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

Acetochlor

Finalised: 31 July 2008

SUMMARY

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

Spain being the designated rapporteur Member State submitted the DAR on acetochlor in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 4 April 2005. Following a quality check on the DAR, the peer review was initiated on 14 December 2005 by dispatching the DAR for consultation of the Member States and the applicant Task Force consisting of Dow AgroSciences and Monsanto Europe S.A. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed on during a written procedure in August – September 2006. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in March 2007.

A final discussion of the outcome of the consultation of experts took place with representatives from the Member States on 27 September 2007 leading to the conclusions as laid down in this report.

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on maize, for full details of the GAP please refer to the attached end points.

The representative formulated products for the evaluation were “GF-675” and “Mon 69447” a 400 g/L capsule suspension (CS) and a 840 g/L emulsifiable concentrate (EC).

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

The residue definition for monitoring in plants has not been concluded on. Acetochlor residues in maize can be determined with a multi-method (The German S19 method has been validated). For N-oxamic acid metabolite 68[2] a LC-MS/MS method is available this metabolite can not be analysed by a multi method. For products of animal origin there are no methods available. At this stage it can not be concluded if this is a data gap or not as the assessment for residues is not complete.

For soil a LC-MS/MS method is available that analyses for acetochlor, t-oxanilic acid (2) [3], t-sulfonic acid (7) [4], t-sulfinylacetic acid (3) [5] , s-sulfonic acid (13)[6] and t-norchloroacetochlor (6) [7]. For surface/ground/drinking water LC-MS/MS methods are available for acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), s-sulfonic acid (13) t-norchloroacetochlor (6) and t-sulfinylacetic acid (3). In addition to this there is also a LC-MS/MS method for t-norchloroacetochlor (6) in drinking water. Air can be analysed for acetochlor by LC-MS/MS.

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. However, it should be noted that there are no spectra, analytical methods or storage stability data for the relevant impurities in the technical material.

Acetochlor has a moderate acute toxicity. The proposed classification is **Xn, R20/22 Harmful by inhalation and if swallowed; Xi, R37/38 Irritating to respiratory system and skin; R43 May cause sensitisation by skin contact**. In short term studies the dog was the most sensitive species showing decreased body weight gain and histopathological findings in kidneys and testes. Many *in vitro* genotoxicity studies showed positive results but the *in vivo* tests did not indicate clearly a mutagenic potential. In long term studies different types of tumours were observed with increased incidences and the classification **Carc. cat.3, R40 Limited evidence of a carcinogenic effect** was proposed. No specific effect on the reproductive parameters was found in multigeneration studies with rats, and no evidence of teratogenicity was observed in rats or rabbits.
The groundwater metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) were considered relevant taking into account the limited information available and the carcinogenic potential of the parent compound. The relative toxicity of the plant and potential surface water metabolite t-norchloro acetochlor (6) in comparison with acetochlor could not be concluded.
The **acceptable daily intake** (**ADI**) is 0.0036 mg/kg bw/day using the LOAEL from the 78-week mouse study with a safety factor of 300. The **acceptable operator exposure level** (**AOEL**) is 0.02 mg/kg bw/day based on the 1-year dog study, with the use of a safety factor of 100. The **acute**

[2] Metabolite 68: [(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid
[3]: Metabolite 2: [(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid
[4] Metabolite 7: 2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[5] Metabolite 3: ({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid
[6] Metabolite 13: 2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[7] Metabolite 6: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide

reference dose (**ARfD**) is 1.5 mg/kg bw, derived from the acute rat neurotoxicity study with the application of a safety factor of 100. Two representative formulations were considered in the exposure assessment. For GF-675, the operator exposure is below the AOEL with the use of gloves. For MON 69447, the estimates with the German and UK models are above the AOEL but a bio-monitoring study measured exposures below the AOEL with the use of closed cabins and gloves.

Metabolism of acetochlor was studied in maize plants upon a pre-emergence treatment. Total residues in the mature grain were low and did not permit an extensive identification of metabolites. The rate of identification in other maize plant parts was limited and the need for further data was identified, in particular with regard to the nature of the residue in plant parts fed to livestock and in immature maize kernels (sweet corn – use withdrawn during the peer review). Also early-post emergence uses are currently not sufficiently addressed by metabolism data.
Based on the available data a number of metabolites were identified and some of them are considered toxicological relevant (potential carcinogenicity). Therefore the residue definition was extensively discussed and it was concluded that for risk assessment all compounds forming EMA (34)[8] and HEMA (33)[9] on hydrolysis as well as hydroxy-oxamic acid (68), all expressed as acetochlor should be considered for maize grain and preliminary also for rotational crops (the latter restricted to cereal grains, root and tuber crops and leafy crops). The need for further rotational crop data was identified.
For monitoring purposes three options for a residue definition were proposed, and risk management consideration is required to decide on the final monitoring definition. Residue trials confirmed that residues in maize kernels, when analysed for the risk assessment residue definition, are below the limit of quantification (LOQ) of 0.05 mg/kg. However, currently insufficient data in terms of quality and magnitude of residues are available to assess the dietary burden of livestock. Consumer exposure estimates therefore only include the exposure from maize grain but don't consider potential exposure from food of animal origin and certain rotational crops. Therefore the consumer risk assessment should be considered as not finalised. It is also noted that there is potential consumer exposure to acotochlor metabolites from ground water used as drinking water, in particular to t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13). A risk assessment showed that the ADI of acetochlor, when applied to the metabolites, might be exceeded only due to the consumption of water containing these metabolites at the level estimated in FOCUS scenarios.

In topsoil under aerobic conditions acetochlor exhibits low to moderate persistence forming the major soil metabolites t-oxanilic acid (2) (max 17 % applied radioactivity (AR)) and t-sulfonic acid (7) (max 11.8%AR) which exhibited moderate to high persistence and t-sulfinylacetic acid (3) (max 18%AR) which exhibited medium to high persistence. The minor soil metabolites s-sulfonic acid (13) (max 9.8%AR) which exhibited moderate to medium persistence and t-norchloro acetochlor (6) (max 3.3%AR) were also identified. Mineralisation of the phenyl radiolabel to carbon dioxide accounted only 0.3-3.1 % of applied radioactivity (AR) after 96 days. The formation of unextractable residues was also a significant sink accounting for 15-41 % AR after 84-90 days. Acetochlor exhibits high to

[8] Chemophore 34: 2-ethyl-6-methyl aniline
[9] Chemophore 33: 2(1-hydroxyethyl)-6-methylaniline

medium mobility in soil. t-oxanilic acid (2), t-sulfinyl acetic acid (3) and t-sulfonic acid (7) exhibit very high to high mobility in soil and s-sulfonic acid (13) exhibits very high mobility in soil. There was no indication that adsorption of either acetochlor or these 4 metabolites was pH dependant.

In natural sediment water systems acetochlor exhibited moderate persistence degrading to the major metabolites t-oxanilic acid (2) (max. 13.1%AR in water) and t-norchloro acetochlor (6) (max 10.4%AR in water 19.2%AR in sediment). The terminal metabolite, CO2, was a small sink in the material balance accounting for only 1.4-2.7 % AR at 100 days. Unextracted sediment residues were the most significant sink for radioactivity representing 24-50 % AR at 100 days. The necessary surface water and sediment exposure assessments were appropriately carried out using the agreed FOCUS scenarios approach for acetochlor at steps 1-4, with spray drift mitigation being applied at step 4. These values are the basis for the risk assessment discussed in this conclusion.

The potential for groundwater exposure from the applied for intended uses above the parametric drinking water limit of 0.1µg/L by parent acetochlor was concluded to be low, in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios. A high potential for groundwater contamination >0.1µg/L over significant areas of the EU by the metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) that have (on the basis of the available mammalian toxicology data) been concluded as relevant metabolites was identified. It was considered that a lysimeter study would be essential to exclude the potential for the presence of additional metabolites in groundwater.

The short-term TER for birds and the acute and long-term TERs for mammals were above the trigger of 10 and 5 in the first-tier risk assessment. A residue decline study was submitted. The acute risk to herbivorous birds was sufficiently addressed on the basis of measured residues. However it was not possible to conclude on the reliability of the suggested PD and PT values to refine the long-term risk to herbivorous birds since no summaries of the supporting studies were made available. The refined risk assessment for insectivorous birds based on crested lark (*Galerida cristata*) was agreed by the meeting. The risk from uptake of contaminated drinking water was assessed as low for mammals. The risk assessment for uptake of contaminated drinking water was discussed in the expert meeting. It was agreed that the risk to mammals is low. However a high acute risk cannot be excluded for birds for post-emergence applications where accumulation of water in leaf axils of maize plants can occur. The risk from secondary poisoning of fish-eating birds and mammals was assessed as low in the first tier but further refinement was required for earthworm-eating birds and mammals. The risk was sufficiently addressed using data from a bioconcentration study with earthworms. The risk from soil metabolites was considered to be low because their log Pow is <3 suggesting a low potential of bioconcentration and bioaccumulation in the food chain. Endpoints from acute toxicity studies with rats were available for the major plant metabolite 68 (N-(6-ethyl-3-hydroxy-2-methylphenyl) and for metabolite 3 (t-sulfonylacetic acid). No information on the toxicity to birds was available. In the risk assessment it was assumed that the metabolites have a similar toxicity to birds as the parent. The acute and long-term TERs for birds and mammals were above the triggers of 10 and 5. However

some uncertainty remains because of the high proportion of not identified residues in the residue trials (up to 39% of TRR) and one of the unknown compounds exceeded the threshold of 10% of TRR.

Acetochlor is very toxic to all groups of aquatic organisms and a high risk was indicated in the risk assessment with FOCUS step3 PECsw. A risk refinement based on endpoints from a static mesocosm and from a mesocosm with a pulsed exposure regime was used to refine the risk in lentic and lotic waterbodies. The experts agreed that the NOAEC of 0.2 µg acetochlor/L for lentic water bodies and the NOAEC of 2 µg acetochlor/L for lotic waterbodies should be used in the risk assessment together with an assessment factor of 2-3. A new risk assessment was prepared by the RMS in addendum 5 (not peer-reviewed) taking into account the recommendations of the expert meeting. The TERs were below the trigger of 2 for all FOCUS step 3 scenarios. In addendum 6 (not peer-reviewed) TERs were calculated for no-spray buffer zones of 25 and 50m. No full scenario resulted in TERs >2 with a no-spray buffer zone of 25m. TERs ≥2 were observed in two full scenarios (D4, D5) out of 8 scenarios if a no-spray buffer zone of 50m is applied but no full scenario achieved TERs ≥3. Overall it is concluded that the risk to aquatic organisms from exposure to acetochlor is high for the representative uses evaluated. The risk from metabolites in water and sediment was assessed as low. The bioconcentration potential of acetochlor was assessed as low.

A high in-field risk was identified for both indicator species for the representative uses with the lead formulation GF-675. Extended laboratory studies indicated a low risk to *Aphidius rhopalosiphi* but the LD_{50} for *Typhlodromus pyri* was below the suggested application rate. However the trigger is met for the off-field area and considering the short half life of acetochlor on vegetation it was considered as likely that recolonisation is possible. In addition no mortality was observed in the standard laboratory tests with the leaf dwelling species *C. carnea* at dose rates of 2000 g a.s./ha. Therefore it was concluded in the expert meeting that the risk to leaf dwelling arthropods is low. The risk to soil surface dwelling arthropods from exposure to acetochlor and its soil metabolites was considered to be low.

The acute risk of acetochlor to earthworms was assessed as low. No long-term risk assessment is triggered because the representative uses cover only one application per year and the field DT90 is <100 days. The acute and long-term risk from soil metabolites to earthworms was assessed as low.

A high risk to non-target terrestrial plants was identified and risk mitigation measures such as a 5m in-field no spray buffer zone are required.

The risk to bees, earthworms, soil-micro organisms, organic matter breakdown and biological methods of sewage treatment was assessed as low for the representative uses of acetochlor.

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

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BACKGROUND

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

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Spain submitted the report of its initial evaluation of the dossier on acetochlor, hereafter referred to as the draft assessment report, to the EFSA on 4 April 2005. Following an administrative evaluation, the EFSA communicated to the rapporteur Member State some comments regarding the format and/or recommendations for editorial revisions and the rapporteur Member State submitted a revised version of the draft assessment report. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the revised version of the draft assessment report was distributed for consultation on 14 December 2005 to the Member States and the applicant Task Force consisting of Dow AgroSciences and Monsanto Europe S.A as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed during a written procedure in August – September 2006 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised by EFSA in March 2007. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place with representatives from Member States on 27 September 2007 leading to the conclusions as laid down in this report.

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

In accordance with Article 11(4) 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 evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received
- the resulting reporting table (rev. 1-1 of 6 October 2006)
- the consultation report

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

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

Given the importance of the draft assessment report including its addendum (compiled version of July 2007 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Acetachlor is the ISO common name for 2-chloro-N-ethoxymethyl-6'-ethylacet-o-toluidide (IUPAC). The active substance is a racemic mixture of two rotational isomers (rotamers) on the nitrogen atom in the structure. It is currently not clear if the isomers are thermally stable or not and if they are they have not been correctly addressed in all areas of the risk assessment.

Acetochlor, belongs to the class of chloroacetanilide herbicides other members of this class include propachlor and metazachlor. It is a selective herbicide, absorbed mainly by the shoots and secondarily by the roots of germinating plants. It may inhibit synthesis of very long chain fatty acids.

The representative formulated products for the evaluation were "GF-675" and "Mon 69447" a 400 g/L capsule suspension (CS) and a 840 g/L emulsifiable concentrate (EC). The representative uses are as a herbicide on maize, for full details of the GAP please refer to the attached end points. It is always used together with the safener dichlormid (N,N-diallyl-2,2-dichloracetamide), which significantly improves crop tolerance.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of acetochlor as manufactured should not be less than 940 g/kg. However, as the toxicology meeting of experts could not agree the specification, the specification for the technical

material as a whole should be regarded as provisional for the moment. Acetochlor is a racemic mixture of rotational isomers (atropoisomers or axial isomers). The fact that the active substance has two isomers was only raised in the physchem meeting of experts and therefore it is not addressed in the DAR. The meeting of experts concluded that acetochlor has two isomers that may be thermally stable and that if they are thermally stable they need to be addressed in all areas of the risk assessment. However, the rapporteur does not fully agree with this. The RMS considers that it is not possible to conclude about the stability of the atropoisomer of acetochlor and the possible atropoisomer selective behaviour of the molecule. From the results of the published papers the RMS considers it is more likely that the compound exists in an equilibrium and the energy barriers of rotation determine the rate of conversion of one atropoisomer to the other and the degree of resolution of the peak in the chromatogram, but these compounds are not chromatographically resolved from each other. Therefore the RMS considers that all environmental and toxicological testing will have experienced both isomers as a racemic mixture and the study of the behaviour of these compounds separately is not justified. This is the opinion of the RMS but not the conclusion of the peer review process.
The technical material contains ethyl chloroacetate (ECA) and 2-ethyl-6-methylaniline (EMA), which have to be regarded as relevant impurities. The maximum content in the technical material should not be higher than 6 g/kg for ECA and 3 g/kg for EMA.

The content of acetochlor in the representative formulations is 400 g/L capsule suspension (CS) and 840 g/L emulsifiable concentrate (EC).

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 acetochlor or the respective formulation. However, the following data gaps were identified:

- spectra for the relevant impurities ECA and EMA
- Validated methods of analysis for ECA and EMA in the formulations
- Storage stability data for ECA and EMA in the formulations

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

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of acetochlor in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.
Therefore, enough data are available to ensure that some quality control measurements of the plant protection product are possible. However, it should be noted that there are data gaps identified for the relevant impurities.

The residue definition for plants has not been concluded on. Acetochlor residues in maize can be determined with a multi-method (The German S19 method has been validated). For N- oxamic acid (68)[10] a LC-MS/MS method is available this metabolite can not be analysed by a multi method. For products of animal origin there are no methods available. At this stage it can not be concluded if this a data gap or not as the assessment for residues is not complete.

For soil a LC-MS/MS method is available that analyses for aetochlor, t-oxanilic acid (2)[11], t-sulfonic acid (7)[12], t-sulfinylacetic acid (3)[13], s-sulfonic (13)[14] and t-norchloroacetochlor (6)[15]. For surface/ground/drinking water LC-MS/MS methods are available for acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), s-sulfonic (13) t-norchloroacetochlor (6) and t-sulfinylacetic acid (3). In addition to this there is also a LC-MS/MS method for t-norchloroacetochlor (6) in drinking water. Air can be analysed for acetochlor by LC-MS/MS. A method for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic

2. Mammalian toxicology

Acetochlor was discussed by the experts in mammalian toxicology in the PRAPeR meeting 19 (round 4, March 2007).

The composition of the toxicological batches with regard to the proposed technical specification (Addendum 2 to Volume 4, January 2007) has been discussed. Due to the fact that limited information was available on the levels of impurities in the toxicological batches, a data gap was identified by the experts. Additional evaluation and/or information were provided in a corrigendum of addendum 2 (March 2007) and in the addendum 4 to Volume 4 (July 2007) but not peer-reviewed.

The experts also considered that the impurity **ECA**[16] was relevant since it is classified as T; R 23/24/25 and should not exceed the level of the technical specification. In the addendum 2 to Volume 4 (January 2007) the RMS considered the structural similarity of the impurities **096** (20), **SB097** (11) and **EP097** (13) with acetochlor and concluded that they would have the same toxicity. However the experts discussed the grouping of the three impurities 11, 12 and 13 proposed by the notifier (meaning that one of them can be present up to 12 g/kg if the others are not present) and agreed that these impurities should be dealt with individually due to missing information on toxicological batches and absence of toxicological data.

EFSA notes that the impurity **EMA**[17] should be considered as relevant even though it is a rat metabolite, due to the fact that it plays a role in the nasal tumor formation and that the experts agreed that nasal tumor formation can be relevant to humans (see 2.5).

[10] Metabolite 68: [(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid
[11] Metabolite 2: [(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid
[12] Metabolite 7: 2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[13] Metabolite 3: ({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid
[14] Metabolite 13: 2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[15] Metabolite 6: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide
[16] ECA: ethyl chloroacetate
[17] EMA : 2-ethyl-6-methylaniline

During the peer review, it was highlighted that the information on the ratio of isomers was missing. However it was agreed that all sources of acetochlor will be the equal mixture of isomers. Therefore this constant ratio would have been tested in the toxicological studies.

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

Acetochlor is rapidly and almost entirely absorbed (>80% in 48h). It is widely distributed in well perfused organs and shows a low potential for bioaccumulation. There is some accumulation in nasal turbinates in rats but not in mice. The elimination occurs mainly via urine (66-72% in 48h) and faeces (12-21% in 48h, from which 80-85% is eliminated through bile).

The main pathway of metabolism is the glutathione conjugation and further mercapturic acid pathway and glucuronidation. In urine, no unchanged acetochlor is found.

2.2. ACUTE TOXICITY

The acute toxicity of acetochlor after oral or inhalative administration is moderate (rat LD_{50} 1929 mg/kg bw, rat LC_{50} 3.99 mg/L/4h), and it is irritating for the respiratory system and for the skin, as well as a skin sensitizer. Based on these results, the proposed classification is **Xn, R20/22 "Harmful by inhalation and if swallowed"; Xi, R37/38 "Irritating to respiratory system and skin", R43 "May cause sensitisation by skin contact"**.

2.3. SHORT TERM TOXICITY

Three dietary studies in rat, four oral studies (dietary and by capsule) in dog and two dermal studies in rat and rabbit are described in the DAR. The dog is the most sensitive species. The experts agreed that the relevant NOAEL is from the 52-week dog study, i.e. 2 mg/kg bw/day based on decreased bodyweight gain and histopathological findings in kidneys and testes observed at 10 mg/kg bw/day.

In addition it was agreed to highlight the proposal for classification **R48/22?** to the competent authority, taking into account the effects observed at 50 mg/kg bw/day in the 52-week dog study (mortalities, severe histopathological changes in the cerebellum, kidneys and testes).

From the dermal studies, the proposed NOAEL is 400 mg/kg bw/day where dermal irritation is observed in rabbits, but no signs of systemic toxicity.

2.4. GENOTOXICITY

Positive and negative results are reported *in vivo* and *in vitro* with technical material of high and low purity (89.9 to 96.7%). Many *in vitro* studies show positive results. The *in vivo* UDS test shows positive results at toxic dose levels and clear negative results are found in micronucleus and dominant lethal studies.

The experts agreed that the substance induces DNA repair synthesis *in vivo*, which was not considered as a clear indication of mutagenicity *in vivo*, and they concluded that this does not affect the risk assessment.

2.5. LONG TERM TOXICITY

From the three chronic rat studies, the systemic NOAEL is 9.4 mg/kg bw/day based on decreased body weight, mild liver toxicity and chronic nephritis. An increased incidence of papillary adenomas of the nasal epithelium is observed in all studies, in both sexes, and is accompanied by increased incidence of hyperplasia of the nasal epithelium. Based on mechanistic studies on acetochlor (and its analogue alachlor), it seems that these nasal adenomas in rats are related to the formation of an active metabolite (DABQI, dialkylbenzoquinoneimine), increased by a specific enzyme of the rat nasal epithelium. Although it is unlikely that sufficient concentrations of the active metabolite would be achieved to initiate this event, the mode of action can still be relevant for humans.

Thyroid follicular adenomas and pituitary tumors were considered by the experts as not relevant to humans or incidental. In the 2-year rat study (Broadmeadow, 1989), the femoral tumors were confirmed in a reevaluation as cartilaginous hyperplasia and not neoplasms. The basal cell tumors of the stomach were concluded to be squamous cell carcinomas and the notifier argued that these lesions are a common finding. A data gap was set by the meeting for historical control data with regard to stomachal and femoral tumors in order to conclude on their relevance. However the experts noted that a sufficient margin of safety will be set when deriving the reference values.

The agreed NOAEL for carcinogenic effects is 9.4 mg/kg bw/day.

In the two chronic mouse studies (78-week and 23-month), the main effects are increased mortality, decreased weight gain, anemia, kidney and liver toxicity. The overall systemic NOAEL was discussed by the experts, based on the effects observed in the kidneys of male mice in the 78-week study (Amyes, 1989). As the significance of tubular basophilia at the low dose is not clear without historical control data (data gap), and as it is accompanied by an increased kidney weight, this was considered as a first step of nephrotoxicity and the dose level of 1.1 mg/kg bw/day was agreed to be the **systemic LOAEL**.

In both studies, lung adenomas and carcinomas are observed with increased incidences in females, often above the historical control values (provided in the addendum 2, January 2007). In the first 23-month study (Ahmed, 1983), a dose-related increased incidence of histiocytic sarcoma of the uterus is observed, above the historical control data for the two high dose groups. From this first study, the experts agreed that the low dose (75 mg/kg bw/day) is a LOAEL for carcinogenic effects, because a slightly increased incidence of histiocytic sarcoma of the uterus is already observed. In the 78-week study a clear **carcinogenic NOAEL** can be established at 11.21 mg/kg bw/day.

In conclusion, taking into account the different tumors observed in both species, the meeting agreed to propose the classification **Carc. cat.3, R40 Limited evidence of a carcinogenic effect**.

EFSA notes that a recent EPA review of the carcinogenic potential of acetochlor was published in May 2007 (after the expert meeting, therefore not peer-reviewed).

2.6. REPRODUCTIVE TOXICITY

Three 2-generation studies in rats are presented in the DAR (two were considered as non acceptable).

The parental NOAEL is 20 mg/kg bw/day based on decreased body weight, changes in some organ weights, and occurrence of nasal hyperplasia. The NOAEL for the reproductive parameters is 61

mg/kg bw/day based on decreased number of implantations, decreased number of live pups at day 1, decreased anogenital distance in F2 males and delayed vaginal opening in F1 females at the high dose. The NOAEL for the offspring is also 20 mg/kg bw/day based on decreased litter weight at day 1, decreased pup bodyweight and increased relative brain weight.

From the two rat teratology studies, the NOAEL for maternal toxicity is 200 mg/kg bw/day, and the NOAEL for developmental toxicity 400 mg/kg bw/day. Acetochlor was not considered teratogenic to rats. From the rabbit teratology study, the parental NOAEL is 50 mg/kg bw/day based on reduced bodyweight, and the NOAEL for developmental toxicity 190 mg/kg bw/day as there is no evidence of teratogenic effect.

2.7. NEUROTOXICITY

Two neurotoxicity studies with rats are presented in the DAR: one acute by gavage, and one subchronic by dietary administration. The agreed NOAEL in the acute study is 150 mg/kg bw, based on reduced motor activity and clinical signs at 500 mg/kg bw. In the subchronic study, the proposed NOAEL is 48 mg/kg bw/day based on reduced body weight (gain).

2.8. FURTHER STUDIES

Mechanistic studies :

The mechanistic studies described in the DAR are related to *in vitro* metabolism, characterisation of protein binding and localization in nasal tissues, cellular proliferation and thyroid toxicity.

The *in vitro* metabolism of acetochlor to a protein reactive metabolite (quinine imine precursor, believed to be responsible for the nasal tumors in rats) is markedly higher in the rats than in the mice or monkeys.

Acetochlor was observed to produce a significant increase in cell proliferation in the olfactory region of the nasal turbinates of the rat in a dose-dependent manner. This suggests that acetochlor may exert its carcinogenic action by mechanism involving increased cell proliferation.

Acetochlor has been shown to produce thyroid tumors in rats through increased hepatic conjugation and compensatory thyroid hyperplasia and ultimately neoplasia.

Studies on metabolites :

Assay	Species	Result
t-oxanilic acid (2)[18]		
In vitro gene mutation	Bacterial cells	negative (+/- S9)
In vitro gene mutation	Mouse lymphoma cells	negative (-S9); positive (+S9)
In vitro chromosome aberrations	Human lymphocytes	negative (+/-S9)
In vivo chromosome aberrations	Mouse (micronucleus test)	negative
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg bw
90-day oral study	Rat	NOAEL: 230 – 268 mg/kg bw/day

[18] Metabolite 2: [(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid

Assay	Species	Result
Teratogenicity study	Rat	maternal NOAEL 500 mg/kg bw/d develop. NOAEL 1000 mg/kgbw/d
t-sulfinylacetic acid (3)[19]		
In vitro gene mutation	Bacterial cells	negative (+/- S9)
In vitro gene mutation	Mouse lymphoma cells	negative (+/- S9)
In vitro chromosome aberrations	Human lymphocytes	negative (+/-S9)
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg bw
90-day oral study	Rat	NOAEL: 265 – 309 mg/kg bw/day
t-norchloro acetochlor (6)[20]		
In vitro gene mutation	Bacterial cells	doubtful results in first assay
In vitro gene mutation	Mouse lymphoma cells	positive
In vitro chromosome aberrations	Human lymphocytes	negative (+/-S9)
In vivo chromosome aberrations	Mouse (micronucleus test)	negative
t-sulfonic acid (7)[21]		
In vitro gene mutation	Bacterial cells	negative (+/- S9)
In vitro gene mutation	Mouse lymphoma cells	negative (+/- S9)
In vitro chromosome aberrations	Human lymphocytes	negative (+/- S9)
In vivo chromosome aberrations	Mouse (micronucleus test)	negative
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg bw
90-day oral study	Rat	NOAEL: 225 – 259 mg/kg bw/day
s-sulfonic acid (13)[22]		
In vitro gene mutation	Bacterial cells	negative (+/- S9)
In vitro gene mutation	CHO/HGPRT	negative (+/- S9)
In vitro chromosome aberrations	Human lymphocytes	negative (+/- S9)
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg bw
N-oxamic acid (68)[23]		
In vitro gene mutation	Bacterial cells	negative (+/- S9)
In vitro chromosome aberrations	Human lymphocytes	negative (+/- S9)
In vivo UDS assay		negative
Acute oral toxicity	Rat	LD_{50} >2000 mg/kg bw

Conclusion for the groundwater/surface water / plant metabolites:

The carcinogenic potential of the groundwater metabolites t-oxanilic acid (**2**), t-sulfinylacetic acid (**3**), t-sulfonic acid (**7**) and s-sulfonic acid (**13**) has been discussed by the experts. Not found in the rat metabolism, they are considered relevant taking into account the carcinogenic potential of acetochlor.

[19] Metabolite 3: ({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid
[20] Metabolite 6: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide
[21] Metabolite 7: 2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[22] Metabolite 13: 2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[23] Metabolite 68: : [(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid

A final conclusion about the genotoxic/carcinogenic potential of *t*-norchloro acetochlor (**6**) could not be reached. The requirement for further evaluation was confirmed by the experts, and it is considered relevant as long as further information is missing.

N-oxamic acid (**68**) is a plant metabolite not found in the rat metabolism. Furthermore, the information available was limited and insufficient to establish an ADI or to determine the relative toxicity in comparison with acetochlor.

2.9. MEDICAL DATA

No local or systemic signs of toxicity were observed in employees who handled acetochlor in laboratories, or during manufacturing process development and operations. No adverse effects were reported in pesticide applicators as a result of mixing and loading and field application of acetochlor.

No cases of human intoxication by acetochlor have been reported.

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

ADI

Considering that the lowest dose level in the 78-week mouse study (Amyes, 1989) was a LOAEL and taking into account the carcinogenic effects in long term studies, the experts decided to use an additional safety factor of 3. The resulting ADI is **0.0036 mg/kg bw/day** with the use of a total safety factor of 300.

AOEL

The dog seems to be the most sensitive species. Initially the RMS proposed to use the NOAEL from the 13-week dog study (10 mg/kg bw/day) and a safety factor of 250 to guarantee the relation LOAEL for carcinogenic effect/AOEL > 1000. Finally the experts decided to use the NOAEL from the 1-year dog study (2 mg/kg bw/day). This is not the most appropriate with regard to the intended uses, but it covers the uncertainties arising from the short term studies in rodents. The resulting AOEL is **0.02 mg/kg bw/day** with the use of a safety factor 100.

ARfD

In the initial DAR, the ARfD was not considered necessary. However the experts agreed to derive an ARfD from the acute neurotoxicity study with rats, with the application of a safety factor of 100. The resulting ARfD is **1.5 mg/kg bw**.

2.11. DERMAL ABSORPTION

For the CS formulations (GF-675, MON 69425) the experts agreed to calculate the absorbed amount together with the stripped skin. Taking into account the *in vivo* study with rats and the *in vitro* study with human skin, the resulting values are 0.5% for the concentrate and 4% for the dilution.

For the EC formulation (MON 69447) an *in vitro* study is available showing a dermal absorption of 3.3% for the concentrate and 50% for the dilution.

2.12. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative formulation GF-675 (400 g acetochlor/L) is a capsule suspension (CS) for field use on maize crops. The representative formulation MON 69447 (840 g acetochlor/L) is an emulsifiable concentrate (EC) for field use on maize and sweet corn crops.
EFSA notes: the experts have not discussed the possible contribution of the safeners to the overall toxicological burden of the formulations (dichlormid in GF-675 (66.7 g/L), and furilazole in MON 69447 (28 g/L)).

Operator exposure

According to the intended uses submitted by the applicant the maximum applied dose is 2.0 kg acetochlor/ha and the minimum volume 100 L of water/ha. The only supported use is boom application (tractor mounted field crop sprayer with hydraulic nozzles).

The estimated operator exposure for **GF-675** is below the AOEL with the use of gloves during mixing/loading and application, and coverall and sturdy footwear during application, according to the German model (work rate 20 ha/day). The exposure estimates for **MON 69447** are higher than the AOEL according to the German model with the use of personal protective equipment (gloves during mixing/loading/application; sturdy footwear, coverall, hood and visor during application) (see results in the table below).

A **bio-monitoring study** with MON-69447 is presented in the DAR. The experts agreed to use this field study as a higher tier approach. Re-calculations were provided in an addendum (June 2007) with revised AOEL and dermal absorption, and normalisation to the standard treated areas used in the German and UK models (see results in the table below). The measured exposures are below the AOEL with closed cabins (20 or 50 ha/day) or open cabins (20 ha/day) when good agricultural practices are respected and protective gloves worn during mixing/loading, unfolding/folding of the boom and during any manipulations of contaminated equipment.
EFSA notes that the use of open cabins with a treated area of 50 ha/day will lead to an exposure above the AOEL.

Estimated exposure presented as % of AOEL (0.02 mg/kg bw/day), according to calculations with the German and UK-POEM models. The default for body weight of operator is 70 kg in the German model and 60 kg in the UK-POEM model.

GF-675 (CS)	No PPE	PPE[1]	PPE[2]	PPE[3]	PPE[4]	PPE[5]
German	272	238	195	-	21	-
UK POEM	2978	-	540	-	-	-
MON 69447 (EC)						
German	3170	-	-	-	-	131
UK POEM	35557	-	5574	-	-	-
Biomonitoring study (20 ha, open cabin)	-	-	-	46	-	-
Biomonitoring study (20 ha, closed cabin)	-	-	-	20	-	-
Biomonitoring study (50 ha, closed cabin)	-	-	-	52	-	-

PPE: personal protective equipment; **PPE[1]**: gloves during M/L; **PPE[2]**: gloves during M/L and A; **PPE[3]**: gloves during M/L, coverall during A; **PPE[4]**: gloves during M/L and A, coverall and sturdy footwear during A; **PPE[5]**: gloves during M/L and A, sturdy footwear + coverall + hood and visor during A.

Worker exposure

The experts agreed that the re-entry exposure to both formulations is negligible since they are applied prior to emergence and early post-emergence in maize crops (and entering the treated area shortly after spraying is not necessary).

Bystander exposure

Based on new calculations provided in addendum 1 (July 2006) and 4 (June 2007), the field application of GF-675 and MON 69447 results in an exposure of bystanders below the AOEL (16 and 93% of the AOEL) according to data from Lloyd and Bell[24] (1983).

3. Residues

Acetochlor was discussed by the experts in the PRAPeR meeting in March 2007 in Parma (PRAPeR 20, Round 4).

The evaluation is based on the notified representative uses. In course of the peer review procedure the applicant decided to no longer support the use on sweet corn. However, for the sake of transparency all information obtained with regard the use on sweet corn will be presented in this document where possible.

[24] Lloyd and Bell, 1983. Hydraulic nozzles : comparative spray drift study.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The nature of the residue in plants following the use of acetochlor was studied in maize upon **pre-emergence** application.

Maize was sown in soil treated with ^{14}C-labelled acetochlor at a slightly exaggerated rate (1.4 N) when compared to cGAP. The crop was grown under greenhouse conditions, and the uptake and metabolism of acetochlor in the plants was investigated until maturity.

Acetochlor was extensively metabolised in the crop. No acetochlor was found in maize grain, fodder or immature maize forage, but a large number of individual metabolites were formed.

The TRR in mature maize grain was low (0.07 mg/kg). Only a few metabolites could be identified, such as *t*-oxanilic acid (2) and *s*-oxanilic acid (12)[25] (together *ca* 5% TRR), N-oxamic acid (68) (*ca* 9% TRR), metabolite (69)[26] (3% TRR), *t*-sulfinylacetic acid (3) (3.5% TRR), all individually below 0.01 mg/kg. Around 26% TRR (0.02 mg/kg) in grains were multi-component but remained unidentified, and another 50% TRR (0.03 mg/kg) were not further analysed as the absolute residue levels were low. No analysis was however performed on the grain in the milky stage (sweet corn).

The nature of the residues in immature forage and mature fodder was complex, with at least 30 individual components present. Even though TRRs were two orders of magnitude higher in maize forage and fodder than in the maize kernels, the rate of identification was again limited. Basically, the same metabolites as in the maize kernels were detected. The metabolite N-oxamic acid (68) was a major compound and represented 23% TRR (1.04 mg/kg) and 13% TRR (0.67 mg/kg) in immature forage and mature fodder, respectively. Later, the applicant explained that the residue allocated to N-oxamic acid (68) consisted of more than one compound (addendum I of July 2006) and therefore the actual level of N-oxamic acid (68) would be lower. However, the rate of unidentified compounds is significant, *ca* 30% TRR (1.56 mg/kg) in fodder and up to 39% TRR (1.55 mg/kg) in forage. The unidentified residues were multicomponent, but whether individual components included in this fraction of unknowns surpass the trigger value for identification or not has been difficult to verify. Given the toxicological relevance of the identified acetochlor metabolites it is not possible to rule out the occurrence of another significant metabolite in forage or fodder that might have a different metabolic behaviour in animals.

It was therefore concluded by the experts in the PRAPeR 20 meeting that the level of identification in the study was not sufficient and a new metabolism study is required to address the residue profile in maize plants (forage, fodder). Residues in these plant parts are of relevance in risk assessment with regard to livestock feeding and may consequently affect consumer exposure through food of animal origin. Moreover, the study does not contain sufficient information that would have supported the use in sweet corn (withdrawn for peer review), and therefore a study that addresses the metabolism in sweet corn will be required if authorisation of uses in sweet corn is sought at MS level.

For mature maize grains however it was agreed by the experts that the residue levels at harvest after a pre-emergence application at 1.4 N GAP rate were low, and that any further identification would be

[25] Metabolite 12: [2,6-dimethylphenyl)amino](oxo)acetic acid
[26] Metabolite 69: [(2-ethyl-3-hydroxy-6-methylphenyl)amino](oxo)acetic acid

extremely difficult. Therefore, in terms of a GAP involving pre-emergence treatment, the experts accepted the metabolism study as sufficient with regard to mature maize grains, but not with regard to maize forage, fodder and immature maize kernels. It is noted that the RMS did not agree with this conclusion but agreed that the issue of residues in maize forage and fodder has not been fully addressed by the current submission (the RMS proposed a respective requirement in Level 4 of the DAR). However, the majority of experts agreed to the requirement of a new pre-emergence metabolism study.

The available maize metabolism study represents a pre-emergence use, but acetochlor was recommended for both, pre-emergence and early **post-emergence** uses (up to BBCH 16). No studies were submitted to support post-emergence i.e. foliar application. The applicant has submitted published papers. Their relevance to support post-emergence applications was discussed by the experts in PRAPeR 20. It was considered whether this information sufficiently demonstrates that metabolism will be the same for post-emergence use as for pre-emergence soil use. The study was designed to determine if initial metabolism is a factor in the selective phytotoxicity of acetochlor in tolerant and susceptible seedlings. The study was on 3 to 5 days old seedlings and metabolism was monitored only for 4 hours following application, where in the field, application can be made up to the 6 leaf stage (BBCH 16) and subsequently crops grow to maturity. Moreover, as this study was a published report from a scientific journal, it did not contain sufficient information on which to reach a regulatory decision. Therefore the experts in PRAPeR 20 concluded that a new foliar metabolism study for maize is required to support uses with post-emergence application. Lately, in the evaluation meeting in September 2007 the RMS indicated that they disagree with the request of a post-emergence study.

The available data show that the metabolism of acetochlor in maize following a pre-emergence treatment is very complex. It has been proposed that, following uptake of intact acetochlor from treated soil, conjugation with glutathione and metabolism to methyl sulfoxide, methyl sulfone and t-sulfinylacetic acid (3) occur. Moreover, oxidative dechlorination followed by cleavage of the ethoxymethyl group to yield t-hydroxy acetochlor (17) [27] is expected to happen. It has also been postulated that following the uptake of soil metabolite t-oxanilic acid (2) cleavage of the ethoxymethyl group and hydroxylation of the phenyl ring to N-oxamic acid (68) and metabolite 69 take place. Also uptake of the metabolites t-sulfonic acid (7) and t-sulfinylacetic acid (3) from soil might occur.

The analytical method for the quantification of acetochlor in maize is based on the fact that most of the plant metabolites of acetochlor produce two common aniline chemophore compounds when hydrolysed under alkaline conditions: EMA (34)[28] and HEMA (33)[29]. That does however not apply to

[27] Metabolite 17: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)-2-hydroxyacetamide
[28] Chemophore 34: 2-ethyl-6-methylaniline
[29] Chemophore 33: 2(1-hydroxyethyl)-6-methylaniline

the N-oxamic acid (68) metabolite. Acetochlor, if present, would be degraded to the common chemophore EMA.

Given the complexity of the metabolic picture and the toxicological relevance (potential carcinogenicity) of some of the acetochlor metabolites, the residue definition was extensively discussed by the experts in the PRAPeR 20 meeting. The experts considered also the available data on rotational crops (refer to 3.1.2).

For maize grain it was concluded that the residue definition for **risk assessment** should include all compounds forming EMA (34) and HEMA (33) on hydrolysis and N-oxamic acid (68) expressed as acetochlor. This definition can be provisionally applied to rotational crops, but needs to be confirmed or rectified upon receipt of the required data on rotational crops (ad interim a restriction could be considered - refer to 3.1.2). After the PRAPeR 20 meeting the RMS indicated that they don't agree with the definition for risk assessment set up by the experts, in particular with the inclusion of N-oxamic acid (68) (RMS comments to ESFA - September 2007).

For maize forage/fodder no residue definition for risk assessment can be proposed as the available data are insufficient and there is a requirement for further data.

Eventually, three options were proposed by the meeting for a residue definition for **monitoring** for the representative crop (maize) and, if it should become necessary, for crops which may be grown in rotation with maize.

Option 1: Acetochlor by default. This definition is not scientifically supported by metabolism data. A validated analytical method to determine acetochlor is available (refer to paragraph 1 of this document).

Option 2: It was proposed to choose N-oxamic acid (68) expressed as acetochlor although it is noted that this compound is not specific to acetochlor, e.g. propisochlor and metolachlor may degrade to the same metabolite. A validated analytical method for monitoring of N-oxamic acid (68) is available (refer to paragraph 1 of this document).

It was agreed that, if this definition is applied, the conversion factor from the monitoring residue definition to the risk assessment residue definition in maize grain could be set as 5. This is based on data from the pre-emergence maize metabolism study on the ratio of N-oxamic acid (68) to the total extractable residues less the polar compounds. As for the rotational crops, the experts felt that depending on environmental conditions, the ratio and levels of metabolites may not always be the same. The reliability of N-oxamic acid (68) as a marker compound is dependent upon the environmental conditions and also the plant back intervals for rotational crops. Thus, for rotational crops no conversion factor can currently be proposed.

Option 3: The residues definition should be the same as for risk assessment, i.e. all compounds forming EMA (34) and HEMA (33) on hydrolysis and N-oxamic acid (68) expressed as acetochlor. This comprehensive residue definition would always cover the majority of residues in maize and/or its rotational crops. However, it would most likely require two separate analyses of samples to monitor for this definition. At least two of the moieties (EMA (34) and N-oxamic acid (68)) are not specific to acetochlor, and possibly metabolites forming HEMA (33) on hydrolysis could also be

formed by other chloroacetanilide compounds. The methods of analysis for determination of all components of the proposed definition have not been validated for monitoring purposes.

A total of 48 supervised residue field trials were conducted in maize in several European countries in Northern and Southern Europe from 1996 to 2000, representing a varied range of climatic and agronomic conditions. Acetochlor formulated as CS and EC was applied either pre-emergence or early post-emergence, in accordance with the critical GAP. The EMA (34) and HEMA (33) chemophore compounds were the residues analysed for in all trials, and, in addition, in most of the trials acetochlor was separately determined. The results generated in the residue trials were however not supported by sufficient storage stability data on HEMA (33) and EMA (34) (see reassessment in corrigendum to the DAR of January 2007), and a new data gap for the submission of such data was identified in the PRAPeR 20 meeting.
In all analysed mature grain samples EMA (34) and HEMA (33) residues were below the LOQ (0.02 mg/kg each), and acetochlor residues, if analysed for, were also all below LOQ (0.01 mg/kg). A significant number of forage samples (PHI>90 days) showed levels of acetochlor related residues higher than 0.05 mg/kg, few exceeding 0.1 mg/kg (HR 0.43 mg/kg). The forage samples did not show residues above the LOQ when analysed specifically for acetochlor.
However, in the European trials evaluated in the DAR the metabolite N-oxamic acid (68) was not determined while it was in the additionally submitted US trials. No residues of N-oxamic acid (68) above the LOQ (0.01 mg/kg) were found in any of the grain samples, but residues were higher in forage/ silage (up to 0.39 mg/kg). It is noted that in the US trials the GAP was slightly different and no report about the soil and the weather conditions were included. Therefore, it was not possible to correlate domains in Europe and USA. The RMS required new European residue trials to measure the residues of acetochlor in maize forage, including the quantification of the metabolite N-oxamic acid (68). The RMS noted that maize fodder is usually not fed to animals, the maize commodity fed to animals is forage taken at silage stage. Thus, the process of ensiling should be taken into account when measuring acetochlor related residues in animal feed. Eventually, new data have been provided analysing for N-oxamic acid (68) in forage and mature grain in northern and southern European trials. This data was evaluated in the addendum 2 of January 2007. As a result, the residue levels in whole maize plant without roots cannot be considered as a 'no residue situation' (residues up to 0.03 mg/kg). The impact of ensiling on the residue level was not investigated. In mature grain N-oxamic acid (68) was never detected. However, the storage period and conditions of the samples were unclear, and potentially there will be a new data gap for storage stability data to support the residue trials with N-oxamic acid (68).
No residue data were submitted to support the initially notified use in sweet corn. Therefore appropriate residue trials will be required if authorisation of uses in sweet corn is sought on MS level.

Field trials demonstrate that residues above 0.1 mg/kg are not likely to occur in the maize grain to be processed. Therefore investigation of the effects of industrial processing and/or household preparation on the nature of the residue and on the residue levels is not required.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Laboratory and field confined rotational crop studies were conducted in the USA (California and North Carolina) with radiolabelled acetochlor at slightly exaggerated rates of *ca* 1.6 N and 1.5 N when compared to cGAP, respectively. Crops typical of those rotated with maize (radish, turnips, millet, wheat, mustard, soybean) were planted in treated soil in either containers or in the field approximately 30, 120 and 365 days after application. Lettuce was planted 162 days after application. The plants were harvested at different intervals up to maturity.

In the laboratory study the TRR reached significant levels in all crops and crop parts. The highest total levels were found in the crops at the intermediate planting interval (120/162 days). The highest TRR (2.76 mg/kg) was found in wheat straw, mature grain contained 0.1 mg/kg. In radish higher residues were found in the foliage (0.67 mg/kg) than in the roots (0.19 mg/kg). Residue levels were slightly lower in both the 30 DAT and 365 DAT crops.
In the field study total residues (TRR) were consistently at least two times lower than in the laboratory study, but partially still at significant levels in edible crop parts at the 365 day plant back interval (e.g. soybeans 0.04 mg/kg). In terms of the differences in total residue levels in the two studies the applicant explained that the low level of metabolites in the in-ground study performed in North Carolina was due to the watering practises and excess of rainfall comparing to the in-boxes study performed in California. However, it follows that the natural downward movement of polar soil metabolites could be reduced in low rainfall sites, where the metabolites could be more available for uptake by crops grown in rotation. Nevertheless the North Caroline site is not representative of the whole European agronomic soils where uses of acetochlor are sought for, thus there still is a concern related to the residue level in succeeding crops at EU level and to address this concern a data requirement has been proposed.

Upon characterisation of the residues the major metabolites identified were *t*-oxanilic acid (2), *s*-oxanilic acid (12), *s*-sulfonic acid (13) and *t*-sulfonic acid (7), *s*-amide methyl sulfone (10)[30], *s*-hydroxy (11)[31] and *t*-amide methyl sulfone (16)[32]. In cereal straw also hydroxyethyl-*t*-oxanilic acid (30)[33] was a major metabolite. The N-oxamic acid (68), the major metabolite isolated in all primary maize commodities, appears in the majority of rotational crops analysed at noticeable concentration. Acetochlor was detected at 0.03 mg/kg in radish leaves sampled 165 days after application but no acetochlor was identified in other crop parts at any sampling. In some crops a significant part of the extractable total residue was not identified (e.g. in turnip tops 45% (0.18 mg/kg), but was found to be multicomponent. Unextractable radioactivity was found to be incorporated into hemicellulose and cellulose. In wheat grain a fair amount was associated with the starch fractions.

[30] Metabolite 10: 2-methylsulfonyl-N-(2-ethyl-6-methylphenyl)acetamide.
[31] Metabolite 11: 2-hydroxy-N-(2-ethyl-6-methylphenyl)acetamide.
[32] Metabolite 16: 2-methylsulfonyl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide.
[33] Metabolite 30: N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]oxamide.

The metabolism of acetochlor in rotational crop plants produces an array of metabolites similar those previously identified in the primary crop metabolism study. The metabolic profile of acetochlor is very complex, with diverse mixture of metabolites observed.

In addition three field studies were conducted at different locations in the USA and residues of three moieties HEMA (33), EMA (34) and HMEA (32)[34] in cereal grain and edible portions of root crops were determined 315 to 530 days after acetochlor application at 1.6 N the notified rate in Europe. The applicant has not yet provided climatic comparison to the EU climate to support the rotation residue trials. The meeting of experts agreed that the applicant should provide climatic data and justification why the rotational crop data generated in the USA can be considered appropriate for EU climatic conditions (must consider both Northern MS and Southern MS). The experts pointed out that it were not appropriate to rely on the OECD Expert Zoning report as this is inconclusive.
In addition the USA trials data analysed besides EMA (34), HEMA (33) also for HMEA (32). This information was included in the EPA short report for acetochlor[35]. HMEA (32) appeared at very low levels in the radish root but was not seen in cereals, potatoes or sugar beet crops. It was suggested that the EPA residue definition may have arisen from other crops including soybean (P/O crop group). A new data gap was identified by the experts for the notifier to provide all available data to correlate the EPA residues definition for rotational crops (where HMEA (32) was included) to allow the European risk assessment procedure to conclude an appropriate residue definition for rotational crops.
The meeting agreed that preliminary, considering all the available rotational crop data, the residue definition for human risk assessment for rotational crops would be the same as for risk assessment for the primary crop, i.e. all compounds forming EMA (34) and HEMA (33) on hydrolysis, plus N-oxamic acid (68) expressed as acetochlor.
Based on available data the experts can confirm there are no residues of concern found in the edible portion of cereals, sugar beets, and potatoes when grown in rotation with maize. The meeting proposed that, if feasible in practice, rotational crops could be restricted to cereal grains, root/ tuber crops and leafy crops until the residue definition for rotational crops has been refined. The residues in straw from cereals grown in rotation will need to be considered for animal intakes and consumption of animal tissues by humans.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Even though in maize grain the residue level is insignificant, for maize fodder (silage) significant residue levels can be expected. Treated maize forage or fodder may be fed to ruminants. Therefore, livestock studies with ruminants are required. It is however noted that currently insufficient data in terms of quality and magnitude of residues are available to assess the dietary burden of livestock fed with treated maize-commodities (silage and forage included) and with rotated crops.

[34] Chemophore 32: 2-hydroxymethyl-6-ethylaniline.
[35] US EPA Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Acetochlor, March 2006

In order to address potentially occurring residues in food of animal origin, four metabolism studies with ^{14}C-acetochlor in goats, with ^{14}C-N-oxamic acid (68) in cows, with sodium salt of ^{14}C-sulfonic acid 2 (Na salt of 24)[36] in goats and with a mixture of metabolites (all radiolabelled) t-hydroxy acetochlor (17), sodium salt of sulfonic acid 2 (Na salt of 24), sodium salt of t-oxanilic acid (Na salt of 2) and sodium salt of t-sulfinyl acetic acid (Na salt of 3) in goats were submitted and evaluated in the DAR.

The RMS noted that in the available plant studies acetochlor itself was not found as a component of the plant residue, and consequently, it may not expected to be present in feed items. Therefore, the RMS concluded that the metabolism study with parent acetochlor in goat is of subordinate importance and that studies conducted with compounds representing EMA and HEMA yielding acetochlor metabolites are more appropriate to evaluate the metabolism in animals and to propose a residue definition for animal commodities. As the livestock exposure assessment is however inconclusive, all available data are summarised below for the sake of transparency.

Following oral dosing of lactating goats with ^{14}C acetochlor for four consecutive days the majority of the administered dose was excreted with urine (50-71%) and faeces (20-29%). The total radioactive residues in animal tissues and milk were low, except in the liver and kidney, and no acetochlor was found. The major component identified in milk (19% TRR) and in urine (24% TRR) was t-amide cysteine (56)[37]. The vast majority of the radioactive residue in muscle, liver and kidney could not be recovered by solvent extraction techniques. Further characterisation of the residue in muscle, liver and kidney showed that the majority was associated with proteins (> 80%), and EMA (34) and HEMA (33) moieties could be detected in the hydrolysates (muscle 29% TRR, liver 43% TRR, kidney 34% TRR). However in all matrices a noticeable portion of the TRR, not characterised as EMA (34) and HEMA (33) moieties, remained unidentified. Acetochlor was completely metabolised by goats to a complex mixture of several components.

In a second ruminant study, ^{14}C-N-oxamic acid (68) (major maize metabolite) was administered to a lactating cow for seven consecutive days. The administered dose was excreted rapidly. At the time of sacrifice, 82.5% of the administered radioactivity was eliminated in the faeces and 8.4% in the urine. The total radioactivity excreted with the milk was 0.008% of the administered dose. The total radioactive residues in edible animal tissues were low, and of the edible matrices only kidney was further analysed. It was found that metabolism of N-oxamic acid (68) is limited with the majority of the residue in both the urine (80% TRR) and faeces (88% TRR) being the unchanged compound. Extraction and fractionation to characterise the residue in the kidney showed 47% of the total residue was unchanged N-oxamic acid (68). The majority of the remaining radioactivity in kidney was associated with unextracted solids (25% TRR) and aqueous soluble components (15% TRR).

In a third ruminant study, ring labelled ^{14}C-sulfonic acid 2 (24) (proposed as representative for HEMA (33) forming metabolites) was administered as sodium salt to lactating goats altogether at

[36] Compound 24: 2-sulfonyl-N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]acetamide
[37] Metabolite 56: 2-cystein-S-yl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide.

three different dose levels (0.5 – 5 mg/kg diet) for either 5 or 28 consecutive days, respectively. Also non radiolabelled compound was submitted at three different dose levels to a subgroup of test animals for 28 consecutive days. Both nature and magnitude of potential residues in ruminants were investigated in this study.

Of the administered radioactivity, 69% were eliminated in faeces and 4% in urine. Less than 0.04% was recovered in milk and tissues. For the animals with the highest dose received, the absolute levels of total radioactivity in tissues were very low in kidney and liver (<0.01 mg/kg), or even below 0.001 mg/kg in blood, muscle, and fat. Specific analysis of milk samples for HEMA (33) and EMA (34) indicated that results were below the limit of detection, too. There was no accumulation of residues observed in milk and edible tissues of lactating goats after a dosing period of 28 consecutive days. The very low total radioactivity in bile and tissues indicated limited absorption of sulfonic acid 2 (24).

In a fourth ruminant study a mixture of four ^{14}C ring labelled metabolites t-hydroxy acetochlor (17), sodium salt of sulfonic acid 2 (Na salt of 24), sodium salt of t-oxanilic acid (Na salt of 2) and sodium salt of t-sulfinyl acetic acid (Na salt of 3) in the ratio 22.3: 43: 33: 1.7 was administered to two lactating goats for five consecutive days. Again, the findings were consistent with that in the previous studies. The majority of radioactivity was eliminated via urine (38 % applied radioactivity) and faeces (33 %). Less than 0.05% of applied radioactivity was recovered in tissues or milk and absolute levels in liver, kidney, blood and milk were very low. No residues were detected in muscle and fat tissue.

Chromatographic profile analysis of urine and faeces samples showed that the composition of metabolites excreted was similar to that of the mixture used as test substance although the t-hydroxy acetochlor (17) appeared in much lower level and the t-sulfinylacetic acid (3), which was lowest already in the dosing material, was impossible to identify. Quantitative hydrolysis of urine and faeces samples showed the majority (59% and 55%) of the residues were present as EMA (34) structure metabolites.

The combined results of the submitted metabolism studies on goats with the metabolism study in cow showed that no accumulation of compounds with EMA (34), HEMA (33) structural moieties or N-oxamic acid (68) should be expected in milk or tissues of ruminants upon exposure to those compounds. However, at the moment, a conclusion cannot be drawn whether the available studies fully cover the residues ruminants may be exposed to as there are outstanding data on plant metabolism. Therefore, the experts of PRAPeR 20 concluded that it is currently not possible to propose a residue definition in ruminant matrices.

It is noted that a hen metabolism study with acetochlor was submitted and evaluated in the DAR, even though not required as residue intake by poultry from maize grains is insignificant (below the trigger value). Whether there might be significant exposure from rotational crops is currently unknown. Moreover, it is unclear whether, given the residue pattern on potential feed items as far as seen from the available plant data, a study with acetochlor would properly address the nature of residues in exposed poultry.

3.3. CONSUMER RISK ASSESSMENT

There are two isomers of acetochlor that appear not to have been addressed by the submitted data (see also paragraph 'The active substance and the formulated product' of this document). Therefore, the experts concluded the applicant should address the consumer exposure to the two acetochlor isomers, whether a change of the isomer ratio may occur when acetochlor is metabolised or degraded and whether a possibly changed ratio of isomers can be considered covered by the available toxicological data and information. It is noted that the RMS disagrees with this requirement.

Due to data gaps identified (data to address livestock exposure and subsequently residues in food of animal origin, rotational crop data) the consumer risk assessment cannot be finalised.

To estimate the exposure of consumers to residues of acetochlor based on the data available, the RMS calculated the Theoretical Maximum Daily Intake (TMDI) based on WHO/GEMS FOOD European diet, UK, German and Spanish consumption data and the proposed MRL for maize grain. It is noted that this latest updated assessment was inserted by the RMS in the list of endpoints only and was not peer reviewed. For maize consumption, the TMDI is expected to be less than 2% of the ADI of 0.0036 mg/kg/bw/day for adults and around 5% of the ADI for the most sensitive populations infants and toddlers. A calculation with the EFSA PRAPeR model, also not peer reviewed, showed the WHO Cluster diet B (all population) is the most critical diet for the consumption of maize grain (3.4% ADI). The IESTI values for maize consumption are well below (0.002%) the ARfD of 1.5 mg/kg bw/day for adults and children, respectively.

There is also the potential of consumer exposure to residues through ground water used as drinking water. A RMS risk assessment (addendum 3 of June 2007 – Not peer reviewed) denoted no exceedance of the reference value (acetochlor ADI) for the consumption of water containing residues of the metabolites t-sulfonic acid (7), t-sulfinylacetic acid (3), t-oxanilic acid (2) and s-sulfonic acid (13) by adults, but with a small margin of safety when the predicted concentrations by the FOCUS GW modelling are used. The results of the risk assessment for the consumption of water by children and infants however show an exceedance of the reference value.

A revised FOCUS GW modelling (refer to chapter 4.2.2 of this document) showed much higher annual average concentrations of the four leaching metabolite than used in the previous assessment and therefore also for adults an exceedance of the reference value might be expected. No updated exposure assessment with regard to the new predicted values of ground water metabolites is available.

3.4. PROPOSED MRLS

An MRL of 0.05* mg/kg is proposed for maize grain based on option 3 of the suggested residue definition for monitoring.

4. Environmental fate and behaviour

Acetochlor was discussed by the Member State experts for environmental fate and behaviour in the PRAPeR meeting 17 (round 4, March 2007). It should be noted that the methods of analysis used to quantify acetochlor in the fate and behaviour studies provided no information on the relative contribution of the two acetochlor isomers (rotamers) to the total acetochlor residues reported. Therefore all acetochlor residues reported in the fate and behaviour sections of the DAR, addenda and this conclusion are for the sum of the 2 isomers (rotamers).

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In topsoil experiments carried out under aerobic conditions in the laboratory (22°C 75% field capacity (FC) or 50% maximum water holding capacity (MWHC) in the dark, the predominant pathway of acetochlor degradation was microbially intermediated oxidative dechlorination to t-oxanilic acid (2) (max. 11-17.1% of applied radioactivity (AR)) subsequently forming t-sulfinylacetic acid (3) (max. 9.2-18%AR), t-sulfonic acid (7) (max. 5.9-11.8%AR) and s-sulfonic acid (13) (max. 1.5-9.8%AR). The metabolite t-norchloro acetochlor (6) was only present at relatively low levels in the available topsoil route of degradation studies accounting for a maximum of 2.9 %AR (aerobic phase of an anaerobic experiment) though in a rate of degradation experiment it was found at up to 3.3%AR[38]. Mineralisation to carbon dioxide accounted for only 11-15%AR after 84 days (carbonyl radiolabel) and 0.3-3.1%AR after 96 days (phenyl radiolabel). The formation of residues not extracted by acetonitile then acetonitrile:water followed by acetonitrile:water Soxhlet extraction or acetonitrile then dilute aqueous ammonium hydroxide then water was also a significant sink for the applied radiolabel (15-41% AR after 84-90 days).

An acceptable anaerobic soil degradation study was not available. However anaerobic soil conditions would not be expected, for the intended use applied for on maize. In a laboratory soil photolysis study, the rate of degradation on light exposed moist soil was comparable to that in the moist dark control experiments, so there was no indication that photodegradation contributes to the breakdown of acetochlor at the soil surface.

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

The rate of degradation of acetochlor was investigated under aerobic conditions at 20-25°C and moisture at around field capacity in 24 soils in the laboratory (pH 4.7-8.1, organic matter (om) 0.7-4.1%, texture loamy sand – clay loam). Acetochlor exhibited low to moderate persistence in soil with the single first order DT_{50} being calculated in the range 3.4-29 (DT_{90} 11.1-96 d) after normalisation to FOCUS reference conditions (20°C, pF2 (-10kPa) soil moisture content).

[38] Note, the fact that t-norchloro acetochlor (6) was present at up to 4.2%AR in the report of the expert meeting (in relation to open point 4.3) is accurate, but this marginally higher value comes from a subsoil experiment (260-305cm sampled layer, see table B.1.2.1-10 of the DAR).

The major soil degradation products (> 10 %AR) were investigate in aerobic laboratory rate of degradation studies (20°C and pF2 (field capacity) soil moisture) where they were applied as test substance to 3 different soils. t-oxanilic acid (2) and t-sulfonic acid (7) exhibited moderate to high persistence in soil with estimated single first-order DT_{50} values of 15-131 days (DT_{90} 50-435 d) and 33-148 days (DT_{90} 108 – 491 d) respectively. t-sulfinylacetic acid (3) exhibited medium to high persistence with single first-order DT_{50} values estimated at 75-112 days (DT_{90} 248-372 d). The minor soil degradation product s-sulfonic acid (13) (<9.8%AR) was also investigated in 3 soils (20°C and 40% MWHC soil moisture). It exhibited moderate to medium persistence with estimated single first-order DT_{50} values of 31-90 days (DT_{90} 102-300 d). Following normalisation to FOCUS reference conditions (20°C, pF2 (-10kPa)) this DT_{50} range becomes 25-75 days.

In a laboratory experiment where a single topsoil (4.3% om, loam soil) was maintained under anaerobic conditions in the dark and dosed with the metabolite s-sulfonic acid (13) (see addendum for the RMS evaluation) single first order DT_{50} of 5.3 days (DT_{90} 17d) were estimated indicating more rapid degradation in anaerobic topsoil than in aerobic topsoil for this metabolite.

Four field dissipation studies where acetochlor was applied were provided. These studies were conducted in France and Italy. Applications were made pre-emergence to plots where maize was sown that subsequently germinated. Single first order DT_{50} for acetochlor were estimated to be in the range 7-17 days (DT90 23-56d). The analysis carried out, only quantified residues of acetochlor. Residues of the soil metabolites identified in the laboratory studies were not determined.

The meeting of experts discussed non standard PEC soil for metabolites that had been calculated assuming a soil mixing depth of 20cm. Information regarding this approach was presented by the applicant and evaluated by the RMS in an addendum. The experts agreed to use the standard calculation approach using the longest laboratory soil DT50 and a mixing depth of 5cm as even the applicants modelling did not demonstrate distribution of the metabolites over the larger 20cm soil layer. The agreed approach was presented by the RMS in the addendum available to the meeting and the resulting metabolite PEC soil can be found in appendix 1.

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

The adsorption / desorption of acetochlor was investigated in ten soils. Calculated adsorption $K_f oc$ values considered acceptable in 9 of these soils varied from 74 to 422 mL/g, (mean 204 mL/g) indicating that acetochlor exhibits high to medium mobility in soil (1/n 0.79 – 1.37, mean 1.03). There was no indication of any relationship between adsorption and any soil characteristic including pH.

The adsorption / desorption of t-oxanilic acid (2) was investigated in six soils. Calculated adsorption $K_f oc$ values considered acceptable in 5 of these soils varied from 17-83 mL/g (mean 35 mL/g) indicating that t-oxanilic acid (2) exhibits very high to high mobility in soil (1/n 0.77 – 1.89, mean

1.4). There was no indication of any relationship between adsorption and any soil characteristic including pH.

The adsorption / desorption of t-sulfinyl acetic acid (3) was investigated in six soils. Calculated adsorption $K_f$oc values varied from 8-58 mL/g (mean 23 mL/g) indicating that t-sulfinyl acetic acid (3) exhibits very high to high mobility in soil (1/n 0.75 – 1.21, mean 0.96). There was no indication of any relationship between adsorption and any soil characteristic including pH.

The adsorption / desorption of t-sulfonic acid (7) was investigated in six soils. Calculated adsorption $K_f$oc values considered acceptable in 5 of these soils varied from 21-68 mL/g (mean 39 mL/g) indicating that t t-sulfonic acid (7) exhibits very high to high mobility in soil (1/n 0.83 – 1.84, mean 1.26). There was no indication of any relationship between adsorption and any soil characteristic including pH.

The adsorption / desorption of s-sulfonic acid (13).was investigated in five soils. Calculated adsorption $K_d$oc values varied from 2-10 mL/g (mean 6.8 mL/g) indicating that s-sulfonic acid (13) exhibits very high mobility in soil. There was no indication of any relationship between adsorption and any soil characteristic including pH.

The adsorption / desorption of t-norchloro acetochlor (6) (major sediment water system metabolite, see 4.2.1, minor in topsoil, max 3.3% AR, see further discussion in 4.2.2) was investigated in five soils. Calculated adsorption $K_f$oc values varied from 41-82 mL/g (mean 55 mL/g) indicating that t-norchloro acetochlor (6) exhibits very high to high mobility (1/n 0.9 – 0.95, mean 0.92). There was no indication of any relationship between adsorption and any soil characteristic including pH.

The mobility of acetochlor was assessed in four different soil types in a not aged laboratory column leaching study. The columns were leached with 509 mm of water in one day. Following the leaching process, 43 – 96 % of column AR was found in the leachate. The radioactivity in the leachates primarily consisted of acetochlor with smaller amounts of t-norchloro acetochlor (6) (1.5 – 2.5%AR) and t-hydroxy acetochlor (17) (0.4 – 2.4%AR) also being identified.

An additional aged laboratory soil column leaching study investigating a single sandy loam soil with 1.1% organic carbon, provided by the applicant during the peer review was also assessed by the RMS and discussed by the experts from the member states (Assessments including clarifications provided by the applicant to questions from the RMS were provided in two addenda). The conclusion of the experts on this study was that it should be considered as supplementary information only, as there was a lot of uncertainty over the identification of metabolites in the study. This uncertainty contributed to the experts considering that a lysimeter study should be required as concluded by the RMS in the original DAR. See section 4.2.2 for further discussion regarding the experts' conclusion that a lysimeter study was necessary.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In laboratory sterile aqueous hydrolysis experiments at pH 5-9 acetochlor was stable at environmentally relevant temperatures. In a laboratory sterile aqueous photolysis experiment acetochlor degraded minimally, indicating direct photolysis will not be a major route of degradation in natural surface water systems.

The water-sediment study (2 systems studied at 20°C in the laboratory) demonstrated acetochlor exhibited moderate persistence dissipating in the total systems with estimated single first order DT_{50} of 17-22 days (DT_{90} 56-75 days). A compartment model implemented in ModelMaker, the details for which were provided in an addendum to the DAR resulted in degradation DT_{50} in the water compartment estimated at 26 to 55 days (geomean 40.5 days) and in the sediment compartment estimated at 9.6 to 7.5 days (geomean 8.6 days). The experts from member states agreed that these values were appropriate for use in FOCUSsw calculations in this case, acknowledging that their derivation was not in complete agreement with FOCUS degradation kinetics guidance. The metabolites t-oxanilic acid (2) and t-norchloroacetochlor (6) were identified as significant degradation products representing maxima of 13.1/ 2.9%AR and 10.4/19.2%AR in water/sediment respectively. The terminal metabolite, CO_2, was a minimal sink in the material balance accounting for only 1.4-2.7% of the applied phenyl ring radiolabel after 100 days(study end). Residues not extracted from sediment by acetonitrile and acetonitrile/water were the most significant sink for radioactivity representing 24-50 % AR at study end.

FOCUS surface water modelling was evaluated up to step 4 for acetochlor and step 2 for the metabolites t-oxanilic acid (2), t-norchloro acetochlor (6), [originating from soil t-sulfinyl acetic acid, (3) t-sulfonic acid (7), s-sulfonic acid (13)] in an addendum. The peer review agreed these PEC up to step 3 as presented in the addendum were appropriate for use in risk assessment. The aquatic risk assessment for acetochlor requires risk mitigation to refine the levels of exposure calculated at step 3, so FOCUS surface water modelling at step 4 is necessary. The experts from the member states agreed that the FOCUS step 4 calculations provided by the applicant during the peer review and assessed by the RMS in the addendum were not acceptable. This was because even when just no spray drift buffer zones had been implemented in the calculations (i.e. when runoff was not mitigated, for example at drainage scenarios) the mitigation was not implemented in the agreed manner. As well as reducing aerial deposition as a result of mitigated drift, the applicant also changed the ratio of the treated area to water body defined for the FOCUS scenarios. Therefore the experts agreed further calculations at step 4 were required where just spray drift was mitigated. For the runoff scenarios where runoff might be mitigated in addition to spray drift reduction, the effect of vegetative buffer strips in reducing runoff as had been proposed by the applicant was discussed by the experts. They noted that in the EFSA PPR Panel opinion on the FOCUS landscape and mitigation report[39] that the efficiency of

[39] Opinion of the Scientific Panel on Plant protection products and their Residues on a request from EFSA on the Final Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment *The EFSA Journal* (2006) 437, 1-30

vegetative strips was not proven, particularly for substances with soil adsorption Koc values <2000mL/g. These values for acetochlor are significantly below this level (see section 4.1.3). After the meeting new simulations were presented by the RMS in an addendum (addendum V to B-8) where only spray drift was mitigated following FOCUSsw guidance without changing the ratio of the treated area to receiving water body. EFSA is content the calculation procedure followed was correct. As the calculations follows standard agreed guidance, used input values and the application pattern and time window agreed as appropriate by the peer review, these PEC values where spray drift only is mitigated with no spray buffers are considered as agreed values that are reliable to use in the EU level aquatic risk assessment. They are therefore included in appendix 1.5 of this document as agreed endpoints. Note: calculations were also presented where in addition to no spray buffers a 75% reduction resulting from the use of drift reducing nozzle technology was factored on top of the no spray buffers. These calculations are correctly done and are also presented in appendix 1.5. Risk managers should however note that the peer review has not confirmed the efficacy of any drift reducing nozzles at the buffer distances for which results are calculated, so the values presented are only indicative of the spray drift reduction that might possibly be achieved when combining a buffer distance with a drift reducing nozzle.

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

Modelling

The peer review agreed that the available FOCUS groundwater scenario modelling for acetochlor active substance carried out for the applied for intended use on maize that utilised the FOCUSPELMO, FOCUSPRZM and FOCUSPEARL models was appropriate[40]. This modelling indicates that annual average concentrations of acetochlor in leachate leaving the top 1m soil column would be significantly less than the parametric drinking water limit of 0.1µg/L at all 8 pertinent FOCUS groundwater scenarios (range of calculated values <0.001 to 0.005 µg/L).

This was not however the case for the soil metabolites t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) for which levels in the soil route of degradation study triggers the requirement for a groundwater exposure assessment. The substance values the peer review considered should have been used as the basis for the modelling input are tabulated below with the values actually used by the applicant in the modelling discussed by the peer review meeting indicated in (parenthesis).

[40] Note a slightly precautionary acetochlor first order soil DT50 of 10.4 days was used, whereas the precise value in accordance with FOCUS guidance would be a median value of 9.6 days.

Substance properties agreed by the member state experts as appropriate for FOCUS leaching modelling (values actually used in the modelling provided by the applicant discussed by the peer review meeting in parenthesis)

	acetochlor	t-oxanilic acid (2)	t-sulfinyl acetic acid (3)	t-sulfonic acid (7)	s-sulfonic acid (13)
Pertinent max. observed formation from acetochlor. (% on molar basis)		17.1 (15.1)	18.1 (11.7)	11.8 (9.1)	9.8 (4.4)
Kfoc (mL/g)	204 (203.5)	35 (24.3)	23 (21.8)	39.2 (28.8)	-
Kdoc (mL/g)	-	-	-	-	6.8 (6.8)
1/n	1.03 (1.03)	1.4 (0.9)	0.96 (0.9)	1.3 (0.9)	1.0 (0.9)
0-30cm Soil DT50 (days)	9.6 (10.4)	38.9 (30)	91.8 (92)	75.8 (89)	42.2 (56)
30-60cm Soil DT50 (days)	19.2 (20.8)	77.8 (60)	183.6 (48.7**)	151.6 (178)	84.4 (112)
60-100cm Soil DT50 (days)	32 (34.7)	129.7 (100)	306 (5.3*)	252.7 (296.7)	140.7 (186.7)
>100cm Soil DT50 (days)	0 (0)	0 (0)	0 (5.3*)	0 (0)	0 (0)

* value from an anaerobic study carried out with topsoil see section 4.1.2

**average of the anaerobic topsoil (5.3 days) and geomean aerobic topsoil (92 days) values

The experts discussed if it was appropriate to use a DT50 from an anaerobic soil laboratory topsoil study (available for t-sulfinyl acetic acid (3)) to represent potential degradation rates in deeper soil layers in FOCUS groundwater simulations. The conclusion of this discussion was that it was inappropriate. The appropriate studies to modify DT50 in deeper soil layers would be studies (anaerobic or aerobic) carried out with subsoil (i.e. that has lower microbial activity more representative of deeper soil layers) or studies on degradation in the saturated zone following guidelines available from the CTB in The Netherlands. Use of degradation rates from sterile soil studies might also be an option. The use of degradation rates from anaerobic topsoil studies was considered to represent too much of a best case without having further evidence that the degradation measured in the study was not microbially mediated.

The experts discussed if it was appropriate as the applicant had proposed to exclude the degradation rate from the loamy sand soil from the regulatory database for the metabolites. They agreed that this was inappropriate as the drop of the microbial activity did not appear to have an effect on the shape of the degradation curve and the initial microbial biomass level was acceptable. Consequently they concluded the geometric mean values for single first order DT50 from all 3 soils should be used for leaching modelling for the metabolites. The experts also discussed the approach used in the groundwater modelling regarding the degree of formation of the metabolites from precursor compounds. They confirmed that best modelling practice would have been to use the kinetic formation fractions of the metabolites to model the pathway of formation and degradation of the different metabolites. If this methodology had been followed then it is usually accepted to use the mean of the kinetic formation fractions as model input. However this methodology was not followed

and currently kinetic formation fraction for the metabolites are not available, so with the available kinetic assessments this best practice approach cannot be followed. The available metabolite leaching simulations apply the metabolites at the soil surface and model their subsequent downward movement as if they were a parent substance. The experts agreed this approach is not outside agreed FOCUS guidance and can be used for this substance, but considered that when this approach is followed the maximum observed formation rate in the available laboratory route of degradation studies (and not a mean maximum observed) should be used to calculate the 'applied' amount of metabolite at the soil surface required for simulations. This agreement was concluded as the maximum observed value depends on the kinetic formation fraction and the degradation rate of the precursor and of the metabolite of interest. Therefore if a mean maximum observed amount was used then the degradation rates would be indirectly averaged a second time in the same modelling exercise.
The experts also noted that the approach of simulating the metabolites as if applied as test substance at the same date as intended for the active substance may also underestimate the leaching potential of the secondary metabolites formed later in the degradation pathway as they have the potential to be formed in deeper soil layers. This is a potential concern regarding the simulated levels of s-sulfonic acid (13).

The meeting of experts therefore identified a data gap for new FOCUS groundwater modelling for the metabolites. However the experts considered that the available groundwater modelling results may be used by risk managers, though they should bear in mind that if the correct input parameters indicated above had been used then higher concentrations than those indicated here in the applicants modelling would be expected. Following the meeting of experts the RMS provided groundwater modelling that used the input parameters agreed by the meeting of experts (with the minor exception that for s-sulfonic acid (13) a slightly less conservative 1/n value of 0.9 and not 1 was used as input) and FOCUS PELMO 3.3.2. (see addendum V to B-8). This modelling also changed the dates that the metabolites were assumed to be applied. The dates selected by the RMS have not been confirmed by the member state peer review though are considered appropriate by PRAPeR experts. The RMS did not provide further modelling with PEARL. The results of the available modelling are set out below.

'Too best case' indicative PEC(gw) – modelling results (80th percentile annual average concentrations leaching below 1m) provided by the applicant

	Scenario	Metabolite (µg/L) Tier 1			
		(2)	**(3)**	**(7)**	**(13)**
PEARL /maize	Chateaudun ©	2.052	0.053	11.006	4.357
	Hamburg (H)	3.319	2.614	14.490	7.062
	Krensmünster (K)	2.729	0.276	11.814	5.410
	Okehampton (N)	3.099	0.698	11.585	4.246
	Piacenza (P)	2.639	0.700	10.902	3.262
	Porto (O)	0.093	0.023	2.477	1.473
	Sevilla (S)	0.387	0.026	3.333	1.465
	Thiva (T)	1.209	0.037	8.287	2.819
PELMO	Scenario	Metabolite (µg/L) Tier 1			
		(2)	**(3)**	**(7)**	**(13)**
	Chateaudun (C)	0.433	0.008	6.759	2.098

	Hamburg (H)	2.141	2.966	13.532	5.468
	Krensmünster (K)	0.922	0.266	10.189	4.102
	Okehampton (N)	1.628	0.378	10.865	4.157
	Piacenza (P)	1.491	0.596	8.836	2.109
	Porto (O)	0.014	0.002	1.481	1.346
	Sevilla (S)	<0.001	<0.001	0.006	0.033
	Thiva (T)	0.003	0.002	1.093	0.167

PEC(gw) in line with peer review agreed input parameters – FOCUS PELMO modelling results (80th percentile annual average concentrations leaching below 1m) provided by the RMS

	Scenario	Metabolite (µg/L) Tier 1			
		(2)	**(3)**	**(7)**	**(13)**
PELMO /maize	Chateaudun (C)	5.84	28.86	22.06	9.74
	Hamburg (H)	15.4	47.6	43.2	27.2
	Krensmünster (K)	11.32	38.2	23.6	12.5
	Okehampton (N)	13.13	41.4	31.9	21.9
	Piacenza (P)	7.83	34.8	20.4	19.8
	Porto (O)	3.62	10.5	17.3	8.9
	Sevilla (S)	0.113	0.188	2.2	0.343
	Thiva (T)	0.4	7.68	19.1	5.4

Experimental measurements / field studies

The experts discussed the proposal from the DAR that a lysimeter study was necessary to better understand the potential for groundwater exposure from breakdown products of acetochlor. The experts agreed that for acetochlor and the metabolites identified in the soil route of degradation studies t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13), that were also analysed for in monitoring and targeted field monitoring studies, a lysimeter study was not essential to estimate the potential leaching risk of these breakdown products. There was however a potential concern when considering the results of the available column leaching experiments and aged column leaching experiment for other potential breakdown products (see section 4.1.3). Based on the results of these studies there are indications that the identified metabolites t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) might have the potential to leach to groundwater and in the aged soil column leaching study evaluated in the addenda, the leachate contained residues that have not had their identity adequately clarified. Some experts also noted that for other acetamide herbicides where lysimeter studies were available, these studies resulted in additional leaching metabolites being identified. The experts in the meeting concluded that it would be essential to have a lysimeter study in order to remove any doubt on the metabolites that need further consideration with respect to potential groundwater contamination. In particular, this information would be needed to confirm the analytes that should be monitored for in current and any future groundwater monitoring programs.

Information on a groundwater monitoring program in France for acetochlor, t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) are outlined in the DAR and addendum. These analytes were not detected >0.05µg/L in any of the 3 sites (one in Aquitaine and two in Poitou Charentes) monitored with monthly samples being taken from the shallow aquifers over 2 years (not explicitly stated but ca. 72 samples taken during 2002 and 2003). The RMS concluded

and experts agreed that evidence for the extent of use of acetochlor in the areas monitored was not strong and further evidence of the extent of use would be necessary in order to use these monitoring results to support a regulatory assessment.

Information on a targeted groundwater monitoring program (experiment) at 9 sites in the Po valley in Northern Italy where t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) have been monitored in April 2005 to October 2006 are outlined in the addenda. Groundwater was sampled bi-monthly (694 samples taken) using piezometer samplers installed in fields cropped with maize with an experimentally specified application regime with applications made at ca. 1.8kg a.s. / ha which is about 90% of the maximum applied for intended EU use. Samples were taken from the shallow groundwater aquifers (saturated zone) present at the sites (depth of upper groundwater surface 0.06-6m). At the sites there is significant groundwater flow introducing the potential for dilution from untreated areas. 'Upgradient' samplers are present to quantify any inputs from elsewhere in the catchments, 'Downgradient' samplers include inputs from the areas of known acetochlor treatment. In interpreting the monitored results it is appropriate to note that s-sulfonic acid (13) is a metabolite of the active substance S-metolachlor which might be a source of this metabolite should this active substance be used elsewhere in the studied catchments. Detections of the metolachlor metabolite MeESA[41], the metolachlor source precursor of s-sulfonic acid (13), was an indication that some of the s-sulfonic acid (13) detected probably did originate from the use of metolachlor.

The monitored levels were:

t oxanilic metabolite (2): <0.05-11.1µg/L; nº detections ≥ 0.1 ug/L= 14; 90th percentile =0.1 ug/L;

t sulfinylacetic acid (3) <0.05-0.74µg/L; nº detections ≥ 0.1 ug/L= 14; 90th percentile =0.01 ug/L;

t sulfonic acid (7): <0.05-11.6 µg/L; nº detections ≥ 0.1 ug/L= 111; 90th percentile =0.25 ug/L;

s-sulfonic acid (13) <0.05-5.97 ug/L nº detections ≥ 0.1 ug/L= 175; 90th percentile =0.28 ug/L

The experts acknowledged that the study was well designed with the site descriptions and selections clearly explained and agreed the assessment by the RMS in the addenda. They wished to highlight that the available results correspond to the first 2 years after the known experimental applications were made, so it cannot be excluded that the results reflect more the background levels at the sites or the results of previous applications at the sites. The experts' conclusions regarding the study were:

The sites are considered to represent vulnerable situations with respect to mass losses from upper soil layers but do not provided a worst cases with respect to concentrations due to potential effect of dilution (effect of dilution due to the ground water flow is not well understood).

Probably, the sampling could be improved in order to get more information for the following seasons. Sampling of soil water above the water table would help to interpret the results.

The study is probably not yet long enough to guarantee that the peak of the mass of the metabolites resulting from the acetochlor applied to the experimental plots has reached the sampling depth.

The history of previous applications of acetochlor in the field would be useful. In this specific case also the information on the applications 'up gradient' would probably be necessary too.

[41] MeESA: 2-[(2-ethyl-6-methylphenyl)(2-methoxy-1-methylethyl))amino]-2-oxoethanesulfonic acid

Taking into consideration the variable hydrology of the sites, the sampling every two months may not be sufficient.

The experts conclusions regarding the studies use in the exposure assessment were:

The available results confirm the leaching potential of the acetochlor metabolites analysed. The meeting expects that the ground water concentrations may increase in the following seasons if the study is continued as planned.

Regulatory end points usually available (FOCUS modelling and lysimeter studies) provide an annual average concentration in water leaving the top soil. In this study, a large proportion of ground water may come from untreated areas. The information in this study does not allow an annual average to be calculated that is the normal endpoint that is used for regulatory decision making under 91/414. The levels measured include processes (potential dilution) that may occur in shallow aquifers that are not usually seen in the other study designs. In this context it is probably appropriate to take concentrations measured in individual samples to compare with regulatory triggers and not annual averages.

A GIS study report was provided and assessed in an addendum that had the aim of putting the monitored Italian groundwater study sites in their geoclimatic context to the rest of the EU in terms of groundwater vulnerability. The GIS study used soil data, climatic data (temperature and precipitation) and ground water maps and land use data for the EU. For ground water assessment not only the depth of the aquifer surface is relevant but also the hydrology in the aquifer. This was not assessed in this GIS exercise. The meeting discussed the conclusion, given in the study, that "the Po valley sites may represent 96 % of the ground water resources under maize growing areas in EU (15 MS) have similar or smaller bulk leaching risk". The experts were not completely convinced by the validity of this conclusion. However even if this conclusion were accepted, simply comparing bulk leaching risk does not imply that the risk of ground water contamination is covered by the Northern Italy monitoring studies up to this percentage. This is because the GIS assessment does not takes into account the hydrology and dilution potential of the receiving ground water which is an important driver for the concentrations measured at the monitored Po valley sites.

In conclusion both modelling and available field measurements confirm that the metabolites t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) will be present in groundwater as a consequence of the applied for intended use at concentrations above the non relevance assessment trigger of 0.75µg/L, so robust data to conclude on the relevance of these metabolites is essential. Field measurements indicate a level of 10µg/L will be exceeded for t-oxanilic acid (2) and t-sulfonic acid (7). It cannot be excluded that higher concentrations than seen in the Po valley field experiments will occur, as aquifer hydrology in other regions may result in less dilution potential than at the investigated sites. Even at the Po valley sites the investigations need to continue as it is likely that the treated fields will need more applications before metabolites in the soil column reach some kind of 'steady state' so at these sites higher concentrations might be expected. The experts concluded that it would be essential to have a lysimeter study in order to remove any doubt on the metabolites that need further consideration with respect to potential groundwater contamination. In particular, should acetochlor be included in annex 1, this information would be needed to confirm

the analytes that should be monitored for in current and any future groundwater monitoring programs / identify further compounds that may require non relevance assessments.

4.3. FATE AND BEHAVIOUR IN AIR

The vapour pressure of acetochlor ($2.2x10^{-5}$ Pa at 20°C) means that acetochlor would be classified under the national scheme of The Netherlands as very slightly volatile, indicating losses due to volatilisation might be expected to be minimal. Calculations using the method of Atkinson for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half life estimated at 2.3 hours indicating the proportion of applied acetochlor that did volatilise would be unlikely to be subject to long range atmospheric transport.

5. Ecotoxicology

Acetochlor was discussed at the PRAPeR experts`meeting for ecotoxicology (PRAPeR 18) in March 2007. A data requirement for submission of a comparison of the tested ecotox batches to the new 5-batch analysis. Based on the available information it was agreed by the experts that the batches used in the studies by Monsanto are sufficiently in compliance with the technical specification to be relied on in the ecotox risk assessment. It was not possible during the meeting to draw a conclusion on the batches from DOW and a data gap was identified. New information was submitted and assessed by the RMS in addendum to Vol. 4 and addendum IV B9 (both are not peer-reviewed). In the risk assessment it was not considered that acetochlor is a mixture of two acetochlor isomers (rotamers). From the available information it is not clear if the proportion of the isomers remains constant after releasing acetochlor in the environment.

5.1. RISK TO TERRESTRIAL VERTEBRATES

The risk to birds and mammals was calculated according to the Guidance Document on Birds and Mammals (SANCO/4145/2000). The representative uses are in maize pre-emergence or early post-emergence. The risk was calculated for a herbivorous and an insectivorous bird as well as for a herbivorous mammal.

The short term risk to birds can be considered as low since the Annex VI trigger value is not breached; but a high acute and long term risk to herbivorous and insectivorous birds was identified in the first tier risk assessment. A residue study was submitted to address the risk to herbivorous birds and information on the representativeness of the residue trials for the various geoclimatic conditions in Europe was submitted and included in addendum 2. The information provided was accepted by the meeting and the acute risk to birds was considered sufficiently addressed. However the long-term TER for herbivorous birds was still below the trigger of 5 taking into account only residue decline. Brant geeze (Branta bernicla) were not considered to be an appropriate focal species by the RMS and a refined risk assessment based on red-legged partridge (*Alectoris rufa*) was submitted and exposure was refined choosing PT and PD values based on information from published literature. However no

study summaries were provided and it was not possible during the expert meeting to conclude on the reliability of the suggested PT and PD values. Hence the data requirement to address the risk to herbivorous birds remains open.

A higher-tier risk assessment for insectivorous birds was included in addendum 1 and further supporting information was included in addendum 2. The crested lark (*Galerida cristata*) was agreed by the experts as a focal species. The suggested PT and PD refinements and the refinement based on measured residues were accepted by the experts. The resulting acute and long-term TERs were above the long-term trigger of 5. It was noted during the meeting that the study of Kostin (1983) cited among other studies in the context of composition of diet was not submitted. The meeting suggested a confirmatory data gap for submission of this study.

The acute and long-term TERs for herbivorous mammals were above the triggers of 10 and 5 in the first-tier risk assessment indicating a low risk from dietary exposure.

The risk to fish-eating birds and mammals was assessed as low in the first-tier risk assessment but the trigger of 5 was breached for earthworm-eating birds and mammals and a data requirement was identified in the DAR. A refined risk assessment based on measured BCF in earthworms was presented in addendum1. The experts agreed that it is likely that the high content of sphagnum peat (10% instead of 5%) did not influence the outcome of the bioconcentration study because of the low K_{oc} value of acetochlor. The experts suggested calculating the BCF on the basis of total radioactivity. The TER calculation with the BCF of 0.316 (based on total radioactivity) would result in TERs above the trigger. Therefore the data requirement was regarded as fulfilled.

An acute risk assessment for birds and mammals from uptake of contaminated drinking water was included in addendum 1 and discussed in the expert meeting. The TER was below the trigger of 10 for birds. It was discussed whether puddle formation or accumulation of drinking water in leaf axils is possible. The RMS considers the exposure of birds and mammals from contaminated drinking water as negligible. However the experts concluded that accumulation of water in leaf axils is likely to occur in maize and hence exposure of birds via drinking water cannot be excluded for post emergence applications and further risk refinement is required. The risk to mammals was considered as addressed by the experts.

A data requirement was set during the peer-review process for the applicant to address the risk to birds and mammals from plant and soil metabolites. The log P_{ow} for the four metabolites in soil is <3 and therefore no assessment of secondary poisoning was triggered. Endpoints from acute toxicity studies with rats were available for the major plant metabolites N-oxamic acid (68) and t-sulfinylacetic acid (3). No information on the toxicity to birds was available. In the risk assessment it was assumed that the metabolites have a similar toxicity to birds as the parent. The acute and long-term TERs for birds and mammals were above the triggers of 10 and 5. However some concerns were raised during the meeting with regard to the high proportion of not identified residues in the residue

trials (up to 39% of TRR). The unknown residues are composed of 35 different components. One of the compounds exceeded the trigger of 10%. The experts agreed to leave the data requirement open because of the high proportion of unknown residues.

5.2. RISK TO AQUATIC ORGANISMS

Acetochlor is very toxic to all groups of aquatic organisms. The lowest endpoints were observed for Algae and *Lemna gibba* and for *Daphnia magna* (chronic). Based on laboratory endpoints no full FOCUS step 4 (the PECsw were not accepted by the fate experts) scenario resulted in TERs above the Annex VI triggers even if a no spray buffer zone of 20 m and drift reduction nozzles are applied as risk mitigation measures. Three indoor microcosm, one outdoor microcosm, one mesocom with static exposure conditions and a mesocosm with a pulsed exposure regime were submitted. The refined risk assessment of the RMS in addendum 1 was based on a NOAEC of 0.2 µg acetochlor/L from the static mesocosm study. The proposed trigger of 2 was met only in one full scenario (D4) out of 8 FOCUS step4 scenarios (which were not accepted by the fate experts) applying a non-spray buffer zone of 20 m and drift reduction nozzles. It was proposed to use the higher endpoint of 2 µg acetochlor/L from the pulsed exposure mesocosm to address the risk in lotic systems. The whole aquatic risk assessment was discussed in the PRAPeR expert meeting. It was agreed to use the NOAEC of 0.2 µg acetochlor/L for lentic waterbodies and the NOAEC of 2 µg acetochlor/L for lotic waterbodies. The experts suggested using peak exposure values instead of time weighted average PECsw since the endpoints were based on nominal concentrations and not on measured concentrations. The experts agreed that a safety factor of 2-3 should be applied to the results of the mesocosms. A new risk assessment was prepared by the RMS in addendum 4 (not peer-reviewed) taking into account the recommendations of the expert meeting. The TERs were below the trigger of 2 for all FOCUS step 3 scenarios. In addendum 5 (not peer-reviewed) TERs were calculated for no-spray buffer zones of 25 and 50 m. No full scenario resulted in TERs >2 with a no-spray buffer zone of 25m. If a no-spray buffer zone of 50 m is applied two full scenarios (D4, D5) out of 8 resulted in a TER of ≥2 but no full FOCUS scenario would meet the trigger of 3. TERs of ≥3 were achieved only in the focus part scenarios D4 stream and D5 stream.

Overall it is concluded that the risk to aquatic organisms from exposure to acetochlor is high for the representative uses evaluated and further risk refinement and substantial risk mitigation measures would be required.

Acetochlor and the metabolite t-norchloro acetochlor (6) were found in concentrations above 10% in the sediment after 14 days in the water sediment study. All FOCUS step 3 scenarios resulted in TERs above the trigger of 10 indicating a low risk to sediment dwelling organisms from expected exposure to acetochlor. No study was conducted with a sediment dwelling organism and t-norchloro acetochlor. However the tests with fish and daphnids suggest a significantly lower toxicity compared to acetochlor. The PECsed are about two orders of magnitude lower than the PECsed for acetochlor. Therefore the risk from t-norchloro acetochlor to sediment dwelling organisms is considered to be low.

The toxicity of the metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and t-norchloro acetochlor (6) was tested with fish, daphnids, algae and *Lemna gibba.* Studies on algae and *Lemna gibba* with the groundwater metabolite s-sulfonic acid (13) was also submitted. Potential exposure to t-hydroxyl acetochlor (17) found only in laboratory soil column leaching study was considered as negligible based on the available fate and behaviour information. The TERs for all the other metabolites identified were above the trigger with FOCUS step1 PECsw values indicating a low risk to aquatic organisms.

A study on the bioconcentration potential in fish was made available as the log P_{ow} exceeds 3. The resulting BCF value of 20 is below the Annex VI trigger value of 100 for non biodegradable substances, indicating a low risk of bioconcentration in fish.

5.3. RISK TO BEES

Acute contact and oral toxicity studies with technical acetochlor and the formulations WF2061 and MON-69447 were available. The acute oral and contact toxicity to bees was also investigated for the metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13). The HQ values were calculated as <50 for technical and formulated acetochlor and its metabolites. The risk to bees is considered to be low for the representative uses evaluated.

5.4. RISK TO OTHER ARTHROPOD SPECIES

Standard laboratory studies with *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Poecilus cupreus*, and *Chrysoperla carnea* with the formulations GF-675 and MON 69451 are available. Extended laboratory studies were conducted with the formulations GF-675 and MON 69477. The formulation MON 69451 was considered not comparable to MON 69477. The new risk assessment for non-target arthropods in addendum 1 was based on endpoints of GF-675 and MON 69477 and the studies with MON 69451 were suggested to be used as additional information only.

Based on HQ values a high in-field risk was identified for both indicator species for the representative uses with the lead formulation GF-675. Extended laboratory studies indicate a low risk to *A. rhopalosiphi* but a LD_{50} of 1691 g a.s./ha was observed in the extended lab study with *T. pyri*. This dose rate is below the application rate of 2000 g a.s./ha for GF-675. Therefore it is likely that populations of predatory mites are adversely affected in the in-field area. However the trigger is met for the off-field area and considering the short half life of acetochlor on vegetation it was considered likely that recolonisation is possible. In addition no mortality was observed in the standard laboratory tests with the leaf dwelling species *C. carnea* at dose rates of 2000 g a.s./ha.

No adverse effects of >50% were observed in the extended laboratory test with the formulation MON 69447 and *A. rhopalosiphi* and *T. pyri* at dose rates of 2100 g a.s./ha.

The toxicity of GF-675 to soil dwelling species *P. cupreus* and *Aleochara bilineata* was tested. No mortality was observed in the study with *P. cupreus* and no adverse effects >50% were observed in the study with *Aleochara bilineata* at a rate of 2000 g a.s./ha.

No adverse effects of >50% were observed in an extended laboratory study with *A. bilineata* and the soil metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3) and t-sulfonic acid (7) at concentrations of 0.507, 0.637 and 0.349 mg/kg. The tested concentrations were similar to the maximum PECsoil calculated by the RMS. Further studies with s-sulfonic acid (13) and a mixture of t-sulfinylacetic acid (3) and t-sulfonic acid (7) were submitted and assessed in addendum 1. No effects of >50% were observed at concentrations of 0.263 mg s-sulfonic acid/kg and 0.678 mg t-sulfinylacetic acid/kg + 0.385 mg t-sulfonic acid/kg. The tested concentrations were similar to the calculated maximum PECsoil. Overall it is concluded that the risk from the soil metabolites to soil surface dwelling arthropods is low.

5.5. RISK TO EARTHWORMS

A study on the acute toxicity of acetochlor to earthworms is available. The result was corrected for the organic content in the soil as the log P_{ow} of acetochlor exceeds two. The acute TER value is above the Annex VI trigger value indicating a low risk to earthworms from acetochlor. No long term studies are considered necessary since acetochlor is suggested to be used only once a year and the DT_{90} field is below 100 days.

Studies on the acute and long term toxicity for the soil metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3) and t-sulfonic acid (7) are available. The result of the studies with t-oxanilic acid (2) and t-sulfinylacetic acid (3) were corrected for the organic content in the soil as their log P_{ow} value exceeds two. The acute risk from these metabolites was assessed as low. The long-term TERs calculated in addendum 2 were below the trigger of 5. However the endpoints (NOECs) were based on the highest tested concentrations. The applicant submitted new long-term studies with higher concentrations tested including a study with s-sulfonic acid (13). The new risk assessment in addendum 3 resulted in long-term TERs >5 for all soil metabolites. The experts in the meeting agreed to the new assessment. Overall it is concluded that the risk to earthworms is low for the representative uses evaluated.

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

No studies with acetochlor are considered necessary to address this Annex point as the DT_{90} field in the soil is below 100 days.

No significant effects on organic matter breakdown were observed in a litterbag study with the soil metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3) and t-sulfonic acid (7) at soil concentrations comparable to the maximum PECsoil values. Therefore the risk to soil non-target macro-organisms is considered to be low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The effects of the lead formulations GF-675 and MON 69947 were tested on soil microbial respiration and nitrogen transformation. Effects were less than 25 % at day 28 at 10 k g a.s/ha and 4.2 kg a.s./ha for GF-675 and MON 69947 respectively. The tested concentrations exceed the representative application rates and therefore the risk to soil non-target micro-organisms from acetochlor is considered to be low for the representative uses evaluated. No effects ≥ 25% were observed in a test with the soil metabolite s-sulfonic acid (13) at a concentration of up to 1.37 mg/kg soil (about 3 times the maximum PECsoil).

A mixture of the soil metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3) and t-sulfonic acid (7) did not lead to effects of ≥ 25% on soil respiration and soil nitrification at concentrations similar to the maximum PECsoil for each metabolite. Therefore the risk to soil micro-organisms was considered to be low for the representative uses evaluated.

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

Studies with technical acetochlor and different formulations on the influence on seedling emergence and plant vigour are available. The risk assessment presented in the DAR was based on SSD (species sensitivity distribution) on endpoints for 21 plant species. The HC5 for seedling emergence and plant vigour were determined as 11.9 and 43.5 g acetochlor/ha requiring a no spray buffer zone of 5m as a risk mitigation measure. The experts disagreed to combine the endpoints from studies with different formulations since different safeners were used which could have influenced the test results. Therefore it was proposed in the meeting that the risk assessment for technical acetochlor could be based on SSD because the number of data points was considered as sufficient. A deterministic approach was suggested for endpoints from studies with the formulation (lowest endpoint and a trigger value of 5). The RMS presented a new risk assessment in the not peer reviewed addendum IV from June 2006. The pre-emergent HC5 for acetochlor was determined as 11.45 g/ha which was similar to the HC5 based on the combined data set. The lowest endpoints for formulation studies were given as 64 (pre-emergence) g a.s./ha and 207 (post-emergence) g a.s./ha. The TER is >5 if a no spray buffer zone is applied.

Overall it is concluded that a high risk to non-target plants cannot be excluded and risk mitigation measures comparable to a no spray buffer zone (in-field) of 5 m is required.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

The EC50 for effects on respiration rate of activated sewage sludge was >1000 mg a.s./L. It is not expected that acetochlor would reach biological sewage treatment plants in amounts exceeding 1000 mg a.s./L if applied according to the GAP.

6. Residue definitions

Soil

Definitions for risk assessment: acetochlor, t-oxanilic acid (2)[42], t-sulfinylacetic acid (3)[43], t-sulfonic acid (7)[44] & s-sulfonic acid (13)[45]

Definitions for monitoring: acetochlor

Water

Ground water

Definitions for exposure assessment: acetochlor, t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) & s-sulfonic acid (13)

Definitions for monitoring: Cannot be finalised without a lysimeter study, at least acetochlor, t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) & s-sulfonic acid (13).

Surface water

Definitions for risk assessment: surface water: acetochlor, t-oxanilic acid (2), t-norchloro acetochlor (6)[46], [originating from soil t-sulfinylacetic acid, (3) t-sulfonic acid (7), s-sulfonic acid (13)]

sediment: acetochlor, t-norchloro acetochlor (6)

Definitions for monitoring: acetochlor, t-oxanilic acid (2), t-norchloro acetochlor (6), t-sulfinylacetic acid, (3) t-sulfonic acid (7) & s-sulfonic acid (13)]

Air

Definitions for risk assessment: acetochlor

Definitions for monitoring: acetochlor

Food of plant origin

Definitions for risk assessment:

Maize grain (pre-emergence uses only) and rotational crops (preliminary, only assessed for cereal grains, root and tuber crops, leafy crops): all compounds forming EMA (34)[47] and HEMA (33)[48] on hydrolysis and N-oxamic acid (68) [49],expressed as acetochlor

Maize fodder/ forage: open, insufficient data

Definitions for monitoring:

Maize grain and rotational crops (edible parts) as indicated above:

[42] Metabolite 2: [(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid
[43] Metabolite 3: ({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid
[44] Metabolite 7: 2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[45] Metabolite 13: 2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[46] Metabolite 6: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide
[47] EMA 34: 2-ethyl-6-methylaniline
[48] HEMA 33: 2-(1-hydroxyethyl)-6-methylaniline
[49] Metabolite 68: : [(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid

Option 1: Acetochlor by default.
Option 2: N-oxamic acid (68) expressed as acetochlor.
Option 3: the same as for risk assessment: all compounds forming EMA (34) and HEMA (33) on hydrolysis and N-oxamic acid (68), expressed as acetochlor.

None required for maize forage or other feed items, if relevant, as currently no MRLs are set for these items.

Food of animal origin
Definitions for risk assessment: not concluded on due to insufficient livestock exposure data
Definitions for monitoring: not concluded on

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

Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
acetochlor	Low to moderate persistence ($DT_{50\ lab}$ = 3.4-29 d, 20°C, pF2 (-10kPa)) ($DT_{50\ field}$ = 7-17 d)	The risk to earthworms and soil micro-organisms was assessed as low.
t-oxanilic acid (2)	Moderate to high persistence ($DT_{50\ lab}$ = 15-131 d, 20°C, pF2 (-10kPa))	The risk to earthworms, soil micro-organisms and no effects on organic matter breakdown at concentrations comparable to the maximum PECsoil.
t-sulfinylacetic acid (3)	Medium to high persistence ($DT_{50\ lab}$ = 75-112 d, 20°C, pF2 (-10kPa))	The risk to earthworms, soil micro-organisms and no effects on organic matter breakdown at concentrations comparable to the maximum PECsoil
t-sulfonic acid (7)	Moderate to high persistence ($DT_{50\ lab}$ = 33-148 d, 20°C, pF2 (-10kPa))	The risk to earthworms, soil micro-organisms and no effects on organic matter breakdown at concentrations comparable to the maximum PECsoil
s-sulfonic acid (13)	Moderate to medium persistence ($DT_{50\ lab}$ = 25-75 d, 20°C, pF2 (-10kPa))	The risk to earthworms and soil micro-organisms was assessed as low

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
acetochlor	High to medium mobility (K_{foc} = 74-422 mL/g)	No	Yes	Yes	Yes
t-oxanilic acid (2)	Very high to high mobility (K_{foc} = 17-83 mL/g)	Data gap identified, available modelling indicated >0.1µg/L at 8/8, >0.75µg/L at 6/8 and >10µg/L at 3/8 FOCUS scenarios, concentrations up to 15.4 µg/L	No	Yes	Harmful to aquatic organisms (algae E_bC50 = 44mg/L), low risk to aquatic organisms in surface water
t-sulfinylacetic acid (3)	Very high to high mobility (K_{foc} = 8-58 mL/g)	Data gap identified, available modelling indicated >0.1µg/L at 8/8, >0.75µg/L at 7/8 and >10µg/L at 6/8 FOCUS scenarios, concentrations up to 47.6µg/L	No, some growth inhibition in Chenopodium album and Echinochloa crusgalli but <50% activity of acetochlor	Yes	Harmful to aquatic organisms (algae E_bC50 = 57 mg/L), low risk to aquatic organisms in surface water

Compound (name and/or code)	**Mobility in soil**	**> 0.1 µg / L 1m depth for the representative uses** **(at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
t-sulfonic acid (7)	Very high to high mobility (K_{foc} = 21-68 mL/g)	Data gap identified, available modelling indicated >0.75µg/L at 8/8 and >10µg/L at 7/8 FOCUS scenarios, concentrations up to 43.2 µg/L	No, some growth inhibition on Echinochloa crusgalli but <50% activity of acetochlor	Yes	Toxic to aquatic organisms (algae E_bC50 = 8.1 mg/L), low risk to aquatic organisms in surface water
s-sulfonic acid (13).	Very high mobility (K_{doc} = 2-10 mL/g)	Data gap identified, available modelling indicated >0.75µg/L at 8/8 and >10µg/L at 4/8 FOCUS scenarios, concentrations up to 27.2 µg/L	No	Yes	Low toxicity to aquatic organisms and low risk to aquatic organisms in surface water

Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Acetochlor water and sediment)	See 5.2.
t-oxanilic acid (2) (water only)	The risk to aquatic organisms was assessed as low

Compound (name and/or code)	**Ecotoxicology**
t-norchloro acetochlor (6) (water and sediment)	The risk to aquatic organisms was assessed as low
t-sulfinylacetic acid (3) (water only; from soil)	The risk to aquatic organisms was assessed as low
t-sulfonic acid (7) (water only;from soil)	The risk to aquatic organisms was assessed as low
s-sulfonic acid (13) (water only;from soil)	The risk to aquatic organisms was assessed as low

Air

Compound (name and/or code)	**Toxicology**
acetochlor	Harmful by inhalation (acute rat LC_{50} 3.99 mg/L/4h)

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

- A revised specification is required where impurities 11, 12 and 13 are specified separately (relevant for all uses evaluated, data gap identified at the meeting of experts toxicology March 2007, proposed submission date unknown, refer to chapter 2)
- Spectra data for the relevant impurities ECA and EMA (relevant for all uses evaluated, data gap identified by EFSA July 2007, proposed submission date unknown, refer to chapter 1 and 2)
- Validated methods of analysis for the relevant impurities ECA and EMA in the formulations (relevant for all uses evaluated, data gap identified by EFSA July 2007, proposed submission date unknown, refer to chapter 1 and 2)
- Storage stability data where the relevant impurities ECA and EMA are analysed before and after storage (relevant for all uses evaluated, data gap identified by EFSA July 2007, proposed submission date unknown, refer to chapter 1 and 2)
- It should be clearly explained how the risk assessment has been addressed for the two rotational isomers of acetochlor. This may be addressed by evidence (actual data) that they are not stable and they rapidly reach an equilibrium (relevant for all uses evaluated, data gap identified at the meeting of experts March 2007, proposed submission date unknown, refer to chapter 1).
- Additional information is required in order to assess if the levels of impurities in the toxicological batches are representative of the technical specification (relevant for all uses evaluated, data gap identified at the meeting of experts March 2007, additional information/assessment provided in corrigendum addendum 2, addendum 3 and addendum 4 to Volume 4 after the experts' meeting).
- Convincing evidence that the groundwater metabolites (t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13)) do not pose a carcinogenic risk to humans (data gap identified at the meeting of experts in March 2007, proposed submission date unknown, refer to chapter 2.8)
- Further assessment of the genotoxic potential *in vivo* of the metabolite t-norchloro acetochlor (6) and of its carcinogenic risk to humans (data gap identified at the meeting of experts in March 2007, proposed submission date unknown, refer to chapter 2.8)
- Historical control data have to be provided for stomachal and femoral tumors (data gap confirmed at the meeting of experts in March 2007, submitted to the RMS in July 2007, refer to chapter 2.5)
- Historical data have to be provided for the renal findings in the long term mouse studies (data gap identified at the meeting of experts in March 2007, proposed submission date unknown, refer to chapter 2.5)
- Metabolism data in maize plants with soil application is required to support the pre-emergence use as the level of identification in maize forage and fodder in the supplied study is not acceptable. (relevant for all representative uses in maize with pre-emergence application, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.1)
- A maize metabolism study with foliar application is required to support the post-emergence uses. (relevant for all representative uses in maize with post-emergence application, data gap identified

in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.1)

- To support the use on sweet corn, metabolism data is required that is sufficient to conclude on the residue situation (metabolic picture, level) in the immature maize kernels. (relevant for all representative uses in sweet corn, data requirement identified in the commenting period on the DAR and confirmed by the meeting of experts PRAPeR 20 in March 2007, use on sweet corn withdrawn during peer review, submission date unknown , refer to point 3.1.1)
- Storage data on the metabolites forming HEMA (33) and EMA (34) consequent to the used analytical method in frozen plant matrices are required to cover the period that the residue trial samples were stored for. It is recommended that the common moiety analytical method used to generate the residue trials results should be used. (relevant for all representative uses in maize, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.1)
- A complete data set of residue trials in sweet corn (immature maize kernels). Data requirement relevant for all representative uses in sweet corn, data requirement identified in the commenting period on the DAR and confirmed by the meeting of experts PRAPeR 20 in March 2007; use on sweet corn withdrawn during peer review, submission date unknown , refer to point 3.1.1)
- Rotational crop data applicable for European conditions and taking into account the residue definition proposed (relevant for all representative uses, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.2)
- Applicant to provide climatic data for rotational crop studies and a justification why the rotational crop data generated in the USA can be considered appropriate for EU climatic conditions (must consider both N-EU and S-EU). (relevant for all representative uses, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.2)
- Applicant to provide all available data to correlate the EPA residues definition for rotational crops (where HMEA (32) was included) to allow to conclude an appropriate residue definition for rotational crops. (relevant for all representative uses, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.1.2)
- Applicant to address the consumer risk assessment for the two acetochlor isomers. (relevant for all representative uses, data gap identified in the meeting of experts PRAPeR 20 in March 2007, submission date unknown , refer to point 3.3)
- FOCUS groundwater modelling for the metabolites (t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13)) is required reflecting the discussions in this conclusion in chapter 4.2.2. (data gap identified at the meeting of experts of March 2007, proposed submission date unknown, refer to chapter 4.2.2). Note the information provided by the applicant in July 2007 and summarised by the RMS in an addendum does not address this data gap.
- A Lysimeter study representing the applied for intended use in maize is required to confirm the metabolites that may have the potential to leach to groundwater (data gap identified in the DAR and confirmed at the meeting of experts of March 2007, proposed submission date unknown, refer to chapter 4.1.3 and 4.2.2)

- Further refinement of the long- term risk to herbivorous birds (relevant for all representative uses evaluated; data requirement identified in the DAR; new risk assessment was submitted but studies which should support the suggested refinement were not submitted and not summarized in an addendum and it was not possible to conclude on the reliability of the suggested refinement steps of PT and PD; no submission date proposed by the applicant; refer to point 5.1.)
- The study of Kostin (1983) needs to be submitted. (relevant for all representative uses evaluated; the experts in the meeting of experts (PRAPeR 18 in March 2007) suggested a confirmatory data gap for submission of this study which was cited among other studies in the context of composition of diet of crested lark *(Galerida cristata*); no submission date proposed by the applicant; refer to point 5.1.)
- The risk to birds from uptake of contaminated drinking water (relevant for post emergence application in maize; data gap identified in the meeting of experts (PRAPeR 18 in March 2007); no submission date proposed; refer to point 5.1.)
- The risk to birds and mammals from uptake of plant metabolites. (relevant for all representative uses; data requirement identified during the peer-review process; data requirement left open in the meeting of experts because of a high proportion of not identified residues (up to 39 % of TRR) in the residue trials; no submission date proposed by the applicant; refer to point 5.1.)
- A high risk to aquatic organisms was identified using higher-tier endpoints and further refinement of the risk is required. (relevant for all representative uses; an open point for new TER calculations was identified in the meeting of experts (PRAPeR 18 in March 2007); the resulting TERs calculated according to the recommendations of the meeting indicate a high risk based on FOCUS step4 calculations; resulting data gap identified after the expert meeting; no submission date proposed by the applicant; refer to point 5.2.)
- Assessment whether the batches used in ecotox studies of DOW are in compliance with the new technical specification. (relevant for all representative uses; data gap identified in the meeting of experts (PRAPeR 18 in March 2007); new information was submitted and assessed in not peer reviewed addenda to Vol.4 and Vol.3 B.9.).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on maize, for full details of the GAP please refer to the attached end points.

The representative formulated products for the evaluation were “GF-675” and “Mon 69447” a 400 g/L capsule suspension (CS) and a 840 g/L emulsifiable concentrate (EC).

The residue definition for monitoring in plants has not been concluded on. Acetochlor residues in maize can be determined with a multi-method (The German S19 method has been validated). For N-

oxamic acid metabolite 68[50] a LC-MS/MS method is available this metabolite can not be analysed by a multi method. For products of animal origin there are no methods available. At this stage it can not be concluded if this is a data gap or not as the assessment for residues is not complete.

For soil a LC-MS/MS method is available that analyses for aetochlor, t-oxanilic acid (2) [51], t-sulfonic acid (7) [52], t-sulfinylacetic acid (3) [53] , s-sulfonic acid (13)[54] and t-norchloroacetochlor (6) [55]. For surface/ground/drinking water LC-MS/MS methods are available for acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), s-sulfonic acid (13) t-norchloroacetochlor (6) and t-sulfinylacetic acid (3). In addition to this there is also a LC-MS/MS method for t-norchloroacetochlor (6) in drinking water. Air can be analysed for acetochlor by LC-MS/MS.

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. However, it should be noted that there are no spectra, analytical methods or storage stability data for the relevant impurities in the technical material.

Acetochlor has a moderate acute toxicity. The proposed classification is **Xn, R20/22 Harmful by inhalation and if swallowed; Xi, R37/38 Irritating to respiratory system and skin; R43 May cause sensitisation by skin contact**. In short term studies the dog was the most sensitive species showing decreased body weight gain and histopathological findings in kidneys and testes. Many in vitro genotoxicity studies show positive results but the in vivo tests do not indicate clearly a mutagenic potential. In long term studies different types of tumours were observed with increased incidences and the classification **Carc. cat.3, R40 Limited evidence of a carcinogenic effect** was proposed. No specific effect on the reproductive parameters was found in multigeneration studies with rats, and no evidence of teratogenicity was observed in rats or rabbits.
The groundwater metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) were considered relevant taking into account the limited information available and the carcinogenic potential of the parent compound. The relative toxicity of the plant metabolite t-norchloro acetochlor (6) in comparison with acetochlor could not be concluded.
The **acceptable daily intake** (**ADI**) is 0.0036 mg/kg bw/day using the LOAEL from the 78-week mouse study with a safety factor of 300. The **acceptable operator exposure level** (**AOEL**) is 0.02 mg/kg bw/day based on the 1-year dog study, with the use of a safety factor of 100. The **acute reference dose** (**ARfD**) is 1.5 mg/kg bw, derived from the acute rat neurotoxicity study with the application of a safety factor of 100. Two representative formulations were considered in the exposure assessment. For GF-675, the operator exposure is below the AOEL with the use of gloves.

[50] Metabolite 68: [(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid
[51]: Metabolite 2: [(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid
[52] Metabolite 7: 2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[53] Metabolite 3: ({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid
[54] Metabolite 13: 2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid
[55] Metabolite 6: *N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide

For MON 69447, the estimates with the German and UK models are above the AOEL but a bio-monitoring study measured exposures below the AOEL with the use of closed cabins and gloves.

Metabolism of acetochlor was studied in maize plants upon a pre-emergence treatment. Total residues in the mature grain were low and did not permit an extensive identification of metabolites. The rate of identification in other maize plant parts was limited and the need for further data was identified, in particular with regard to the nature of the residue in plant parts fed to livestock and in immature maize kernels (sweet corn – use withdrawn during the peer review). Also early-post emergence uses are currently not sufficiently addressed by metabolism data.
Based on the available data a number of metabolites were identified and some of them are considered toxicological relevant (potential carcinogenicity). Therefore the residue definition was extensively discussed and it was concluded that for risk assessment all compounds forming EMA (34)[56] and HEMA (33)[57] on hydrolysis as well as hydroxy-oxamic acid (68), all expressed as acetochlor should be considered for maize grain and preliminary also for rotational crops (the latter restricted to cereal grains, root and tuber crops and leafy crops). The need for further rotational crop data was identified.
For monitoring purposes three options for a residue definition were proposed, and risk management consideration is required to decide on the final monitoring definition. Residue trials confirmed that residues in maize kernels, when analysed for the risk assessment residue definition, are below the limit of quantification (LOQ) of 0.05 mg/kg. However, currently insufficient data in terms of quality and magnitude of residues are available to assess the dietary burden of livestock. Consumer exposure estimates therefore only include the exposure from maize grain but don't consider potential exposure from food of animal origin and certain rotational crops. Therefore the consumer risk assessment should be considered as not finalised. It is also noted that there is potential consumer exposure to acotochlor metabolites from ground water used as drinking water, in particular to t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13). A risk assessment showed that the ADI of acetochlor, when applied to the metabolites, might be exceeded only due to the consumption of water containing these metabolites at the level estimated in FOCUS scenarios.

The information available on the fate and behaviour in the environment is sufficient to carry out an appropriate environmental exposure assessment at the EU level with the notable exceptions that further data are necessary to address the groundwater exposure potential of metabolites. For the applied for intended uses, the potential for groundwater exposure by just the active substance acetochlor above the parametric drinking water limit of 0.1 µg/L, is low. Further data (a lysimeter study) are necessary to ensure all pertinent metabolites that may leach to groundwater are identified. The available information (FOCUS groundwater modelling and field experiments carried out in Italy) indicate that the metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) have the potential to contaminate groundwater at concentrations >0.75 µg/L. Contamination of groundwater >10 µg/L is also a potential concern for these 4 metabolites with field experiment evidence confirming this for t-oxanilic acid (2), and t-sulfonic acid (7). With the

[56] Chemophore 34: 2-ethyl-6-methyl aniline
[57] Chemophore 33: 2(1-hydroxyethyl)-6-methylaniline

toxicological data available to the peer review these 4 metabolites with the potential to be present in groundwater currently (September 2007) have to be considered as relevant.

The short-term risk to birds was demonstrated to be low in the first-tier risk assessment. The refinement of the acute risk to herbivorous birds and the acute and long-term risk to insectivorous birds was accepted in the expert meeting. However it was not possible to conclude on the reliability of the suggested quantitative refinement of PD and PT values to refine the long-term risk to herbivorous birds since no summaries of the supporting studies were made available. A high acute risk to birds from uptake of contaminated drinking water cannot be excluded for the post emergence applications. Some uncertainty remains with regard to exposure to plant metabolites because of the high proportion of not identified residues in the residue trials (up to 39% of TRR) and one of the unknown compounds exceeded the threshold of 10% of TRR.

Acetochlor is very toxic to all groups of aquatic organisms and a high risk to aquatic organisms was indicated based on FOCUS step3 PECsw. Based on agreed mesocosm endpoints for lentic and lotic waterbodies no FOCUS step 3 scenario exceeded the trigger of 2. TERs ≥2 were observed in two full FOCUS step4 scenarios (D4, D5) out of 8 scenarios if a no-spray buffer zone of 50m is applied. No full FOCUS step 4 scenario resulted in TERs ≥3 (the upper range of the suggested assessment factors) even with a no-spray buffer zone of 50 metres.

Adverse effects are likely to occur on predatory mites in the in-field area. However based on the available information it was concluded by the experts that relonisation within one year should be possible.

A high risk to non-target terrestrial plants was identified and risk mitigation measures such as a 5m in-field no spray buffer zone are required.

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

- Appropriate PPE is needed in order to have the operator exposure below the AOEL (refer to 2.12).
- A high risk was identified for aquatic organisms. Risk mitigation such as no-spray buffer zones of >50 m were not sufficient to achieve TERs above the agreed trigger range (2-3) in situations represented by all the pertinent FOCUS scenarios. Only in geoclimatic conditions represented by the 2 FOCUS scenarios D4 &D5 and the lower agreed trigger range of 2 does the assessment indicate that a no spray buffer zone of 50 metres would be sufficient mitigation.
- An in-field no spray buffer zone of 5m is required to protect non target plants in the off-field area.
- If feasible in practice, rotational crops could be restricted to cereals (grains), root/ tuber crops and leafy crops until the residue definition for rotational crops has been refined.
- A restriction to fed cereal forage, fodder or straw from both primary and rotated cereal crops to livestock might be considered.

Critical areas of concern

- The technical material specification is currently not supported.
- The consumer risk assessment is not finalised.
- A high risk to aquatic organisms.
- A high potential for groundwater contamination >0.1µg/L over significant areas of the EU by the metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) that have been concluded as relevant metabolites following the 'Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC'[58] and using the available toxicological data base.
- A lysimeter study is considered essential to exclude the presence of additional metabolites in groundwater. This study was not available.
- Potential for human exposure when surface water is used for drinking water abstraction to t-norchloro acetochlor (6) t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) that have been concluded as relevant metabolites following the 'Guidance document on the assessment of the relevance of metabolites in groundwater' and using the available toxicological data base.

[58] Sanco/221/2000-rev.10-final, 25 February 2003.

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

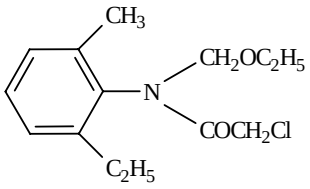
(Abbreviations used in this list are explained in appendix 2)

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

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

Rapporteur Member State	Spain (ESPAÑA)
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2-chloro-N-ethoxymethyl-6'-ethylacet-*o*-toluidide
Chemical name (CA) ‡	2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide
CIPAC No ‡	496
CAS No ‡	34256-82-1
EC No (EINECS or ELINCS) ‡	251-899-3 (EINECS)
FAO Specification (including year of publication) ‡	No FAO specification
Minimum purity of the active substance as manufactured ‡	940 g/Kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	(ECA) Ethyl chloroacetate (6 g/kg) EMA 2-ethyl-6-methylaniline (3 g/kg)
Molecular formula ‡	$C_{14}H_{20}ClNO_2$
Molecular mass ‡	269.77
Structural formula ‡	

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

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	10.6°C (99.9 %)
Boiling point (state purity) ‡	172°C (at 0. 665 KPa) (99.9 %)
Temperature of decomposition (state purity)	237-239ºC (at 98.78 KPa) (99.9 %)
Appearance (state purity) ‡	Pure material: Pale yellow, free-flowing liquid (99.9 %) Technical material: Pale yellow, free-flowing liquid (95.0 %)
Vapour pressure (state temperature, state purity) ‡	2.2 x 10^{-5} Pa (20°C) (99.9 %) 4.6 x 10^{-5} Pa (25°C) (99.9 %)
Henry's law constant ‡	2.1 x 10^{-3} $Pa.m^3.mol^{-1}$
Solubility in water (state temperature, state purity and pH) ‡	pH 6.89: 282 mg/L - at 20°C in distilled water (99.9%) Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range
Solubility in organic solvents ‡ (state temperature, state purity)	n-heptane >5000 p-xylene >5000 1,2-dichloroethane >5000 methanol >5000 acetone >5000 ethyl acetate >5000 all values in g/L at 20 °C (95%)
Surface tension ‡ (state concentration and temperature, state purity)	46.3 mN/m at 20°C (90% of saturation concentration) (99.9%)
Partition co-efficient ‡ (state temperature, pH and purity)	pH 6.5: log $P_{O/W}$: 4.14 at 20 °C (99.9%) Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range
Dissociation constant (state purity) ‡	No dissociation constant (Ka) could be determined experimentally. Calculated Ka = 1.02 for the basic group (AR)NHCOR

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

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	(99.9%) λ_{max}[nm] ε[$L*mol^{-1}*cm^{-1}$] neutral medium: MeOH 273 448 265 538 acid medium: 0.1 M aqueous HCl / methanol (1/9 v/v) 273 466 265 552 acid medium: 0.1 M aqueous HCl / methanol (1/9 v/v) 273 451 265 531
Flammability ‡ (state purity)	Not applicable, active substance is not a solid or a gas. Flash point: 160ºC (95.0%)
Explosive properties ‡ (state purity)	Not explosive when exposed to thermal or mechanical stress (95%)
Oxidising properties ‡ (state purity)	Not oxidising (theoretical assessment)

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

Summary of representative uses evaluated *

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
Maize *Zea mays* L.	France	Trophee (GF-675)	F	Annual weeds (grasses & dicots)	CS	400	Mechanical sprayer, broadcast	Pre-sowing to 3 leaves. Apr-Jun	1	--	0.3-2.0	100-400	1.2-2.0	N/S	*Pre-sowing with soil incorporation for some specific uses only: seed production, corn sown under plastic or very dry soil situations *10 % of farmers spray at about 100 L/ha, 90 % at higher spray volumes [1]
Maize *Zea mays* L.	Spain	Trophy (GF-675)	F	Annual weeds (grasses & dicots)	CS	400	Mechanical sprayer, broadcast	Post-sowing to 3 leaves. Apr-May	1	--	0.3-1.33	150-400	1.2-2.0	N/S	[1]
Maize *Zea mays* L.	Italy	Trophy 40CS (GF-67	F	Annual weeds (grasses &	CS	400	Mechanical sprayer,	Pre-sowing to 3 leaves.	1	--	0.3-1.33	150-400	1.2-2.0	N/S	[1]

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

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			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)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)	(m)	
		5)		dicots)			broadcast	Mar-Jun							
Maize *Zea mays* L.	France	Harness Microtech (MON 69425)	F	Annual weeds, grasses and dicots	CS	400	Mechanical sprayer, broadcast	Pre-plant to 3 leaves. Apr-Jun	1	--	0.4-1.0	200-400	1.6-2.0	N/A	* Same product as Trophee * Pre-sowing with soil incorporation for some specific uses only: seed production, corn sown under plastic or very dry soil situations *10 % of farmers spray at about 100 L/ha, 90 % at higher spray volumes [1]
Maize *Zea mays* L.	France	MON 69447	F	Annual weeds, grasses and dicots	EC	840	Mechanical sprayer, broadcast	Pre-plant to early post-emerg. of the crop, up to 6	1	--	Up to 2.016	100-400	Up to 2.016	N/A	Currently in registration process [1]

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
								leaves. Apr-Jun							
Sweet corn *Zea mays* L.	France	MON 69447	F	Annual weeds, grasses and dicots	EC	840	Mechanical sprayer, broadcast	Pre-emerg. of the crop. Apr-Jun	1	--	Up to 2.016	100-400	Up to 2.016	90 days	Currently in registration process [1]
Maize *Zea mays* L.	Spain	Harness Plus (MON 69447)	F	Annual weeds, grasses and dicots	EC	840	Mechanical sprayer, broadcast	Pre-plant to early post-emerg. of the crop; weeds before 2 leaves. Apr-May	1	--	0.21-1.008	200-400	0.84-2.016	N/A	Possible application in preplant followed by shallow incorporation. Rate adaptation according to soil texture and mixture with other herbicides (atrazine or mixture of alachlor/atrazine) [1]
Maize *Zea mays*	Italy	Bolero (MON	F	Annual weeds,	EC	840	Mechanical	Pre-plant to 4 leaves	1	--	0.252 -	200-400	1.008-2.016	NA	Pre-plant application

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)		
L.		69447)		grasses and dicots			sprayer, broadcast	of the crop. Mar-Jun			1.008				recommended with 2-5 cm incorporation Rate adaptation according to time of application, weed infestation, irrigation and mixture with other herbicides [1]

∗For uses where the column "Remarks" is marked in grey further consideration is necessary.
Uses should be crossed out when the notifier no longer supports this use(s).

(a)For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b)Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c)*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d)*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

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

(f)All abbreviations used must be explained

(g)Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h)Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

(i)g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j)Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k)Indicate the minimum and maximum number of application possible under practical conditions of use

(l)The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m)PHI - minimum pre-harvest interval

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

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			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)	g as/hL min – max (l)	water L/ha min – max	g as/ha min – max (l)	(m)	
[1] Section residues: Consumer risk assessment not finalised															

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

Appendix 1.2: Methods of Analysis

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

Technical as (analytical technique)	GC-FID
Impurities in technical as (analytical technique)	High boiling point impurities: GC/FID. Low boiling point impurities: GC-FID and GC/MS for confirmation. Additive: GC-RI.
Plant protection product (analytical technique)	GC-FID.

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not concluded on.
Food of animal origin		Open not concluded on.
Soil		Acetochlor
Water	surface	Acetochlor and t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) *s*-sulfonic acid metabolite (13) and t-norchloroacetochlor (6)
	drinking/ground	Provisional: Acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) and s-sulfonic acid (13) Data gap for lysimeter study.
Air		Acetochlor

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Maize grain: Acetochlor Multiresidues Method DFG S19 GC/MS (LOQ 0.01 mg/kg) LC/MS/MS (LOQ 0.01 mg/kg) For the oxamic acid metabolite (68) in forage:. HPLC/MS-MS (ESI ionization mode) (LOQ: 0.01 mg/Kg.)

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

Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Analytical methods may be required depending on the conclusions of the residues section of the DAR
Soil (analytical technique and LOQ)	Acetochlor, LC/MS/MS (LOQ 0.03 mg/kg).
Water (analytical technique and LOQ)	Provisional: Ground water: For Acetochlor oxanilic acid (2), acetochlor sulfonic acid (7) and acetochlor sulfinylacetic acid (3): Multiresidues Method ES-ME-0552-01 LC/MS/MS (LOQ 0.05 µg/l for compounds 7 and 3 and 0.1 µg/l for compound 2) Surface water: For Acetochlor oxanilic acid (2), acetochlor sulfonic acid (7) and acetochlor sulfinylacetic acid (3): Multiresidues Method ES-ME-0552-01 LC/MS/MS (LOQ 0.05 µg/l for compounds 7 and 3 and 0.1 µg/l for compound 2) For Acetochlor and t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) s-sulfonic acid metabolite (13) and t-norchloroacetochlor (6): LC/MS/MS (LOQ 0.05 µg/l for each compound) Drinking water: For Acetochlor and t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) and t-norchloroacetochlor (6): LC/MS/MS (LOQ 0.05 µg/l for each compound)
Air (analytical technique and LOQ)	For acetochlor: LC/MS/MS (LOQ: 0.6 µg/m^3)
Body fluids and tissues (analytical technique and LOQ)	Acetochlor is not classified as toxic or highly toxic; therefore, analytical methods for the determination of residues in body fluids and tissue were not developed.

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

	RMS/peer review proposal
Acetochlor	None

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

Appendix 1.3: Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Rapid and almost complete, based on urine and bile excretion (>80%) in rat at 10 mg/kg bw/day, repeated dose.
Distribution ‡	Widely distributed.
Potential for accumulation ‡	No evidence
Rate and extent of excretion ‡	Relatively rapid (48 h: 85.85-86.47% in male-females). In urine, 61.75-71.05% and in faeces, 24.-15.42% in male-female rats at 10 mg/kg bw/day, repeated dose.
Metabolism in animals ‡	Acetochlor undergoes conjugation and mixed function oxygenation. The main metabolite identified in rat and monkey was the ***tert*-mercatpturic acid** with 25-27% of the radioactivity excreted in monkey urine
Toxicologically relevant compounds ‡ (animals and plants)	
Toxicologically relevant compounds ‡ (environment)	

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1929mg/kg bw	**R22**
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	3.99mg/L/4h Exposure nose-only. Test material: aerosol	**R20**
Skin irritation ‡	Irritant	**R38**
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitising; Modified Buehler test and GPMT of Magnusson and Kligman	**R 43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Kidney and testes, histopathological alterations (dog)	
Relevant oral NOAEL ‡	2 mg/kg bw/day (1-year dog)	**R48 /22?**
Relevant dermal NOAEL ‡	400 mg/kg bw/d (21-day rabbit)	

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

Relevant inhalation NOAEL ‡	No data - not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

…… …..	Positive *in vitro*, *in vivo* UDS positive at toxic dose levels, negative in micronucleus and dominant lethal studies.	

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

Target/critical effect ‡	Anaemia, kidney and liver (mice and rats)	
Relevant NOAEL ‡	LOAEL: 1.1 mg/kg bw/day (2-year mouse) NOAEL: 9.4 mg/kg bw/day (2-year rat)	
Carcinogenicity ‡	Rat: adenomas in nasal epithelium at 47.5 mg/kg bw/d, stomachal and femoral tumours. Mouse: lung adenomas and carcinomas, uterine histiocytic sarcoma.	**Carc .Cat. 3 R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: decreased bodyweight and increased liver weight. Offspring: reduced litter and pup weight, delayed vaginal opening. Reproduction: decreased number of implantations, decreased number of live pups.	
Relevant parental NOAEL ‡	20 mg/kg bw/day	
Relevant reproductive NOAEL ‡	61 mg/kg bw/day	
Relevant offspring NOAEL ‡	20 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Decreased bodyweight gain (rats and rabbits). Decreased food consumption, increased water consumption, delayed ossification at	

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

	maternal toxic dose (rats).	
Relevant developmental, maternal NOAEL ‡	50 mg/kg bw/day (rabbit) 200 mg/kg bw/day (rat)	
Relevant developmental, offspring NOAEL ‡	190 mg/kg bw/day (rabbit) 150 mg/kg bw/day (rat)9	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Acute NOAEL = 150mg/kg bw (rat)	
Repeated neurotoxicity ‡	90-day NOAEL=47.6mg/kg bw/day (rat)	
Delayed neurotoxicity ‡	No data- not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Nasal Tumours: the mechanism involves metabolism to a quinone-imine, the formation of protein adducts, cell deaths and compensatory hyperplasia leading to the adenomas. Comparison between rats and other species of the metabolic cascade leading to the quinone-imine indicate that the production of these chemicals was greater in rats. Thyroid Tumours: it appears that acetochlor induces an increased hepatic enzymatic conjugation leading to a compensatory increase in TSH levels.
Studies performed on metabolites or impurities ‡	
Toxicity of metabolites	
metabolite 68, , N-(6-ethyl-3 hydroxy-2-methylphenyl) oxamic acid, PJ2. (maize metabolite)	Acute oral LD50>2000 mg/kg bw (rat)
	No genotoxic potential (in vitro, in vivo)
metabolite 2, t-oxanilic acid, oxamic acid (surface water, ground water and soil metabolite)	Acute oral LD50>2000mg/kg bw. (rat)
	Short term toxicity, 90 days dietary toxicity study in rats. NOAEL= 230mg/kg/day (m)
	Reproductive toxicity, Developmental study in rats. NOAEL maternal toxicity = 500 mg/kg bw/day NOAEL for developmental = 1000 mg/kg bw/day

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

	No genotoxic potential (in vitro, in vivo)
metabolite 3, thioacetic acid sulphoxide, t-sulfinylacetic acid. (ground water and soil metabolite)	Acute oral LD50 > 2000mg/kg (rat)
	Short term toxicity: NOAEL=265mg/kg/day (m) 90 d rat
	No genotoxic potential (in vitro)
metabolite 7, tert-sulfonic acid, t-sulfonic acid (ground water and soil metabolite)	Acute oral LD50>2000mg/kg (rat)
	Short term toxicity: NOAEL= 225mg/kg/day (m)90 d rat.
	No genotoxic potential (in vitro, in vivo)
metabolite 6. t-norchloro acetochlor, (surface water metabolite)	Genotoxicity: Positive results in vitro. Inconclusive in vivo. Further data is required.
Metabolite 13, s-sulfonic acid (ground water and soil metabolite)	Acute oral LD50 > 2000 mg/Kg. (rat)
	No genotoxic potential (in vitro)
Toxicity of impurities	
ECA (3)	Classified by ECB as T; R23/24/25 N; R50
096 (20), SB097 (11) and EP097(13)	Given its close structural similarity to acetochlor, it is presumably very similar from a toxicological perspective,
EMA (15)	Intermediate in the rat metabolism and play a role in the nasal tumour formation.

Medical data ‡ (Annex IIA, point 5.9)

No evidence of adverse effects to workers of manufacturing plants, agricultural worker and consumer.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.0036 mg/kg bw/day	78 weeks in mice	300
AOEL ‡	0.02 mg/kg bw/day	1 year dog	100

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

ARfD ‡	1.50 mg/kg bw/day	Acute Neurotoxicity Study in rats	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation (e.g. name 50 % EC)	GF-675 (400 g/L CS): Concentrate product = 0.5% Diluted product = 4% Based on *in vivo* rat data corrected for *in vitro* rat and human data MON 69447 (840 g/L EC): Concentrate product = 3.3% Diluted product = 50% Based on an *in vitro* human skin penetration experiment

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

Exposure scenarios (Annex IIIA, point 7.2)

Operator	
GF-675 Tractor-mounted/trailed boom sprayer: hydraulic nozzles	German Model (Gloves in M/L and A and sturdy and coverall in application) = 20% AOEL. UK POEM (gloves) • Volume 400L/ha = 100% AOEL • Volume 100L/ha = 500% AOEL Acceptable for proposed uses
MON 69447 Tractor-mounted/trailed boom sprayer: hydraulic nozzles	Tier I and II: German Model (Gloves in M/L and A, and hood and visor and coverall and sturdy footwear) = 100% AOEL. UK-POEM (gloves) • Volume 400 L/ha = 1400% AOEL • Volume 100 L/ha = 5550% AEOEL Tier III: Bio-monitoring study (gloves in M/L and coverall in A), 20 ha • open cabin = 46% AOEL • closed cabin = 20 % AOEL Bio-monitoring study (gloves in M/L and coverall in A), 50 ha • closed cabin = 52% AOEL Acceptable for proposed uses
Workers	Exposure unlikely for pre-emergence and early post emergence.
Bystanders	
GF-675	16% AOEL (Lloyd and Bell, 1983). Acceptable for proposed uses
MON 69447	93% AOEL (Lloyd and Bell, 1983). Acceptable for proposed uses

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

	RMS/peer review proposal
Acetochlor	Xn, R20/22; Xi, R37/38; R43; Carc. Cat. 3, R40 R48/22?

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

Appendix 1.4: Residues

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

Plant groups covered	Cereals (maize) pre-emergence
Rotational crops	Radish, wheat, lettuce, turnip, millet, soybean, mustard
Plant residue definition for monitoring	Applicable to cereals and, if necessary, to rotational crops: Option 1: acetochlor (default) Option 2: N-oxamic acid (68) expressed as acetochlor Option 3: all compounds forming EMA (34)[59] and HEMA (33)[60] on hydrolysis plus N-oxamic acid (68)[61], expressed as acetochlor
Plant residue definition for risk assessment	Applicable to cereal grains and limitedly applicable to rotational crops: all compounds forming EMA (34) and HEMA (33) on hydrolysis plus N-oxamic acid (68), expressed as acetochlor Unable to conclude on cereal plant parts other than grains (data gap) **Note:** With regard to rotational crops the definition is provisional, pending confirmation by further data for pulses/ oilseeds and cereal plant parts other than grains (data gap). If feasible, a restriction in rotation to cereal grains, root/tuber crops, and leafy crops could be considered.
Conversion factor (monitoring to risk assessment)	open

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

Animals covered	goat, cow
Time needed to reach a plateau concentration in milk and eggs	n/a
Animal residue definition for monitoring	not concluded on
Animal residue definition for risk assessment	not concluded on

[59] 2-ethyl-6-methylaninline
[60] 2-(1-hydroxyehtyl)-6-methylaniline
[61] N-(6-ethyl-3-hydroxy-2-methylphenyl) oxamic acid

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

Conversion factor (monitoring to risk assessment)	open
Metabolism in rat and ruminant similar (yes/no)	open
Fat soluble residue: (yes/no)	yes

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

Radish, wheat, turnip, mustard, millet, soybean. The TRR in the crops was higher in the laboratory study than in the field study. USA field trials submitted for wheat, oat, soybean, sorghum, sugar beets and potatoes. Validation pending missing information on climatic conditions regarding EU maize growing zones.

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

Amount of N-oxamic acid (68) remained constant in fortified maize samples (frozen) for at least two years. New study required to address stability of EMA (34) and HEMA (33) forming metabolites.

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

Not necessary. No accumulation of compounds with HEMA, EMA or metabolite 68 structural moieties expected in milk or edible animal tissues of lactating ruminants.

	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)	open	Not expected	open
Potential for accumulation (yes/no):	n/a	n/a	n/a
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	n/a	n/a	n/a
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	n/a	n/a	n/a
Liver	n/a	n/a	n/a

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

Kidney	n/a	n/a	n/a
Fat	n/a	n/a	n/a
Milk	n/a		
Eggs		n/a	

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

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL ** estimated from trials according to the representative use	HR ** (c)	STMR ** (b)
Maize	Mediterranean	**HEMA (33)** maize grain: 17 x < 0.02 mg/kg maize forage/fodder: open **EMA (34)** maize grain: 17 x < 0.02 mg/kg maize forage/fodder: open **N-oxamic acid (68)** maize grain: 4 x <0.003 mg/kg whole plant ***: 3x<0.01, 1x 0.03 mg/kg	expressed as acetochlor; validity subject to confirmation of storage stability for EMA (34) and HEMA (33) and to clarification of storage period and conditions for N-oxamic acid (68)	0.05*	< 0.05	< 0.05
Maize	Northern	**HEMA (33)** maize grain: 31 x < 0.02 mg/kg maize forage/fodder: open **EMA (34)** maize grain: 31 x < 0.02 mg/kg maize forage/fodder: open	expressed as acetochlor; validity subject to confirmation of storage stability for EMA (34) and HEMA (33) and to clarification of storage period and conditions for N-oxamic	0.05*	< 0.05	< 0.05

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

		N-oxamic acid (68) maize grain: 4 x <0.003 mg/kg whole plant ***: 2x<0.01, 2x 0.02 mg/kg	acid (68)			

(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

* LOQ
** maize grain
*** Clarification requested on plant parts analysed for residues of N-oxamic acid (68)

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

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

ADI	0.0036 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	0.58 **Note:** Assessment not peer reviewed
TMDI (% ADI) according to national (UK) diets	1.65, 1.89, 4.89, 5.01 adults, children, toddler and infant, respectively **Note:** Assessment not peer reviewed
TMDI (% ADI) according to national (Germany) diets	0.30% school girl **Note:** Assessment not peer reviewed
TMDI (% ADI) according to national (Spain) diets	0.12%, 0.43% adult and children respectively **Note:** Assessment not peer reviewed
IEDI (WHO European Diet) (% ADI)	not applicable
NEDI (specify diet) (% ADI)	not applicable
Factors included in IEDI and NEDI	not applicable
ARfD	1.50 mg/kg bw/day

Note: Also no peer reviewed assessment available on the consumer exposure to residues from drinking water. For further information refer to paragraph 3.3 of the EFSA conclusion.

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

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

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

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

Maize (grain)	based on Option 3 of the proposed monitoring residue definition 0.05* mg/kg

* LOQ

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

Appendix 1.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	0.29-3.1% after 90 d, [^{14}C-phenyl]-acetochlor (n= 2) 11-14.9 % after 84 d, [^{14}C-carbonyl]-acetochlor(n= 3) Sterile conditions: 1.86 % after 90 d [^{14}C-phenyl]-acetochlor (n= 1) 0.38 % after 120 d [^{14}C-phenyl]-acetochlor (n= 1)
Non-extractable residues after 100 days ‡	14.6- 31.3 % after 90 d, [^{14}C-phenyl]-acetochlor (n= 2) 16.7-40.6 % after 84 d, [^{14}C-carbonyl]-acetochlor (n= 3) Sterile conditions: 26.25 % after 90 d [^{14}C-phenyl]-acetochlor (n= 1) 8.55 % after 120 d [^{14}C-phenyl]-acetochlor (n= 1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	t-oxanilic acid (2) 11-17.1% at 90-30 d (n= 5) t-sulfinylacetic acid (3) 9.2-18 % at 80-56 d (n= 5) t-sulfonic acid (7) 5.9-11.8% at 180 d (n=5) [^{14}C-phenyl]-acetochlor & [^{14}C-carbonyl]-acetochlor s-sulfonic acid (13) 1.5– 9.8 % at 168d [^{14}C-carbonyl]-acetochlor (n=3)

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

Anaerobic degradation ‡

Non-extractable residues after 100 days	19.7 % after 90 d (60 d under anaerobic conditions) , [^{14}C-carbonyl]-acetochlor (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	identification of new metabolites under anaerobic conditions cannot be established because of the design of the study. Not relevant for the representative use assessed for annex I inclusion.

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	photolysis will not be a major route of degradation in the environment.

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

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	Organic matter %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
silty clay loam	4.1	6.9	22°C/81% 0.33 bar	14.3/47.5	15.9	0.995	SFO
silty clay loam	3.4	6.2	25°C/75%FC	10/33.2	11.8	0.990	SFO
silty loam	1.7	6.3	20°C/pF2	7.9/26.4	7.9	0.993	SFO
silty clay loam	2.0	6.0	20°C/pF2	16.3/54.0	16.3	0.994	SFO
silty clay loam	2.0	6.0	20°C/pF2	10.3/34.2	10.3	-	SFO
silty clay loam	**3.9**	**5.5**	**20°C/pF2**	**29/96.3**	**29 (*)**	**-**	**SFO**
sandy loam	3.5	6.0	20°C/pF2	9.4/31.4	9.4	0.998	SFO
sandy loam	3.5	6.0	20°C/pF2	7.9/26.2	7.9	-	SFO
loam	1.3	7.9	20°C/pF2	3.4/11.1	3.4	1	SFO
silt loam	1.3	5.0	20°C/40% MHWC	23.7/78.8	14.43	0.975	SFO
silt loam	1.3	5.0	20°C/40% MHWC	16.4/54.5	9.99	0.99.3	SFO
clay loam	2.4	7.5	20°C/40% MHWC	12.9/43	7.46	0.937	SFO
clay loam	2.4	7.5	20°C/40% MHWC	13.7/45.5	7.92	0.981	SFO
loam	2.8	8.0	20°C/40% MHWC	11.7/39	7.16	0.967	SFO
-	-	-	20°C/40% MHWC	9.9/33.0	9.9	0.997	SFO
silt loam	1.2	8.1	25°C/75%FC	8.2/27.3	9.4	0.993	SFO
sandy loam	2.4	4.7	25°C/75%FC	12.3/40.9	14.2	0.992	SFO
loamy sand	0.7	7.1	20°C/40% MHWC	9.6/32.0	7.4	0.993	SFO
loamy sand	0.7	7.1	20ºC/40% MHWC	6.7/22.4	5.1	0.987	SFO
loamy sand	1.0	7.2	20ºC/40% MHWC	7.8/26.0	6.0	0.999	SFO

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

loamy sand	1.0	7.2	20ºC/40% MHWC	12.9/42.8	9.9	0.982	SFO
loamy sand	1.0	7.2	20ºC/40% MHWC	12.5/41.4	9.6	0.993	SFO
sandy loam	0.8	6.2	20/40% MHWC	7.7/25.7	5.2	0.996	SFO
sandy loam	2.4	6.7	20;18/ 10.3gw/100gsoil	12.3/40.7	12.3	0.990	SFO
sandy loam	2.4	6.7	20/pF2	17.3/57.6	17.3	0.981	SFO
Geometric mean/median					9.53/9.6		
Mean					10.6(**)		

(*) selected for PECs estimation
(**) selected for modelling

t-sulfonic acid	Aerobic conditions							
Soil type	Organic carbon %	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
loamy sand	1.0	4.2	20°C/pF2	148/491	-	148	0.92	SFO
Silty clay loam	3.3	6.6	20°C/pF2	89/294	-	89	0.88	SFO
clay	5.2	7.2	20°C/pF2	33/108	-	33	0.97	SFO
Geometric mean/median						75.75(*)/89		

(*) selected for PECgw estimation and modelling

t-oxanilic acid	Aerobic conditions							
Soil type	Organic carbon %	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
loamy sand	1.0	4.2	20°C/pF2	131/434	-	131	0.94	SFO
Silty clay loam	3.3	6.6	20°C/pF2	15/50	-	15	0.99	SFO
clay	5.2	7.2	20°C/pF2	30/98	-	30	0.96	SFO
Geometric mean/median						38.92(*)/30		

(*) selected for PECgw estimation and modelling

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

t-sulfinylacetic acid	Aerobic conditions							
Soil type	Organic carbon %	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
loamy sand	1.0	4.2	20°C/pF2	112/372	-	112	0.95	SFO
Silty clay loam	3.3	6.6	20°C/pF2	75/248	-	75	0.8	SFO
clay	5.2	7.2	20°C/pF2	92/305	-	92	0.82	SFO
Geometric mean/median						91.77(*)/92		

(*) selected for PECgw estimation and modelling

s-sulfonic acid	Aerobic conditions							
Soil type	Organic carbon %	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Silt loam	1.85	7.3	20°C/40% MHWC	30.6/101.7	-	24.81	0.99	SFO
Clay loam	0.8	5.7	20°C/40% MHWC	90.3/299.8	-	75.45	0.97	SFO
Loam	1.5	7.6	20°C/40% MHWC	54.5 /181.0	-	40.1	0.99	SFO
Geometric mean/median						42.18(*) /40.1		

(*) selected for modelling

t-sulfinylacetic acid	Aerobic conditions							
Soil type	Organic matter %	pH	t. °C	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Loam	4.3	7.0	20°C	5.3 /17.5		N/A	0.94	SFO

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

Field studies ‡

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth [1] (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (r^2)	Method of calculation
Silt loam	France	1.6	8.0	10 & 30	11	36.54	-	SFO
Clay loam	France	1.9	6.2	10 & 30	7	23.25	-	SFO
Sandy loam	Italy	1.2	5.8	10 & 30	17	56.47	-	SFO
Clay loam	Italy	1.7	8.2	10 & 30	13.4	44.51	-	SFO
Geometric mean/median[2]						-		

[1] Sampling immediately after the application was conducted at 10 cm, the rest of the samplings were conducted at 30 cm
[2] Geometric mean/median has not been estimated since the data were not normalized to the same conditions of temperature and humidity

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	3.2	6.8	4.3	136	7.5	239	1.16
Loamy sand	1.1	6.3	1.7	150	0.81	74	0.86
Sandy loam	1.5	6.5	2.1	138	5.9	389	1.37
Sand	0.45	5.4	0.13	28	1.9	428[2]	2.16[2]
Sand	0.9	5.7	2.4	277	1.9	216	1.03
Sandy loam	4.7	5.3	17	377	20	422	1.07
Silt Loam	0.696	8.1	0.96	138	1.08	155	0.97
Silty clay loam	1.972	6.2	1.74	88	2.66	135	0.79
Sand	0.4	6.5	0.62	151	0.37	92.5	1.23
Sandy Loam	1.392	4.7	1.13	81	1.58	113.5	0.86
Arithmetic mean/median				156		204	1.03
pH dependence, Yes or No			No				

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

t-oxanilic acid							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	3.2	6.8	0.42	14	0.77	24	1.38
Loamy sand	1.1	6.3	0.35	32	0.19	17	0.77
Sandy loam	1.5	6.5	0.33	22	1.2	83	1.89
Sand	0.45	5.4	0.13	29	0.55	124[2]	2.24[2]
Sand	0.9	5.7	0.26	30	0.27	31	1.12
Sandy loam	4.7	5.3	0.86	19	0.91	20	1.04
Arithmetic mean/median						35(*)	1.4(*)
pH dependence (yes or no)			No				

(*) selected for modelling

t-sulphonic acid							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	3.2	6.8	0.68	22	1.6	52	1.48
Loamy sand	1.1	6.3	0.38	34	0.23	21	0.83
Sandy loam	1.5	6.5	0.47	32	6.4	430[2]	2.53[2]
Sand	0.45	5.4	0.15	33	0.3	68	1.84
Sand	0.9	5.7	0.27	31	0.27	31	1.10
Sandy loam	4.7	5.3	0.95	21	1.1	24	1.08
Arithmetic mean/median						39.2 (*)	1.26(*)
pH dependence (yes or no)			No				

(*) selected for modelling

t-sulfinylacetic acid							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay	3.2	6.8	0.41	13	0.25	8	0.85
Loamy sand	1.1	6.3	0.28	26	0.29	26	1.01
Sandy loam	1.5	6.5	0.2	14	0.38	25	1.21
Sand	0.45	5.4	0.17	38	0.26	58	1.15
Sand	0.9	5.7	0.21	24	0.1	12	0.75
Sandy loam	4.7	5.3	0.73	16	0.43	9	0.83

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

Arithmetic mean/median		23 (*)	0.96 (*)
pH dependence (yes or no)	No		

(*) selected for modelling

s-sulfonic acid							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	2.98	7.5	0.05	2	-	-	-
Loam	1.17	7.33	0.06	5	-	-	-
Silty clay loam	2.67	5.42	0.28	10	-	-	-
Loamy sand	2.17	5.7	0.15	7	-	-	-
Silt loam	1.91	5.5	0.2	10	-	-	-
Arithmetic mean/median							
pH dependence (yes or no)			No				

(*) selected for modelling

t-norchloro acetochlor							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	3.0	7.8	0.77	44	0.72	41	0.95
Sandy loam	3.8	7.2	1.5	68	1.27	58	0.91
Sand	0.5	5.7	0.27	95	0.24	82	0.9
Silty Clay loam	4.3	5.3	1.13	45	1.02	41	0.94
Arithmetic mean/median						55.5 (*)	0.925
pH dependence (yes or no)			No				

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

Column leaching ‡	Eluation (mm): *508.77* mm
	Leachate: *96-43*% total residues in leachate Analysis indicated that the major organosoluble components in all cases was acetochlor. It was shown that 1.5-2.5% of AR was t-norchloro acetochlor (6) and 0.4-2.4% AR t-hydroxy acetochlor (17) . The remainder of the organic soluble material consisted in several impurities present in the original acetochlor.

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

Aged residues leaching ‡	The identification of metabolites is not clear in the chromatograms given in the report. Suplementary information
Lysimeter/ field leaching studies ‡	DR confirmed by the PRAPeR meeting 17

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 29 days Kinetics: 1st order Field or Lab: representative worst case from lab studies.
Application data	Crop: maiz Depth of soil layer: 5 cm % plant interception: Pre-emergence therefore no crop interception Number of applications: 1 Interval (d): no relvant Application rate(s): 2100 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	2.8	-	-	-
Short term 24h	2.734	2.767	-	-
2d	2.669	2.734		
4d	2.545	2.670		
Long term 7d	2.369	2.578	-	-
28d	1.434	2.201		
50d	0.848	1.634		
100d	0.257	1.064		

t-oxanilic acid Method of calculation	Molecular weight relative to the parent: 0.982 DT_{50} (d): 131 days Kinetics: SFO

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

		Field or Lab: representative worst case from lab studies.		
Application data		maximum observed 17.1% TAR(by HPLC)		
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				
Short term 24h	0.468	0.469		
2d	0.465	0.468		
4d	0.460	0.465		
Long term 7d	0.453	0.461		
28d	0.405	0.437		
50d	0.361	0.413		
100d	0.277	0.365		
Plateau concentration	x mg/kg after n yr			

t-sulfonic acid

Method of calculation		Molecular weight relative to the parent: 1.167 DT_{50} (d): 148 days Kinetics: SFO Field or Lab: representative worst case from lab studies.		
Application data		maximum observed 11.8% TAR(by HPLC)		
	5cm			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				
Short term 24h	0.384	0.385		
2d	0.382	0.384		
4d	0.379	0.382		
Long term 7d	0.373	0.380		
28d	0.338	0.362		
50d	0.305	0.344		
100d	0.242	0.308		

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

t-sulfinylacetic acid				
Method of calculation	Molecular weight relative to the parent: 1.264 DT_{50} (d): 112 days Kinetics: SFO Field or Lab: representative worst case from lab studies.			
Application data	maximum observed 18% TAR(by HPLC)			
	5cm			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum predicted	0.637	-		
Short term 24h	0.632	0.635		
2d	0.633	0.633		
4d	0.629	0.629		
Long term 7d	0.610	0.623		
28d	0.536	0.585		
50d	0.468	0.548		
100d	0.343	0.475		
Plateau concentration	x mg/kg after n yr			

s-sulfonic acid				
Method of calculation	Molecular weight relative to the parent: 0.954 DT_{50} (d): 90.3 days Kinetics: SFO Field or Lab: representative worst case from lab studies.			
Application data	maximum observed 9.8% TAR(by HPLC)			
	5cm			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Maximum predicted	0.262	-		
Short term 24h	0.260	0.260		
2d	0.258	0.261		

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

4d	0.254	0.260		
Long term 7d	0.248	0.255		
28d	0.211	0.236		
50d	0.178	0.217		
100d	0.121	0.183		
Plateau concentration	x mg/kg after n yr			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: stable
	pH 7: stable
	pH 9: stable
Photolytic degradation of active substance and metabolites above 10 % ‡	photolysis will not be a major route of degradation in the environment.
Quantum yield of direct phototransformation in water at ☒ > 290 nm	See physical and chemical properties section
Readily biodegradable ‡ (yes/no)	No data submitted, substance considered not ready biodegradable.

Degradation in water / sediment

Parent	Distribution (eg max in water 95.6 after 0 d. Max. sed 21.5 % after 7 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Old Basing	7.5	7.8	20	16.9/56.1	0.99	25.9/85.3	0.98	9.6/32	0.87	SFO
Virginia water	7.4	7.1	20	22.5/74.7	0.97	55.1/177.1	0.99	7.5/25.03	0.92	SFO
Geometric mean/median				19.5/64.73		37.8/122.9		8.9/28.3		
Mean				19.7/65.4 (*)		40.5/131.2 (*)		8.55/28.52 (*)		

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

t-oxanilic acid (2)	Distribution (eg max in water 13.1 % TAR after 70 d. Max. sed 2.9% TAR after 70 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Old Basing	7.5	7.8	20	no estimated		no estimated		no estimated		
Virginia water	7.4	7.1	20	no estimated		no estimated		no estimated		
Geometric mean/median										

t-norchloroacetochlor (6)	Distribution (eg max in water 10.4 after 100 d. Max. sed 19.2% TAR after 70 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Old Basing	7.5	7.8	20	no estimated		no estimated		no estimated		
Virginia water	7.4	7.1	20	no estimated		no estimated		no estimated		
Geometric mean/median										

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Old Basing	7.5	7.8	Max. 1.4% TAR after 100 d (end of the study)		Max 50.2 % TAR after 100 d (end of the study)
Virginia water	7.4	7.1	Max. 2.7% TAR after 100 d (end of the study)		Max 24.5 % TAR after 100 d (end of the study)

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

Parent Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol):269.77 Water solubility (mg/L): 282 Kfoc (L/kg): 203.5 (mean value of 9 values) DT_{50} soil: 10.4 days (Lab. mean value of norm values)

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

	DT50 water/sediment system (d): 19.7 d DT50 water (d): 40.5 d DT50 sediment (d): 8.6 d Crop interception (%): 0
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: 2.2×10^{-3} mPa Kfoc: 203.5 (mean value) 1/n: 1.03 (mean value)
Application rate	Crop: maiz Crop interception:0 Number of applications: 1 Interval (d): no relevant Application rate(s): 2016 g as/ha
Main routes of entry	2.8% drift from 1 meter Runoff/drainage 10% at Step 1 Runoff/drainage 4% (SE) and 2% (NE) FOCUSsw2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	547.1		1080.0	
	24 h	523.7	535.4	1070.0	1070.0
	2 d	504.9	524.8	1030.0	1060.0
	4 d	469.4	505.9	955.3	1020.0
	7 d	420.7	479.6	856.2	973.4
	14 d	325.9	425.5	663.3	864.5
	21 d	252.5	379.5	513.8	771.5
	28 d	195.6	340.4	398.0	691.9
	42 d	117.4	278.0	238.8	565.2

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	95.2	---	182.9	---
	24 h	92.5	93.9	176.7	179.8
	2 d	89.7	92.5	171.4	176.9
	4 d	84.5	89.8	161.3	171.6

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

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	7 d	77.1	85.9	147.3	164.1
	14 d	62.4	77.7	119.1	148.4
	21 d	50.4	70.5	96.3	134.7
	28 d	40.8	64.3	77.9	122.7
	42 d	26.7	53.9	50.9	103.0
Southern EU	0 h	176.2	---	347.7	---
	24 h	172.1	174.2	328.7	338.2
	2 d	167.0	171.9	318.9	331.0
	4 d	157.1	166.9	300.1	320.2
	7 d	143.5	159.8	274.0	305.9
	14 d	116.0	144.5	221.6	276.4
	21 d	93.8	131.2	179.2	250.8
	28 d	75.9	119.5	144.9	228.5
	42 d	49.6	100.3	94.8	191.7

Step 3: PEC SW (µg/L)

Location	D3	D4		D5		D6	R1		R2	R3	R4
Waterbody	ditch	pond	stream	pond	stream	ditch	pond	stream	stream	stream	stream
GlobalMax	10.566	0.432	8.919	0.428	10.349	10.633	0.764	22.94	15.095	10.342	54.605
TWA 1d	8.206	0.426	0.693	0.422	4.02	9.693	0.756	9.9	7.3	3.917	41.135
TWA 2d	5.284	0.423	0.349	0.419	2.02	8.425	0.749	4.955	3.654	1.967	20.641
TWA 4d	2.721	0.416	0.177	0.413	1.012	5.535	0.735	2.479	1.828	0.985	10.329
TWA 7d	1.559	0.408	0.103	0.404	0.578	3.315	0.723	1.417	1.045	0.563	5.904
TWA 14d	0.781	0.385	0.054	0.384	0.289	1.682	0.706	1.16	0.849	0.304	3.749
TWA 21d	0.521	0.364	0.037	0.365	0.193	1.13	0.677	0.827	0.566	0.213	2.565
TWA 28d	0.391	0.345	0.029	0.347	0.145	0.854	0.642	0.642	0.457	0.268	1.954
TWA 42d	0.26	0.313	0.021	0.314	0.096	0.576	0.574	0.459	0.311	0.199	1.34
TWA 50d	0.219	0.295	0.018	0.297	0.081	0.486	0.554	0.386	0.28	0.167	1.126
TWA 100d	0.109	0.211	0.011	0.213	0.041	0.247	0.426	0.193	0.141	0.084	0.563

Step 3: PEC SED (µg/kg)

Location	D3	D4		D5		D6	R1		R2	R3	R4
Waterbody	ditch	pond	stream	pond	stream	ditch	pond	stream	stream	stream	stream
GlobalMax	2.25	0.359	0.39	0.337	1.402	3.192	0.746	4.04	3.00	1.377	13.604
TWA 1d	2.128	0.359	0.194	0.337	1.052	3.145	0.744	2.716	2.109	1.026	10.926
TWA 2d	1.876	0.359	0.141	0.337	0.792	3.018	0.743	2.03	1.613	0.769	8.594

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

Location	D3	D4		D5		D6	R1		R2	R3	R4
Waterbody	ditch	pond	stream	pond	stream	ditch	pond	stream	stream	stream	stream
TWA 4d	1.452	0.358	0.10	0.337	0.565	2.655	0.74	1.446	1.174	0.545	6.313
TWA 7d	1.104	0.358	0.075	0.336	0.415	2.146	0.734	1.067	0.877	0.4	4.733
TWA 14d	0.738	0.356	0.051	0.334	0.269	1.459	0.72	0.873	0.797	0.268	3.636
TWA 21d	0.555	0.353	0.04	0.33	0.2	1.103	0.703	0.794	0.634	0.216	2.85
TWA 28d	0.442	0.348	0.033	0.325	0.16	0.883	0.683	0.689	0.518	0.232	2.365
TWA 42d	0.311	0.331	0.025	0.31	0.113	0.621	0.637	0.511	0.39	0.205	1.719
TWA 50d	0.264	0.319	0.023	0.299	0.096	0.528	0.607	0.448	0.337	0.18	1.474
TWA 100d	0.134	0.24	0.014	0.226	0.049	0.269	0.46	0.238	0.182	0.093	0.763

Step 4 PECsw (µg/L)

PEC_{SW} (µg/L); GlobalMax	**FOCUS scenarios / Waterbody type**										
	D3	**D4**		**D5**		**D6**	**R1**		**R2**	**R3**	**R4**
	ditch	**pond**	**stream**	**pond**	**stream**	**ditch**	**pond**	**stream**	**stream**	**stream**	**stream**
20 m drift buffer [1]	0.954	0.187	1.037	0.183	1.2	0.977					
25m drift buffer	0.771	0.163	0.84	0.158	0.969	0.797	0.592	22.94	15.095	3.835	54.605
50m drift buffer.	0.395	0.1	0.433	0.096	0.497	0.42	0.552	22.94	15.095	3.835	54.605
5m drift buffer with DRN.	0.866	0.1	0.943	0.095	1.089	0.892					
10m drift buffer with DRN.	0.459	0.073	0.503	0.069	0.578	0.484					
14 m drift buffer with DRN.	0.335	0.061	0.367	0.057	0.421	0.359					
25m drift buffer with DRN	0.193	0.044	0.213	0.04	0.242	0.216	0.517	22.94	15.095	3.835	54.605
50m drift buffer with DRN.	0.099	0.028	0.112	0.024	0.124	0.122	0.507	22.94	15.095	3.835	54.605

t-oxanilic acid

Parameters used in FOCUSsw step 1 and 2

Molecular weight:265 g/mol
Water solubility (mg/l):10000
Soil or water metabolite:soil and water metabolite
Koc (L/kg): 24
DT_{50} soil: 58.7 days (Worst case at 20ºC pF2 and in soils at pH>5; Lab. SFO)
DT50 water/sediment system (d): 10000
DT50 water (d):10000
DT50 sediment (d):10000
Crop interception (%):0
Maximum occurrence observed (% molar basis with respect to the parent)
Water/sediment: 15.1% AR (100 DAT)

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

	Soil: 17.1% TAR (HPLC)
Application rate	Crop: maize Number of applications: 1 Interval (d): no relevant Application rate(s): 2100 g as/ha Depth of water body: 30 cm
Main routes of entry	2.8 % drift from 1 meter runoff/drainage 10% at Step 1 runoff/drainage 4% (SE) and 2 %(NE) FOCUSsw 2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	116.5			
	24h			26.86	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	4 d	24.56			
	5 d			5.64	
Southern EU	4 d	46.33			
	5 d			10.64	

t-norchloroacetochlor Parameters used in FOCUSsw step 1 and 2	Molecular weight:235.3 g/mol Water solubility (mg/l):10000 Soil or water metabolite: water metabolite Kfoc (L/kg): 55.5 DT_{50} soil: 149 d DT50 water/sediment system (d): 10000 DT50 water (d):10000 DT50 sediment (d):10000 Crop interception (%):0 Maximum occurrence observed (% molar basis with respect to the parent) Water/Sediment: 22.9% AR (70 DAT) Soil: 1.8% TAR (HPLC)

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

Application rate	Crop: maize Number of applications: 1 Interval (d): no relevant Application rate(s): 2100 g as/ha Depth of water body: 30 cm
Main routes of entry	2.8 % drift from 1 meter runoff/drainage 10% at Step 1 runoff/drainage 4% (SE) and 2 %(NE) FOCUSsw 2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	18.64			
	24h			10.19	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	4 d	6.57			
	5 d			3.6	
Southern EU	4 d	9.47			
	5 d			5.21	

t-sulfonic acid Parameters used in FOCUSsw step 1 and 2	Molecular weight:315 g/mol Water solubility (mg/l):10000 Soil or water metabolite: soil metabolite Koc (L/kg): 28.8 DT_{50} soil: 90 d DT50 water/sediment system (d): 10000 DT50 water (d):10000 DT50 sediment (d):10000 Crop interception (%):0 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 6.5 % AR (100 DAT) Soil: 11.8 % TAR (HPLC)

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

Application rate	Crop: maize Number of applications: 1 Interval (d): no relevant Application rate(s): 2100g as/ha Depth of water body: 30 cm
Main routes of entry	2.8 % drift from 1 meter runoff/drainage 10% at Step 1 runoff/drainage 4% (SE) and 2 %(NE) FOCUSsw 2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	94.77			
	24h			23.95	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	4 d	19.52			
	5 d			4.93	
Southern EU	4 d	37.62			
	5 d			9.51	

t-sulfinyl acetic acid Parameters used in FOCUSsw step 1 and 2	Molecular weight: 341 g/mol Water solubility (mg/l):10000 Soil or water metabolite: soil metabolite Koc (L/kg): 22 DT_{50} soil: 93days DT50 water/sediment system (d): 10000 DT50 water (d):10000 DT50 sediment (d):10000 Crop interception (%):0 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 2.6 % AR (100 DAT) Soil: 18 % TAR (HPLC)

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

Application rate	Crop: maize Number of applications: 1 Interval (d): no relevant Application rate(s): 2100 g as/ha Depth of water body: 30 cm
Main routes of entry	2.8 % drift from 1 meter runoff/drainage 10% at Step 1 runoff/drainage 4% (SE) and 2 %(NE) FOCUSsw 2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	155.16			
	24h			35.66	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	4 d	30.62			
	5 d			7.04	
Southern EU	4 d	60.62			
	5 d			13.92	

s-sulfonic acid Parameters used in FOCUSsw step 1 and 2	Molecular weight: 257.3 g/mol Water solubility (mg/l):10000 Soil or water metabolite: soil metabolite Koc (L/kg): 7 (mean value) DT_{50} soil: 59 days (Median of three values) DT50 water/sediment system (d): 10000 DT50 water (d):10000 DT50 sediment (d):10000 Crop interception (%):0 Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment:- Soil: 9.8 % TAR (HPLC)

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

Application rate	Crop: maize Number of applications: 1 Interval (d): no relevant Application rate(s): 2100 g as/ha Depth of water body: 30 cm
Main routes of entry	2.8 % drift from 1 meter runoff/drainage 10% at Step 1 runoff/drainage 4% (SE) and 2 %(NE) FOCUSsw 2

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	64.82		4.54	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	4 d	12.22		0.86	
Southern EU	4 d	24.44		1.71	

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	<u>For FOCUS gw modelling, values used –</u> Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: PELMO; PEARL; PRZM Scenarios (list of names): Chateaudun (C) Hamburg (H) Krensmünster (K) Okehampton (N) Piacenza (P) Porto (O) Sevilla (S) Thiva (T) Crop: Maize Mean parent DT_{50lab} 10.4 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.2). K_{foc}: mean 203.5 l/kg (n=9), $^1/_n$= 1.03 Metabolites: Data Gap identified during PRAPeR

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

Application rate	meeting 17 Parent Application rate: 2100 g/ha. No. of applications: 1 Time of application (month or season): spring (10 days before emergence)

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PEARL /maize	Chateaudun	0.000242			
	Hamburg	0.000695			
	Jokioinen				
	Kremsmunster	0.000349			
	Okehampton	0.000934			
	Piacenza	0.004995			
	Porto	0.000000			
	Sevilla	0.000013			
	Thiva	0.000201			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PELMO /maize	Chateaudun	0.000			
	Hamburg	0.000			
	Jokioinen				
	Kremsmunster	0.000			
	Okehampton	0.000			
	Piacenza	0.002			
	Porto	0.000			
	Sevilla	0.000			
	Thiva	0.000			

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
PRZM /maize					

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

	Chateaudun	$0.182\ 10^{-6}$			
	Hamburg	$0.5071\ 10^{-4}$			
	Jokioinen				
	Kremsmunster	$0.3107\ 10^{-6}$			
	Okehampton	$0.4701\ 10^{-5}$			
	Piacenza	$0.4196\ 10^{-3}$			
	Porto	$0.359\ 10^{-11}$			
	Sevilla	$0.1590\ 10^{-12}$			
	Thiva	$0.58\ 10^{-10}$			

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	see physical and chemical properties section
Photochemical oxidative degradation in air ‡	DT_{50} of 2.3 hours derived by the Atkinson method of calculation (12h; $1.5\ 10^6$ OH/m^3)
Volatilisation ‡	No studied no data requested
Metabolites	No relevant

PEC (air)

Method of calculation	no EU guidance adopted yet

$PEC_{(a)}$

Maximum concentration	no EU guidance adopted yet

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	**Soil:** acetochlor, t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) **Surface Water:** acetochlor, t-oxanilic acid (2), t-norchloro acetochlor (6), t-sulfinyl acetic acid (3) (from soil), t-sulfonic acid (7) (from soil), s-sulfonic acid (13) (from soil) **Sediment:** acetochlor and t-norchloro-acetochlor (6) **Ground water**: acetochlor, t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13)

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

	Air: acetochlor

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

Soil (indicate location and type of study)	No data provided
Surface water (indicate location and type of study)	Active substance (1) France (key maize-growing areas) - water for human consumption study: A small number of low level detections (<0.05 to 2.6 µg L^{-1}) of acetochlor were found in raw surface water samples during and shortly after the spring herbicide application season. Water treatment systems are effective in removing acetochlor residues since no detectable residues were found in treated water samples. (n= 120 samples from 6 locations) (2) France (key maize-growing areas) – raw surface water study. Detections of acetochlor in surface water are greatest in magnitude and frequency during and shortly after the spring application season (n= 142 samples from 3 locations) Receiving water: peaks of <0.05-4.66 µg/l (3) Acetochlor was monitored in France through local monitoring networks. Acetochlor was detected in two samples from two sites out of a total of 11 samples collected from four sites in 1998-1999. The two findings were 0.007 and 0.4 µg L^{-1}
Ground water (indicate location and type of study)	Active substance (1) Acetochlor has been monitored in ground water in key maize growing areas of France in 2002 and 2003. Acetochlor was not detected in raw drinking water obtained from groundwater sources (n= 54 samples; 3 locations). Metabolites Selected groundwater samples from the monitoring studies conducted by the Acetochlor Registration Partnership in the USA and from the acetochlor monitoring program conducted in France in 2002 were analyzed for the presence of trace levels of acidic degradates of acetochlor (metabolites 2, 3 and 7) None of the analyzed compounds exceeded

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

	0.05 µg/L in any of the samples from the 2002 acetochlor monitoring study conducted in France (n=36 samples; 3 locations). From the USA monitoring program The *t*-sulfonic metabolite (7) of acetochlor is the most frequently found degradate. Its level exceeded 0.1 µg/L in 45% of the analysed samples (maximum 4.. Only one sample showed t-oxanilic (2) and t-sulfinylacetic acid (3) residue levels exceeding the quantification limit of 0.05 µg/L. (n=20 from 7 states). t-oxanilic (2) <0.05- 1.21µg/l t-sulfinylacetic acid (3): <0.05 -0.161µg/l *t*-sulfonic metabolite (7): <0.05-4.06 µg/l Monitoring study in Northern Italy (Apr 2005-Oct2006)- Results of the 1st year Acetochlor metabolites have been monitored in ground water in key maize growing areas of Italy in 2005 and 2006 (9 locations, n=694 samples): t sulfonic metabolite (7): *<0.05-11.6 µg/l*; nº detections ≥ 0.1 ug/L= 111; 90th percentile =0.25 ug/L t-oxanilic metabolite (2): *<0.05-11.1*µg/l; nº detections ≥ 0.1 ug/L= 14; 90th percentile =0.1 ug/L t-sulfinylacetic acid (3) *<0.05-0.74*µg/l; nº detections ≥ 0.1 ug/L= 14; 90th percentile =0.01 ug/L EMAsESA (13) metabolite (13) *<0.05-5.97* ug/L nº detections ≥ 0.1 ug/L= 175; 90th percentile =0.28 ug/L This metabolite can be also produced from the Methachlor ESA metabolite so the percentage of metabolite (13) produced from acetochlor metabolite 7 cannot be determined
Air (indicate location and type of study)	No data provided

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

Not ready biodegradable; Candidate for R53

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

Appendix 1.6: Effects on non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	Acetochlor	Acute	LD_{50} 928 mg a.s./kg bw	
	GF-675	Acute	LD_{50}1345 mg a.s./kg bw	
	MON 69447	Acute	LD_{50} 375 mg a.s./kg bw	
Mallard duck	Acetochlor	Short-term	LC_{50}1057 mg a.s./kg $_{bw}$/d	(5620 mg as/kg)
Mallard duck	Acetochlor	Long-term	NOEC 5.5 mg a.s./kg $_{bw}$/d	(30 mg as/kg)
Mammals ‡				
rat	Acetochlor	Acute	LD_{50} 1929 mg/kg$_{bw}$/d females	
rat	MON 69447	Acute	LD_{50} 1000 mg as /kg$_{bw}$/d males	
rat	Acetochlor	Long-term	NOEL 20 mg/kg$_{bw}$/d (rat)	
Additional higher tier studies ‡ No submitted				

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

Crop and application rate

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivorous	Acute	133.3	2.8	10
Medium herbivorous	Short-term	61.3	**17.2**	10
Medium herbivorous	Long-term	32.5	0.17	5
insectivorous	Acute	109	3.4	10

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

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
insectivorous	Short-term	60.8	**17.5**	10
insectivorous	Long-term	60.8	**17.5**	5
vermivorous	Long-term	82.3	0.06	5
Piscivorous	Long-term	0.010	**550**	5
Medium herbivorous bird	Acute	87.3*	**4.3**	10
Insectivorous bird	Acute	287.1*	**1.4**	10
Higher tier refinement (Birds)[1]				
herbivorous	Acute	23.1	**16.73**	10
herbivorous	Short-term			10
herbivorous	Long-term	0.874	**6.29**	5
insectivorous	Acute	3.64	**103**	10
insectivorous	Short-term			10
insectivorous	Long-term	0.874	**6.29**	5
vermivorous	Long-term	0.07	**78.6**	5
Piscivorous	Long-term			5
Tier 1 (Mammals)				
herbivorous	Acute	49.1	**20**	10
herbivorous	Long-term	11.96	1.7	5
vermivorous	Long-term	104.7	0.19	5
piscivorous	Long-term	0.0066	**3030**	5
Higher tier refinement (Mammals)				
herbivorous	Long-term	1.06	**19**	
vermivorous	Long-term	0.09	**22.2**	5
piscivorous	Long-term			5
piscivorous	Long-term			5

* Daily intake [mg as./kg bw/day]
[1] Acute and long term refinement based on crested lark (insectivorous species)

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

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Acetochlor	96 hr (static)	Mortality, EC_{50}	0.36 (mm)
Oncorhynchus mykiss	Acetochlor	60 days (flow-through)	Growth NOEC	0.13 (mm)
Bluegill sunfish	Preparation GF.675	96 hr static	Mortality, EC_{50}	1.07 a.s.
Oncorhynchus mykiss	Preparation MON 69447	96 hr (flow-through)	Mortality, EC_{50}	0.547 a.s.
Oncorhynchus mykiss	*t*-oxanilic acid (2)	96 hours static	Mortality LC50	> 93
Oncorhynchus mykiss	*t*-sulfinylacetic acid (3)	96hours static	Mortality LC_{50}	>120
Oncorhynchus mykiss	*t*-sulfonic acid (7)	96 hours static	Mortality LC_{50}	>180
Oncorhynchus mykiss	*t*-norchloro acetochlor (6)	96 hours static	Mortality LC_{50}	42
Aquatic invertebrate				
Daphnia magna	a.s.	48 h (static)	Mortality, EC_{50}	8.6
Daphnia magna	a.s.	21 d (static)	Reproduction, NOEC	0.0221
Daphnia magna	WF 2061 (68.8% w/w)	48h (static)	EC_{50}	7.4 a.s.
Daphnia magna	GF-675	48h (static)	Mortality, EC_{50}	> 6.4 a.s.
Daphnia magna	*t*-oxanilic acid (2)	48 h static	EC_{50} NOEC	>120 120
Daphnia magna	*t*-sulfinylacetic acid (3):	48 h static	EC_{50} NOEC	>120 120
Daphnia magna	*t*-sulfonic acid (7): R290131 (97%)	48 h static	EC_{50} NOEC	>120 120

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Daphnia magna	*t*-norchloro acetochlor (6): Compound 31 (99.5%)	48 h static	EC_{50} NOEC	170 100
Sediment dwelling organisms				
Chironomus riparius	Technical	28 d (static)	21d NOEC	1.6
	Metabolite 2	28 d (static)	NOEC	
Algae				
P. subcapitata.	Technical	72 h	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.00031 0.00052
P. subcapitata	Technical	120 h (static)	Growth rate: E_rC_{50}	0.0019
Anabaena flos-aquae	Technical	120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	32 110
Navicula pelliculosa	Technical	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.3 2.3
Skeletonema costatum	Technical	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0043 0.010
Skeletonema costatum	Technical	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0078 0.0210
P. subcapitata	GF-675	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.00077 0.0010
P. subcapitata	MON 69447	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.00071 0.00155
P. subcapitata	*t*-oxanilic acid (2): R290130 (97% w/w)	72 hours static	E_bC_{50} E_rC_{50} $NOE_{r/b}C$	44 42 32
P. subcapitata	*t*-sulfinylacetic acid (3):R243797 (99% w/w)	72 hours static	E_bC_{50} E_rC_{50} NOE_bC NOE_rC	57 68 32 56
P. subcapitata	*t*-sulfonic acid (7): R290131 (97% w/w)	72 hours static	E_bC_{50} E_rC_{50} $NOE_{b/r}C$	8.1 17 3.2

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
P. subcapitata	*t*-norchloro acetochlor (6): Compound 31 (99.5% w/w)	72 hours static	E_bC_{50} E_rC_{50} NOE_bC NOE_rC	0.34 0.49 0.12 0.24
P. subcapitata	s- sulfonic acid	72 hours static	E_bC_{50} E_rC_{50} NOE_bC	>124 >124 >124
Plant				
Lemna gibba	Technica1	7 days	7 d EC_{50} (frond nº)	0.0027
Lemna minor	MON 69447	14 days	7 d-EC_{50} (frond nº)	0.00257
Lemna gibba	GF-675	14 days	7d-EC_{50} (frond nº)	> 0.00054
Lemna gibba	*t*-oxanilic acid (2): MON 52755 (94.6% w/w)	7 days static	EC_{50} (frond nº) ErC_{50} NOEC (both)	>123 >123 123
Lemna gibba	*t*-sulfinylacetic ac (3): MON 52709 (98.6% w/w)	7 days static	EC_{50} (frond nº) ErC_{50} NOEC (both)	>112 >112 112
Lemna gibba	*t*-sulfonic acid (7): MON 52754 (94.6% w/w)	7 days static	EC_{50} (frond nº) ErC_{50} NOEC	> 140 > 140 > 140
Lemna gibba	*s-sulfonic MON 52765 (86.8% w sodium salt)*	7 days static	EC_{50} (frond nº) ErC_{50} NOEC (both	> 150 > 150 > 150
Lemna gibba	*Norchloroacetochlor MON 52706 (99.5% w/w)*	7 days static	EC_{50} (frond nº) ErC_{50} NOEC (both	19 49 4.8
Higher plant				
Indicate species.	a.s.	14 d (static)	Fronds, EC_{50}	Not required
	Preparation	14 d (static)	Fronds, EC_{50}	Not required
	Metabolite 1	14 d (static)	Fronds, EC_{50}	Not required

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

Microcosm or mesocosm tests

An outdoor microcosm study provided evidence that exposure levels up to and including 31.23 µg/L acetochlor did not result in effects upon, macrophytes.

An outdoor static mesocosm study provided evidence that exposure levels up to and including 0.2 µg a.s./L acetochlor did not result in effects upon, phyto plankton, macrophytes, amphipods, mollusc, annelids and aquatic insects.

Based on static mesocosm a toxicity value (NOEC) of 0.2 µg a.s./L was proposed for risk assessment of lotic systems. Based on pulse exposure mesocosm study and static mesocosm data, a toxicity value (NOAEC) of 2.0 µg a.s./L was proposed for risk assessment of lotic systems.

Three single-species, 27-day exposure studies (TNO/R2004/054; TNO/R2004/055; TNO/R2004/056) conducted in indoor tanks at 15°C using two different sources of *E. canadensis* resulted in NOEC or NOAEC values of 8.0 µg a.s./L. in the two first studies and a NOEC or NOAEC values of 16 µg a.s./L in the last one

An outdoor single-pulse exposure mesocosm study (TN-2005-076) 19 µg a.s./L (max tested dose) did not affect the development of the mesocosm ecosystem; the macrophytes *Elodea Canadensis, Myriophyllum spicatum* and *Lemna gibba* and the emergence of the chironomid *Corynoneura carriana* $NOEC_{community}$=19 µg a.s./L

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

FOCUS Step1

Crop and application rate: Maize at 2.016 kg Acetochlor /ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
Acetochlor	*Oncorhynchus mykiss*	0.36	Acute	547.1		0.66	100
Acetochlor	*Oncorhynchus mykiss*	0.13	Chronic	547.1		0.237	10
Acetochlor	*D .magna*	7.4	Acute	547.1		13.52	100
Acetochlor	*D .magna*	0.0221	Chronic	547.1		0.040	10
Acetochlor	*P. subcapitata*	0.00031	Chronic	547.1		0.0005	10
Acetochlor	*Lemna minor*	0.00257	Chronic	547.1		0.0046	10
Acetochlor	*C. riparius*	1.6	Chronic	547.1		2.92	10

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

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i	PEC_{twa}	TER	Annex VI Trigger
t-oxanilic acid	*P. subcapitata*	44	Acute	116.5		377	10
t-sulfinylacetic	*P. subcapitata*	57	Acute	155.1		367	10
t-sulfonic acid	*P. subcapitata*	8.1	Acute	94.7		85.5	10
t-norchloro acetochlor	*P. subcapitata*	0.34	Acute	18.64		18.3	10
s-sulfonic acid	*P. subcapitata*	124	Acute	64.82		1913	10
t-sulfonic acid	*L. gibba*	> 140	Chronic	94.7		1477	10
s sulfonic acid	*L. gibba*	> 150	Chronic	64.82		2314	10
t-norchloroacetochlor	*L.gibba*	19	Chronic	18.64		1019	10

FOCUS Step 2

Crop and application rate: Maize at 2.016 kg Acetochlor /ha**,** Southern Europe (worst case scenarios)

Test substance	N/S	Organism	Toxicity end point (mg/L)	Time scale	PEC	TER	Annex VI Trigger
Acetochlor	S	*Oncorhynchus mykiss*	0.36	Acute	176.2	2.04	100
Acetochlor	S	*Oncorhynchus mykiss*	0.13	Chronic	176.2	0.74	10
Acetochlor	S	*D .magna*	7.4	Acute	176.2	42	100
Acetochlor	S	*D .magna*	0.0221	Chronic	176.2	0.12	10
Acetochlor	S	*P. subcapitata*	0.00031	Chronic	176.2	0.0015	10
Acetochlor	S	*Lemna minor*	0.00257	Chronic	176.2	0.0145	10
Acetochlor	S	*C. riparius*	1.6	Chronic	176.2	9.16	10

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Crop and application rate: Maize at 2.016 kg Acetochlor /ha.

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

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC sw (initial)	TER	Annex VI trigger
Acetochlor	D3	ditch	*O .mykiss*	Acute	0.36	10.566	34.1	100
Acetochlor	D4	pond	*O .mykiss*	Acute	0.36	0.432	833	100
Acetochlor	D4	stream	*O .mykiss*	Acute	0.36	8.919	40.4	100
Acetochlor	D5	pond	*O .mykiss*	Acute	0.36	0.428	841	100
Acetochlor	D5	stream	*O .mykiss*	Acute	0.36	10.349	34.8	100
Acetochlor	D6	ditch	*O .mykiss*	Acute	0.36	10.633	33.9	100
Acetochlor	R1	pond	*O .mykiss*	Acute	0.36	0.764	471	100
Acetochlor	R1	stream	*O .mykiss*	Acute	0.36	22.94	15.7	100
Acetochlor	R2	stream	*O .mykiss*	Acute	0.36	15.095	23.9	100
Acetochlor	R3	stream	*O .mykiss*	Acute	0.36	10.342	34.8	100
Acetochlor	R4	stream	*O .mykiss*	Acute	0.36	54.605	6.59	100
Acetochlor	D3	ditch	*O .mykiss*	Chronic	0.13	10.566	12.3	10
Acetochlor	D4	pond	*O .mykiss*	Chronic	0.13	0.432	301	10
Acetochlor	D4	stream	*O .mykiss*	Chronic	0.13	8.919	14.6	10
Acetochlor	D5	pond	*O .mykiss*	Chronic	0.13	0.428	304	10
Acetochlor	D5	stream	*O .mykiss*	Chronic	0.13	10.349	12.6	10
Acetochlor	D6	ditch	*O .mykiss*	Chronic	0.13	10.633	12.2	10
Acetochlor	R1	pond	*O .mykiss*	Chronic	0.13	0.764	170	10
Acetochlor	R1	stream	*O .mykiss*	Chronic	0.13	22.94	5.67	10
Acetochlor	R2	stream	*O .mykiss*	Chronic	0.13	15.095	8.61	10
Acetochlor	R3	stream	*O .mykiss*	Chronic	0.13	10.342	12.6	10
Acetochlor	R4	stream	*O .mykiss*	Chronic	0.13	54.605	2.38	10
Acetochlor	D3	ditch	*D .magna*	Acute	7.4	10.566	700	100
Acetochlor	D4	pond	*D .magna*	Acute	7.4	0.432	17129	100
Acetochlor	D4	stream	*D .magna*	Acute	7.4	8.919	829	100
Acetochlor	D5	pond	*D .magna*	Acute	7.4	0.428	17289	100
Acetochlor	D5	stream	*D .magna*	Acute	7.4	10.349	715	100
Acetochlor	D6	ditch	*D .magna*	Acute	7.4	10.633	696	100
Acetochlor	R1	pond	*D .magna*	Acute	7.4	0.764	9686	100
Acetochlor	R1	stream	*D .magna*	Acute	7.4	22.94	322	100

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

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC sw (initial)	TER	Annex VI trigger
Acetochlor	R2	stream	*D .magna*	Acute	7.4	15.095	490	100
Acetochlor	R3	stream	*D .magna*	Acute	7.4	10.342	715	100
Acetochlor	R4	stream	*D .magna*	Acute	7.4	54.605	135	100
Acetochlor	D3	ditch	*D .magna*	Chronic	0.0221	10.566	2.09	10
Acetochlor	D4	**pond**	*D .magna*	Chronic	0.0221	0.432	51.2	10
Acetochlor	D4	stream	*D .magna*	Chronic	0.0221	8.919	2.48	10
Acetochlor	D5	pond	*D .magna*	Chronic	0.0221	0.428	51.6	10
Acetochlor	D5	stream	*D .magna*	Chronic	0.0221	10.349	2.14	10
Acetochlor	D6	ditch	*D .magna*	Chronic	0.0221	10.633	2.08	10
Acetochlor	R1	pond	*D .magna*	Chronic	0.0221	0.764	28.9	10
Acetochlor	R1	stream	*D .magna*	Chronic	0.0221	22.94	0.963	10
Acetochlor	R2	stream	*D .magna*	Chronic	0.0221	15.095	1.46	10
Acetochlor	R3	stream	*D .magna*	Chronic	0.0221	10.342	2.14	10
Acetochlor	R4	stream	*D .magna*	Chronic	0.0221	54.605	0.405	10
Acetochlor	D3	ditch	*P. subcapitata*	Acute	0.00031	10.566	0.03	10
Acetochlor	D4	**pond**	*P. subcapitata*	Acute	0.00031	0.432	0.71	10
Acetochlor	D4	stream	*P. subcapitata*	Acute	0.00031	8.919	0.034	10
Acetochlor	D5	pond	*P. subcapitata*	Acute	0.00031	0.428	0.72	10
Acetochlor	D5	stream	*P. subcapitata*	Acute	0.00031	10.349	0.03	10
Acetochlor	D6	ditch	*P. subcapitata*	Acute	0.00031	10.633	0.03	10
Acetochlor	R1	pond	*P. subcapitata*	Acute	0.00031	0.764	0.405	10
Acetochlor	R1	stream	*P. subcapitata*	Acute	0.00031	22.94	0.013	10
Acetochlor	R2	stream	*P. subcapitata*	Acute	0.00031	15.095	0.020	10
Acetochlor	R3	stream	*P.*	Acute	0.00031	10.342	0.029	10

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

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC sw (initial)	TER	Annex VI trigger
			subcapitata					
Acetochlor	R4	stream	*P. subcapitata*	Acute	0.00031	54.605	0.005	10
Acetochlor	D3	ditch	*Lemna gibba*	Acute	0.0027	10.566	0.25	10
Acetochlor	D4	**pond**	*Lemna gibba*	Acute	0.0027	0.432	6.25	10
Acetochlor	D4	stream	*Lemna gibba*	Acute	0.0027	8.919	0.30	10
Acetochlor	D5	pond	*Lemna gibba*	Acute	0.0027	0.428	6.30	10
Acetochlor	D5	stream	*Lemna gibba*	Acute	0.0027	10.349	0.26	10
Acetochlor	D6	ditch	*Lemna gibba*	Acute	0.0027	10.633	0.25	10
Acetochlor	R1	pond	*Lemna gibba*	Acute	0.0027	0.764	3.534	10
Acetochlor	R1	stream	*Lemna gibba*	Acute	0.0027	22.94	0.117	10
Acetochlor	R2	stream	*Lemna gibba*	Acute	0.0027	15.095	0.17	10
Acetochlor	R3	stream	*Lemna gibba*	Acute	0.0027	10.342	0.261	10
Acetochlor	R4	stream	*Lemna gibba*	Acute	0.0027	54.605	0.049	10
Acetochlor	D3	ditch	*C. riparius*	Chronic	1.6	10.566	151.4	10
Acetochlor	D4	**pond**	*C. riparius*	Chronic	1.6	0.432	3703	10
Acetochlor	D4	stream	*C. riparius*	Chronic	1.6	8.919	179.3	10
Acetochlor	D5	pond	*C. riparius*	Chronic	1.6	0.428	3738	10
Acetochlor	D5	stream	*C. riparius*	Chronic	1.6	10.349	154.6	10
Acetochlor	D6	ditch	*C. riparius*	Chronic	1.6	10.633	150.4	10
Acetochlor	R1	pond	*C. riparius*	Chronic	1.6	0.764	2094	10
Acetochlor	R1	stream	*C. riparius*	Chronic	1.6	22.94	69.7	10
Acetochlor	R2	stream	*C. riparius*	Chronic	1.6	15.095	105.9	10
Acetochlor	R3	stream	*C. riparius*	Chronic	1.6	10.342	154.7	10
Acetochlor	R4	stream	*C. riparius*	Chronic	1.6	54.605	29.3	10
Acetochlor	D3	**ditch**	*Lemna minor*	Chronic	0.00257	10.566	0.24	10
Acetochlor	D4	pond	*Lemna minor*	Chronic	0.00257	0.432	5.94	10
Acetochlor	D4	**stream**	*Lemna minor*	Chronic	0.00257	8.919	0.288	10

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

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC sw (initial)	TER	Annex VI trigger
Acetochlor	D5	**pond**	*Lemna minor*	Chronic	0.00257	0.428	6.0	10
Acetochlor	D5	**stream**	*Lemna minor*	Chronic	0.00257	10.349	0.248	10
Acetochlor	D6	**ditch**	*Lemna minor*	Chronic	0.00257	10.633	0.242	10
Acetochlor	R1	**pond**	*Lemna minor*	Chronic	0.00257	0.764	3.36	10
Acetochlor	R1	**stream**	*Lemna minor*	Chronic	0.00257	22.94	0.11	10
Acetochlor	R2	**stream**	*Lemna minor*	Chronic	0.00257	15.095	0.171	10
Acetochlor	R3	**stream**	*Lemna minor*	Chronic	0.00257	10.342	0.249	10
Acetochlor	R4	**stream**	*Lemna minor*	Chronic	0.00257	54.605	0.047	10

FOCUS Step 3

Crop and application rate: **Maize at 2.016 kg Acetochlor /ha.**

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	PECsw (µg a.s./L)	TER	Annex VI trigger
Acetochlor	D3	ditch	Aquatic communities	Chronic	0.2	10.566	0.019	2-3
Acetochlor	D4	pond	Aquatic communities	Chronic	0.2	0.432	0.46	2-3
Acetochlor	D4	stream	Aquatic communities	Chronic	2.0	8.919	0.22	2-3
Acetochlor	D5	pond	Aquatic communities	Chronic	0.2	0.428	0.47	2-3
Acetochlor	D5	stream	Aquatic communities	Chronic	2.0	10.349	0.19	2-3
Acetochlor	D6	ditch	Aquatic communities	Chronic	0.2	10.633	0.019	2-3

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

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	PECsw (µg a.s./L)	TER	Annex VI trigger
Acetochlor	R1	pond	Aquatic communities	Chronic	0.2	0.764	0.26	2-3
Acetochlor	R1	stream	Aquatic communities	Chronic	2.0	22.94	0.087	2-3
Acetochlor	R2	stream	Aquatic communities	Chronic	2.0	15.095	0.132	2-3
Acetochlor	R3	stream	Aquatic communities	Chronic	2.0	10.342	0.193	2-3
Acetochlor	R4	stream	Aquatic communities	Chronic	2.0	54.605	0.037	2-3

FOCUS Step 4

Crop and application rate: Maize at 2.016 kg Acetochlor /ha.

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
D3	ditch	Aquatic communities	Chronic	0.2	25 m drift buffer zone	0.771	0.25	2-3
D4	pond	Aquatic communities	Chronic	0.2	25 m drift buffer zone	0.163	1.2	2-3
D4	stream	Aquatic communities	Chronic	2.0	25 m drift buffer zone	0.84	2.3	2-3
D5	pond	Aquatic communities	Chronic	0.2	25 m drift buffer zone	0.158	1.3	2-3
D5	stream	Aquatic communities	Chronic	2.0	25 m drift buffer	0.969	2	2-3

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

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
					zone			
D6	ditch	Aquatic communities	Chronic	0.2	25 m drift buffer zone	0.797	0.25	2-3
R1	pond	Aquatic communities	Chronic	0.2	25 m drift buffer zone	0.592	0.34	2-3
R1	stream	Aquatic communities	Chronic	2.0	25 m drift buffer zone	22.94	0.08	2-3
R2	stream	Aquatic communities	Chronic	2.0	25 m drift buffer zone	15.095	0.13	2-3
R3	stream	**Aquatic communities**	Chronic	2.0	25 m drift buffer zone	3.835	0.52	2-3
R4	stream	**Aquatic communities**	Chronic	2.0	25 m drift buffer zone	54.605	0.04	2-3
D3	ditch	Aquatic communities	Chronic	0.2	50 m drift buffer	0.395	0.50	2-3
D4	pond	Aquatic communities	Chronic	0.2	50 m drift buffer	0.0999	2	2-3
D4	stream	Aquatic communities	Chronic	2.0	50 m drift buffer	0.433	4.6	2-3
D5	pond	Aquatic communities	Chronic	0.2	50 m drift buffer	0.0955	2	2-3
D5	stream	Aquatic communities	Chronic	2.0	50 m drift	0.497	4	2-3

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

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
					buffer			
D6	ditch	Aquatic communities	Chronic	0.2	50 m drift buffer	0.42	0.47	2-3
R1	pond	Aquatic communities	Chronic	0.2	50 m drift buffer	0.552	0.38	2-3
R1	stream	Aquatic communities	Chronic	2.0	50 m drift buffer	22.94	0.08	2-3
R2	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer	15.095	0.13	2-3
R3	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer	3.835	0.52	2-3
R4	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer	54.605	0.04	2-3
D3	ditch	Aquatic communities	Chronic	0.2	25 m drift buffer and DRN	0.193	10	2-3
D4	pond	Aquatic communities	Chronic	0.2	25 m drift buffer and DRN	0.044	4.5	2-3
D4	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	0.213	9.4	2-3
D5	pond	Aquatic communities	Chronic	0.2	25 m drift buffer and DRN	0.040	5	2-3

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

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
D5	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	0.242	8	2-3
D6	ditch	Aquatic communities	Chronic	0.2	25 m drift buffer and DRN	0.216	0.92	2-3
R1	pond	Aquatic communities	Chronic	0.2	25 m drift buffer and DRN	0.517	0.38	2-3
R1	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	22.94	0.08	2-3
R2	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	15.095	0.13	2-3
R3	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	3.835	0.52	2-3
R4	stream	Aquatic communities	Chronic	2.0	25 m drift buffer and DRN	54.605	0.04	2-3
D3	ditch	Aquatic communities	Chronic	0.2	50 m drift buffer and drainage	0.099	2	2-3

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

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
D4	pond	Aquatic communities	Chronic	0.2	50 m drift buffer and drainage	0.0283	7	2-3
D4	stream	Aquatic communities	Chronic	2.0	50 m drift buffer and drainage	0.112	18	2-3
D5	pond	Aquatic communities	Chronic	0.2	50 m drift buffer and drainage	0.0239	8.4	2-3
D5	stream	Aquatic communities	Chronic	2.0	50 m drift buffer and drainage	0.124	16	2-3
D6	ditch	Aquatic communities	Chronic	0.2	50 m drift buffer and drainage	0.122	1.6	2-3
R1	pond	Aquatic communities	Chronic	0.2	50 m drift buffer and drainage	0.507	0.39	2-3
R1	stream	Aquatic communities	Chronic	2.0	50 m drift buffer and drainage	22.94	0.08	2-3
R2	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer and drainage	15.095	0.13	2-3

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

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg a.s./L)	Buffer zone distance	PECsw (µg a.s./L)	TER	Annex VI trigger
R3	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer and drainage	3.835	0.52	2-3
R4	stream	**Aquatic communities**	Chronic	2.0	50 m drift buffer and drainage	54.605	0.04	2-3

Bioconcentration					
	Acetochlor	Norchloro acetochlor	Acetochlor sulfinil acetic	Acetochlor sulfonic acid	Acetochlor Oxanilic acid
$logP_{O/W}$	4.14	3.0	2.1	1.2	2.2
Bioconcentration factor (BCF) ‡	20				
Annex VI Trigger for the bioconcentration factor	1000				

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)
Acetochlor	> 100 a.s.	> 200 a.s.
Preparation WF-2061 (68.6% w/w as)	> 116 a.s.	> 200 a.s.
Preparation MON 69447	>153 a.s.	> 154 a.s.
t-oxanilic acid	>86.9 a.s	> 92.3 a.s.
t-sulfinylacetic	> 91.6 a.s.	> 93.9 a.s.
t-sulfonic	> 95.1 a.s.	> 93.5 a.s.
s-sulfonic	> 86.7 a.s.	> 92.1 µg a.s.
Field or semi-field tests		

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Not required		

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

Crop and application rate: Maize at 2.016 kg Acetochlor /ha.

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	13.9	50
a.s.	oral	> 20	50
WF-2061	Contact	10.8	50
WF-2061	oral	17.4	50
MON 69447	Contact	13.09	50
MON 69447	oral	13.1	50
t-oxanilic acid	Contact	< 22	
t-oxanilic acid	oral	< 23.2	
t-sulfynylacetic	Contact	< 21.5	
t-sulfynylacetic	oral	< 22	
t-sulfonic	Contact	< 21.5	
t-sulfonic	oral	< 21.2	
Sec-sulfonic	Contact	< 21.9	
Sec-sulfonic	oral	< 23.2	

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	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri	GF-675	Mortality	831 a.s
Aphidius rhopalosiphi	GF-675	Mortality	156 a.s
P. cupreus	GF 675	Mortality	M= 0% at 2000 g a.s./ha
Chrysoperla carnea	GF 675	Mortality	M= 0% at 2000 g a.s./ha

Crop and application rate: Maize at 2.016 kg Acetochlor /ha.

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

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
GF-675	*Typhlodromus pyri*	831 a.s.	2.42	0.0065	2
GF-675	*Aphidius rhopalosiphi*	156 a.s	12.8	0.35	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
Aphidius rhopalosiphi	adults	MON 69447	0.084 2100	Mortality	M = 0.0%, R = 0.86 M = 20 %, R = 0.59	50 %
Aphidius rhopalosiphi	adults	GF-675	Rate response	Mortality	LR_{50} > 2000, P=0.43 at highest dose	50 %
Typhlodromus pyri	adults	MON 69447	0.084 2100	Mortality	M = 23.0%, R = 1.09 M = 17.0%, R = 1.00	50 %
Typhlodromus pyri	adults	GF-675	Rate response	Mortality	LR_{50}=1691, R=46.9% at 250g a.s/ha R=57.6% at 500 g a.i/ha	50 %
Aleochara bilineata	adults	GF-675	2.0	Mortality	M = 18.7%, P = 2.1% reduc. M = 22.5%, P = 3.0% reduc	

[1] indicate whether initial or aged residues M = corrected mortality, R = reproductive capacity, F = feeding capacity, P = reduction in parasitism rate
[2] for preparation indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
No data available

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

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia foetida	Acetochlor	Acute 14 days	LC_{50corr} 105.5 mg a.s./kg d.w.soil
	a.s. ‡	Chronic	Not required
Eisenia foetida	MON69447	Acute 14 days	LC_{50} 221 mg a.s./kg d.w.soil
	Preparation	Chronic 8 weeks	
	oxanilic acid	Acute 14 days	-LC_{50corr} > 500 mg /kg soil
	t-sulfinylacetic acid	Acute 14 days	LC_{50corr} > 500 mg /kg soil
	t-sulfonic acid	Acute 14 days	-LC_{50} > 500 mg /kg soil
	s-sulfonic acid	Acute 14 days	LC_{50} > 800 mg /kg soil
	t-oxanilic acid	Chronic	NOEC (correc)= 3.39 mg a.s./kg soil
	t-sulfinylacetic acid	Chronic	NOEC (correc)= 3.44 mg a.s./kg soil
	t-sulfonic acid	Chronic	NOEC = 3.71mg a.s./kg soil
	s-sulfonic acid	Chronic	NOEC = 10.5 mg a.s./ Kg soil
Other soil macro-organisms: no data available			
Soil micro-organisms. Maximum application rate			
Nitrogen mineralisation	GF-675		< 25% at 1× (=2 kg a.s./ha) and 5× (=10 kg a.s./ha) Maximum application dose rate ; 100 DAT
	MON 69447		< 25% at 2× Maximum application dose rate (equivalent to 2.11 Kg a.s./ha) ; 28 DAT
	t-sulfinylacetic		< 25% at 1x and 5x their expected peak concentration in soil (equivalent to 0.689 mg/kg dry soil and 5 x), 28 DAT

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

Test organism	Test substance	Time scale	End point[1]
	t-sulfonic acid		< 25% at 1x and 5x their expected peak concentration in soil (equivalent to appl. rate of 0.410 mg/kg dry soil and 5x), 28 DAT
	t-oxanilic acid		< 25% at 1x and 5x their expected peak concentration in soil (equivalent to appl. rate of 0.517 mg/kg dry soil and 5X), 28 DAT
Carbon mineralisation	GF-675		< 25% at 1× and 5× Maximum application dose rate (equivalent to 2 and 10 Kg a.s./ha , respectively); 100 DAT
	MON 69447		< 25% at 2× Maximum application dose rate (equivalent to 2.11 Kg a.s./ha) ; 28 DAT
	t-sulfinylacetic		< 25% at 1x their expected peak concentration in soil (equivalent to 0.689 mg/kg dry soil and 5 x), 28 DAT
	t-sulfonic acid		< 25% at 1x and 5x their expected peak concentration in soil (equivalent to appl. rate of 0.410 mg/kg dry soil and 5X) , 28 DAT
	t-oxanilic acid		< 25% at 1x and 5x their expected peak concentration in soil (equivalent to appl. rate of 0.517 mg/kg dry soil and 5X), 28 DAT
Field studies Litter bag study: The three acetochlor metabolites t-oxanilic acid (MON 52755), t-sulfinylacetic acid (MON 52709) and t-sulfoni acid (MON 52754) had no detrimental effect on the breakdown of straw in soil at the maximum expected soil concentrations if acetochlor is applied according with the GAP. Not required			

[1] indicate where end point has been corrected due to log P_{OW} > 2.0

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

Toxicity/exposure ratios for soil organisms

Crop and application rate: Maize at 2.016 kg Acetochlor /ha.

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
Eisenia foetida	a.s. ‡	Acute	2.81	37	10
	a.s. ‡	Chronic			5
	Preparation	Acute			10
	Preparation	Chronic			5
	t-oxanilic acid (2)	Acute	0.470	1063	10
	t-oxanilic acid (2)	Chronic	0.470	7.2	5
	t-sulfinylacetic acid (3)	Acute	0.637	784	10
	t-sulfinylacetic acid (3)	Chronic	0.637	5.40	5
	t-sulfonic acid (7)	Acute	0.386	2590	10
	t-sulfonic acid (7)	Chronic	0.386	14.2	5
	s-sulfonic	Acute	0.262	3053	10
	s-sulfonic	Chronic	0.262	40	5

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

Exposure type	**Deterministic approach (g a.s./ha)**	**5th centile from SSD (g a.s./ha)**	**Initial maximum exposures based on spray drift in areas adjacent to applied fields (g a.s./ha)[1]**					
			No drift reduction			**Drift reduction nozzles**		
			1 m	**5 m**	**10 m**	1 m	5 m	10 m
Pre-emergent[2]	64	11.45	55.8	11.5	5.85	9.49	1.95	0.994
Post-emergent[3]	207	20	56.1	11.5	5.85	9.49	1.95	0.994

[1] Initial maximum exposures based on the application rate of 2.016 kg acetochlor/ha. Shaded initial maximum exposure values based on spray drift give TER values greater than 1.
[2] The effect of pre-emergence exposure is based on species sensitivities for shoot dry weight from seedling emergence studies.

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

[3] The effect of post-emergence exposure is based on species sensitivities for shoot dry weight from vegetative vigor studies.

The lowest 5th centile LR_{50} used in the risk assessment was 11.45 g a,s/ha in the pre-emergence type. The initial maximum exposure based on the spray drift areas was 11.5 g a.s./ha. The 5th centile of 11.45 g as/ha based on seeding emergence is greater than the maximum predicted exposure at 10 m from treated field edges TER >1.

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

No field studies available

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

Test type/organism	Endpoint
Activated sludge	The EC_{50} was above the limit of solubility in water >1000 mg/L. Acetochlor has low toxicity to the respiration of activated sludge.
Pseudomonas sp	No data available

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

Compartment	
soil	Acetochlor
water	Acetochlor
sediment	Acetochlor
groundwater	Acetochlor

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,

	RMS/peer review proposal
Preparation	N R 50/53,

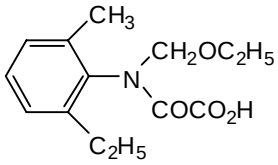
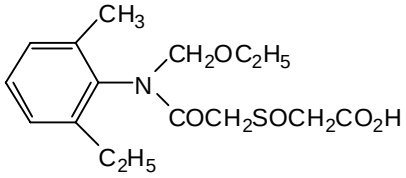
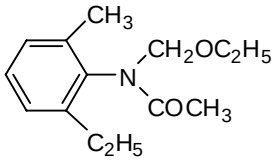
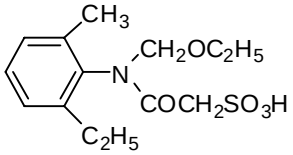
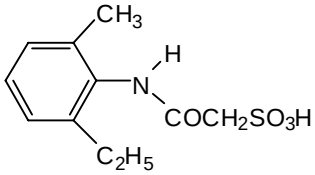
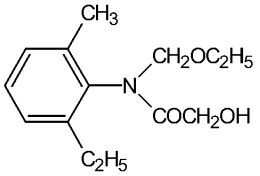
‡ Endpoints identified by EU-Commission as relevant for Member States when applying the Uniform Principles

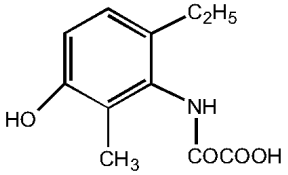
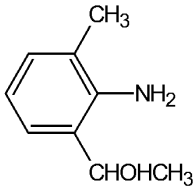
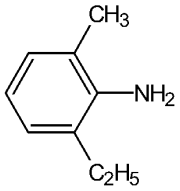
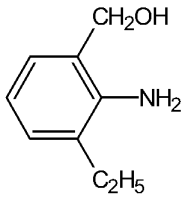
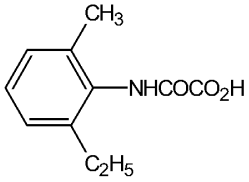
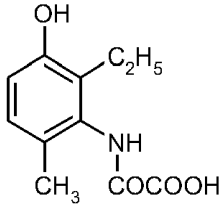
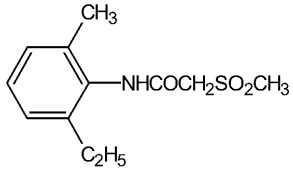
APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

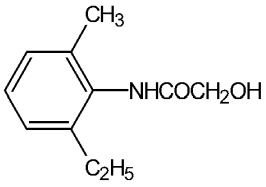
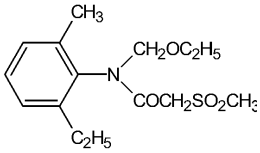
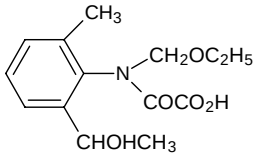
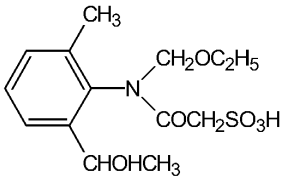
ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry

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

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
t-oxanilic acid (2) R290130, compound 17, MON 52766, ICIA5796/17	[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino](oxo)acetic acid	
t-sulfinylacetic acid (3) thioacetic acid sulphoxide, acetochlor thioacetate, R243797,Compound 48, MON 52709, ICIA5796/48	({2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethyl}sulfinyl)acetic acid	
t-norchloro acetochlor (6) des-chloro acetochlor, acetochlor NCA, R243661 Compound 31 R243661 MON 52706, ICIA5796/31, CP101592	*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	
t-sulfonic acid (7) R290131 Compound 24, MON52754, ICIA5796/24	2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid	
s-sulfonic acid (13) Compound 32 CP 92428	2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid	
t-hydroxy acetochlor (17) Compound 20 CP 68365-3	*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)-2-hydroxyacetamide	

N-oxamic acid (68) Compound 57 1 of 2 components of PJ2,	[(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid	
HEMA (33) CP109703	2(1-hydroxyethyl)-6-methylaniline	
EMA (34) Compound 52 CP 68594	2-ethyl-6-methylaniline	
HMEA (32) CP 105966	2-hydroxymethyl-6-ethylaniline	
s-oxanilic acid (12) Compound 27 CP 91301	[2,6-dimethylphenyl)amino](oxo)acetic acid	
Metabolite 69 (69) Compound 55 ICIA5676/55	[(2-ethyl-3-hydroxy-6-methylphenyl)amino](oxo)acetic acid	
s-amide methyl sulfone (10) Compound 14 ICIA5676/14	2-methylsulfonyl-N-(2-ethyl-6-methylphenyl)acetamide	

s-hydroxy (11) Compound 6	2-hydroxy-N-(2-ethyl-6-methylphenyl)acetamide	
t-amide methyl sulfone (16) Compound 12	2-methylsulfonyl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide	
hydroxyethyl-*t*-oxanilic acid (30)	N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]oxamide	
Sulfonic acid 2 (24)	2-sulfonyl-N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]acetamide	
t-amide cysteine (56) Compound 44	2-cystein-S-yl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide