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

Aclonifen

Finalised: 31 July 2008

SUMMARY

Aclonifen is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on aclonifen in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 11 September 2006. The peer review was initiated on 24 November 2006 by dispatching the DAR for consultation of the Member States and the sole applicant Bayer CropScience AG. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in March-April 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in June-July 2008 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a pre-emergence herbicide as proposed by the applicant. Full details of the GAP can be found in the attached list of end points.

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

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

Adequate methods are available to monitor all compounds given in the respective residue definition. Residues in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine residues of aclonifen.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that some quality control measurements of the plant protection product are possible. The exception to this is the relevant impurity phenol where there is no method to monitor it in the formulation. It was concluded during the peer review process that the specification is not supported and a data gap has been identified. In addition it was considered by the meeting of experts mammalian toxicology that phenol is a relevant impurity. The meeting of experts discussed that as the technical material is a wet cake a TK specification should be required but no conclusion was reached on this in the meeting.

Mammalian toxicology of aclonifen was assessed in a series of investigations. Aclonifen is absorbed rapidly to an extent of about 80% and is distributed widely in the body. It has no potential for accumulation. It is excreted rapidly and almost completely and it is extensively metabolised. Aclonifen is of very low acute toxicity. It is neither a skin nor an eye irritant but has skin sensitising properties. A classification as **Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed. Short term studies were carried out with dogs, mice and rats and the lowest NOAEL of 3.6 mg/kg bw/d was obtained in rats (effects on body weight, liver and kidney). Aclonifen is not genotoxic. Two chronic rat studies and a carcinogenicity study with mice have been carried out. While the thyroid tumours seen in rats and the bladder tumours observed in mice were considered not relevant for human risk assessment the brain tumours seen in the rat could not be dismissed and a classification as **Xn; Carc. Cat. 3 R40 "Harmful; Limited evidence of a carcinogenic effect"** was proposed. Aclonifen did not exert specific effects on reproduction and was neither teratogenic in rats nor in rabbits. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were set at 0.07 mg/kg bw/d. An acute reference dose (ARfD) was not allocated. Operator exposure amounted to 16.1% of the AOEL when wearing personal protective equipment (PPE) in the German model. When no PPE is worn in the German model and in all scenarios in the UK POEM exposures exceeded the AOEL. Exposure of bystanders and unprotected re-entry workers was estimated to amount to 4.6% and 2.9% of the AOEL respectively.

The metabolism of aclonifen was investigated in wheat, peas and potatoes. However in the meeting of experts PRAPeR 45 no conclusion could be reached on the cereal and potato metabolism studies because there were no GAPs for these crops in the representative uses evaluated. So only the pea study was considered further. The pea study is representative of the relevant metabolism group for sunflowers which is the supported crop. This study showed that there are no significant residues in peas or in podded peas the major residue in the vinings was aclonifen. The residue definition for pulses and oilseeds was set as aclonifen only. The rotational crop metabolism study showed that in the majority of crops no significant residues would occur. However, for root and tuber crops it showed that residues could be expected. A data gap was set for a rotational crop residue study. The

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need for animal studies was not triggered. A goat metabolism study was evaluated in the DAR but the peer review did not conclude on its acceptability. A full set a residue data were available for the north and south of Europe all residues were <0.02 mg/kg at harvest. The consumer risk assessment could not be concluded because of the data gap identified for rotational crops. A risk assessment based on intakes of sunflower showed that the TMDI did not exceed 1 % of the ADI, no acute risk assessment was necessary.

The route of degradation in soil under dark aerobic conditions was investigated in two studies in a total of five soils. Albeit the drawbacks identified in these studies, the meeting of experts agreed that the data submitted was enough to satisfy the regulatory requirements. Practically the totality of the extracted radioactivity consisted on parent compound with only very minor metabolites detected. Mineralization was negligible or very low (CO_2: 0.7 – 5.2 % AR). Unextracted soil residue increase continuously up to 40.9 – 63.7 % AR at the end of the experiments.

According the photolysis in soil study, photolysis may contribute slightly to the degradation of aclonifen in soil. No metabolite exceeded 5 % AR.

Degradation of aclonifen in soil under anaerobic conditions was investigated in one of the studies presented in the dossier but it was not considered reliable. A data gap, which was considered not essential to finalize the risk assessment of the EU representative uses, was identified by the meeting of experts.

Aclonifen may be considered moderate to high persistent in soil under aerobic conditions at 20 °C (DT_{50} = 32.2 – 134 d).

Kinetics of all aerobic degradation data was re-evaluated with non linear regression to first order kinetic and values obtained were normalized to 20 °C and pF2. Since the report was not available in the updated dossier, the meeting identified a formal data gap for the applicant to incorporate this report (Hardy, I. and Patel, M. 2008) into it. The meeting of experts agreed the end points proposed by the RMS in table 66 of addendum 1.

Two field dissipation studies are available in Northern Europe (1 study in Germany, 4 sites) and Southern Europe (1 study in Spain and France, 1 site each). First order half lives between 57 d – 195 d were observed in these trials. The two soil accumulation trials performed in Germany were considered not adequate to address the potential accumulation of aclonifen in soil. Accumulated, PEC soil were calculated by the RMS and presented in addendum 1 based on the worst case field half life, annual application of 2400 g/ha and no interception. Plateau steady state was calculated after 10 yr over a mixing layer of 20 cm. Actual and TWA PEC_S were calculated adding the result of the annual application on a 5 cm mixing layer over the plateau. The calculation was agreed by the experts in the meeting. Aclonifen may be considered practically immobile in soil (K_{oc} = 5318 – 10612).

Aclonifen is stable to hydrolysis at pH 5, 7 and 9. The aqueous photolysis study and the subsequent RMS model calculation show that photolysis may contribute in a limited extend to the degradation of aclonifen in the aquatic environment. Aclonifen is not readily biodegradable.

Degradation of aclonifen was investigated in one study with two water sediment systems (pH_{water} = 6.7 – 7.5; pH_{sed} = 6.8 – 8.4, OC 3.8 – 5.7 %, clay 10.54 – 28.99 %) incubated under dark aerobic conditions at 20 °C. In both water / sediment systems aclonifen steadily partitioned to the sediment

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and degraded. None of the metabolites observed reached 5 % AR in any of the phases. Mineralization was negligible in both systems (max CO_2 = 2.07 % AR) and unextractable residue in the sediment amounted up to 65.6 -76.5 % AR at the end of the experiments (180 d). Separated half lives for the water and sediment phases were considered unreliable and not representing true degradation by the experts. The meeting agreed that total system half lives could be used for the risk assessment (DT_{50} = 17.3 d). New FOCUS $PEC_{SW/SED}$ up to STEP 4 (including effect of spray drift and run off mitigation by buffer and vegetative strips) using the agreed input parameters were available in addendum 1. The calculations were agreed for the STEP 3 and the STEP 4 when only spray drift mitigation was assumed. Therefore, only $PEC_{SW/SED}$ presented in Table 17 of addendum 1 may be considered peer reviewed for the EU risk assessment.
Aclonifen is not considered to pose a risk for contamination of ground water above the trigger of 0.1 µg / L when used according the GAPs for the representative use evaluated. Concentrations in air and transport through air are considered negligible for aclonifen.

The acute and short-term first-tier TERs for insectivorous birds and the acute TER for insectivorous mammals exceeded the trigger of 10 but the long-term risk needed further refinement. The refinement of PT was rejected in the experts´ meeting since it was not sufficiently supported with data. A data gap was identified to submit a new refined long-term risk assessment for birds and mammals. The long-term endpoint (35 mg a.s./kg bw/d) used in the original risk assessment for mammals in the DAR was discussed in the meeting. Statistically significant effects on body weight were observed at the dose of 35 mg a.s./kg bw/d. The effects were <10% but a reduced fitness and thus adverse effects on populations of wild mammals under realistic environmental conditions cannot be excluded. The experts agreed that the NOEC of 8 mg a.s./kg bw/d should be used in the risk assessment. The risk of secondary poisoning of earthworm- and fish-eating birds and fish-eating mammals was assessed as low. The risk to earthworm-eating mammals needs further refinement. The risk from uptake of contaminated drinking water was considered to be low since the product is applied to bare soil.
The lowest endpoints were observed in studies with fish, algae and higher aquatic plants. The experts accepted the use of 4-day time weighted average PECsw values to refine the risk to higher aquatic plants. The use of time weighted average values was also accepted for growth effects on fish but concerns were raised with regard to the long time interval of 28 days. It was suggested that the time window may be revised at MS level when guidance will be available from the e-link workshop. Effects on hatch success of fish were also observed in the early life stage test. Effects on hatch success can be caused by short exposure peaks. The experts agreed that the NOEC hatch success should be compared to initial PECsw values which lead to TERs significantly below the trigger of 10. However the TERs for algae are lower and the risk to fish would be covered by the risk mitigation required for algae. Even if a no-spray buffer zone of 40 m in combination with run-off mitigation by 80/95% is applied then the TERs are above the trigger in only one full FOCUS step 4 scenario (D5) and in the part scenario R1 (pond). It is noted that the suggested reduction of spray-drift entry exceeds the recommendation of the FOCUS Landscape report and uncertainty remains also with regard to the PECsw following the proposed run-off mitigation. The full scenarios R3, R4 and the part scenario

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R1(stream) still result in TERs below the trigger of 10. Overall it is concluded that the representative use of aclonifen poses a high risk to aquatic organisms.
Brassica napus was the most sensitive non-target plant species tested. It reacted very sensitive under high temperature and high soil moisture growth conditions. Even an in-field no-spray buffer zone of 50 m would not be sufficient to achieve a TER of >5 for the ER_{50} of 1.12 g a.s./ha for *Brassica napus*. Under field exposure conditions the observed endpoints were significantly higher. However the experts identified uncertainties with regard to the influence of the weather conditions on the dissipation of aclonifen, the application pattern and actual exposure in the field studies. A data gap was identified in the experts´ meeting for the applicant to provide a refined risk assessment for non-target plants.

The risk to bees, other non-target arthropods, earthworms, soil non-target macro- and micro-organisms and biological methods of sewage treatment was assessed as low for the representative use of aclonifen.

Key words aclonifen peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Aclonifen is one of the 84 substances of the third stage Part B covered by the amended Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on aclonifen, hereafter referred to as the draft assessment report, received by EFSA on 11 September 2006. The draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1490/2002 on 24 November 2006 to the Member States and the main applicant Bayer CropScience AG as identified by the rapporteur Member State.

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

Taking into account the requested information received from the applicant, a scientific discussion took place in expert meetings in March-April 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in June-July 2008 leading to the conclusions as laid down in this report.

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

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

The documentation developed during the peer review was compiled as a **peer review report** comprising the documents summarising and addressing the comments received on the initial

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evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev.1-1 of 29 January 2008)

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

- the reports of the scientific expert consultation
- the evaluation table (rev.2-1 of 24 July 2008)

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

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Aclonifen is the ISO common name for 2-chloro-6-nitro-3-phenoxyaniline (IUPAC).

Aclonifen belongs to the class of nitrophenyl ether herbicides, this group includes for example bifenox and fomesafen. Aclonifen inhibits carotenoid biosynthesis; the target enzyme is not known. It is a systemic, selective herbicide.

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

The evaluated representative use is as a pre-emergence herbicide on sunflower. Full details of the GAP can be found in the attached list of end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

At the moment no minimum purity of aclonifen as manufactured can be given, because further clarification is needed. The meeting of experts considered the specification and batch data and came to the conclusion that the available data did not support the specification. A data gap was identified for a revised specification. The meeting of experts also discussed the fact that as the material is a wet cake a specification should be provided for this TK. It was also considered that as the analysis had been conducted on dried material perhaps some volatile impurities may have been lost. No conclusion was reached by the meeting on either of these two points.

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The technical material contains phenol, which has to be regarded as a relevant impurity. No maximum level can be set at this time because the technical specification has not been agreed.

The content of aclonifen in the representative formulation is 600 g/L (pure).

Beside the specification, the assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of aclonifen or the respective formulation.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of aclonifen in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. For the relevant impurity phenol there is no method of analysis to quantify it in the formulation. There is no requirement for this method at EU level as this impurity can not increase on storage. However, a method can be requested at Member State level.

However, sufficient test methods and data relating to physical, chemical and technical properties and analytical methods are available to ensure that at least limited 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. aclonifen in food of plant origin and aclonifen in soil water and air.

Food of plant origin can be analysed by the German S19 multi-residue method GC-ECD with an LOQ of between 0.01-0.05 mg/kg depending on the matrix. The confirmatory method was either by GC-MS or LC-MS/MS. For food of animal origin a method is not required as no MRLs are proposed see section 3.2. Soil is analysed by GC-ECD with an LOQ of 0.01 mg/kg and confirmation by GC-MS. Water is analysed by GC-ECD with an LOQ of 0.05 µg/L and confirmation by GC-MS. Air is analysed by GC-ECD with an LOQ of 0.25 µg/m3 a confirmatory method is not required as sufficient methods are available for soil and water and they can be used for confirmation.

A method for body fluids and tissues is not required as the active substance is not classified as toxic or highly toxic.

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2. Mammalian toxicology

Aclonifen is an existing active substance (list 3B) and was discussed at the meeting of experts for mammalian toxicology (PRAPeR 44, round 9) in April 2008. Phenol (impurity AE F 131477) was because of its intrinsic hazards (classified by ECB as mutagenic category 3, toxic by oral dermal and inhalation route and corrosive) considered as a relevant impurity.

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

Aclonifen is rapidly absorbed when applied orally (approximately 80% within 24 hours based on urinary and biliary excretion). It is widely distributed. Residues are found mainly in liver, kidneys, lung, thyroid and skin/fur. There is no evidence for accumulation. Bile excretion studies indicate a significant enterohepatic circulation of aclonifen-related material. Excretion is nearly complete within 48 hours. Renal excretion ranged from 38% - 50% in males and from 39% - 65% in females in the different studies available. Most of the remaining material is voided via the faeces. Aclonifen is extensively metabolised, the main pathways being hydroxylation of the phenyl ring, cleavage of the ether bond, reduction of the nitro group and subsequent acetylation, methylation and phase II type conjugations with sulphate or glucuronic acid.

2.2. Acute toxicity

Aclonifen is of very low acute toxicity by the oral (LD_{50} > 5000 mg/kg bw), dermal (LD_{50} > 5000 mg/kg bw) and inhalation route (LC_{50} > 5.06 mg/L) in the rat and also by the oral route in the mouse (LD_{50} > 5000 mg/kg bw). Aclonifen was slightly transiently irritant to rabbit skin and not irritant to rabbit eyes. While in a Buehler test negative results were obtained, aclonifen caused delayed contact hypersensitivity in guinea pigs in a Magnusson & Kligman skin sensitisation test. Based on the available data on acute effects a classification as **Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed.

2.3. Short term toxicity

With rats three 90-day dietary studies and a 28-day dermal study are reported, with mice a 28-day and with dogs a 26-week dietary study have been carried out. In the three dietary rat studies the same doses were applied (50 - 5000 ppm) and generally similar effects (decreased body weight, changes in blood chemistry indicative of liver damage, increased liver and kidney weights, liver and kidney pathology) that were consistently more severe in males, have been reported. The lowest NOAEL obtained in these investigations was 3.6 mg/kg bw/d based on findings of follicular cell hypertrophy in the thyroid, histopathology and increased organ weights in liver and kidneys at higher doses. From the dermal study a NOAEL of 500 mg/kg bw/d was derived based on reduced number of white blood cells in both sexes and lowered body weight, food consumption and glucose levels in males at 1000 mg/kg bw/d. The NOAEL in the mouse study was established at 121.2 mg/kg bw/d based on decreased body weight and toxicity in liver, kidneys and ovaries. From the dog study a NOAEL of 15 mg/kg bw/d (500 ppm) was derived based on decreased body weight, changes in clinical chemistry and hepatomegaly occurring at the highest dose of 5000 ppm.

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2.4. GENOTOXICITY

Aclonifen was negative in an adequate test battery of four *in vitro* and one *in vivo* genotoxicity test.

2.5. LONG TERM TOXICITY

Two 2-year combined chronic/carcinogenicity studies with rats and one 80-week carcinogenicity study with mice are reported in the DAR. The results from the first study with rats were re-evaluated and the experts agreed to set a systemic NOAEL at 7.0 mg/kg bw/d (200 ppm) based on changes in clinical parameters and decreased body weights at the highest dose (1600 ppm). An oncogenic NOAEL was not derived since the thyroid C-cell tumours found in females at higher dose were considered incidental and not treatment related. In the second rat study the systemic NOAEL was set at 7.6 mg/kg bw/d based on liver hypertrophy in both sexes and decreased body weight at high dose. In females, at the high dose (86 mg/kg bw/d) malignant astrocytomas were detected. In the mouse carcinogenicity study the systemic NOAEL was set at 7.1 mg/kg bw/d based on decreased body weight gain and urinary bladder transitional cell hyperplasia. At the highest dose (7000 ppm) urinary bladder tumours were found in two males and one female. At PRAPeR 44, April 2008 the experts agreed that when taking into account also that aclonifen is not genotoxic it was reasonable to attribute the bladder tumours in mice to the continuous irritation of the tissue at high doses of aclonifen. The astrocytomas in rats, however, were caused by a different mechanism and due to the rarity of this tumour type remained to be a concern. Consequently, a classification for aclonifen as **Xn; Carc. Cat. 3 R40 "Harmful; Limited evidence of a carcinogenic effect"** was proposed.

2.6. REPRODUCTIVE TOXICITY

With rats a two-generation study and a developmental study and with rabbits a developmental study are reported. In the two-generation study, the NOAEL for parental effects was set at 8 mg/kg bw/d based on decreased body weight and food consumption and that for the offspring at 35 mg/kg bw/d based on decreased birth weights and postnatal bodyweight gain in F1 and F2 pups. No effects on reproduction were observed up to the top dose of 120 mg/kg bw/d. Aclonifen was not teratogenic in the rat developmental study, the NOAEL for maternal and developmental effects of 60 mg/kg bw/d was derived from decreased bodyweight of both dams and foetuses. In the rabbit the highest dose level of 25 mg/kg bw/d did not exert any maternal toxicity and as aclonifen was also devoid of any embryotoxicity the maternal and developmental NOAEL were set at this dose.

2.7. NEUROTOXICITY

Based on the chemical structure and the mode of action of aclonifen no neurotoxicity studies are necessary. Evaluation of neurotoxicity endpoints (various reflex tests) in a 90-day feeding study in rats did not reveal any evidence of a neurotoxic potential.

2.8. FURTHER STUDIES

In an *in vivo* assay with rats aclonifen did not bind to DNA in cells of the urinary bladder and liver (chromatin binding, however, was observed).

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2.9. MEDICAL DATA

There are no reports of adverse effects on health in manufacturing or agricultural use of aclonifen.

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

At the meeting of experts the **ADI** and the **AOEL** were set at 0.07 mg/kg bw/d based on the NOAEL obtained in the first 2-year chronic rat study, applying a safety factor of 100. It was pointed out also that the value for the ADI was supported also by the NOAELs derived from the two generation study and the carcinogenicity study with mice, the value for the AOEL also by the two generation study and in addition by the short term oral rat studies. As proposed by the RMS the experts concluded not to allocate an **ARfD** since the data available did not show an acute toxicological alert.

2.11. DERMAL ABSORPTION

Based on an *in vivo* dermal absorption study with rats and a comparative *in vitro* study with rat and human skin the experts agreed to set the values of dermal absorption for the preparation "BANDUR" at 2% for the concentrate and at 10% for the spray diluted product. Since the amount of substance detected in the stratum corneum was considered as absorbed (in contrast to the original DAR where it was considered as not absorbed) the new agreed values are higher than those proposed initially by the RMS.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection "BANDUR" (EXP 04209) is formulated as a suspension concentrate containing 600 g/L aclonifen. It is used as a contact herbicide for the pre-emergence control of annual grass and broad-leaved weed species in sunflower fields.

Based on the revised values for dermal absorption agreed upon at the meeting of experts, the RMS has provided updated exposure calculations in an addendum to the DAR (May, 2008).

Operator exposure

According to the intended use submitted by the applicant the maximum applied dose of aclonifen is 2.4 kg/ha and the minimum volume is 200 L water/ha. It is applied once a year using a vehicle-mounted or a drawn boom sprayer. The exposures have been estimated using the German model and the UK POEM and are presented below.

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In the table below the estimated exposures are given in % of the AOEL of 0.07 mg/kg bw/d.

	Without PPE	With PPE [1]	With PPE [2]
German Model	248.4%	201.9%	16.1%
UK POEM	1318.6%	207.1%	--------

PPE - Personal protective equipment

[1]Gloves during mixing/loading in the German model; Gloves during mixing/loading and application in the UK POEM

[2]Gloves, standard protective garment and sturdy footwear during mixing/loading and application in the German model

Bystander exposure

Predicted exposure for an unprotected bystander from application of "BANDUR", was assessed according to Lloyd and Bell, 1983[2] and will be 4.6% of the short term systemic AOEL of 0.07 mg/kg bw/d.

Worker exposure

Although at the meeting of experts it was noted that based on the intended use of the preparation as a pre-emergence herbicide exposures due to re-entry activities are not expected, the RMS has provided a revised assessment in an addendum to the DAR (May, 2008) and the predicted exposure based on the German model for re-entry workers[3] even if no PPE is worn amount to 2.9% of the systemic AOEL of 0.07 g/kg bw/d.

3. Residues

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism of aclonifen has been investigated in peas, wheat and potatoes following either pre-emergence or post-emergence application of [14C-aniline]-labelled aclonifen. Peas are representative for the crop group pulses & oilseeds thus covering the intended use in sunflowers. Studies with phenyl-labelled material have not been performed. The potential metabolites arising from the phenyl ring as a result of cleavage of the diphenyl ether linkage would be phenol and hydroquinone, both of which are naturally occurring in plants. Ether cleavage degradation products are of negligible importance in the metabolic pathway of aclonifen.

[2]Lloyd GA and Bell GJ (1983) Hydraulic nozzles: comparative spray drift study. UK Ministry of Agriculture Fisheries and Food.

[3] Hoernicke E, Nolting HG, Westphal D (1998) Hinweise in der Gebrauchsanleitung zum Schutz von Personen bei Nachfolgearbeiten in mit Pflanzenschutzmitteln behandelten Kulturen (worker re-entry) (1998) Nachrichtenblatt des Deutschen Pflanzenschutzdienstes. Vol 50 (10) 1998.

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Following pre-emergence treatment with [14C]-aclonifen at 2.97 kg as/ha (1.2 normal rate for the representative crop sunflower) the total radioactive residues in human-edible parts of pea plants at all the commercial harvest growth stages (mangetout, fresh peas, dry peas) were found to be at low levels ranging from 0.005 to 0.055 mg as-eq/kg. The major part of the residue in peas was unextractable. Detailed characterisation of the residue was only performed with the vining and pod samples bearing higher residues. Total residues in the vinings ranged from 0.318 to 2.928 mg as-eq/kg and in the pods from 0.005 to 0.209 mg as-eq/kg, > 80 % of which was extractable. The major compound in the extractable residue was always aclonifen (42 - 76 % TRR), accompanied by low amounts of RPA 508285[4] and RPA 407074[5] (6 - 7 % TRR each). Following post-emergence treatment at 394 g as/ha the residues in human-edible parts of pea plants were lower than those found after pre-emergence treatment. The levels in vinings were, however, considerably higher and were almost entirely composed of aclonifen.

Following treatment with [14C]-aclonifen at 3.25 kg as/ha pre-emergence the residue levels in wheat plants were low in all samples. TRR in forage wheat ranged from 0.035 to 0.094 mg as-eq/kg, At harvest TRR in the grain was 0.037 mg as-eq/kg and was 0.374 mg as-eq/kg in straw + chaff. The composition of the residue in straw and chaff was found to comprise aclonifen 0.026 mg/kg plus small amounts of the metabolites RPA 407291[6] 0.025 mg/kg and RPA 407288[7] 0.013 mg/kg (< 10 % TRR each) and RPA 508285 0.022 mg/kg (> 10 % TRR according to HPLC analyses) plus a number of unidentified compounds that were polar in nature. The unextractable portion of the residue represented < 20 % TRR except with grain (43 %). The significant differences between HPLC and TLC are probably due to matrix effects.

The residue level in wheat grain following post-emergence application of aclonifen at 303 g/ha was extremely low (0.008 mg/kg) and unextractable. In forage wheat and straw + chaff TRR ranged from 1.457 to 2.466 mg as-eq/kg. This residue was nearly completely extractable and consisted mainly of aclonifen with only negligible amounts of metabolites which were already identified in the pre-emergence study.

Following soil application of [14C]-aclonifen at 2.5 kg as/ha, three quarters of recovered radioactivity were found in the non-edible potato tops. Translocation of aclonifen and/or its degradation products was mainly acropetal. The higher amount of radioactivity in peel compared to the pulp and the presence of aclonifen in peel but not in pulp suggested that uptake into tubers occurred via the peel which was in contact with the treated soil. Main residue in peel was aclonifen. The remaining part of the extractable residue in peel as well as the extractable residue in pulp was distributed among numerous unknown polar compounds in low individual amounts. In all plant parts about half of the total radioactivity was bound to the plant material and was not extractable.

[4] RPA 508285: 3-amino-2-chloro-4-nitrophenol
[5] RPA 407074: 4-(3-amino-2-chloro-4-nitrophenoxy)phenol
[6] RPA 407291: 3-chloro-4-phenoxybenzene-1,2-diamine
[7] RPA 407288: 3,4-diamino-2-chlorophenol

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After foliar application > 99 % of applied radioactivity remained associated with the potato tops indicating only a very low tendency to translocate basipetally. Foliar application resulted in higher tuber residues than soil application, although using a lower application rate. Residues were only characterised in potato tops. Aclonifen 10.8 mg/kg (7.5 % TRR), RPA 407074 10.6 mg/kg (7.4 % TRR) and two other minor metabolites at 3.8 mg/kg (2.8 % TRR) and 3.8 mg/kg (2.8% TRR). Mainly the residue consisted of polar compounds in very low individual amounts. 34 % of the residue remained unextractable.

The labelling in the single position was justified as follows. The presence of the electron donating amino group on the aromatic ring in aclonifen seems to inhibit nucleophilic attack on the aniline ring by glutathione. Instead any cleavage of aclonifen would most likely occur by oxidative mechanisms following metabolism of the herbicide to the metabolites RPA 407074 and RPA 407291. In comparison to the glutathione mediated cleavage of other diphenyl ether herbicides these reactions would be slow and would account for the low levels of cleavage degradation products (RPA 508285 and RPA 407288) which have been observed in plant metabolism studies with [14C-aniline]-labelled aclonifen (only in cereal straw and in pea vinings in very small amounts). This was considered acceptable for the representative crop sunflower, but this should be reconsidered if other crops are to be authorised.

The meeting of experts PRAPeR 45 were initially asked to consider if the level of identification in these metabolism studies was sufficient. Given that the representative use is sunflower the experts were unable to decide if the potato and cereal metabolism studies are acceptable as they did not know what the use pattern/GAP was for these crops or crop groups. The meeting of experts were therefore only able to take account of the pea study and could not set a residue definition for all plant commodities. The meeting of experts mammalian toxicology were asked to consider the toxicity of the identified metabolites and they concluded that most of the metabolites are covered by the toxicological end points of the parent compound, except RPA 407288 for which no toxicological data are available. However, RPA 407288 was not identified in the pea study and other metabolites were only identified at significant levels in the pea vines. The metabolites therefore don't need to be included in the residue definition for pulses and oilseeds. The meeting concluded that the pea study was acceptable and that a residue definition of aclonifen could be set for the metabolism group pulses and oilseeds.

Supervised field residue trials were performed with aclonifen in France (19 trials, representing Northern and Southern European areas) and Germany (1 trial) between 1990 and 1994 and in 2001. Aclonifen was applied to soil prior to emergence of the sunflowers with application rates ranging from 2100 to 4800 g as/ha. For Northern Europe, 9 field trials were found to match the critical GAP,

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for Southern Europe 8 trials (+ 3 overdosed trials, which have also been considered):
N: < 0.01 (3); < 0.02 (6) mg/kg
HR: 0.02 mg/kg STMR: 0.02 mg/kg
S: < 0.02 mg/kg (11)
HR: 0.02 mg/kg STMR: 0.02 mg/kg
No residues above the LOQ for aclonifen have been found in sunflower seed at harvest. Evidence was supplied that showed residues would have been stable in the residue trial samples during the freezer storage period prior to analysis.

As residues did not exceed the 0.1 mg/kg level and Total maximum daily intake does not exceed 10 % of the ADI processing studies are not required. However, so processing studies were available but they were not conducted in accordance with the guidance documents and were not considered further.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

The nature and quantities of residues of aclonifen in succeeding crops was investigated using [14C-aniline]-radiolabelled aclonifen. The radiochemical purity was > 98 % and the specific activity after mixing with non-radiolabelled compound was 0.72 MBq/mg. Three representative crops were used for the study. Carrot (Daucus carrota cv Early Nantes) was selected as the root crop, spinach (Spinacea oleracea cv Cezanne F1) was selected as the leafy vegetable crop and barley (Hordeum vulgare cv Riviera or cv Halcyon) was selected as the cereal crop. Aclonifen was applied as an acetonitrile spray solution to the bare soil of 10 outdoor plots in Essex, UK, at an application rate of 3.72 kg as/ha which is equivalent to 1.5 times the normal rate. The total radioactive residue (TRR) in soil decreased from 8.70 mg/kg to 1.65 mg/kg during the study period. After the first ageing period of 29 days, more than 50 % of the initial amount of aclonifen had dissipated. This is in line with field dissipation studies according to which DT50 soil values between 13 and 195 days have been reported. The extractable fraction decreased from 98 % to about 17 % along with the formation of up to 84.5 % of bound residues. The radioactive residue became less available for plant uptake with time. TRRs in carrot foliage, spinach, immature barley, barley grain and barley chaff remained below 0.1 mg/kg during all three rotation intervals (plantings at 29, 120 and 365 days after treatment). The residue level in carrot and spinach decreased from the first to the third rotation interval. TRR in immature barley, remained nearly constant throughout the rotation intervals. TRR in carrot root reached a maximum of 0.491 mg as-eq/kg at harvest after the first rotation interval. The residue level decreased to 0.200 mg as-eq/kg after the second and 0.035 mg as-eq/kg after the third rotation interval. Residues in barley straw amounted to 0.245 mg as-eq/kg at harvest after the first rotation interval and decreased to 0.040 and 0.077 mg as-eq/kg after the second and the third interval, respectively.
The only significant component of the extractable residue in soil was aclonifen itself, as shown by HPLC and TLC. Carrot samples contained one major radioactive component in all samples from all plantings (according to HPLC examinations). In the carrot roots this accounted for the entire extractable residue. The identity of the component was confirmed as aclonifen by TLC. In foliage extracts there were up to five other minor components, one of which co-chromatographed with RPA 508285. The levels of radioactivity in the spinach sample extracts from the later plantings were too

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low for meaningful results to be obtained from their chromatographic examination. Extraction was therefore only performed with the 29 day planting samples. The extract of the harvest sample consisted of two radioactive components in a 1:1 ratio. One of these was found to be aclonifen, the other was a slightly more polar unknown compound. As with spinach, the extracts of the barley samples from the later plantings contained too little radioactivity to warrant chromatographic examination. Consequently, only samples from the 29 day planting have been analysed. The grain sample extract was found to comprise a single polar peak (identity of the compound unknown). The straw sample extract contained a number of radioactive components, all < 10 % TRR. These included aclonifen and RPA 508285 (tentatively identified by co-chromatography) and at least four unknown compounds. Known metabolites RPA 407288 and RPA 407291 did not co-chromatograph with any of the metabolites found in the samples.

Uptake of radioactive residues into rotational crops was observed for all investigated crops (root crop, leafy crop, cereal crop) but was not pronounced for leafy and cereal crops. The radioactive residue became less available for plant uptake with time. TRRs in carrot foliage, spinach, immature barley, barley grain and barley chaff remained below 0.1 mg/kg during all three rotation intervals (29, 120 and 365 days). TRR in carrot root reached a maximum of 0.491 mg as-eq/kg after the first rotation interval, decreasing to 0.200 mg as-eq/kg after the second and to 0.035 mg as-eq/kg after the third rotation interval. Residues in barley straw amounted to 0.245 mg as-eq/kg after the first rotation interval, decreasing to 0.040 and 0.077 mg as-eq/kg after the second and the third interval, respectively.
The extractable residue in carrot root consisted exclusively of aclonifen which was also the only major component in carrot foliage and the only identifiable compound in spinach. Barley grain contained one major polar component which could not be identified. Taking into account the low absolute amount of this metabolite (0.004 mg/kg), identification is not required. Barley straw comprised aclonifen and RPA 508285 in minor amounts. In none of the samples further compounds occurred in individual amounts > 10 %. The unidentified compounds predominantly were polar in nature. It can be concluded from the study that the only significant residue to be considered in rotational crops is the parent aclonifen.

The meeting of experts PRAPeR considered the rotational crop metabolism study and concluded that no significant residues would occur in all crop groups except root and tuber crops. It was concluded that positive residues of aclonifen could occur in rotational root and tuber crops. It was proposed that there could be a restriction not to plant root and tuber crops after application of aclonifen but no clear plant back interval was proposed. The meeting concluded that such a restriction was not possible and agreed that there should be a data gap for a rotational crop residue study.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

The need for animal studies is currently not triggered. However, a lactating goat study was supplied. The metabolite identification in this study was questioned but this was not addressed. Therefore it can not be concluded if this study is acceptable. If other crops are authorised or if significant residues

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occur in rotational crops (data gap identified for a rotational crop study) then this study must be re-evaluated taking in to account the level of animal intake.

3.3. CONSUMER RISK ASSESSMENT

The experts in residues (PRAPeR 45) have concluded that currently the consumer risk assessment cannot be finalised. The experts have identified that further data is necessary to conclude on the final risk assessment as the residue levels in rotational crops have not been concluded on.

In a preliminary assessment, based on the presumption that residues only occur in the primary crop sunflower and not in the rotational crops the TMDI does not exceed 1% of the ADI using the WHO model cluster group B and the EFSA model. An acute risk assessment is not necessary as it was not necessary to set an ARfD.

3.4. PROPOSED MRLS

An MRL of 0.02 mg/kg for aclonifen has been proposed for the primary crop sunflowers however, it can not be concluded if MRLs are needed for residues in rotational crops.

4. Environmental fate and behaviour

Fate and behaviour in the environment was discussed in the meeting of experts PRAPeR 42 (March – April 2008), on basis of the DAR (August 2006) and the Addendum 1 (March 2008). A new Addendum 3 (May 2008) has been made available after the meeting of experts.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Studies were only performed with aclonifen labelled at the aniline ring. The potential metabolites arising from the phenyl ring as a result of cleavage of the diphenyl ether linkage would be phenol and hydroquinone, both of which are naturally occurring in the environment. The relevance of these potential metabolites was not considered either in the DAR or in the peer review. Phenol is classified as toxic and may deserve further consideration in case amounts significantly above the natural background level would be produced due to the use of aclonifen. The slow rate of degradation of aclonifen in soil may prevent the build up of these metabolites in most of the situations. However, further data may still be needed by MSs to finalize the risk assessment at national level.

The route of degradation in soil under dark aerobic conditions was investigated in two studies in a total of five soils (pH 6.5 – 7.3, OC 1.1 – 1.9 %, clay 5.4 – 24.5 %). The actual pH was not determined on the soils but based on historical records for the first study (three soils). The range of pH in the soils investigated was too narrow with respect of naturally occurring pH's. However, the

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meeting of experts agreed that the data submitted was enough to satisfy the regulatory requirements taking into account the wider pH range investigated when field studies are considered (pH 5.9-8.2).

In the first study, some experiments were performed with soil moisture of 60 % FC and others with 30 % FC. Also an experiment was performed at concentrations ten times lower than intended. Practically the totality of the extracted radioactivity consisted in parent compound with only very minor metabolites detected. In this study, extraction method changed after DAT 7 from a harsh one (soxhlet) to a milder one (room temperature). The meeting of experts criticized this procedure as not following good study design and practice. In relation with the parent compound, the argumentation presented by the applicant based on the recoveries obtained in the sterile soil experiments, where soft extraction was used for all data points, was accepted by the meeting as an indication that extraction of parent is expected to have been efficient enough in the samples extracted with this method. There is potentially greater uncertainty in the extraction efficiency for breakdown products, as the breakdown products were not present in the sterile experiments. However, the meeting accepted that major metabolic fraction M1 was the origin of the chromatographic distribution and likely to be associated with soil colloidal components.

Mineralization was negligible or very low (CO_2: 0.7 – 5.2 % AR). Unextracted soil residue increase continuously up to 42.5 – 57.6 % AR at the end of the study (118 DAT) in the experiments performed at the concentration intended to mimic the application rate proposed as representative (2.5 Kg / ha). However, in the experiments performed at lower concentrations (0.25 Kg / ha) or under drier conditions (30 % FC) amount of unextractable was only of 21.2 % AR and 7.2 % AR respectively at the end of the study.

In the second route study, application rate was about three times intended rate (10 mg/kg approx. 7.5 kg/ha). The study was performed at 40 % MWHC and 22 ºC. Up to 19 – 21 % AR was characterized as extractable degradation products. The amount increase with more polar solvent and was separated in various compounds < 5 % AR by sequential TLC. Since no fraction accounted for more than 5 % AR, no identification of metabolites was performed. Unextractable radioactivity accounted for a maximum of 40.9 – 63.7 % AR. This unextractable fraction was not solubilised by 2N HCl or 12.5 N NaOH after 5 h reflux indicating that it is constituted by strongly bounded or incorporated residues. Mineralization was practically negligible in this study (max. CO_2 = 3 % AR).

According the photolysis in soil study available, photolysis may contribute slightly to the degradation of aclonifen in soil. No metabolite exceeded 5 % AR.

Degradation of aclonifen in soil under anaerobic conditions was investigated in one of the studies presented in the dossier. However, the meeting of experts found this study not acceptable due to the low recoveries (67 % AR) and the uncertainty associated to potential volatile components. Therefore, the meeting identified a data gap that was not considered essential to finalize the risk assessment of the EU representative uses.

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

The rate of degradation of aclonifen was investigated in the studies already summarized in the route section. An additional study (anonymous, 1982) was performed with unlabeled aclonifen in two soils (pH 6.0 – 7.0, OC 1.06 – 2.6 %, clay 14.5 – 24.7 %). Degradation under dark aerobic conditions at 10 °C was also investigated in a study with two soils (pH 6.8 – 7.2, OC 1.16 – 1.55 %, clay 9-23 %).

Aclonifen may be considered moderate to high persistent in soil under aerobic conditions at 20 °C (DT_{50} = 32.2 – 134 d).

Kinetics of all aerobic degradation data was re-evaluated with non linear regression to first order kinetic and values obtained were normalized to 20 °C and pF2. The re-evaluation was presented by the applicant to the RMS, who assessed and summarized it in addendum 1. However, the study report was not available in the updated dossier. Therefore, the meeting identified a formal data gap for the applicant to incorporate this report (Hardy, I. and Patel, M. 2008) into the updated dossier.

In the study anonymous (1982), nominal concentration at time 0 were considered for the kinetic fitting of the data originally presented in the DAR. This was considered not adequate by the meeting of experts (moreover when analytical recoveries were available). In the addendum the fitting excludes DAT 0 and only 4 data points are used; one less than the minimum 5 data points required by FOCUS. However, the experts agreed to exceptionally maintain these values in the data set because removing them has no impact on the calculated geometric mean. The meeting of experts agreed the end points proposed by the RMS in table 66. However, it was agreed that no dramatic impact would be expected in the results of the FOCUS modelling performed with a slightly shorter geometric mean half life.

Two field dissipation studies are available: one in Northern Europe (1 study in Germany, 4 sites) and the other in Southern Europe (1 study in Spain and France, 1 site each). First order half lives between 57 d – 195 d were observed in these trials.

Two soil accumulation trials were performed in Germany (pH 5.9 – 6.1; OM 2.3 – 3.3 %). In these studies no accumulation was observed and an estimated half life of 30 d was calculated. The meeting of experts found that the dissipation rates in these sites were fast compared to the longer values obtained in some of the field dissipation studies. Therefore, the experts concluded that these experiments cannot be used to exclude potential for accumulation of aclonifen in soil.

Accumulated, PEC soil were calculated by the RMS and presented in addendum 1 based on the worst case field half life, annual application of 2400 g/ha and no interception. Plateau steady state was calculated after 10 yr over a mixing layer of 20 cm. Actual and TWA PEC_S were calculated adding the result of the annual application on a 5 cm mixing layer over the plateau. The calculation was agreed by the experts in the meeting.

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

A batch adsorption / desorption study in three soils (pH 5.7 - 7.3; OC 1.1- 2.5 %; clay 3.8 - 17.9 %) is available for aclonifen. This substance may be considered practically immobile in soil (K_{oc} = 5318 –

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10612). Since only three experimental values are available, the lowest value, instead of the mean, has to be used in FOCUS modelling.

Column leaching studies and aged column leaching studies are available and confirmed that the substance is not mobile. Also non extractable residue in soil resulted to be immobile.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

According the hydrolysis study available, aclonifen is stable to hydrolysis at pH 5, 7 and 9. The aqueous photolysis study shows that aclonifen is slowly degraded by photolysis in water (DT_{50} = 197 d). The RMS calculated with ABIWAS 2.0 software that the experimental value presented in the dossier equates to environmental conditions half lives of 9-51 d in July to 94.5 - 1040 d in December at 55 °N. Further clarification on the RMS calculation was required during the peer review. Clarification provided in addendum 1 was not found satisfactory by the experts in the meeting. Additional information has been provided by the RMS in addendum 3. Taking into consideration that the calculation is for northern EU latitudes, higher contribution of photolysis could be expected for southern latitudes. However, the RMS, as author of these later calculations, is of the opinion that the overall contribution of aqueous photolysis to the environmental degradation of aclonifen in water should not be considered relevant. This is the conclusion that was originally reached when the results of the aqueous photolysis study are considered directly considered.

Aclonifen was found to be not readily biodegradable in the available study.

Degradation of aclonifen was investigated in one study with two water sediment systems (pH_{water} = 6.7 – 7.5; pH_{sed} = 6.8 – 8.4, OC 3.8 – 5.7 %, clay 10.54 – 28.99 %) incubated under dark aerobic conditions at 20 °C. In both water / sediment systems aclonifen steadily partitioned to the sediment and degraded. None of the metabolites observed reached 5 % AR in any of the phases. Mineralization was negligible in both systems (max CO_2 = 2.07 % AR) and unextractable residue in the sediment amounted up to 65.6 -76.5 % AR at the end of the experiments (180 d). Separated half lives for the water and sediment phases were considered unreliable and not representing true degradation by the experts. The meeting agreed that total system half lives could be used for the risk assessment since this overcomes any difficulty associated to the fact that experiments were carried out applying the substance above the solubility limit. The meeting agreed that quality of one of the fits does not fulfil FOCUS requirements and that the longest half life (DT_{50} = 17.3 d) must be used for risk assessment. New FOCUS $PEC_{SW/SED}$ up to STEP 4 (including effect of spray drift and run off mitigation by buffer and vegetative strips) using the agreed input parameters were available in addendum 1. The calculations were agreed for the STEP 3 and the STEP 4 when only spray drift mitigation was assumed. With respect to STEP 4 calculations accounting for run-off mitigation, the calculation was not reported in a transparent way either in the addendum or in the applicants report and therefore they were not validated by the meeting. After the experts meeting, further clarification has been provided by the RMS, in Addendum 3. Since this information is not available in the report presenting the modelling results, it is assumed that the clarification and additional calculations presented in addendum 3 have been provided in consultation with the applicant. In this clarification, it is stated that SWAN has been used for STEP 4 calculations. A mention to this tool was introduced in the

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FOCUS Landscape report (FOCUS, 2008) modified after the EFSA's panel opinion. Assumptions reported in addendum 3 with respect to efficiency of VFS with regard to reduction of water and sediment loads are in line with the ones proposed in FOCUS Landscape. It is claimed that SWAN automatically assumes mitigation in the upstream catchments. However, the lack of publicly available manuals for SWAN software in the FOCUS webpage does not allows an independent verification of this. New modelling has been performed to demonstrate that the mitigation assumed does not result in a reduction on the runoff to surface water higher than 90 %. However, the argumentation is based on he resulting PEC_{SW} and not on the runoff loads. In fact most of the runoff comes from suspended matter and soil loads for which mitigation is higher than 90 % when a vegetative buffer strip of 20 m is assumed. Therefore, calculations should be based on a vegetative buffer strip of a maximum of 10m. Also new calculations have been presented to account for further spray drift buffer zone (up to 45 m) additional to the 20 m vegetative buffer strip to mitigate runoff. EFSA noted that spray drift mitigation is higher than 95 % for some of the sunflower scenarios when a spray drift buffer of 45 m is assumed. This mitigation exceeds the maximum spray drift mitigation realistically attainable according FOCUS Landscape. Addendum 3 does not quote any reference to any updated report for these calculations. Since the details given in addendum 3 are missing in the original report (Hardy, I. and Patel, M. **2008**) a new or amended report would need to be provided for proper peer review. Whereas the RMS is of the opinion that results presented under Addendum 3 simply follow the noted version of the FOCUS Landscape and mitigation guidance document[8], substantial issues remain open and the calculations may not be considered peer reviewed without further consideration of the MS's experts. Therefore, only $PEC_{SW/SED}$ presented in Table 17 of addendum 1 may be considered peer reviewed for EU risk assessment.

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

Potential contamination of ground water for the use of aclonifen in sunflower was addressed following the FOCUS GW scheme with FOCUS PELMO (v 3.3.2). The resulting 80th percentile annual average concentrations of aclonifen at 1m depth were below 0.001 µg / L in the two (Piacenza and Sevilla) relevant FOCUS scenarios. Average of the three available K_{oc} (instead of worst case) was used in the calculation and only results with one FOCUS model were provided. However, the meeting of experts, based on expert judgement, agreed that the regulatory trigger of 0.1 µg / L is not expected to be exceeded when the worst case K_{oc} or other FOCUS model would be used.

[8] The **FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment** started its work in 2002. A draft report was finalised in 2005 and has subsequently been modified to account for comments from the EFSA PPR Panel. The final report (two volumes) was formally noted in March 2008 and is available for download in: http://viso.jrc.it/focus/lm/. Volume 1 includes the PPR Panel opinion in full as an Annex.

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4.3. FATE AND BEHAVIOUR IN AIR

Due to the low potential of volatilization as derived from physic-chemical properties, the volatilization experiments available and the estimated photochemical transformation half life (1.2 d), the environmental concentrations in air and the transport through air are considered negligible.

5. Ecotoxicology

Aclonifen was discussed in the meeting of experts on ecotoxicology PRAPeR 42 (March – April 2008), on basis of the DAR (August 2006) and the Addendum 1 (March 2008). A new Addendum 3 (May 2008) has been made available after the meeting of experts. A data gap was identified in the meeting for a full specification of the material used in the ecotoxicological studies as well as an assessment of the compliance with the technical specification.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The representative use evaluated is the use as a pre-emergence herbicide in sunflower at a rate of 1 x 2.4 kg a.s./ha. The risk assessment was conducted only for insectivorous birds. The risk to herbivorous birds was considered to be low since aclonifen is applied to bare soil. The acute and short-term first-tier TERs for insectivorous birds exceeded the trigger of 10 but the long-term risk needed further refinement. The refined risk assessment was based on white wagtail (*Motacilla alba*) as a focal species and a PT of 0.2. The refinement of PT was rejected in the experts´ meeting since the PT was based on observations of occurrence of white wagtail in different habitats but not based on e.g. radio-tracking data. The experts were also concerned about the choice of the focal species since other studies indicated that skylark (*Alauda arvensis*) is more abundant as white wagtail in fields at early growth stages. A data gap was identified by the experts for the applicant to submit a new refined long-term risk assessment for birds.

A medium herbivorous mammal is the standard generic focal species for the risk assessment in leafy crops. Since aclonifen is applied pre-emergence it was considered more appropriate to focus the risk assessment on insectivorous mammals. The acute TER was above the trigger of 10 but the long-term risk assessment needed refinement. The refined long-term TERs were calculated for *Sorex araneus* (common shrew), *Micromys minutus* (harvest mouse) and *Apodemus sylvaticus* (wood mouse). The suggested PT value of 0.2 was rejected by the experts since it was not sufficiently justified by data. The RMS informed that a new radio-tracking study with mammals was made available but was not included in the original dossier and hence was not taken into account to refine the risk assessment. A data gap was identified by the experts for the applicant to submit a new long-term risk assessment for insectivorous mammals. The long-term endpoint (35 mg a.s./kg bw/d) used in the original risk assessment in the DAR was discussed in the meeting. Statistically significant effects on body weight were observed at the dose of 35 mg a.s./kg bw/d. The effects were <10% but a reduced fitness and thus adverse effects on populations of wild mammals under realistic environmental conditions cannot be excluded. The experts agreed that the NOEC of 8 mg a.s./kg bw/d should be used in the risk

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assessment. The RMS updated the long-term mammal risk assessment in addendum 3. The overall outcome does not change.

The log Pow of aclonifen is >3 triggering a risk assessment for secondary poisoning. The long-term TERs for fish-eating birds and mammals were above the trigger of 5. A new TER calculation for earthworm-eating birds and mammals with new PEC_s was presented in the not-peer reviewed addenda 3. The recalculated TERs were also above the trigger of 5 for birds but the TER for earthworm-eating mammals (based on the new agreed NOEC) was below the trigger of 5 and needs further refinement. The risk from uptake of contaminated drinking water was considered to be low since the product is applied to bare soil.

5.2. RISK TO AQUATIC ORGANISMS

The lowest endpoints were observed in studies with algae (EbC50 = 0.0067 mg a.s./L), higher aquatic plants (EbC50 = 0.005 mg a.s./L) and in long-term studies with fish (35-d early life stage study NOEC = 0.005 mg a.s./L). A revised risk assessment was presented in addendum 3 from May 2008. The TERs based on FOCUS step3 PECsw exceeded the Annex VI triggers for all scenarios (D5, R1, R3, R4) for *Chironoumus riparius* but no full scenario resulted in TERs above the triggers for fish, daphnids, algae, higher aquatic plants. Risk mitigation comparable to a reduction of entry into surface water by 90% would lead to TERs greater than the Annex VI triggers for fish and aquatic invertebrates.

The risk assessment for aquatic plants was refined by using a 4-d time weighted average PECsw. This refinement step was agreed by the experts since the test media was renewed every 3-4 days ensuring relatively constant exposure. The TERs were above the trigger of 10 for the FOCUS scenarios D5 and R1 but not for scenarios R3 and R4.

The use of weighted average PECsw was also accepted by the experts in relation to long-term effects on growth of fish. However concerns were raised regarding the long time window of 28 days (no measurements of fish growth was conducted before day 28 and therefore not possible to detect a potential earlier onset of growth effects). It was suggested that the time window may be revised at MSs level when guidance will be available from the e-link workshop. However it was unclear whether effects on hatch success would be covered by the use of time weighted average values since reduced hatch success could also be induced by a short exposure peak. The experts agreed that the NOEC hatch success (NOEC = 0.011 mg a.s./L) should be compared to initial PECsw values and also be presented in the risk assessment. The TER is significantly below the trigger of 10 based on the maximum initial PECsw from the worst-case scenario R3. However the risk to fish based on hatch success would be covered by the risk mitigation necessary for algae.

The RMS recalculated the TERs for algae in the not peer-reviewed addendum 3 including a no-spray buffer zone of 40 m in combination with run-off mitigation by 80/95%. The suggested risk mitigation exceeds the maximum suggested by the FOCUS Landscape report and uncertainty remains also with regard to the PECsw following the proposed run-off mitigation. (see point 4.2.1). However, even with the suggested mitigation the TERs are above the trigger in only one full scenario (D5) and in the part

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scenario R1 (pond). The full scenarios R3, R4 and the part scenario R1(stream) still results in TERs below the trigger of 10.

The risk from bioconcentration was assessed as low. The experimentally derived BCF of 2896 is above the trigger of 100 for not readily biodegradable substances. However the substance was eliminated rapidly from fish tissues (95% within 8.8 days) and the substance dissipates rapidly from the water phase. Therefore the risk of bioaccumulation was considered to be low.

Overall it is concluded that the representative use of aclonifen poses a high risk to aquatic organisms.

5.3. RISK TO BEES

The acute oral and contact toxicity of aclonifen to bees is low. The acute oral and contact HQ values were calculated as 22.4 and 24. The HQ values are below the trigger of 50. The risk to bees is considered to be low for the representative use in sunflower.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory tests were conducted with the formulation Bandur SC 600 and *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Chrysoperla carnea* and the ground dwelling arthropods *Poecilus cupreus* and *Pardosa sp*. The in-field and off-field HQ values for *A. rhopalosiphi* were lower than the trigger of 2. The off-field HQ for *T. pyri* was also <2 but not the in-field HQ value. Significant mortality of >50% was observed also in an extended laboratory test where the predatory mites were exposed to fresh resides on leafs. However since the product is applied pre-emergence the risk to leaf dwelling non-target arthropods in the in-field area is considered to be low. Since the off-field risk for *T. pyri* was assessed as low it could be assumed that there is potential of recovery. Ground dwelling arthropods are more likely to be exposed. The in-field and off-field risk to the other non-target organisms tested in standard laboratory tests (including the ground dwelling species *P. cupreus* and *Pardosa sp*.) was assessed as low.

Additional extended laboratory studies were conducted with *Chrysoperla carnea*, the ground dwelling spider *Pardosa sp*. and the soil dwelling mite *Hypoaspis aculeifer*. The observed effects were <50% at the in-field application rates suggesting a low risk.

Overall it is concluded that the risk to non-target arthropods is low for the representative use of aclonifen as a pre-emergence herbicide.

5.5. RISK TO EARTHWORMS

The acute and long-term (reproductive) toxicity was tested with formulated aclonifen. The endpoints were corrected by a factor of 2 since the log Pow of aclonifen is >2. The acute endpoint observed for technical a.s. (LC_{50} = 150 mg a.s./kg soil) was higher than the acute toxicity of formulated aclonifen (LC_{50} = 95 mg a.s./kg soil). However since all studies were conducted with formulated aclonifen a potential increased toxicity of the formulation is covered in the risk assessment. The acute and long-term TERs were above the triggers of 10 and 5 based on the maximum plateau PECsoil of 3.5 mg

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a.s./kg soil. Two earthworm field studies were also submitted but assessed as not valid by the RMS. The field studies are not necessary to reach a final conclusion since the first-tier TERs already indicate a low risk to earthworms from the representative use of aclonifen.

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

A litterbag study and a study with the soil dwelling mite *Hypoaspis aculeifer* were submitted since the field DT_{90} of aclonifen in soil is >365 days. The test results with H. aculeifer suggest that survival is more affected than reproduction (LR50 = 126.2 mg a.s./kg soil, NOECreproduction >133 mg a.s./kg soil). The long-term TER is 3.8 based on the NOEC for mortality (13.3 mg a.s./kg soil) and the maximum plateau PECsoil of 3.5 mg a.s./kg soil. Nevertheless the long-term risk to soil dwelling mites was considered to be low since reproduction was not affected and the mortality was only 13% at the next higher tested concentration of 42.1 mg a.s./kg soil. The in-field risk for *H. aculeifer* based on lethal effects was assessed as low (see point 5.4. on non-target arthropods).

No effects on organic matter breakdown was observed in the litterbag study at the tested application rates of 1010 g a.s./ha + 2400 g a.s./ha (equivalent to 4.5 mg a.s./kg soil). The amount of applied aclonifen exceeds the calculated maximum plateau PECsoil. Overall it is concluded that the risk to soil dwelling non-target macro-organisms and organic matter breakdown can be considered as low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

No effects of ≥25 % on soil respiration and nitrification were observed at concentrations of up to 15 kg a.s./ha or 30 kg formulation/ha. The applied rates cover the maximum plateau PECsoil. Therefore it can be concluded that the risk to soil non-target micro-organisms is low for the representative use of aclonifen.

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

Several studies investigating herbicidal effects of formulated aclonifen were submitted. *Brassica napus*, *Lolium perenne* and *Lactuca sativa* were the most sensitive species out of 14 tested species. The lowest endpoint (ER_{50} = 1.12 g a.s./ha) was observed for *Brassica napus* under high temperature and high soil moisture conditions. Studies with *Lactuca sativa*, *Lolium perenne* and *Brassica napus* were performed under field exposure conditions. The observed endpoints were significantly higher than the endpoints from the laboratory studies. The RMS suggested using the endpoints from the field studies to refine the risk assessment. Several uncertainties in relation to the field studies were identified by the experts: the influence of the weather conditions on the dissipation of aclonifen, the application pattern and actual exposure. This information may be available to the applicant and could be addressed in future. In the meantime the experts suggested using the lowest observed ER50 of 1.12 g a.s./ha in the risk assessment. Even an in-field no-spray buffer zone of 50m would not be sufficient as a risk mitigation measure if the endpoint of 1.12 g a.s./ha is used together with a safety factor of 5. A data gap was identified in the experts´ meeting for the applicant to provide a refined risk assessment for non-target plants. It may be built on re-assessment of available data including clarification about the exposure conditions in the field studies. Explanations on the relative sensitivity

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of the species and on the exposure conditions should be provided for both laboratory and field studies.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No adverse effects were observed on respiration of activated sewage sludge up to the highest tested concentration of 1000 mg a.s./L. The risk to biological methods of sewage treatment is considered to be low if aclonifen is applied according to the proposed GAP.

6. Residue definitions

Soil

Definition for risk assessment: aclonifen

Definition for monitoring: aclonifen

Water

Ground water

Definition for exposure assessment: aclonifen

Definition for monitoring: aclonifen

Surface water

Definition for risk assessment: aclonifen

Definition for monitoring: aclonifen

Air

Definition for risk assessment: aclonifen

Definitions for monitoring: aclonifen

Food of plant origin

Definition for risk assessment: aclonifen for the metabolism group pulses and oilseeds only.

Definition for monitoring: aclonifen for the metabolism group pulses and oilseeds only.

Food of animal origin

Definition for risk assessment: not required.

Definition for monitoring: not required.

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
Aclonifen	moderate to high persistent in soil (DT_{50} = 32.2 – 134 d)	The toxicity and the risk to soil dwelling organisms was assessed as low.

Ground water

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
Aclonifien	immobile in soil (K_{oc} = 5318 – 10612)	No	Yes	Yes	Yes

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Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Aclonifen (water and sediment)	Very toxic to aquatic organisms. A high risk to aquatic organisms cannot be excluded.

Air

Compound (name and/or code)	**Toxicology**
Aclonifen	Not acutely toxic by inhalation (LC_{50} > 5.06 mg/L)

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

- A revised technical specification has been identified as a data gap (relevant for all uses, data gap identified by meeting of experts April 2008, date of submission unknown, refer to chapter 1)
- Rotation crop residue study has been identified as a data gap (relevant for all uses, data gap identified by meeting of experts April 2008, data submitted but not evaluated or peer reviewed, refer to chapter 3)
- A formal data gap has been identified for report *Kinetic modelling analysis of aclonifen from aerobic soil degradation studies normalised to 20 ℃ and pF2, report-No.VC/08/016B*; Hardy, I. and Patel, M. **2008** (relevant for all representative uses evaluated; submission date proposed by the notifier: already available; refer to point 4.1)
- A data gap for a study to investigate the route and rate of degradation of aclonifen in soil under anaerobic conditions has been identified (data gap not considered essential to finalize the risk assessment of the representative EU uses proposed; refer to point 4.1)
- A formal data gap has been identified for report *Predicted environmental concentrations in surface water and sediment for aclonifen following pre-emergence application to sunflowers at 200 g / ha, report-No. VC/08?016C;* Hardy, I. and Patel, M. **2008** (relevant for all representative uses evaluated; submission date proposed by the notifier: already available, however a new or amended report to include details on implementation of vegetative strips run off mitigation would need to be provided; refer to point 4.2)
- A new refined long-term risk assessment for birds is needed (relevant for all uses evaluated; data gap identified in the meeting of experts (PRAPeR 43) in April 2008; no submission date proposed by the applicant; refer to point 5.1.)
- A new long-term risk assessment for insectivorous and earthworm eating mammals (relevant for all uses evaluated; data gap identified in the meeting of experts (PRAPeR 43) in April 2008; no submission date proposed by the applicant; refer to point 5.1.)
- The aquatic risk assessment needs further refinement (relevant for all uses evaluated; data gap identified by EFSA after the meeting of experts (PRAPeR 43) in April 2008; no submission date proposed by the applicant; refer to point 5.2.)
- A refined risk assessment for non-target plants (relevant for all uses evaluated; data gap identified in the meeting of experts (PRAPeR 43) in April 2008; no submission date proposed by the applicant; refer to point 5.8.)
- A full specification of the material used in the ecotoxicological studies needs to be provided (relevant for all uses evaluated, data gap identified in the meeting of experts (PRAPeR 43) in April 2008; no submission date proposed by the applicant; refer to point 5.)

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CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a pre-emergence herbicide as proposed by the applicant. Full details of the GAP can be found in the attached list of end points.

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

Adequate methods are available to monitor all compounds given in the respective residue definition. Residues in food of plant origin can be determined with a multi-method (The German S19 method has been validated). For the other matrices only single methods are available to determine residues of aclonifen.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that some quality control measurements of the plant protection product are possible. The exception to this is the relevant impurity phenol where there is no method to monitor it in the formulation. It was concluded during the peer review process that the specification is not supported and a data gap has been identified. In addition it was considered by the meeting of experts mammalian toxicology that phenol is a relevant impurity. The meeting of experts discussed that as the technical material is a wet cake a TK specification should be required but no conclusion was reached on this in the meeting.

In rats aclonifen is absorbed rapidly to an extent of about 80% and distributed widely in the body. It has no potential for accumulation. Enterohepatic circulation of aclonifen is significant. The substance is excreted rapidly and almost completely within 48 hours after application via the urine and faeces. It is extensively metabolised. Aclonifen is of very low acute toxicity. It is neither a skin nor an eye irritant. Aclonifen was positive in a Magnussen & Kligman skin sensitisation test with guinea pigs. Based on the data available for acute toxicity a classification as **Xi; R43 "Irritant; May cause sensitisation by skin contact"** is proposed for aclonifen. Short term studies were carried out with dogs, mice and rats. In the latter species the lowest short-term NOAEL of 3.6 mg/kg bw/d was obtained based on effects on body weight, blood chemistry, increased liver and kidney weights and pathology. Aclonifen is not genotoxic. Two chronic rat studies and a carcinogenicity study with mice have been carried out. The systemic NOAELs in the rat studies were set at 7.0 and 7.6 mg/kg bw/d respectively based on signs of general toxicity (decreased bodyweight, changed clinical parameters, liver effects). In the first rat study thyroid tumours occurred while in the second one astrocytomas (rare malignant brain tumours) could be detected. In the mouse study bladder tumours at high dose where seen. While the PRAPeR experts dismissed both the thyroid and bladder tumours as not relevant for human risk assessment, the brain tumours remained of concern and consequently a classification as **Xn; Carc. Cat. 3 R40 "Harmful; Limited evidence of a carcinogenic effect"** was proposed. A two generation study and one developmental study with rats and one with rabbits have

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been reported and although aclonifen exerted general toxicity signs in these studies neither specific effects on reproduction nor teratogenic effects could be observed. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) were derived from the first 24-month rat study applying a safety factor of 100. An acute reference dose (ARfD) was not allocated. In consideration of a dermal absorption of 2% for the concentrate and 10% for the spray dilution of the preparation the operator exposures were 16.1% and 207.1% of the AOEL when wearing personal protective equipment (PPE) in the German model and the UK POEM. When no PPE is worn values rise to 248.4 % in the German model and to 1318.6% in the UK POEM. Exposure of bystanders and unprotected re-entry workers was estimated to amount to 4.6% and 2.9% of the AOEL respectively.

The metabolism of aclonifen was investigated in wheat, peas and potatoes. However in the meeting of experts PRAPeR 45 no conclusion could be reached on the cereal and potato metabolism studies because there were no GAPs for these crops in the representative uses evaluated. So only the pea study was considered further. The pea study is representative of the relevant metabolism group for sunflowers which is the supported crop. This study showed that there are no significant residues in peas or in podded peas the major residue in the vinings was aclonifen. The residue definition for pulses and oilseeds was set as aclonifen only. The rotational crop metabolism study showed that in the majority of crops no significant residues would occur. However, for root and tuber crops it showed that residues could be expected. A data gap was set for a rotational crop residue study. The need for animal studies was not triggered. A goat metabolism study was evaluated in the DAR but the peer review did not conclude on its acceptability. A full set a residue data were available for the north and south of Europe all residues were <0.02 mg/kg at harvest. The consumer risk assessment could not be concluded because of the data gap identified for rotational crops. A risk assessment based on intakes of sunflower showed that the TMDI did not exceed 1 % of the ADI, no acute risk assessment was necessary.

The route of degradation in soil under dark aerobic conditions was investigated in two studies in a total of five soils. Albeit the drawbacks identified in this studies, the meeting of experts agreed that the data submitted was enough to satisfy the regulatory requirements. Practically the totality of the extracted radioactivity consisted in parent compound with only very minor metabolites detected. Mineralization was negligible or very low (CO_2: 0.7 – 5.2 % AR). Unextracted soil residue increase continuously up to 40.9 – 63.7 % AR at the end of the studies.
According the photolysis in soil study available, photolysis may contribute slightly to the degradation of aclonifen in soil. No metabolite exceeded 5 % AR.
Degradation of aclonifen in soil under anaerobic conditions was investigated in one of the studies presented in the dossier that was not considered reliable. Therefore, the meeting identified a data gap that was not considered essential to finalize the risk assessment of the EU representative uses.
Aclonifen may be considered moderate to high persistent in soil under aerobic conditions at 20 °C (DT_{50} = 32.2 – 134 d).
Kinetics of all aerobic degradation data was re-evaluated with non linear regression to first order kinetic and values obtained were normalized to 20 °C and pF2. Since the report was not available in

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the updated dossier, the meeting identified a formal data gap for the applicant to incorporate this report (Hardy, I. and Patel, M. 2008) into it. The meeting of experts agreed the end points proposed by the RMS in table 66 of addendum 1.

Two field dissipation studies are available in North Europe (1 study in Germany, 4 sites) and Southern Europe (1 study in Spain and France, 1 site each). First order half lives between 57 d – 195 d were observed in these trials. The two soil accumulation trials performed in Germany were considered not to adequately address the potential accumulation of aclonifen in soil. Accumulated, PEC soil were calculated by the RMS and presented in addendum 1 based on the worst case field half life, annual application of 2400 g/ha and no interception. Plateau steady state was calculated after 10 yr over a mixing layer of 20 cm. Actual and TWA PEC_S were calculated adding the result of the annual application on a 5 cm mixing layer over the plateau. The calculation was agreed by the experts in the meeting. Aclonifen may be considered practically immobile in soil (K_{oc} = 5318 – 10612).

Aclonifen is stable to hydrolysis at pH 5, 7 and 9. The aqueous photolysis study and the subsequent RMS model calculation show that photolysis may contribute in a limited extend to the degradation of aclonifen in water environment. Aclonifen is not readily biodegradable.

Degradation of aclonifen was investigated in one study with two water sediment systems (pH_{water} = 6.7 – 7.5; pH_{sed} = 6.8 – 8.4, OC 3.8 – 5.7 %, clay 10.54 – 28.99 %) incubated under dark aerobic conditions at 20 °C. In both water / sediment systems aclonifen steadily partitioned to the sediment and degraded. None of the metabolites observed reached 5 % AR in any of the phases. Mineralization was negligible in both systems (max CO_2 = 2.07 % AR) and unextractable residue in the sediment amounted up to 65.6 -76.5 % AR at the end of the experiments (180 d). Separated half lives for the water and sediment phases were considered unreliable and not representing true degradation by the experts. The meeting agreed that total system half lives could be used for the risk assessment (DT_{50} = 17.3 d). New FOCUS $PEC_{SW/SED}$ up to STEP 4 (including effect of spray drift and run off mitigation by buffer and vegetative strips) using the agreed input parameters were available in addendum 1. The calculations were agreed for the STEP 3 and the STEP 4 when only spray drift mitigation was assumed. Therefore, only $PEC_{SW/SED}$ presented in Table 17 of addendum 1 may be considered peer reviewed for EU risk assessment.

Aclonifen is not considered to pose a risk for contamination of ground water above the trigger of 0.1 µg / L when used according the GAPs for the representative use evaluated. Concentrations in air and transport through air are considered negligible for aclonifen.

The first-tier long-term risk assessment for birds and mammals needed refinement. The refinement of PT was not sufficiently supported with data and a data gap was identified to submit a new refined long-term risk assessment for birds and mammals. An new (lower) long-term endpoint for mammals was agreed in the experts` meeting (NOEC of 8 mg a.s./kg bw/d). The risk of secondary poisoning of earthworm- and fish-eating birds and fish-eating mammals as well as the risk from uptake of contaminated drinking water was assessed as low. However the risk to earthworm-eating mammals needs further refinement. Aclonifen is very toxic to fish, algae and higher aquatic plants. Refinement of the risk assessment using time weighted average PECsw was accepted for *Lemna gibba* and fish (growth effects) but not for effects on hatch success. The TERs for algae are lower and the risk to fish

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would be covered by the risk mitigation required for algae. However even if a no-spray buffer zone of 40 m in combination with run-off mitigation by 80/95% is applied then the TERs are above the trigger in only one full FOCUS step 4 scenario (D5) and in the part scenario R1 (pond). It is noted that the suggested reduction of spray-drift entry exceeds the recommendation of the FOCUS Landscape report and uncertainty remains also with regard to the PECsw following the proposed run-off mitigation. The full scenarios R3, R4 and the part scenario R1(stream) still result in TERs below the trigger of 10. Overall it is concluded that the representative use of aclonifen poses a high risk to aquatic organisms. The non-target plant *Brassica napus* reacted very sensitive under high temperature and high soil moisture growth conditions. Even an in-field no-spray buffer zone of 50 m would not be sufficient to achieve a TER of >5 using the lowest ER_{50} for *Brassica napus* of 1.12 g a.s./ha. Under field exposure conditions the observed endpoints were significantly higher. However the experts identified uncertainties with regard to the influence of the weather conditions on the dissipation of aclonifen, the application pattern and actual exposure in the field studies. A data gap was identified in the experts´ meeting for the applicant to provide a refined risk assessment for non-target plants.

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

- For operators personal protective equipment is needed.

Critical areas of concern

- There is no minimum purity for the active substance and no agreed specification for the impurities
- The consumer risk assessment can not be finalised due to the data gap for rotational crop residue trials.
- The long-term risk to birds and mammals needs further refinement.
- The risk to aquatic organisms.
- The risk to non-target plants in the off-field area needs further refinement.

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

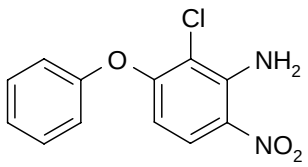
(Abbreviations used in this list are explained in appendix 2)

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

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

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	–

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-chloro-6-nitro-3-phenoxyaniline
Chemical name (CA) ‡	2-chloro-6-nitro-3-phenoxybenzenamine
CIPAC No ‡	498
CAS No ‡	74070-46-5
EC No (EINECS or ELINCS) ‡	277-704-1
FAO Specification (including year of publication) ‡	None
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Phenol maximum level open
Molecular formula ‡	$C_{12}H_9ClN_2O_3$
Molecular mass ‡	264.7 g/mol
Structural formula ‡	

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Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	81.2 °C (996 g/kg)
Boiling point (state purity) ‡	Decomposition before boiling
Temperature of decomposition (state purity)	297 °C (996 g/kg)
Appearance (state purity) ‡	yellow powder (996 g/kg, pure and 994 g/kg, technical material)
Vapour pressure (state temperature, state purity) ‡	1.6×10^{-5} Pa at 20 °C 1.4×10^{-4} Pa at 35 °C 1.1×10^{-3} Pa at 50 °C (all 993 g/kg) 3.2×10^{-5} Pa at 25 °C (calculated)
Henry's law constant ‡	3.03×10^{-3} Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH) ‡	1.40 mg/L at 20 °C (997 g/kg) at pH 5, 7 and 9
Solubility in organic solvents ‡ (state temperature, state purity)	*n*-hexane: 4.8 g/L toluene: 442 g/L dichloromethane: > 820 g/L methanol: 49.2 g/L 2-propanol: 25.9 g/L *n*-octanol: 34.7 g/L acetone: > 730 g/L ethyl acetate: > 600 g/L acetonitrile: 482 g/L all at 25 °C (993 g/kg)
Surface tension ‡ (state concentration and temperature, state purity)	72.0 mN/m at 20 °C, 90% saturated solution (994 g/kg)
Partition co-efficient ‡ (state temperature, pH and purity)	4.37 (~~no~~ pH 5-6, distilled water; no purity stated)
Dissociation constant (state purity) ‡	Not measurable, by calculation constant is -3.15.
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	neutral: $\varepsilon = 18987$ L mol^{-1} cm^{-1} ($\lambda = 238$ nm) $\varepsilon = 8431$ L mol^{-1} cm^{-1} ($\lambda = 310$ nm) $\varepsilon = 6143$ L mol^{-1} cm^{-1} ($\lambda = 390$ nm) (all 997 g/kg) no significant differences in acid and basic media.

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Flammability ‡ (state purity)	not highly flammable no self-ignition between room temp. and melting point (EEC A16)	(994 g/kg) (994 g/kg)
Explosive properties ‡ (state purity)	not explosive	(994 g/kg)
Oxidising properties ‡ (state purity)	not oxidising	(994 g/kg)

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Summary of representative uses evaluated (aclonifen)*

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	kg as/hL min - max (l)	water L/ha min - max	kg as/ha min - max (l)	(m)	
Sunflower	EU	Bandur	F	monocot and dicot weeds	SC	600 g/L	overall spray	pre-emergence	1	n. a.	0.6 - 1.2	200 - 400	2.4	n. a.	[1] [2]

[1] Technical specification not agreed.
[2] Data gaps were identified in section 5 with regard to the long-term risk to birds and mammals, the risk to aquatic organisms and non-target plants.

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

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Chapter 2.2 Methods of Analysis

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

Technical as (analytical technique)	RP-HPLC / UV
Impurities in technical as (analytical technique)	RP-HPLC / UV GC/FID
Plant protection product (analytical technique)	HPLC/UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Aclonifen
Food of animal origin		not relevant
Soil		Aclonifen
Water	surface	Aclonifen
	drinking/ground	Aclonifen
Air		Aclonifen

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-ECD 0.01 mg/kg (wheat grain, barley grain, corn grain, tomato) GC-ECD 0.02 mg/kg (lemon, sunflower seed) GC-ECD 0.05 mg/kg (corn silage) GC-MSD 0.01 mg/kg (potato) LC-MS/MS 0.01 mg/kg (sunflower seed, dry pea, onion)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant, no MRL proposed
Soil (analytical technique and LOQ)	GC-ECD 0.01 mg/kg (sandy clay loam, sandy silt loam) GC-MSD 0.01 mg/kg
Water (analytical technique and LOQ)	GC-ECD 0.05 µg/L (tap water, mineral water, river water, pond water) GC-MSD 0.05 µg/L (river water, pond water)
Air (analytical technique and LOQ)	GC-ECD 0.25 µg/m³ (warm, humid air)
Body fluids and tissues (analytical technique and LOQ)	Not relevant, because active substance not classified as toxic or highly toxic (T/T+)

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

	RMS/peer review proposal
Active substance	None

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Chapter 2.3 Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid (approx. 80 % within 24 h, based on urinary and biliary excretion; lower absorption at high dose level)
Distribution ‡	Widely distributed. After repeated oral dosing (14 d) mainly found in liver, kidney, lung, thyroid and skin/fur
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	Nearly complete (within 48 h); 39 - 65 % in females 38 - 50 % in males via urine, most of the remaining material via faeces
Metabolism in animals ‡	Extensive, main pathways: hydroxylation of the phenyl ring, cleavage of the ether bond, reduction of the nitro group and subsequent acetylation, methylation, and phase II type conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Aclonifen
Toxicologically relevant compounds ‡ (environment)	Aclonifen

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 5000 mg/kg bw	
Rat LD_{50} dermal ‡	> 5000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.06 mg/L/4h, nose-only	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitiser (M & K)	**R 43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Kidney and liver: organ weight↑, clinical chemistry changes, macroscopical and histological findings indicative of kidney damage (rat:, nephrosis, nephritis, necrosis); bw↓	
Relevant oral NOAEL ‡	3.6 mg/kg bw/day, (90-d, rat) 15 mg/kg bw/day (26-week, dog)	
Relevant dermal NOAEL ‡	500 mg/kg bw/day (28-d, rat, 5 days application per week)	
Relevant inhalation NOAEL ‡	No data available, not required	

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Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential	

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

Target/critical effect ‡	Urinary bladder (mouse): urothelial hyperplasia; thyroid (rat) and liver: organ weight↑; body weight↓	
Relevant NOAEL ‡	7 mg/kg bw/day (2-year, rat) 7.1 mg/kg bw/day (18 month, mouse)	
Carcinogenicity ‡	Astrocytomas at 86 mg/kg bw/day, (females) rat. Bladder tumors at about 700 mg/kg bw/day mouse (these tumours are considered of no relevance to humans)	**R 40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: Decreased bodyweight gain and food consumption Reproductive: None Offspring: Birth weight and bodyweight gain of pups decreased at parentally toxic doses	
Relevant parental NOAEL ‡	Rat: 8 mg/kg bw/d	
Relevant reproductive NOAEL ‡	Rat: 120 - 140 mg/kg bw/d	
Relevant offspring NOAEL ‡	Rat: 35 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Rat maternal: Decreased body weight Rat foetuses: Decreased foetal weight at a maternally toxic dose (600 mg/kg bw) Rabbit: Maternal: None Developmental: None	
Relevant maternal NOAEL ‡	Rat: 60 mg/kg bw/d Rabbit: 25 mg/kg bw/d (highest dose tested)	
Relevant developmental NOAEL ‡	Rat: 60 mg/kg bw/d Rabbit: 25 mg/kg bw/d (highest dose tested)	

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Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data available, not required	
Repeated neurotoxicity ‡	No data available, not required	
Delayed neurotoxicity ‡	No data available, not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Aclonifen was found to bind to chromatin but not to naked DNA in mouse liver and bladder.
Studies performed on metabolites or impurities ‡	No data available, not required

Medical data ‡ (Annex IIA, point 5.9)

No evidence of adverse effects

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.07 mg/kg bw	2-year, rat supported by multigeneration study in rat and carcinogenicity study in mouse	100
AOEL ‡	0.07 mg/kg bw/d	2 year rat, supported by the multigeneration study and subchronic studies in the rat	100
ARfD ‡	Not allocated, not necessary (no acute toxicological alerts)		

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (Bandur 600 g/L)	2 % for the concentrate, 10 % for the dilution (based on rat in vivo and rat and human in vitro data)

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Exposure scenarios (Annex IIIA, point 7.2)

Operator	Acceptable for proposed use (herbicide on sunflower fields to bare soil: 2.4 kg as/ha). - 16% of the systemic AOEL (German model; gloves during mixing/loading; gloves and protective garment during application) - 207% of the systemic AOEL (UK-POEM; gloves during mixing/loading and application)
Workers	Unlikely exposure under the proposed conditions of use
Bystanders	Acceptable for proposed use

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

	RMS/peer review proposal
Substance classified (name)	Xi, R 43, Xn; Carc. Cat.3 R 40

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Chapter 2.4 Residues

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

Plant groups covered	Pulses and oilseeds (peas).
Rotational crops	leafy crops (spinach), cereals (barley), root vegetables (carrot)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Sunflower oil and pressed cake
Residue pattern in processed commodities similar to residue pattern in raw commodities?	The nature of the residue could not be investigated because residues were always < LOQ in raw and processed commodities.
Plant residue definition for monitoring	Aclonifen
Plant residue definition for risk assessment	Aclonifen
Conversion factor (monitoring to risk assessment)	not applicable

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

Animals covered	Not triggered for the representative uses. Note: a lactating goat study was supplied but as there were unidentified metabolites no conclusion on its acceptability was reached in the peer review process.
Time needed to reach a plateau concentration in milk and eggs	
Animal residue definition for monitoring	
Animal residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

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

Relevant residue: Aclonifen The transfer of aclonifen into human-edible commodities derived from leafy crops and cereals is negligible (< 0.02 mg/kg), residues in human-edible commodities derived from root crops levels have not been established yet as there is a data gap.-

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

Stable at -18 °C for at least 24 months in sunflower seed, pea and tomato and for at least 12 months in maize grain, maize forage and potato.

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

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
sunflower	Northern Region, field use	3 x < 0.01 mg/kg, 6 x < 0.02 mg/kg	None	0.02	0.02	0.02
	Mediterranean Region, field use	11 x < 0.02 mg/kg	None	0.02	0.02	0.02

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

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

ADI	0.07 mg/kg bw
TMDI (% ADI) according to WHO European diet (EFSA model)	0,02 % (WHO cluster diet B, highest TMDI value calculated for appropriate WHO diet with the EFSA model) intake based on sunflower seed only Risk assessment can not be finalised as residues in rotational root crops may need to be taken in to account (data gap).
TMDI (% ADI) according to national (to be specified) diets (EFSA model)	0.01 % (FR all population, highest TMDI value calculated for MS diet with the EFSA model) intake based on sunflower seed only Risk assessment can not be finalised as residues in rotational root crops may need to be taken in to account (data gap).
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	not applicable
ARfD	not allocated
IESTI (% ARfD)	not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not required
Factors included in IESTI and NESTI	not applicable

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Sunflower seed/oil	11	not allocated*	--	--
Sunflower seed/pressed cake	11	not allocated*	--	--

* all residues were < LOQ (raw crops and processed commodities), transfer factor could not be derived

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

Plant matrices	0.02* mg/kg for sunflower seed (aclonifen)
Animal matrices	No MRLs have been proposed for animal products as intakes do not trigger study requirements.

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

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Chapter 2.5 Fate and behaviour in the environment

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

Mineralisation after 100 days ‡	*0.7 – 5.2* % after 118 d [U-^{14}C-aniline]-labelled *2.6* % after 90/ 104 d [U-^{14}C-aniline]-labelled
Non-extractable residues after 100 days ‡	*7.2 – 57.6* % after 118 d, [U-^{14}C-aniline]-labelled *40.9 / 56.4* % after 104/ 90 d, [U-^{14}C-aniline]-labelled
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	no metabolites > 5 % determined in the studies Material bound to aqueous soluble soil colloids was observed (M1) at a range of 1 to 12 % of applied radioactivity but it does not seem to be a metabolite.

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

Anaerobic degradation ‡

Mineralisation after 100 days	No acceptable data available, data not required for the intended uses assessed at EU level.
Non-extractable residues after 100 days	No acceptable data available, data not required for the intended uses assessed at EU level.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No acceptable data available, data not required for the intended uses assessed at EU level.
Soil photolysis ‡	artificial sun light, 30 d, loamy sand, 22 °C Mineralisation after 30 d: 4.1 % non-extractable residues after 30 d: 5.3 %
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No metabolites > 5 % (ambient extracts) observed in the studies

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (site)	X[9]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (chi^2)	Method of calculation

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

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Laboratory studies ‡

Parent	Aerobic conditions						
Aldhams House (94/8/2) silty sand		6.7	20 °C / 60 % FC	134 / 443	93.6	10.4	SFO
Shelley Field (94/9/2) silty loam		7.0	20 °C / 60 % FC	73 / 242	51.0	7.2	SFO
Westleton (94/10/2) silty loam		6.8	20 °C / 60 % FC	95 / 315	66.4	5.4	SFO
Westleton (94/10/2) silty sand		6.8	20 °C / 30 % FC	>> 118 d			reduced soil moisture
sandy loam Arable		7.3	22 °C / 40 % MWHC	32/ 107	29.5	10.1	SFO
sandy loam Standard soil 2.3		6.6	22 °C / 40 % MWHC	78/ 259	72.6	4.8	SFO
loamy sand (Speyer 2.2 A)		6.0	22 °C / 40 % MWHC	93/309	83.7	0.7	SFO, initial residue at day14
loamy sand (Speyer 2.2 B)		6.0	22 °C / 40 % MWHC	76/ 254	68.7	2.7	SFO, initial residue at day14
sandy loam (Speyer 2.3)		7.0	22 °C / 40 % MWHC	34 / 114 53/ 177	41.9	2	SFO, initial residue at day14
loamy sand Westleton		6.8	10 °C / 50 % MWHC	222/ 740	86.5	3.4	SFO
clay loam Stockland		7.2	10 °C / 50 % MWHC	206 / 684 218/ 723	61.8	3.2	SFO
Geometric mean/median (DT_{50})					**62.3/67.6**		

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Laboratory studies ‡

Parent	Aerobic conditions

Field studies ‡

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used)	Location (country or USA state)	X [1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (chi^2)	DT_{50} (d) Norm.	Method of calculation
silty loam	Goch-Nierswalde, Germany		5.9	0 – 10	61	202	13.3		SFO
silty loam	Meißner-Vockerode, Germany		6.4	0 – 10	119	395	25.9		SFO
sandy loam	Schwichteler, Germany		6.3	0 – 30	195	649	11.3		SFO
sandy loam	Niederkirchen, Germany		7.3	0 – 30	13 / 57[1]	188.7	7.2		FOMC (α = 0.72, β= 8.29)
clay loam (cropped with sunflower)	Almacelles, Spain		7.8	0 – 30	51/ 108[1]	357	18.5		FOMC (α = 1.279, β= 70.628)
sandy silt loam (cropped with sunflower)	Cruas, France (Southern EU)		8.2	0 – 30	31	104	~~0.95~~ 14.7		SFO
Geometric mean/median (DT_{50}) for SFO					**80.4 / 84.5**	-	-		**not normalised**

[1] first order DT_{50} (DT_{50} = DT_{90}/3.32 see FOCUS Degradation Kinetics)

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

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Soil accumulation and plateau concentration ‡	Germany: 3 year study, 2 soils (silty loam), application of BANDUR SC 600 g/L every year in spring with 2700 g as/ha: No accumulation of aclonifen residues was observed at the two accumulation study trial sites, but the dissipation at the sites was too rapid to represent a realistic worst case. Measured plateau concentrations: Werl: 1.0115 mg/kg at day 0, 0.0153 mg/kg at day 350 Bibertal: 0.7392 mg/kg at d 0, 0.0290 mg/kg at day 357 Calculation of PECsoil accumulation: 2400 g as/ha, no interception, one application per year, soil density: 1.5 g/cm³ DT_{50} = 195 d (max. field trials) background concentration over 20 cm: 0.3008 mg/kg PEC_{ini} (5 cm): 3.2 mg/kg $PEC_{soil,accumulated}$ = 0.3008 mg/kg + PEC_{ini} = 3.5008 mg/kg

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[10]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Speyer 2.3			22 °C	-		-	-
Geometric mean/median							

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
loam	1.1	6.4			58.5	5318	0.878
sandy loam	1.7	7.3			92.6	5447	0.885
Loamy sand	2.5	5.7			265.3	10612	1.003
Arithmetic mean/median for PELMO calculation				**K_{foc}** =		**7126**	**0.922**
pH dependence, Yes or No			no				

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

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

Column leaching ‡	Eluation (mm): 400 mL Time period (d): 48 h Three soils: Speyer 2.1, 2.2 and 2.3
	Aclonifen was not detected in leachate (LOD < 2 µg / 386 mL or 0.3 % of applied).
Aged residues leaching ‡	1st study: Aged for (d): 1 month Time period (d): 48 h irrigation Eluation (mm): 200 mm in 2 days
	Aclonifen and it potential soil metabolites RPA 407074, RPA 508285, RPA 407291 and RPA 407288 were not detected in leachate (LOD < 4 µg / 400 mL or 0.5 % of applied).
Aged residues leaching ‡	2nd study: Aged for (d): 32 d Time period (d): 3 d irrigation Eluation (mm): 1040 mL
	Extract. residues: 95 % (Sp. 2.1), 85 % (sandy loam) Non extract. residues: 3.7 % (Sp. 2.1), 12.98 % (Sandy loam) Volatiles: 0.04 % (Sp. 2.1) 0.11 % (sandy loam) Leachate: 0.18 % (sand) Radioactivity in top 5 cm between 92.1 (Clay) and 98.2 (Speyer 2.1): Extract. radioactivity between 63 and 92 %
Lysimeter/ field leaching studies ‡	Location: Study type (e.g. lysimeter, field): lysimeter Soil properties: texture, pH = , OC = , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: x years, x applications per year Duration. Application rate: x g/ha/year Average annual rainfall (mm): x mm Average annual leachate volume (mm): x mm % radioactivity in leachate (maximum/year): x % AR

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Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): x µg/L active substance, x µg/L Met I, xµg/L Met VII. Unidentified radioactivity, no of components, x µg/L parent equivalents. Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): x µg/L active substance, x µg/L Met I, xµg/L Met VII. Unidentified radioactivity, no of components, x µg/L parent equivalents. Amount of radioactivity in the soils at the end of the study = % AR; XX % AR as parent, XX % AR as Met 1

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 195 days (worst case field degradation) Kinetics: SFO
Application data	Crop: sunflower Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Interval (d): - Application rate(s): 2400 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.20		not applicable	
Short term 24 h	3.1886	3.1943	not applicable	not applicable
2 d	3.1773	3.1887	not applicable	not applicable
4 d	3.1548	3.1774	not applicable	not applicable
Long term 7 d	3.1214	3.1605	not applicable	not applicable
28 d	2.8968	3.0459	not applicable	not applicable
50 d	2.6789	2.9318	not applicable	not applicable
100 d	2.2427	2.6931	not applicable	not applicable
Plateau concentration	Calculated (DT_{50} = 195 d) Final background conc. for a soil depth of 20 cm : 0.3008 mg/kg			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5- pH 9: hydrolytically stable, (incubation time 31 d between 22 °C and 70 °C) No metabolites > 10 % determined
Photolytic degradation of active substance and metabolites above 10 % ‡	DT_{50}: h Natural light, 40°N; DT_{50} days pH 7, intensity 324 W/m² at 25 °C (290 – 400 nm) as: residue 87.65 % after 16 d (DT_{50}: 197 d) No metabolites > 10 % determined
Quantum yield of direct phototransformation in water at Σ > 290 nm	$5.19 \cdot 10^{-6}$ mol · Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	not readily biodegradable

Degradation in water / sediment

Parent	Distribution: in sediment max of 53.4 % at day 7; in water max of 98.3 % at day 0 No metabolites > 5 % at two subsequent measures in water and sediment									
Water / sediment system	pH water	pH sed.	t. °C	DT_{50} - DT_{90} whole sys.	St. (chi²)	DT_{50} - DT_{90} water	St.	DT_{50} - DT_{90} sed.	St. (chi²)	Method of calculation
I Manning-tree	6.7	6.8	20	11.2/ 37.9	- 18.9	3.2/- -	- -	92/- -	-.	SFO (non-linear) SFO
II Ongar	7.5	8.4	20	- 17.3/ 57.7	- 13.4	5.6/-	- -	no decl.*	- -	SFO (non-linear) SFO
DT_{50} Geometric mean/median[1)]						4.2/4.4 [1)]		1000** [1)]		SFO (non-linear)

(* no decline, ** 1000 d worst case assumption, [1)] For PECsw and PECsed calculations separated DT_{50} for water and sediment cannot be used, instead worst case $DT_{50\ whole\ sys}$. of 17.3 d to be used.)

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Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed.	Mineralisation x % after n d (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
I Manning-tree	6.7	6.8	0.75 % after 180 d	77 % after 180 d	77 % after 180 d
II Ongar	7.5	8.4	1.32 % after 180 d	66 % after 180 d	66 % after 180 d

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

Parent Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight (g/mol): 264.7 Water solubility (mg/L): 1.4 Koc (L/kg): 7126 (Arith. Mean, n = 3) DT_{50} soil (d): 53.90 (Geom. Mean, n = 10), Lab DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 4.40 (Arith. Mean, n = 2) DT_{50} sediment (d): 1000.0 (worst case assumption) Crop interception (%): 0
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Vapour pressure: : 0.321 x 10^{-4} Pa (25°C) Kom/Koc: 7126 (Arith. Mean, n = 3) 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively): 0.922 DT_{50} soil (d): 57.7 (Geom. Mean, n = 10, Lab) (RMS: 62.3 should have been used) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 17.3 (worst case total system DT_{50}) DT_{50} sediment (d): 1000.0 (worst case assumption)
Application rate	Crop: Sunflower Crop interception: 0 Number of applications: 1 Application rate(s): 2400 g as/ha Region and Season of Application: North Europe (Mar. - May); South Europe, Mar. - May Depth of water body: 30 cm Application window: spring, pre-emergence, last possible application date as crop emergence

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Main routes of entry	2.7590 % drift from 1 meter % runoff/drainage: 2.00 (North Europe) 4.00 (South Europe)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	98.25	n.a.*	5430	n.a.*
	24 h	n.a.*	n.a.*	n.a.*	n.a.*
	2 d	n.a.*	n.a.*	n.a.*	n.a.*
	4 d	n.a.*	n.a.*	n.a.*	n.a.*
	7 d	n.a.*	n.a.*	n.a.*	n.a.*
	14 d	n.a.*	n.a.*	n.a.*	n.a.*
	21 d	n.a.*	n.a.*	n.a.*	n.a.*
	28 d	n.a.*	n.a.*	n.a.*	n.a.*
	42 d	n.a.*	n.a.*	n.a.*	n.a.*

(* FOCUS STEP 2 simulation submitted)

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	22.0720		1.16E+03	
	24 h	7.4820	14.7770	1.14E+03	1.15E+03
	2 d	3.6185	10.1636	1.13E+03	1.14E+03
	4 d	16.7379	8.2694	1.1E+03	1.13E+03
	7 d	13.5322	10.8396	1.05E+03	1.1E+03
	14 d	12.2165	11.8515	946.6214	1.05E+03
	21 d	11.0287	11.7719	854.5812	1.E+03
	28 d	9.9564	11.4498	771.4901	953.2550
	42 d	8.1144	10.6346	628.7593	868.0719

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FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0 h	31.2102		2.19E+03	
	24 h	26.2964	28.7533	2.16E+03	2.18E+03
	2 d	25.9150	27.4295	2.13E+03	2.16E+03
	4 d	25.1686	26.4849	2.07E+03	2.13E+03
	7 d	24.0891	25.6880	1.98E+03	2.08E+03
	14 d	21.7469	24.2932	1.79E+03	1.98E+03
	21 d	19.6324	23.0861	1.61E+03	1.89E+03
	28 d	17.7236	21.9801	1.46E+03	1.8E+03
	42 d	14.4446	19.9962	1.19E+03	1.64E+03

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 La Jailliere	Pond	0 h	0.503		3.522	
		24 h	0.477	0.490	3.521	3.522
		2 d	0.453	0.477	3.518	3.521
		4 d	0.411	0.454	3.508	3.520
		7 d	0.359	0.424	3.485	3.518
		14 d	0.275	0.369	3.406	3.506
		21d	0.219	0.328	3.310	3.487
		28 d	0.174	0.295	3.203	3.463
		42 d	0.112	0.243	2.985	3.403

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FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 La Jailliere	Stream	0 h	10.269		0.269	
		24 h	0.000	0.382	0.258	0.264
		2 d	0.000	0.191	0.247	0.258
		4 d	0.000	0.096	0.229	0.248
		7 d	0.000	0.055	0.205	0.235
		14 d	0.000	0.027	0.164	0.209
		21 d	0.000	0.018	0.137	0.189
		28 d	0.000	0.014	0.118	0.174
		42 d	0.000	0.009	0.094	0.151
R1 Weiher-bach	Pond	0 h	0.518		9.221	
		24 h	0.491	0.504	9.221	9.221
		2 d	0.467	0.491	9.219	9.221
		4 d	0.424	0.468	9.211	9.220
		7 d	0.366	0.437	9.198	9.218
		14 d	0.277	0.377	*	9.211
		21 d	0.216	0.336	*	9.198
		28 d	0.290	0.317	*	9.145
		42 d	0.324	0.328	*	8.965
R1 Weiher-bach	Stream	0 h	8.626		62.339	
		24 h	0.001	1.764	62.204	62.294
		2 d	0.001	0.888	62.064	62.226
		4 d	0.001	0.446	61.860	62.109
		7 d	0.000	0.401	61.478	61.934
		14 d	0.000	0.308	60.696	61.526
		21 d	0.000	0.237	60.144	61.324
		28 d	0.283	0.202	61.637	61.169
		42 d	0.004	0.174	60.305	61.034

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FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R3 Bologna	Stream	0 h	12.145		43.275	
		24 h	0.008	3.641	43.166	43.245
		2 d	0.003	1.823	43.019	43.180
		4 d	0.003	0.913	42.736	43.042
		7 d	0.006	0.746	42.603	42.885
		14 d	0.005	0.443	41.706	42.540
		21 d	0.003	0.298	42.068	42.186
		28 d	0.010	0.333	41.345	42.048
		42 d	0.004	0.225	40.185	41.841
R4 Roujan	Stream	0 h	8.627		47.609	
		24 h	0.001	4.531	296.721	297.545
		2 d	0.001	3.202	295.537	297.065
		4 d	0.001	1.609	293.315	296.044
		7 d	0.000	0.930	290.290	294.479
		14 d	0.001	0.566	284.259	291.136
		21 d	0.031	0.446	278.966	288.157
		28 d	0.021	0.405	281.558	285.971
		42 d	0.009	0.350	271.591	282.982

* Simulated period too short for calculation

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 La Jailliere	Pond	0 h	0.257		1.838	

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FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5 La Jailliere	Stream	0 h	1.563		0.041	
R1 Weiher-bach	Pond	0 h	0.395		8.621	
R1 Weiher-bach	Stream	0 h	3.03		62.230	
R3 Bologna	Stream	0 h	3.939		42.948	
R4 Roujan	Stream	0 h	5.994		297.637	

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For $FOCUS_{gw}$ modelling, values used – Modelling using FOCUS model(s), with appropriate $FOCUS_{gw}$ scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.2: Scenarios (list of names): Piacenza, Sevilla Crop: sunflower interception: 0 Parent $DT_{50lab/field}$: 57.3 d (laboratory data, arr. mean, n = 10) (normalisation to 10 kPa or pF2, 20 °C with Q10 of 2.2). Koc: 7126 L/kg (arr. mean, n = 3), 1/n = 0.922.
Application rate	Application rate: 2400 g/ha No. of applications: 1 Time of application (month or season): spring 2-days pre-emergence

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS PELMO sunflower 2400 kg/ha triennial	Piacenza	< 0.001			
	Sevilla	< 0.001			

Model / Crop	Scenario	Metabolite X (µg/L)	Metabolite (µg/L)		
			1	2	3
	Chateaudun				
	Hamburg				
	Jokioinen				
	Kremsmunster				
	Okehampton				
	Piacenza				
	Porto				
	Sevilla				
	Thiva				

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

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

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

Direct photolysis in air ‡	not relevant
Quantum yield of direct phototransformation	not relevant
Photochemical oxidative degradation in air ‡	AOP-calculations: AOP version 1.91: DT_{50} = 1.2 d (= 30.2 h, 24 hr day; 0.5 x 10^6 OH/cm^3)

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Volatilisation ‡	not relevant
	from soil surfaces (BBA guideline): after 24 hours less than 2.5 % of the applied dose was volatilised (recovery 105 %)
Metabolites	not applicable

PEC_{air}

Method of calculation	not applicable*

$PEC_{(a)}$

Maximum concentration	not applicable*

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	(Metabolites with >10 % of as or >5 % of as in 2 sequential measures)
	Soil aclonifen
	Surface Water aclonifen
	Groundwater aclonifen
	Air aclonifen

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)	Aclonifen residues were analysed for in Norwegian surface waters as part of the JOVA Monitoring Programme carried out from 1995 to 1999 in 12 selected streams and rivers. The published results showed that of the 739 surface water samples analysed for aclonifen, 99 % were below the limit of detection of 0.02 µg/L. Of the 4 samples that were above this level, only one finding (at 0.1 µg/L) was above the concentration limit of 0.07 µg/L set as acceptable for surface water by the Norwegian institutes. The average concentration of samples in which residues were detected was 0.05 µg/L.
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	not available

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

candidate for R53

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Chapter 2.6 Ecotoxicology

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	Aclonifen	acute	LD_{50} > 2000	not relevant
Coturnix coturnix japonica	Aclonifen	acute	LD_{50} > 15000	not relevant
Serinus canarius	Aclonifen	acute	LD_{50} > 15000	not relevant
	Preparation	not relevant		
	Metabolite	not relevant		
Colinus virginianus	Aclonifen	Short-term, 5 d dietary	LD_{50} > 1027	LC_{50} > 5000
Coturnix coturnix japonica	Aclonifen	long-term, 6 weeks dietary	NOEL reproduction > 141	NOEC Reproduction > 1000
Mammals ‡				
Rattus spec. and mouse	Aclonifen	acute, oral	LD_{50} > 5000	not relevant
Rattus spec.	BANDUR SC 600 g/L	acute, oral	LD_{50} 5596 = 2770 mg as	not relevant
	Metabolite	not relevant		
Rattus spec.	Aclonifen	long-term, 2-generation, reproduction	NOEL reproduction: 8	NOEC reproduction: 125
Additional higher tier studies ‡				
None (not required)				

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

Sunflower, application rate 2.4 kg as/ha, pre-emergence

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Medium herbivorous birds	Not relevant	-	-	10
Insectivorous birds	Acute Aclonifen	130	> 15	10
Insectivorous birds	Short-term Aclonifen	72	> 14	10

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

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Indicator species/Category[2]	Time scale		ETE	TER[1]	Annex VI Trigger[3]
Insectivorous birds	Short-term	Metabolite	Not relevant	-	10
Insectivorous birds	Long-term	Aclonifen	72	≥ 1.9	5
Higher tier refinement (birds)					
Earthworm eating birds	Long-term	Aclonifen	6.36	≥ 22	5
* PT = 0.2 not agreed upon in PRAPeR 43					
Tier 1 (Mammals)					
Medium herbivorous mammal	Not relevant		-	-	10
Small insectivorous mammal	Acute	Aclonifen	21	131	10
Small insectivorous mammal	Acute	Metabolite	Not relevant	-	10
Small insectivorous mammal	Long-term	Aclonifen	7.7	1.0	5
Small earthworm eating mammal	Long-term	Aclonifen	7.81	1.0	5
Higher tier refinement (mammals)					
* PT = 0.2, relevant species and respective FIR/bw not agreed upon in PRAPeR 43					

[1] in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Aclonifen	96 h (static)	Mortality, LC_{50}	0.67 nom
Pimephales promelas	Aclonifen	35 d ELS (flow-through)	Growth, NOEC Hatch, NOEC	0.005 nom 0.011 nom
Oncorhynchus mykiss	BANDUR SC 600 g/L	21 d (flow-through)	Mortality, LC_{50}	0.021 mm (0.01 as)

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

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Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Aquatic invertebrate				
Daphnia magna	Aclonifen	48 h (static)	Mortality, EC_{50}	1.2 nom 0.952 mm
Daphnia magna	Aclonifen	21 d (semi-static)	Reproduction, NOEC	0.016 mm
Daphnia magna	BANDUR SC 600 g/L	21 d (static)	Reproduction, NOEC	0.104 mm (0.053 as)
Sediment dwelling organisms				
Chironomus riparius	Aclonifen	28 d spiked water (static)	Emergence/ development, NOEC	0.472 initial measured conc.
Chironomus riparius	Aclonifen	28 d spiked sediment (static)	Emergence/ development, NOEC	32 mg/kg nom
Chironomus riparius	BANDUR SC 600 g/L		Not performed	-
Algae				
Desmodesmus subspicatus	Aclonifen	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0067 nom 0.0069 nom
Desmodesmus subspicatus	Aclonifen	96 h (static) water / sediment system	Biomass: E_bC_{50} Growth rate: E_rC_{50}	not valid
Navicula pelliculosa	Aclonifen	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.47 mm 1.2 mm
Pseudokirchneriella subcapitata	BANDUR SC 600 g/L	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.021 nom (0.01 as) 0.069 nom (0.035 as)
Higher plant				
Lemna gibba	Aclonifen	14 d (static)	Biomass: E_bC_{50} Growth rate fronds: E_rC_{50}	0.006 mm 0.012 mm
Lemna gibba	BANDUR SC 600 g/L	7 d (semi-static)	Biomass: E_bC_{50} Growth rate fronds:	0.01 mm (0.005 as) 0.043 mm

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

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Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
			E_rC_{50}	(0.022 as)
Microcosm or mesocosm tests				
None (not required)				

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

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

FOCUS Step1

Sunflower, application rate 2.4 kg as/ha, pre-emergence, one application

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PECi	TER	Annex VI Trigger[1]
Not performed, not relevant. Expected that trigger will be failed						

[1] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[2] only required for herbicides
[3] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

FOCUS Step 2

Sunflower, application rate 2.4 kg as/ha, pre-emergence, one application

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC_{sw}[3] max. (µg/L or µg/kg dw for sed)	TER	Annex VI Trigger[4]
		Not performed, not relevant. Expected that trigger will be failed					

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used.
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a

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

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trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

5 only required for herbicides

6 consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Sunflower, application rate 2.4 kg as/ha, pre-emergence, one application

Test substance	Scenario[1]	Water body type[2]	Test organism[3] most sensitive	Time scale	Toxicity endpoint (mg as/L)	PEC_{SW}[4] (µg as/L) or PEC_{SED} (µg as/kg)	TER	Annex VI trigger[5]
Aclonifen	R3	Stream	*Oncorhynchus mykiss*	Acute	LC_{50} 0.67	PEC_{max} 12.145	55	100
Aclonifen	R4	Stream	*Oncorhynchus mykiss*	Long-term	NOEC 0.005	$PEC_{twa\ 28\ d}$ 0.405	12.3	10
Aclonifen	R3	Stream	*Daphnia magna*	Acute	LC_{50} 1.2	PEC_{max} 12.145	99	100
Aclonifen	R3	Stream	*Daphnia magna*	Long-term	NOEC 0.016	PEC_{max} 12.145	1.3	10
Aclonifen	R1	Stream	*Chironomus riparius*	Long-term	NOEC 32 (mg as/kg)	$PEC_{SED\ max}$ 297.9	107	10
Aclonifen	R3	Stream	*Desmodesmus subspicatus*	Long-term	E_bC_{50} 0.0067	PEC_{max} 12.145	0.55	10
Product	R3	Stream	*Lemna gibba*	Long-term	E_bC_{50} 0.005	PEC_{max} 12.145	0.41	10

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

2 ditch/stream/pond

3 include critical groups which fail at Step 2.

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

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

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

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FOCUS Step 4

Sunflower, application rate 2.4 kg as/ha, pre-emergence, one application

Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	reduction level of risk mitigation measures	PEC_{SW}[4] (µg as/L)	TER	Annex VI trigger[5]
R3	Stream	*Oncorhynchus mykiss*	Acute	LC_{50} 0.67	50 %	PEC_{max} 6.07	110	100
R3	Stream	*Daphnia magna*	Acute	LC_{50} 0.952	50 %	PEC_{max} 6.07	157	100
R3	Stream	*Daphnia magna*	Long-term	NOEC 0.016	90 %	PEC_{max} 1.215	13	10
D5 D5 R1 R1 R3 R4	Pond Stream Pond Stream Stream Stream	*Desmodesmus subspicatus,*	Long-term	E_bC_{50} 0.0067	95 %	PEC_{max} 0.025 0.513 0.026 0.431 0.607 0.431	266 13 259 16 11 16	10
D5 D5 R1 R1 R3 R4	Pond Stream Pond Stream Stream Stream	*Desmodesmus subspicatus*	Long-term	E_bC_{50} 0.0067	FOCUS Step 4 40 m spray drift buffer + 20 m ve-getated buffer strip for run-off mitigation[6]	PEC_{max} 0.133 0.611 0.136 0.718 0.942 1.434	50.4 11.0 49.3 9.3 7.1 4.7	10
D5 D5 R1 R1 R3	Pond Stream Pond Stream Stream	*Lemna gibba*	Long-term	E_bC_{50} 0.005	FOCUS Step 3	$PEC_{twa, 4d}$ 0.454 0.096 0.468 0.446 0.913 1.609	11 52 11 10.7 5.5 3.1	10

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

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Scenario [1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (mg as/L)	reduction level of risk mitigation measures	PEC_{SW}[4] (µg as/L)	TER	Annex VI trigger[5]
R4	Stream							

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 3.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[6] 20 m vegetated buffer strip (80 % reduction of water load and 95 % reduction of sediment load leading to ≤ 80 % run off reduction)

Bioconcentration

	Active substance	Metabolite 1	Metabolite 2	Metabolite 3
log $P_{O/W}$	4.37	Not relevant		
Bioconcentration factor (BCF)[1] ‡	2896 [^{14}C]*			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	2.0 days			
(CT_{90})	95 % elimination after 8.8 days, whole fish			
Level and nature of residues (%) in organisms after the 14 day depuration phase After 20 days depuration phase	- 0.6 % [^{14}C] mostly as aclonifen - 1.0 %			

[1] only required if log $P_{O/W}$ > 3.
* based on total [^{14}C], max. kinetic BCF, whole fish

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
as ‡	> 107	> 100
Preparation[1]	> 236 µg	> 205 µg formulation/bee

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

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Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
	formulation/bee	
Metabolite 1	not relevant	not relevant
Field or semi-field tests		
not required		

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
as (2400 g/ha, lab)	Contact (48 h)	< 24.0	50
as (2400 g/ha, lab)	oral (48 h)	< 22.4	50
Preparation (4800 g/ha, lab)	Contact (48 h)	< 23.4	50
Preparation (4800 g/ha, lab)	oral (48 h)	< 20.3	50

Field or semi-field tests not required

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Preparation (Bandur SC 600 g/L)	Mortality	102 g as/ha
Aphidius rhopalosiphi ‡	Preparation (Bandur SC 600 g/L)	Mortality	> 2930 g as/ha

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Crop and application rate: sunflower and 2400 g as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
preparation	*Typhlodromus pyri*	102 g as/ha	23.5	1.3	2
preparation	*Aphidius rhopalosiphi*	> 2930 g as/ha	< 0.8	0.045	2

[1] indicate distance assumed to calculate the drift rate

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Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% effect[3]	Trigger value
Typhlodromus pyri	Proto-nymphs	BANDUR SC 600 g/L, glass plate, 14 days	2930 as initial	Mortality (14 d)	97.65 %	50 %
Typhlodromus pyri	Proto-nymphs	BANDUR SC 600 g/L, cowpea leaves, 2-D, 14 days	2970 as initial 118.8 as initial	Mortality (7 d) Mortality (7 d) Fecundity (14 d)	60 % 14 % 18 %	50 %
Aleochara bilineata	Adults	BANDUR SC 600 g/L, quartz sand, 12 days	3300 as initial	Mortality (12 d) Feeding rate Fecundity Hatching rate	0 % 0 % 0 % 0 %	50 %
Poecilus cupreus	Adults	BANDUR SC 600 g/L, quartz sand, 14 days	3300 as initial	Mortality (14 d) Feeding rate	0 % 0 %	50 %
Chrysoperla carnea	Larvea	BANDUR SC 600 g/L, glass plate, 66 days	721 as initial	Mortality (22 d) Reproduction (66 d)	3.7 % 0 %	50 %
Chrysoperla carnea	Larvea	BANDUR SC 600 g/L, bean leaves, 41 days	2364 as initial	Mortality (41 d) Reproduction (41 d)	0 % 3.7 %	50 %
Pardosa spec.	Adults	BANDUR SC 600 g/L, quartz sand, 28 days	3300 as initial	Mortality (14 d) Mortality (28 d)	41.7 % 58.3 %	50 %
Pardosa spec.	Adults	BANDUR SC 600 g/L, LUFA soil (sand), 14 days	2970 as initial	Mortality (14 d) Feeding rate (14 d)	0 % 0 %	50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] indicate if positive percentages relate to adverse effects or not

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Field or semi-field tests
Field or semi-field tests were not required.

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

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
Eisenia foetida	Aclonifen (as)	acute, 14 days	LC_{50corr} 150 mg as/kg dw soil
Eisenia foetida	BANDUR SC 600 g/L	acute, 14 days	LC_{50corr} 97 mg as/ kg dw soil
Eisenia fetida andrei	BANDUR SC 600 g/L	chronic, 8 weeks	Reproduction $NOEC_{corr}$ 45 mg as/ kg dw soil
Other soil macro-organisms			
Hypoaspis aculeifer	Preparation: BANDUR SC 600 g/L, LUFA soil (sand)	Chronic 28 days	LR_{50} 126.2 mg as/kg dw soil (94.6 kg as/ha) NOEC Mortality 13.3 mg as/kg dw soil (10 kg as/ha)
Soil micro-organisms			
Nitrogen mineralisation	Aclonifen (as)	28 days	20 mg as/kg dw soil (15 kg as/ha): 22 % inhibition on N_{tot} at day 28
	BANDUR SC 600 g/L	28 days	Clay loam soil: 20 mg as/kg dw soil (15 kg as/ha = 30 kg product/ha) 18 % inhibition on N_{tot} at day 28 4 mg as/kg dw soil (3 kg as/ha = 6 kg product/ha) 5 % effect on N_{tot} at day 28
	Metabolite	28 days	Not relevant
Carbon mineralisation	Aclonifen (as)	28 days	Sandy soil 4 mg as/kg dw soil (3 kg as/ha): 8 % effect at day 28 Loamy soil 20 mg as/kg dw soil (15 kg as/ha): 25 % effect at day 28 at

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

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	BANDUR SC 600 g/L	28 days	Clay loam and sandy loam soil: 20 mg as/kg dw soil (15 kg as/ha = 30 kg product/ha): 2 % effect at day 28 4 mg as/kg dw soil (3 kg as/ha = 6 kg product/ha): 3 % effect at day 28
	Metabolite	28 days	Not relevant
Field studies[2]			
Two earthworm field studies submitted with the dossier are not considered here for reasons of invalidity and non-suitability for assessing the risk of earthworm populations in undisturbed areas (off-field). A litter bag test was conducted with BANDUR. The test item did not have a significant adverse effect on organic matter decomposition even if exposed to the long-term PEC of aclonifen.			

[1] indicate where endpoint has been corrected due to log $P_{o/w}$ > 2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate: sunflower and 2400 g as/ha, pre-emergence

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	Aclonifen (as)	Acute	3.501 mg/kg (plateau PEC)	43	10
	Aclonifen (as)	Chronic		Not relevant	5
Eisenia foetida	BANDUR SC 600 g/L	Acute	3.501 mg as/kg (plateau PEC)	28	10
	BANDUR SC 600 g/L	Chronic	3.501 mg as/kg (plateau PEC)	13	5
Eisenia foetida	Metabolite	Acute		Not relevant	10
	Metabolite	Chronic		Not relevant	5
Other soil macro-organisms					
Soil mite	as ‡			Not relevant	

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Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
	BANDUR SC 600 g/L	Chronic	3.501 mg as/kg (plateau PEC)	3.8	5
	Metabolite 1			Not relevant	

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (plateau PEC = background concentration (20 cm tillage depth) + PEC_{ini})

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Brassica napus	BANDUR SC 600 g/L	13.7 as [3]	1.12 as [4] 25.7 as	1.4 as (5 m + 90 % drift reduction)	9.8 / 0.8 18.4	5

[1] exposure estimation based on Ganzelmeier drift data
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] test under condition of medium temperature and high soil moisture
[4] test under condition of high temperature and high soil moisture, toxicity of as to *B. napus* was considerably reduced (21-d ED_{50} > 19.8 g as/ha) under more realistic condition (medium temperature and high or medium soil moisture)

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

Test type/organism	endpoint
Activated sludge	Aclonifen (as): EC_{50} > 1000 mg as/L, NOEC ≥ 1000 mg/L
Pseudomonas sp.	BANDUR SC 600 g/L: EC_{10} 0.04 mg as/L, EC_{50} 0.54 mg as/L

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

Compartment	
soil	Parent (aclonifen)
water	Parent (aclonifen)

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sediment	Parent (aclonifen)
groundwater	Parent (aclonifen)

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

	RMS/peer review proposal
Active substance	N, R 50/53, dangerous to the environment toxic to aquatic organisms, may cause long-term effects

	ECB decision (22th ATP of Annex I to Directive 67/548/EEC)
Active substance	N, R 50/53

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

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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

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LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

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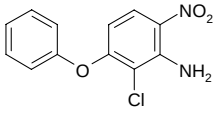
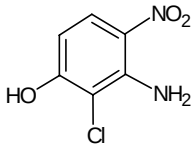
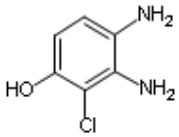
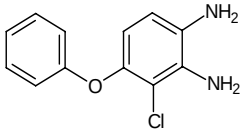
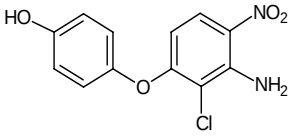
APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
aclonifen	IUPAC: 2-chloro-6-nitro-3-phenoxyaniline CA: 2-chloro-6-nitro-3-phenoxybenzenamine	
RPA 508285	3-amino-2-chloro-4-nitrophenol	
RPA 407288	3,4-diamino-2-chlorophenol	
RPA 407291	3-chloro-4-phenoxybenzene-1,2-diamine	
RPA 407074	4-(3-amino-2-chloro-4-nitrophenoxy)phenol	

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