CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance acetochlor[1]

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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[3] as amended by Commission Regulation (EC) No. 1095/2007. This Regulation required 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 European Commission.

Spain being the designated rapporteur Member State submitted the DAR on acetochlor in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, 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 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 the EFSA Conclusion finalised on 31 July 2008 (EFSA Scientific Report (2008) 153)

Following the Commission Decision of 05 December 2008 (2008/934/EC)[4] concerning the non-inclusion of acetochlor in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants made a resubmission application for the inclusion of acetochlor in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/20085. The resubmission dossier included further data in response to the issues and concerns identified in the DAR leading to the decision on non-inclusion.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Spain being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 22 April 2010.

[1] On request from the European Commission, Question No EFSA-Q-2010-01022, issued on 15 April 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L 224, 21.08.2002, p. 25
[4] OJ L 246, 21.09.2007, p.10
[5] OJ L 15, 18.01.2008, p.5

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In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicants for comments on 26 April 2010. The EFSA collated and forwarded all comments received to the Commission on 9 June 2010.

The collated comments were also forwarded to the RMS for compilation in the format of a Reporting Table. The applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the European Commission requested the EFSA to conduct a focussed peer review in the area of mammalian toxicology, residues, fate and behaviour and ecotoxicology and deliver its conclusions on acetochlor.

The conclusion of the resubmission was reached on the basis of the evaluation of the representative uses as a herbicide on maize as proposed by the applicant. Full details of the GAP can be found in Appendix A.

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

Residues in food of plant origin are analysed using a common moiety method by LC-MS/MS, data gaps have been identified for validation of the extraction and hydrolysis steps for each metabolite and ILV for the method. Consequently, no valid method is available to quantify residues in food of plant origin. For products of animal origin a method is not required as no MRLs are proposed.

For soil a LC-MS/MS method is available that analyses for acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) and s-sulfonic acid (13).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 quality control measurements of the plant protection product are possible.

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. Based on the findings in the 52-week study in dog the risk phrase **R48/22 "Harmful: danger of serious damage to health by prolonged exposure if swallowed"**. 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), s-sulfonic acid (13) and t-norchloro acetochlor (6) were considered toxicologically relevant taking into account the limited information available and the carcinogenic potential of the parent compound. The reference values of acetochlor are applicable to the plant metabolite N-oxamic acid (68).

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 and coverall during mixing/loading and application, and sturdy footwear during application. 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 tractors and gloves during mixing/loading and coverall during application.

Metabolism of acetochlor was studied in maize plants upon pre-emergence and post-emergence application. Acetochlor was seen to be extensively metabolised, the residues being composed of numerous individual metabolites of which, more than 30 were identified, each accounting for less than 3% of the TRR. The residue definitions were therefore extensively discussed during the PRAPeR 20 and the teleconference TC46 and it was finally agreed to define the residue for monitoring as "all compounds forming EMA (34) and HEMA (33) on hydrolysis expressed as acetochlor", considering that the common moieties method developed by the applicant is able to take into account a significant part of the residues. The N-oxamic acid (68) metabolite was added to the EMA and HEMA forming metabolites, in the residue definition for risk assessment and a conversion factor of 2 was proposed for the consumer risk assessment. These residue definitions are also relevant to assess the residues in rotational crops.

Supervised trials confirmed that residues in maize grains, when analysed for EMA and HEMA, are below the limit of quantification. Inversely, significant residues were detected in maize forage. Based on the different ruminant metabolism studies, it was concluded that no residues are expected to be present in animal matrices when considering the intakes resulting from the residues present in maize forage and maize grains. Therefore, the setting of a residue definition and MRLs for products of animal origin was considered not necessary.

No chronic or acute risks were identified when the consumer exposures to food commodities are calculated using the EFSA PRIMo Model and the MRL proposed for maize grains and oil seeds. However, it must be highlighted that the potential consumer exposure exceeds the ADI value in many scenario, when the predicted concentrations of the ground water metabolites are considered. In addition, intakes for toddlers and infants resulting from the water consumption are at times above the threshold value of 20% ADI recommended by the WHO, when calculations are conducted using the concentrations measured in a monitoring program conducted in Northern Italy.

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 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) and t-norchloro acetochlor (6) exhibit very high mobility in soil. There was no indication that adsorption of either acetochlor or these 5 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, CO_2, 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 and runoff mitigation being applied at

step 4. These exposure assessments as required for metabolites were completed at steps 1-2.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. A data gap is identified for the stability of the metabolites t-norchloroacetochlor (6) and t-hydroxyacetochlor (17) in stored frozen groundwater samples. These data are required to finalise the groundwater exposure assessment for these two metabolites.

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 the suggested PD and PT values to refine the long-term risk to herbivorous birds were assessed and considered as not supported by the submitted data. The refined risk assessment for insectivorous birds based on crested lark (*Galerida cristata*) was agreed by the meeting. The risk from consumption of contaminated water was assessed as low for mammals.. It was agreed in the expert meeting, that the risk to mammals is low. However a high acute risk was indicated 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 N-oxamic acid (68) and for metabolite 3 (t-sulfinylacetic 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 unidentified residues in the residue trials (up to 39% of TRR) and one of the unknown compounds exceeded the threshold of 10% of TRR. The risk from plant metabolites to herbivorous birds was addressed in the additional report.

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 water bodies. 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 water bodies should be used in the risk assessment together with an assessment factor of 2-3. No FOCUS step 4 scenario resulted in a TER exceeding the trigger of 2 even when no-spray buffer zones of 20m and vegetated filter strips of 20m were applied to mitigate the risk. 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 arthropod 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 re-colonisation 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, soil macro-organisms, 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[6], as amended by Commission Regulation (EC) No 1095/2007[7] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request European Commission a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State. Acetochlor is one of the 79 substances of the third stage, part A of the review programme covered by the Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007 designating Spain as rapporteur Member State (RMS).

In accordance with the provisions of Article 10(1) of the amended Regulation (EC) No 1490/2002, 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 11(2) of the Regulation (EC) No 1490/2002 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 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 the EFSA Conclusion finalised on 31 July 2008 (EFSA Scientific Report (2008) 153, 1-13)

Following the Commission Decision of 05 December 2008 (2008/934/EC)[8] concerning the non-inclusion of acetochlor in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants made a resubmission application for the inclusion of acetochlor in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[9]. The resubmission dossier included further data in response to the issues and concerns identified in the DAR and the EFSA conclusion.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Spain being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Spain 2010). The Additional Report was received by the EFSA on 22 April 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 26 April 2010. The EFSA collated and forwarded all comments received to the European Commission on 9 June 2010.

[6] OJ L224, 21.08.2002, p.25
[7] OJ L246, 21.9.2007, p.19
[8] OJ L 333, 11.12.2008, p- 11
[9] OJ L 15, 18.01.2008, p.5

The collated comments were also forwarded to the RMS for compilation in the format of a Reporting Table. The applicants were invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicants' response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report and the comments received, the European Commission decided to further consult the EFSA. By written request, received by the EFSA on 15 July 2010, the European Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on acetochlor within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicants in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicants in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the European Commission on 14 July 2010; the applicants were also invited to give their view on the need for additional information. On the basis of the comments received, the applicants' responses to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology, residues, fate and behaviour and ecotoxicology and that further information should be requested from the applicant in the areas of residues and fate and behaviour.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in March-April 2011.

The conclusion from the original review was reached on the basis of the evaluation of the representative uses as presented in the DAR. The conclusion of the peer review of the resubmission was reached on the basis of the evaluation of the same representative uses. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A.

The documentation developed during the resubmission peer review was compiled as a Peer Review Report (EFSA, 2011) comprising the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's Additional Report:

- the comments received
- the resulting reporting table (rev. 1-1, 7 July 2010)
- the evaluation table (13 April 2011)
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the Additional Report including its addendum (compiled version of January 2011 containing all individually submitted addenda; Spain, 2011) 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 documents of the Peer Review Report (EFSA, 2007) and the final addendum (Spain, 2007) developed and prepared during the course of the initial review process are made publicly available as

part of the background documentation to the original conclusion finalised on 31 July 2008 (EFSA, 2008)

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Acetochlor 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 was demonstrated in the resubmission that these isomers are thermally stable and as such they must be considered in 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), respectively. The representative uses are as a herbicide on maize, for full details of the GAP please refer to Appendix A.. It is always used together with the safener dichlormid (N,N-diallyl-2,2-dichloracetamide), which significantly improves crop tolerance.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of acetochlor as manufactured should not be less than 940 g/kg. Acetochlor is a racemic mixture of rotational isomers (atropisomers or axial isomers). 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).

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.

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

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 and the relevant impurities in the technical material and in the representative formulation as well as for the determination of the significant impurities in the technical material.

Therefore, enough data are available to ensure that quality control measurements of the plant protection product are possible.

Residues in food of plant orrigin are analysed using a common moiety method by LC-MS/MS, data gaps have been identified for validation of the extraction and hydrolysis steps for each metabolite and ILV for the method. Consequently, no valid method is available to quantify residues in food of plant origin.For products of animal origin a method is not required as no MRLs are proposed.

For soil a LC-MS/MS method is available that analyses for acetochlor, t-oxanilic acid (2), t-sulfonic acid (7), t-sulfinylacetic acid (3) and s-sulfonic (13). 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 toxicity

The following guidance documents were used in the production of this conclusion: SANCO/221/2000 rev. 10 (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004b) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009b).

Acetochlor was discussed during the PRAPeR 19 (round 4, March 2007) and the PRAPeR 83 (round 20, October 2010) expert meetings.

Based on the information provided in the Additional Report and previous addenda to Volume 4, the complete specification of the batches used in the toxicological studies is not available, but the weight of evidence suggests that they are representative of the proposed technical specification.

The impurities ECA (classified as T; R23/24/25) and EMA (due to the fact that it plays a role in the nasal tumour formation and the experts agreed that nasal tumour formation can be relevant to humans, see 2.5) are considered toxicologically relevant.

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 low and high 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 re-evaluation of the 2-year rat study by Broadmeadow, the femoral tumors were confirmed as cartilaginous hyperplasia and not neoplasms. Gastric neoplasms in the forestomach at the high dose level (67 mg/kg bw/d) were diagnosed as squamous cell carcinomas, above historical control data, and were considered relevant findings.

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 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 (using lower doses). The occurrence of tubular basophilia at the low dose, above historical control data and accompanied by an increased kidney weight, 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 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 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 tumours observed in both species, the meeting agreed to propose the classification **Carc. cat.3, R40 Limited evidence of a carcinogenic effect**.

2.6. Reproductive toxicity

Three 2-generation studies in rats are presented in the DAR (two were considered as not 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 tumours 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 tumours in rats through increased hepatic conjugation and compensatory thyroid hyperplasia and ultimately neoplasia.

Studies on metabolites:

Assay	Species	Result
t-oxanilic acid (2)		
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
Teratogenicity study	Rat	maternal NOAEL 500 mg/kg bw/d develop. NOAEL 1000 mg/kgbw/d
t-sulfinylacetic acid (3)		
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)		
In vitro gene mutation	Bacterial cells	doubtful results in first assay
In vitro gene mutation	Mouse lymphoma cells	positive

Assay	Species	Result
In vitro chromosome aberrations	Human lymphocytes	negative (+/-S9)
In vivo chromosome aberrations	Mouse (micronucleus test)	negative
t-sulfonic acid (7)		
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)		
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)		
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
28-day oral toxicity	Rat	NOAEL 1142 mg/kg bw/d (top dose)

Conclusion for the groundwater/surface water / plant metabolites:

Toxicokinetic studies with rats and mice were also provided for the metabolites t-oxanilic acid (2) and t-sulfonic acid (7), technically produced as a racemic mixture, showing a lower oral absorption and no distribution in the nasal tissue. These two metabolites were rapidly excreted, mainly unchanged (min 75% as parent, though isomer ratios were not reported). For all groundwater metabolites, the contribution of each rotamer to the toxicological profile of the mixture has not been quantified. Based on all data available, the experts in PRAPeR 83 agreed that the reference values of acetochlor would be applicable to the groundwater metabolites t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7) and s-sulfonic acid (13) (provided they are present with an isomer ratio of 1:1). However, due to the carcinogenic properties of acetochlor, they have to be considered as toxicologically relevant groundwater metabolites. Similarly, the groundwater metabolite t-norchloro acetochlor (6) is also toxicologically relevant based on its genotoxic (see table above) and carcinogenic potential (from acetochlor), and no reference values were agreed.

N-oxamic acid (**68**) is a plant metabolite not found in the rat metabolism. Based on the available toxicological data (see table above), showing a lower acute and subacute toxicity than acetochlor, the experts in PRAPeR 83 agreed to apply the reference values of 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) 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, an 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') 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 crops.

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 and coverall during application.

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	3150	-	-	-	-	131
UK POEM (100L dilution)	35550	-	5550	-	-	-
UK POEM (400L dilution)			1435			
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 recalculations 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, respectively) according to data from Lloyd and Bell[10] (1983).

3. Residues

The conclusion in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), and the recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

In the course of the initial peer-review, acetochlor was discussed in the meeting of experts for residues in March 2007 (PRAPeR 20) on the basis of the Draft Assessment Report of March 2005. Following the non-inclusion decision, additional studies were provided and evaluated in the Additional Report of April 2010, in order to support the re-submission of the active substance according to the Commission Regulation (EC) No 33/2008. After submission of the Additional Report, an experts' teleconference meeting took place in November 2010 (TC 46), the discussions being focussed on the plant residue definition.

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

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

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 initially investigated in maize upon **pre-emergence** application. In addition and as requested following the first peer review, a new metabolism study using **post-** and **pre-emergence** applications was provided and evaluated in the AR of April 2010.

- The pre-emergence study provided in the framework of the first peer review was conducted on maize 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 metabolism of acetochlor in the plants was investigated until maturity. Acetochlor was extensively metabolised and 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 collected 105 days after application was low (0.07 mg/kg). Only a few metabolites could be identified, such as *t*-oxanilic acid (2) and *s*-oxanilic acid (12) (together *ca* 5% TRR), N-oxamic acid (68) (*ca* 9% 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 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. Considering this insufficient level of identification, the experts in the PRAPeR 20 meeting concluded that a new metabolism study should be required to address the residue profile in maize plants (forage, fodder). Moreover, as acetochlor is recommended for both, pre-emergence and early post-emergence uses (up to BBCH 16), a metabolism study supporting this use pattern is necessary.

As required, a new metabolism study conducted in maize and involving either pre-emergence or post-emergence treatment was provided and assessed in the AR of April 2010. The study was conducted on maize grown outdoor, at a dose rate of 3360 g a.s./ha (1.7N), the post-emergence treatment taking place at growth stage BBCH 16-17 (6-7 leaves), 41 days after the pre-emergence application. Total radioactive residues in sweet corn and mature grains were low (0.01 to 0.04 mg/kg). Inversely, significant TRRs were measured in forage and stover, the levels being higher upon post-emergence treatment (3.45 and 6.41 mg/kg) than after pre-emergence (0.67 and 1.84 mg/kg). Most of the radioactivity was extractable by mean of solvents (*ca* 60% in grain, 80% in other matrices). Chromatographic analysis showed the different plant extracts to be composed of a multiple number of individual fractions, confirming a very extensive metabolism of acetochlor in maize plant. More than 50 individual compounds were characterised, of which, more than 30 were identified, each accounting for less than 3% TRR, except the *t*-sulfonic acid (7) and the N-oxamic acid (68) metabolites that represented 3 to 6% of the TRR in the pre-emergence forage and stover samples, and the *s*-sulfinylacetic acid free and glucose conjugate and the *t*-sulfinyllactic acid (21) that accounted for 3%

to 12% TRR in the post-emergence forage and stover samples. This new metabolism study confirmed the presence of previously identified metabolites, in addition to a number of supplementary ones.

These metabolism studies allow to propose the following metabolism pathway:

- Following post emergence application, the metabolism proceeds mainly by an initial conjugation with the glutathione to give the *t*-cysteine conjugate (56) which undergoes further oxidations leading to the *t*-amide methyl sulfoxide (15), *t*-amide methyl sulfone (16) metabolites and to the *t*-sulfinyllactic metabolites (21). Further metabolites are then formed by combination of dealkylation, oxidation, hydroxylation or conjugations. A secondary pathway involves the formation of the *t*-hydroxyacetochlor (17) which undergoes further transformations to the *s*-oxanilic acid (12), *s*-hydroxy (11) metabolites.
- Although the primary pathway occurring via the initial glutathione conjugation described above is also a significant pathway following pre-emergence application, the uptake of the major soil metabolites *t*-oxanilic acid (2) and *t*-sulfonic acid (3), result in a different metabolite distribution, where the *t*-oxanilic acid derivative metabolites are the most abundant.

In conclusion, even if seen to be very extensive for the two different application patterns with more than 10 common metabolites, the metabolism profiles appear to be slightly different, the oxanilic acid metabolites being predominant following pre-emergence application, as the result of the uptake of main soil metabolites, whereas the sulfinyl acid metabolites resulting from the glutathione conjugation appear to be major following post-emergence application.

Given the complexity of the metabolic picture the applicants tried to investigate common moiety methods that could take into account structurally related metabolites. Acid hydrolysis techniques indicated that a large part of the radioactive residues was converted to the common chemophore analytes; EMA (34), HEMA (33), HMEA (32) and 5-OH aniline. In the post-emergence samples, up to 64% of the radioactive residues were converted to EMA in stover, up to 11% to HEMA in grain and less than 1% to HMEA and 5-OH aniline. In the pre-emergence samples, up to 28% (forage), 21% (grain) and 12% (forage) of the radioactive residues were converted to EMA, HEMA and 5-OH aniline respectively, the HMEA related radioactivity accounting for less than 3%. Globally, irrespective of the application pattern, this hydrolysis study shows that 37 to 49%, 35 to 72% and 25 to 33% of the residues can be converted to EMA and HEMA in maize forage, stover and grain respectively. An analytical method for the quantification of acetochlor in maize was therefore developed where the plant metabolites of acetochlor are analysed as EMA and HEMA under alkaline hydrolysis conditions. This method does however not apply to the N-oxamic acid (68) metabolite.

Faced with the complexity of the metabolic picture and the toxicological properties of parent acetochlor (potential carcinogenicity), the plant residue definition was extensively discussed by the experts in the PRAPeR 20 meeting, but also during the teleconference TC 46 in the course of the resubmission.

- **For monitoring**, different options were examined. The proposals where the residue definition is limited to the parent acetochlor or to the N-oxamic acid (68) metabolite were considered not appropriate, as these two compounds cannot be considered as relevant markers for the residues. Acetochlor is extensively metabolised and therefore no longer present in plant, and N-oxamic acid (68) alone accounted for less than 1.5% TRR in forage and stover samples after post emergence application, and for only 6% TRR under pre-emergence application. Moreover, the data from the supervised residue trials confirm that acetochlor and N-oxamic acid (68) are almost not present in maize forage or maize grain. As a common moieties method where a significant part of the residue can be degraded and analysed as EMA and HEMA after alkaline hydrolysis is available, it was agreed to define the residue for monitoring as “all compounds forming EMA and HEMA on hydrolysis expressed as acetochlor”. It must however be noted that EMA and HEMA are not specific to acetochlor. These moieties can also result from the hydrolysis of other chloroacetanilide compounds such as propisochlor and metolachlor.

- **For risk assessment**, the definition initially proposed during the PRAPeR 20 meeting as: "all compounds forming EMA plus HEMA on hydrolysis and N-oxamic acid (68) expressed as acetochlor", was confirmed during teleconference meeting TC 46. Based on the new pre-emergence metabolism study, a conversion factor of 2 was proposed, considering the total identified metabolites (34% TRR) and the total metabolites analysed as EMA/HEMA (19% TRR). It must be highlighted that this conversion factor is an overestimate since it includes all identified metabolites and not only EMA/HEMA and N-oxamic acid (68) as stated in the definition for risk assessment, but this worst case approach was considered necessary, having regard to the toxicological profile of the parent acetochlor (potential carcinogenicity, see section 2).

A total of 46 supervised residue field trials were provided, conducted on maize in several European countries in Northern and Southern Europe from 1996 to 2000 and representing a large range of climatic and agronomic conditions. Acetochlor formulated as CS and EC was applied at a dose rate ranging from 1890 to 2100 g/ha, either as pre-emergence or post-emergence (BBCH 14 to 18), in accordance with the critical GAP. All samples were analysed for the EMA and HEMA and additionally for acetochlor in most of the trials. A new storage stability study conducted with HEMA and EMA was received and evaluated in the Assessment Report of April 2010 in order to address the data gap identified in the course of the first peer review. These data confirm that HEMA and EMA residues are stable up to 315 days in maize matrices when stored in frozen conditions at -18°C. Storage conditions prior to analysis of the samples in the different residue studies were detailed in the addendum of December 2010 where it is stated that most of the analyses were performed 3 to 10 months after sampling, in compliance with the stability data. However some inconsistencies were observed in the assessment of these data and clarifications on the storage conditions are still required.

In all grain samples collected at maturity, EMA, HEMA and acetochlor residues were below the LOQs, irrespective of the application pattern. Inversely, significant EMA and HEMA levels were detected in the forage samples collected 77 to 161 days after application. Higher residue levels were observed for post-emergence application, up to 0.43 mg/kg for the sum HEMA+EMA, whereas the maximum level measured for pre-emergence application was only 0.10 mg/kg. The forage samples did not show residues above the LOQ when analysed specifically for acetochlor, except in one situation.

Concern was raised in the course of the first review regarding the possible levels of the N-oxamic acid (68) metabolite in maize, which was considered as not sufficiently addressed by the US trials evaluated in the DAR of March 2005. Eight additional trials conducted in Southern and Northern EU in 2005 were therefore submitted in the framework of the resubmission process to confirm that the N-oxamic acid (68) metabolite is not present in maize grain at harvest following post-emergence application of acetochlor at BBCH stage 14 to 16. In the same way, this metabolite was in most of the cases, not detected in immature plants (forage), except in some situations at a maximum level of 0.03 mg/kg.

No residue data were submitted to support the initially notified use in sweet corn. Therefore appropriate residue trials have to be required if authorisation on sweet corn is sought at 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 with radiolabelled acetochlor at slightly exaggerated rates of *ca* 1.7 and 1.5 N. Crops (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 (California), the TRRs reached significant levels in all crops and crop parts. The highest total levels were found at the intermediate planting interval (120/162 days). The highest TRR was found in wheat straw (2.76 mg/kg) and 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 (North Carolina), TRRs were consistently at least more than 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 field study performed was due to the watering practises and excess of rainfall compared to the laboratory study. 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.

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), s-hydroxy (11) and t-amide methyl sulfone (16), metabolites belonging to the EMA class metabolites. In cereal straw also hydroxyethyl-t-oxanilic acid (30) (HEMA metabolite) was a major metabolite. The N-oxamic acid (68) 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.

In conclusion, the metabolism of acetochlor in rotational crop plants produces an array of metabolites similar to those previously identified in the primary crop metabolism study.

In addition, numerous field studies conducted over several growing seasons, under diverse climatic and soil conditions throughout the USA in a total of 25 US states, were provided and partially evaluated in the addendum to the DAR of July 2006 and January 2007. Residue levels were investigated in cereals (wheat, oat, sorghum), soybean, sugar beet and potato, grown in rotation to a maize treated with acetochlor at an application rate of 3360 g/ha (1.7 N). Rotational crop samples were collected 150 to 530 days after the treatment on maize and analysed for EMA and HEMA. In addition, sugar beet and potato samples were also analysed for acetochlor and wheat, sorghum and soybean samples for the HMEA metabolites. The applicant explained that the HMEA class metabolites were analysed for, as two metabolites yielding HMEA were seen to be present in the soybean foliage (both, up to 13% TRR) in a metabolism study conducted on soybean in the early 1980's, but not submitted in the dossier.

At harvest, in mature plants, EMA and HEMA residue levels were always below the LOQ (0.01 or 0.02 mg/kg) in cereals grains, potato tubers and sugar beet roots and tops. HMEA and acetochlor, when analysed for, were also not detected in these commodities. However, detectable residues were observed in soya bean grain, in almost half of the locations, but in limited levels, up to 0.03 mg/kg for EMA and 0.07 mg/kg for HEMA, the HMEA levels being below the LOQ, except in one location (0.03 mg/kg). In contrast, significant residues were observed in immature feed commodities (forage) and in straw/hay collected at maturity. The residue levels observed for each of the 3 class metabolites were consistent with the conclusion of the confined rotational crop studies. EMA metabolites were the most abundant compound, detected in almost all the samples, up to 0.73 mg/kg, HEMA metabolites were detected in almost half of the samples, up to 0.3 mg/kg and HMEA metabolites were exclusively detected in the soya forage and hay, up to 0.15 mg/kg, but not in the cereal samples.

A concern was raised during the PRAPeR 20 expert meeting regarding the acceptability of these US rotational crop studies as no comparison to the EU climate was provided. Climatic data were submitted and evaluated in the Additional Report of April 2010, and it was concluded that the climatic

conditions in the majority of the sites where the US trials were conducted are comparable to the main EU maize growing regions. Given the wide distribution of soil types, of the climatic conditions and the large number of data submitted, EFSA is of the opinion that these US rotational crop trials cover the EU conditions and therefore that no additional data are required.

In conclusion, the data provided on rotational crops confirm that the residue definitions set for primary crops are also applicable to the rotational crops where the residues in food commodities are mainly composed of the EMA and HEMA class metabolites. HMEA metabolites were not detected in cereal grains or soya beans (except one situation out of 18) and its inclusion in the residue definition for risk assessment is therefore not relevant. No residues are expected in rotational crops except in oilseed/pulse crops, as total EMA and HEMA residues in soya beans were measured up to 0.10 mg/kg in crops grown in rotation with maize treated at a dose 3360 g/ha (1.7N). Residues above the LOQ (0.02 mg/kg) in pulse/oilseed crops grown in rotation with maize can not be excluded. Having regard to the residue levels observed in these overdosed trials, an MRL of 0.05* mg/kg would appear sufficient to accommodate residues that have the potential to be present in oilseeds when grown as following crops.

Significant EMA and HEMA residues are expected in feed commodities from crops grown in rotation to maize, (up to 0.10 mg/kg in cereal straw in the overdosed US trials), but the contribution of the residues present in rotational crops to the overall animal intakes, is already covered by the intake resulting from the residues in maize silage, that represents 100% of the ruminant diet.

3.2. Nature and magnitude of residues in livestock

When considering the residue levels in grain and silage resulting from the use of acetochlor on maize, significant residue intakes are expected by beef and dairy cattle and therefore a livestock study on ruminant is required. As the metabolism in maize was seen to be very extensive with a great number of metabolites identified, four different animal metabolism studies were submitted, conducted with different compounds, supposed to represent the vast majority of the metabolites identified in plant. The following studies were assessed in the DAR of March 2005 in order to investigate the metabolism in ruminant:

- One study in goat conducted with ^{14}C-acetochlor,
- One study in cow conducted with ^{14}C-N-oxamic acid (68),
- One study in goats conducted with ^{14}C-sulfonic acid 2 (Sodium salt), representative of the metabolites analysed as HEMA.
- One study in goat and with a mixture of the radiolabelled metabolites *t*-hydroxy acetochlor (17), sulfonic acid 2 (sodium salt of 24), *t*-oxanilic acid (sodium salt of 2) and *t*-sulfinyl acetic acid (sodium salt of 3) and representative of the metabolites yielding EMA.

It should be noted that acetochlor itself was not found as a component of the plant residues, and consequently, it may not be expected to be present in feed items. The metabolism study conducted with the parent acetochlor is therefore of subordinate importance. The three studies conducted with the N-oxamic acid (68) metabolite and with the compounds representative of the EMA and HEMA metabolites are more appropriate to evaluate the metabolism in animals and to propose a residue definition for animal commodities.

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 where no acetochlor was found. The major component identified in milk (19% TRR) and in urine (24% TRR) was t-amide cysteine (56). 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 the ruminant study, ^{14}C-N-oxamic acid 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 the 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) (representative for HEMA forming metabolites) was administered as sodium salt to lactating goats altogether at three different dose levels (0.5-5 mg/kg diet) for either 5 or 28 consecutive days. 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 representative of the EMA forming metabolites was administered to two lactating goats for five consecutive days. Again, the findings were consistent with those 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.

No residue definition for ruminant products was proposed following the 2005 review, as it was considered that the nature of the residues in plants has not been sufficiently investigated to estimate the intakes by animals and that information was missing on the residues levels in rotational crops. This point was not re-discussed in the framework of the resubmissions, but EFSA is of the opinion that the setting of a residue definition and MRLs for animal products is not necessary, based on the supported use on maize. When considering a maximum residue level of 0.86 mg/kg in maize silage (HR 0.43 mg/kg x CF 2), intakes are calculated to be 0.16 and 0.18 mg/kg bw for dairy and beef cattle respectively. Based on these intakes, the TRRs in the different animals matrices, expressed on a 1N rate basis, are expected to be less 0.003, 0.001 and 0.02 mg/kg when considering the metabolism studies conducted with the N-oxamic acid (68) metabolite and the compounds representative of the HEMA and EMA metabolites, respectively. Consequently, no individual compound is expected to be present in significant level in animal matrices and it is therefore concluded that MRLs for animal products are not required when considering the representative use on maize.

3.3. Consumer risk assessment

When considering solely the residue levels in food commodities resulting from the use of actetochlor, no chronic or acute consumer concern was identified The TMDI calculated using the EFSA PRIMo rev.2 model, the proposed MRLs for maize grain and for oilseeds as rotational crops and the conversion factor of 2 for risk assessment, is 11% of the ADI and the IESTI less than 0.1% of the ARfD. Having regard to these low intakes, the isomeric composition of the acetochlor residues in maize grain is considered of limited impact on the consumer risk assessment and therefore, no additional information on the possible selective degradation of the isomers in plants is required.

However, consumers might also be exposed to acetochlor residues through the consumption of water, as some metabolites are predicted to be present at significant levels (>0.75 µg/L) in ground water. Using the water consumption figures proposed by the WHO guideline (WHO, 2009), and the sum of the predicted levels of the metabolites *t*-oxanilic acid (2), *t*-sulfinyl acetic acid (3), *t*-sulfonic acid (7) and s-sulfonic acid (13), intakes from water are calculated to represent more than 100% of the ADI for infant and toddler in all of the Northern scenarios (up to 260%, Hamburg scenario) and for infants in two Southern scenarios. The assessment was performed using the sum of the predicted concentrations since it was agreed that the toxicological reference values of the parent acetochlor are also applicable to these four metabolites (see section 2.8). Moreover in three Italian sites, the intake for toddlers and infants resulting from the water consumption are yet above the threshold value of 20% ADI recommended by the WHO (up to 90%), when calculations are conducted using the concentrations measured for the metabolites (2), (3), (7) and (13) in a monitoring program conducted in Northern Italy in a total of 10 sites. In addition, it must be highlighted that these exceedences are estimated without accounting for the additional uncertainty on the risk characterisation resulting from the unknown isomeric composition of the ground water metabolites. Moreover, the groundwater metabolite *t*-norchloro acetochlor (6) that is considered toxicologically relevant and that could also leach into groundwater in amounts >0.1 µg/L or >0.75µg/L, respectively (refer to 4.2.2) has not been considered in the consumer risk assessment, since toxicological reference values were not agreed for this metabolite (refer to 2.8).

3.4. Proposed MRLs

Since most of the samples from the residue trials were analysed with an analytical method achieving a LOQ of 0.02 mg/kg for EMA and HEMA respectively (total LOQ 0.04 mg/kg), an MRL of 0.05* mg/kg is proposed for maize grain.

In addition, an MRL of 0.05* mg/kg would also be sufficient for oilseed crops, to accommodate residues that have the potential to be present in oilseeds when grown as following crops.

Based on the supported use on maize, the setting of MRLs for the products of animal origin is considered not necessary.

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) and teleconference 48 (December 2010). It should be noted that the methods of analysis used to quantify acetochlor and its transformation products in the fate and behaviour studies provided no information on the relative contribution of the two acetochlor isomers (rotamers) or breakdown products that may also consist of rotamers[11] to the total acetochlor or transformation product residues reported. Therefore all acetochlor or breakdown product residues reported in the fate and behaviour sections of the DAR, AR, addenda and this conclusion are for the sum of 2 isomers (rotamers) where these exist. In the context of the environmental risk assessment for parent acetochlor (that has a DT90 in laboratory incubations of < 96 days), sufficient evidence has been provided to conclude that there would not be significant change in the ratio of acetochlor

[11] this potentially includes t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-norchloro acetochlor(6), t-sulfonic acid (7) and s-sulfonic acid (13)

rotamers in the environmental matrices of soil and natural sediment water systems[12]. For the transformation products, the applicant provided an argumentation that information on exposure of individual rotamers was not necessary to conclude on the risk, as there were sufficient margins of safety in the risk assessments. This is discussed further in sections 5, 3.3 and 2.8. Note as indicated in section 3.3 this argumentation has not been accepted regarding the consumer risk assessment.

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[13]. Mineralisation to carbon dioxide accounted for only 11-15%AR after 84 days (carbonyl radiolabel) and 0.3-3.1%AR after 90 days (phenyl radiolabel). The formation of residues not extracted by acetonitrile 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)[14].

The major soil degradation products (> 10 %AR) were investigated in aerobic laboratory rate of degradation studies (20°C and pF2 (field capacity) soil moisture) where they were applied as test substances 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} 50-434 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. The minor soil degradation product t-norchloro acetochlor (6) (≤3.3%AR) was also investigated in 3 soils (20°C and 45% MWHC

[12] For a more detailed discussion of this evidence, please see the peer review report (EFSA, 2011), evaluation table for the resubmission application (13/04/2011), point of clarification for the applicant 4.3)
[13] 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).
[14] Normalisation carried using a Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7

soil moisture). It exhibited moderate to medium persistence with estimated single first-order DT_{50} values of 32-64 days (DT_{90} 106-212 d). Following normalisation to FOCUS reference conditions (20°C, pF2 (-10kPa)) this DT_{50} range becomes 28-47 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 t-sulfinylacetic acid (3) (see addendum for the RMS evaluation) a single first order DT_{50} of 5.3 days (DT_{90} 17d) was estimated, indicating more rapid degradation in anaerobic topsoil than in aerobic topsoil for this metabolite.

Four field dissipation studies from Europe 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.

In the resubmission application field dissipation studies were provided from 6 trial sites in the USA. In these studies analyses were made for acetochlor, t-oxanilic acid (2), t-sulfinylacetic acid (3) and t-sulfonic acid (7). Degradation DT_{50} (single first order, normalised to FOCUS reference conditions (20°C, pF2 (-10kPa) in accordance with FOCUS (2006) kinetics guidance[15]) and kinetic formation fractions were determined. The teleconference discussion of Member State experts agreed that it was appropriate for these endpoints from 4 of these trial sites to be used in FOCUS modelling simulations (Normalised DT50 range 5.3-24.4, 35-82.1, 54.9-131.8 and 48.6-164.6 days respectively). The reason for excluding two of the trial sites was that soil temperatures at these sites were higher than the temperature range for which the Q10 has been validated, so the normalisation procedure used was considered too uncertain.

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 A.

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_{Foc} 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_{Foc} 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_{Foc} 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.

[15] Normalisation carried using a Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7

The adsorption / desorption of t-sulfonic acid (7) was investigated in six soils. Calculated adsorption K_{Foc} values considered acceptable in 5 of these soils varied from 21-68 mL/g (mean 39 mL/g) indicating that 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_{doc} 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_{Foc} 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.

The adsorption / desorption of t-hydroxy acetochlor (17) was investigated in five soils. Calculated adsorption K_{doc} values varied from 55-95 mL/g (mean 74.2 mL/g) indicating that t-hydroxy acetochlor (17) exhibits high mobility. There was no indication of any relationship between adsorption and any soil characteristic including pH.

An additional aged laboratory soil column leaching study investigating a single sandy loam soil with 1.1% organic carbon, provided by the applicant was also assessed by the RMS (Assessments including clarifications provided by the applicant to questions from the RMS were provided in two addenda and the Additional Report prepared following the resubmission application). In the soil column there were 8 identified compounds and 7 unidentified compounds. No individual compound (except acetochlor) accounted for >0.5%AR in any soil layer segment (at the end of leaching). Neither t-norchloro acetochlor (6) nor t-hydroxy acetochlor (17) were found in the leachate of this study. t-oxanilic acid (2) (8.8%AR), t-sulfinylacetic acid (3) (2.7%AR) and t-sulfonic acid (7) (3%AR)were identified in the leachate. Finally it was demonstrated by the applicant that the radioactivity (prominent spots of high intensity) that the RMS and experts attending PRAPeR meeting 17 had had concerns about, were actually the active substance acetochlor. Now that a clearer characterisation of the radioactivity in this aged column leaching study was available, the RMS argumentation in the Additional Report that a lysimeter study was no longer necessary for acetochlor was not challenged during the peer review of the Additional Report. Therefore the data gap for a lysimeter study that was identified in the original DAR and confirmed in PRAPeR meeting 17 is not included in this conclusion (see also section 4.2.2).

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 (following FOCUS, 2001 guidance) was evaluated up to 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) and s-sulfonic acid (13)] in an addendum to the DAR. Laboratory substance input values were used for these step 1 and 2 assessments. During the peer review it was agreed that these PEC as presented in the addendum to the DAR were appropriate for use in risk assessment. For acetochlor FOCUS surface water modelling was evaluated at Steps 3 (FOCUS, 2001 guidance) and 4 (FOCUS, 2001 and 2007 guidance) with the most recent assessment from the Additional Report[16] (that also used laboratory substance input values) being the most appropriate one that is relied on and discussed here. At Step 4 both spray drift and runoff were mitigated with spray drift being mitigated by 57.1% (pond) to 91% (stream, represented by 20m buffer zones) and solute runoff input reduced by 80% and erosion runoff input reduced by 90%. These values are in line with the FOCUS (2007) landscape and mitigation guidance. The results of these simulations can be found in Appendix A[17]. Risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS landscape and mitigation guidance acknowledges that for substances with K_{Foc} < 2000 mL/g (i.e. acetochlor), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

4.2.2. Potential for ground water contamination of the active substance and their metabolites, degradation or reaction products

Modelling

The peer review agreed that the available FOCUS (2000) groundwater scenario modelling for acetochlor active substance carried out for the applied for intended use on maize (that was in line with EFSA (2004)) that utilised the FOCUSPELMO, FOCUSPRZM and FOCUSPEARL models was appropriate[18]. This modelling indicates that annual average concentrations of acetochlor in leachate leaving the top 1m soil column would be 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 0.0176 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 (PRAPeR teleconference 48) agreed should be used as the basis for the modelling input are tabulated below (with the DT_{50} value actually used for acetochlor which was slightly different being indicated in parenthesis).

[16] A Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7 was used in these step 3 and 4 simulations.
[17] The Additional Report also contains PEC with greater mitigation (with 50m no spray drift buffers and combinations of 20m no spray drift buffers with low drift nozzles). These PEC are not included in Appendix A, as the resulting spray drift mitigation is more than the 95% reduction maximum specified in the FOCUS 2007 guidance.
[18] Note a slightly precautionary acetochlor first order soil DT_{50} of 10.4 days was used, whereas the precise value in accordance with FOCUS guidance would be a median value of 9.6 days based on laboratory values, for the modelling where a Q10 of 2.2 was used. For the modelling using the field first order soil DT_{50} a slightly precautionary value of 12.13 days (compared to 10.2 days) was used (for the modelling where a Q10 of 2.58 (EFSA, 2007) was used).

Substance properties agreed by the member state experts as appropriate for FOCUS leaching modelling (acetochlor DT50 value actually used in the modelling for acetochlor in parenthesis). DT50 values originate from normalised field studies (see section 4.1.2) except s-sulfonic acid (13) which is a normalised laboratory value

	acetochlor	t-oxanilic acid (2)	t-sulfinyl acetic acid (3)	t-sulfonic acid (7)	s-sulfonic acid (13)
K_{Foc} (mL/g)	203.5	35	23	39.2	-
K_{doc} (mL/g)	-	-	-	-	6.8
1/n	1.03	1.4[19]	0.96	1.3	1.0
kinetic formation from acetochlor. (on molar basis)		0.07072	0.03438	0.04254	-
kinetic formation from t-sulfonic acid (7) (on molar basis)		-	-	-	1
Soil DT_{50} (days)	10.2 (12.13)	53.5	58.3	87.4	42.2
Q10	2.58	2.58	2.58	2.58	2.58
Walker equation coefficient	0.7	0.7	0.7	0.7	0.7

The RMS completed modelling using these input parameters using the models FOCUS PEARL 3.3.3 and FOCUSPELMO 3.3.2 for the representative use being assessed. The detailed results of this modelling for annual applications at the maximum recommended label rate can be found in Appendix A[20]. Synopses of the results are presented in the tables following section 6 of this conclusion. The modelling shows that at all 8 pertinent FOCUS groundwater scenarios the parametric drinking water limit of 0.1µg/L is exceeded for all these relevant metabolites with the 80th percentile annual average concentrations being in the range 1.189 µg/L (for t-sulfinylacetic acid (3)) to 22.23 µg/L (for t-sulfonic acid (7))[21].

For the metabolite t-norchloroacetochlor (6) that was formed in a column leaching study, groundwater modelling was carried out using PEARL 3.3.3[22] following the approach of applying the metabolite at the soil surface at a dose rate calculated on the basis of it's maximum observed concentration (in this case 3.3% on a molar basis) with an application timing 64 days later than that defined at each scenario for acetochlor. A DT_{50} of 39 days (the geomean single first order laboratory value is comparable at 35.4 days), K_{Foc} of 55.5mL/g and 1/n of 0.925 were used in simulations. The modelling shows that at 6 out of the 8 pertinent FOCUS groundwater scenarios the parametric drinking water limit of 0.1µg/L was exceeded for this relevant metabolites with the 80th percentile annual average concentrations at these 6 scenarios being in the range 0.236 µg/L (Thiva) to 0.786 µg/L (Piacenza).The detailed results of this modelling for annual applications at the maximum recommended label rate can be found in Appendix A.

Experimental measurements / field studies

The experts at PRAPeR meeting 17 discussed the proposal from the DAR that a lysimeter study was necessary to better understand the potential for groundwater exposure from breakdown products of

[19] 1/n of 1.3 was used in PEARL 3.3.3 simulations as this is the maximum value the model allows to be input
[20] Risk managers and others may wish to note that the additional report also contains results from simulations for a lower application rate and applications being made only every second or third year. These were not included in Appendix A as the applicant did not request any restriction regarding not applying every year (maize may be grown continuously) and EFSA is tasked with concluding on the maximum label rates requested in the application. In these simulations all these relevant metabolites are still predicted to exceed 0.1µg/L over a broad range of geoclimatic conditions.
[21] Range quoted is for the highest value from each model in accordance with the EFSA (2004) opinion.
[22] A Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7 was used in these simulations.

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 had been 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 had been 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 had 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 PRAPeR 17 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. Consequent to the clarifications provided on the radioactivity in the aged column leaching study in the Additional Report (see section 4.1.3) and the fact that t-norchloro acetochlor (6) has been assessed via simulation modelling (see above) and t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) have been analysed for in selected groundwater samples from the available targeted groundwater monitoring program (see below), it is now concluded that a lysimeter study is not essential to finalise the groundwater exposure assessment for metabolites.

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 December 2007 are outlined in the Additional Report. Groundwater was sampled bi-monthly (609 cluster samples taken) using piezometer samplers (2 per cluster) 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 one site (6) there was significant groundwater flow and at the other 8 sites it has been concluded there is also groundwater flow. Therefore this introduces 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[23], 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): <0.05-9.14 µg/L; nº detections ≥ 0.1 ug/L= 106

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

t sulfinylacetic acid (3): <0.05-0.608 µg/L; nº detections ≥ 0.1 ug/L= 15

t sulfonic acid (7): <0.05-7.91 µg/L; nº detections ≥ 0.1 ug/L= 155

s-sulfonic acid (13) <0.05-13.18 ug/L; nº detections ≥ 0.1 ug/L= 186

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 Additional Report. The experts' conclusions regarding the study were:

The sites were considered to represent vulnerable situations with respect to mass losses from upper soil layers, but may not provide a worst case with respect to concentrations, due to the potential effect of dilution. (The effect of dilution due to the ground water flow at the sites was not well reported so was not well understood by Member State experts). The applicant provided a modelling exercise that used a combination of MACRO and Darcy's Law, calibrated to each site, that they proposed provided good evidence that with the exception of 1 site (site 6), groundwater flow at the sites was low, resulting in limited dilution potential in the groundwater under the treated fields. The Member State experts at teleconference 48 felt that whilst the parameterisation of the MACRO part of this modelling exercise might be reasonable, some of the assumptions used to implement the groundwater flow description using Darcy's Law were not adequately justified and referenced. They therefore concluded that this exercise was not sufficient to conclude that there was low dilution potential at the sites. They considered that the measured MeESA residues in the upstream samplers was evidence that contradicted the Darcy's Law calculations proposed to demonstrate low groundwater flow rates (and consequently low dilution potential from outside the treated area at the sites).

Sampling of soil water above the water table would have helped to interpret the results.

The history of previous applications of acetochlor, and if carried out metolachlor in the fields treated by the experimenters would have been useful. Also information on the applications (of both acetochlor and S-metolachlor) made 'up gradient' in the monitored groundwater catchments would have been helpful for interpreting results.

The experts' conclusions regarding the studies used in the exposure assessment were:

The available results confirm the leaching potential of the acetochlor metabolites analysed.

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 appropriate to take concentrations measured in individual samples (in this case themean of the duplicate piezometers) to compare with regulatory triggers and not annual averages.

Selected piezometer samples from sites 3 and 10 that contained the highest levels of the other (acidic) acetochlor metabolites were also analysed for t-norchloro acetochlor (6) and t-hydroxy acetochlor (17). At site 10 in the 15 samples analysed 14 had t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) <0.05 µg/L. t-norchloro acetochlor (6) was detected once at 0.06µg/L. t-hydroxy acetochlor (17) was detected once at 0.13µg/L (mean results of piezometer clusters for the positive detections). At site 3 in the 17 samples analysed all had t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) <0.05 µg/L. (when results from piezometer B that was demonstrated to have become contaminated are excluded). Note that a data gap is identified for the applicant to demonstrate the stability of t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) residues in stored frozen water samples. Whilst the applicant provided some plausible argumentation why these residues would be expected to

be stable in the frozen samples, they referred to experimental data that had not been included in their regulatory applications.

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 groundwater 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 experts at the PRAPeR 17 meeting discussed the conclusion, given in the study, that "the Po valley sites may represent 96 % of the groundwater 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 was accepted, simply comparing bulk leaching risk does not imply that the risk of groundwater contamination is covered by the Northern Italy monitoring studies up to this percentage. This is because the GIS assessment does not take into account the hydrology and dilution potential of the receiving groundwater which is an important driver for the concentrations measured at the monitored Po valley sites. The experts participating in teleconference 48 also concluded that it was not reasonable to extrapolate the monitored levels in the groundwater at these sites to a wider range of geoclimatic conditions across Europe, based on the information that had been presented by the applicant. This conclusion, was as a consequence of it not having been clearly demonstrated, that lateral shallow groundwater flow could be excluded, as an important hydrological phenomenon at the monitored sites.

In conclusion, both modelling and available field measurements confirm that the metabolites t-oxanilic acid (2), 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 was needed. See sections 2.8, 3.3 and 7 where the pertinent data available, are discussed. For t-sulfinyl acetic acid (3) the modelling indicates significant exceedence of 0.75 µg/L but the field concentrations were only up to 0.6µg/L, though the dose rate applied in the field experiments was lower than the representative use that is being assessed. Field measurements indicate a level of 10µg/L will be exceeded for t-oxanilic acid (2) (actual concentration up to 9.14µg/L though the experiment was under dosed compare to the representative use that is being assessed) and s-sulfonic acid (13). The available modelling indicates that t-norchloro acetochlor (6) has the potential to exceed 0.1 µg/L (highest concentration modelled was 0.786 µg/L) but this was not confirmed in the available field monitoring where the maximum concentration was 0.06 µg/L. A reliable modelling assessment was not available for t-hydroxy acetochlor (17) (a soil reliable DT50 is not available), the available field monitoring indicates low potential for exceedence of 0.1 µg/L with only 1 sampling (out of 15) having a detectable concentration at 0.13µg/L. However these monitoring results for t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) are subject to confirmation that these residues are stable in stored frozen water samples. Therefore it is concluded that the assessment of the potential for groundwater exposure by t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) cannot finalised with the data that could be considered by the peer review. 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.

4.3. Fate and behaviour in air

The vapour pressure of acetochlor (2.2×10^{-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

The risk assessment was based on the following documents: European Commission (2002 a,b,c), SETAC (2001), EFSA (2009).

Acetochlor was discussed at the PRAPeR experts`meeting for ecotoxicology (PRAPeR 18) in March 2007 and in November 2010 (PRAPeR 85). 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). Further assessment of the ecotox batches was presented in the additional report. It was concluded that the technical specification is supported by the ecotox batches tested.

In the risk assessment it was considered that the acetochlor transformation products t-oxanilic acid (2), t-sulfinyl acetic acid (3), t-norchloro acetochlor(6), t-sulfonic acid (7), and s-sulfonic acid (13) may each be present as a mixture of isomers (rotamers). From the available information it is not clear if the proportion of the transformation product isomers that may be present after releasing acetochlor in the environment may change with time (see section 4) and so may not be the same as the 50:50 test substances that is expected to have been used to get ecotoxicological endpoints for these metabolites. However TER values in the risk assessments consequent to the representative use for these meatbolites indicate a sufficient margin of safety (TERs exceed the trigger by almost 2 times based on FOCUS step1 PECsw for t-norchloro acetochlor and by more than two times for all other metabolites). The risk to wildlife for these metabolites can be concluded to be low even in the most challenging situation that all the toxicity is attributed to one isomer and all the exposure is to that same isomer.

5.1. Risk to terrestrial vertebrates

The risk to birds and mammals was calculated according to the Guidance Document on Birds and Mammals (European Commission, 2000c). 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 TER values are above the Annex VI trigger value; 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 PRAPeR 18 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 remained open. Further information on the refinement of the risk assessment was provided in the addendum from July 2010. The new information and suggested refinements of the risk assessment for red-legged partridge were discussed in the PRAPeR 85 expert meeting. The experts expressed concern that the studies supporting the PD refinement were not conducted in maize fields and hence may not represent the food composition in a maize growing area. The suggested PT refinement was not accepted on the basis of the available data. Concerns were raised since studies were not restricted to areas where maize fields were the major land use and extrapolation between species and countries was considered uncertain. In the discussions it was noted that the EFSA guidance document (EFSA 2009) suggests herbivorous birds such as wood pigeon and

grey partridge as generic focal species. Therefore it was concluded that the risk to medium herbivorous birds needs to be addressed for the use in maize and a data gap was identified

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 triggers. 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 study was submitted and accepted in the peer review.

The acute and long-term TERs for herbivorous mammals were above the triggers of 10 and 5 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 not et 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 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 drinking contaminated 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 consumption of contaminated 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.

The risk to birds from drinking contaminated water in leaf axils was refined reducing the amount of consumed water by the water taken up in the food. However this refinement was not accepted by the experts because the water from food intake was already included in the underlying equation for the daily drinking water demand. A qualitative assessment of the risk to birds from drinking contaminated water was also included in the Additional Report. The assessment was based on the argumentation that water would not accumulate in the leaf axils in early growth stages of maize and that birds would not be able to drink from maize leaf axils. This argumentation was not substantiated by any experimental data. It was noted that exposure of birds drinking contaminated water from leaf axils was considered a relevant scenario in the new EFSA guidance document (EFSA 2009). The potential exposure via drinking contaminated water from leaf axils is two times greater than the LD50. A very high acute risk to birds via this exposure route cannot be excluded. Therefore a data gap was identified in the PRAPeR 85 expert meetings to refine the risk assessment for the uptake of contaminated water.

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 unidentified 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 risk from plant metabolites to birds and mammals was assessed as low in the additional report.

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).

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.

A new aquatic risk assessment was presented in the Additional Report based on NOAEC of 0.2 µg acetochlor/L for lentic water bodies and the NOAEC of 2 µg acetochlor/L for lotic water bodies together with an assessment factor of 2-3. With accepted risk mitigation (20m no-spray buffer zone and 20 m vegetated filter strip for run-off mitigation) none of the FOCUS step 4 scenarios exceeded the trigger of 2 indicating a high risk to the aquatic environment.

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) were 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.

Literature data and studies summarized in the Additional Report gave some indication of endocrine disrupting effects in amphibians via the thyroidea. During the discussion in the expert meeting it was noted that thyroidal effects were also observed in mammals. Endocrine effects on tadpoles were observed at a concentration of 2 µg a.s./L. It is recognised that the acceleration of metamorphosis of larvae may have an ecologically relevant impact on amphibian populations and also the concentration of 2 µg a.s./L is a lowest observed effect concentration and not a NOEC. A data gap was identified by the experts to address the risk to amphibians from endocrine disruption with an appropriate amphibian metamorphosis study. A standard toxicity trigger value of 10 was suggested to be applied in the risk assessment.

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

6.1. Soil

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

Definitions for monitoring: acetochlor

6.2. Water

6.2.1. Ground water

Definitions for exposure assessment: acetochlor, t-oxanilic acid (2), t-sulfinylacetic acid (3), t-sulfonic acid (7), s-sulfonic acid (13) & t-norchloroacetochlor (6).

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

6.2.2. Surface water

Definitions for risk assessment:

surface water: acetochlor, t-oxanilic acid (2), t-norchloro acetochlor (6), [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)

6.3. Air

Definitions for risk assessment: acetochlor

Definitions for monitoring: acetochlor

6.4. Food of plant origin

Definitions for risk assessment: Cereals and rotational crops: all compounds forming EMA (34) and HEMA (33) on hydrolysis and N-oxamic acid (68) ,expressed as acetochlor

Definitions for monitoring: Cereals and rotational crops: all compounds forming EMA (34) and HEMA (33) on hydrolysis expressed as acetochlor.

6.5. Food of animal origin

Definitions for risk assessment: Not proposed and not required

Definitions for monitoring: Not proposed and not required

7. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

7.1. 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,and soil micro-organisms was assessed as low 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 and soil micro-organisms was assessed as low 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 and soil micro-organisms was assessed as low 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

7.2. Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological relevance
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)	modelling indicated >0.75µg/L at 8/8 and >10µg/L at 5/8 FOCUS scenarios, concentrations up to 21.97 µg/L	No	Yes The reference values of acetochlor would be applicable. However, due to the carcinogenic properties of acetochlor, it is a relevant groundwater metabolite.	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)	modelling indicated >0.75µg/L at 8/8 FOCUS scenarios, concentrations up to 8.481µg/L	No, some growth inhibition in *Chenopodium album* and *Echinochloa crusgalli* but <50% activity of acetochlor	Yes The reference values of acetochlor would be applicable. However, due to the carcinogenic properties of acetochlor, it is a relevant groundwater metabolite.	Harmful to aquatic organisms (algae E_bC50 = 57 mg/L), low risk to aquatic organisms in surface water

t-sulfonic acid (7)	Very high to high mobility (K_{Foc} = 21-68 mL/g)	modelling indicated >0.75µg/L at 8/8 and >10µg/L at 6/8 FOCUS scenarios, concentrations up to 22.23 µg/L	No, some growth inhibition on *Echinochloa crusgalli* but <50% activity of acetochlor	Yes The reference values of acetochlor would be applicable. However, due to the carcinogenic properties of acetochlor, it is a relevant groundwater metabolite.	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)	modelling indicated >0.75µg/L at 8/8 FOCUS scenarios, concentrations up to 9.868 µg/L	No	Yes The reference values of acetochlor would be applicable. However, due to the carcinogenic properties of acetochlor, it is a relevant groundwater metabolite.	Low toxicity to aquatic organisms and low risk to aquatic organisms in surface water
t-norchloroacetochlor (6).	Very high mobility (K_{Foc} = 41-82 mL/g)	modelling indicated >0.1µg/L at 6/8 FOCUS scenarios, >0.75µg/L at 1/8 FOCUS scenarios, concentrations up to 0.786 µg/L	No data available, Data gap	Yes, based on the carcinogenic properties of acetochlor and positive results in an *in vitro* gene mutation test with mammalian cells.	Very toxic to aquatic organisms (algae E_bC50 = 0.34 mg/L), low risk to aquatic organisms in surface water

7.3. 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

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

7.4. 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

- Validation of the hydrolysis and extraction steps for all metabolites in the plant method as well as ILV for the method (relevant for all uses evaluated, proposed submission date unknown, refer to chapter 1)

- The period that, the residue trial samples were stored for has to be clarified to judge whether the results are covered by the available freezer storage stability study (Relevant for the representative use on maize, data gap identified by EFSA, submission date unknown, refer to chapter 3)

- Applicant to address the consumer risk assessment for the two isomers of acetochlor groundwater and surface water metabolites . (relevant for all representative uses, data gap identified by EFSA, submission date unknown , refer to points 2.8 and 3.3)

- Evidence is outstanding for the stability of t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) in groundwater samples stored frozen covering the duration that samples were stored before analysis. (relevant for all represebtative uses, information is available but was not provided in the dossier and could therefore not be taken into consideration.)

- Further refinement of the long- term risk to herbivorous birds (relevant for all representative uses evaluated; data gap identified in the PRAPeR 85 meeting; 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; the studies were summarised in the additional report but the provided information did not support the suggested refinements, no submission date unknown 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 and 85); ; a new assessment was submitted and presented in the additional report but the information provided did not support the suggested refinement; no submission date proposed; 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; 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 in March 2007; the outcome of the evaluation has not changed in the resubmission and the data gap remains open; no submission date proposed by the applicant; refer to point 5.2.)

- The risk to amphibians from endocrine disruption needs to be addressed with an appropriate amphibian metamorphosis study. (relevant for all representative uses evaluated; data gap identified by the PRAPeR 85 meeting, no submission date proposed by the applicant; refer to point 5.2)

- The pesticidal activity of t-norchloroacetochlor needs to be addressed. (relevant for all representative uses evaluated; no submission date proposed by the applicant; refer to point 6.)

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide on maize, full details of the GAP can be found in Appendix A

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) respectively.

Plants are analysed using a common moiety method by LC-MS/MS, data gaps have been identified for validation of the extraction and hydrolysis steps for each metabolite and ILV for the method. Consequently, no valid method is available to quantify residues in food of plant origin. For products of animal origin a method is not required as no MRLs are proposed.

For soil a LC-MS/MS method is available that analyses for acetochlor, t-oxanilic acid (2) , t-sulfonic acid (7) , t-sulfinylacetic acid (3) and s-sulfonic acid (13). 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 quality control measurements of the plant protection product are possible.

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. Based on the findings in the 52-week study in dog the risk phrase **R48/22 “Harmful: danger of serious damage to health by prolonged exposure if swallowed”**. 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) s-sulfonic acid (13) and t-norchloro acetochlor (6) were considered toxicologically relevant taking into account the limited information available and the carcinogenic potential of the parent compound. The reference values of acetochlor are applicable to the plant metabolite N-oxamic acid (68).

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 coveralls and sturdy 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 tractors with closed cabins and coveralls.

Metabolism of acetochlor was studied in maize plants upon pre-emergence and post-emergence application. Acetochlor was seen to be extensively metabolised, the residues being composed of numerous individual metabolites of which, more than 30 were identified, each accounting for less than 3% of the TRR. The residue definitions were therefore extensively discussed during the PRAPeR 20 and the teleconference TC46 and it was finally agreed to define the residue for monitoring as "all compounds forming EMA (34) and HEMA (33) on hydrolysis expressed as acetochlor", considering that the common moieties method developed by the applicant is able to take into account a significant part of the residues. The N-oxamic acid (68) metabolite was added to the EMA and HEMA forming metabolites, in the residue definition for risk assessment and a conversion factor of 2 was proposed for

the consumer risk assessment. These residue definitions are also relevant to assess the residues in rotational crops.

Supervised trials confirmed that residues in maize grains, when analysed for EMA and HEMA, are below the limit of quantification. Inversely, significant residues were detected in maize forage. Based on the different ruminant metabolism studies, it was concluded that no residues are expected to be present in animal matrices when considering the intakes resulting from the residues present in maize forage and maize grains. Therefore, the setting of a residue definition and MRLs for products of animal origin was considered not necessary.

No chronic or acute risks were indentified when the consumer exposures are calculated using the EFSA PRIMo Model and the MRL proposed for maize grains. However it must be highlighted that the potential consumer exposure exceeds the ADI value in many scenarios, when the predicted concentrations of the ground water metabolites are considered.

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 exceptions that further data are necessary to address the stability in frozen groundwater samples of the metabolites t-norchloroacetochlor (6) and t-hydroxyacetochlor (17). These data are required before the groundwater exposure assessment for these two metabolites can be finalised. Whilst the isomer (rotamer) ratio of acetochlor transformation products and whether these change with time in different environmental compartments is not known., this information is not essential to complete the EU level assessment with the conclusion that the groundwater metabolites are relevant. However to complete a definitive risk assessment to consumers drinking water containing these metabolites, information on this would be required. 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. 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. FOCUS groundwater modelling indicated that t-norchloroacetochlor has the potential to contaminate groundwater at concentrations >0.75 µg/L, though this was not confirmed by the results of the field experiments in Italy, where concentrations were only up to 0.06µg/L. Contamination of groundwater >10 µg/L consequent to the representative use assessed is also a concern for the metabolites t-oxanilic acid (2), and s-sulfonic acid (7) when considering the results of both the FOCUS modelling and the Italian field experiments. With the toxicological data available to the peer review these 4 metabolites with the potential to be present in groundwater currently (February 2011) 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. The suggested refinement of PD and PT values to refine the long-term risk to herbivorous birds was not supported by the submitted data. A high acute risk to birds from uptake of contaminated drinking water was indicated for the post emergence applications.

Acetochlor is very toxic to all groups of aquatic organisms and a high risk to aquatic organisms was indicated. Even with FOCUS step 4 PECsw including 20 m no-spray buffer zones and 20 m vegetated filter strips no scenario resulted in a TER above the trigger.

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 recolonisation 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).
- An in-field no spray buffer zone of 5m is required to protect non target plants in the off-field area.
- Water treatment procedures used for water that is abstracted from surface water, so that it can be used for drinking water purposes, would need to demonstrate, that they efficiently remove the surface water metabolites of acetochlor (*t*-oxanilic acid (2), *t*-sulfinylacetic acid (3), *t*-sulfonic acid (7) s-sulfonic acid (13) and t-norchloro acetochlor (6)). For metabolites 2,3,7 and 13 this is necessary in order to have consumer exposure of these 4 metabolites below the ADI. For metabolite 6 there is the concern that the available data indicate it is genotoxic.

ISSUES THAT COULD NOT BE FINALISED

- The groundwater exposure assessment for the metabolites t-norchloracetochlor (6) and t-hydroxyacetochlor (17) cannot be finalised whilst their stability in frozen stored groundwater samples remains to be addressed.
- The potential for endocrine disruption effects to cause a risk to amphibians needs to be addressed.

CRITICAL AREAS OF CONCERN

- A high risk to aquatic organisms. Even with a refined endpoint and a no-spray buffer zone of 20m and 20m vegetated buffer strip no FOCUS step 4 scenario resulted in a TER above the suggested trigger of 2
- A high long-term risk to herbivorous birds cannot be excluded.
- A high acute risk to birds from drinking contaminated water was indicated for post-emergence applications.
- 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'[24] and using the available toxicological data base.
- Potential human exposure above 100% of the ADI when predicted concentrations of the ground water 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 are taken into account. In regions with intensive maize cultivation, concentrations in surface water of these 4 metabolites have the potential to be higher than those predicted for groundwater. Consequently in such intensive maize cultivation regions where surface water is abstracted for drinking water, there is also the potential for human exposure above 100% of the ADI. Note, exceedences of the ADI have been estimated without accounting for the additional uncertainty in the risk characterisation, that results from possible changes in the isomeric composition of these metabolites.

[24] European Commission (2003) Sanco/221/2000-rev.10-final, 25 February.

- Potential human exposure when surface water is abstracted for drinking water, of the surface water metabolite t-norchloro acetochlor (6), which has been concluded as relevant from a toxicological hazard assessment perspective when using the available data and following groundwater relevance guidance. It should also be noted that the toxicological data for t-norchloro acetochlor (6) indicate it is genotoxic.

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[25] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

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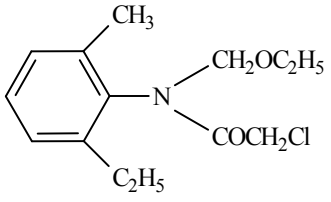
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

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
EEC No (EINECSor ELINCS)	251-899-3 (EINECS)
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured (g/kg)	940 g/Kg (racemic mixture of atropoisomers)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	(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	

Physical-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 %)
Appearence (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^{-3} Pa (25°C) (99.9 %)
Henry's law constant	2.1 x 10^{-3} Pa.m³.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	No dissociation constant (Ka) could be determined experimentally. Calculated Ka = 1.02 for the basic group (AR)NHCOR
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)

Summary of representative uses evaluated (acetochlor)*

Crop and/or situation (a)	Member State, Country or Region	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, g/kg (i)	Method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	kg as/hl min-max (l)	Water l/ha min-max	kg as/ha min-max (l)		
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
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] [2] [3]
Maize *Zea mays* L.	Italy	Trophy 40CS (GF-675)	F	Annual weeds (grasses & dicots)	CS	400	Mechanical sprayer, broadcast	Pre-sowing to 3 leaves. Mar-Jun	1	--	0.3-1.33	150-400	1.2-2.0	N/S	
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 leaves. Apr-Jun	1	--	Up to 2.016	100-400	Up to 2.016	N/A	Currently in registration process [1] [2] [3]

Crop and/or situation (a)	Member State, Country or Region	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, g/kg (i)	Method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (min)	kg as/hl min-max (l)	Water l/ha min-max	kg as/ha min-max (l)		
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)
Maize *Zea mays* L.	Italy	Bolero (MON 69447)	F	Annual weeds, grasses and dicots	EC	840	Mechanical sprayer, broadcast	Pre-plant to 4 leaves of the crop. Mar-Jun	1	--	0.252-1.008	200-400	1.008-2.016	NA	Pre-plant application recommended with 2-5 cm incorporation Rate adaptation according to time of application, weed infestation, irrigation and mixture with other herbicides [1] [2] [3]

* 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
(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

(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	(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
[1] Section residues: Consumer risk assessment inducates that the ADI is exceeded from exposue via drinking water of metabolites of acetochlor [2] Section environmental fate and behaviour. FOCUS modelling for all FOCUS groundwater scenarios and targeted monitoring data indicate relevant metabolites will exceed the parametric drinking water limit of 0.1µg/L, additionally the assessment of the potential for ground water exposure by t-norchloro acetochlor (6) and t-hydroxy acetochlor (17) was not finalised. [3] A high risk to aquatic organisms was indicated, a high acute risk to birds from drinking contaminated water was indicated for post-emergence applications, a high long-term risk to birds cannot be excluded. The potential for endocrine disruption effects to cause a risk to amphibians was not addressed.	

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. GC-MS relevant impurities 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		**A**ll compounds forming EMA (34) and HEMA (33) on hydrolysis expressed as acetochlor.
Food of animal origin		Not required
Soil		Acetochlor, t-oxanilic acid (**2**), t-sulfonic acid (**7**), t-sulfinylacetic acid (**3**) and s-sulfonic acid (**13**)
Water	surface	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)
	drinking/ground	Acetochlor, t-oxanilic acid (**2**), t-norchloro acetochlor (**6**), t-sulfonic acid (**7**), t-sulfinylacetic acid (**3**) and s-sulfonic acid (**13**)
Air		Acetochlor

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	For EMA (2-ethyl-6-methylaninline) and HEMA (2-(1-hydroxytethyl)-6-methylaniline) derived metabolites (expressed as mg acetochlor/Kg) maize : LC-MS/MS (LOQ 0.005 mg/Kg for both EMA and HEMA) ILV and validation of the extraction and hydrolysis of each metabolite.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required.
Soil (analytical technique and LOQ)	For Acetochlor, t-oxanilic acid (**2**), t-sulfonic acid (**7**), t-sulfinylacetic acid (**3**) and *s*-sulfonic acid metabolite (13) in loam and clay soil:

	LC/MS/MS (LOQ 0.03 mg/kg) for each compound.
Water (analytical technique and LOQ)	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

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:	Low: some accumulation in nasal turbinates in rats but not in mice.
Rate and extent of excretion:	Relatively rapid (~86% within 48 h). Mainly in urine (66-72 %) and in faeces (12-21%, from which 80-85% via bile)
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 significant compounds (animals and plants)	Acetochlor
Toxicologically relevant compounds (environment)	Acetochlor, t-oxanilic acid, t-sulfinylacetic acid, t-norchloro acetochlor, t-sulfonic acid, s-sulfonic acid

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	1929 mg/kg bw	**R22**
Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	3.99 mg/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	**R43**
Respiratory system irritation	Irritant	**R37**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Kidney and testes (histopathological alterations) (dog) Liver and kidney (rat)	
Relevant oral NOAEL	2 mg/kg bw/d (1-yr dog) 16 mg/kg bw/d (13-wk rat)	**R48 /22**
Relevant dermal NOAEL	400 mg/kg bw/d (21-d rabbit, local NOAEL)	
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. No genotoxic potential relevant to humans.	

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

Target/critical effect	Anemia, kidney and liver toxicities (mice and rats)	
Relevant NOAEL	LOAEL: 1.1 mg/kg bw/d (2-yr mice) NOAEL: 9.4 mg/kg bw/d (2-yr rat)	
Carcinogenicity	Rat: adenomas in nasal epithelium at 47.5 mg/kg bw/d . Gastric tumours. Mouse: lung adenomas and carcinomas, uterine histiocytic sarcomas.	**Carc. Cat. 3 R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Parental: decreased bodyweight, -increased liver weight and nasal hyperplasia Offspring: reduced litter and pup weight, delayed vaginal opening, increased relative brain weight. Reproduction: decrease number of implantations, decrease number of live pups.	
Relevant parental NOAEL	20 mg/kg bw/d (200 ppm)	
Relevant offspring NOAEL	20 mg/kg bw/d (200 ppm)	
Relevant reproductive NOAEL	61 mg/kg bw/d	

Developmental toxicity (Annex IIA, point 5.6)

Developmental target / critical effect	Maternal: decreased bodyweight gain (rat, rabbit), decreased food consumption and increased water consumption (rat) Developmental: delayed ossification at maternal toxic dose (rat); none (rabbit)	
Relevant maternal NOAEL	200 mg/kg bw/d (rat) 50 mg/kg bw/d (rabbit)	
Relevant developmental NOAEL	400 mg/kg bw/d (rat) 190 mg/kg bw/d (rabbit)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	Acute NOAEL = 150 mg/kg bw (rat)	
Repeated neurotoxicity	90-d NOAEL = 48 mg/kg bw/d (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: acetochlor induces an increased hepatic enzymatic conjugation leading to a compensatory increase in TSH levels.

Toxicity of metabolites	
N-oxamic acid (68) (maize metabolite)	Acute oral LD_{50}>2000 mg/kg bw (rat)
	No genotoxic potential *(in vitro, in vivo)*
	28-d NOAEL = 1142 mg/kg bw/d (rat)
***t*-oxanilic acid** (2) (surface water, ground water and soil metabolite)	Acute oral LD_{50} > 2000 mg/kg bw (rat)
	No genotoxic potential *(in vitro, in vivo)*
	90-day : NOAEL = 230 mg/kg bw/d (rat)
	Reproductive toxicity (developmental rat): NOAEL maternal toxicity = 500 mg/kg bw/d NOAEL for developmental = 1000 mg/kg bw/d
***t*-sulfinylacetic acid** (3) (ground water and soil metabolite)	Acute oral LD_{50} > 2000 mg/kg bw (rat)
	90-day NOAEL = 265 mg/kg bw/d (rat)
	No genotoxic potential (*in vitro*)
***t*-sulfonic acid** (7) (ground water and soil metabolite)	Acute oral LD_{50} > 2000 mg/kg bw (rat)
	90-day NOAEL = 225 mg/kg bw/d (rat)
	No genotoxic potential *(in vitro, in vivo)*
***t*-norchloro acetochlor** (6) (surface water and ground water metabolite)	Genotoxicity: Positive results *in vitro.* Inconclusive in vivo.
s-sulfonic acid (13) (ground water and soil metabolite)	Acute oral LD_{50} > 2000 mg/kg bw (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 plays a role in the nasal tumour formation.

Human Medical data (Annex IIA, point 5.9)

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

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.0036 mg/kg bw/d	78- wk mice	300*
AOEL	0.02 mg/kg bw/d	1-yr dog	100
ARfD	1.50 mg/kg bw	acute neurotoxicity rat	100

* Additional safety factor of 3 because of the use of a LOAEL.

Dermal absorption (Annex IIIA, point 7.3)

Product information:	**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

Acceptable exposure scenarios (including method of assessment)

Operator	
GF-675 Tractor-mounted/trailed boom sprayer: hydraulic nozzles	German Model (gloves during mixing/loading (M/L) and application (A); sturdy and coverall during A) : 21% of AOEL. UK POEM (gloves during M/L and A) • Applied in 400L water/ha: 140% of AOEL • Applied in 100L water/ha: 540% of AOEL
MON 69447 Tractor-mounted/trailed boom sprayer: hydraulic nozzles	Tier I and II: German Model (gloves during M/L and A; hood, visor, coverall and sturdy footwear during A) = 131% of AOEL. UK-POEM (gloves during M/L and A) • Applied in 400L water/ha: 1435% of AOEL • Applied in 100L water/ha: 5550% of AOEL Tier III: Bio-monitoring study (gloves during M/L and coverall during A), 20 ha • open cabin = 46% of AOEL • closed cabin = 20 % of AOEL Bio-monitoring study (gloves during M/L and coverall during A), 50 ha • closed cabin* = 52% of AOEL
Workers	Exposure unlikely for pre-emergence and early post emergence.
Bystanders	
GF-675	16% of AOEL (Lloyd and Bell, 1983).
MON 69447	93% of AOEL (Lloyd and Bell, 1983).

*During the use of an open cabin for a treated area of 50 ha, the exposure estimate will exceed the AOEL.

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review proposal
Acetochlor	R22;R20; R37;R38; R43; Carc. Cat. 3, R40;R48/22

Residues

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

Plants group covered	Cereals (maize) pre- and post-emergence.
Rotation crops	Radish, wheat, lettuce, turnip, millet, soybean, mustard
Metabolism in rotational crops similar to metabolism in primary crops?	Yes. EMA, HEMA metabolites and N-oxamic acid identified as the major metabolites in rotational crops.
Processed commodities	Not evaluated and not required as residues in maize grains <LOQ.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	All compounds forming EMA (34) and HEMA (33) on hydrolysis, expressed as acetochlor.
Plant residue definition for risk assessment	Applicable to cereal grains and rotational crops: All compounds forming EMA (34) and HEMA (33) on hydrolysis plus *N*-oxamic acid (68), expressed as acetochlor.
Conversion factor (monitoring to risk assessment)	2

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

Animals covered	Goat (acetochlor, EMA and HEMA metabolites) Cow (*N*-oxamic acid)
Time needed to reach a plateau concentration in milk and eggs	n/a
Animal residue definition for monitoring	Not proposed and not required
Animal residue definition for risk assessment	Not proposed and not required
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

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

Confined studies on radish, wheat, turnip, mustard, millet, soybean. TRRs were higher in the laboratory than in the field study. Numerous cold USA field trials submitted for wheat, oat, soybean, sorghum, sugar beets and potatoes and conducted at 3360 g a.s./ha (1.7N). EMA/HEMA residues not expected to be present in food commodities, except in oilseed/pulses grains. Significant EMA/HEMA residues present in cereal forage and straw. HMEA metabolites confirmed not to be present in food commodites.

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

EMA and HEMA forming metabolites stable 10 months in maize grain, forage and stover, when stored frozen at -18°C N-oxamic acid (68) residue stable maize samples for at least 2 years, when stored frozen at -18°C.

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 4.3 mg/kg DM[(a)]	No	Yes 0.66 mg/kg DM[(a)]
Potential for accumulation (yes/no):	No		
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No[(a)]	-	-
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

(a): Intakes calculations based on a STMR of 0.02 mg/kg for maize grain, a HR of 0.43 mg/kg for maize silage and a conversion factor of 2 for risk assessment.

(b) When considering the three different metabolism studies, the following TRRs are expected in animal matrices (expressed on a 1N dose rate basis):
- N-Oxamic acid study: ≤0.003 mg/kg in all matrices,
- EMA metabolites study: ≤0.003 mg/kg except in liver (0.013 mg/kg) and kidney (0.021 mg/kg)
- HEMA metabolites study: <0.001 mg/kg in all matrices

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

Crop	Northern/ Southern Region, field or Indoor	Trials results relevant to the representative uses (a) EMA/HEMA residue levels	Recommendation/comments	MRL estimated from trials according to representative use	HR (c)	STMR (b)
Maize grain	Northern	**Pre:** 8x <0.01/<0.01, 9x <0.02/<0.02 **Post:** 6x <0.01/<0.01, 6x <0.02/<0.02	Pre: Pre-emergence application Post: Post-emergence application Additional data on acetochlor residue levels: 12x <0.01	0.05*	0.04 (EMA+ HEMA)	0.04 (EMA+ HEMA)
	Southern	**Pre:** 5x <0.01/<0.01, 8x <0.02/<0.02 **Post:** 2x <0.01/<0.01,				
Maize forage Pre-emergence	Northern	<0.01/<0.01, 0.02/<0.01, 6x <0.02/<0.02, 0.03/0.01, 0.05/0.02, 0.05/0.03	Forage samples collected 90 to 161 days after a single pre-emergence application at 2000 g a.s./ha Additional data on acetochlor residue levels: 14x <0.01	Not relevant	0.10 (EMA+ HEMA)	0.04 (EMA+ HEMA)
	Southern	<0.01/<0.01, 3x 0.01/<0.01, 3x 0.02/0.01, 8x <0.02/<0.02, 0.04/0.06				
Maize forage Pre-emergence	Northern	0.01/0.01, 0.02/0.01, 0.021/0.012, <0.02/<0.02, 2x 0.02/<0.02, 0.03/<0.02, 0.06/<0.02, 0.05/0.048, 0.076/0.025, 0.10/0.02, 0.14/<0.02, 0.20/0.01, 0.407/0.022	Post emergence application from BBCH 14 to BBCH 18 at a dose rate of 1890 t0 2100 g a.s./ha. Additional data on acetochlor residue levels: 11x <0.01, 0.05	Not relevant	0.43 (EMA+ HEMA)	0.06 (EMA+ HEMA)
	Southern	0.039/0.013, 0.052/0.022				

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

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

ADI	0.0036 mg/kg bw/day
TMDI (% ADI) according EFSA PRIMo Model	Highest TMDI: 11% ADI (WHO Cluster B) However, it must be highlighted that **an exceedence of the ADI is noticed** when the additional exposure resulting from the presence in drinking water of the ground water metabolites (2), (3), (7) and (13) is considered (up to 260% for infant, Hamburg scenario).
TMDI (% ADI) according to national (to be specified) diets	Not performed, not required
IEDI (WHO European Diet) (% ADI)	Not performed, not required
NEDI (specify diet) (% ADI)	Not performed, not required
Factors included in the calculation	MRL of 0.05 mg/kg for maize grain, oilseeds and CF of 2
ARfD	1.50 mg/kg bw
IESTI (% ARfD) according to EFSA PROMO Model	<0.1% ARfD (maize grain) ~~0.002%~~
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not performed, not required
Factors included in the calculation	MRL of 0.05 mg/kg for maize grain, oilseeds and CF of 2

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

Crop/proccessed crop	Number of studies	Processing factor		Amount (%) transferred
		Transfer Factor	Yield factor	
Not provided and not required				

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

Plant products

Maize (grain)	0.05* mg/kg
Oilseeds (as rotational crops)	0.05* mg/kg

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

Fate and Behaviour in the Environmental

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

Mineralisation 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) – 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. No 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.

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 mater %	pH	°C /humidity	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10k Pa[£]	St. (r^2)	Method of calculation
silty clay loam	4.1	6.9	22 ºC/ 50% MHWC	14.3/47.5	16.5	0.995	SFO
silty clay loam	3.4	6.2	22ºC/75% FC	10/33.2	10	0.990	SFO
silty loam	1.7	6.3	20ºC/pF2	7.9/26.4	7.9	0.993	SFO
silty clay loam	2.0	6.0	20ºC/pF2	16.3/54.0	16.3	0.994	SFO
silty clay loam	2.0	6.0	20ºC/pF2	10.3/34.2	10.3	-	SFO
silty clay loam	**3.9**	**5.5**	**20ºC/pF2**	**29/96.3**	**29 (*)**	**-**	**SFO**
sandy loam	3.5	6.0	20ºC/pF2	9.4/31.4	9.4	0.998	SFO
sandy loam	3.5	6.0	20ºC/pF2	7.9/26.2	7.9	-	SFO
loam	1.3	7.9	20ºC/pF2	3.4/11.1	3.4	1	SFO
silt loam	1.3	5.0	20ºC/40% MHWC	23.7/78.8	14.43	0.975	SFO
silt loam	1.3	5.0	20ºC/40% MHWC	16.4/54.5	9.99	0.993	SFO
clay loam	2.4	7.5	20ºC/40% MHWC	12.9/43	7.46	0.937	SFO
clay loam	2.4	7.5	20ºC/40% MHWC	13.7/45.5	7.92	0.981	SFO
loam	2.8	8.0	20ºC/40% MHWC	11.7/39	7.16	0.967	SFO

-	-	-	20ºC/40% MHWC	9.9/33.0	9.9	0.997	SFO
silt loam	1.2	8.1	22ºC/75% FC	8.2/27.3	8.0	0.993	SFO
sandy loam	2.4	4.7	22ºC/75% FC	12.3/40.9	12.0	0.992	SFO
loamy sand	0.7	7.1	20ºC/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
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					9.41/9.6		

(*) selected for PECs estimation

[£] Normalisation used a Q10 of 2.58 and a Walker equation coefficient of 0.7.

t-sulfonic acid (7)	Aerobic conditions							
Soil type	Organic carbon %	pH (0.01 M $CaCl_2$)	t. ºC / % Humidity	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 ºC/pF2	148/491	-	148	0.92	SFO
Silty clay loam	3.3	6.6	20 ºC/pF2	89/294	-	89	0.88	SFO
clay	5.2	7.2	20 ºC/pF2	33/108	-	33	0.97	SFO
Geometric mean						75.75(*)		

(*) selected for PECgw estimation and modelling

t-oxanilic acid (2)	Aerobic conditions							
Soil type	Organic carbon %	pH (0.01 M $CaCl_2$)	t. ºC / % Humidity	DT_{50}/DT_{90} (d)	F.F. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10 kPa	St. (r^2)	Method of calculation
loamy sand	1.0	4.2	20 ºC/pF2	131/434	-	131	0.94	SFO
Silty clay loam	3.3	6.6	20 ºC/pF2	15/50	-	15	0.99	SFO
clay	5.2	7.2	20 ºC/pF2	30/98	-	30	0.96	SFO
Geometric mean						38.92(*)		

(*) selected for PECgw estimation and modelling

t-sulfinylacetic acid (3)	Aerobic conditions							
Soil type	Organic carbon %	pH (0.01 M $CaCl_2$)	t. ºC / % Humidity	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 ºC/ pF2	112/372	-	112	0.95	SFO
Silty clay loam	3.3	6.6	20 ºC/ pF2	75/248	-	75	0.8	SFO
clay	5.2	7.2	20 ºC/ pF2	92/305	-	92	0.82	SFO
Geometric mean						91.77 (*)		

(*) selected for PECgw

s-sulfonic acid(13)	Aerobic conditions							
Soil type	Organic carbon %	pH	t. ºC / % MHWC	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	20ºC/40% MHWC	30.6/101.7	-	24.81	0.99	SFO
Clay loam	0.8	5.7	20ºC/40% MHWC	90.3/299.8	-	75.45	0.97	SFO
Loam	1.5	7.6	20ºC/40% MHWC	54.5 /181.0	-	40.1	0.99	SFO

Geometric mean				42.18(*)		

(**) selected for modelling

t-norchloro acetochlor (6)	Aerobic conditions								
Soil type	Organic carbon %	pH	t. °C / % MHWC	DT_{50}/DT_{90} (d)	F.F. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	CI for k parameter	Method of calculation
Loamy sand	1.72	5.74	20ºC/45% MHWC	33/110		33.3	0.997	0.019169 0.022588	SFO
Sandy loam	1.12	7.32	20ºC/45% MHWC	32/106		28.1	0.979	0.017072 0.026433	SFO
Clay Loam	1.75	7.23	20ºC/45% MHWC	64/212		47.5	0.981	0.009182 0.012563	SFO
Geometric mean						35.4(*)			

(*) A DT50= 39 d was used in FOCUS GW modelling, This change is not expected to have a significant impact in the results of the calculation

soil dependence (yes / no) (if yes type of dependence)	No

t-sulfinylacetic acid (3)	**Anaerobic conditions**							
Soil type	Organic matter %	pH (0.01 M $CaCl_2$)	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	20ºC	5.3 /17.5		N/A	0.94	SFO

Field studies

Parent	Aerobic conditions							
Soil type (inidicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth[1] (cm)	DT_{50} (d)	DT_{90}(d)	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

Metabolites not analysed in the field studies tabulated above.

Field studies conducted in USA

Parent	Aerobic conditions								
Soil type (inidicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth[1] (cm)	DT_{50} norm (d)	DT_{90}(d)	Lower CI for k parameter	X^2 error level	Method of calculation
Loam	Colo IA	4.5	6.5	0-15 cm	24.4		0.02700	3.2	SFO
Loam	Geneseo IL	4.8	7.7	0-15 cm	8.5		0.0567	23.7	SFO
Loam	Hollandale,MN	4.2	7.7	0-15 cm	10		0.04779	26.4	SFO
Loam	New Holland, OH	2.2	6.7	0-15cm	5.3		0.11057	24.3	SFO
Geometric mean					10.2[1]				

1: PECgw calculation for metabolies conducted with a DT50parent of 12.13. This value was considered valid comparable. The difference between the value used in the modeling and geomean DT50 value will not have a significant impact in the results of PECgw

Field studies conducted in USA

t-sulfinyl acetic acid (3)	Aerobic conditions							
Soil type (inidicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth[1] (cm)	DT_{50} norm (d) (Lower CI for k parameter)	Ff (lower CI)	St. (χ^2 error level)	Method of calculation
Loam	Colo IA	1.2	6.0	0-15 cm	54.9 (0.00124)	0.06105 (0.02389)	16.9	SFO-SFO
Loam	Geneseo IL	4.8	7.7	0-15 cm	58.3[2] (0.00319)	0.03843	12.1	SFO-SFO
Loam	Hollandale,MN	4.2	7.7	0-15 cm	131.8[1] (-0.00698)	0.01308	18.1	SFO-SFO
Loam	New Holland, OH	2.2	6.7	0-15cm	72.9[1] (-0.01177)	0.02494	36.9	SFO-SFO
Arithmetic mean						0.03438		

1Not considered in the modeling because they fail the statistical acceptance criteria
2: Value selected for FOCUS GW modeling

Field studies conducted in USA

t-oxanilic acid (2)	Aerobic conditions							
Soil type (inidicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth[1] (cm)	DT_{50} norm (d) (Lower CI for k parameter)	Ff (lower CI)	St. (χ^2 error level)	Method of calculation
Loam	Colo IA	1.2	6.0	0-15 cm	43.9 (0.00623)	0.0965 (0.05455)	24.7	SFO-SFO
Loam	Geneseo IL	4.8	7.7	0-15 cm	35 (0.01060)	0.07403	17.1	SFO-SFO
Loam	Hollandale,MN	4.2	7.7	0-15 cm	65.1 (0.00324)	0.03340	18.8	SFO-SFO
Loam	New Holland, OH	2.2	6.7	0-15cm	82.1 (0.00154)	0.07896	29.7	SFO-SFO
Geometric mean for DT_{50}/arithmetic mean for Ff					53.5	0.07072		

Field studies conducted in USA

t-sulfonic acid (7)	Aerobic conditions							
Soil type (inidicate if bare or cropped soil was used).	Location (country or USA state).	%OC	pH	Depth[1] (cm)	DT_{50} norm (d) (Lower CI for k parameter)	Ff (lower CI)	St. (χ^2 error level)	Method of calculation
Loam	Colo IA	1.2	6.0	0-15 cm	93 (0.00259)	0.06183 (0.03673)	29.8	SFO-SFO
Loam	Geneseo IL	4.8	7.7	0-15 cm	48.6 (0.00464)	0.04332	9.0	SFO-SFO
Loam	Hollandale,MN	4.2	7.7	0-15 cm	78.3 (0.00314)	0.03340	31.3	SFO-SFO
Loam	New Holland, OH	2.2	6.7	0-15cm	164.6 (-0.00067)	0.03098	20.9	SFO-SFO
Geometric mean for DT_{50}/arithmetic mean for Ff					87.4	0.04254		

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent									
	OM %	OC %[1]	Soil pH	Kd	Kf	Koc	Kfoc	1/n	r^2
Clay	5.4	3.2	6.8	4.3	7.5	136	239	1.16	0.9
Loamy sand	1.9	1.1	6.3	1.7	0.81	150	74	0.86	0.76
Sandy loam	2.6	1.5	6.5	2.1	5.9	138	389	1.37	1.0
Sand	0.77	0.45	5.4	0.13	1.9	28	428[2]	2.16[2]	0.86
Sand	1.5	0.9	5.7	2.4	1.9	277	216	1.03	0.68
Sandy loam	8.0	4.7	5.3	17	20	377	422	1.07	0.78
Silt Loam	1.2	0.696	8.1	0.96	1.08	138	155	0.97	-
Silty clay loam	3.4	1.972	6.2	1.74	2.66	88	135	0.79	-
Sand	0.7	0.4	6.5	0.62	0.37	151	92.5	1.23	-
Sandy Loam	2.4	1.392	4.7	1.13	1.58	81	113.5	0.86	-
Arithmetic mean value						156	204	1.03	-
pH dependence, Yes or No				No					

[1] OC%= OM%/1.724; [2] Value no considered in the calculation of the mean value because 1/n > >1

t-oxanilic acid (2)									
	OM %	OC %[1]	Soil pH	Kd	Kf	Koc	Kfoc	1/n	r^2
Clay	5.4	3.2	6.8	0.42	0.77	14	24	1.38	0.28
Loamy sand	1.9	1.1	6.3	0.35	0.19	32	17	0.77	0.68

Sandy loam	2.6	1.5	6.5	0.33	1.2	22	83	1.89	1.00
Sand	0.77	0.45	5.4	0.13	0.55	29	124[2]	2.24[2]	0.64
Sand	1.5	0.9	5.7	0.26	0.27	30	31	1.12	0.8
Sandy loam	8.0	4.7	5.3	0.86	0.91	19	20	1.04	0.9
Arithmetic mean						24.3	35 (*)	1.4 (*)	
pH dependence, Yes or No				No					

[1] OC%= OM%/1.724 [2] Value no considered in the calculation of the mean value because 1/n > >1
(*) selected for modelling

t-sulfonic acid (7)									
	OM %	OC %[1]	Soil pH	Kd	Kf	Koc	Kfoc	1/n	r^2
Clay	5.4	3.2	6.8	0.68	1.6	22	52	1.48	0.76
Loamy sand	1.9	1.1	6.3	0.38	0.23	34	21	0.83	0.69
Sandy loam	2.6	1.5	6.5	0.47	6.4	32	430[2]	2.53[2]	0.83
Sand	0.77	0.45	5.4	0.15	0.3	33	68	1.84	0.51
Sand	1.5	0.9	5.7	0.27	0.27	31	31	1.10	0.27
Sandy loam	8.0	4.7	5.3	0.95	1.1	21	24	1.08	0.95
Arithmetic mean						28.8	39.2 (*)	1.26 (*)	
pH dependence, Yes or No				No					

[1] OC%= OM%/1.724
[2] no considered in the geometric mean/median and mean calculation
(*) selected for modelling

t-sulfinylacetic acid (3)									
	OM %	OC %[1]	Soil pH	Kd	Kf	Koc	Kfoc	1/n	r^2
Clay	5.4	3.2	6.8	0.41	0.25	13	8	0.85	0.95
Loamy sand	1.9	1.1	6.3	0.28	0.29	26	26	1.01	0.99
Sandy loam	2.6	1.5	6.5	0.2	0.38	14	25	1.21	0.99
Sand	0.77	0.45	5.4	0.17	0.26	38	58	1.15	0.94
Sand	1.5	0.9	5.7	0.21	0.1	24	12	0.75	1
Sandy loam	8.0	4.7	5.3	0.73	0.43	16	9	0.83	0.97
Arithmetic mean						21.8	23 (*)	0.96 (*)	
pH dependence, Yes or No				No					

[1] OC%= OM%/1.724
(*) selected for modelling

s-sulfonic acid (13)								
	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n	r^2
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					6.8 (*)			
pH dependence, Yes or No					No			

(*) selected for modelling

t-norchloro acetochlor (6)								
	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n	R^2
Loamy sand	3.0	7.8	0.77	0.72	44	41	0.95	1
Sandy loam	3.8	7.2	1.5	1.27	68	58	0.91	1
Sand	0.5	5.7	0.27	0.24	95	82	0.9	1
Silty Clay loam	4.3	5.3	1.13	1.02	45	41	0.94	1
Mean value					63	55.5 (*)	0.925	
pH dependence, Yes or No			No					

(*) selected for modelling

t-hydroxy acetochlor (17)								
	OC %	Soil pH	Kd	Kf	Koc	Kfoc	1/n	R^2

Clay Loam	2.98	7.5	2.85		95			
Loam	1.17	7.33	0.67		58			
Silty clay loam	2.67	5.42	2.06		77			
Loamy sand	2.3	5.6	1.27		55			
Silt loam	1.91	5.5	1.64		86			
Arithmetic mean					74.2			
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 applied 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.
Aged residues column leaching	ageing period: 12 days, aged soil contained: acetochlor (49.5%) t-oxanilic acid (**2**) (11%AR), t-sulfinylacetic acid (**3**) (2.9%)**,** t-hydroxyacetochlor (**17**) (1.2%), t-amide methyl sulfone (**16**) (1.7), t-norchloroacetochlor, (**6**) (trace), t-sulfonic acid (**7**) (1.6%), t-thioacetic acid (**4**) (trace) and t-amide methylsulfoxide (**15**) (1.3%). Eluation (mm): *200* mm
	Leachate: *16.7-17.2-43*% total applied residues in leachate Analysis indicated that acetochlor was not present. The components in leachate were: t-oxanilic acid (**2**) (8.8%AR), t-sulfinylacetic acid (**3**) (2.7%AR), t-sulfonic acid (**7**) (3%AR) and 3 unknown fractions that accounted individually for <0.1-1% AR. t-norchloro acetochlor (6) and and t-hydroxy acetochlor (17) were not present in the leachate.
Lysimeter study	No study available. Not required.

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	-	-
	21d	1.695	2.201		
	28d	1.434	2.041		
	50d	0.848	1.634		
	100d	0.257	1.064		

t-oxanilic acid (2)
Method of calculation

	Molecular weight relative to the parent: 0.982 DT_{50} (d): 131 days Kinetics: SFO Field or Lab: representative worst case from lab studies.
Application data	maximum observed 17.1% TAR(by HPLC)

		5cm			
$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average		
Maximum predicted		0.47	-		
Short term	24h	0.468	0.469		
	2d	0.465	0.468		
	4d	0.460	0.465		
Long term	7d	0.453	0.461		
	21d	0.421	0.445		
	28 d	0.405	0.437		
	50d	0.361	0.413		
	100d	0.277	0.365		

t-sulfonic acid (7)
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 TWA		
Maximum predicted		0.3860	-		
Short term	24h	0.384	0.385		
	2d	0.382	0.384		
	4d	0.379	0.382		
Long term	7d	0.373	0.380		
	21d	0.350	0.367		
	28 d	0.338	0.362		
	50d	0.305	0.344		
	100d	0.242	0.308		

t-sulfinylacetic acid (3)
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			
$PEC_{(s)}$		Single	Single		

(mg/kg)		application Actual	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		
	21d	0.559	0.597		
	28 d	0.536	0.585		
	50d	0.468	0.548		
	100d	0.343	0.475		

s-sulfonic acid (13)

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		
Maximum predicted		0.262	-		
Short term	24h	0.260	0.260		
	2d	0.258	0.261		
	4d	0.254	0.260		
Long term	7d	0.248	0.255		
	21d	0.223	0.242		
	28 d	0.211	0.236		
	50d	0.178	0.217		
	100d	0.121	0.183		

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 λ> 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 w	pH sed	t. °C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} Water (deg)	St. (r^2)	DT_{50}- DT_{90} Sed (deg)	St. (r^2)	Model
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				19.5/64.73		37.8/122.9		8.9/28.3		
Arithmetic mean				19.7/65.4 (*)		40.5/131.2 (*)		8.55/28.52		

(*) selected for modelling, following guidance the geometric mean should be selected.

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 w	pH sed	t. °C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Model
Old Basing	7.5	7.8	20	not estimated		not estimated		not estimated		
Virginia water	7.4	7.1	20	not estimated		not estimated		not 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 w	pH sed	t. °C	DT_{50}-DT_{90} whole	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Model
Old Basing	7.5	7.8	20	not estimated		not estimated		not estimated		
Virginia water	7.4	7.1	20	not estimated		not estimated		not estimated		
Geometric mean/median										

Mineralization and non extractable residues				
Water/sediment system	pH w	pH sed	Mineralization	Non-extractable residues in sed
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) 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: $2.2x10^{-3}$ 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) FOCUSsw 2

FOCUS STEP 1	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	547.1		1080.0	
	1	523.7	535.4	1070.0	1070.0

	2	504.9	524.8	1030.0	1060.0
	4	469.4	505.9	955.3	1020.0
	7	420.7	479.6	856.2	973.4
	14	325.9	425.5	663.3	864.5
	21	252.5	379.5	513.8	771.5
	28	195.6	340.4	398.0	691.9
	42	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
	0	95.2	---	182.9	---
	1	92.5	93.9	176.7	179.8
	2	89.7	92.5	171.4	176.9
	4	84.5	89.8	161.3	171.6
	7	77.1	85.9	147.3	164.1
	14	62.4	77.7	119.1	148.4
	21	50.4	70.5	96.3	134.7
	28	40.8	64.3	77.9	122.7
	42	26.7	53.9	50.9	103.0
	0	176.2	---	347.7	---
	1	172.1	174.2	328.7	338.2
	2	167.0	171.9	318.9	331.0
	4	157.1	166.9	300.1	320.2
	7	143.5	159.8	274.0	305.9
	14	116.0	144.5	221.6	276.4
	21	93.8	131.2	179.2	250.8
	28	75.9	119.5	144.9	228.5
	42	49.6	100.3	94.8	191.7

Step 3 and Step4 : Range of global maximum PEC SW (µg/L)

Model Step	Water Body	PECsw (ug/l)
Step 3	steam/ditch	8.92-56.2
	Pond	0.434-0.808
Step 4a, 20 m buffer Drift only reduction	steam/ditch	0.954-56.2
	Pond	0.190-0.647
Step 4a, 20 m buffer drift + run-off reduction (runoff reduction factor: 0.8; erosion reduction factor: 0.9)	steam/ditch	0.956-13.4
	Pond	0.190-0.228

Calculations with combination of drift mitigation measures (buffer zones + low drift technology), which exceed the cap of 95% spray drift reduction prescribed in FOCUS Landscape and mitigation guidance for EU level assessment are available in the updated AR.

t-oxanilic acid (2)
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) 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
	0	116.5	-		
	1			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	24.56			
	5			5.64	
Southern EU	4	46.33			
	5			10.64	

t-norchloroacetochlor (6) 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)
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

	0	18.64	-		
	1			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	6.57			
	5			3.6	
Southern EU	4	9.47			
	5			5.21	

t-sulfonic acid (7) 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)
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
	0	94.77	-		
	1			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	19.52			
	5			4.93	
Southern EU	4	37.62			
	5			9.51	

t-sulfinyl acetic acid (3) 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)
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
	0	155.16	-		
	1			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	30.62			
	5			7.04	
Southern EU	4	60.62			
				13.92	

s-sulfonic acid (13) 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)
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
	0	64.82	-		
	0			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	12.22			

	4			0.86	
Southern EU	4	24.44			
	4			1.71	

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

Method of calculation and type of study: modelling	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: 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 2.58). K_{foc}: mean 203.5 L/kg (n=9), $^1/_n$= 1.03 Metabolites: For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: PEARL 3.3.3 t-norchloroacetochlor (6) Geo mean DT50 = 39 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Mean Koc: 55.5 L/kg; n=0.925
Application rate	Parent Application rate: 2100 g/ha. No. of applications: 1 Time of application (month or season): spring (10 days before emergence) t-norchloroacetochlor (6) Aplication rate: 0.06 kg/ha and 0.04 No. of applications: 1 Time of application (month or season): 64 days fater the date of application of acetochlor

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

	Scenario	Parent (µg/L)	Metabolite (µg/L) Tier 1			
PEARL /maize			**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Chateaudun (C)	0.000242	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Hamburg (H)	0.000695	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Krensmünster (K)	0.000349	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Okehampton (N)	0.000934	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Piacenza (P)	0.004995	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Porto (O)	0.000000	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**

	Sevilla (S)	0.000013	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**
	Thiva (T)	0.000201	**Not estimated**	**Not estimated**	**Not estimated**	**Not estimated**

	Scenario	Parent (µg/L)	Metabolite (µg/L)
PRZM /maize	Chateaudun (C)	$0.182\ 10^{-6}$	not used for metabolites
	Hamburg (H)	$0.5071\ 10^{-4}$	
	Krensmünster (K)	$0.3107\ 10^{-6}$	
	Okehampton (N)	$0.4701\ 10^{-5}$	
	Piacenza (P)	$0.4196\ 10^{-3}$	
	Porto (O)	$0.359\ 10^{-11}$	
	Sevilla (S)	$0.1590\ 10^{-12}$	
	Thiva (T)	$0.58\ 10^{-10}$	

	Scenario	t-norchloroacetochlor (µg/L) Tier 1 based on an equivalent application rate of acetochlor of 2.016 kg/ha
		EVERY YEAR
FOCUS PEARL 3.3.3 /maize	Chateaudun (C)	**0.391673**
	Hamburg (H)	**0.572620**
	Krensmünster (K)	**0.419277**
	Okehampton (N)	**0.591241**
	Piacenza (P)	**0.786180**
	Porto (O)	0.009103
	Sevilla (S)	0.073775
	Thiva (T)	**0.236285**

Method of calculation and type of study: modelling	<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; and FOCUS PEARL 3.3.3 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} 12.13d[£] (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). K_{foc}: mean 203.5 l/kg (n=9), $^1/_n$= 1.03 Kfom= 118.3 L/kg Metabolites: <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: FOCUS PEARL 3.3.3, FOCUS PELMO **t-oxanilic acid (2)** Geo mean DT50f= 53.5d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Mean Kfoc 35 L/kg; mean 1/n= 1.3; Kfom= 20.3 L/kg FF 0.07072 **t-sulfynilacetic acid (3)** worst case DT50f: 58.3d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Mean Kfoc 23 L/kg; mean 1/n= 0.96; Kfom= 13.34 L/kg FF0.03438 **t-sulfonic acid (7)** Geo mean DT50f : 87.44 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Mean Kfoc: 39.2 L/kg;mean 1/n= 1.3; Kfom= 22.7L/kg FF 0.04254 **s-sulfonic acid (13)** Geo mean DT50 = 42.2 d (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58). Mean Koc: 6.8 l/kg; n=1 Kfom= 3.94L/kg FF 1 from t-sulfonic acid
Application rate	Parent Application rate: 2016 g/ha. No. of applications: 1 Time of application (month or season): spring (10 days before emergence) 20 years of consequtive application

* Kom =Koc/1.724

[£]In any future modelling the appropriate value to use would be 10.2 days..

20 years of consequtive application

	Scenario	Parent (µg/L)	Metabolite (µg/L) Tier 1			
			t-sulfonic acid	**t-oxanilic acid**	**t-sulfinylacetic acid**	**s-sulfonic acid**
FOCUS PELMOL /maize	Chateaudun (C)	0.000	**15.896**	**11.969**	4.657	7.863
	Hamburg (H)	0.001	**22.230**	**21.970**	8.481	9.062
	Krensmünster (K)	0.000	**20.575**	**17.034**	5.785	9.868
	Okehampton (N)	0.000	**15.868**	**14.885**	6.167	6.550
	Piacenza (P)	0.007	**12.121**	**10.629**	5.434	4.521
	Porto (O)	0.000	6.227	5.243	0.868	4.131
	Sevilla (S)	0.000	1.450	0.787	0.034	0.989
	Thiva (T)	0.000	6.189	2.344	0.845	3.907

20 years of consequtive application

P E	Scenario	Parent	Metabolite (µg/L) Tier 1

		(µg/L)	t-sulfonic acid	t-oxanilic acid	t-sulfinylacetic acid	s-sulfonic acid
	Chateaudun (C)	0.0018	13.8414	13.117	5.9216	5.8657
	Hamburg (H)	0.005	19.7205	19.0025	8.3157	8.2470
	Krensmünster (K)	0.0029	11.8982	11.5322	5.5357	5.1575
	Okehampton (N)	0.0087	12.1749	12.3403	5.8233	4.7181
	Piacenza (P)	0.0176	9.8614	9.4537	5.187	3.5195
	Porto (O)	0.000000	5.3718	3.9938	1.1894	3.3995
	Sevilla (S)	0.0001	6.4936	4.0344	2.0079	4.0727
	Thiva (T)	0.0009	**10.0629**	7.8930	3.9280	4.7952

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 metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	**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), t-norchloroacetochlor (6) **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 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). <0.05- 1.21µg/l (AcOXA) t-sulfinylacetic acid (**3**): <0.05 -0.161µg/l (AcSAA) *t*-sulfonic metabolite (**7**): <0.05-4.06 µg/l (AcESA) Acetochlor metabolites have been monitored in ground water in key maize growing areas of Italy in 2005 -2007 (9 locations, n pair of piezometers=609): The application rate made to the treated fields was 1.8 kg/ha over the duration of the monitoring (i.e. only 90% of the representative intended use)

Maximum concentration expressed as the Mean from a Piezometer Cluster (µg/l) found in the monitoring conducted in Northern Italy

	t sulfonic metabolite (7):	s-sulfonic acid (13)	t-oxanilic acid (2)	t-sulfinylacetic acid (3):	MeESA[1]
site 2	0.21	0.67	<0.05	<0.05	0.17

site 3	2.29	13.18	0.72	0.08	3.24
site 4	1.19	0.3	1.05	<0.05	1.29
site 5	0.2	0.15	0.14	0.05	0.32
site 6	5.5	1.72	2.28	0.61	10.12
site 7	0.45	0.33	0.19	<0.05	0.86
site 8	0.1	0.18	0	0.17	2.33
site 9	<0.05	<0.05	<0.05	<0.05	<0.05
site 10	7.91	4.02	9.14	0.6	5.07

(1) MeESA is a metolachlor metabolite, that is also a precursor of s-sulfonic acid (13)

A small subset of groundwater samples collected from the groundwater study conducted in northern Italy was analyzed for two additional minor soil metabolites, t-norchloroacetochlor (6) and hydroxyacetochlor (17).

Samples from both piezometers in a single cluster from each of Sites 3 and 10 that showed the highest concentrations of the acid metabolites in groundwater were analyzed for the presence of these minor degradates as they were expected to provide a worst case for detection of acetochlor metabolites

Site 3: The detections of norchloroacetochlor in groundwater from Site 3 corresponded to the increased concentrations of the acidic metabolites observed in the main study which had been proposed as arising from inadvertent contamination of the piezometer

Site 10: there was only a single detection of each analyte above 0.05 µg/L. A groundwater sample from June 2007 from Piezometer B had a concentration of 0.07 µg/L of norchloroacetochlor and 0.211 µg/L of hydroxyacetochlor. In the second piezometer of the pair concentrations were <0.05µg/L (consequently mean values of these samples are 0.06 and 0.15µg/L respectively).

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 readily biodegradable; Candidate for R53

Section **Chapter 6 Ecotoxicology**

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 dicofol/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)

Maize at 2.016 kg acetochlor/ha

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
Active substance				
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
insectivorous	Short-term	60.8	17.5	10
insectivorous	Long-term	60.8	**0.09**	5
vermivorous	Long-term	82.3	0.06	5
Piscivorous	Long-term	0.010	550	5

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Medium herbivorous bird	Acute	87.3*	**4.3**	10
Insectivorous bird	Acute	287.1*	**1.4**	10
Drinking water	Acute-Leaf scenario	DWR = 0.46 L/kg bw/d	**1**	10
Drinking water	Acute-Puddle scenario	DWR = 0.46 L/kg bw/d	3254.7	5
Drinking water	Long-term-Puddle scenario	DWR = 0.46 L/kg bw/d	19.3	5
Plant metabolites				
herbivorous bird-N-oxamic acid	Acute	22.1	17	10
herbivorous bird-t-sulfinyllactic acid	Acute	22.8	16	10
herbivorous bird-s-sulfinyllactic acid	Acute	9.76	38	10
herbivorous bird-N-oxamic acid	Short-term	17.0	> 62	10
herbivorous bird-t-sulfinyllactic acid	Short-term	17.8	> 59	10
herbivorous bird-s-sulfinyllactic acid	Short-term	7.57	> 139	10
herbivorous bird-N-oxamic acid	Long-term	0.71	7.7	5
herbivorous bird-t-sulfinylactic acid	Long-term	0.74	7.4	5
herbivorous bird-s-sulfinylactic acid	Long-term	0.32	17	5
Higher tier refinement (Birds)[1]				
herbivorous	Acute	23.1	**16.73**	10
herbivorous	Short-term			10
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

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
vermivorous	Long-term	104.7	0.19	5
piscivorous	Long-term	0.0066	**3030**	5
water consumption	Acute-Puddle scenario	DWR = 0.24	6722	5
Water consumption	Long-term-Puddle scenario	DWR = 0.24	134.3	5
Plant metabolites				
herbivorous mammal-N-oxamic acid	Acute	8.13	> 246	10
herbivorous mammal-t-sulfinyllactic acid	Acute	8.41	> 237	10
herbivorous mammal-s-sulfinyllactic acid	Acute	3.60	> 555	10
herbivorous mammal-N-oxamic acid	Long-term	0.177	113	5
herbivorous mammal-t-sulfinyllactic acid	Long-term	0.185	1432	5
herbivorous mammal-s-sulfinyllactic acid	Long-term	0.079	3354	5
Higher tier refinement (Mammals)				
herbivorous	Long-term	1.06	**19**	
vermivorous	Long-term	0.09	**22.2**	5

*** Daily intake [mg as./kg bw/day]**

[1]Acute and long term refinement based on crested lark (insectivorous species)

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[1] (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.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
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
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

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
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
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
Microcosm or mesocosm tests				

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
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 (NOAEC) 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

Maize at 2.016 kg Acetochlor /ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i (µg/L)	PEC_{twa}	TER	Annex VI Trigger[1]
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
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

Maize at 2.016 kg Acetochlor /ha. Southern Europe (worst case scenarios)

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
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*[5]	0.00257	Chronic	176.2	0.0145	10
Acetochlor	S	*C. riparius*	1.6	Chronic	176.2	9.16	10

[1] indicate whether Northern of Southern
[2] include critical groups which fail at Step 1.
[3] indicate whether maximum or twa values have been used (µg/L).
[4] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[5] only required for herbicides
[6] consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Maize at 2.016 kg Acetochlor /ha.

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[1] sw (initial)	TER	Annex VI trigger[5]
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

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[1] sw (initial)	TER	Annex VI trigger[5]
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
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. subcapitata*	Acute	0.00031	10.342	0.029	10
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

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[1] sw (initial)	TER	Annex VI trigger[5]
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
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
Metabolites								
Product								

[1] actual PEC_{sw}, were used

FOCUS Step 3. Higher Tier risk assessment refinement. Toxicity data from mesocosm studies

Maize at 2.016 kg Acetochlor /ha.

Test substance	Scenario	Water body	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	PEC [1] sw (µg a.s./L)	TER	Annex VI trigger
Acetochlor	D3	ditch	Aquatic communities	Chronic	0.2	10.566	**0.019**	2
Acetochlor	D4	pond	Aquatic communities	Chronic	0.2	0.432	**0.46**	2
Acetochlor	D4	stream	Aquatic communities	Chronic	2.0	8.919	**0.22**	2
Acetochlor	D5	pond	Aquatic communities	Chronic	0.2	0.428	**0.47**	2
Acetochlor	D5	stream	Aquatic communities	Chronic	2.0	10.349	**0.19**	2
Acetochlor	D6	ditch	Aquatic communities	Chronic	0.2	10.633	**0.019**	2
Acetochlor	R1	pond	Aquatic communities	Chronic	0.2	0.764	**0.26**	2
Acetochlor	R1	stream	Aquatic communities	Chronic	2.0	22.94	**0.087**	2
Acetochlor	R2	stream	Aquatic communities	Chronic	2.0	15.095	**0.132**	2
Acetochlor	R3	stream	Aquatic communities	Chronic	2.0	10.342	**0.193**	2
Acetochlor	R4	stream	Aquatic communities	Chronic	2.0	54.605	**0.037**	2

[1]. PECsw global maximum

FOCUS Step 4. Higher Tier risk assessment refinement. Toxicity data from mesocosm studies

Maize at 2.016 kg Acetochlor /ha.

Test substance	Scenario	Water body	Test organism	Time scale	Toxicity endpoint (µg a.s./L)	PEC [1] sw (µg a.s./L)	TER	Annex VI trigge
Refinement 1: 20 m drift buffer and 20 m vegetated filter strip								
Acetochlor	D3	ditch	Aquatic communities	Chronic	0.2	0.954	**0.2**	2
Acetochlor	D4	pond	Aquatic communities	Chronic	0.2	0.190	**1.1**	2
Acetochlor	D4	stream	Aquatic communities	Chronic	2.0	1.040	1.9	2
Acetochlor	D5	pond	Aquatic communities	Chronic	0.2	0.203	**1.0**	2
Acetochlor	D5	stream	Aquatic communities	Chronic	2.0	1.052	1.9	2
Acetochlor	D6	ditch	Aquatic communities	Chronic	0.2	1.044	0.2	2
Acetochlor	R1	pond	Aquatic communities	Chronic	0.2	0.228	**0.9**	2
Acetochlor	R1	stream	Aquatic communities	Chronic	2.0	5.141	**0.4**	2
Acetochlor	R2	stream	Aquatic communities	Chronic	2.0	3.550	**0.6**	2
Acetochlor	R3	stream	Aquatic communities	Chronic	2.0	1.200	**1.7**	2
Acetochlor	R4	stream	Aquatic communities	Chronic	2.0	13.384	**0.1**	2

[1]. PECsw global maximum

Bioconcentration					
	Active substance	Norchloro acetochlor	Acetochlor sulfinil acetic	Acetochlor sulfonic acid	Acetochlor Oxanilic acid
	Acetochlor				
$logP_{O/W}$	4.14	3.0	2.1	1.2	2.2
Bioconcentration factor (BCF)[1] ‡	20				
Annex VI Trigger for the bioconcentration factor	100				
Clearance time (days) (CT_{50})					
(CT_{90})					
Level and nature of residues (%) in organisms after the 14 day depuration phase					

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

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		
Not required		

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

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

Test substance	Route	Hazard quotient	Annex VI Trigger
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[1])
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

[1]

Maize at 2.016 kg Acetochlor /ha.

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]	HQ in-field	HQ off-field	Trigger value
Aphidius rhopalosiphi	adults	MON 69447	0.084 2100	Mortality	M = 0.0%, R = 0.86 M = 20 %, R = 0.59			
Aphidius rhopalosiphi	adults	GF-675	Rate response	Mortality	LR_{50} > 2000, P=0.43 at highest dose			

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	Effect[3]	HQ in-field	HQ off-field	Trigger value
Typhlodromus pyri	adults	MON 69447	0.084 2100	Mortality	M = 23.0%, R = 1.09 M = 17.0%, R = 1.00			
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			
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 preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests

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 ai/kg soil
	t-sulfinylacetic acid	Chronic	NOEC (correc)= 3.44 mg as/kg soil
	t-sulfonic acid	Chronic	NOEC = 3.71mg as/kg soil
	s-sulfonic acid	Chronic	NOEC = 10.5 mg a.s./ Kg soil
Other soil macro-organisms			

Test organism	Test substance	Time scale	End point[1]
Soil mite	a.s. ‡		
	Preparation		
	Metabolite 1		
Collembola			
	a.s. ‡	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	Preparation		
	Metabolite 1		
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
	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

Test organism	Test substance	Time scale	End point[1]
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 Pow >2.0 (e.g. LC_{50corr})

Toxicity/exposure ratios for soil organisms

Maize at 2.016 kg Acetochlor /ha.

Test organism	Test substance	Time scale	Soil PEC[2]	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
Other soil macro-organisms					
Soil mite	a.s. ‡				
	Preparation				
	Metabolite 1				
Collembola	a.s. ‡				
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Exposure type	**Deterministic approach (g a.s./ha)**	**5th centile from SSD**	**Initial maximum exposures based on spray drift in areas adjacent to applied fields (g a.s./ha)[1]**

		(g a.s./ha)						
			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.
[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)

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

Test type/organism	end point
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	

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

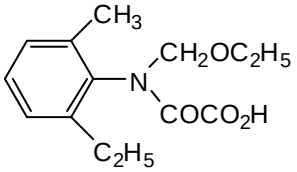
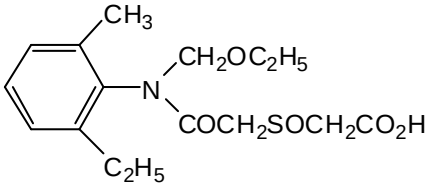
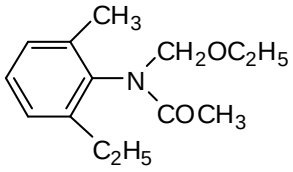
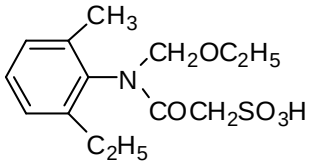
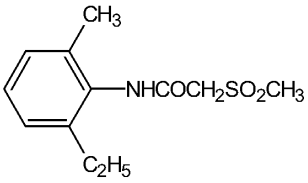
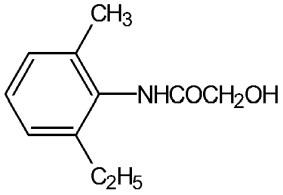
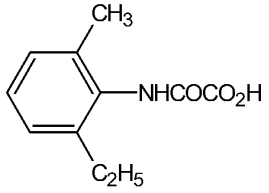
Compartment	
soil	Acetochlor
water	Acetochlor
sediment	Acetochlor
groundwater	Acetochlor

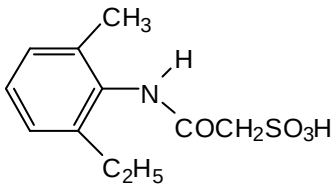
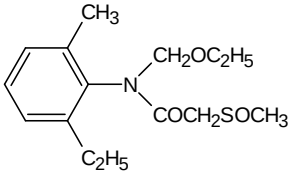
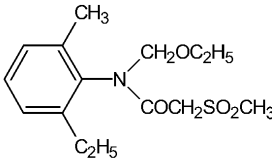
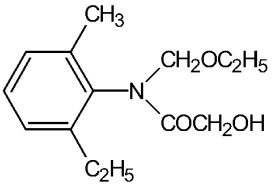
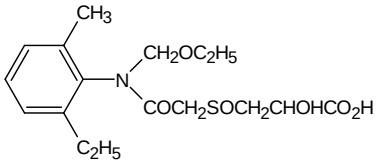
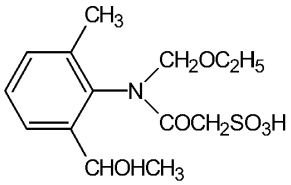
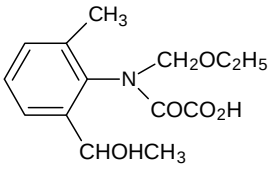
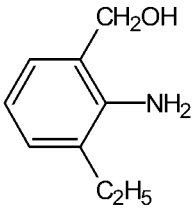
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

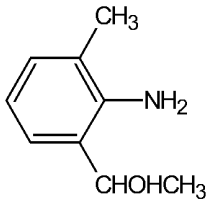
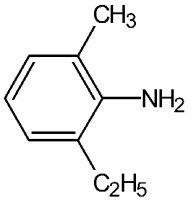
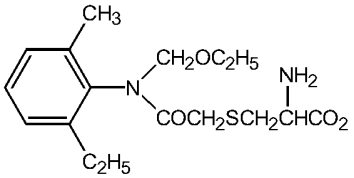
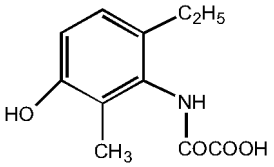
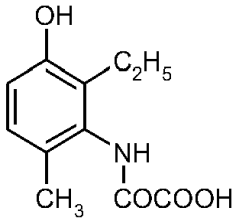
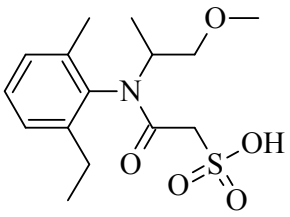
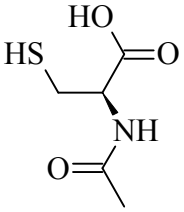
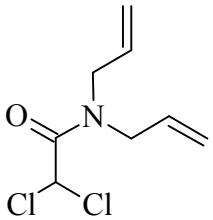
	RMS/peer review proposal
Active substance	R 50/53, N

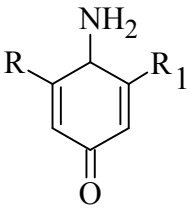
	RMS/peer review proposal
Preparation	R 50/53, N

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
t-oxanilic acid (2) R290130, compound 17, MON 52766, ICIA5796/17 t-OXA AcOXA	[(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 t-SSA AcSAA	({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 t-NCA	*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)acetamide	
t-sulfonic acid (7) R290131 Compound 24, MON52754, ICIA5796/24 t-ESA AcESA	2-[(ethoxymethyl)(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic 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	
s-oxanilic acid (12) Compound 27 CP 91301	[2,6-dimethylphenyl)amino](oxo)acetic acid	

s-sulfonic acid (13) Compound 32 CP 92428 s-ESA EMAsESA	2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethanesulfonic acid	
t-amide methyl sulfoxide (15) Compound 11	2-methylsulfinyl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl) acetamide	
t-amide methyl sulfone (16) Compound 12	2-methylsulfonyl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide	
t-hydroxy acetochlor (17) Compound 20 CP 68365-3 t-HYD	*N*-(ethoxymethyl)-*N*-(2-ethyl-6-methylphenyl)-2-hydroxyacetamide	
t-sulfinyllactic acid (21)	2-(2-carboxy-2-hydroxyethyl) sulfinyl- N-ethoxymethyl-N-(2-ethyl-6-methylphenyl) acetamide	
Sulfonic acid 2 (24)	2-sulfonyl-N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]acetamide	
hydroxyethyl-*t*-oxanilic acid (30)	N-ethoxymethyl-N-[2-(1-hydroxyethyl)-6-methylphenyl]oxamide	
HMEA (32) CP 105966	2-hydroxymethyl-6-ethylaniline	

HEMA (33) CP109703	2(1-hydroxyethyl)-6-methylaniline	
EMA (34) Compound 52 CP 68594	2-ethyl-6-methylaniline	
t-amide cysteine (56) Compound 44	2-cystein-S-yl-N-ethoxymethyl-N-(2-ethyl-6-methylphenyl)acetamide	
N-oxamic acid (68) Compound 57 1 of 2 components of PJ2,	[(6-ethyl-3-hydroxy-2-methylphenyl)amino](oxo)acetic acid	
Metabolite 69 (69) Compound 55 ICIA5676/55	[(2-ethyl-3-hydroxy-6-methylphenyl)amino](oxo)acetic acid	
MeESA	2-[(2-ethyl-6-methylphenyl)(2-methoxy-1-methylethyl)amino]-2-oxoethanesulfonic acid	
-	*tert*-mercapturic acid	
dichlormid	N,N-diallyl-2,2-dichloracetamide	

DABQI	dialkylbenzoquinoneimine	

ABBREVIATIONS

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