toxicity to mammals	NOAEL 3000 mg as/kg diet (from rat multi-generation study) NOAED 11.8 mg as/kg bw/d
Acute toxicity to birds ‡	LD_{50} > 2250 mg as/kg bw (bobwhite quail and mallard duck)
Dietary toxicity to birds ‡	LC_{50} > 5620 mg as/kg diet (bobwhite quail and mallard duck) LD_{50} > 1610 mg as/kg bw/d (mallard duck)
Dietary toxicity to birds	NOEC 5620 mg as/kg diet (bobwhite quail and mallard duck)
Reproductive toxicity to birds ‡	NOAEL 1250 mg as/kg diet (bobwhite quail and mallard duck) NOAED 142 mg as/kg bw/d (bobwhite quail)

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

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Annex VI Trigger
0.0275	maize/ potato/ tomato	herbivorous mammal	acute	7462	10
0.0275	maize/ potato/ tomato	herbivorous mammal	long-term	73	5
0.0275	maize/ potato/ tomato	herbivorous bird	acute	> 1236	10
0.0275	maize/ potato/ tomato	herbivorous bird	short-term	> 1926	10
0.0275	maize/ potato/ tomato	herbivorous bird	long-term	321	5
0.0275	maize/ potato/ tomato	insectivorous bird	acute	> 1510	10
0.0275	maize/ potato/ tomato	insectivorous bird	short-term	> 1941	10
0.0275	maize/ potato/ tomato	insectivorous bird	long-term	171	5

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

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	Endpoint	Toxicity (mg/l)
Laboratory tests ‡				
L.macrochirus	Rimsulfuron	acute (96 h)	mortality, LC_{50}	> 390 mg/L
O.mykiss	Rimsulfuron	acute (96 h)	mortality, LC_{50}	> 390 mg/L
O.mykiss	Rimsulfuron	long-term (21 d)	growth, NOEC	125 mg/L
O.mykiss	Rimsulfuron	long-term (ELS, 90 d)	growth, NOEC	125 mg/L
D.magna	Rimsulfuron	acute (48 h)	immobilisation, EC_{50}	> 360 mg/L
D.magna	Rimsulfuron	chronic (21 d)	reproduction, NOEC	1 mg/L
S.capricornutum	Rimsulfuron	chronic (72 h)	biomass, EC_{50}	1.2 mg/L
L.minor	Rimsulfuron	long-term (14 d)	fronds, EC_{50}	0.0046 mg/L
O.mykiss	IN-70941	acute (96 h)	mortality, LC_{50}	> 110 mg/L
D.magna	IN-70941	acute (48 h)	immobilisation, EC_{50}	95 mg/L
S.capricornutum	IN-70941	chronic (72 h)	biomass, EC_{50}	> 8.9 mg/L
S. gairdneri (O.mykiss)	IN-70942	acute (96 h)	mortality, LC_{50}	180 mg/L
D.magna	IN-70942	acute (48 h)	immobilisation, EC_{50}	178 mg/L
S.capricornutum	IN-70942	chronic (72 h)	biomass, EC_{50}	> 10 mg/L
L.gibba	IN-70942	long-term (14 d)	fronds, EC_{50}	> 0.02 mg/L
C riparius	IN-70942	long-term (28 d)	emergence, development, NOEC	> 200 µg/kg sediment
O.mykiss	IN-E9260	acute (96 h)	mortality, LC_{50}	> 314 mg/L
D.magna	IN-E9260	acute (48 h)	immobilisation, EC_{50}	184 mg/L
S.subspicatus	IN-E9260	chronic (72 h)	biomass, EC_{50}	> 100 mg/L
L.gibba	Rimsulfuron 25 WG	long-term (14 d)	fronds, EC_{50}	0.03 mg/L
L.gibba	Rimsulfuron 25 WG + IN-KG691	long-term (14 d)	fronds, EC_{50}	0.16 mg/L
Microcosm or mesocosm tests				
Not relevant				

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

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

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Annex VI Trigger
0.0275	Field crop	L.minor	long-term	1	18.4	10

Bioconcentration

Bioconcentration factor (BCF) ‡	Log Pow below relevant trigger
Annex VI Trigger:for the bioconcentration factor	not relevant (log $P_{ow} < 3$)
Clearance time (CT_{50}) (CT_{90})	
Level of residues (%) in organisms after the 14 day depuration phase	

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

Acute oral toxicity DPX-E9636	LD_{50} > 100 µg/bee
Acute oral toxicity DPX-E9636 plus IN-KG691	LD_{50} = 41.1 µg/bee
Acute contact toxicity DPX-E9636 plus IN-KG691	LD_{50} = 27.9 µg/bee

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

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Annex VI Trigger
Laboratory tests				
0.020	field crop	oral	0.20	50
0.020	field crops	oral	0.49	50
0.020	field crops	contact	0.72	50

Field or semi-field tests Rimsulfuron had no impact on honeybee mortality, flight intensity, behaviour, colony condition or brood development following application to flowering *Phacelia tanacetifolia* in a cage test (80 g Rimsulfuron 25 WG or Rimsulfuron 25 WG + IN-KG 691 surfactant)

‡ 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)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Annex VI Trigger
Laboratory tests ‡						
T. pyri	proto-nymphs	DPX-E9636 25 WG + IN KG691*	4.4 (1.1) 110 (27.5) 4.4 (1.1) + 0.4* 110 (27.5) + 0.4* 0.016* 0.4 *	mortality/ fertility	9/0 8/0 3/0 11/0 2/0 11/10	30
A. rhopalosiphi	imagines	DPX-E9636 25 WG	150 (37.5)	mortality/ parasitation capacity	14/1	30
C. carnea	larvae	DPX-E9636 25 WG	150 (37.5)	mortality/ fertility	4/22	30
A. bilineata	imagines	DPX-E9636 25 WG	4.4 (1.1) 110 (27.5)	mortality/ parasitation capacity	0/5 0/22	30

Field or semi-field tests
not required

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity ‡	**Rimsulfuron**: LC_{50} > 1000 mg as/kg **Rimsulfuron 25WG**: LC_{50} > 1000 mg Prod./kg LC_{50} > 250 mg as./kg **Rimsulfuron 25WG + Exell**: LC_{50} > 1000 mg Prod./kg LC_{50} > 22.5 mg as./kg
Reproductive toxicity ‡	**IN-70941**: NOEC 0.18 mg/kg **IN-70942**: NOEC 0.18 mg/kg **IN-E9260**: NOEC 0.18 mg/kg

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

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Annex VI Trigger
Rimsulfuron 25WG (PEC_{soil} 0.03 mg as/kg)				
2 x 13.75	tomato	acute	> 8333	10
Rimsulfuron 25WG + Exell (PEC_{soil} 0.03 mg as/kg)				
2 x 13.75	tomato	acute	> 750	10
IN-70941(PEC_{soil} 0.0404 mg/kg)				
2 x 13.75	tomato	long-term	4.5	5
IN-70942(PEC_{soil} 0.0136 mg/kg)				
2 x 13.75	tomato	long-term	13.2	5
IN-E9260(PEC_{soil} 0.0196 mg/kg)				
2 x 13.75	tomato	long-term	9.2	5

Effects on other soil non-target macro-organisms (Annex III,A point 10.6.2)

Folsomia candida (Collembola)	**IN-70941**: NOEC ≥ 0.183 mg/kg **IN-70942**: NOEC ≥ 0.183 mg/kg **IN-E9260**: NOEC ≥ 0.183 mg/kg

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization ‡	No effects > 25 % for the 25 % WG formulation alone and in combination with Exell, and the metabolites IN –70941 and IN-E9260
Carbon mineralization ‡	No effects > 25 % for the 25 % WG formulation alone and in combination with Exell, and the metabolites IN –70941 and IN-E9260

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

Greenhouse test	*Sorghum bicolor* (most sensitive species): ED_{50} technical rimsulfuron 0.17 g as/ha ED_{50} 25 WG formulation 4.89 g product/ha (corresponds to 1.22 g as/ha)

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

Toxicity/exposure ratios for terrestrial non-target plants (Annex IIIA, point 10.8)

Distance from treated area (m)	Drift (%)	Amount of drift (g as/ha)	TER (Sorghum bicolor, ED50 0.17 g/ha)	TER (Sorghum bicolor, ED50 1.22 g/ha)
Maize/Potato, 1 application (20 g as/ha)				
1	2.77	0.544	0.3	2.2
5	0.57	0.144	1.5	10.7
Tomato, 2 applications (15 + 12.5 = 27.5 g as/ha) representing worst case				
1	2.38	0.655	0.3	1.9
5	0.47	0.129	1.3	9.5

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	N; R 50/53 Very toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

‡ 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
RMS	rapporteur Member State
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