CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Oxyfluorfen is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Spain, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 11e, to withdraw support for the inclusion of oxyfluorfen in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of oxyfluorfen in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Dow AgroSciences and Makhteshim Agan made a resubmission application for the inclusion of oxyfluorfen in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

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 13 January 2010.

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 15 January 2010. The EFSA collated and forwarded all comments received to the Commission on 1 March 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology and deliver its conclusions on oxyfluorfen.

1 On request from the European Commission, Question No EFSA-Q-2010-00676, issued on 17 November 2010.

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3 OJ L224, 21.08.2002, p.25

4 OJ L 246, 21.9.2007, p. 19

5 OJ L 333, 11.12.2008, p. 11

6 OJ L 15, 18.01.2008, p. 5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of oxyfluorfen as a herbicide on grapes, pome fruit and sunflowers, as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

No critical areas of concern were identified in the physical-chemical properties section. Several data gaps were identified for the technical materials and one data gap for the Plant Protection Product.

In the mammalian toxicology section a critical area of concern was identified in relation to the compliance of the batches tested to the proposed specification, which could not be demonstrated.

Based on the metabolism studies conducted on three different plant groups, the plant residue definition for monitoring and risk assessment was defined as oxyfluorfen only. A single data gap was identified in the residue section concerning additional residue data on sunflower in Northern EU. No areas of concern were identified with respect to consumer exposure.

The data available on fate and behaviour in the environment were essentially sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. However, a data gap is identified for justification of the higher concentrations in soil of the impurity RH-4672 (I-3) measured in the Californian field dissipation trials with respect to the levels of the same compound in the technical product. No areas of concern were identified with respect to the potential for groundwater contamination.

Critical areas of concern were identified for the risk to algae and *Lemna* for all representative uses, the risk from bioaccumulation and biomagnification in the aquatic food chains and for the missing aquatic risk assessments for all representative uses for the metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27. Data gaps remain to address the risk to earthworm-eating mammals and the risk to soil-living macro-organisms from the use in pome fruits and grapes. Risk mitigation equivalent to 5 m no-spray buffer zones was required to identify a low off-field risk for non-target organisms for all representative uses. Additionally, risk mitigation equivalent to 5 m no-spray buffer zones was required to identify a low risk to non-target plants for the representative uses in pome fruits and grapes. The risk to bees, non-target micro-organisms and biological methods for sewage treatment was assessed as low for all representative uses.

KEY WORDS

Oxyfluorfen, peer review, risk assessment, pesticide, herbicide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] 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 of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicants for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Oxyfluorfen is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Spain, which was received by the EFSA on 31 July 2006 (Spain, 2006).

The peer review was initiated by dispatching the DAR to Member States on 22 October 2007 and to the applicants Dow AgroSciences and Makhteshim Agan on 4 October 2007 for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR.

The peer review process was subsequently terminated following the applicants' decision, in accordance with Article 11e, to withdraw support for the inclusion of oxyfluorfen in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of oxyfluorfen in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants Dow AgroSciences and Makhteshim Agan made a resubmission application for the inclusion of oxyfluorfen in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, 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 13 January 2010 (Spain, 2010a).

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicants for comments on 15 January 2010. In addition, the EFSA conducted a public consultation

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

on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 1 March 2010. At the same time, the collated comments were 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' responses were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 22 March 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on oxyfluorfen 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 Commission on 26 March 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' response 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, environmental fate and behaviour, and ecotoxicology and that further information should be requested from the applicants in the areas of identity, mammalian toxicology, environmental fate and behaviour and ecotoxicology.

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, including those issues to be considered in consultation with Member State experts, and the additional information to be submitted by the applicants, 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, together with the outcome of the expert discussions where these took place, 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 October 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a herbicide on grapes, pome fruit and sunflowers, as proposed by the applicants. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 7 April 2010),
- the Evaluation Table (4 November 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of October 2010 containing all individually submitted addenda) (Spain, 2010b) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Oxyfluorfen is the ISO common name for 2-chloro-α,α,α-trifluoro-*p*-tolyl 3-ethoxy-4-nitrophenyl ether (IUPAC).

The representative formulated product for the evaluation was 'Goal 4F' or 'Goal 480 SC' a suspension concentrate (SC) containing 480 g/l oxyfluorfen.

The representative uses evaluated comprise outdoor spraying against annual grasses and broadleaved weeds in grapes, pome fruit and sunflowers. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of the active substance as manufactured is 970 g/kg. The technical material contains the relevant impurity N,N-dimethylnitrosamine. The maximum content of this impurity in the technical material is provisionally set at <50 µg/kg.

The Makhteshim Agan source was considered not equivalent on the basis of a Tier I equivalence assessment but was considered equivalent following a Tier II assessment (see section 2).

The following data gaps for the technical materials were identified.

- A revised specification to include the relevant impurity (Makhteshim Agan).
- Validation of the method of analysis for impurity 4 (Makhteshim Agan).
- Validation data for the impurity method at appropriate concentrations (Dow AgroSciences).
- GLP 5 batch with analysis for the relevant impurity (Dow AgroSciences)

Because of the above listed data gaps, the technical specifications should be regarded as provisional.

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

For the supported Plant Protection Product a data gap was identified for the effect of low temperatures on stability.

Residues in plants and soil can be determined with a multi-residue method (DFG S19). A method for residues in products of animal origin is not required as no MRLs are proposed, however a method is available. Residues in water can be analysed by GC-MS and in air by GC-ECD. Methods of analysis for body fluids and tissues are not required because the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

Oxyfluorfen was discussed during PRAPeR 81 in August-September 2010.

Acute toxicity and mutagenicity testing of the Makhteshim Agan and DowAgrosciences substance did not provide significantly different results (Tier II). However, for both applicants the compliance of the batches tested in the mammalian toxicology data package to the proposed specifications could not be fully demonstrated, indicating a critical area of concern. In addition, the proposed specifications are still provisional. The impurity N,N-dimethylnitrosamine is considered relevant.

The stability of the technical materials used in the toxicological tests was not confirmed and a data gap was identified.

Oxyfluorfen has a low acute oral, dermal and inhalative toxicity. It is not a skin or eye irritant, or a skin sensitiser. The relevant oral short-term toxicity No Observed Adverse Effect Level (NOAEL) is 2.17 mg/kg bw/day, due to decreases in bodyweight gains, increases in absolute and relative liver weight, anaemia and alterations in clinical chemistry parameters in the dog. In addition, alterations in the spleen, kidney and haematopoietic system were recorded in rats. Oxyfluorfen is devoid of any genotoxic potential. For chronic repeated exposures mice showed the highest sensitivity, with a NOAEL of 0.28 mg/kg bw/day; in the same species an increased incidence of liver cell adenocarcinoma in males occurred at 30.69 mg/kg bw/day (based on this the classification as Carc Cat 3 R40 "limited evidence of a carcinogenic effect" was proposed; the NOAEL for carcinogenicity was set at 3 mg/kg bw/day). Oxyfluorfen did not show effects on fertility or development as there was no maternal toxicity. In a multigeneration study in rat the relevant parental, offspring and reproductive NOAELs were 6.8 mg/kg bw/day, 20 mg/kg bw/day and 91 mg/kg bw/day, respectively. In a rabbit developmental toxicity study the relevant maternal and developmental NOAELs were 30 mg/kg bw/day, whereas in rats they were 1000 mg/kg bw/day. The Acceptable Daily Intake (ADI) is 0.003 mg/kg bw/day, based on the NOAELs of the long term toxicity study in mice, with a Safety Factor (SF) of 100. The Acceptable Operator Exposure Level (AOEL) is 0.013 mg/kg bw/day, from the relevant short-term NOAEL in dogs, SF 100 and correction for oral absorption of 60%. The Acute Reference Dose (ARfD) is 0.3 mg/kg bw based on the developmental toxicity NOAEL in rabbit, SF 100. Operator exposure levels are below the AOEL for tractor-mounted applications with the use of PPE (gloves during mixing and loading (M/L) and coverall during application for the sunflower scenario, and gloves during M/L and application and coverall and sturdy footwear during application for the pome fruits and the grape scenarios). No re-entry exposure is expected for the proposed scenarios. The bystander exposure is below the AOEL.

3. Residues

Metabolism in plants was investigated in root/tuber crops (onion), fruit crops (tomato, peach and apple) and leafy crops (alfalfa), using ^{14}C-label on the chlorophenyl or nitrophenyl ring and on the trifluoromethyl group. The active substance was applied post-emergence on onion and alfalfa, directly onto the soil in dormant apple and peach trees, and pre-plantation of tomato.

Total radioactive residues in fruit crops were very low (<0.004 mg/kg), even in the plots treated at an exaggerated 8N dose rate. Therefore, the characterisation of the residues was mainly attempted in the alfalfa study conducted with the chlorophenyl label, where TRRs were up to 0.199 mg/kg. However, the low radioactivity in the different extracts and fractions did not permit a definite characterisation of the residues. Oxyfluorfen was almost not detected (2% TRR, 0.001 mg/kg) and only trifluoroacetic acid (TFAA) was observed as a major metabolite, its amounts increasing with time from 17% to 53% TRR (0.02 to 0.11 mg/kg). The rotational crop study confirmed the limited uptake of residues, the TRRs in the different plant parts being mostly below 0.01 mg/kg, irrespective of the plant back intervals. Globally the different studies show oxyfluorfen to be rapidly and extensively degraded in plants. The metabolism proceeds first by cleavage of the parent structure at the ether bond between the two phenyl rings, followed by further degradations of the chlorophenyl ring to TFAA. Based on these studies, the residue definition for monitoring was limited by default to oxyfluorfen only. Considering that TFAA was not detected in onion, tomato, peach and apple, and taking into account that TFAA is not specific to oxyfluorfen, it was decided not to include this compound in the residue definition for risk assessment and the same definition as for monitoring was proposed.

Supervised residue trials on sunflower, grape and apple conducted over several growing seasons were provided. No residues above the LOQ were detected in any sample analysed and the MRLs were proposed at the value of 0.01 mg/kg. Having regard to the no-residue situation, no additional trials were required, except for sunflower in Northern EU, as no data were provided for this zone. These residue data are supported by the storage stability study showing oxyfluorfen residues to be stable up to 3 years in plant matrices.

Metabolism and feeding studies conducted on goat and poultry were provided, although the intakes were calculated to be far below the trigger value of 0.1 mg/kg DM. The metabolism studies, conducted with the parent oxyfluorfen, showed the residue in animal matrices to be mainly composed of the parent and metabolites structurally related to the parent. These studies have however to be considered as not appropriate since they were conducted with oxyfluorfen, whereas the plant metabolism data have shown the parent is not present in plant commodities following application of oxyfluorfen as a herbicide. It is therefore not possible to conclude, as suggested by these metabolism studies, that residues in animal matrices are mainly composed of the parent and/or structurally related compounds. Nevertheless, and having regard to the limited intakes by animals, it was concluded that no residue definitions and MRLs have to be proposed for animal matrices.

No chronic or acute concerns were identified for the consumers, the highest TMDI and IESTI being only 5% of the ADI (DE child) and less than 1% of the ARfD (apple), when the estimates are calculated using the EFSA PRIMo model.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark (5 soils investigated with oxyfluorfen uniformly labelled with ^{14}C in either the chlorophenyl ring or the nitrophenyl ring), oxyfluorfen exhibited medium to very high persistence, forming no major (> 10% applied radioactivity (AR)) or minor non-transient (> 5% AR at least 2 consecutive sampling times[11]) soil metabolites. Mineralisation to carbon dioxide ranged from 0.8-15% AR after 90-91 days. The formation of unextractable residues (not extracted by methanol:water or Soxhlet methanol:water) were a significant sink, accounting for 10.1-43.1% AR after 90-91 days. Soil photolysis was shown to be a significant route of degradation for oxyfluorfen. Photolysis proceeds via cleavage of the ether bridge and no photo-degradates > 5% AR were formed. Dissipation of oxyfluorfen under field conditions was investigated in seven different sites and on bare soils, three in North America (2 sites in California, USA and 1 site in British Columbia, Canada) and four in Europe (England, Northern France, Spain and Italy). In the original DAR soil residues for the impurities RH-0671 (I-8), RH-4672 (I-3) and RH-2382 (I-6) were also reported, indicating that concentrations of RH-4672 (I-3) were > 10% of the parent concentrations. In order to check that the impurities come from the test substance applied in the trial and not from the degradation of the active substance, the applicant indicated that when the concentration is expressed as a proportion of the active substance, the level of the impurity RH-4672 (I-3) is 14.4% (Final Addendum (Spain, 2010b)). However, it is noted that under field conditions, residues of I-3 were measured up to 26%[12] (Madera site) of the initial measured concentration of oxyfluorfen after 7 d. It is the opinion of the EFSA that, considering the chemical structure of I-3, it is very unlikely that this molecule is formed through the biological or chemical degradation of the active substance and therefore it is highly improbable that I-3 is a soil major metabolite of oxyfluorfen. However, a data gap is identified for justifications on the higher concentrations in soil of the impurity RH-4672 (I-3) measured in the Californian field dissipation trials with respect to the levels of the same compound in the technical product. As the final reports of field studies were not available to determine the long-term accumulation of oxyfluorfen in soil, estimates of accumulation were based on calculations using realistic worst-case parameters (application rate 1440 g/ha on pome fruits and vines, no plant interception and longest field DT_{50} of 172 days). These calculations resulted in a maximum plateau value of 2.50 mg/kg after six years of annual applications (pome fruits and vines). Oxyfluorfen can be considered slightly mobile to immobile in soil. There was no indication that adsorption of oxyfluorfen was pH dependent.

[11] Criteria triggering a groundwater exposure assessment as outlined in the Guidance on the relevance of metabolites in groundwater (European Commission, 2003).

[12] Estimated summing the residues of the active substance measured over the 0-30cm soil depth, I-3 was only detected in the top 0-7cm at 7 days.

Oxyfluorfen is stable to hydrolysis at pH 4 to 9 but is rapidly degraded by sunlight in aqueous solution. Major photoproducts were observed: RH-123394 (17.4% AR at 1d), RH-35451 (23% AR at 15d), RH-45469 (10% AR at 1d), MW 306 and MW 347 (quantification uncertain since they co-eluted; two peaks accounting for 27% AR at 0.33d), MW 274 (13.3% AR at 2d) and unidentified Deg 27 (11% AR at 2d). In laboratory incubations in dark aerobic natural sediment water systems (4 systems investigated with oxyfluorfen uniformly labelled with ^{14}C in either the chlorophenyl ring or the nitrophenyl ring), oxyfluorfen dissipated rapidly from the water phase by degradation and adsorption to the sediment. In the whole systems oxyfluorfen exhibited moderate persistence, forming no major metabolites. The radioactivity that partitioned to sediment that was not oxyfluorfen was primarily accounted for as the unextracted fraction (not extracted by acetonitrile:water or Soxhlet acetonitrile:water). Mineralisation of both the radiolabels was insignificant. For the representative uses assessed in orchards, vineyards and sunflowers, the predicted environmental concentrations (PEC) in surface water and sediment were calculated using the FOCUS surface water models and scenarios (FOCUS, 2001) for oxyfluorfen and the aqueous photodegradation products RH-123394, RH-35451, RH-45469, MW 306, MW 347, MW 274, RH-34670 and unidentified Deg 27 following FOCUS Step 1-4[13] approaches. At Step 4 mitigation of inputs via spray drift (no spray buffer zones) and runoff (vegetative buffer strips) are considered, according to FOCUS (2007) Landscape and mitigation Guidance. Since in orchards and vineyards oxyfluorfen is applied as a banded application to the soil below the crop row, and the area between the rows is not treated, in the simulations for pome fruit and vines the actual area treated was parameterised as *ca.* 1/3 of the total area in the FOCUS Step 3 and 4 calculations in respect of the dose reaching the soil. These Step 3 and 4 calculations utilised spray drift values for tractor-mounted hydraulic sprayers as defined by FOCUS for arable crops (as the application is a ground spray) with no reduction in the label dose (in contrast to the approach for the dose arriving at the soil surface). In response to EFSA and Member States seeking clarification on the way spray drift mitigation measures were implemented at Step 4, the RMS confirmed (Final Addendum (Spain, 2010b)) that a buffer zone of ≥ 100 m will result in a spray drift reduction exceeding the maximum value of 95% recommended by the FOCUS Landscape and mitigation Guidance in the water bodies ditch and stream and therefore this extent of spray drift mitigation can only be accepted for ponds. The PEC surface water and sediment included in Appendix A respect the cap on spray drift mitigation of 95%. Additionally, the fate experts in PRAPeR 78 agreed that the spray drift input data derived from a field study designed to measure drift from banded ground-spray applications in orchards and vineyards, when a pedestrian boom sprayer was used for applications, should not be used in the risk assessment due to the limited extent of the available data compared to the size of the dataset used to derive the agreed FOCUS spray drift values.

The necessary groundwater exposure assessment was appropriately carried out using FOCUS (2000) scenarios and model (PELMO 3.3.3[14]). The potential for groundwater exposure from the representative uses by oxyfluorfen above the parametric drinking water limit of 0.1 µg/L, was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

5. Ecotoxicology

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

The acute risk to birds and mammals and the short-term risk to birds from direct dietary exposure was assessed as low for the representative uses, based on the old guidance document for Birds and Mammals (European Commission, 2002c). Additionally, the long-term risk to birds and mammals from direct dietary exposure was identified as low for all representative uses, based on the new guidance document for Birds and Mammals (EFSA, 2009). Moreover, the risk to fish-eating birds and mammals was assessed as low for all representative uses, as was also the case for earthworm-eating

[13] Step 3 and 4 Simulations appropriately utilised the Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7.
[14] Simulation appropriately utilised the Q10 of 2.58 (EFSA, 2007) and Walker equation coefficient of 0.7.

birds. Whereas the risk was assessed as low for earthworm-eating mammals following sunflower application, it was not possible to identify a low risk to earthworm-eating mammals following applications in pome fruits and grapes even with PT refinements. A data gap remains to address the risk to earthworm-eating mammals from the uses in pome fruits and grapes. The risk to birds and mammals from consumption of contaminated drinking water was assessed as low for all representative uses. No risk assessment was provided for plant metabolites, as no relevant metabolites were identified in plant material. Toxicokinetic studies with oxyfluorfen in rat indicated a low potential for bioaccumulation and the possibility of biomagnification along the food chain was considered unlikely.

Based on the data available, oxyfluorfen was assessed as very toxic to aquatic organisms. Algae and *Lemna* were identified as the most sensitive species. The toxicity of the technical substance was in the same range as the lead formulation. A low risk was identified for fish (acute and long-term), invertebrates (long-term) and sediment-dwellers in all scenarios, based on $FOCUS_{SW}$ Step 3 for sunflower uses. Additionally a low risk was identified for the same groups of organisms for uses in pome fruits and grapes, but including mitigation measures equivalent to 20 m no-spray buffer zones. Drift mitigation was however insufficient to address the risk to algae and *Lemna* for any of the representative uses and the acute risk to invertebrates for the use in pome fruits and grapes. Refinements of the risk assessment for algae and *Lemna* based on bioassays adding sediment, risk mitigation measures equivalent to 100 m no-spray buffer zones or reduction of the application rate below the proposed GAP were not accepted by Member State experts (PRAPeR 80, August 2010). A data gap remains to address the risk to algae and *Lemna* for all representative uses and the acute risk to invertebrates for the representative uses in pome fruits and grapes. The risk to aquatic organisms from the three metabolites RH-123394, RH-35451 and RH-34670 was assessed as low, based on FOCUSsw Step 2 for use in sunflowers and based on FOCUSsw Step 4 (20m no-spray buffer zone) for uses in pome fruits and grapes. A data gap remains to address the risk to aquatic organisms for the aquatic metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27. Based on the bioaccumulation data available for fish, the triggers for assessing biomagnification in aquatic food chains were met. A modelling study was provided in an addendum to the Additional Report (Final Addendum (Spain, 2010b)). Data from this modelling indicated that although oxyfluorfen has the potential to bioconcentrate in aquatic organisms, the risk of bioaccumulation, biomagnification and resulting long-term effects in aquatic food chains is expected to be low for pelagic organisms, based on the worst case uses of oxyfluorfen in pome fruits and grapes. A data gap however remains for the applicant to address the risk from bioaccumulation and biomagnification in aquatic food chains including sediment-dwellers, based on DT_{50} estimates covering also the sediment for all representative uses. It was noted during the peer review that in case concerns remain, it would be possible to address the issue of bioaccumulation with a new BCF study according to the OECD 305 and a fish dietary test.

A risk assessment for the representative uses indicated a high risk in-field for non-target arthropods, based on effects on the predatory mite *Typhlodromus pyri*. No effects on other arthropods such as spiders, beetles, ladybirds, lacewings or parasitic *hymenoptera* were indicated. A higher tier risk assessment for off-field non-target arthropods indicated a low risk for all representative uses, when buffer zones up to 5 m were applied. A field study was provided in the Additional Report covering all representative uses. The study did not identify any significant effects on surface-living non-target invertebrates, indicating a low in-field risk to non-target arthropods. Concerns may however remain for Member States regarding how representative the field study is in relation to national conditions. EFSA further notes that the concentration in soil within the study did not cover the plateau concentration expected in soil from the representative uses and should not be used to address effects to soil-living macro-organisms.

A low risk was observed for earthworms *Eisenia foetida*. However, calculated TER values with additional soil-dwelling collembola, *Folsomia candida,* were seen to be lower than the Annex VI trigger. A litter bag study was provided, which addressed the risk for the representative use in sunflower. A data gap remains to address the risk for soil-living macro-organisms for the representative uses in pome fruits and grapes.

The risk to non-target plants was assessed as low for the representative use in sunflower, without any mitigation. Risk mitigation equivalent to 5 m no-spray buffer zones was however required to identify a low risk to non-target plants for the representative uses in pome fruits and grapes.

The risk to bees, non-target micro-organisms and biological methods for sewage treatment was assessed as low for all representative uses.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
oxyfluorfen	Medium to very high persistence Single first order laboratory DT_{50} 62-434 days (20°C, pF2 soil moisture) Single first order and First-Order Multi-Compartment field DT_{50} 37-172 days	A low risk was identified for earthworms. The risk to soil-dwelling species was assessed as low for the representative use in sunflower. A data gap remains to address the risk to soil-dwelling species for the representative uses in pome fruits and grapes.

6.2. 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 activity
oxyfluorfen	Slightly mobile to immobile K_{Foc} 2891-13711 mL/g	no	yes	yes	yes

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
oxyfluorfen	Based on the data available oxyfluorfen was assessed as very toxic to aquatic organisms. A high risk was identified for algae and *Lemna* for all representative uses.
RH-123394 (from aqueous photolysis)	The risk to aquatic organisms was assessed as low.
RH-35451 (from aqueous photolysis)	The risk to aquatic organisms was assessed as low.
RH-45469 (from aqueous photolysis)	A data gap remains to address the risk to aquatic organisms for all representative uses.
MW 306 (from aqueous photolysis)	A data gap remains to address the risk to aquatic organisms for all representative uses.
MW 347 (from aqueous photolysis)	A data gap remains to address the risk to aquatic organisms for all representative uses.
MW 274 (from aqueous photolysis)	A data gap remains to address the risk to aquatic organisms for all representative uses.
unidentified Deg 27 (from aqueous photolysis)	A data gap remains to address the risk to aquatic organisms for all representative uses.

6.4. Air

Compound (name and/or code)	Toxicology
oxyfluorfen	Low acute toxicity via inhalation

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

- A revised specification to include the relevant impurity (Makhteshim Agan) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Validation of the method of analysis for impurity 4 (Makhteshim Agan) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Validation data for the impurity method at appropriate concentrations (Dow AgroSciences) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- GLP 5 batch with analysis for the relevant impurity (Dow AgroSciences) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)
- Cold temperature stability for the Plant Protection Product (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 1)
- The compliance of the tested batches to the proposed specification has to be demonstrated (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 2)
- The stability of the technical materials used in the toxicological tests needs to be confirmed (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 2)
- Additional trials on sunflower in Northern EU are required in order to confirm the MRL derived from Southern trials only (relevant for the representative use on sunflower; submission date proposed by the applicants: unknown; see section 3)
- Justifications for the higher concentrations in soil of the impurity RH-4672 (I-3) measured in the Californian field dissipation trials with respect to the levels of the same compound in the technical product (relevant for all representative uses evaluated ; submission date proposed by the applicants: unknown; see section 4)
- The risk to earthworm-eating mammals remains to be addressed (relevant for the representative uses in pome fruits and grapes; submission date proposed by the applicants: unknown; see section 5)
- The acute risk to aquatic invertebrates remains to be addressed (relevant for the representative uses in pome fruits and grapes; submission date proposed by the applicants: unknown; see section 5)
- The risk to algae and *Lemna* remains to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 5)
- The risk to aquatic organisms from the metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27 remains to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 5)
- The risk from bioaccumulation and biomagnification in aquatic food chains including sediment-dwellers based on DT_{50} estimates covering also the sediment needs to be addressed (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 5)

- The risk to soil-living macro-organisms needs to be addressed (relevant for the representative uses in pome fruits and grapes; submission date proposed by the applicants: unknown; see section 5)

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The use of PPE is needed to reach operator exposure levels below the AOEL for tractor-mounted applications (see section 2).
- A no-spray buffer zone of 5 m was needed to identify a low off-field risk to non-target arthropods for all representative uses (see section 5).
- A no-spray buffer zone of 5 m was needed to identify a low risk to non-target plants for the representative uses in pome fruits and grapes (see section 5)

ISSUES THAT COULD NOT BE FINALISED

- Risk assessment to identify the risk of oxyfluorfen to earthworm-eating mammals from uses in pome fruits and grapes.
- Risk assessment to identify the risk of oxyfluorfen to aquatic invertebrates from uses in pome fruits and grapes.
- Risk assessment to identify the risk of oxyfluorfen to soil-living macro-organisms from uses in pome fruits and grapes.

CRITICAL AREAS OF CONCERN

- For both applicants the compliance of the batches tested in the mammalian toxicology data package to the proposed specifications could not be fully demonstrated.
- Drift mitigation was insufficient to address the risk to algae and *Lemna* for all representative uses.
- No aquatic risk assessments were provided for any of the representative uses for the metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27.
- The risk from bioaccumulation and biomagnification in aquatic food chains needs to be fully addressed.

REFERENCES

EFSA (European Food Safety Authority), 2007. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32

EFSA (European Food Safety Authority). 2009. Guidance Document on Risk Assessment for Birds & Mammals. EFSA Journal 2009; 7(12):1438.

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance oxyfluorfen.

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

European Commission, 2003. Guidance document on assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. SANCO/221/2000-rev 10-final, 25 February 2003.

FOCUS (2000). "FOCUS Groundwater Scenarios in the EU review of active substances". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000-rev.2. 202 pp, as updated by the Generic Guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002

FOCUS (2001). "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.

Spain, 2006. Draft Assessment Report (DAR) on the active substance oxyfluorfen prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, July 2006.

Spain, 2010a. Additional Report to the Draft Assessment Report on the active substance oxyfluorfen prepared by the rapporteur Member State Spain in the framework of Commission Regulation (EC) No 33/2008, January 2010.

Spain, 2010b. Final Addendum to the Additional Report on oxyfluorfen, compiled by EFSA, October 2010.

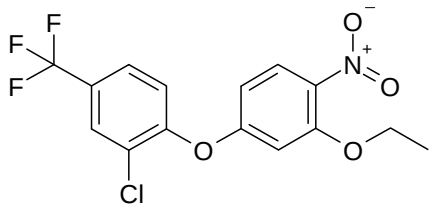
APPENDICES

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)	Oxyfluorfen
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	Spain

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	2-chloro-α,α,α-trifluoro-*p*-tolyl 3-ethoxy-4-nitrophenyl ether
Chemical name (CA)	2-chloro-1-(3-ethoxy-4-nitrophenoxy)-4-trifluoromethyl)benzene
CIPAC No	538
CAS No	42874-03-3
EEC No (EINECSor ELINCS)	255-983-0 (EINECS)
FAO Specification (including year of publication)	No FAO specification
Minimum purity of the active substance as manufactured (g/kg)	970 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	N,N-dimethylnitrosamine Provisional <50 µg/kg=0.05ppm=50ppb
Molecular formula	$C_{15}H_{11}ClF_3NO_4$
Molecular mass	361.70
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	84.5-86.0 ºC (99.2%)
Boiling point (state purity)	Decomposition was observed before boiling occurred (99.8%)
Temperature of descomposition (state purity)	Decomposes at approximately 331 - 333 °C (99.8%)
Appearence (state purity)	Brown crystalline solid (99.2%)
Vapour pressure (state temperature, state purity)	$2.6 * 10^{-5}$ Pa at 25°C (99.2%)
Henry's law constant (Pa m^3 mol^{-1})	H = $2.382 * 10^{-2}$ Pa * m^3/mole at 25°C
Solubility in water (state temperature, state purity and pH)	0.116 mg/L (Unbuffered water at 25 °C, 99.1%)
	Effect of pH not required since active substance does not dissociate at 25°
Solubility in organic solvents (state temperature, state purity)	n-heptane 3.8 g/L Xylene >244 g/L 1,2-dichloroethane >323 g/L methanol 30 g/L acetone 134 g/L ethyl acetate 132 g/L octanol 10.1 g/L All determined at 20 ºC and 99.2% purity
Surface tension (state concentration and temperature, state purity)	72.19 mN/m at 19°C (90% of saturation concentration, purity of 99.2%)
Partition co-efficient (state temperature, pH and purity)	Log P_{ow} = 4.86 at 18 °C in unbuffered water and 99.2% purity
	Effect of pH was not investigated since there is no dissociation in water in the environmentally relevant pH-range
Dissociation constant (state purity)	Oxyfluorfen does not dissociate in water (99.2%).
UV/VIS absorption (max.) incl. ε (state purity, pH)	λmax [nm] ε [$L*mol^{-1}*cm^{-1}$] neutral: 275 nm 6135 320 nm 4730 acidic: 273 nm 6276 320 nm 4730 basic: 273 nm 6445 320 nm 4828
Flammability ‡ (state purity)	Not flammable. (99.2%)
Explosive properties ‡ (state purity)	Not explosive (99.2%)
Oxidising properties	Not oxidising (99.2%)

Summary of representative uses evaluated name of active substance or the representative variant)*

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc a.s (i)	Method Kind (f-h)	Growth stage & season (j)	Num-ber max (k)	Interval between apps. (min)	kg a.s./hL min-max	water (L/ha) min-max	kg a.s./ha min-max		
grapes	Northern and Southern Europe	Goal 4F	F	annual grasses, broadleaves	SC	480 g/l	Boom spraying Directed spray to ground	dormant (Nov.15th-Feb. 1st) BBCH 00	1		-	200-1000,	0.48-1.44	6 months	Banded application [1] [2] [3]
pome fruits	Northern and Southern Europe	Goal 4F	F	annual grasses, broadleaves, annual weeds	SC	480 g/l	Boom spraying Directed spray to ground	dormant (Nov.15th-Feb. 1st) or BBCH 00	1		-	200-1000	0.48-1.44	6 months	Banded application [1] [2] [3]
sunflower	Northern and Southern Europe	Goal 4F or Goal 480 SC	F	annual grasses, broadleaves	SC	480 g/l	Boom spraying	Pre-emergence BBCH 00	1		-	200-1000	0.192-0.24	2-3 months	[1] [3]

[1] A high risk and data gaps were identified for *Lemna* and algae, the risk from bioaccumulation and biomagnification in the aquatic food chains was not fully addressed and the aquatic risk assessments for the metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27 were missing (section 5).
[2] A high risk to earthworm-eating mammals, aquatic invertebrates and soil-living macro-organisms was indicated and data gaps were identified (section 5)
[3] The compliance of the batches tested in the mammalian toxicology data package to the proposed specifications could not be fully demonstrated (section 2)

RISK ASSESSMENT WAS MADE CONSIDERING THE WORST CASE SCENARIO FOR EACH CROP

(a) For crops, the EU and Codex classifications (both) should be used: where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting or suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph No. 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI – minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical as (principle of method)	Method TM-86-05-04: Technical substance is dissolved in ethyl acetate with internal standard and determined by GC-FID Confirmation: GC/MS
Impurities in technical as (principle of method)	Method TM-86-05-04: Technical substance is dissolved in ethyl acetate with internal standard and the impurities above 1 g/kg determined by GC-FID Confirmation: GC/MS Water: Karl-Fischer titration An inorganic impurity: extracted with water and analyzed by HPLC with an ion-exchange column and conductivity detection N,N-dimethylnitrosamine (relevant impurity): Method NS-35-003.02: GC/TEA Open for further data, see data gaps in the EFSA conclusion.
Plant protection product (principle of method)	Method TM-86-05-04: GC-FID with internal standard Confirmation: GC/MS

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Oxyfluorfen
Food of animal origin		Not required
Soil		Oxyfluorfen
Water	surface	Oxyfluorfen
	drinking/ground	Oxyfluorfen
Air		Oxyfluorfen

Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Oxyfluorfen: Method Applicable for the quantitative determination of residues of oxyfluorfen in plant materials for all types of crops with a LOQ of 0.01 mg/kg for each crop. Determination by GC-ECD and GC-MS for confirmation. The method has been independently validated for grapes and wheat grain.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Oxyfluorfen: Method applicable for the quantitative determination of residues of oxyfluorfen in animal materials (milk, meat, liver, fat and eggs) with a LOQ of 0.01 mg/kg for each commodity. Determination by GC-ECD and GC-MS for confirmation. The method has been independently validated for milk

	and fat. Method not required as no MRLs are proposed.
Soil (principle of method and LOQ)	Oxyfluorfen: Method applicable for the quantitative determination of residues of oxyfluorfen in soil with a LOQ of 0.05 mg/kg. Determination by GC-ECD and GC-MS for confirmation.
Water (principle of method and LOQ)	Oxyfluorfen: Water samples are extracted with isooctane and determined by GC-MS LOQ=0.05 µg/l
Air (principle of method and LOQ)	Oxyfluorfen: Adsorption on Tenax tubes and determination by GC-ECD Confirmation: Different column LOQ = 0.09 µg/m^3
Body fluids and tissues (principle of method and LOQ)	Not required because the active substance is not classified as toxic or very toxic.

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review proposal
Oxyfluorfen	with regard to physical/chemical data. No specific classification required

Impact on Human and Animal Health

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

Rate and extent of oral absorption:	60% based on urinary and biliary excretion within 24 h
Distribution:	Highest concentrations in fat, adrenals, liver, thyroid, ovaries and bone marrow
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	Rapid and extensive (82-95%) within 48h, mainly via bile 35.83%, faeces 39.16% and urine 4.66%.
Metabolism in animals	Significant metabolic transformation. Faeces: parent compound, RH-45469, the hydro-oxyfluorfen (RH-34670), and amino metabolites. Urine: RH-34800, RH-45298-C. No parent compound.
Toxicologically significant compounds (animals, plants and environment)	Oxyfluorfen

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	LD_{50} > 5000 mg/kg bw	
Rat LD_{50} dermal	LD_{50} > 5000 mg/kg bw	
Rat LC_{50} inhalation	LC_{50} rat >3.71 mg/L Exposure nose-only. Test material: aerosol	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non-sensitising	
Respiratory system irritation	Non-irritant	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver, spleen, and haematopoietic system / decreases in bodyweight gains, increases in absolute and relative liver and spleen weights, anaemia and alterations in clinical chemistry parameters	
Relevant oral NOAEL	2.17 mg/kg/bw/day (90-day dietary study in female dog, supported by the 2-yr study in dog)	
Relevant dermal NOAEL	100 mg/kg/bw/day (rat)	
Relevant inhalation NOAEL	No data - not required	

Genotoxicity (Annex IIA, point 5.4)

No genotoxic potential.	

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

Target/critical effect	Liver (mice)	
Relevant NOAEL	0.28 mg/kg bw/day (mice)	
Carcinogenicity	Increased incidence of liver cell adenocarcinoma in male mice at 30.69 mg/kg bw/day (NOAEL for carcinogenicity 3.0 mg/kg bw/day)	Carc cat 3 R40

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	General toxicity: Decrease bw, bw gain and food consumption. Liver: hepatocellular hypertrophy Kidneys: mineralised concretions in renal pelvis, hyperplasia of the pelvic and papillary utothelium. Reduced number of live pups per litter	
Relevant parental NOAEL	6.8 mg/kg bw/day (M/F) parental toxicity	
Relevant offspring NOAEL	20 mg/kg bw/day (females)	
Relevant reproductive NOAEL	91 mg/kg bw/day (males)	
Developmental target / critical effect	In rabbits: Decreased bw/ bw gain and food intake in dams Increased incidence of post-implantation loss Decreased foetal bw and generalised delay of ossification. In rat and rabbits: No evidence of teratogenicity	
Relevant maternal NOAEL	1000 mg/kg bw/day. Rat 30 mg/kg bw/day. Rabbit	
Relevant developmental NOAEL	1000 mg/kg bw/day. Rat 30 mg/kg bw/day. Rabbit	

Neurotoxicity (Annex IIA, point 5.7)

No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanistic studies	Primary response in the liver of mice was histopathologic degeneration (vacuolization/fatty changes and isolated cell necrosis accompanied by hepatocellular hypertrophy). These changes appear to be stimulating a pronounced regenerative hepatocellular cell proliferation by 28-days dosing which were reversible with cessation of exposure
Studies performed on metabolites or impurities	
Toxicity of metabolites	No data-not required
Toxicity of impurities	No data-not required

Medical data (Annex IIA, point 5.9)

No detrimental effects on health in manufacturing personnel. Symptoms of systemic illness in agricultural worker and consumers: headache, dizziness, nausea, eye irritation, skin irritation, vomiting, change in taste, disorientation, throat & lung irritation, night sweats, enlarged liver with jaundice, and initial shortness of breath. No studies on the exposure of the general population or epidemiological studies available.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.003 mg/kg bw/day	Long term. Mice	100
AOEL	0.013 mg/kg bw/day	Short-term. Dog	100*
ARfD	0.30 mg/kg bw	Developmental study. Rabbit	100

*Correction for oral absorption 60%

Dermal absorption (Annex IIIA, point 7.3)

Product information: Study done with Goal 2EC	4.16 % (undiluted), 14.4% (diluted) Rats *in vivo* study

Acceptable exposure scenarios (including method of assessment)

Operators	Tractor/mounted/trailed boom sprayer applications 40.9% of the AOEL for sunflower. BBA model using PPE* 73.36 % of the AOEL for pome fruit/vines. BBA model using PPE** 280.12 % of the AOEL for sunflowers. UK POEM model using PPE*** (5 L container) 1680% of the AOEL for pome fruit/vines. UK POEM model using PPE***(5 L container) *gloves during M/L and coverall during application ** gloves during M/L and application and coverall and sturdy footwear during application *** gloves during M/L and application
Workers	Exposure assessment not required.
Bystanders	6.2% of AOEL as worst case estimation according to Rautmann et al., 2001 18.8 % of the AOEL as worst case estimation according to Lloyd and Bell, 1983.

Classification and proposed labelling (Annex IIA, point 10)

	RMS and peer review proposal
Oxyfluorfen	R40 Carcinogenic Cat 3

Residues

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

Plant groups covered	Fruit crops: (apple, peach and tomato), Root/tuber crops: (onion) Leafy crops: (alfalfa)
Rotational crops	Tomato, pepper, squash, Swiss chard, beet, turnips, collards, spring and winter wheat
Metabolism in rotational crops similar to metabolism in primary crops?	No conclusion possible since residues in rotational crops too low to allow identification of metabolites (most values <0.01 mg/kg)
Processed commodities	Not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	Oxyfluorfen
Plant residue definition for risk assessment	Oxyfluorfen
Conversion factor (monitoring to risk assessment)	Not required

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

Animals covered	Goats, hens but not appropriate since performed with oxyfluorfen, whereas parent and structurally related metabolites not present in feedstuff.
Time needed to reach a plateau concentration in milk and eggs	Not applicable
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (yes/no)	Yes (for oxyfluorfen)
Fat soluble residue: (yes/no)	No conclusion

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

TRR <0.01 mg/kg in all plant parts, except in cereal straw and chaff at plant back intervals of 0, 31 and 61 days (0.02 to 0.06 mg/kg).

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

- Oxyfluorfen residues stable up to 36 months when stored frozen at -10°C in water containing matrices (alfalfa, apple, banana, cabbage, cotton, onion, orange, peach, strawberry), starch matrices (wheat grain), oily

matrices (cotton seed, almond) and soil. - Stable up to 12 months when stored frozen at -10ºC in feedstuff of animal origin (milk and eggs) or 14 months (beef liver and muscle).

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No[1]	No[1]	No
Potential for accumulation (yes/no):			
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)			
	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		-	

[1]: However, livestock feeding studies in lactating ruminants and poultry were submitted and were evaluated in the DAR.

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

Crop	Northern or Southern, field or glasshouse	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL estimated from trials according representative use	HR (b)	STMR (c)
Sunflower	South	7x <0.01	2 trials conducted with a dose rate of 329 and 353 g/ha 2 additional trials required in North EU to confirm MRL.	0.01*	<0.01	<0.01
Apple	North	2x <0.005, 1x <0.01	7 trials conducted with a single application at 1281 to 1440 g a.s./ha. No additional trials requested since all values <LOQ.	0.01*	<0.01	0.005
	South	2x <0.005, 24x <0.01				
Grapes	North	2x <0.005, 3x <0.01	9 trials conducted with a single application at 1281 to 1440 g a.s./ha. No additional trials requested since all values < LOQ.	0.01*	<0.01	<0.01*
	South	1x <0.005, 3x <0.01				

*: When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.
a: Numbers of trial in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 2x 0.1, 2 x 0.15, 0.17
b: Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to cGAP
c: Highest residue

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

ADI	**0.003 mg/kg bw/day**
TMDI (% ADI) according to (EFSA PRIMo rev 2)	Highest TMDI: 5% ADI (DE child)
TMDI (% ADI) according to national (to be specified) diets	not necessary
IEDI (WHO European Diet) (% ADI)	not necessary
NEDI (specify diet) (% ADI)	not necessary
Factors included in IEDI and NEDI	not necessary
ARfD	**0.30 mg/kg bw**
IESTI (% ARfD) (EFSA PRIMo rev 2)	Highest IESTI: Apples: 0.3% Pears: 0.3% Table grapes: 0.2%
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not necessary
Factors included in IESTI and NESTI	not necessary

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Not required as residues in crops <0.01 mg/kg				

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

Sunflower seeds	0.01* mg/kg
Pome fruit	0.01* mg/kg
Grapes	0.01* 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 Environment

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

Mineralization after 100 days ‡	0.8-15% after 90-91 d, [^{14}C-CPR] Oxyfluorfen -label (n= 5) 0.9 -1.0% after 91 d, [^{14}C-NPR] Oxyfluorfen -label (n= 2)
Non-extractable residues after 100 days ‡	10.1-43.1 % after 90-91 d, [^{14}C-CPR] Oxyfluorfen -label (n= 5) 12.7-23.8 % after 91 d, [^{14}C-NPR] Oxyfluorfen -label (n= 2)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Metabolites > 10% were not observed during the aerobic degradation studies in soil

CPR= chlorophenyl ring
NPR= nitrophenyl ring

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

Anaerobic degradation ‡

Mineralization after 100 days	0.6% after 60 DAT, [^{14}C-CPR] Oxyfluorfen -label (n= 1) 0.5% after 60 DAT, [^{14}C-NPR] Oxyfluorfen -label (n= 1)
Non-extractable residues after 100 days (Aerobic conditions were maintained during the first 30 days of incubation)	10% after 60 DAT, [^{14}C-CPR] Oxyfluorfen -label (n= 1) 11.2% after 60 DAT, [^{14}C-NPR] Oxyfluorfen -label (n= 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Metabolites > 10% were not observed during the anaerobic degradation studies in soil

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Metabolites > 5% were not observed during the photolysis study in soil

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	% Clay	% OM	pH	t. °C / %Gravimetric water content	DT_{50} /DT_{90} (d)	DT_{50} (d) *20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	10	1.3	6.5	25//7.2	533/1771	434	0.9014	SFO
Clay loam	28	3.2	6.3	25/22.7	251/834	348	0.912	SFO
Sandy loam	7.6	2.9	7.4	20/21.99	77/255	77	0.9850	SFO
Sandy loam	13.0	3.4	7.4	20/21.8	68/225	68	0.9973	SFO
Clay loam	30.9	1.9	6.5	20/24.2	69/231	62	0.9968	SFO
Geomean						138		

* normalised assuming a Q10 of 2.58 and Walker equation coefficient of 0.7

Parent		Aerobic conditions						
Soil type	% Clay	% OM	pH	t. °C / %Gravimetric water content	DT_{50} /DT_{90} (d)	DT_{50} (d) *10°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	10	1.3	6.5	25//7.2	533/1771	836	0.9014	SFO
Clay loam	28	3.2	6.3	25/22.7	251/834	878	0.912	SFO
Sandy loam	7.6	1.7	7.4	20/21.99	77/255	198.8	0.9850	SFO
Sandy loam	13.0	2.0	7.4	20/21.8	68/225	175.6	0.9973	SFO
Clay loam	30.9	1.1	6.5	20/24.2	69/231	160.8	0.9968	SFO

* normalised assuming a Q10 of 2.58 and Walker equation coefficient of 0.7

Field dissipation studies ‡

Parent	Aerobic conditions						
Soil type (indicate if bare or cropped soil was used).	Location (Country or USA state).	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St.(r^2)	Method of calculation
Loamy sand (bare soil)	California	6.4-6.1	0-15	31.4	274.1	>0.9	FOMC
Clay loam (bare soil)	California	6.9-7.1	0-15	Dissipation of Oxyfluorfen was seen throughout the study. The proposed DT_{50}			

Loam (bare soil)	British Columbia, Canada	7.0	0-8	value was not considered valid because the goodness of fit was not good enough			
Silty clay loam	UK	7.22	0-10	Experimental data varied widely not being possible to determine properly any dissipation parameter. It is considered inconclusive.			
Clay loam	IT	7.46	0-10	37	530	0.9	FOMC
Clay loam	ES	7.4	0-10	51	292	0.985	FOMC
Clay loam	FR	7.0	0-10	172	571	0.743	SFO

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Calculated accumulated concentrations in soil were 0.42 mg/kg from the use in sunflowers and 1.5 mg/kg from the use on vines and pome fruit, see PEC(soil) section

Laboratory studies ‡

Parent	Anaerobic conditions: (Aerobic conditions were maintained during the first 30 days of incubation)					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	6.5	No degradation was observed.				

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy Loam	0.765	6.5	-	-	61.78	8076	0.787
Sand	0.294	7.3	-	-	8.5	2891	0.962
Silty Clay Loam	0.706	7.0	-	-	96.8	13711	0.994
Clay Loam	1.765	6.9	-	-	98.58	5585	0.853
Arithmetic mean						7565.75[1]	0.90
pH dependence, Yes or No			No				

[1] available FOCUS SW calculation based on a value for K_{Foc}= 5657 ml/g and 1/n= 0.873. The highest K_{Foc} value was not considered in selection of the value for the SW calculation. Available FOCUS GW calculation used values of K_{Foc}= 2801 ml/g and 1/n= 0.962 (sand soil, representing lowest adsorption, though actual value agreed for this soil is 2891 mL/g).

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

Column leaching ‡	N/A
Aged residues leaching ‡	N/A
Lysimeter/ field leaching studies ‡	N/A

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): *172* days Kinetics: SFO Field or Lab: representative worst case from field studies.
Application data	Crop: pome fruits/vines and sunflowers Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cc % plant interception: Dormancy (pome fruits and vines) and Pre-emergence (sunflower) therefore no crop interception Number of applications: 1 Interval (d): N/A Application rate(s): 1440 g as/ha (pomes and vines) and 240 g/ha (sunflower).

$PEC_{(s)}$ (mg/kg)		Single application Actual (pome fruits/vines)	Single application TWA	Single application Actual (sunflowers)	Single application TWA (sunflowers)
Initial		1.920		0.320	
Short term	24h	1.912	1.916	0.319	0.319
	2d	1.905	1.912	0.317	0.319
	4d	1.889	1.905	0.315	0.317
Long term	7d	1.867	1.893	0.311	0.316
	28d	1.715	1.816	0.286	0.303
	50d	1.57	1.739	0.262	0.290
	100d	1.283	1.580	0.214	0.263
Plateau @	Max	2.5	1.3	0.42	0.22
6 years	Min	0.57		0.10	

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: stable
	pH 7: stable
	pH 9: stable

Photolytic degradation of active substance and metabolites above 10 % ‡

RH-123394: 17.4%

RH-35451: 23%

RH-45469: 10.5%

MW 306: 27%[a]

MW 347: 27 %[a]

MW 274: 13.3 %

not identified Deg 27: 11.0% (only in one sample)

([a]not individually quantified but this is the maximum of two peaks combined)

Theoretical DT_{50} values (days)				
Latitude	**Spring**	**Summer**	**Autumn**	**Winter**
30	0.35	0.31	0.49	0.67
40	0.38	0.31	0.64	1.05
50	0.43	0.33	0.96	2.09
60	0.51	0.35	1.79	2.44

Metabolites

Theoretical DT_{50} values (days) 40N				
compound	**Spring**	**Summer**	**Autumn**	**Winter**
RH-45469	1.5	1.2	2.6	4.6
RH-123394	1.0	0.8	1.8	10.5
Deg 27	6.0	4.8	3.1	18.5

Quantum yield of direct phototransformation in water at Σ > 290 nm

1.06×10^{-4} molecules/photon

Readily biodegradable ‡ (yes/no)

No. Not readily biodegradable.

Summary of water/sediment DT_{50} data for oxyfluorfen for FOCUS modeling

Parent	Distribution: max. in sediment 73.7-75% AR after 2-7 days. Max in water 53% AR at day 0 FOCUS DK level PI									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50} whole sys.	St. (r^2)	DT_{50} water	St. (r^2)	DT_{50} sed	St. (r^2)	Method of calculation
Sandy loam [^{14}C-CPR] label	7.47	8.24	20	39.6	0.97					SFO
Sandy loam [^{14}C-NPR] label	8.23	7.24	20	31.5	0.96					SFO (estimated as HS DT_{90} (104.5days)/ 3.32)
Silt loam [^{14}C-CPR] label	7.17	8.08	20	29.6	0.99					SFO
Silt loam [^{14}C-NPR] label	7.98	7.09		18.5	0.97					SFO
Geomean				**28.7**[2]		1000[1]		1000[1]		

[1]FOCUS default value
[2]available FOCUS SW calculations were based on a marginally different average value of 29.2 days.

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

Parent Parameters used in FOCUSsw step 1 and 2	Molecular weight 361.7 (g/mol): Water solubility 0.116 (mg/L): K_{OC} 5657 (L/kg): DT_{50} soil (d):*138* days (Geomean value from Lab. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 29.2 Crop interception (%): 0 Default FOCUS Drift values
Parameters used in FOCUSsw step 3 (if performed)	Vapour pressure: $2.6x10^{-5}$ Pa Koc: 5657 (L/kg): 1/n: 0.873 (Freundlich exponent for soil) Default FOCUS ground spray Drift values Q10 2.58, Walker equation coefficient 0.7
Application rate	<u>Crop: vine/ pome fruits</u> Crop interception: 0 Number of applications: *1* Interval (d): *N/A* Application rate(s): Oxyfluorfen is intended to be used as a banded application on the plantation lines or around each tree 480 g as/ha for runoff/erosion entries and 1440 g as/ha for drift entries Application window: Oct Feb (FOCUS Step 1-2) 15 Nov-31 Dec (FOCUS Step 3) <u>Crop: sunflowers</u>

Crop interception: 0 Number of applications: *1* Interval (d): *N/A* Application rate(s): 240 g as/ha Application window: Mar-May (FOCUS Step 1-2) application window finishes 15 d before emergence (FOCUS Step 3)

A) SUNFLOWER

FOCUS STEP 1	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	11.5720		529.7643	
	1	9.3974	10.4847	531.6102	530.6873
	2	9.1769	9.8857	519.1395	528.0187
	4	8.7514	9.4241	495.0688	517.5138
	7	8.1499	9.0054	461.0392	500.5159
	14	6.9022	8.2571	390.4569	462.6435
	21	5.8455	7.6245	330.6804	428.3428
	28	4.9506	7.0648	280.0552	397.4239
	42	3.5508	6.1138	200.8696	344.3737

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0	4.0503	---	222.1125	---
	1	3.9263	3.9883	221.9586	222.0355
	2	3.9236	3.9566	221.8048	221.9586
	4	3.9182	3.9388	221.4975	221.8049
	7	3.9100	3.9282	221.0374	221.5745
	14	3.8911	3.9144	219.9675	221.0383
	21	3.8723	3.9035	218.9028	220.5038
	28	3.8535	3.8933	217.8433	219.9710
	42	3.8163	3.8739	215.7395	218.9106

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	2.2146	---	118.3391	---
	1	2.0919	2.1532	118.2571	118.2981
	2	2.0905	2.1222	118.1751	118.2571
	4	2.0876	2.1056	118.0114	118.1752
	7	2.0832	2.0969	117.7663	118.0524
	14	2.0731	2.0876	117.1962	117.7667
	21	2.0631	2.0811	116.6290	117.4819
	28	2.0531	2.0753	116.0645	117.1981
	42	2.0333	2.0646	114.9436	116.6331

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	**pond**	0 h	0.0501		0.596	
		24 h	0.0482	0.0491	0.596	0.596
		2 d	0.0464	0.0482	0.596	0.596
		4 d	0.0432	0.0465	0.596	0.596
		7 d	0.0392	0.0442	0.596	0.596
		14 d	0.0323	0.0398	0.595	0.596
		21d	0.0274	0.0365	0.594	0.596
		28 d	0.024	0.0337	0.592	0.595
		42 d	0.0189	0.0295	0.589	0.595
D5	**stream**	0 h	1.024		0.027	
		24 h	0.000001	0.0381	0.0265	0.0268
		2 d	0.000001	0.0191	0.0259	0.0265
		4 d	0.000001	0.00953	0.0249	0.026
		7 d	0.000002	0.00544	0.0235	0.0252
		14 d	0.000001	0.00272	0.0208	0.0237
		21 d	0.000001	0.00182	0.0186	0.0223
		28 d	0.000001	0.00136	0.0168	0.0212
		42 d	0.000001	0.000908	0.0141	0.0192
R1	**pond**	0 h	0.0759		3.64	
		24 h	0.0742	0.0751		3.638
		2 d	0.0726	0.0743		3.636
		4 d	0.0697	0.073		3.631
		7 d	0.0658	0.0713		3.625
		14 d	0.0588	0.0679		3.611
		21 d	0.0543	0.0667		3.59
		28 d	0.0635	0.0652		3.557
		42 d	0.0531	0.0615		3.476
R1	**stream**	0 h	0.863		14.158	
		24 h	0.000038	0.216	14.14	14.152
		2 d	0.000036	0.109	14.122	14.143
		4 d	0.000033	0.0547	14.087	14.125
		7 d	0.000029	0.0454	14.036	14.1
		14 d	0.000022	0.033	13.924	14.042
		21 d	0.000432	0.0254	13.821	13.987
		28 d	0.000488	0.0215		13.96
		42 d	0.000364	0.0181		13.866
R3	**stream**	0 h	1.211		17.355	
		24 h	0.000694	0.364	17.313	17.345
		2 d	0.000172	0.182	17.265	17.325
		4 d	0.000157	0.0911	17.174	17.281
		7 d	0.364	0.0696	17.046	17.215
		14 d	0.218	0.0476	16.769	17.071
		21 d	0.315	0.0455	16.52	16.936
		28 d	0.00211	0.0431	16.545	16.838
		42 d	0.00175	0.0344	16.39	16.732

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R4	**stream**	0 h	0.86		33.311	
		24 h	0.000056	0.487	33.209	33.278
		2 d	0.000054	0.344	33.105	33.234
		4 d	0.00005	0.173	32.906	33.145
		7 d	0.000046	0.0993	32.63	33.005
		14 d	0.000082	0.0549	32.066	32.699
		21 d	0.00231	0.0435	31.557	32.42
		28 d	0.00171	0.0409	32.049	32.234
		42 d	0.00085	0.0354	31.081	32.023

FOCUS STEP 4 20 m (runoff + drift)	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D5	**pond**	0 h	0.0214		0.264	
		24 h	0.0206	0.021	0.264	0.264
		2 d	0.0198	0.0206	0.264	0.264
		4 d	0.0185	0.0199	0.264	0.264
		7 d	0.0167	0.0189	0.264	0.264
		14 d	0.0137	0.017	0.263	0.264
		21 d	0.0116	0.0155	0.263	0.264
		28 d	0.0101	0.0143	0.262	0.263
		42 d	0.00785	0.0125	0.26	0.263
D5	**stream**	0 h	0.118		0.00334	
		24 h	0	0.00441	0.00329	0.00332
		2 d	0	0.0022	0.00324	0.00329
		4 d	0	0.0011	0.00315	0.00324
		7 d	0	0.00063	0.00302	0.00318
		14 d	0	0.000315	0.00275	0.00303
		21 d	0	0.00021	0.00252	0.0029
		28 d	0	0.000158	0.00233	0.00278
		42 d	0	0.000105	0.00202	0.00258
R1	**pond**	0 h	0.0214		0.816	
		24 h	0.0206	0.021		0.816
		2 d	0.0198	0.0206		0.815
		4 d	0.0185	0.0199		0.814
		7 d	0.0167	0.0189		0.813
		14 d	0.0136	0.0178		0.81
		21 d	0.0172	0.0173		0.805
		28 d	0.0166	0.0173		0.797
		42 d	0.0132	0.0165		0.78
R1	**stream**	0 h	0.0999		0.84	
		24 h	0.000003	0.0516	0.838	0.839
		2 d	0.000003	0.026		0.838
		4 d	0.000003	0.013		0.834
		7 d	0.000003	0.0107		0.832
		14 d	0.000002	0.0077		0.827
		21 d	0.000026	0.00585		0.823
		28 d	0.000033	0.0049		0.823

FOCUS STEP 4 20 m (runoff + drift)	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.000027	0.00418		0.816
R3	**stream**	0 h	0.14		1.012	
		24 h	0.000074	0.062	1.008	1.011
		2 d	0.000015	0.0333	1.003	1.009
		4 d	0.000014	0.021	0.995	1.005
		7 d	0.087	0.0121	0.983	0.999
		14 d	0.0535	0.0106	0.959	0.986
		21 d	0.0767	0.00936	0.938	0.974
		28 d	0.000158	0.00853	0.961	0.969
		42 d	0.000143	0.00689	0.963	0.968
R4	**stream**	0 h	0.14		1.883	
		24 h	0.000203	0.116	1.875	1.88
		2 d	0.00011	0.0818	1.866	1.876
		4 d	0.000133	0.0409	1.851	1.869
		7 d	0.000119	0.0234	1.829	1.858
		14 d	0.000072	0.0129	1.786	1.835
		21 d	0.000058	0.00936	1.749	1.814
		28 d	0.105	0.00957	1.843	1.804
		42 d	0.000068	0.00823	1.761	1.804

FOCUS STEP 4 20 m runoff + 100 m drift	**Water body**	**Day after overall maximum**	**PEC_{SW} (µg/L)**		**PEC_{SED} (µg/kg)**	
			Actual	**TWA**	**Actual**	**TWA**
D5	**pond**	0 h	0.00629		0.0821	
		24 h	0.00606	0.00617	0.0821	0.0821
		2 d	0.00583	0.00606	0.0821	0.0821
		4 d	0.00543	0.00584	0.0821	0.0821
		7 d	0.00492	0.00555	0.0821	0.0821
		14 d	0.00401	0.00499	0.082	0.0821
		21 d	0.00335	0.00455	0.0818	0.0821
		28 d	0.00289	0.00419	0.0816	0.082
		42 d	0.00222	0.00363	0.0811	0.082
R1	**pond**	0 h	0.0153		0.689	
		24 h	0.015	0.0152		0.688
		2 d	0.0147	0.015		0.688
		4 d	0.0142	0.0147		0.687
		7 d	0.0135	0.0144		0.685
		14 d	0.0122	0.0136		0.681
		21 d	0.0112	0.0133		0.676
		28 d		0.013		0.668
		42 d		0.0122		0.649

B) VINES AND POME FRUITS

FOCUS STEP 1	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0	32.18		1.06E+03	
	1	19.83	26.00	1.12E+03	1.09E+03

FOCUS STEP 1	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	2	19.37	25.85	1.10E+03	1.10E+03
	4	18.47	19.20	1.04E+03	1.07E+03
	7	17.20	17.89	9.73E+02	1.03E+03
	14	14.57	13.84	8.24E+02	9.54E+02
	21	12.34	15.99	6.98E+02	8.83E+02
	28	10.45	16.29	5.91E+02	8.19E+02
	42	7.49	13.28	4.24E+02	7.10E+02

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Southern EU	0	9.61		289.69	
	1	9.61	9.61	497.04	393.36
	2	9.60	9.61	496.69	445.11
	4	9.59	9.60	496.00	470.73
	7	9.57	9.59	494.97	481.34
	14	9.52	9.57	492.58	487.56
	21	9.48	9.55	490.19	488.83
	28	9.34	9.48	483.11	487.74
	42	9.61		289.69	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0	11.45		601.23	
	1	11.44	11.45	600.81	601.02
	2	11.44	11.44	600.39	600.81
	4	11.42	11.44	599.56	600.39
	7	11.40	11.42	598.32	599.77
	14	11.34	11.40	595.42	598.32
	21	11.29	11.37	592.54	596.87
	28	11.23	11.34	589.67	595.43
	42	11.12	11.29	583.98	592.56

FOCUS STEP 3 Pome fruits	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	**ditch**	0 h	9.053		6.42	
		24 h	4.081	6.936	6.251	6.392
		2 d	0.459	4.411	6.008	6.323
		4 d	0.0242	2.262	5.562	6.141
		7 d	0.0177	1.301	5.002	5.853
		14 d	0.0109	0.657	4.058	5.262
		21 d	0.00725	0.441	3.44	4.795
		28 d	0.00506	0.332	3.012	4.424
		42 d	0.00287	0.223	2.467	3.876
D4	**pond**	0 h	0.311		3.125	
		24 h	0.3	0.305	3.125	3.125
		2 d	0.29	0.3	3.124	3.125
		4 d	0.272	0.29	3.122	3.125
		7 d	0.248	0.277	3.117	3.124
		14 d	0.209	0.252	3.106	3.121
		21 d	0.172	0.232	3.098	3.118
		28 d	0.142	0.213	3.094	3.114
		42 d	0.105	0.182	3.087	3.108
D4	**stream**	0 h	7.642		0.885	
		24 h	0.000301	1.181	0.856	0.874
		2 d	0.000278	0.591	0.828	0.86
		4 d	0.000242	0.295	0.776	0.834
		7 d	0.000206	0.169	0.709	0.797
		14 d	0.000149	0.0845	0.589	0.723
		21 d	0.000359	0.0587	0.538	0.668
		28 d	0.000019	0.0444	0.476	0.629
		42 d	0.000009	0.0297	0.388	0.563
D5	**pond**	0 h	0.311		3.721	
		24 h	0.301	0.306	3.72	3.721
		2 d	0.291	0.301	3.717	3.721
		4 d	0.273	0.291	3.706	3.72
		7 d	0.251	0.279	3.678	3.717
		14 d	0.213	0.254	3.592	3.708
		21 d	0.187	0.236	3.531	3.696
		28 d	0.169	0.221	3.492	3.68
		42 d	0.145	0.199	3.447	3.644
D5	**stream**	0 h	8.451		2.416	
		24 h	0.038	3.23	2.336	2.394
		2 d	0.00271	1.619	2.25	2.356
		4 d	0.00237	0.811	2.093	2.278
		7 d	0.00197	0.464	1.892	2.168
		14 d	0.00132	0.233	1.546	1.951
		21 d	0.000916	0.156	1.312	1.781
		28 d	0.000662	0.117	1.147	1.646
		42 d	0.000382	0.0781	0.934	1.444
R1	**pond**	0 h	0.311		3.724	
		24 h	0.299	0.305	3.724	3.724
		2 d	0.289	0.299	3.723	3.724
		4 d	0.269	0.289	3.723	3.724
		7 d	0.245	0.275	3.72	3.723
		14 d	0.202	0.248	3.712	3.723
		21 d	0.173	0.228	3.701	3.721
		28 d	0.151	0.211	3.686	3.719

FOCUS STEP 3 Pome fruits	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		42 d	0.122	0.186	3.651	3.714
R1	**stream**	0 h	5.989		1.383	
		24 h	0.000366	1.279	1.366	1.376
		2 d	0.000344	0.64	1.349	1.367
		4 d	0.000308	0.32	1.318	1.351
		7 d	0.000261	0.183	1.276	1.329
		14 d	0.000182	0.0916	1.197	1.283
		21 d	0.000049	0.0611	1.137	1.245
		28 d	0.000036	0.0458	1.09	1.212
		42 d	0.000022	0.0306	1.141	1.189
R2	**stream**	0 h	7.899		6.215	
		24 h	0.000102	0.696	6.192	6.206
		2 d	0.000097	0.348	6.17	6.195
		4 d	0.000087	0.174	6.127	6.174
		7 d	0.000075	0.0995	6.068	6.143
		14 d	0.000054	0.0498	5.949	6.077
		21 d	0.000027	0.0332	5.849	6.02
		28 d	0.000111	0.0355	5.763	5.968
		42 d	0.000077	0.0253	5.616	5.877
R3	**stream**	0 h	8.244		6.014	
		24 h	0.000578	1.496	5.954	5.994
		2 d	0.000542	0.748	5.893	5.966
		4 d	0.000483	0.374	5.781	5.908
		7 d	0.000408	0.214	5.635	5.827
		14 d	0.00122	0.168	5.368	5.667
		21 d	0.00121	0.113	5.171	5.536
		28 d	0.000882	0.0872	5.019	5.427
		42 d	0.00053	0.0586	4.798	5.254
R4	**stream**	0 h	5.898		1.744	
		24 h	0.000173	0.851	1.723	1.737
		2 d	0.000164	0.426	1.701	1.727
		4 d	0.000148	0.213	1.661	1.708
		7 d	0.000127	0.122	1.606	1.681
		14 d	0.000092	0.0609	1.594	1.663
		21 d	0.000068	0.0459	1.582	1.653
		28 d	0.000053	0.0438	1.575	1.639
		42 d	0.000034	0.0406	1.518	1.625

FOCUS STEP 3 vines	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	**ditch**	0 h	9.134		27.772	
		24 h	8.214	8.652	27.642	27.759
		2 d	7.42	8.227	27.31	27.721
		4 d	5.797	7.43	26.31	27.573
		7 d	2.994	6.118	23.486	27.197
		14 d	0.0458	3.737	18.76	25.526
		21 d	0.00672	2.497	15.895	23.612
		28 d	0.0158	1.876	14.001	21.913
		42 d	0.00757	1.255	11.581	19.271
R1	**pond**	0 h	0.311		3.699	
		24 h	0.299	0.305	3.699	3.699
		2 d	0.289	0.299	3.699	3.699
		4 d	0.269	0.289	3.698	3.699
		7 d	0.244	0.275	3.696	3.699
		14 d	0.202	0.248	3.688	3.698
		21 d	0.172	0.227	3.676	3.697
		28 d	0.15	0.211	3.661	3.695
		42 d	0.121	0.185	3.626	3.689
R1	**stream**	0 h	5.95		1.309	
		24 h	0.00024	1.056	1.293	1.302
		2 d	0.000227	0.528	1.277	1.294
		4 d	0.000203	0.264	1.248	1.28
		7 d	0.000173	0.151	1.21	1.259
		14 d	0.000122	0.0756	1.137	1.216
		21 d	0.000037	0.0504	1.081	1.181
		28 d	0.000027	0.0378	1.037	1.151
		42 d	0.000016	0.0252	1.093	1.131
R2	**stream**	0 h	7.896		6.197	
		24 h	0.0001	0.692	6.174	6.188
		2 d	0.000095	0.346	6.152	6.177
		4 d	0.000086	0.173	6.11	6.156
		7 d	0.000074	0.0989	6.051	6.125
		14 d	0.000053	0.0495	5.933	6.06
		21 d	0.000026	0.033	5.834	6.003
		28 d	0.000109	0.0352	5.748	5.951
		42 d	0.000076	0.0251	5.602	5.861
R3	**stream**	0 h	8.232		5.971	
		24 h	0.000529	1.444	5.912	5.951
		2 d	0.000497	0.722	5.852	5.923
		4 d	0.000443	0.361	5.743	5.867
		7 d	0.000375	0.207	5.6	5.788
		14 d	0.00116	0.164	5.338	5.631
		21 d	0.00119	0.11	5.145	5.503
		28 d	0.000863	0.0845	4.995	5.396
		42 d	0.00052	0.0567	4.778	5.226
R4	**stream**	0 h	5.889		1.735	
		24 h	0.000182	0.823	1.709	1.725
		2 d	0.000173	0.412	1.683	1.713
		4 d	0.000156	0.206	1.635	1.689
		7 d	0.000135	0.118	1.572	1.655
		14 d	0.000098	0.0589	1.455	1.586
		21 d	0.000074	0.0393	1.368	1.529

FOCUS STEP 3 vines	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d	0.00006	0.0436	1.301	1.481
		42 d	0.000039	0.03	1.203	1.405

FOCUS STEP 4 Pome fruit 20 m (runoff +drift)	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	**ditch**	0 h	0.674		0.488	
		24 h	0.304	0.516	0.479	0.486
		2 d	0.0336	0.328	0.466	0.483
		4 d	0.00134	0.168	0.441	0.473
		7 d	0.00101	0.0965	0.408	0.457
		14 d	0.00071	0.0487	0.347	0.422
		21 d	0.000523	0.0326	0.302	0.392
		28 d	0.000395	0.0246	0.269	0.367
		42 d	0.000247	0.0165	0.223	0.328
ºD4	**pond**	0 h	0.129		1.395	
		24 h	0.125	0.127	1.395	1.395
		2 d	0.12	0.125	1.394	1.395
		4 d	0.113	0.12	1.393	1.395
		7 d	0.103	0.115	1.391	1.394
		14 d	0.0858	0.104	1.387	1.393
		21 d	0.0742	0.0962	1.384	1.392
		28 d	0.061	0.089	1.382	1.39
		42 d	0.0447	0.0765	1.379	1.388
ºD4	**stream**	0 h	0.767		0.0974	
		24 h	0.000021	0.118	0.0962	0.0972
		2 d	0.00002	0.0593	0.0943	0.0965
		4 d	0.000018	0.0296	0.0907	0.0949
		7 d	0.000016	0.0169	0.086	0.0937
		14 d	0.000013	0.00848	0.0805	0.0894
		21 d	0.000353	0.00793	0.0724	0.0864
		28 d	0.000013	0.00631	0.066	0.0831
		42 d	0.000003	0.00435	0.0567	0.0803
D5	**pond**	0 h	0.129		1.599	
		24 h	0.125	0.127	1.599	1.599
		2 d	0.121	0.125	1.597	1.599
		4 d	0.113	0.121	1.593	1.599
		7 d	0.104	0.115	1.582	1.598
		14 d	0.0874	0.105	1.549	1.594
		21 d	0.0764	0.0974	1.524	1.589
		28 d	0.0686	0.0911	1.508	1.583
		42 d	0.0582	0.0817	1.489	1.568
D5	**stream**	0 h	0.848		0.244	
		24 h	0.00372	0.324	0.239	0.243
		2 d	0.000197	0.162	0.232	0.24
		4 d	0.000179	0.0813	0.22	0.234
		7 d	0.000156	0.0465	0.204	0.226
		14 d	0.000116	0.0233	0.174	0.208
		21 d	0.000088	0.0156	0.152	0.194
		28 d	0.000068	0.0117	0.135	0.182
		42 d	0.000043	0.00783	0.112	0.162
R1	**pond**	0 h	0.129		1.807	
		24 h	0.124	0.126	1.807	1.807

FOCUS STEP 4 Pome fruit 20 m (runoff +drift)	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		2 d	0.12	0.124	1.807	1.807
		4 d	0.112	0.12	1.806	1.807
		7 d	0.101	0.114	1.806	1.807
		14 d	0.0832	0.103	1.802	1.806
		21 d	0.0705	0.094	1.796	1.806
		28 d	0.0614	0.0869	1.79	1.805
		42 d	0.0492	0.0762	1.773	1.802
R1	**stream**	0 h	0.678		1.055	
		24 h	0.000123	0.429	1.043	1.05
		2 d	0.000163	0.215	1.03	1.044
		4 d	0.000147	0.107	1.008	1.032
		7 d	0.000128	0.0615	0.978	1.016
		14 d	0.000094	0.0308	0.921	0.983
		21 d	0.000071	0.0206	0.879	0.955
		28 d	0.000055	0.0154	0.846	0.932
		42 d	0.000038	0.0134	0.92	0.925
R2	**stream**	0 h	0.793		0.406	
		24 h	0.000008	0.0698	0.403	0.405
		2 d	0.000008	0.0349	0.401	0.404
		4 d	0.000007	0.0175	0.396	0.401
		7 d	0.000006	0.00998	0.39	0.398
		14 d	0.000005	0.00577	0.377	0.391
		21 d	0.000003	0.00543	0.366	0.385
		28 d	0.000012	0.00488	0.357	0.379
		42 d	0.000009	0.00361	0.343	0.37
R3	**stream**	0 h	0.827		0.481	
		24 h	0.000047	0.181	0.474	0.478
		2 d	0.000045	0.1	0.467	0.475
		4 d	0.000041	0.0506	0.454	0.469
		7 d	0.000036	0.029	0.437	0.459
		14 d	0.00014	0.0252	0.404	0.441
		21 d	0.000147	0.0169	0.38	0.425
		28 d	0.000111	0.0133	0.361	0.411
		42 d	0.000067	0.00896	0.333	0.39
R4	**stream**	0 h	0.592		0.315	
		24 h	0.000016	0.169	0.31	0.313
		2 d	0.000015	0.092	0.306	0.311
		4 d	0.000014	0.046	0.297	0.308
		7 d	0.000013	0.0263	0.285	0.302
		14 d	0.00001	0.0132	0.283	0.296
		21 d	0.000008	0.0105	0.281	0.295
		28 d	0.000007	0.00999	0.28	0.291
		42 d	0.000005	0.00924	0.27	0.29

FOCUS STEP 4 Pome fruit 20 m run off + 100 m drift	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
ºD4	**Pond**	0 h	0.0379		0.494	
		24 h	0.0366	0.0372	0.494	0.494
		2 d	0.0354	0.0366	0.493	0.494
		4 d	0.0331	0.0354	0.493	0.494
		7 d	0.0301	0.0337	0.493	0.493
		14 d	0.0249	0.0306	0.492	0.493
		21 d	0.0261	0.0286	0.491	0.493
		28 d	0.0217	0.0275	0.491	0.493
		42 d	0.0156	0.0244	0.49	0.492
D5	**pond**	0 h	0.038		0.496	0.496
		24 h	0.0367	0.0373	0.496	0.496
		2 d	0.0355	0.0367	0.495	0.496
		4 d	0.0333	0.0355	0.494	0.495
		7 d	0.0305	0.0339	0.492	0.494
		14 d	0.0254	0.0309	0.484	0.493
		21 d	0.022	0.0285	0.479	0.492
		28 d	0.0196	0.0265	0.475	0.488
		42 d	0.0164	0.0236	0.47	0.486
R1	**pond**	0 h	0.0416		0.822	
		24 h	0.0404	0.041	0.822	0.822
		2 d	0.0392	0.0404	0.822	0.822
		4 d	0.0372	0.0393	0.822	0.822
		7 d	0.0345	0.0379	0.821	0.822
		14 d	0.0296	0.0349	0.82	0.822
		21 d	0.0262	0.0326	0.817	0.821
		28 d	0.0236	0.0307	0.814	0.821
		42 d	0.0218	0.0282	0.809	0.82

FOCUS STEP 4 Vines 20 m runoff + 20 m drift	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6	ditch	0 h	0.68		2.208	
		24 h	0.611	0.644	2.199	2.207
		2 d	0.551	0.612	2.178	2.204
		4 d	0.426	0.551	2.099	2.195
		7 d	0.212	0.451	1.92	2.17
		14 d	0.00289	0.271	1.602	2.059
		21 d	0.00052	0.181	1.386	1.931
		28 d	0.00125	0.136	1.231	1.813
		42 d	0.000665	0.0911	1.034	1.62
R1	pond	0 h	0.129		1.794	
		24 h	0.124	0.126	1.794	1.794
		2 d	0.12	0.124	1.794	1.794
		4 d	0.111	0.12	1.793	1.794
		7 d	0.101	0.114	1.792	1.794
		14 d	0.0829	0.103	1.789	1.793
		21 d	0.0702	0.0938	1.783	1.792
		28 d	0.061	0.0867	1.776	1.792
		42 d	0.0488	0.0759	1.76	1.789
R1	stream	0 h	0.658		1.035	
		24 h	0.000113	0.414	1.023	1.03
		2 d	0.000155	0.207	1.011	1.024
		4 d	0.000141	0.104	0.99	1.013
		7 d	0.000122	0.0592	0.961	0.997
		14 d	0.00009	0.0297	0.907	0.965
		21 d	0.000068	0.0198	0.866	0.939
		28 d	0.000053	0.0149	0.834	0.917
		42 d	0.000037	0.0129	0.909	0.911
R2	stream	0 h	0.792		0.404	
		24 h	0.000008	0.0694	0.401	0.403
		2 d	0.000007	0.0347	0.399	0.401
		4 d	0.000007	0.0174	0.394	0.399
		7 d	0.000006	0.00992	0.388	0.396
		14 d	0.000005	0.00568	0.375	0.389
		21 d	0.000003	0.00535	0.364	0.383
		28 d	0.000011	0.00484	0.355	0.377
		42 d	0.000009	0.00358	0.341	0.368
R3	stream	0 h	0.826		0.473	
		24 h	0.000043	0.176	0.466	0.471
		2 d	0.000041	0.0987	0.46	0.468
		4 d	0.000037	0.0498	0.447	0.461
		7 d	0.000033	0.0285	0.431	0.452
		14 d	0.000132	0.0246	0.399	0.434
		21 d	0.000143	0.0164	0.375	0.419
		28 d	0.000108	0.0129	0.356	0.406
		42 d	0.000065	0.00868	0.329	0.385
R4	stream	0 h	0.591		0.274	
		24 h	0.00002	0.178	0.269	0.272
		2 d	0.000019	0.0956	0.264	0.27
		4 d	0.000018	0.0478	0.255	0.265
		7 d	0.000016	0.0274	0.243	0.259
		14 d	0.000013	0.0137	0.22	0.245

FOCUS STEP 4 Vines 20 m runoff + 20 m drift	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		21 d	0.00001	0.00915	0.202	0.234
		28 d	0.000009	0.0102	0.188	0.225
		42 d	0.000006	0.00699	0.167	0.209

Water photodegradation metabolites	RH-123394 Molecular weight: 332 g/mol Maximum occurrence observed 17.4% RH-35451 Molecular weight: 331 g/mol Maximum occurrence observed 23 % RH-45469 Molecular weight: 345 g/mol Maximum occurrence observed 10.5% MW 306 Molecular weight:306 g/mol Maximum occurrence observed 27%[a] MW 347 Molecular weight:347 g/mol Maximum occurrence observed 27%[a] MW 274 Molecular weight:274 g/mol Maximum occurrence observed 13 % RH-34670 Molecular weight:333 g/mol Maximum occurrence observed <10 % unidentified Deg 27 Maximum occurrence observed 11 % Method of calculation: $PEC_{initial,\ parent} \times \frac{\text{max \% met}}{100} \times \frac{\text{m.wt. metab}}{\text{m.wt. parent}}$

[a] not individually quantified but this is the maximum of two peaks combined

		Step 1	Step 2	Step 3	Step 4 20 m(drift + runoff)
		PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual
Sunflower	RH12394	1.85	0.65	Not calculated	Not calculated
	RH-35451	2.44	0.85		
	RH-45469	1.16	0.41		
	MW 306	2.65	0.93		
	MW 347	3.00	1.05		
	MW274	1.17	0.41		
	RH-34670	1.07	0.37		
	Deg 27	1.27	0.45		

Pome fruits/vines	°	Step 1	Step 2	Step 3[a]	Step 4[a] 20 m(drift + runoff)
		PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual	PEC_{SW} (µg/L) Max Actual
Sunflower	RH12394	5.15	1.83	1.46	0.14
	RH-35451	6.79	2.41	1.93	0.18
	RH-45469	3.23	1.15	0.92	0.09
	MW 306	7.37	2.62	2.09	0.19
	MW 347	8.36	2.97	2.37	0.22
	MW274	3.25	1.16	0.92	0.09
	RH-34670	2.97	1.06	0.84	0.08
	Deg 27[b]	3.54	1.26	1.00	0.09

[a] based on the worst case observed in step 3 and step 4 for these crops.
[b] mass weight supposed to be the same as parent compound

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.3 Scenarios (list of names): Chateaudun, Hamburg, Jokioinen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: Vines, pome fruits and sunflower parent DT_{50lab} *138* d (geo mean DT_{50} lab normalised to 10kPa or pF2, 20 °C with Q10 of 2.58). K_{FOC}: parent, lowest value 2801 mL/g* (K_{Fom} 1624.5 mL/g), $^1/_n$= 0.962. (worst case seen in the adsorption/desorption study.) Q10 of 2.58 and Walker equation coefficient 0.7 * endpoint that could have been used following guidance (but was not) is 7566mL/g $^1/_n$= 0.9.
Application rate	Pome fruits/vines Application rate: *1440* g/ha. No. of applications: 1 Time of application (month or season): 1st December Sunflowers Application rate: *240* g/ha. No. of applications: 1 Time of application (month or season): 30 d before emergence

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

	Scenario	Parent (µg/L)		
		Orchard	**Vineyard**	**Sunflower**
FOCUS PEARL 3.3.3	Chateaudun	0.000003	0.000007	NR
	Hamburg	0.000007	0.000005	NR
	Jokioinen	0.000000	NR	NR
	Kremsmunster	0.000001	0.000001	NR
	Okehampton	0.000006	NR	NR

	Piacenza	0.001612	0.001791	0.000076
	Porto	0.000000	0.000000	NR
	Sevilla	0.000000	0.000001	0.000000
	Thiva	0.000006	0.000009	NR

NR = not relevant for this crop

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

Photochemical oxidative degradation in air ‡	DT_{50} of 11.1 hours derived by the Atkinson model (APOWin 1.91). OH concentration assumed =1.5x10^6 radicals/cc

PEC (air)

Method of calculation	The low vapour pressure of 2.6 x 10^{-5} Pa at 25 °C and Henry's Law constant of 2.382 x 10^{-2} Pa m^3 mol^{-1} (see phys-chem section) indicate that Oxyfluorfen will not partition into air to a significant extent. Any Oxyfluorfen that might reach the air after application will be short-lived with an estimated atmospheric half-life of 11.1 hours.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: Oxyfluorfen Surface Water: Oxyfluorfen RH-123394 RH-35451 RH-45469 MW 306 MW 347 MW 274 unidentified Deg 27 Sediment: Oxyfluorfen Ground water: Oxyfluorfen Air: Oxyfluorfen

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

Surface water (indicate location and type of study)	monitoring in surface water and sediment from the river Evrotas (Greece) in 1991-1992 Oxyfluorfen was not detected in any of 35 water samples and 35 sediment samples monitoring in surface water from the Arno river (Italy) from 1992 to 1995 No Oxyfluorfen was detected in 116 water samples analysed during the first three years of monitoring. In the final year (1995), Oxyfluorfen was detected in 2

samples from a total of 51 water samples analysed, at a maximum level of 0.11 µg/L.

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

Candidate for R 53 as oxyfluorfen is not readily biodegradable.

Effects on non-target Species

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	Technical Oxyfluorfen	Acute	> 2150	
Bobwhite quail	GOAL 4F Herbicide 42.09%	Acute	LD_{50} > 2250 (formulated) LD_{50} > 947 (a.s.)	
Bobwhite quail	Technical Oxyfluorfen	Short-term	LD_{50}> 462	> 5000
Mallard duck (*Anas platyrhynchos*)	Technical Oxyfluorfen	Long-term	NOEL = 64.7	500
Mammals ‡				
Rat	Technical Oxyfluorfen	Acute-oral	> 5000	
Rat	Technical Oxyfluorfen	Long-term, 2 years (oral)	NOAEL = 20	
Additional higher tier studies ‡				

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

Sunflowers-pre-emergence 240 g as/ha
Pome/vines-pre-emergence 1.44 kg as/ha

Indicator species/Category²	Time scale	ETE	TER	Annex VI Trigger
Tier 1 – uptake via diet (Birds)				
Insectivorous bird-240 g as/ha-sunflower	Acute	13	> 73	10
Insectivorous bird-1.44 kg as/ha- pome/vines	Acute	78	>12	10
Insectivorous bird-240 g as/ha-sunflower	Short-term	7.2	64	10
Insectivorous bird-1.44 kg as/ha –pome/vines	Short-term	43.4	> 10.6	10
Insectivorous bird-240 g as/ha-sunflower	Long-term	7.2	8.94	5
Insectivorous bird-1.44 kg as/ha-pome/vines	Long-term	43.43	**1.49**	5
Higher tier refinement – uptake via diet (Birds)				
Insectivorous bird-1.44 kg as/ha-pome/vines	Long-term	11.23	5.7[1]	5

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger
Tier 1– uptake via drinking water (Birds)				
Insectivorous bird-1.44 kg as/ha-Pome/vines	Acute	0.006	157833	10
Tier 1 – secondary poisoning (Birds)				
Earthworm-eating bird-1.44 kg as/ha-Pome/vines	Long-term	7.21	8.28	5
Fish-eating bird-1.44 kg as/ha-Pome/vines	Long-term	5.25	12.31	5
Tier 1– uptake via diet (Mammals)				
Insectivorous mammals-240 g as/ha-Sunflowers	Acute	3.36	> 1488	10
Insectivorous mammals-1.44 kg as/ha-pome/vines	Acute	12.7	> 394	10
Insectivorous mammals-240 g as/ha-Sunflowers	Long-term	0.77	26	5
Insectivorous mammals-1.44 kg as/ha-pome/vines	Long-term	4.62	**4.3**	5
Higher tier refinement – uptake via diet (Mammals)				
Insectivorous mammals- 1.44 kg as/ha-pome/vines	Long-term oral	3.6	5.5[1]	5
Tier 1– uptake via drinking water (Mammals)				
Mammals-1.44 kg as/ha-pome/vines	Acute	207	24	10
Tier 1 – secondary poisoning (Mammals)				
Earthworm-eating mammals-240 g as/ha-sunflowers	Long-term	1.24	11.47	5
Fish-eating mammals-240 g as/ha-sunflowers	Long-term	2.17	9.17	5
Earthworm-eating mammals-1.44 kg as/ha-Pome/vines	Long-term	7.63	**1.92**	5
Fish-eating mammals-1.44 kg as/ha-Pome/vines	Long-term	3.25	6.15	5
Higher tier refinement – uptake via diet (Mammals)				
Earthworm-eating mammals-1.44 kg as/ha-Pome/vines	Long-term	3.8	**3.9**[2]	5

[1] TER refined values using RUD values of 7.5 (mean value for ground dwelling invertebrates without interception) from the new Guidance document for Birds and Mammals,
[2] TER refined value using specific PT of 0.5

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] (µg as/L)
Laboratory tests ‡				
Fish				
Aquatic vertebrate: fish Bluegill sunfish	Oxyfluorfen (71.4%)	96 h-Static	LC_{50}	210 (mm)
Aquatic vertebrate: fish Fathead minnow	Oxyfluorfen (71%)	34-d Flow-through	NOEC	38 (mm)
Aquatic invertebrate				
Aquatic crustacean *Daphnia magna*	Oxyfluorfen (96%)	48-h Static	EC_{50}	72 (mm)
Aquatic crustacean *Daphnia magna*	Oxyfluorfen (71.8%)	21 days Flow-through	NOEC	13 (mm)
Bivalve Eastern oyster *Crassostrea virginica*	Oxyfluorfen (71.4 %)	96-h Flow-through	$EC_{50\ (mortality)}$ $EC_{50\ (growth)}$	>219.7 (mm) 69.3 (mm)
Sediment dwelling organisms				
Aquatic insect *Chironomus riparius*	Oxyfluorfen (99.3%)	28 days Static	NOEC	80 (mm)
Algae				
Algae *Selenastrum subcapitata*	GOAL 4F (42.09%)	96-h Static	E_bC_{50}	0.172 (mm) 0.4 µg Goal/L
Pseudokirchneriella subcapitata	Oxyfluorfen (99.19%)	10-days Static, Sediment-water	E_bC_{50} E_rC_{50}	**>2.9** (mm)
Pseudokirchneriella subpitata	RH-123394	72-h Static	E_yC_{50} E_rC_{50}	**64** (mm) 240 (mm)
Pseudokirchneriella subpitata	RH-35451	72-h Static	E_yC_{50}	**210** (mm)
Pseudokirchneriella subpitata	RH-34670	72-h Static	E_yC_{50} E_rC_{50}	**6.0** (mm) 9.9 (mm)
Higher plant				
Plant *Lemna gibba*	Oxyfluorfen (99.3%)	14d Renewal	E_bC_{50}	**0.32** (mm)
Lemna gibba	Oxyfluorfen (99.3%)	14 days water sediment study	EC_{50} NOEC	**4.13** (mm) 1.95 (mm)
Lemna gibba	RH-123394	7-day Static	E_rC_{50} E_yC_{50}	**>610** (mm)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg as/L)
Lemna gibba	RH-35451	7-day Static	E_rC_{50} E_vC_{50}	**370** (mm)
Lemna gibba	RH-34670	7-day Static	E_rC_{50} E_vC_{50}	110 (mm)**14** (mm)
Microcosm or mesocosm tests				
No studies available				

[1] indicate whether based on nominal (nom) or mean measured concentrations (mm).

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

Tier 1: Maximum PEC_{sw} values and TER values for oxyfluorfen (pomes 1.44 kg a.s./ha, banded applications)

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Sed. dweller prolonged	Algae acute	Aquatic plants
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC_{50}
		210	38	72	13	80	0.17	0.32
FOCUS Step 1	32.18	**6.5**	**1.2**	**2.2**	**0.4**	**2.5**	**0.0**	**0.0**
FOCUS Step 2								
North Europe	11.45	**18.34**	**3.32**	**0.20**	**1.14**	**6.99**	**0.01**	**0.03**
South Europe	9.61	**21.9**	**4.0**	**7.5**	**1.4**	**8.3**	**0.0**	**0.0**
FOCUS Step 3								
D3 / ditch	9.05	**23.20**	**4.20**	**7.96**	**1.44**	**8.84**	**0.02**	**0.04**
D4 / pond	0.311	675.24	122.19	231.51	41.80	257.23	**0.55**	**1.09**
D4 / stream	7.642	**27.48**	**4.97**	**9.42**	**1.70**	10.47	**0.02**	**0.04**
D5 / pond	0.311	675.24	122.19	231.51	41.80	257.23	**0.55**	**1.09**
D5 / stream	8.451	**24.85**	**4.50**	**8.52**	**1.54**	**9.47**	**0.02**	**0.04**
R1 / pond	0.311	675.24	122.19	231.51	41.80	257.23	**0.55**	**1.09**
R1 / stream	5.989	**35.06**	**6.34**	**12.02**	**2.17**	13.36	**0.03**	**0.06**
R2 / stream	7.899	**26.59**	**4.81**	**9.12**	**1.65**	10.13	**0.02**	**0.04**
R3 / stream	8.244	**25.47**	**4.61**	**8.73**	**1.58**	**9.70**	**0.02**	**0.04**
R4 / stream	5.898	**35.61**	**6.44**	**12.21**	**2.20**	13.56	**0.03**	**0.06**

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Sed. dweller prolonged	Algae acute	Aquatic plants
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC_{50}
		210	38	72	13	80	0.17	0.32
Annex VI Trigger		**100**	**10**	**100**	**10**	**10**	**10**	**10**

Refinement 1: Maximum PECsw and TER values for oxyfluorfen (pomes 1.44 kg a.s./ha, banded applications)

Scenario	PEC global max (µg/L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Sed. dweller prolonged	Algae acute	Aquatic plants
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC_{50}
		210	38	72	13	80	0.17	0.32
Refinement 1: 20 m non-spray buffer zone								
FOCUS Step 4								
D3 / ditch	0.674	311.57	56.38	106.82	19.29	118.69	**0.25**	**0.50**
D4 / pond	0.129	1627.91	294.57	558.14	100.78	620.16	**1.32**	**2.64**
D4 / stream	0.767	273.79	49.54	**93.87**	16.95	104.30	**0.22**	**0.44**
D5 / pond	0.129	1627.91	294.57	558.14	100.78	620.16	**1.32**	**2.64**
D5 / stream	0.848	247.64	44.81	**84.91**	15.33	94.34	**0.20**	**0.40**
R1 / pond	0.129	1627.91	294.57	558.14	100.78	620.16	**1.32**	**2.64**
R1 / stream	0.678	309.73	56.05	106.19	19.17	117.99	**0.25**	**0.50**
R2 / stream	0.793	264.82	47.92	**90.79**	16.39	100.88	**0.21**	**0.43**
R3 / stream	0.827	253.93	45.95	**87.06**	15.72	96.74	**0.21**	**0.41**
R4 / stream	0.592	354.73	64.19	121.62	21.96	135.14	**0.29**	**0.57**
Annex VI Trigger		**100**	**10**	**100**	**10**	**10**	**10**	**10**

Tier 1: Maximum PECsw and TER values for oxyfluorfen (vines 1.44 kg a.s./ha, banded applications)

Scenario	PEC global max (µg/L)	fish acute	Fish prolonged	Daphnia acute	Daphnia prolonged	Sed. dweller prolonged	Algae acute	Aquatic plants
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC_{50}
		210	38	72	13	80	0.17	0.32
FOCUS Step 1	32.18	**6.5**	**1.2**	**2.2**	**0.4**	**2.5**	**0.0**	**0.0**
FOCUS Step 2								
North Europe	11.45	**18.34**	**3.32**	**0.20**	**1.14**	**6.99**	**0.01**	**0.03**
South Europe	9.61	**21.9**	**4.0**	**7.5**	**1.4**	**8.3**	**0.0**	**0.0**
FOCUS Step 3								
D6 / ditch	9.05	**23.20**	**4.20**	**7.96**	**1.44**	**8.84**	**0.02**	**0.04**
R1 / pond	0.311	675.24	122.19	231.51	41.80	257.23	**0.55**	**1.09**
R1 / stream	5.95	**35.29**	**6.39**	**12.10**	**2.18**	13.45	**0.03**	**0.06**
R2 / stream	7.896	**26.60**	**4.81**	**9.12**	**1.65**	10.13	**0.02**	**0.04**
R3 / stream	8.232	**25.51**	**4.62**	**8.75**	**1.58**	**9.72**	**0.02**	**0.04**
R4 / stream	5.889	**35.66**	**6.45**	**12.23**	**2.21**	13.58	**0.03**	**0.06**
Annex VI Trigger		**100**	**10**	**100**	**10**	**10**	**10**	**10**

Refinement 1: Maximum PECsw and TER values for oxyfluorfen (vines 1.44 kg a.s./ha, banded applications)

Scenario	**PEC global max (µg/L)**	**fish acute**	**Fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Sed. dweller prolonged**	**Algae acute**	**Aquatic plants**
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC_{50}
		210	38	72	13	80	0.17	0.32
Refinement 1: 20 m non-spray buffer zone								
FOCUS Step 4								
D6 / ditch	0.674	311.57	56.38	106.82	19.29	118.69	**0.25**	**0.50**
R1 / pond	0.129	1627.91	294.57	558.14	100.78	620.16	**1.32**	**2.64**
R1 / stream	0.658	319.15	57.75	109.42	19.76	121.58	**0.26**	**0.52**
R2 / stream	0.792	265.15	47.98	**90.91**	16.41	101.01	**0.21**	**0.43**
R3 / stream	0.826	254.24	46.00	**87.17**	15.74	96.85	**0.21**	**0.41**
R4 / stream	0.591	355.33	64.30	121.83	22.00	135.36	**0.29**	**0.58**
Annex VI Trigger		**100**	**10**	**100**	**10**	**10**	**10**	**10**

Tier I: Maximum PECsw and TER values for oxyfluorfen (sunflowers 0.24 kg a.s./ha)

Scenario	**PEC global max (µg L)**	**fish acute**	**Fish prolonged**	**Daphnia acute**	**Daphnia prolonged**	**Sed. dweller prolonged**	**Algae acute**	**Aquatic plants**
		Bluegill sunfish	***P. promelas***	***Daphnia magna***	***Daphnia magna***	***C. riparius***	***S. S. subcapitata***	***L. gibba***
		LC_{50}	NOEC	EC_{50}	NOEC	NOEC	E_bC_{50}	E_bC50
		210	38	72	13	80	0.17	0.32
FOCUS Step 1	11.57	**18.2**	**3.3**	**6.2**	**1.1**	**6.9**	**0.0**	**0.0**
FOCUS Step 2								
North Europe	4.05	**51.85**	**9.38**	**1.54**	**3.21**	19.75	**0.04**	**0.08**
South Europe	2.21	**95.0**	17.2	**32.6**	**5.9**	36.2	**0.1**	**0.2**
FOCUS Step 3								
D5 / pond	0.0501	4191.62	758.48	1437.13	259.48	1596.81	**3.39**	**6.79**
D5 / stream	1.024	205.08	37.11	**70.31**	12.70	78.13	**0.17**	**0.33**
R1 / pond	0.0759	2766.80	500.66	948.62	171.28	1054.02	**2.24**	**4.48**
R1 / stream	0.863	243.34	44.03	**83.43**	15.06	92.70	**0.20**	**0.39**
R3 / stream	1.211	173.41	31.38	**59.45**	10.73	66.06	**0.14**	**0.28**
R4 / stream	0.86	244.19	44.19	**83.72**	15.12	93.02	**0.20**	**0.40**
Annex VI Trigger		**100**	**10**	**100**	**10**	**10**	**10**	**10**

FOCUS$_{sw}$ step 4

Refinement 1: Maximum PECsw and TER values for oxyfluorfen (sunflowers 0.24 kg a.s./ha)

Scenario	PEC global max (µg/L)	Daphnia acute	Algae acute	Aquatic plants
		Daphnia magna	*S. subcapitata*	*L. gibba*
		EC_{50}	EbC_{50}	E_bC_{50}
		72	0.17	0.32
Refinement 1: 20 m non-spray buffer zone				
FOCUS Step 4				
D6 / ditch	0.674	3364	**7.94**	15.89
R1 / pond	0.129	610	**1.44**	**2.88**
R1 / stream	0.658	3364	**7.94**	15.89
R2 / stream	0.792	720	**1.70**	**3.40**
R3 / stream	0.826	514	**1.21**	**2.43**
R4 / stream	0.591	514	**1.21**	**2.43**
Annex VI Trigger		**100**	**10**	**10**

Tier I TER values for metabolites RH-34670, RH-35451 and RH-123394 (pome,vines, 1.44 kg a.s./ha band applications; sunflowers 0.240 kg as/ha).

Species	EC 50 (µg a.s./L)	FOCUS STEP	PECsw (µg a.s./L)	TER
Pome and vines				
RH-123394				
Algae	64	Step 1	5.15	12.4
Aquatic plants	> 610	Step 1	5.15	> 118
RH-35451				
Algae	210	Step 1	6.79	30.9
Aquatic plants	370	Step 1	6.79	54
RH-34670				
Algae	6	Step 1	2.97	**2.0**
		Step 2	1.06	**5.6**
		Step 3	0.84	**7.1**
		Step 4-20 m	0.08	25
Aquatic plants	14	Step 1	2.97	**4.7**
		Step 2	1.06	13.2
Sunflowers				
RH-123394				
Algae	64	Step 1	1.85	34
Aquatic plants	> 610	Step 1	1.85	> 32
RH-35451				
Algae	210	Step 1	2.44	86
Aquatic plants	370	Step 1	2.44	152
RH-34670				
Algae	6	Step 1	1.07	**5.6**
		Step 2	0.37	16
Aquatic plants	14	Step 1	1.07	13
Annex VI Trigger				**10**

Bioconcentration

	Oxyfluorfen	New study (Blankinship et al., 2006)
$logP_{OW}$	4.86	4.86
Bioconcentration factor (BCF) *	1075 – 2200x	184 (DT_{50} of 6.3 hours) 809 (DT_{50} of 57 hours) 1151 (DT_{50} of 105 hours)
Annex VI Trigger for the bioconcentration factor	100	100
Clearance time (days) (CT_{50})	5-7 days	
(CT_{90})		
Level and nature of residues (%) in organisms after the 14 day depuration phase	18%	
Level and nature of residues (%) in organisms after different water concentration depuration time (DT_{50})	DT_{50}= 6.3 h DT_{50}= 57 h DT_{50}= 105 h	6% after 18 days ** 15% after 18 days ** 30% after 25 days**

* based on total ^{14}C, ** It is not a true depuration phase as organisms were not transferred to clean water

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)
Oxyfluorfen Technical substance	LD_{50} > 100 µg/bee	LD_{50} > 100 µg/bee
Preparation[1]		
Metabolite 1		
Field or semi-field tests		
Indicate if not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

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

Test substance	Route	Hazard quotient	Annex VI Trigger
Sunflowers-240 g as/ha			
Oxyfluorfen Technical	Inhalation	2.4	50
Oxyfluorfen Technical	Oral	2.4	50
Pome/vines 1.44 kg as/ha			
Oxyfluorfen Technical	Inhalation	14.4	50
Oxyfluorfen Technical	Oral	2.4	50

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 ‡	GOAL 4F (42.09%)	Mortality	M = 98 %. LR_{50} < 1.44 kg as/ha R not determined
Aphidius rhopalosiphi ‡	GOAL 4F (42.09%)	Mortality	M = 0 % P = 0 % Fecundity not affected
Poecilus cupreus	GOAL 4F (42.09%)	Mortality	M = 0 % F not affected
Pardosa sp	GOAL 4F (42.09%)	Mortality	M = 33.3 % LR_{50} > 1.44 kg a.s./ha F not affected

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Sunflowers (240 g as/ha). Pome/vines (1.44 kg as/ha). No accurate LR_{50} available

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri				2
	Aphidius rhopalosiphi				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 (kg as/ha)	End point	% effect	Trigger value
Typhlodromus pyri	protony mphs	GOAL 4F (42.09%), fresh residues on leaves	0.00037 0.00111 0.00333 0.01 0.03 0.09	Mortality Reproduction	>50 % LR_{50} = 1.57 g as/ha No reproduction effect up to 1.11 g/ha	50 %
Coccinella septempunctata	2 or 3 day larvae	GOAL 4F (42.09%), fresh residues on leaves	0.0333 0.240 1.44	Mortality Reproduction	LR_{50} > 1.44 kg a.s./ha R = + 13.57 R = -61.58 R =-24.58	50 %
Chrysoperla carnea	2 or 3 day larvae	GOAL 4F (42.09%), fresh residues on leaves	0.0333 0.240 1.44	Mortality Reproduction	LR_{50} > 1.44 kg a.s./ha Reproduction not affected in any treatment	50 %

Species	Life stage	Test substance, substrate and duration	Dose (kg as/ha)	End point	% effect	Trigger value
Hypoaspis aculeifer	27 days old	GOAL 4F (42.09%), soil treatment	mg as/kg 1.25a 2.5a 5a 10a 15a 25a	Mortality Reproduction	LR_{50} = 3.42 mg as /kg equivalent to LR_{50}= 2.565 kg as/ha R = - 28.1 R = - 59.2 R = - 72.1 R = - 66.0 R= - 71.9 R = -70.9	50 %

Notes: * M = mortality (%), R = reproduction-fecundity (%), P = parasitism, F = food consumption; Positive values indicate better performance than the control

Field or semi-field tests
The trial was performed from June 2007 until June 2008 on a pastureland at Kennels Farm, Chilworth, Southampton, UK. Bare soil application-Broadcast AR = 0.24 kg as/ha Band application: B1) Plateau-0.435 kg as/ha, B2) 1.44 kg as/ha The broadcast application rate of Goal 4F (0.24 kg a.s./ha) did not significantly affect numbers of any of the above taxonomic groups on any sampling occasion (ANOVA, P > 0.05). The strip application rate of Goal 4F (1.44 kg a.s./ha, applied in addition to a rate intended to achieve a soil plateau concentration equivalent to 0.58 mg a.s./kg soil) did not significantly affect numbers of any of the above taxonomic groups on any sampling occasion, with the single exception of a significant reduction in the numbers of *Symphypleona* in the soil-core samples taken 3 months after treatment (105 DAT). The numbers of *Symphypleona* reached comparable levels to those in the control by the end of the trial. Numbers of these springtails were not affected in the adjacent unsprayed strip of ground. **There were no long-term treatment effects of Goal 4F on the soil meso- and macro-fauna at maximum applications to bare soil in sunflower and pome/vine applications.**

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 **[mg a.s/kg dry soil]**[1]
Earthworms (*Eisenia foetida*)			
	Oxyfluorfen Technical (99.25)	Acute 14 days	LC_{50corr} > 500 mg a.s./kg soil
	Goal 4F (42.09%)	Acute 14 days	LC_{50corr} > 210 mg a.s./kg soil
	Goal 2XL (P) (23.2 % w/w)	Chronic 8 weeks	$NOEC_{corr}$ = 12 mg a.s./kg soil
Field studies[2]			
Collembola (*Folsomia candida*)			
	Test substance	Chronic	NOEC mg a.s./kg d.w.soil (mg a.s/ha)

Test organism	Test substance	Time scale	End point **[mg a.s/kg dry soil]**[1]
	Goal 4F (480 g a.s./L)	28 days	LC_{50} = 2.78 NOEC = 1.25
	Metabolite 1		
Soil micro-organisms			
Nitrogen mineralisation	Goal 4F (480 g a.s./L)	28 days	No effects up to 1.44 kg as/ha (1.96 mg as/kg) and 7.2 kg as/ha (9.60 mg as/kg) at 28 days
Carbon mineralisation	Goal 4F (480 g a.s./L)	28 days	No effects up to 1.44 kg as/ha (1.96 mg as/kg) and 7.2 kg as/ha (9.60 mg as/kg) at 28 days
Field studies[2]			
Litter bag study (Mallet, MJ, 2003): No significant adverse effect was observed on breakdown of organic matter in soil. This study was considered valid only for sunflower use.			

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

Toxicity/exposure ratios for soil organisms

Sunflowers- 240 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	Oxyfluorfen Technical (99.25)	Acute	0.42	> 1190	10
Eisenia foetida	Goal 4F (42.09%)	Acute	0.42	>500	10
Eisenia foetida	Goal 2XL (P) (23.2 % w/w)	Chronic	0.42	28.7	5
Other soil macro-organisms					
Collembola	Goal 4F (480 g a.s./L)	Chronic	0.42	**2.9**	5
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] plateau PEC

Pome/vines-1.44 kg as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	Oxyfluorfen Technical (99.25)	Acute	2.5	>200	10
Eisenia foetida	Goal 4F (42.09%)	Acute	2.5	>84.2	10
Eisenia foetida	Goal 2XL (P) (23.2 % w/w)	Chronic	2.5	4.8[3]	5
Other soil macro-organisms					
Collembola	Goal 4F (480 g a.s./L)	Chronic	2.5	0.5[4]	5
	Preparation				
	Metabolite 1				

[1] to be completed where first Tier triggers are breached
[2] plateau PEC.
[3] This value does not take into account the application type of oxyfluorfen (band application),
[4] Field study shows a low risk.

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

Preliminary screening data

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} vegetative vigour[1]	ER_{50} Seedling emergence[1]	Exposure[1] (mg as/kg soil)	TER	Trigger
Pome/vines - 1.44 kg as/ha						
	Goal 2XL (P) (23.2 % w/w)	HC_5 = 14.6 g/ha	HC_5 = 13.4 g/ha	5m-8.20	> 1	1[2]
Sunflowers - 240 g as/ha						
	Goal 2XL (P) (23.2 % w/w)	HC_5 = 14.6 g/ha	HC_5 = 13.4 g/ha	1m- 6.6	> 1	1[2]

[1] 5th percentile ER_{50} for shoot weight obtained from a species sensitivity distribution (SSD) of the data from the vegetative vigour or seedling emergence study.

[2] If the ED50 for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable

Mitigation measure

Buffer zones of 5 m are needed to protect non target plants from the use of oxyfluorfen on pome/vines. No buffer zones are required for sunflower use.

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

Test type/organism	end point
Activated sludge	EC_{50}> 1000 mg/L.
Pseudomonas sp	

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

Compartment	
soil	Oxyfluorfen
water	Oxyfluorfen. The risk to aquatic organisms from the metabolites RH-45469, MW 306, MW 347, MW 274 and unidentified Deg 27 remains to be addressed.
sediment	Oxyfluorfen
groundwater	Oxyfluorfen
air	Oxyfluorfen

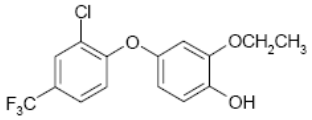
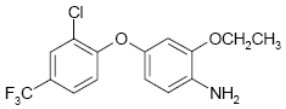
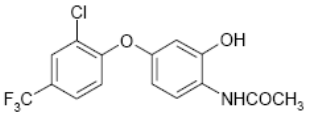
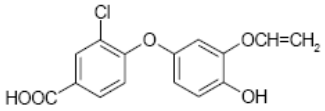
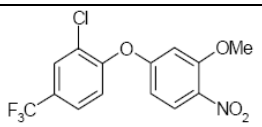
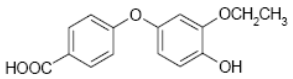
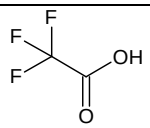
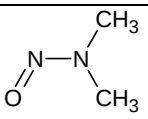
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

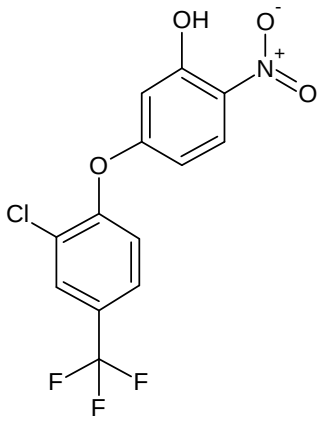
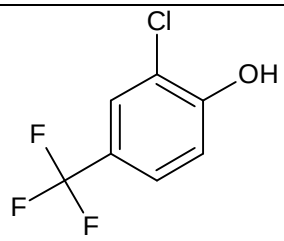
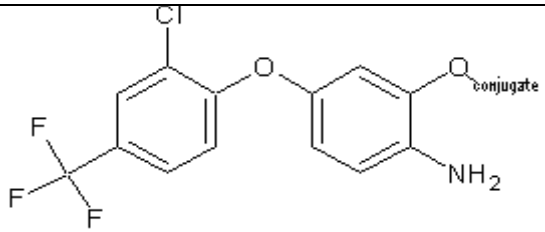
	RMS/peer review proposal
Active substance	N, R50/R53 Very toxic to aquatic organisms, may cause long-term adverse effect to the aquatic environment

RMS/peer review proposal

Preparation	N, R50/R53 Very toxic to aquatic organisms, may cause long-term adverse effect to the aquatic environment

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
RH-123394	**4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-ethoxyphenol	
RH-35451	**4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-ethoxyaniline	
RH-45469	**5-[2-chloro-4-(trifluoromethyl)phenoxy]-2-[(methoxymethyl)amino]phenol	
MW 306	**3-chloro-4-[3-(ethenyloxy)-4-hydroxyphenoxy]benzoic acid	
MW 347	**2-chloro-1-(3-methoxy-4-nitrophenoxy)-4-(trifluoromethyl)benzene	
MW 274	**4-(3-ethoxy-4-hydroxyphenoxy)benzoic acid	
Deg 27	Not identified	Not identified
Trifluoroacetic acid (TFAA)	Trifluoroacetic acid	
N,N-dimethylnitrosamine	N,N-dimethylnitrosamine	

Code/Trivial name*	Chemical name	Structural formula
RH-34670	5-[(2-chloro-α,α,α-trifluoro-p-tolyl)oxy]-2-nitrophenol	
RH-34800	**2-chloro-4-(trifluoromethyl)phenol	
RH-45298 C	**2-amino-5-[2-chloro-4-(trifluoromethyl)phenoxy]phenol-conjugate	

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

* The metabolite name in bold is the name used in the conclusion.

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECD	electron capture detector
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
ETE	estimated theoretical exposure
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first-order multi-compartment

g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-TEA	gas chromatography with thermal energy analysis
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
HC	hazard concentration
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
HS	hockey stick
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose

MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation

wk	week
yr	year