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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance fluazifop-P (evaluated variant fluazifop-P-butyl)[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State, France, for the pesticide active substance fluazifop-P are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009. The conclusions were reached on the basis of the evaluation of the representative uses of fluazifop-P as a herbicide in pome fruit, on peas (green without pods), beans (green with pods), pulses (dry peas and dry beans), potato, and oilseed rape. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

Fluazifop-P, peer review, risk assessment, pesticide, herbicide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Regulation (EC) No 1107/2009 (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure for the assessment of applications for amendment to the conditions of approval of active substances.

Fluazifop-P was approved on 1 January 2012 by Commission Implementing Regulation (EU) No 788/2011, following a peer review of the risk assessment as set out in the EFSA Conclusion on fluazifop-P, published on 26 November 2010. It was a specific provision of the approval that only uses as a herbicide for orchards (basal application) with one application may be authorised. In accordance with Article 7 of Regulation (EC) No 1107/2009, France subsequently received an application from Syngenta Crop Protection AG for amendment to the conditions of approval of the active substance fluazifop-P to lift the restriction and allow other uses as a herbicide to be authorised.

The RMS provided its initial evaluation of the dossier in the form of an Addendum to the Additional Report, which was received by the EFSA on 30 March 2012. The peer review was initiated on 2 April 2012 by dispatching the DAR for consultation of the Member States and the applicant, Syngenta Crop Protection AG. EFSA also provided comments.

Following consideration of the comments received on the Addendum, it was concluded that EFSA should organise an expert consultation in the area of mammalian toxicology, and that EFSA should adopt a conclusion on whether fluazifop-P can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009, also taking into consideration recital (10) of the Regulation.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of fluazifop-P as a herbicide in pome fruit, on peas (green without pods), beans (green with pods), pulses (dry peas and dry beans), potato, and oilseed rape, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

No areas of concern or data gaps were identified in the section identity, physical and chemical properties and analytical methods.

The technical specification is not supported by the batches used in the toxicological studies and a data gap and a critical area of concern have been identified.

Additional data are required to address the magnitude of the residues in processed peas (green without pods), beans (green with pods) and pulses (peas and beans, dry). Supervised residue trials are also required to confirm the no-residue situation in pome fruit in Southern Europe.

The data available on fate and behaviour in the environment were considered insufficient to carry out a complete environmental exposure assessment at the EU level for the representative uses. Several data gaps were identified for further investigation of the route of degradation of fluazifop-P-butyl in the environment, and for more reliable data for the properties of the metabolites Compound X and Compound IV. The potential for groundwater exposure from the representative uses by the metabolite Compound X above the parametric drinking water limit of 0.1 μg/L was concluded to be high in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. Data gaps were identified for a reliable estimation of the leaching potential of Compounds IV and X.

A data gap was identified to further address the long-term risk to herbivorous mammals for the representative uses on pome fruit, peas and beans. A data gap was also identified to further address the risk to fish and aquatic invertebrates for the metabolite Compound IV in the water phase for all representative uses. Mitigation measures comparable to in-field no-spray buffer zones up to 10m were necessary to protect terrestrial non-target plants.

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BACKGROUND

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure for the assessment of applications for amendment to the conditions of approval of active substances. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant(s) for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 12 of the Regulation, EFSA is required to adopt a conclusion on whether an active substance can be expected to meet the approval criteria provided for in Article 4 of the Regulation (also taking into consideration recital (10) of the Regulation) within 120 days from the end of the period provided for the submission of written comments, subject to an extension of 30 days where an expert consultation is necessary, and a further extension of upto 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Fluazifop-P was approved on 1 January 2012 by Commission Implementing Regulation (EU) No 788/2011[4], following a peer review of the risk assessment as set out in the EFSA Conclusion on fluazifop-P, published on 26 November 2010 (EFSA, 2010). It was a specific provision of the approval that only uses as a herbicide for orchards (basal application) with one application may be authorised. In accordance with Article 7 of Regulation (EC) No 1107/2009, France (hereinafter referred to as the rapporteur Member State, 'RMS') subsequently received an application from Syngenta Crop Protection AG for amendment to the conditions of approval of the active substance fluazifop-P to lift the restriction and allow other uses as a herbicide to be authorised.

The RMS provided its initial evaluation of the dossier on fluazifop-P in the form of an Addendum to the Additional Report, which was received by the EFSA on 30 March 2012 (France, 2011). The peer review was initiated on 2 April 2012 by dispatching the Addendum to Member States and the applicant, Syngenta Crop Protection AG, for consultation and comments. EFSA also provided comments. In addition, the EFSA conducted a public consultation on the Addendum. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 12(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 18 July 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that no additional information should be requested from applicant, and that the EFSA should organise an expert consultation in the area of mammalian toxicology.

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 an expert consultation, were compiled by the EFSA in the format of an Evaluation Table.

[3] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.

[4] Commission Implementing Regulation (EU) No 788/2011 of 5 August 2011 approving the active substance fluazifop-P, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ No L 203, 6.8.2011, p. 21-25.

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 consultation where this 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 September – October 2012.

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 in pome fruit, on peas (green without pods), beans (green with pods), pulses (dry peas and dry beans), potato, and oilseed rape, as proposed by the applicant. 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, 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 (EFSA, 2012) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the Addendum to the Additional Report,
- the Reporting Table (18 July 2012),
- the Evaluation Table (17 October 2012),
- the report of the scientific consultation with Member State experts (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the Addendum to the Additional Report including its addendum (compiled version of September 2012 containing all individually submitted addenda (France, 2012)) 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

Fluazifop-P is the ISO common name for (*R*)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionic acid (IUPAC). However the data submitted in the dossier refer to the variant fluazifop-P-butyl, which is the modified ISO common name for butyl (*R*)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionate (IUPAC).

The representative formulated product for the evaluation was 'Flusilade Max', an emulsifiable concentrate (EC), containing 125 g/l fluazifop-P-butyl, registered under different trade names in Europe.

The representative uses evaluated comprise spraying in pome fruit, on peas (green without pods), beans (green with pods), pulses (dry peas and dry beans), potato, and oilseed rape against annual and perennial grasses. 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 following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000) and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of fluazifop-P-butyl technical material is 900 g/kg. The minimum purity of fluazifop-P-butyl technical material in the FAO specification 467.205/TC (2000) is 900 g/kg.

The impurity 2-chloro-5-(trifluoromethyl)pyridine (R150881) was considered to be a relevant impurity in fluazifop-P-butyl technical material based on its hazards, with a maximum limit of 1.5 g/kg (see section 2).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of fluazifop-P-butyl or the representative formulation. The main data regarding the identity of fluazifop-P-butyl and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of fluazifop-P-butyl and the relevant impurity in the technical material and for the determination of the active substance in the representative formulation. A CIPAC method is also available for the determination of fluazifop-P-butyl in the technical material and the representative formulation. Adequate analytical methods are available to monitor the compounds in the residue definitions in food of plant and animal origin and the environmental matrices. Analytical methods for the determination of residues in body fluids and tissues are not required as fluazifop-P-butyl is not classified as toxic or highly toxic.

2. Mammalian toxicity

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

Fluazifop-P-butyl was discussed at the PRAPeR 81 and the Pesticides Peer Review TC 75 experts' meeting and teleconference on mammalian toxicology. The technical specification is not supported by the batches used in the toxicological studies and a data gap and a critical area of concern have been identified. The impurity 2-chloro-5-(trifluoromethyl)pyridine (R150881) is considered to be a toxicologically relevant impurity due to its genotoxic potential (maximum content in the technical specification 1.5 g/kg).

Oral absorption was estimated at higher than 80%. There was no evidence of accumulation. Comparative metabolism studies have shown that the major metabolite is the *R* enantiomer form of fluazifop acid. The rapid hydrolysis of *RS* fluazifop-butyl to the *R* fluazifop acid suggests that there is relatively little exposure to the *S* enantiomer in the dietary studies, especially at low dose levels. Thus dietary studies conducted with the racemic mixture, of either fluazifop-butyl or fluazifop acid, are considered equivalent to studies conducted with fluazifop-P-butyl alone.

Low acute toxicity is observed when fluazifop-P-butyl is administered by the oral, dermal and inhalation routes. No skin or eye irritation was observed, but there was potential for skin sensitisation.

In short-term oral studies with rats, dogs and hamsters, the critical effects were observed in the liver (all species), kidney and spleen (rats and hamster). In addition, decreased plasma cholesterol levels were observed in rats and dogs. Cataracts were also observed in dogs. The rat was the most sensitive species. The relevant short-term oral NOAEL is 0.9 mg/kg bw per day (90-d study).

No potential for genotoxicity is attributed to the active substance.

In long-term studies with rats, mice and hamsters, the critical effects were observed in the liver (all species) and kidney (rats and hamsters). In addition, cataracts were observed in hamsters. The overall relevant long-term NOAEL is 1 mg/kg bw per day. No evidence of carcinogenicity was observed.

Fertility and overall reproductive performance was not impaired in the reproduction toxicity studies; the parental and offspring NOAELs are 0.8 mg/kg bw per day, whereas the reproductive NOAEL is 7 mg/kg bw per day. In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal NOAELs are 20 mg/kg bw per day for the rat and 10 mg/kg bw per day for the rabbit. In rats, the agreed overall developmental NOAEL is 2 mg/kg bw per day based on increased incidences of kinked ureters and/or dilated ureter observed at 20 mg/kg bw per day. These observations are thought to reflect a slight delay in pup development. In rabbits, the developmental NOAEL is 10 mg/kg bw per day.

No potential for neurotoxicity was observed in the standard toxicity studies.

Classification and labelling with R43 (May cause sensitisation by skin contact) and R48/22 (Danger of serious damage to health by prolonged exposure if swallowed; based on eye effects observed in hamster and dogs) in addition to the current classification and labelling as Repr. Cat. 3, R63 (CLP00, Annex VI to Regulation (EC) No 1272/2008) are proposed[5].

The acceptable daily intake (ADI) is 0.01 mg/kg bw per day (expressed as fluazifop acid), based on the overall long-term NOAEL of 1 mg/kg bw per day and applying a safety factor of 100. The acceptable operator exposure level (AOEL) of fluazifop-p-butyl is 0.02 mg/kg bw per day, based on the NOAEL of 2 mg/kg bw per day found in the developmental rat study supported by the 90-d rat study and applying a safety factor of 100. No correction for oral absorption is needed to derive the AOEL. The acute reference dose (ARfD) is 0.017 mg/kg bw (expressed as fluazifop acid) based on the NOAEL of 2 mg/kg bw per day for developmental effects observed in the developmental rat study, and applying a safety factor of 100.

Toxicological studies provided for Compound X indicated that it is not toxicologically relevant according to the guidance document on groundwater metabolites in the absence of genotoxicity and developmental toxicity. The ADI of the parent fluazifop-P is applicable to Compound X. The ARfD of Compound X is 0.6 mg/kg bw based on the NOAEL of 60 mg/kg bw per day for maternal and developmental toxicity in rat, 100 safety factor applied.

[5] It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

The relevant dermal absorption values for 'Fusilade Max' are 1% for the concentrate and 6.5% for the dilution.

'Fusilade Max' is applied against grass weeds in different crops. Tractor-mounted application is considered for peas, beans, oilseed rape and potatoes. Hand-held application is considered for pome fruit. For tractor-mounted application, the estimated operator exposure is below the AOEL (85% of the AOEL) even without the use of personal protective equipment (PPE) during mixing and loading and application according to the German Model. For hand-held application, the estimated operator exposure is below the AOEL (59% of the AOEL) if gloves are used during mixing and loading and application according to the UK POEM and considering a volume of dilution of 500L. Worker and bystander exposure is below the AOEL (30.4% and 1.4% of the AOEL, respectively).

3. Residues

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

The metabolism of fluazifop-P-butyl has been investigated in leafy vegetables (celery leaves) and also in lettuce regarding the phenyl label moiety, root and tuber vegetables (carrot and sugar beet) and oilseeds (soya beans and cotton plants). A metabolism study was also considered on vine grapes with basal soil application of fluazifop-P-butyl labelled on both phenyl and pyridyl moieties resulting in negligible residue levels in the fruit (below 0.01 mg/kg) and no further characterisation of the total residues was attempted. The parent fluazifop-P-butyl was recovered in lettuce and cotton plants (up to 50% and 24% of TRR, respectively) but was not detected in the root crops, or at a trace level in celery leaves (2 % of TRR). The predominant compound of the total residues in all crops was fluazifop, free and conjugated (20 to 70% of TRR). Minor metabolites contained either the phenyl or the pyridyl ring following hydrolytic ester linkage cleavage of the acid fluazifop to give compounds III (R118106) and X, respectively. Compound III was recovered at a low level in all crops (<0.01-0.02 mg/kg) while compound X accounted for *circa* 10% of TRR (0.064 mg/kg) in celery leaves only and occurred at a negligible level (<0.01 mg/kg) in root/tuber and oilseeds crops. A similar metabolic pattern was observed in root crops and cotton plants for both the racemate fluazifop-butyl and the active *R* enantiomeric form fluazifop-P-butyl. Furthermore, the *R*/*S* ratio of the parent compound remained unchanged in plants suggesting no enantiomeric conversion. A confined rotational crop metabolism study showed a more intensive degradation of fluazifop-P-butyl compared to the primary crops as only Compound X, either free or hexose conjugated, was recovered at relevant levels in harvested wheat (forage, straw, grain) (30-70% TRR), lettuce (64% TRR) and carrot (root, foliage) (44-60% TRR) sown 60 days after fluazifop-P-butyl bare soil treatment (2.7 N rate). Compound X is the predominant metabolite in soil and it is assumed that its presence in the edible parts of the rotated crops is due to its uptake from the soil. Since the metabolic pattern of the parent fluazifop-P-butyl was similar in soil at all sampling time intervals, the nature of the residues in rotated crops is expected to be similar at 30-day and 270-day plant back intervals and was not further investigated.

The residue definition for monitoring is proposed as the sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers). During the Pesticides Peer Review Teleconference TC 75 on mammalian toxicology, the experts concluded that Compound X was not genotoxic and that the ADI of the parent fluazifop-P-butyl also applies to Compound X (section 2). Therefore, EFSA proposes to set the residue definition for risk assessment as the sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers). EFSA is of the opinion that it is not expected to monitor significant levels of Compound X in the edible parts of the representative uses with regard to the available metabolism data in primary crops. Furthermore, cold rotational crop field trials were submitted where wheat, lettuce and carrot were rotated with oilseed rape treated as a primary crop at a dose rate of 375 g a.s./ha, or the rotated crops were planted on soils treated once at dose rates of 375 and 475 g a.s./ha of fluazifop-P-butyl, respectively. These trials showed that the residue levels of total fluazifop and total Compound X (free and conjugated) were below the limit of quantification of the respective analytical methods in lettuce head, carrot root and wheat (forage, straw, grain) at plant back intervals of 1, 2, 4 and 6 months. Significant residue levels of Compound X were detected in carrot foliage only (0.03-0.13 mg/kg, 1N rate). EFSA is therefore of the opinion that the residue definition for monitoring and risk assessment set in primary crops should also apply to rotational crops in view of the non-toxicological relevance of Compound X.

A sufficient number of supervised residue trials have been reported for the representative uses in pome fruit (Northern Europe), on peas (green without pods), beans (green with pods), pulses (peas and beans, dry), potatoes and oilseed rape. Additional trials are required to confirm the no-residue situation for pome fruit in Southern Europe. The samples were analysed for total fluazifop, i.e. fluazifop-butyl, fluazifop and its conjugates and fluazifop esters expressed as fluazifop. It was accepted that the submitted analytical methods convert all conjugates of fluazifop and fluazifop esters into fluazifop. The storage time interval of the samples in the corresponding residue trials for all crops was covered by acceptable storage stability data for 18 months. Fluazifop-P butyl is not expected to degrade beyond the stable fluazifop under hydrolysis conditions used in the analytical method SOP RAM 287/02. However, it should be highlighted that the nature of the residues in processed products has not been investigated according to the current standard hydrolytic conditions. Processing factors were proposed for processed potatoes (peeled and cooked potatoes, chips and dried potatoes) and oilseed rape (rape seed cake and crude/refined oil). No processing data were provided on pulses, peas (green without pods) and beans (green with pods) despite their significant residues, and therefore data gaps were identified.

Metabolism studies were performed in lactating goats and poultry. The major part of the radioactivity was recovered in the excreta (up to 95 % of the total applied radioactivity). The highest total residue levels were recovered in ruminant liver and kidney, and in eggs and poultry fat, and were shown to be principally constituted of fluazifop and its conjugates. Parent was detected at a trace level in poultry liver only (0.7 % of TRR).The residue definitions for risk assessment and monitoring have therefore been set as the sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers). Based on the livestock feeding studies MRLs were proposed for animal matrices.

No chronic and acute intake concerns were identified for consumers. Using the EFSA PRIMo model, the STMRs derived for the representative uses, the available processing factors, and the MRLs proposed for animal products, the highest IEDI is 28.6% of the ADI (FR toddler). The highest acute intake was calculated to be 63.3% of the ARfD for potato (UK infant). Finally, it is not excluded that a consumer risk assessment from the consumption of drinking water would be triggered (section 4).

4. Environmental fate and behaviour

It should be noted that the methods of analysis used in the fate and behaviour studies were not stereo-selective and some studies used the racemic mixture of the enantiomers. However, based on the results of some additional studies using stereo-selective analysis, it was concluded that the results of the studies included in the fate and behaviour chapter are appropriate to be used for the assessment of the *R* enantiomer of both fluazifop-P-butyl and fluazifop-P.

In soil laboratory incubations under aerobic conditions in the dark, fluazifop-P-butyl exhibits very low to low persistence, forming fluazifop-P and two other major (>10% applied radioactivity (AR)) soil metabolites, Compound X and Compound IV. It is noted that Compound IV was observed as a minor metabolite in soil incubations at room temperature, but was measured as major in a study at 10°C. The rate of mineralisation to carbon dioxide for the pyridyl label was ca. 9 % recovered radioactivity (RR) after 84 days or 16.7 % AR after 120 days. Formations of unextractable residues were a sink for the phenyl label accounting for 29.9-55.4 % RR after 84 days or 32.1% AR after 120 days. A data gap was identified for an appropriate soil degradation study under anaerobic conditions. No novel metabolites were identified in the study on photolysis in soil. Fluazifop-P exhibited low to moderate persistence. Metabolite Compound X might be classified to exhibit moderate to medium persistence in soil, however a data gap has been identified for further investigation of the degradation kinetics of this metabolite. Regarding the other secondary metabolite Compound IV, no reliable estimation for degradation was available due to the poor kinetic fitting, although three kinetic estimations originating from two soils were considered better than the others, and might be acceptable. Therefore these data, although considered as uncertain, were not completely removed from the further assessments. It was also considered that this parameter (soil DT_{50}) has a relatively low or no impact on the available exposure estimations (predicted environmental concentrations (PEC)) for soil and surface water in this case. It was considered that in order to reduce this uncertainty, investigation of the degradation rate in soil incubations dosed with this metabolite would be necessary. A data gap was identified for the determination of the degradation rate of Compound IV in at least one, but preferably three, soils. Based on the available data, metabolite Compound IV might be classified to exhibit moderate to high persistence in soil. Dissipation of fluazifop-P-butyl was investigated in a number of field trials, however none of them were considered as reliable, therefore they were not used further in the risk assessment.

Regarding the mobility, only indicative data on a single soil were available for fluazifop-P-butyl, which indicated slight mobility for this compound. It was considered however that in this case no further data are necessary. Fluazifop-P exhibits very high to high mobility, while the metabolite Compound X exhibits very high mobility in soil. Regarding Compound IV, only an uncertain indicative value based on an HPLC method was available. This value indicates medium mobility in soil for Compound IV. A data gap was identified for a more reliable estimation of the adsorption potential of this metabolite.

PECsoil for fluazifop-P-butyl and fluazifop-P were calculated based on the worst-case laboratory DT_{50}. For the metabolites Compound X and Compound IV reliable initial PECsoil values are available.

The hydrolysis of fluazifop-P-butyl is pH dependent. The hydrolysis product fluazifop-P is stable to hydrolysis. In an aqueous photolysis study of fluazifop-P-butyl two major (referred as U7 and U1) and some minor metabolites were formed. Since fluazifop-P emerges easily and quickly in aquatic environments, studying the photo-degradation of fluazifop-P was found to be relevant in this case. A data gap was therefore identified for such a study.

In laboratory incubations in aerobic natural sediment water systems, fluazifop-P-butyl rapidly degraded in the water phase (mainly hydrolysed to fluazifop-P) with negligible partition into the sediment. In addition to fluazifop-P, Compound X as a major metabolite was formed. Compound IV was also formed, but only in the sediment at a maximum level of 9.9 % AR. The formation of fluazifop-P in the water phase approached the 100 % level and was found in the sediment at a maximum of 18% AR on day 30. Mineralisation to carbon dioxide accounted for about 13 - 32 % AR, while residues not extracted from the sediment represented 21 - 40 % AR at the end of the study. The necessary surface water and sediment exposure assessments (PEC) were carried out using the FOCUS (FOCUS, 2001) step 1 and step 2 approach for fluazifop-P-butyl and its metabolites including fluazifop-P. Moreover, PEC values for surface water and sediment were calculated for fluazifop-P-butyl using the FOCUS step 3 approach[6]. It is noted that for the orchard use at step 3, 50 % crop interception and treatment to the whole area was simulated.

The necessary groundwater exposure assessments were carried out using FOCUS (FOCUS, 2000) scenarios and models (PELMO 3.3.2 and PEARL 3.3.3[7]). The potential for groundwater exposure from the representative uses by fluazifop-P-butyl and fluazifop-P above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. The potential for groundwater exposure by the toxicologically not relevant metabolite Compound X was concluded to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. It should be noted that the soil DT_{50}

[6] Simulations utilised Q10 of 2.2 and Walker equation coefficient of 0.7
[7] Simulations utilised Q10 of 2.2 and Walker equation coefficient of 0.7

used in the simulations for Compound X is uncertain due to the uncertainty of the information available for the fitting. Moreover, for some soils the fits of the degradation kinetics were clearly poor. Therefore these fits could not be validated and a data gap relating to this was identified (see above). It cannot be excluded therefore that the leaching potential of Compound X was underestimated by the available modelling. No reliable PECgw calculation is available for Compound IV. Therefore a data gap was identified for estimation of the leaching potential of this metabolite using reliable input parameters. It is noted however, that at a late stage of the peer-review process the RMS performed PECgw calculations using those degradation endpoints that were considered more reliable than others (see discussion on this issue above). These calculations indicated that the potential for groundwater exposure by this metabolite above the parametric drinking water limit of 0.1 µg/L might be concluded to be low, however uncertainties remain and the data gap is maintained.

Fluazifop-P-butyl has a potential for volatilisation, however estimations for short-range transport that used the EVA 2.0 model (FOCUS, 2008) indicated that deposition via air after volatilisation is not significant compared to the deposition from spray drift. The estimated atmospheric half-life is shorter than 2 days. Therefore, long-range transport through the atmosphere is not expected.

5. Ecotoxicology

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

Toxicity data were provided for fluazifop-P-butyl and fluazifop-butyl, fluazifop-P and fluazifop, Compound X, and the representative preparation ‘Fusilade Max’. Fluazifop-butyl and fluazifop are a racemic mixture (1:1) of the *S*-enantiomer and *R*-enantiomer, therefore any toxic effects due to fluazifop-P-butyl or fluazifop-P would be detected in these studies.

A low acute, short-term and long-term risk for insectivorous birds and a low acute risk for herbivorous mammals was assessed at the first-tier for the representative uses in pome fruit and leafy crops (i.e. oilseed rape, beans, peas and potatoes), according to the guidance document (EC, 2002c).

The long-term risk to small herbivorous mammals for the representative use in pome fruit was not initially estimated because it was considered to be of low concern by the RMS, in view of the basal application around trees. However, a first-tier TER of 0.48 was calculated during the PRAPeR 80 Experts’ Meeting on ecotoxicology, indicating a potential high risk. The experts acknowledged that the type of application may reduce the exposure, however, insufficient data were available to quantify such a reduction. Furthermore, on the basis of the mode of action, exposure cannot be excluded over a period of 7-10 days and the onset of effects may occur within this period. Therefore a data gap was identified for the applicant to further refine the long-term risk assessment for small herbivorous mammals for the use in pome fruit and also to quantitatively clarify in the GAP table, the area to be treated in terms of kg a.s./ha of treated area.

The long-term risk to medium herbivorous mammals was assessed as high in oilseed rape, beans and peas at the first-tier. A refined risk assessment was provided based on measured residues and residue decline from residue trials. For oilseed rape 10 residue trials were available and the TER based on the arithmetic mean of the initial residue and on the residue decline (i.e.DT50 of 7 days) was above the trigger (TER=5.1).

No residue trials were available for peas and beans and a dataset for other leafy crops was taken into account to derive the geometric mean DT50 of 4.55 days. However, the experts questioned such an extrapolation due to uncertainties regarding the influence of application rate and growth stage on residue decline. In the above mentioned residue dataset, various crop stages were treated and the residue analysis was performed independently of crop stage and application rate. It was recommended that trials should be interpreted crop by crop with extrapolation being made explicitly. Therefore, the arithmetic mean DT50 of 7.9 days from kale was suggested to be used as a worst case. TERs were further revised during the written procedure based on a DT50 of 7.9 days (ftwa = 0.46). The resulting

TERs, calculated according to the guidance documents European Commission (2002c) and EFSA (2009), were below the trigger, indicating a high risk. Therefore, a data gap was identified to further address the risk for medium herbivorous mammals for the use in peas and beans.

The long-term risk to mammals was assessed as low for the representative use in potato.

Since the log Pow of fluazifop-P-butyl is 4.5 the risk of secondary poisoning was assessed. The TERs for earthworm- and fish-eating birds and mammals were above the Annex VI trigger, indicating a low risk. The risk from consumption of contaminated drinking water was assessed as low.

Fluazifop-P-butyl is very toxic to aquatic organisms. The lowest endpoint driving the aquatic risk assessment was observed in a study with the formulation on algae (EbC50= 0.024 mg a.s./L). The risk to aquatic organisms was assessed as low at FOCUSsw step 1-2 for the representative uses in pome fruit and potatoes and at FOCUSsw step 3 for the use on peas, beans and oilseed rape. The risk for the metabolites fluazifop-P and Compound X was assessed as low. The risk for sediment-dwelling organisms for the metabolites fluazifop-P and Compound IV was assessed as low on the basis of the NOEC from *D.magna* and step 3 PECsed values. The risk for the aqueous photolysis metabolites U1 and U7 was considered as low, even assuming that their toxicity is 10 times greater than the most sensitive endpoints. The risk for Compound IV in the water phase was estimated by EFSA based on PECsw step 2 and assuming that the toxicity of this metabolite is 10 times greater than the most sensitive endpoints. A high risk was identified for fish and *D. magna* (acute) for all representative uses, therefore a data gap was identified.

The in-field risk to non-target arthropods (*Typhlodromus pyri* and *Aphidius rhopalosiphi*) was assessed as high at the first tier according to the guidance SETAC (2001). Extended laboratory studies on *T. pyri* were submitted and the magnitude of effects (60%) was slightly above the recommended trigger (i.e.50%). However, the off-field risk was assessed as low and, based on the residue decline and the time of application, the experts concluded that recovery in the treated field area for the most sensitive species may occur within one year.

The risk to soil-dwelling organisms was assessed as low. The experts agreed that the available field study on earthworms is sufficient to also address the risk from exposure to metabolites, which are more persistent than the parent.

The risk for non-target terrestrial plants was indicated as low with the application of mitigation measures comparable to in-field no-spray buffer zones up to 10m for leafy crops (i.e. oilseed rape, beans, peas and potato) and up to 5m for pome fruit.

The risk was assessed as low for the other non-target organisms i.e. bees, soil microorganisms and methods of sewage treatment.

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
fluazifop-P-butyl	Very low to low persistence Single first order DT_{50} 0.3-2.9 days (20°C, 40% MWHC, n=3)	The risk for soil-dwelling organisms was assessed as low. LC50corr>500 mg a.s./kg d.w. soil (*Eisenia foetida*)
fluazifop-P	Low to moderate persistence[a] Single first order DT_{50} 2.7-38.6 days or biphasic DT_{90} 19.7-43.7 days (20°C, 40% MWHC or pF2 soil moisture, n=9)	The risk for soil-dwelling organisms was considered as low.
Compound X	Moderate to medium persistence estimated[a,b]	The risk for soil-dwelling organisms was considered as low.
Compound IV	Moderate to high persistence estimated[b]	The risk for soil-dwelling organisms was considered as low.

(a): The best fit for some soils (for all soils for Compound X) were obtained by using first order multi-compartment or double first order in parallel model. In these cases, pseudo DT_{50} was considered in the classification.

(b): Available degradation endpoints are uncertain, therefore the classifications for persistence are uncertain, as well. Regarding Compound X, a data gap has been set for further investigation of the degradation kinetics. Regarding Compound IV, a data gap has been set for at least one additional soil DT_{50}.

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

fluazifop-P-butyl	Slight mobility[a] K_{doc} 3394 mL/g	No	Yes	Yes	Very toxic to aquatic organisms. The lowest endpoint driving the aquatic risk assessment was observed in a study with 'Fusilade Max' on algae (E_bC50= 0.024 mg a.s./L, regulatory concentration including a safety factor of 10 = 0.0024 mg a.s./L). The risk to aquatic organisms was assessed as low.
fluazifop-P	Very high to high mobility K_{Foc} 38.5-83.6 mL/g	No	Yes	Yes	The risk for aquatic organisms was assessed as low.
Compound X	Very high mobility K_{Foc} 15.6-38 mL/g	Yes (FOCUS)[b]; trigger 0.1µg/L exceeded for 5 of 6 scenarios for winter oil seed rape, 7 of 9 scenarios for potato, 5 of 9 scenarios for apple, 3 of 4 scenarios for peas and 4 of 5 scenarios for beans	No	No (based on the hazard assessment, however a consumer risk assessment from the consumption of groundwater is not available[b])	The risk for aquatic organisms was assessed as low.
Compound IV	Medium mobility estimated[c]	Data gap[d]	No	No data available.	A high risk was identified for fish and *D. magna* (acute) in the water phase, therefore a data gap was identified.

(a): only one value is available; considered as only indicative
(b): the soil DT_{50} used in the exposure calculations is uncertain and might be underestimated, as a consequence PECgw results might be underestimated. Currently the predicted concentrations are <0.75µg/L. If with less uncertain DT_{50} estimates, groundwater modelling indicated concentrations >0.75µg/L a consumer risk assessment would be triggered. Such an assessment is not available.
(c): K_{doc} 313 mL/g determined by HPLC method; considered as only indicative. A data gap has been set for better estimation of the adsorption potential
(d): rough estimations using uncertain input parameters are available in the LoEP. These calculations indicate PECgw < 0.1µg/L for the relevant FOCUS scenarios

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
fluazifop-P-butyl	Very toxic to aquatic organisms. The lowest endpoint driving the aquatic risk assessment was observed in a study with ‘Fusilade Max’ on algae (E_bC50= 0.024 mg a.s./L, regulatory concentration including a safety factor of 10 = 0.0024 mg a.s./L). The risk to aquatic organisms was assessed as low.
fluazifop-P	The risk for aquatic organisms was assessed as low.
Compound X	The risk for aquatic organisms was assessed as low.
Compound IV	A high risk was identified for fish and *D. magna* (acute) in the water phase, therefore a data gap was identified.
U1[a]	The risk for aquatic organisms was assessed as low.
U7[a]	The risk for aquatic organisms was assessed as low.

(a): formed in the aqueous photolysis study

6.4. Air

Compound (name and/or code)	Toxicology
fluazifop-P-butyl	Low acute toxicity (LC50>5.2 mg/L/4h, nose only).

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- A search of the scientific peer-reviewed open literature relevant to the scope of the application for amendment to the conditions of approval, dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of dossier. To be conducted and reported in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092, 49 pp.).

- The equivalence of the batches tested in the toxicological studies with the technical specification has to be demonstrated (relevant for all representative uses, submission date proposed by the applicant: unknown, see section 2).

- Data to address the magnitude of the residues in processed pulses (peas and beans, dry), peas (green without pods) and beans (green with pods) (relevant for the representative uses on pulses, peas (without pods) and beans (green with pods); submission date proposed by the applicant: unknown, see section 3).

- Residue trials to confirm the no-residues situation for Southern European pome fruit (relevant for the representative uses in Southern Europe on pome fruit; submission date proposed by the applicant: unknown, see section 3).

- An appropriate soil degradation study under anaerobic conditions (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, however the applicant has indicated that a new study is already ongoing; see section 4).

- A photo-degradation study for fluazifop-P in water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown, however the applicant has indicated that a new study is already ongoing; see section 4).

- The degradation kinetics of Compound X needs to be further investigated and more reliable DT_{50} values to be derived. Consequently FOCUS PEC calculations will need to be repeated when more reliable DT50 values become available. Any new simulations would need to follow up to date scenario definitions and Q10 value[8] (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- The determination of the degradation rate of Compound IV at least in one soil is necessary. In order to reduce the existing uncertainty in the estimation of the soil DT_{50}, soil incubations on at least three soils dosed with this metabolite might be necessary (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Reliable estimation of the adsorption potential of Compound IV (e.g. a batch adsorption study) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

- Estimation of the leaching potential (calculations of PECgw using up to date scenario definitions and Q10 value) of Compound IV using reliable input parameters (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).

[8] Following EFSA (2007) and FOCUS (2001, 2009).

- The long-term risk assessment for herbivorous mammals needs to be further refined, including quantitative clarification of the area to be treated within orchards in terms of kg a.s./ha of treated area (relevant for the representative uses in pome fruit, and the uses in peas and beans; submission date proposed by the applicant: unknown; see section 5).

- The risk to fish and aquatic invertebrates from the metabolite Compound IV in the water phase needs to be further addressed (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 5).

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

- For hand-held basal application to pome fruit the estimated operator exposure is below the AOEL (59% AOEL) if gloves are used during mixing and loading and application according to the UK POEM and considering a volume of dilution of 500L (i.e. the AOEL is exceeded if a volume of dilution of 200 L is considered) (see section 2).

- The available assessments for groundwater considered biennial applications for the oilseed rape, potato, pea and bean uses, therefore the assessments cover only those situations when the active substance is applied once in every two years in the same field.

- The available assessments for the environmental compartments (surface water, ground water) for the representative uses on pome fruit (basal treatment) cover only those situations when 30 % of the orchard alone is treated and the weeds cover at least 25 % of the surface of the treated area.

- Mitigation measures comparable to in-field no-spray buffer zones up to 10m for leafy crops (i.e. oilseed rape, beans, peas and potato) and up to 5m for pome fruit were necessary to protect terrestrial non-target plants.

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. There is a data gap for further investigation of the degradation kinetics of Compound X to determine more reliable soil DT_{50} values that should be used in the FOCUS modelling. Once these data are available, more reliable estimations of PECgw and PECsw/sed for this metabolite need to be performed. If concentrations from these simulations for PECgw are predicted to be >0.75µg/L, then a consumer risk assessment from the consumption of groundwater containing Compound X is triggered.

2. There are data gaps for further investigation of the properties of Compound IV. Once these data are available, more reliable estimations of the leaching potential (PECgw) of this metabolite need to be performed.

3. The risk assessment for fish and aquatic invertebrates for the metabolite Compound IV in the water phase could not be finalised for the representative uses.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

4. The technical specification is not supported by the batches used in the toxicological studies.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

In addition to the concerns identified, all columns are grey as the technical specification is not supported by the batches tested in the toxicological studies used to derive the toxicological reference values.

Representative use		**Pome fruit ground directed spray**	**Peas (green without pods)**	**Beans (green with pods)**	**Pulses (dry peas and dry beans)**	**Potato**	**Oilseed rape**
Operator risk	Risk identified						
	Assessment not finalised						
Worker risk	Risk identified						
	Assessment not finalised						
Bystander risk	Risk identified						
	Assessment not finalised						
Consumer risk	Risk identified						
	Assessment not finalised						
Risk to wild non target terrestrial vertebrates	Risk identified	X	X	X	X		
	Assessment not finalised						
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified						
	Assessment not finalised						
Risk to aquatic organisms	Risk identified						
	Assessment not finalised	X[3]	X[3]	X[3]	X[3]	X[3]	X[3]
Groundwater exposure active substance	Legal parametric value breached						

	Assessment not finalised						
Groundwater exposure metabolites	Legal parametric value breached						
	Parametric value of 10µg/L[(a)] breached						
	Assessment not finalised	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[1,2]	X[1,2]
Comments/Remarks							

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

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APPENDICES

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

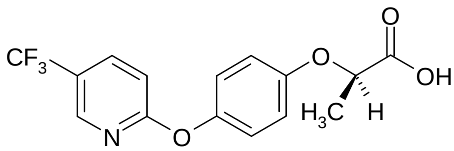
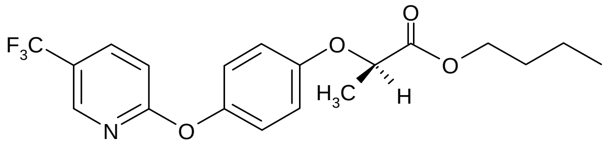
Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	fluazifop-P The variant evaluated is fluazifop-P-butyl
Function (e.g. fungicide)	Herbicide

Rapporteur Member State	France
Co-rapporteur Member State	

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	(*R*)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionic acid (fluazifop-P) butyl (*R*)-2-{4-[5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionate (fluazifop-P-butyl)
Chemical name (CA)	(2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoic acid (fluazifop-P) butyl (2*R*)-2-[4-[[5-(trifluoromethyl)-2-pyridinyl]oxy]phenoxy]propanoate (fluazifop-P-butyl)
CIPAC No	467 (fluazifop-P) 467.205 (fluazifop-P-butyl)
CAS No	83066-88-0 (fluazifop-P) 79241-46-6 (fluazifop-P-butyl)
EEC No (EINECS or ELINCS)	fluazifop-P : none fluazifop-P-butyl : 274-125-6
FAO Specification (including year of publication)	fluazifop-P : none fluazifop-P-butyl FAO specification No467.205/TC (2000) Min: 900 g/kg
Minimum purity of the active substance as manufactured (g/kg)	900 g/kg (in fluazifop-P-butyl)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	2-chloro-5-(trifluoromethyl)pyridine Max 1.5 g/kg Open for others
Molecular formula	$C_{15}H_{12}F_3NO_4$ (fluazifop-P) $C_{19}H_{20}F_3NO_4$ (fluazifop-P-butyl)
Molecular mass	327.4 g/mol (fluazifop-P) 383.4 g/mol (fluazifop-P-butyl)

Structural formula	fluazifop-P  fluazifop-P-butyl 

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	-46°C (Solidification point i.e. glass transition temperature) (purity: 98.3%)
Boiling point (state purity) ‡	> 216°C at 101.3 kPa(purity : 98.3%)
Temperature of decomposition (state purity)	The sample starts to decompose at 216°C (purity: 98.3%)
Appearance (state purity) ‡	Pure active substance: pale yellow clear liquid (98.3%) Technical grade active substance: dark brown opaque liquid (92.2%)
Vapour pressure (state temperature, state purity) ‡	1.2 10^{-4} Pa at 20°C (purity: 98.3%)
Henry's law constant ‡	$4.9x10^{-2}$ $Pa.m^3.mol^{-1}$ at 20°C
Solubility in water (state temperature, state purity and pH) ‡	pH 5 = 0.93 mg/L at 20°C (purity : 98.3%)
Solubility in organic solvents ‡ (state temperature, state purity)	At 20°C (92.2%): Miscible in all proportions in : xylen, 1,2-dichloroethane, ethyl acetate, methanol, acetone, 1-octanol heptane: miscible at concentration ≥60% w/w; brown precipitate produced at concentration ratios ≤ 58% w/w
Surface tension ‡ (state concentration and temperature, state purity)	66.1 mN/m at 20°C ± 0.5°C (purity: 92.2%)
Partition co-efficient ‡ (state temperature, pH and purity)	pH not relevant – log P_{ow} 4.5 at 20°C (purity: 93.7%)
Dissociation constant (state purity) ‡	No pKa was found of 1.0 to 12.0
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Molar extinction rates were determined to be: Wavelenght (nm) – Molar extinction coefficient (l/mol.cm) 270.2 – 6160 255.4 – 4590 223.7 – 16600 (purity: 95.1%)
Flammability ‡ (state purity)	Not flammable (purity: 92.2%)
Explosive properties ‡ (state purity)	Not explosive (purity: 92.2%)
Oxidising properties ‡ (state purity)	Not oxidizing ((purity: 92.2%)

Summary of representative uses evaluated (fluazifop-P-butyl)*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pome fruit	Northern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	-	1	-	0.050-0.125	200-500	0.250	28	One application every year-Basal application
	Southern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	-	1	-	0.050-0.125	200-500	0.250	28	One application every year-Basal application
Peas (green without pods)	Northern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.094-0.250	150-400	0.375	35	One application every two years
Peas (green without pods)	Southern EU Members states SEU	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.078-0.208	150-400	0.3125	35	One application every two years

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Beans (green with pods)	Northern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.094-0.250	150-400	0.375	28	One application every two years
Beans (green with pods)	Southern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.078-0.208	150-400	0.3125	28	One application every two years
Pulses (dry peas and dry beans)	Northern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.094-0.250	150-400	0.375	90	One application every two years
Pulses (dry peas and dry beans)	Southern EU Members states SEU	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering Before BBCH 59	1	-	0.078-0.208	150-400	0.3125	90	One application every two years
Potato	Northern and southern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-flowering, pre-tuber formation and before any row closure Before BBCH 40	1	-	0.094-0.250	150-400	0.250	90	One application every two years
Oilseed Rape	Northern and southern EU Members states	FUSILADE ® MAX	F	Annual and Perennial grasses	EC	125 g/l	Spray	Pre-BBCH 50	1	-	0.094-0.250	150-400	0.375	95	One application every two years

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

Methods of Analysis

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

Technical as (analytical technique)	GC-FID and HPLC-UV
Impurities in technical as (analytical technique)	GC-FID and HPLC-UV
Plant protection product (analytical technique)	HPLC-UV; chiral column

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Food of animal origin		Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Soil		Fluazifop and fluazifop-butyl
Water	surface	Fluazifop and fluazifop-butyl
	drinking/ground	Fluazifop and fluazifop-butyl
Air		Fluazifop-butyl
Body fluids and tissues		Not required (not T or T+)

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	for non oily crops : HPLC-UV, HPLC-MS/MS, GC-MS LOQ = 0.01- 0.05 mg/kg For oily crops and oil: HPLC-MS/MS LOQ = 0.02 mg/kg
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS LOQ = 0.01mg/kg milk, egg, liver, muscle, fat and kidney
Soil (analytical technique and LOQ)	GC-MS, LOQ = 0.01mg/kg
Water (analytical technique and LOQ)	HPLC-UV, GC-MS LOQ = 0.1µg/L
Air (analytical technique and LOQ)	GC-NPD LOQ : 0.001 – 0.003 mg/kg
Body fluids and tissues (analytical technique and LOQ)	GC-MS LOQ = 0.01 mg/kg (not required)

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

	RMS/peer review proposal

Active substance	none

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Higher than 80% based on radiolabel recovered from urine, bile, cage wash, faeces and tissues.
Distribution ‡	Fat, kidneys and liver. Enterohepatic recirculation in male rats.
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	*ca* 90% in female rats via urine with $t_{1/2}$=2.5h *ca* 90% in male rats via urine and bile with $t_{1/2}$=33-38h
Metabolism in animals ‡	Extensively metabolised to the carboxylic acid metabolite fluazifop acid, further conjugated with taurine.
Toxicologically relevant compounds ‡ (animals, plants and environment)	Fluazifop-P-butyl and fluazifop acid.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	2451 mg/kg bw (rat) > 2000 mg/kg bw (mouse)	
Rat LD_{50} dermal ‡	> 2110 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.2 mg/L/4 h(nose only)	
Skin irritation ‡	Non-irritating	
Eye irritation ‡	Non-irritating	
Skin sensitisation ‡	Sensitizing (LLNA)	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Kidney, spleen and liver. Cataract, decreased plasma cholesterol levels	R48/22
Relevant oral NOAEL ‡	90 d rat: 0.9 mg/kg bw per day 90-d and 1-year dog: 25 mg/kg bw per day (fluazifop-butyl) 90-d hamster: 78 mg/kg bw per day	
Relevant dermal NOAEL ‡	21-d rabbit: 100 mg/kg bw per day (fluazifop-butyl)	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	No genotoxic potential (*in vitro* and *in vivo*)	

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

Target/critical effect ‡	Kidney, liver Eye (cataract)	R48/22
Relevant NOAEL ‡	2-year rat: 1 mg/kg bw per day (fluazifop acid) 81-weeks mice: 1 mg/kg bw per day (fluazifop acid) 81-weeks hamster: 12.1 mg/kg bw per day	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental: Decreased testes and epididyme weight. Reproductive: extended gestation period, reduced litter size. Offspring: increased liver and kidney weight; decreased, spleen, , testes and uterine weights	
Relevant parental NOAEL ‡	0.8 mg/kg bw per day (fluazifop-butyl)	
Relevant reproductive NOAEL ‡	7 mg/kg bw per day (fluazifop-butyl)	
Relevant offspring NOAEL ‡	0.8 mg/kg bw per day (fluazifop-butyl)	

Developmental toxicity

Developmental target / critical effect ‡	**Rat** Maternal: reduced body weight and food consumption. Developmental: kinked ureters and/or dilated ureter. **Rabbit** Maternal: reduced body weight Developmental: minor skeletal defects and variants at maternal toxic dose levels.	
Relevant maternal NOAEL ‡	Rat: 20 mg/kg bw per day Rabbit: 10 mg/kg bw per day	

Relevant developmental NOAEL ‡	Rat: 2 mg/kg bw per day Rabbit: 10 mg/kg bw per day	R63

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Not chemically related to known neurotoxic substances; no indication of neurotoxic effects in the standard toxicity studies.	
Repeated neurotoxicity ‡	Not chemically related to known neurotoxic substances; no indication of neurotoxic effects in the standard toxicity studies.	
Delayed neurotoxicity ‡	No delayed neurotoxic effect in the hen.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Fluazifop-p-butyl and fluazifop-butyl: peroxisome proliferation in mouse and male rat at high doses; no effect in human hepatocytes *in vitro*; no increase in hepatocyte replication in any species. Fluazifop-p-butyl, fluazifop-butyl and their predominant metabolite fluazifop acid: human oestrogen and androgen receptor binding studies *in vitro*: no estrogenic, anti-estrogenic, androgenic or anti-androgenic activity.
Studies performed on metabolites or impurities ‡ 5-(trifluoromethyl)-2(1H)-pyridinone (Compound X)	
	ADME study (oral): 97 % absorption; complete excretion as unchanged parent within 24 h in urine (87 %) and bile (9 %); 0.4 % excreted in faeces. LD50 (rat): 3866 and 3417 mg/kg bw (m & f) 28-d rat: NOAEL 176 mg/kg bw per day Genotoxicity testing: the weight of evidence suggests it is not an *in vivo* genotoxic agent. Developmental toxicity (rat): NOAEL (maternal and developmental) 60 mg/kg bw per day. ADI=0.01 mg/kg bw per day (the same as the parent fluazifop-P) ARfD=0.6 mg/kg bw (developmental rat toxicity study, UF of 100).

Medical data ‡ (Annex IIA, point 5.9)

	Several records of adverse reactions after exposure with formulation, mainly transient irritation of eyes and upper airways.

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.01 mg/kg bw per day (expressed as fluazifop acid)	2-y rat with fluazifop acid	100
AOEL ‡	0.02 mg/kg bw per day (expressed as fluazifop-p-butyl)	Rat developmental toxicity fluazifop-p-butyl (supported by the 90-d rat study)	100
ARfD ‡	0.017 mg/kg bw (expressed as fluazifop acid)	Rat developmental toxicity fluazifop-p-butyl and calculated from difference in molecular weight (supported by the 90-d rat study)	100

Dermal absorption ‡ (Annex IIIA, point 7.3)

Fusilade max® 125 EC	1% (concentrate) 6.5 (typical spray solution)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	<u>Peas and beans, oilseed rape and potatoes</u> Tractor: UK POEM with PPE (all phases) 108/45 % of AOEL (150/400 L); BBA without PPE 85 % AOEL <u>Pome fruit</u> Hand-held sprayer: UK POEM with PPE 141/59 % of AOEL (200 L/500 L)
Workers	30.4% of AOEL (scouting)
Bystanders	1.4 % of AOEL

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

Substance classified	Fluazifop-P
Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	Repr. Cat. 3 R63 or Repr. 2 (H361d)

Peer review proposal*	Under Council Directive 67/548/EEC[9] Xn R48/22 R63 R43 Under Regulation (EC) No 1272/2008)[10] STOT RE 2 (H373) Repr. 2 (H361d) Skin. Sens. 1 (H317)

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

[9] OJ No 196, 16.08.1967, p. 001-0098
[10] OJ No L 353, 31.12.2008, p. 0001-1355

Residues

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

Plant groups covered	-Leafy vegetables (celery, and lettuce), -Root vegetables (carrots and sugar beets), -Oilseeds (soya beans and cotton plants) -Fruit crops (vine grapes) – basal spray application.
Rotational crops	Wheat, lettuce, carrot
Metabolism in rotational crops similar to metabolism in primary crops?	No. Rotational crops metabolism studies showed an intensive degradation of Fluazifop-p-butyl compared to the primary crops as only Compound X either free or hexose conjugated was recovered at relevant levels in harvested wheat (forage, straw, grain), lettuce and carrot (root, foliage) sown 60 days after soil treatment.
Processed commodities	-Potatoes (peeled and cooked potatoes, chips and dried potatoes) -Oilseed rape (rape seed cake, crude and refined oil). Data are required to address the magnitude of the residues in processed pulses (peas and beans, dry), peas (green without pods) and beans (green, with pods).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes Fluazifop-p-butyl is not expected to degrade beyond the stable fluazifop under hydrolysis conditions used in the analytical method SOP RAM 287/02.
Plant residue definition for monitoring	Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Plant residue definition for risk assessment	Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Conversion factor (monitoring to risk assessment)	N/A

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

Animals covered	Goat, hen
Time needed to reach a plateau concentration in milk and eggs	3 days (milk), 7 days (eggs)
Animal residue definition for monitoring	Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Animal residue definition for risk assessment	Sum of all the constituent isomers of fluazifop, its esters and its conjugates expressed as fluazifop (sum of isomers)
Conversion factor (monitoring to risk assessment)	None.
Metabolism in rat and ruminant similar (yes/no)	Yes

Fat soluble residue: (yes/no)	No Log P_{ow}=4.5 but from the livestock feeding studies, there is no indication of accumulation in fat.

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

	Cold rotational crops field trials on wheat, carrot and lettuce either rotated to oilseed rape treated as a primary crop at a dose rate of 375 g a.s./ha or planted on soils treated once at dose rates of 375 and 475 g a.s./ha of fluazifop-P-butyl, respectively (1 N rate). The residue levels of total fluazifop and total compound X (free and conjugated) were below the LOQ (<0.01 mg/kg) of the methods in lettuce head, carrot root and wheat (forage, straw, grain) at plant back intervals of 1, 2, 4 and 6 months. Quantifiable residue levels of compound X were recovered only in carrot foliage (0.03-0.13 mg/kg).

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

	Residues of total fluazifop are stable for at least 18 months at < -18°C in high water, dry and oily content matrices.

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes 2.17/2.23 mg/kg DM (Dairy/beef cattle) expressed as fluazifop.	Yes 1.60 mg/kg DM expressed as fluazifop.	Yes 2.48 mg/kg DM expressed as fluazifop.
Overdosing factor	1.4 N	1.6 N	
Potential for accumulation (yes/no):	No	No	No data in pigs requested since the metabolism of fluazifop-P-butyl is similar in rat and in ruminants.
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	Yes	
Muscle	<0.02	0.02	
Liver	0.03	0.05	
Kidney	0.02	n/a	
Fat	<0.02	0.02	
Milk	0.04		
Eggs		<0.02	

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (mg total fluazifop/kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Pome fruits	**N (250g a.s./ha)**	<0.02, <0.03 x 3,<0.04 x 3, <0.05 x 2	Because methods PPRAM 62/1 and RAM 62/2 are only validated for LOQ of 0.05 mg/kg, all the residue trials are in fact considered as below the LOQ of 0.05 mg/kg.	0.05* (provisional)	0.05	0.05
	S (250g a.s./ha)		Additional residue trials are required to confirm the no-residue situation for pome fruit in Southern Europe.			
Peas (green without pods)	**N (350g a.s./ha)**	<0.03, 0.19, 0.26, 0.27, 0.41, 0.48, 0.8		2	0.8	0.27
	S (312.5g a.s./ha)	0.07, 0.09, 0.22, 0.36, 0.77, 1			1	0.29
Beans (green with pods)	**N (350g a.s./ha)**	0.08, 0.17, 0.23, 0.25, 0.29, 0.38, 0.40, 0.55		1	0.55	0.27
	S (312.5g a.s./ha)	0.02 x 2, 0.05, 0.20, 0.27, 0.32, 0.6, 0.84			0.84	0.24
Pulses	**N (350g a.s./ha)**	0.02, 0.08, 0.09, 0.10, 0.11, 0.18, 0.26, 0.34, 0.57, 0.61, 0.64, 0.72, 0.79, 0.97, 1.10, 2.8		5	2.8	0.46
	S (312.5g a.s./ha)	0.01 x2, <0.05, 0.06, 0.08, 0.09, 0.19, 0.23, 0.54, 1.8, 3.1			3.1	0.09

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (mg total fluazifop/kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Oilseed rape	**N (375g a.s./ha)**	1.5, 1.5, 1.7, 2.1, 2.2, 2.4, 2.6, 2.9, 3.2, 3.3		10	3.3	2.3
	S (375g a.s./ha)	0.36, 0.49, 2.3, 2.3, 4.7			4.7	2.3
Potatoes	**N (250g a.s./ha)**	<0.01, 5x 0.01; 0.05; 0.06; 0.07		0.1	0.07	0.01
	S (250g a.s./ha)	9 x < 0.01, 3 x 0.01, 0.03, 0.05			0.05	0.01

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

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

ADI	0.01 mg/kg bw per day (expressed as fluazifop acid)
TMDI (% ADI) according to EFSA PRIMO rev.2A	77.3% of the ADI (WHO cluster diet E)
IEDI (% ADI)	28.6% of the ADI (FR toddler)[(1),(2)]
Factors included in IEDI	-STMR values for pome fruit, pulses, peas (green without pods), beans (green with pods) (see summary table of residue data) -STMR values for potatoes and oilseed rape seed (see summary table of residue data) -Processing factors for potatoes (dried potatoes) and oilseed rape seed (refined oil). -MRLs for animal commodities.
ARfD	0.017 mg/kg bw (expressed as fluazifop acid)
IESTI (% ARfD) (EFSA PRIMO rev.2A)	63.3% of ARfD (Potatoes) 49.5% of ARfD (Beans with pods) 36.5% of ARfD (Milk and milk products) 28.8% of ARfD (Apples) [(2)] 26.8% of ARfD (Pears)
Factors included in IESTI	-HR values for pome fruit and potatoes (see summary table of residue data) -STMR values for pulses, peas (green without pods), beans (green with pods), oilseed rape seed. -MRLs for animal commodities

[(1)]: Provisional calculation pending the additional data required on the magnitude of the residues in processed pulses (peas and beans, dry), peas (green, without pods) and beans (green, with pods).
[(2)]: Provisional calculation pending the outcome of the requested residue trials on pome fruit for Southern Europe.

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

Crop/ process/ processed product	Number of studies	Processing factors (Highest values)	Amount transferred (%) (Optional)
Potatoes/peeling/peeled potatoes	2	1.20	
Potatoes/peeling cooking/cooked potatoes	2	1.11	
Potatoes/peeling chips/chips	2	2.81	
Potatoes/peeling drying/dried potatoes	2	5.27	
Oilseed rape/pressing/crude oil	2	0.101	
Oilseed rape/pressing/refined expeller oil	2	0.05	

Oilseed rape/pressing/ Expeller press cake	2	1.79	

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

Pome fruit....................................	0.05*mg/kg(2)
Peas, green without pods.............................	2 mg/kg
Beans, green with pods.........................	1 mg/kg
Pulses (peas, beans, dry)..........	5 mg/kg
Oilseed rape seed	10 mg/kg
Potatoes	0.1 mg/kg
Milk	0.05 mg/kg
Eggs	0.02*mg/kg
Ruminants/poultry muscle, fat	0.02 mg/kg
Edible offals	0.05 mg/kg

Fate and behaviour in the environment

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

Mineralization after 100 days ‡	Laboratory (20°C, 40% MHC) 22.5-26.2 % RR* after 84 d, 31.9-32.2 % RR after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 3) 8.9-9.6 % RR after 84 d, 17.7-18.8 % RR after 168 d, [^{14}C-pyridyl, fluazifop-butyl]-label (n = 2) 16.7% AR at 120 d. [^{14}C-pyridyl, fluazifop-P-butyl]-label (n=1) 34.8% AR at 120 d. [^{14}C-phenyl, fluazifop-P-butyl]-label (n=1)
Non-extractable residues after 100 days ‡	Laboratory (20°C, 40% MHC) 29.9-55.4 % RR after 84 d, 28.3-48 % RR after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 3) 27.5-39.6 % RR after 84 d, 21.7-40.9 % RR after 168 d, [^{14}C-pyridyl, fluazifop-butyl]-label (n = 2) 28.9% AR at 120 d. [^{14}C-pyridyl, fluazifop-P-butyl]-label (n=1) 32.1% AR at 120 d. [^{14}C-phenyl, fluazifop-P-butyl]-label (n=1)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	**Fluazifop-P** 78-83.4 % RR at 2 d, [^{14}C-phenyl]-label (n = 2) 79.8 % AR at 6 h, [^{14}C-phenyl R]-label (n = 1) 80.8 % AR at 6 h, [^{14}C-phenyl S]-label (n = 1) 67.3% AR at 1 d. [^{14}C-pyridyl, fluazifop-P-butyl]-label (n=1) 69.1% AR at 1 d. [^{14}C-phenyl, fluazifop-P-butyl]-label (n=1) **Compound X** 25.1-22 % RR at 84 d, [^{14}C-pyridyl] label (n = 2) 24.9% AR at 28 d. [^{14}C-pyridyl, fluazifop-P-butyl]-label (n=1) **Compound IV** 12.9% RR at 84 d at 10°C [^{14}C-phenyl]-label (n=1)

*: % of recovered radioactivity (RR) are accepted with regard to good recovery of applied radioactivity (AR)
n corresponds to the number of soils

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

Anaerobic degradation ‡
(Flooding on treated soil on DAT 0 or DAT 21, no red-ox monitoring)

Mineralization after 100 days	Flooded soil on DAT 0 6.1-2.8 % RR * after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 2) 3.7-2.0 % RR after 168 d, [^{14}C-pyridyl, fluazifop-butyl]-label (n = 2) Flooded soil on DAT 21 (8.8% RR CO_2, 40.8% RR fluazifop acid) 15.8 % RR after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 1) Sterile conditions: no data
Non-extractable residues after 100 days	Flooded soil on DAT 0 4.0-7.0 % RR after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 2) 4.4-3.0 % RR after 168 d, [^{14}C-pyridyl, fluazifop-butyl]-label (n = 2) Flooded soil on DAT 21 (35.2% RR non extractable residues) 25 % RR after 168 d, [^{14}C-phenyl, fluazifop-butyl]-label (n = 1)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Flooded soil on DAT 0 **Fluazifop acid** – 89.6-90.3 % RR at 2 d, [^{14}C-phenyl] label (n = 2) Flooded soil on DAT 21 (8.6% unidentified residues) **Unidentified residues** – 24.4% RR after 84 d, 32.9 % RR after 168 d, [^{14}C-phenyl]-labels (n = 1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Less than 10% degradation of fluazifop-P-butyl in 15 equivalent days of Florida summer sunlight

*: % of recovered radioactivity (RR) are accepted with regard to good recovery of applied radioactivity (AR)

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

Laboratory studies ‡

Fluazifop-P-butyl	Aerobic conditions						
Soil type	%OM	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	χ^2 % error	Method of calculation
Sandy Clay Loam (phenyl)	4.6	6	20°C / 40%	0.4 / 1.3	0.4	14.2%	SFO
Sandy Clay Loam (pyridil)	4.6	6	20°C / 40%	3.3 / 11.1	3.3	0.2%	SFO
Clay	14.2	7.4	20°C / 40%	0.3 / 1.1	0.3	1.3%	SFO
Loamy Sand	2.1	5.4	20°C / 40%	2.9 / 9.6	2.9	0.1%	SFO
Geometric mean (n=3)					1.0		

Fluazifop-P	Aerobic conditions						
Soil type	%OM	pH H_2O/KCl	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	χ^2 % error	Method of calculation
From aerobic degradation study of fluazifop-butyl							
Sandy Clay Loam (phenyl)	4.6	6.0	20°C / 40%	10.4 / 34.7	10.4	6.5%	SFO
Sandy Clay Loam (pyridyl)	4.6	6.0	20°C / 40%	17.8 / 59.0	17.8	5.1%	SFO
Clay (phenyl)	14.2	7.4	20°C / 40%	17.5 / 58.1	17.5	2.3%	SFO
Clay (pyridyl)	14.2	7.4	20°C / 40%	5.1 / 35.8 (FOMC)	14.9 (SFO)	0.8% / 3.1%	FOMC / SFO
Loamy sand (phenyl)	2.1	5.4	20°C / 40%	38.6 / 128.1	38.6	2.2%	SFO
From aerobic degradation study of fluazifop-P							
Silt loam	3.3	7.0/6.2	20°C / pF2	8.3 / 27.6	8.3	8.7%	SFO

Sandy clay loam	3.6	5.8/4.9	20°C / pF2	7.3 / 32.0 (DFOP)	8.2 (SFO)	2.3% / 4.7%	DFOP / SFO
Sandy loam	3.8	7.2/6.6	20°C / pF2	2.7 / 9.1	2.7	14.6%	SFO
Loamy sand	1.6	5.3/4.3	20°C / pF2	7.7 / 43.7 (FOMC)	9.1 (SFO)	3.4% / 6.4%	FOMC / SFO
Sandy clay loam	5.3	7.1/6.3	20°C / pF2	2.1 /21 (DFOP)	6.4 (SFO, from FOMC)	4.8% / 7.6%	DFOP / FOMC
Clay loam	7.4	7.7/7.1	20°C / pF2	1.6 / 19.7 (DFOP)	4.9 (SFO, from FOMC)	9.4% / 10.6%	DFOP / FOMC
Geometric mean (for modelling)					9.1 (n=9)		

Compound X	Aerobic conditions						
From aerobic degradation study of Compound X							
Soil type	%OM	pH H_2O	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	χ^2 % error	Method of calculation
Sandy clay loam	5.9	6.0	20°C / pF2	5.1 / 38.6 (DFOP)	28.2 (SFO from FOMC)	7.5% / 7.5%	DFOP / FOMC
Sandy loam	2.6	6.1	20°C / pF2	11.6 / 158.8 (DFOP)	-	2.5%	DFOP
Loamy sand	7.4	8.0	20°C / pF2	29.1 / 208.1 (DFOP)	-	2.5%	DFOP
Silty clay loam	5.3	5.3	20°C / pF2	11.9 / 255.2 (FOMC)	58.5 (SFO from longest phase DFOP)	2.9% / 3.9%	FOMC / DFOP

Note: endpoints for Compound X are considered as uncertain due to that the fits and the relevant statistics could not been peer-reviewed properly

Compound IV	Aerobic conditions							
From aerobic degradation study of fluazifop-butyl								
Soil type	%OM	pH H_2O	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	χ^2 % error	Method of calculation
Sandy Clay Loam (phenyl)	4.6	6.0	20°C / 40%	39.6 / 132	0.07 [a,b]	39.6[a,b]	27	SFO
Sandy Clay Loam (pyridyl)	4.6	6.0	20°C / 40%	82.9 / 275	0.06 [a,b]	82.9[a,b]	25	SFO
Clay (pyridyl)	14.2	7.4	20°C / 40%	105 / 348	0.03[b]	105[b]	49	SFO

[a)] two values should be averaged (e.g. geomean. for DT_{50}, arithmetic mean for the ff) before used in any modelling since they are originating from one soil
[b)] values are uncertain due to relatively poor fit

Field studies ‡

None of the available field trials are considered reliable enough to be used for risk assessment.

pH dependence (yes / no) (if yes type of dependence) ‡	Not established (note: the first step of degradation of fluazifop-P-butyl is hydrolysis, which is pH dependent)
Soil accumulation and plateau concentration ‡	Not relevant

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Fluazifop-P-butyl							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	1.22	5.4	43	3394*	-	-	-
pH dependence, Yes or No			Cannot be determined				

* due to deficiencies reported about this study, these data should only be considered as indicative.

Fluazifop-P							
Soil Type	OC %	Soil pH H_2O/KCl	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.9	7.0/6.2	0.6-3.4	32-179	0.8	40.1	0.68
Sandy clay loam	2.1	5.8/4.9	0.7-2.1	33-100	0.9	42.2	0.78
Sandy loam	2.2	7.2/6.6	0.5-13.7	23-300	0.8	38.5	0.50
Loamy sand	0.9	5.3/4.3	0.6-1.5	5.9-478	0.8	83.6	0.82
Sandy clay loam	3.1	7.1/6.3	0.7-9.1	23-294	1.2	39.2	0.56
Clay loam	4.3	7.7/7.1	1.2-24.9	28-579	2.1	48.7	0.52
Arithmetic mean					1.10	48.72	0.64*
pH dependence (yes or no)			No				

*1/n values is considered uncertain therefore the default value of 0.9 was used for exposure calculation

Compound X							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	1.74	7.5	0.29-0.61	17-35	0.34	16.8*	0.81
Sandy loam	0.58	6.0	0.19-0.34	33-59	0.21	28.6*	0.82
Sandy loam	2.96	8.5	0.48-0.70	16-24	0.51	15.6*	0.89
Silty clay	2.03	5.6	0.74-1.39	36-68	0.78	38	0.82
Arithmetic mean					0.46	24.7	0.84
pH dependence (yes or no)			No				

* p criterion (soil/solution ratio * Kf) is < 0.3 for these soils. Therefore according to OECD 106, a correction for Koc was applied.

Compound IV Data gap, a Kdoc estimated by HPLC was available and was agreed as appropriate for use in an EU level exposure assessment

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

Column leaching ‡	Not submitted
Aged residues leaching ‡	3 soils with both phenyl and pyridyl label (n=6) Aging time : 3 weeks Elution : 808 mm over 11 weeks Leachate : 0.01-38.21% of applied radioactivity Compound X : found up to 93.5% of recovered radioactivity after 4 weeks of elution, 8.2% of applied radioactivity in leachates with pyridyl label after 3 weeks of elution Fluazifop-P : found up to 80.2% of recovered radioactivity (2.7% of applied) in leachates with phenyl label after 3 weeks of elution Small amounts of Compound IV found in leachates
Lysimeter/ field leaching studies ‡	Not submitted

PEC (soil) (Annex IIIA, point 9.1.3)

Winter oilseed rape, Potatoes, Peas and Beans

Parent (**Fluazifop-p-butyl**) Method of calculation	DT_{50} (d): 2.9 days Kinetics: SFO Field or Lab: worst-case from lab studies
Application data	Crop: **potatoes, oilseed rape, peas, beans** Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: no crop interception Number of applications: 1 Interval (d): not relevant Application rate(s): 375 g a.s./ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.500		Not relevant	
Short term	24h	0.394	0.445		
	2d	0.310	0.397		
	4d	0.192	0.322		
Long term	7d	0.0938	0.243		
	21d	0.00330	0.0990		
	28d	6.2e-04	0.0746		
	50d	3.23e-06	0.0418		
	100d	2.08e-11	0.0209		
Plateau concentration		Not relevant			

Fluazifop-P Method of calculation	Molecular weight relative to the parent: 327.3 / 383.4 DT_{50} (d): 38.6 days Kinetics: SFO Field or Lab: worst-case from lab studies			
Application data	Application rate assumed 100% conversion of fluazifop-P-butyl to fluazifop-P			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.427		Not relevant	
Short term 24h	0.419	0.423		
2d	0.412	0.419		
4d	0.397	0.412		
Long term 7d	0.376	0.401		
21d	0.293	0.355		
28d	0.258	0.335		
50d	0.174	0.282		
100d	0.071	0.198		
Plateau concentration	Not relevant			

Compound X Method of calculation	Molecular weight relative to the parent: 163.0 / 383.4 DT_{50} (d): not used			
Application data	Application rate assumed compound X is formed at a maximum of 25.1% of the applied dose			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0533		Not relevant	
Plateau concentration	Not calculated			

Compound IV Method of calculation	Molecular weight relative to the parent: 255.2 / 383.4 DT_{50} (d): not used			
Application data	Application rate assumed compound IV is formed at a maximum of 12.9% of the applied dose			
$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.043		Not relevant	

Plateau concentration	Not calculated

Pome fruit

Parent (**Fluazifop-p-butyl**) Method of calculation	DT_{50} (d): 2.9 days Kinetics: SFO Field or Lab: worst-case from lab studies
Application data	Crop: **orchards** Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 25% Number of applications: 1 Interval (d): not relevant Application rate(s): 250 g a.s./ha All cropped area treated.

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.25		Not relevant	
Short term	24h	0.197	0.2225		
	2d	0.155	0.1985		
	4d	0.096	0.161		
Long term	7d	0.0469	0.1215		
	21d	0.00165	0.0495		
	28d	0.00031	0.0373		
	50d	1.615E-06	0.0209		
	100d	1.04E-11	0.01045		

Plateau concentration	Not relevant

Fluazifop-P Method of calculation	Molecular weight relative to the parent: 327.3 / 383.4 DT_{50} (d): 38.6 days Kinetics: SFO Field or Lab: worst-case from lab studies
Application data	Application rate assumed 100% conversion of fluazifop-P-butyl to fluazifop-P

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.2135		Not relevant	
Short term	24h	0.2095	0.2115		
	2d	0.206	0.2095		
	4d	0.1985	0.206		
Long term	7d	0.188	0.2005		

21d	0.1465	0.1775		
28d	0.129	0.1675		
50d	0.087	0.141		
100d	0.0354	0.099		
Plateau concentration	Not relevant			

Compound X Method of calculation	Molecular weight relative to the parent: 163.0 / 383.4 DT_{50} (d): not used
Application data	Application rate assumed compound X is formed at a maximum of 25.1% of the applied dose

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.02665		Not relevant	
Plateau concentration	Not calculated			

Compound IV Method of calculation	Molecular weight relative to the parent: 255.2 / 383.4 DT_{50} (d): not used
Application data	Application rate assumed compound IV is formed at a maximum of 12.9% of the applied dose

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.0215		Not relevant	
Plateau concentration	Not calculated			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: Fluazifop-p-butyl is stable at 25 °C pH 5: Fluazifop-P is stable at 25 °C
	pH 7: Fluazifop-p-butyl DT_{50} = 78 d at 25 °C (1st order, r^2= 0.993), Fluazifop-P acid: 24.1 % AR (30 d) pH 7: Fluazifop-P is stable at 25 °C
	pH 9: Fluazifop-p-butyl DT_{50} = 29 h at 25 °C (1st order, r^2= 0.994), Fluazifop-P acid: 79 % AR (3 d) pH 9: Fluazifop-P is stable at 25 °C

Photolytic degradation of active substance and metabolites above 10 % ‡	Fluazifop-p-butyl DT_{50} : 6 days (Florida Summer Sunlight 30°N) Estimated DT_{50} 11-200 days for 5 cm, 33-490 days for 30 cm (Mid-European conditions) U7 = 4H-pyrano[2,3-b]pyridine-6-carboxylic acid (max 12.4 %) U1 = 6-(trifluoromethyl)-2-azabicyclo[2.2.0]hex-5-en-3-one or 6-(trifluoromethyl)-2-azabicyclo[2.2.0]hex-1(6)-en-3-one (max 10.8 %).
Quantum yield of direct phototransformation in water at Σ > 290 nm	5.8 10^{-3} mol Einstein $^{-1}$
Readily biodegradable ‡ (yes/no)	substance considered not readily biodegradable

Degradation in water / sediment

Fluazifop-p-butyl	Distribution : not detected in water after 1 day in both systems, not detected to maximum 3.1% AR after 2 d in sediment (Virginia), maximum 1.8-1.5% after 4-6 h in sediment (Old Bassin)									
Water / sediment system	pH water phase	pH sed H_2O KCl	t. °C	DT_{50}-DT_{90} whole sys.	χ^2 % error	DT_{50}-DT_{90} water	χ^2 % error	DT_{50}- DT_{90} sed	χ^2 % error	Method of calculation
Virginia – two labels (1.0 OC%)	# 7-9 (graphic)	5.5 5.4	20	0.1 d	33.3/ 41.1	0.1 d	41.6/ -	-	-	SFO
Old Bassin – two labels (6.6 OC%)	# 8-9 (graphic)	8.1 7.5	20	0.1 d	21.5/ 49.7	0.1 d	17.4/ 49.0	-	-	SFO
Geometric mean				0.1 d		0.1 d				
Fluazifop-P	Distribution : Virginia–pyridyl label: max in water 96.9% AR after 2 d. Max. sed 5.5% AR after 14 d Virginia–phenyl label: max in water 91.9% AR after 1 d. Max. sed 9.8% AR after 59 d Old Bassin–pyridyl label: max in water 89.2% AR after 4 h. Max. sed 18% AR after 30 d Old Bassin–phenyl label: max in water 91.2% AR after 1 d. Max. sed 18.1% AR after 30 d									
Water / sediment system	pH water phase	pH sed H_2O KCl	t. °C	DT_{50}-DT_{90} whole sys.	χ^2 % error	DT_{50}- DT_{90} water	χ^2 % error	DT_{50}- DT_{90} sed	χ^2 % error	Method of calculation
Virginia – pyridyl label (1.0 OC%)	# 7-9 (graphic)	5.5 5.4	20	342 d [a]	13.3	152 d [a]	0.13	-	-	SFO
Virginia - phenyl label (1.0 OC%)	# 7-9 (graphic)	5.5 5.4	20	163 d [a]	8.3	141 d [a]	6.5	-	-	SFO
Old Bassin – pyridyl label (6.6 OC%)	# 8-9 (graphic)	8.1 7.5	20	54.9 d	12.8	38.0 d	3.12	-	-	SFO

Old Bassin – phenyl label (6.6 OC%)	# 8-9 (graphic)	8.1 7.5	20	49.5 d	12.2	44.9 d	7.0	-	-	SFO
Geometric mean				111 d		78d		-		

[a] extrapolated beyond study duration

Compound 4	Distribution : Virginia–pyridyl label: Max. sed 9.9% AR after 59 d Virginia–phenyl label: Max. sed 3.7% AR after 59 d Old Bassin–pyridyl label: Max. sed 8.4% AR after 59 d Old Bassin–phenyl label: Max. sed 9.5% AR after 100 d
Compound 10	Distribution : Virginia–pyridyl label: max in water 33.3% AR after 59 d. Max. sed 4% AR after 59 d Old Bassin–pyridyl label: max in water 16.3% AR after 59 d. Max. sed 8.1% AR after 59 d

Mineralization and non extractable residues

Water / sediment system	pH water phase	pH sed H_2O KCl	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
Virginia – pyridyl label (1.0 OC%)	# 7-9 (graphic)	5.5 5.4	13.3% AR after 100 d	39.6% AR after 100 d	39.6% AR after 100 d
Virginia – phenyl label (1.0 OC%)	# 7-9 (graphic)	5.5 5.4	14.7% AR after 100 d	20.8% AR after 100 d	20.8% AR after 100 d
Old Bassin – pyridyl label (6.6 OC%)	# 8-9 (graphic)	8.1 7.5	13.1% AR after 100 d	29.5% AR after 100 d	29.5% AR after 100 d
Old Bassin – phenyl label (6.6 OC%)	# 8-9 (graphic)	8.1 7.5	32% AR after 100 d	37.4% AR after 100 d	37.4% AR after 100 d

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

Fluazifop-P-butyl Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2, version 1.1 Molecular weight (g/mol): 383.4 Water solubility (mg/L): 1.1 at 20°C Kfoc = 3394 DT_{50} soil (d): 2.9 DT_{50} whole system (d): 0.1 DT_{50} water (d): 0.1 DT_{50} sediment (d): 1000 Crop interception (%): minimal crop cover 40% (winter oilseed rape), 15% (potatoes), 25% (peas and beans), 20% (pome fruit – hand application. crop < 50cm)
Parameters used in FOCUSsw step 3	Version control no.'s of FOCUS software: SWASH 2.1, Image Drift calculator 1.2, MACRO 4.4.2, PRZM_SW 1.1.1 and TOXWA 2.2.1

	Vapour pressure: 1.2 10^{-4} Pa at 20°C Kdoc = 3394 ;1/n = 1 Q_{10} : 2.2 Crop interception: - Winter oilseed rape / potatoes / peas and beans : calculated by models - Pome fruit : 50% (application type set to soil incorporation, field crop drift loadings added manually in TOXSWA)
Application rate	Crop: Winter oilseed rape / potatoes / peas and beans / pome fruit Number of applications: 1 Interval (d): not applicable Application rate(s): 375 / 250 / 375 / 250 g as/ha Application window: autumn / spring / spring / spring

Only initial PEC are reported.

FOCUS STEP 1 **(Fluazifop-P-butyl)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape / peas and beans	0 h	26.1		768	
Pome fruit / potatoes	0 h	17.4		512	

FOCUS STEP 2 **(Fluazifop-P-butyl)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU, Winter oilseed rape	0 h	3.45		96.3	
Southern EU, Winter oilseed rape	0 h	3.45		78.6	
Northern EU, Potatoes	0 h	2.30		38.6	
Southern EU, Potatoes	0 h	2.30		72.1	
Northern EU, Peas and beans	0 h	3.45		52.0	
Southern EU, Peas and beans	0 h	3.45		96.3	
Northern EU, Pome fruit	0 h	2.30		36.7	
Southern EU, Pome fruit	0 h	2.30		68.1	

FOCUS STEP 3 **(Fluazifop-P-butyl)** Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
Pome fruit	D3 / ditch	0 h	1.58		0.344	
	D4 / pond	0 h	0.055		0.019	
	D4 / stream	0 h	1.26		0.058	
	D5 / pond	0 h	0.055		0.014	
	D5 / stream	0 h	1.24		0.031	

FOCUS STEP 3 **(Fluazifop-P-butyl)** Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
	R1 / pond	0 h	0.055		0.014	
	R1 / stream	0 h	1.04		0.105	
	R2 / stream	0 h	1.38		0.095	
	R3 / stream	0 h	1.47		0.206	
	R4 / stream	0 h	1.04		0.109	
Winter oilseed rape	D2 / ditch	0 h	2.40		0.441	
	D2 / stream	0 h	2.14		0.393	
	D3 / ditch	0 h	2.38		0.313	
	D4 / pond	0 h	0.082		0.014	
	D4 / stream	0 h	2.05		0.242	
	D5 / pond	0 h	0.082		0.011	
	D5 / stream	0 h	2.21		0.249	
	R1 / pond	0 h	0.082		0.013	
	R1 / stream	0 h	1.57		0.152	
	R3 / stream	0 h	2.20		0.382	
Potatoes	D3 / ditch	0 h	1.31		0.164	
	D4 / pond	0 h	0.053		0.010	
	D4 / stream	0 h	1.11		0.059	
	D6 / ditch (1st)	0 h	1.28		0.136	
	D6 / ditch (2nd)	0 h	1.28		0.079	
	R1 / pond	0 h	0.053		0.018	
	R1 / stream	0 h	0.890		0.488	
	R2 / stream	0 h	1.20		1.11	
	R3 / stream	0 h	1.28		0.814	
Peas and beans	D3 / ditch	0 h	1.96		0.373	
	D4 / pond	0 h	0.079		0.015	
	D4 / stream	0 h	1.62		0.067	
	D5 / pond	0 h	0.079		0.017	
	D5 / stream	0 h	1.61		0.039	
	D6 / ditch	0 h	1.95		0.248	
	R1 / pond	0 h	0.079		0.018	
	R1 / stream	0 h	1.36		0.143	
	R2 / stream	0 h	1.80		0.100	
	R3 / stream	0 h	1.92		0.271	

FOCUS STEP 3 **(Fluazifop-P-butyl)** Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
	R4 / stream	0 h	1.36		0.936	

Fluazifop-P	
Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2, version 1.1 Molecular weight (g/mol): 327 Water solubility (mg/L): 780 at 20°C Kfoc = 48.7 DT_{50} soil (d): 9.1 DT_{50} whole system (d): 111 DT_{50} water (d): 111 DT_{50} sediment (d): 1000 Crop interception (%): minimal crop cover 40% (winter oilseed rape), 15% (potatoes), 25% (peas and beans), 20% (pome fruit – hand application. crop < 50cm)
Application rate	Crop: Winter oilseed rape / potatoes / peas and beans / pome fruit Number of applications: 1 Interval (d): not applicable Application rate(s): 375 / 250 / 375 / 250 g as/ha Maximum % formed in soil: 100% Maximum amount formed in water: 100% Application window: autumn / spring / spring / spring

FOCUS STEP 1 **(Fluazifop-P)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape / peas and beans	0 h	103		49.8	
Pome fruit / potatoes	0 h	68.7		32.5	

FOCUS STEP 2 **(Fluazifop-P)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU, Winter oilseed rape	0 h	24.9		12.1	
Southern EU, Winter oilseed rape	0 h	20.5		9.93	
Northern EU, Potatoes	0 h	10.2		4.95	
Southern EU, Potatoes	0 h	18.6		9.02	
Northern EU, Peas and beans	0 h	13.82		6.70	
Southern EU, Peas and beans	0 h	24.9		12.1	
Northern EU, Pome fruit	0 h	9.71		4.71	
Southern EU, Pome fruit	0 h	17.6		8.54	

Compound X	Version control no. of FOCUS calculator: Steps 1-2, version 1.1

Parameters used in FOCUSsw step 1 and 2	Molecular weight (g/mol): 163 Water solubility (mg/L): 6000 Soil or water metabolite: Kfoc = 24.7 (average) DT_{50} soil (d): 49.9 (the used value is uncertain, this parameter has relatively low impact to the initial PEC) DT_{50} whole system (d): 1000 DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Maximum % formed in soil: 25% Maximum amount formed in water: 37.4%

FOCUS STEP 1 **(Compound X)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape / peas and beans	0 h	13.4		3.31	
Pome fruit / potatoes	0 h	8.94		2.20	

FOCUS STEP 2 **(Compound X)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU, Winter oilseed rape	0 h	4.19		1.03	
Southern EU, Winter oilseed rape	0 h	3.46		0.85	
Northern EU, Potatoes	0 h	1.74		0.43	
Southern EU, Potatoes	0 h	3.11		0.77	
Northern EU, Peas and beans	0 h	2.36		0.58	
Southern EU, Peas and beans	0 h	4.19		1.03	
Northern EU, Pome fruit	0 h	1.65		0.41	
Southern EU, Pome fruit	0 h	2.95		0.73	

Compound IV

Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: Steps 1-2, version 1.1 Molecular weight (g/mol): 255.2 Water solubility (mg/L): 1000 Soil or water metabolite:both Kfoc = 313 mL/g (the used value is uncertain) DT_{50} soil (d): 31 (the used value is uncertain, this parameter has relatively low impact to the initial PEC) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Maximum % formed in soil: 12.9% Maximum % formed in water/sediment system: 10%

FOCUS STEP 1 **(Compound IV)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA

FOCUS STEP 1 **(Compound IV)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Winter oilseed rape / peas and beans	0 h	7.80		24.19	
Pome fruit / potatoes	0 h	5.20		16.13	

FOCUS STEP 2 **(Compound IV)** Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU, Winter oilseed rape	0 h	2.26		7.0	
Southern EU, Winter oilseed rape	0 h	1.84		5.70	
Northern EU, Potatoes	0 h	0.90		2.79	
Southern EU, Potatoes	0 h	1.69		5.25	
Northern EU, Peas and beans	0 h	1.22		3.75	
Southern EU, Peas and beans	0 h	2.26		7.0	
Northern EU, Pome fruit	0 h	0.86		2.65	
Southern EU, Pome fruit	0 h	1.60		4.96	

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Model(s) used: FOCUS-PEARL v.3.3.3, FOCUS PELMO v.3.3.2 Scenarios (list of names): Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva. Q10 = 2.2 **Fluazifop-P-butyl** DT_{50}:0.3 d (shortest laboratory values, worst-case for metabolites) Kd_{OC}: 3394 mL/g (n=1) $^{1}/_{n}$= 1 **Fluazifop-P** DT_{50}: 9.1 d (geo.mean, n=9) Kf_{OC}: 48.7 mL/g (average of 6 values) $^{1}/_{n}$= 0.9 (default value) Formation fraction : 100% from parent **Compound X** DT_{50}: 49.9 d (geo.mean, n=4) (the used value is highly uncertain) Kf_{OC}: 24.7 mL/g (average of 4 values) $^{1}/_{n}$= 0.84 (average of 4 values) Formation fraction : 40% from fluazifop-P **Compound IV** DT_{50} and formation fraction values are uncertain. Both the following combinations where used: - DT_{50}: 105 d with f.f.: 3% from fluazifop-P - DT_{50}: 57.3 d with f.f.: 6.5% from fluazifop-P

	Kf_{OC}: 313 mL/g (the used value is uncertain) $^1/_n$= 1 (default)
Application rate	**Winter oilseed rape**: a single application of 375 g ester/ha every 2 years, August-October, 40% interception, 46 years **Potatoes**: a single application of 250 g/ha every 2 years, March-September, 15% interception, 46 years **Pome fruit**: a single application of 250 g/ha every year, 1st April, basal treatment assuming 30% area treated, with 25% weed interception (overall 77.5% equivalent total interception), 26 years **Peas**: a single application of 375 g/ha every 2 year, April-June, 35% interception, 46 years **Beans**: a single application of 375 g/ha every 2 year, April-June, 25% interception, 46 years

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

FOCUS PELMO Winter oilseed rape	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV DT_{50} 105d – f.f. 3% / DT_{50} 57.3d – f.f. 6.5%
	Chateaudun	< 0.001	< 0.001	0.247	0.003 / 0.001
	Hamburg	< 0.001	0.001	0.561	0.010 / 0.003
	Jokioinen	-	-	-	-
	Kremsmunster	< 0.001	< 0.001	0.297	0.007 / 0.002
	Okehampton	< 0.001	< 0.001	0.509	0.010 / 0.003
	Piacenza	< 0.001	0.023	0.728	0.024 / 0.014
	Porto	< 0.001	< 0.001	0.037	<0.001 / <0.001
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

FOCUS PELMO Potatoes	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV DT_{50} 105d – f.f. 3% / DT_{50} 57.3d – f.f. 6.5%
	Chateaudun	< 0.001	< 0.001	0.053	0.001 / <0.001
	Hamburg	< 0.001	< 0.001	0.165	0.003 / <0.001
	Jokioinen	< 0.001	< 0.001	0.024	<0.001 / <0.001
	Kremsmunster	< 0.001	< 0.001	0.060	0.001 / <0.001
	Okehampton	< 0.001	< 0.001	0.108	0.002 / <0.001
	Piacenza	< 0.001	<0.001	0.263	0.012 / 0.005
	Porto	< 0.001	< 0.001	< 0.001	<0.001 / <0.001
	Sevilla	< 0.001	< 0.001	< 0.001	<0.001 / <0.001
	Thiva	< 0.001	< 0.001	< 0.001	<0.001 / <0.001

FOCUS PELMO Pome fruit	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV DT_{50} 105d – f.f. 3% / DT_{50} 57.3d – f.f. 6.5%
	Chateaudun	< 0.001	< 0.001	0.137	0.007 / 0.002
	Hamburg	< 0.001	< 0.001	0.094	0.004 / 0.001
	Jokioinen	< 0.001	< 0.001	0.034	0.001 / <0.001
	Kremsmunster	< 0.001	< 0.001	0.080	0.004 / 0.001
	Okehampton	< 0.001	< 0.001	0.085	0.004 / 0.001
	Piacenza	< 0.001	< 0.001	0.163	0.013 / 0.006
	Porto	< 0.001	< 0.001	0.001	<0.001 / <0.001
	Sevilla	< 0.001	< 0.001	0.024	<0.001 / <0.001
	Thiva	< 0.001	< 0.001	0.035	0.002 / <0.001

FOCUS PELMO Peas	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV DT_{50} 105d –f.f. 3% / DT_{50} 57.3d – f.f. 6.5%
	Chateaudun	< 0.001	< 0.001	0.016	<0.001 / <0.001
	Hamburg	< 0.001	< 0.001	0.210	0.004 / 0.001
	Jokioinen	< 0.001	< 0.001	0.049	<0.001 / <0.001
	Kremsmunster	-	-	-	-
	Okehampton	< 0.001	< 0.001	0.130	0.003 / <0.001
	Piacenza	-	-	-	-
	Porto	-	-	-	-
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

FOCUS PELMO Beans	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV DT_{50} 105d –f.f. 3% / DT_{50} 57.3d – f.f. 6.5%
	Chateaudun	-	-	-	-
	Hamburg (Field)	< 0.001	< 0.001	0.250	0.005 / 0.001
	Jokioinen	-	-	-	-
	Kremsmunster (Field)	< 0.001	< 0.001	0.162	0.003 / <0.001
	Okehampton (Field)	< 0.001	< 0.001	0.177	0.005 / 0.001
	Piacenza	-	-	-	-
	Porto (Vegetable)	< 0.001	< 0.001	< 0.001	<0.001 / <0.001
	Sevilla	-	-	-	-
	Thiva(Vegetable)	< 0.001	< 0.001	0.001	<0.001 / <0.001

FOCUS PEARL Winter oilseed rape	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV
	Chateaudun	< 0.001	< 0.001	0.349	Not calculated
	Hamburg	< 0.001	< 0.001	0.613	Not calculated
	Jokioinen	-	-	-	-
	Kremsmunster	< 0.001	< 0.001	0.362	Not calculated
	Okehampton	< 0.001	< 0.001	0.582	Not calculated
	Piacenza	< 0.001	< 0.001	0.745	Not calculated
	Porto	< 0.001	< 0.001	0.053	Not calculated
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

FOCUS PEARL Potatoes	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV
	Chateaudun	< 0.001	< 0.001	0.304	Not calculated
	Hamburg	< 0.001	< 0.001	0.284	Not calculated
	Jokioinen	< 0.001	< 0.001	0.161	Not calculated
	Kremsmunster	< 0.001	< 0.001	0.220	Not calculated
	Okehampton	< 0.001	< 0.001	0.280	Not calculated
	Piacenza	< 0.001	0.001	0.348	Not calculated
	Porto	< 0.001	< 0.001	0.003	Not calculated
	Sevilla	< 0.001	< 0.001	0.048	Not calculated
	Thiva	< 0.001	< 0.001	0.109	Not calculated

FOCUS PEARL Pome fruit	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV
	Chateaudun	< 0.001	< 0.001	0.132	Not calculated
	Hamburg	< 0.001	< 0.001	0.148	Not calculated
	Jokioinen	< 0.001	< 0.001	0.054	Not calculated
	Kremsmunster	< 0.001	< 0.001	0.099	Not calculated
	Okehampton	< 0.001	< 0.001	0.107	Not calculated
	Piacenza	< 0.001	0.001	0.180	Not calculated
	Porto	< 0.001	< 0.001	0.001	Not calculated
	Sevilla	< 0.001	< 0.001	0.107	Not calculated
	Thiva	< 0.001	< 0.001	0.086	Not calculated

FOCUS PEARL Peas	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV
	Chateaudun	< 0.001	< 0.001	0.099	Not calculated
	Hamburg	< 0.001	< 0.001	0.350	Not calculated
	Jokioinen	< 0.001	< 0.001	0.205	Not calculated
	Kremsmunster	-	-	-	-
	Okehampton	<0.001	<0.001	0.302	Not calculated
	Piacenza	-	-	-	-
	Porto	-	-	-	-
	Sevilla	-	-	-	-
	Thiva	-	-	-	-

FOCUS PEARL Beans	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Fluazifop-P	Compound X	Compound IV
	Chateaudun	-	-	-	-
	Hamburg (Field)	< 0.001	< 0.001	0.406	Not calculated
	Jokioinen	-	-	-	-
	Kremsmunster (Field)	< 0.001	< 0.001	0.352	Not calculated
	Okehampton (Field)	< 0.001	< 0.001	0.349	Not calculated
	Piacenza	-	-	-	-
	Porto (Vegetable)	< 0.001	< 0.001	0.008	Not calculated
	Sevilla	-	-	-	-
	Thiva(Vegetable)	< 0.001	< 0.001	0.201	

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not determined in air
Photochemical oxidative degradation in air ‡	DT_{50} of 4.3 hours derived by the Atkinson model (version 1.8)
Volatilisation ‡	Dissipation including volatilisation from plant surfaces (SETAC guideline): 23.9 % after 24 hours
	Dissipation including volatilisation from soil surfaces (SETAC guideline): 15.1% after 24 hours
Metabolites	Not determined

PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.

$PEC_{(a)}$

Maximum concentration	Negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology or for which a groundwater assessment is triggered).	Soil: fluazifop-P-butyl, fluazifop-P, Compound X, Compound IV Surface Water: fluazifop-P-butyl, fluazifop-P, compound X, compound IV, U1 and U7 (photolytic compounds) Ground water: fluazifop-P-butyl, fluazifop-P, compound

	X, compound IV Air: fluazifop-P-butyl

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	Germany (1990-91, 38 wells): no residues of fluazifop and Compound X were measured (both < LOD of 0.1 µg/L) Italy (1989 to 1994, 11-12 wells): no residues of fluazifop were measured (< LOD of 0.1 µg/L) Denmark (1999-2007): five sites, annual average concentrations at 1 m depth of fluazifop-P-butyl and fluazifop-P below 0.1 µg/L. Individual concentration values were found above 0.1 µg/L.
Air (indicate location and type of study)	No data

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

R 53

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Anas platyrhynchos	Fluazifop-P-butyl	Acute	> 3960	
Colinus virginianus	Fluazifop-P-butyl	Acute	> 2000*	
Anas platyrhynchos	Fluazifop-P-butyl	Short-term	> 942*	> 4850
Colinus virginianus	Fluazifop-P-butyl	Short-term	> 1070	> 5230
Colinus virginianus	Fluazifop-butyl	Long-term	3.95	50 (highest test concentration)
Colinus virginianus	Fluazifop-P-butyl	Long-term	86.8*	1000
Mammals ‡				
mouse	Fluazifop-P-butyl	Acute	> 2000	
rat	Fluazifop-butyl	Long-term	NOAEL: 6.72*, **	
Additional higher tier studies ‡				
Not required				

* endpoints used in the TER calculations
** At PRAPeR meeting 80, it was agreed to use the NOAEL for reproduction of 6.72 mg/kg bw/d for the long-term risk assessment.

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

Pome fruit 250 g a.s./ha around the base of trees

Indicator species/Category	Time scale	ETE mg/kg bw/d	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivore / Orchard	Acute	13.52	> 148	10
Small insectivore / Orchard	Short-term	7.54	> 120	10
Small insectivore / Orchard	Long-term	7.54	11.5	5
Worm-eating bird / Orchard	Long-term	0.31[a]	280	5
Fish-eating bird / Orchard	Long-term	0.0023[b]	38000	5
Higher tier refinement (Birds): not necessary				
Tier 1 (Mammals)				
Small herbivore / Orchard	Acute	49.35	> 41	10
Small insectivore / Orchard	Acute	2.2	> 909	10
Small herbivore / Orchard	Long-term	13.9	**0.48**	5

Indicator species/Category	Time scale	ETE mg/kg bw/d	TER	Annex VI Trigger
Small insectivore / Orchard	Long-term	0.8	8.4	5
Worm-eating mammal / Orchard	Long-term	0.38[a]	17.7	5
Fish-eating mammal / Orchard	Long-term	0.0014[b]	4800	5
Higher tier refinement (Mammals): Data gap				

[a] based on the maximum twa-21 d PECs of 0.099 mg a.s./kg soil
[b] based on the maximum twa-21 d PECsw of 0.033 µg a.s./L (step 3)

Oilseed rape at 375 g a.s./ha (autumn application), Beans and peas at 375 g a.s./ha (spring application)

Indicator species/Category	Time scale	ETE mg/kg bw/d	TER	Annex VI Trigger
Tier 1 (Birds)				
Medium herbivore / Leafy crop	Acute	24.8	> 81	10
Medium herbivore / Leafy crop	Short-term	11.4	> 83	10
Medium herbivore / Leafy crop	Long-term	4.8	18	5
Small insectivore / Leafy crop	Acute	20.28	> 99	10
Small insectivore / Leafy crop	Short-term	11.31	> 83	10
Small insectivore / Leafy crop	Long-term	11.31	7.7	5
Worm-eating bird	Long-term	0.31[a]	280	5
Fish-eating bird	Long-term	0.0023[b]	38000	5
Drinking water consumption from surface water[f]	Acute	0.000648	1×10^{6}	10
Drinking water consumption from via puddle of sprayed liquid or reservoirs held in the axils of leaves[f]	Acute	135	29	10
Higher tier refinement (Birds): not necessary				
Tier 1 (Mammals)				
Medium herbivore / Leafy crop	Acute	9.14	> 219	10
Medium herbivore / Oilseed rape, peas, beans	Long-term	1.77	**3.8**	5
Worm-eating mammal	Long-term	0.38[a]	17.7	5
Fish-eating mammal	Long-term	0.0014[b]	4800	5
Drinking water consumption from surface water[f]	Acute	0.000384	$>1\times10^{6}$	10
Drinking water consumption from via puddle of sprayed liquid or reservoirs held in the axils of leaves[f]	Acute	80	>25	10

Indicator species/Category	Time scale	ETE mg/kg bw/d	TER	Annex VI Trigger
Higher tier refinement (Mammals)				
Medium herbivore / Oilseed rape	Long-term	1.32[c]	5.1	5
Medium herbivore / peas, beans 375 g/ha	Long-term	1.92[d] 2.48[e]	**3.5**[d] **2.7**[e]	5
Medium herbivore / peas, beans 312.5 g/ha	Long-term	1.6[d] 2.06[e]	**4.2**[d] **3.3**[e]	5

[a] based on the maximum twa-21 d PECs of 0.099 mg a.s./kg soil
[b] based on the maximum twa-21 d PECsw of 0.033 µg a.s./L (step 3)
[c] based on mean measured residues in oilseed rape of 11.2 mg a.s./kg and foliage DT50 of 7 days (i.e. ftwa =0.42)
[d] based on the worst-case mean DT50 = 7.9 d from the kale residue trials, RUD = 40 and FIR/bw = 0.28 (EC, 2002 c)
[e] based on the worst-case mean DT50 = 7.9 d from the kale residue trials, RUD = 28.7 and FIR/bw = 0.5 (EFSA, 2009)
[f] It covers also the use on potato and pome fruit.

Potatoes at 250 g a.s./ha (spring application)

Indicator species/Category	Time scale	ETE mg/kg bw/d	TER	Annex VI Trigger
Tier 1 (Birds)				
Small insectivore / Leafy crop	Acute	13.52	> 148	10
Small insectivore / Leafy crop	Short-term	7.54	> 120	10
Small insectivore / Leafy crop	Long-term	7.54	11.5	5
Worm-eating bird	Long-term	0.31[a]	280	5
Fish-eating bird	Long-term	0.0023[b]	38000	5
Higher tier refinement (Birds): not necessary				
Tier 1 (Mammals)				
Small insectivore / Potatoes	Acute	2.2	> 909	10
Small insectivore / Potatoes	Long-term	0.8	8.4	5
Worm-eating mammal	Long-term	0.38[a]	17.7	5
Fish-eating mammal	Long-term	0.0014[b]	4800	5
Higher tier refinement (Mammals): not necessary				

[a] based on the maximum twa-21 d PECs of 0.099 mg a.s./kg soil
[b] based on the maximum twa-21 d PECsw of 0.033 µg a.s./L (step 3)

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests ‡				

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Fish				
Cyprinus carpio	Fluazifop-butyl	96 hr (flow-through)	Mortality, EC_{50}	1.31 (mm)
Oncorhynchus mykiss	Fluazifop-butyl	96 hr (flow-through)	Mortality, EC_{50}	1.41 (mm)
Oncorhynchus mykiss	Fluazifop	96 hr (semi-static)	Mortality, EC_{50}	117 (mm)
Oncorhynchus mykiss	Compound X	96 hr (static)	Mortality, EC_{50}	240 (nom)
Oncorhynchus mykiss	Fusilade Max (EC 125 g/L)	96 hr (static)	Mortality, EC_{50}	20 f.p.(nom) 2.65 a.s. (nom) 1.6 a.s. (mm)
Pimephales promelas	Fluazifop-P-butyl	ELS 32 d (flow-through)	Hatching, survival and growth NOEC	0.077 (mm)
Pimephales promelas	Fluazifop-P	ELS 32 d (flow-through)	Hatching, survival and growth NOEC	1.46 (mm)
Aquatic invertebrate				
Daphnia magna	Fluazifop-P-butyl	48 h (static)	Mortality, EC_{50}	> 0.62 (mm)
Crassostrea virginica	Fluazifop-P-butyl	48 h (flow-through)	Mortality, EC_{50}	0.53 (mm)
Mysidopsis bahia	Fluazifop-P-butyl	48 h (flow-through)	Mortality, EC_{50}	0.54 (mm)
Daphnia magna	Fluazifop	48 h (static)	Mortality, EC_{50}	240 (nom)
Daphnia magna	Compound X	48 h (static)	Mortality, EC_{50}	681 (nom)
Daphnia magna	Fusilade Max (EC 125 g/L)	48 h (static)	Mortality, EC_{50}	20 f.p.(nom) 2.65 a.s. (nom) 2.1 a.s. (mm)
Mysidopsis bahia	Fluazifop-butyl	28 d (flow-through)	Reproduction, NOEC	0.0477 (mm)
Daphnia magna	EC (240 g Fluazifop-butyl/L)	21 d (flow-through)	Reproduction, NOEC	0.25 a.s. (mm)
Sediment dwelling organisms (data not required)				
Algae				
Pseudokirchneriella subcapitata	Fluazifop-P-butyl	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 1.8 (mm) > 1.8 (mm)
Navicula pelliculosa	Fluazifop-P-butyl	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.51 (mm) 1.4 (mm)
Pseudokirchneriella subcapitata	Fluazifop	96 h (static)	Cell density: EC_{50}	> 46.8 (mm)
Pseudokirchneriella subcapitata	Compound X	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	340 (nom) 860 (nom)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Pseudokirchneriella subcapitata	Fusilade Max (EC 125 g/L)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.184 f.p. ($_{mm}$) 0.024 a.s. 0.672 f.p.($_{mm}$) 0.088 a.s.
Pseudokirchneriella subcapitata	Fusilade Max (EC 125 g/L)	72 h (static, test with sediment)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.1 f.p. ($_{nom}$) 0.15 a.s. >1.2 f.p.($_{nom}$) >0.16 a.s.
Navicula pelliculosa	Fusilade Max (EC 125 g/L)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.7 f.p. ($_{nom}$) 0.22 a.s. 11 f.p.($_{nom}$) 1.46 a.s.
Higher plant				
Lemna gibba	Fluazifop-P-butyl	14 d (static)	Fronds, EC_{50}	> 1.4 ($_{mm}$)
Lemna gibba	Fusilade Max (EC 125 g/L)	7 d (static)	Yield and growth rate, EC_{50}	> 100 ($_{nom}$) > 13.6 a.s.
Microcosm or mesocosm tests (not required)				

f.p. formulated product

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

FOCUS Step1

Winter oilseed rape, peas and beans, 375 g a.s./ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	PEC_{twa}	TER	Annex VI Trigger
Fluazifop-butyl	Fish	1.31	Acute	0.0261		**50**	100
Fluazifop-P-butyl	Fish	0.077	Chronic	0.0261		**3**	10
Fluazifop-P-butyl	Aquatic invertebrates	0.53	Acute	0.0261		**20**	100
Fluazifop-butyl (EC 240 g a.s./L)	Aquatic invertebrates	0.25	Chronic	0.0261		**9.6**	10
Fluazifop-P-butyl	Algae	0.51	Chronic	0.0261		20	10
Fluazifop-P-butyl	Higher plants	>1.4	Chronic	0.0261		> 54	10
Fusilade Max	Fish	1.6 (a.s.)	Acute	0.0261		**61**	100
Fusilade Max	Aquatic invertebrates	2.1 (a.s.)	Acute	0.0261		**81**	100
Fluazifop-butyl	Mysid shrimp	0.0477	Chronic	0.0261		**1.8**	10
Fusilade Max	Algae	0.024 (a.s.)	Chronic	0.0261		**0.92**	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	PEC_{twa}	TER	Annex VI Trigger
Fusilade Max	Higher plants[2]	> 13.6	Chronic	0.0261		> 521	10

Pome fruit and potatoes, 250 g a.s./ha

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	PEC_{twa}	TER	Annex VI Trigger
Fluazifop-butyl	Fish	1.31	Acute	0.0174		**75**	100
Fluazifop-P-butyl	Fish	0.077	Chronic	0.0174		**4.4**	10
Fluazifop-P-butyl	Aquatic invertebrates	0.53	Acute	0.0174		**30**	100
Fluazifop-butyl (EC 240 g a.s./L)	Aquatic invertebrates	0.25	Chronic	0.0174		14	10
Fluazifop-butyl	Mysid shrimp	0.0477	Chronic	0.0174		**2.7**	10
Fusilade Max	Fish	1.6 (a.s.)	Acute	0.0174		**92**	100
Fusilade Max	Aquatic invertebrates	2.1 (a.s.)	Acute	0.0174		121	100
Fusilade Max	Algae	0.024 (a.s.)	Chronic	0.0174		**1.4**	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	PEC_{twa}	TER	Annex VI Trigger
Fluazifop	Fish	117	Acute	0.103		1136	100
Fluazifop-P	Fish	1.46	Chronic	0.103		14	10
Fluazifop	Aquatic invertebrates	240	Acute	0.103		2300	100
Fluazifop	Algae	>46.8	Chronic	0.103		> 454	10
Compound X	Fish	240	Acute	0.0134		18000	100
Compound X	Aquatic invertebrates	681	Acute	0.0134		51000	100
Compound X	Algae	340	Chronic	0.0134		25000	10

FOCUS Step 2

Winter oilseed rape, peas and beans 375 g a.s./ha at BBCH 11-19, Northern and Southern Europe

Test substance	N/S	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	TER	Annex VI Trigger
Fluazifop-butyl	N/S	Fish	1.31	Acute	0.00345	380	100
Fluazifop-P-butyl	N/S	Fish	0.077	Chronic	0.00345	22	10

Test substance	N/S	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	TER	Annex VI Trigger
Fluazifop-P-butyl	N/S	Aquatic invertebrates	0.53	Acute	0.00345	154	100
Fluazifop-butyl (EC 240 g a.s./L)	N/S	Aquatic invertebrates	0.25	Chronic	0.00345	72	10
Fluazifop-butyl	N/S	Mysid shrimp	0.0477	Chronic	0.00345	13.8	10
Fusilade Max	N/S	Fish	1.6 (a.s.)	Acute	0.00345	464	100
Fusilade Max	N/S	Aquatic invertebrates	2.1 (a.s.)	Acute	0.00345	609	100
Fusilade Max	N/S	Algae	0.024 (a.s.)	Chronic	0.00345	**7**	10

Pome fruit and potatoes, 250 g a.s./ha, Northern and Southern Europe

Test substance	N/S[1]	Organism	Toxicity end point (mg/L)	Time scale	PEC_i mg/L	TER	Annex VI Trigger
Fluazifop-butyl	N/S	Fish	1.31	Acute	0.0023	570	100
Fluazifop-P-butyl	N/S	Fish	0.077	Chronic	0.0023	33	10
Fluazifop-P-butyl	N/S	Aquatic invertebrates	0.53	Acute	0.0023	230	100
Fluazifop-butyl	N/S	Mysid shrimp	0.0477	Chronic	0.0023	21	10
Fusilade Max	N/S	Fish	1.6 (a.s.)	Acute	0.0023	696	100
Fusilade Max	N/S	Algae	0.024 (a.s.)	Chronic	0.0023	10.4	10

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Winter oilseed rape, 375 g a.s./ha

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC_i mg/L	TER	Annex VI trigger
Fusilade Max	D2	ditch	algae	chronic	0.024 (a.s.)	0.00240	10	10
Fusilade Max	D2	stream	algae	chronic	0.024 (a.s.)	0.00214	11	10
Fusilade Max	D3	ditch	algae	chronic	0.024 (a.s.)	0.00238	10	10
Fusilade Max	D4	pond	algae	chronic	0.024 (a.s.)	0.000082	290	10
Fusilade Max	D4	stream	algae	chronic	0.024 (a.s.)	0.00205	12	10
Fusilade Max	D5	pond	algae	chronic	0.024 (a.s.)	0.000082	290	10
Fusilade Max	D5	stream	algae	chronic	0.024 (a.s.)	0.00221	11	10
Fusilade Max	R1	pond	algae	chronic	0.024 (a.s.)	0.000082	290	10
Fusilade Max	R1	stream	algae	chronic	0.024 (a.s.)	0.00157	15	10

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC_i mg/L	TER	Annex VI trigger
Fusilade Max	R3	stream	algae	chronic	0.024 (a.s.)	0.00220	11	10

Peas and beans, 375 g a.s./ha

Test substance	Scenario	Water body type	Test organism	Time scale	Toxicity end point (mg/L)	PEC_i mg/L	TER	Annex VI trigger
Fusilade Max	D3	ditch	algae	chronic	0.024 (a.s.)	0.00196	12	10
Fusilade Max	D4	pond	algae	chronic	0.024 (a.s.)	0.000079	300	10
Fusilade Max	D4	stream	algae	chronic	0.024 (a.s.)	0.00162	15	10
Fusilade Max	D5	pond	algae	chronic	0.024 (a.s.)	0.000079	300	10
Fusilade Max	D5	stream	algae	chronic	0.024 (a.s.)	0.00161	15	10
Fusilade Max	D6	ditch	algae	chronic	0.024 (a.s.)	0.00195	12	10
Fusilade Max	R1	pond	algae	chronic	0.024 (a.s.)	0.000079	300	10
Fusilade Max	R1	stream	algae	chronic	0.024 (a.s.)	0.00136	18	10
Fusilade Max	R2	stream	algae	chronic	0.024 (a.s.)	0.00180	13	10
Fusilade Max	R3	stream	algae	chronic	0.024 (a.s.)	0.00192	13	10
Fusilade Max	R4	stream	algae	chronic	0.024 (a.s.)	0.00136	18	10

Bioconcentration				
	Fluazifop-P-butyl	Fluazifop-butyl	Fluazifop	Compound 10
$\log P_{O/W}$	4.5	> 3	-0.8 (pH 7)	≤ 0.89 (pH 4-10)
Bioconcentration factor (BCF)[1] ‡	-	320		
Annex VI Trigger for the bioconcentration factor		1000		
Clearance time (days) (CT_{50})		About 1 d		
(CT_{90})		< 3 d		
Level and nature of residues (%) in organisms after the 14 day depuration phase		1%		

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

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Fluazifop-P-butyl	> 200	> 200
Fusilade Max (EC 125 g/L)	382 (a.s.)	> 100 (a.s.)

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

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

Maximum application rate 375 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 1.9	50
a.s.	Oral	< 1.9	50
Fusilade Max	Contact	< 3.8	50
Fusilade Max	Oral	1	50

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

Laboratory tests with standard sensitive species (Tier 1)

Species	Test Substance	End point	Effect (LR_{50} g/ha)
Typhlodromus pyri ‡	Fusilade Max (EC 125 g/L)	Mortality	5.6 g a.s./ha
Aphidius rhopalosiphi ‡	Fusilade Max (EC 125 g/L)	Mortality	177 g a.s./ha

Maximum application rate 375 g a.s./ha (in-field) and maximum drift rate 10.4 g a.s./ha at 1 m (off-field)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field Tier 1	HQ off-field Tier 1	Trigger
Fusilade Max (EC 125 g/L)	*Typhlodromus pyri*	5.6	**67**	1.9	2
Fusilade Max (EC 125 g/L)	*Aphidius rhopalosiphi*	177	**2.1**	0.06	2

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
T. pyri	nymph	Fusilade Max (EC 125 g/L) Leave, 7 d + 7 d	375 (a.s.) i 200 (a.s.) i 15 (a.s.) i 15 (a.s.) i	Mortality Mortality Mortality LR50 Reproduction	60 % 44 % 12 % 174 g a.s./ha 8 %	50 %

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect[3]	Trigger value
A. rhopalosiphi	adult	YF7662A 125 g/L EC formulation Seedling, 2 d + 15 d	375 (a.s.) i	Mortality Parasitism	0 % 25 %	50 %
A. rhopalosiphi	adult	Fusilade Max (EC 125 g/L)	0.75, 1.5 and 3 L/ha	LR50 Parasitism	> 3 L/ha (375 g a.s./ha) < 0% (3 L/ha)	 50%
E. balteatus	larvae	YF7662A 125 g/L EC formulation Seedling, larvae devt. + 20 d	375 (a.s.) i	Mortality Reproduction	< 0 % 3 %	50 %
C. carnea	larvae	Fusilade Max (EC 125 g/L) Leaves, larvae devt. + 20 d	1000 (a.s.) i	Mortality Reproduction	19 % 6 %	50 %
P. cupreus	adult	YF7662 125 g/L EC formulation Soil, 6 d	1875 (a.s.) i	Mortality Predation	0 % 12 %	50 %
Pardosa sp.	adult	YF7662 125g/L EC formulation Soil, 6 d	1875 (a.s.) i	Mortality Predation	40 % < 0 %	50 %

[1] indicate whether initial (i) or aged (a) residues
[2] for preparations dose is expressed in units of a.s.
[3] positive percentages relate to adverse effects

Field or semi-field tests (not required)

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

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia foetida	Fluazifop-butyl	Acute 14 d	LC_{50} > 1000 mg a.s./kg d.w.soil $LC_{50\ corr}$ > 500 mg a.s./kg d.w. soil
Eisenia foetida	Compound X	Acute 14 d	LC_{50} > 1000 mg/kg d.w.soil
Soil micro-organisms			
Nitrogen mineralisation	Fusilade Max		-21.6 to 13.1% effect during 98 days and -1.7% at day 28 at 5 mg a.s./kg d.w.soil (3.75 kg a.s./ha)
Carbon mineralisation	Fusilade Max		-7.7 to 14.4% effect during 98 days and -0.4% effect at day 28 at 5 mg a.s./kg d.w.soil (3.75 kg a.s./ha)
Field studies			

Test organism	Test substance	Time scale	End point
Earthworm field study: two successive annual applications of fluazifop-butyl (as a 25% w/v EC formulation) at rates up to 5 kg a.s./ha had no adverse effects on earthworm population numbers or weight. The risk to soil organisms from exposure to metabolites is sufficiently covered by the field study.			

Notes: Fluazifop-acid is expected to be present in all tests conducted with fluazifop-butyl and Fusilade Max. Compound X is expected to be present in the earthworm field study and the 98 d-tests on nitrogen and carbon mineralisation.

Toxicity/exposure ratios for soil organisms

Maximum application rate 375 g a.s./ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	a.s. ‡	Acute	0.5	> 1000	10
Eisenia foetida	Compound 10	Acute	0.0533	> 19000	10

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

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

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided Compound X is not herbicidally active compared to the parent compound

TER for non target terrestrial plant (leafy crop use. max application rate of 375 g a.s./ha, off-crop)

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure (g/ha)	TER	Trigger
Echinochloa crus-galli	Fusilade Max		37.1 (a.s.)	10.4 (a.s.) at 1 m (2.77% drift)	**3.6**	5
Echinochloa crus-galli	Fusilade Max		37.1 (a.s.)	2.1 (a.s.) at 5 m (0.57% drift)	18	5
Zea mays	Fusilade Max	9.1 (a.s.)		10.4 (a.s.) at 1 m (2.77% drift)	**0.9**	5
Zea mays	Fusilade Max	9.1 (a.s.)		2.1 (a.s.) at 5 m (0.57% drift)	**4.3**	5
Zea mays	Fusilade Max	9.1 (a.s.)		1.1 (a.s.) at 10 m (0.29% drift)	8.3	5

TER for non target terrestrial plant (pome fruit use. 250 g a.s./ha, off-crop)

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger value
Echinochloa crus-galli	Fusilade Max		37.1 (a.s.)	6.9 (a.s.) at 1 m	5.4	5
Zea mays	Fusilade Max	9.1 (a.s.)		6.9 (a.s.) at 1 m	**1.3**	5
Zea mays	Fusilade Max	9.1 (a.s.)		1.4 (a.s.) at 5 m	6.5	5

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

Not required

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

Test type/organism	end point
Activated sludge	NOEC = 20 mg a.s./L (continuous exposure) NOEC = 50 mg a.s./L (shock dosed exposure)
Pseudomonas sp	Not required

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

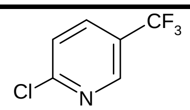
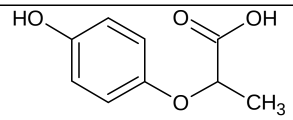
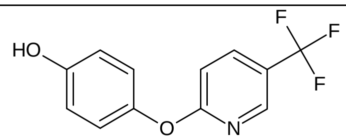
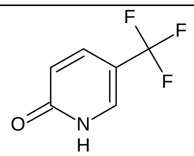
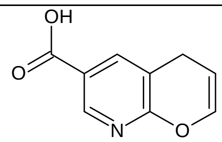
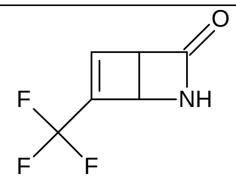
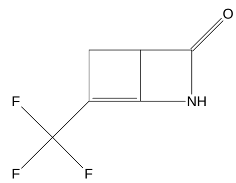
Compartment	
soil	Fluazifop-P-butyl, Fluazifop-P
water	Fluazifop-P-butyl, Fluazifop-P
sediment	Fluazifop-P-butyl, Fluazifop-P
groundwater	Fluazifop-P-butyl, Fluazifop-P

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	fluazifop-P (butyl ester) N, R50/53, S60, S61 (source: ATP 28)

	RMS/peer review proposal
Preparation	N, R50/53, S60, S61

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
R 150881	2-chloro-5-(trifluoromethyl)pyridine	
Compound 3 Compound III R118106	(*RS*)-2-(4-hydroxyphenoxy)propanoic acid	
Compound 4 **Compound IV**	4-{[5-(trifluoromethyl)-2-pyridinyl]oxy}phenol	
Compound 10 **Compound X** Reference X	5-(trifluoromethyl)-2(1*H*)-pyridinone	
U7	4*H*-pyrano[2,3-*b*]pyridine-6-carboxylic acid	
U1	6-(trifluoromethyl)-2-azabicyclo[2.2.0]hex-5-en-3-one 6-(trifluoromethyl)-2-azabicyclo[2.2.0]hex-1(6)-en-3-one	 or 

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
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
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
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
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)
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
g	gram
GAP	good agricultural practice

GC	gas chromatography
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
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
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
mN	milli-newton
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
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
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