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

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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 the Netherlands for the pesticide active substance flupyradifurone and the assessment of applications for maximum residue levels are reported. The context of the peer review was that required by Regulation (EC) No 1107/2009 of the European Parliament and of the Council. The conclusions were reached on the basis of the evaluation of the representative uses of flupyradifurone as an insecticide on hops and field and glasshouse lettuce. Maximum residue levels were assessed in pome fruits, grapes, fruity vegetables watermelon, lettuce and cucurbits. 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, and the proposed maximum residue levels are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

KEY WORDS

flupyradifurone, peer review, risk assessment, pesticide, insecticide, maximum residue level

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[1] On request from the European Commission, Question No EFSA-Q-2014-00074, approved on 30 January 2015.

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[3] The list of end points for the section on residues has been corrected due to several errors and formatting issues. An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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SUMMARY

Flupyradifurone is a new active substance for which in accordance with Article 7 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council (hereinafter referred to as 'the Regulation'), the rapporteur Member State (RMS), the Netherlands, received an application from Bayer CropScience AG for approval. In accordance with Article 8(1)(g) of the Regulation, Bayer CropScience AG submitted applications for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005. Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 21 June 2012.

The RMS provided its initial evaluation of the dossier on flupyradifurone in the Draft Assessment Report (DAR), which was received by the EFSA on 1 February 2014. The DAR included a proposal to set maximum residue levels, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 5 February 2014 by dispatching the DAR for consultation of the Member States and the applicant Bayer CropScience AG.

Following consideration of the comments received on the DAR, it was concluded that additional information should be requested from the applicant, and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether flupyradifurone can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation. Furthermore, this conclusion also addresses the assessment required from EFSA under Article 12 of Regulation (EC) No 396/2005, provided the active substance will be approved under Regulation (EC) No 1107/2009 without restrictions affecting the residue assessment.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of flupyradifurone as an insecticide in hops and field and glasshouse lettuce as proposed by the applicant. MRLs were assessed in apples/pears, grapes, tomatoes, peppers, cucurbits, watermelon and lettuce. Full details of the representative uses and the proposed MRLs can be found in Appendix A to this report.

A data gap was identified in relation to the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

Sufficient information was provided to confirm the effectiveness of flupyradifurone against the target insects when applied according to the GAPs reported under the representative uses.

No data gaps were identified in the area of identity, physical/chemical/technical properties and methods of analysis.

In the mammalian toxicology area, data gaps were identified to address the relevance of the individual impurities present in the technical specification in comparison with the toxicological profile of the parent compound. The interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However, data gaps were identified for Level 2 tests currently indicated in the OECD Conceptual Framework, to address the potential for endocrine-mediated mode of action regarding the reproductive effects observed in a 2-generation reproductive toxicity in rats (reduced number of implantation sites and oestrus cycle, reduced litter size -reduced number of pups born and higher number of stillborn), and noting that further tests might be necessary pending on the outcome (issue not finalised).

Based on the available information, plant and animal residue definitions were proposed for enforcement and risk assessment. The GAP supporting the representative use of flupyradifurone on lettuce under greenhouse conditions result in an exceedance of the ARfD and therefore, the MRL for lettuce was derived from the outdoor GAP reported in the MRL application. Data gaps were identified for the submission of new animal feeding studies conducted with the metabolite DFA and of additional field rotational crop studies.

The import tolerance requests, reported in the MRL application, were not considered, pending the submission of documentations providing evidence for the registration of the active substance in the exporting countries. In contrast, maximum residue level requests related to the EU GAPs were fully supported by the available data and separate MRLs were proposed for flupyradifurone and DFA respectively. In addition, default MRL values were proposed to cover the residues of flupyradifurone and DFA expected in rotational crops.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. A critical area of concern was identified, the active substance flupyradifurone has a high potential to exceed the parametric drinking water limit of 0.1µg/L in groundwater as represented by the 80th percentile annual average concentration moving below 1m depth, in geoclimatic situations represented by the FOCUS scenarios in hops (4 out of 7 scenarios), field lettuce (4 out of 7 scenarios) and protected lettuce (6 out of 7 scenarios). A data gap was proposed for information to address the effect of water treatment processes on the nature of residues of the active substance and metabolites when surface water is abstracted for drinking water and metabolites when groundwater is abstracted for drinking water to address Article 4 (approval criteria for active substances) 3(b) of Regulation (EC) No 1107/2009. Whilst robust information regarding this was not available, the consumer risk assessment is considered not finalised.

Data gaps were identified in the ecotoxicology section: to further address the potential for endocrine disruption of flupyradifurone; to further address a scientific peer-reviewed open literature search on the active substance and its relevant metabolites; to further address the long-term risk to small herbivorous mammals from dietary routes in lettuce and to further address the chronic risk to aquatic invertebrates for the representative field uses in lettuce. A data gap was proposed for the submission of the studies found by the applicant during the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

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BACKGROUND

Regulation (EC) No 1107/2009 of the European Parliament and of the Council[4] (hereinafter referred to as 'the Regulation') lays down, *inter alia*, the detailed rules as regards the procedure and conditions for 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 up to 150 days where additional information is required to be submitted by the applicant(s) in accordance with Article 12(3).

Flupyradifurone is a new active substance for which in accordance with Article 7 of the Regulation, the rapporteur Member State (RMS) the Netherlands (hereinafter referred to as the 'RMS') received an application from Bayer CropScience AG for approval of the active substance flupyradifurone. In accordance with Article 8(1)(g) of the Regulation, Bayer CropScience AG submitted an application for maximum residue levels as referred to in Article 7 of Regulation (EC) No 396/2005.[5] Complying with Article 9 of the Regulation, the completeness of the dossier was checked by the RMS and the date of admissibility of the application was recognised as being 21 June 2012.

The RMS provided its initial evaluation of the dossier on flupyradifurone in the Draft Assessment Report (DAR), which was received by the EFSA on 1 February 2014 (Netherlands, 2014). The DAR included a proposal to set MRLs, in accordance with Article 11(2) of the Regulation. The peer review was initiated on 5 February 2014 by dispatching the DAR for consultation of the Member States and the applicant Bayer CropScience AG, for consultation and comments. EFSA also provided comments. In addition, the EFSA conducted a public consultation on the DAR. 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 20 June 2014. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant and that the EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology.

The outcome of the telephone conference, together with the 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.

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[4] 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 L 309, 24.11.2009, p. 1-50.

[5] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

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.

In accordance with Article 12 of the Regulation, the EFSA should adopt a conclusion on whether flupyradifurone can be expected to meet the approval criteria provided for in Article 4 of the Regulation taking into consideration recital (10) of the Regulation and give a reasoned opinion concerning maximum residue levels as referred to in Article 10(1) of Regulation (EC) No 396/2005. A final consultation on the conclusions arising from the peer review of the risk assessment and on the reasoned opinion concerning maximum residue levels took place with Member States via a written procedure in January 2015.

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 of flupyradifurone as an insecticide on hops and field and glasshouse lettuce as proposed by the applicant and the reasoned opinion assessment of maximum residue levels in pome fruits, grapes, fruity vegetables watermelon, lettuce and cucurbits. A list of the relevant end points for the active substance as well as the formulation and the proposed maximum residue levels 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, 2015) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the DAR,
- the Reporting Table (24 June 2014)
- the Evaluation Table (30 January 2015),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its final addendum (compiled version of January 2015 containing all individually submitted addenda (Netherlands, 2015)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Flupyradifurone is the ISO common name for 4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl)amino]furan-2(5*H*)-one (IUPAC).

The representative formulated product for the evaluation was 'Sivanto SL 200' a soluble concentrate (SL) containing 200 g/L flupyradifurone.

The representative uses evaluated comprise spray applications to control *Phorodon humuli* in hops in Northern Europe and *Nasonovia ribisnigri* in lettuce in the EU. Full details of the GAP can be found in the list of end points in Appendix A.

Data were submitted to conclude, that the uses of flupyradifurone according to the representative uses proposed at EU level, result in a sufficient insecticidal efficacy against the target insects, following the guidance document SANCO/10054/2013 - rev. 3 (European Commission, 2013).

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed during the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), SANCO/10597/2003 – rev. 10.1 (European Commission, 2012), SANCO/825/00 rev. 8.1 (European Commission, 2010) and SANCO/221/2000-rev. 10 – final (European Commission, 2003)

The minimum purity of the active substance as manufactured is 960 g/kg. No FAO specification exists.

The proposed specification is based on batch data from pilot scale production. It should be noted that the 5-batch analysis from full scale production will need to be reconsidered. 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 flupyradifurone or the representative formulation. The main data regarding the identity of flupyradifurone and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of flupyradifurone in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

Two separate residue definitions for monitoring were proposed in food of plant and animal origin: flupyradifurone and the second, its metabolite DFA expressed as DFA (see Section 3). Appropriate single HPLC-MS/MS methods exist for monitoring residues in food and feed of plant origin with LOQs of 0.01 mg/kg flupyradifurone and with LOQs of 0.02 mg/kg DFA respectively, in all commodities, except for hops, for which the respective LOQs were 0.05 mg/kg a.s. and 0.10 mg/kg DFA. Residues of flupyradifurone and DFA in food of animal origin can be monitored with single HPLC-MS/MS method with LOQs of 0.01 mg/kg a.s. and 0.02 mg/kg DFA respectively, in all matrices.

HPLC-MS/MS methods exist for monitoring flupyradifurone in the environmental matrices with LOQs of 5 µg/kg in soil, 0.05 µg/L in surface water and drinking water and 7 µg/m^3 in the air, respectively. The active substance is not classified or proposed to be classified as toxic according to

Regulation (EC) No 1272/2008 (CLP Regulation),[6] therefore a method of analysis is not required for body fluids and tissues.

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/10597/2003 – rev. 10.1 (European Commission, 2012) and Guidance on Dermal Absorption (EFSA PPR Panel, 2012).

Flupyradifurone was discussed at the Pesticides Peer Review Expert Meeting 122 in November 2014.

The technical specification is supported by the toxicological assessment; however the relevance of the individual impurities present in the technical specification in comparison with the toxicological profile of the parent compound has not been addressed and a data gap was identified.

Flupyradifurone is almost completely absorbed after oral administration, it is widely distributed, moderately metabolised and rapidly excreted mainly via urine; no potential for accumulation was observed. Low to moderate acute toxicity was observed when flupyradifurone is administered by the oral, dermal or inhalation routes. Slight eye irritation, but no skin irritation or potential for skin sensitisation were attributed to the active substance. Target organs of flupyradifurone are the liver and thyroid in rats, liver and kidney in mouse, and kidney and skeletal muscles in dog. The relevant short term NOAEL is 6 mg/kg bw per day based on reduced body weight gain and thyroid weight observed in the 90-day dietary study in rats, and the relevant long term NOAEL is 15.8 mg/kg bw per day based on organ weight changes associated with histopathological findings in the liver and thyroid from the 2-year study in rat. No potential for genotoxicity, carcinogenicity or neurotoxicity were attributed to the active substance. Flupyradifurone did not present an immunotoxic potential in a 28-day immunotoxicity study in rats.

Flupyradifurone is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, (no harmonised classification is currently available), and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. With regards to the assessment for a potential endocrine-mediated mode of action, in a two-generation reproductive toxicity study, reproductive effects characterised by reduced number of oestrous cycles, reduced litter size and reduced number of implantation sites were observed at doses indicative of parental and offspring's toxicity such as decreased body weight and body weight gain. Although the reduced body weight may be an explanation for the reproductive effects observed, the experts agreed that there was insufficient evidence demonstrating that the mode of action was not endocrine-mediated and a data gap was set for Level 2 tests currently indicated in the OECD Conceptual Framework (OECD, 2012), and analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors (EFSA, 2013), noting that further tests might be necessary pending on the outcome (issue not finalised). The parental and offspring NOAELs were set at 6.4 mg/kg bw per day and the reproductive NOAEL at 32 mg/kg bw per day. In the rat developmental toxicity study, increased variations on the developing foetuses were observed at maternally toxic doses (reduced body weight and liver weight), while in the rabbit study, no adverse effects on the development were observed at doses causing maternal toxicity (reduced body weight observed within the first days of dosing); the rabbit maternal NOAEL was set at 15 mg/kg bw per day.

Toxicological studies were provided on four flupyradifurone metabolites, difluoroacetic acid (DFA), difluoroethyl-amino-furanone (DFEAF), (6-chloropyridin-3-yl)methanol (CHMP) and 6-chloronicotinic acid (6-CNA). Regarding DFA (metabolite found in plants, livestock and environment,

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[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substancnes and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355.

see section 3 and 4) and DFEAF, the experts concluded that the reference values of the parent are applicable to both metabolites. Furthermore, DFA is not relevant from the toxicological point of view up to stage 3 of step 3 of the guidance document on the assessment of metabolites in groundwater (European Commission, 2003).

As the RMS could not assess the potentially relevant studies published in the open literature as a detailed assessment of the relevant papers has not been provided together to the actual submission of these. A data gap was set for a transparent study-by-study justification of the relevant studies found by the applicant during the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

The acceptable daily intake (ADI) of flupyradifurone is 0.064 mg/kg bw per day, based on the parental and offspring’s NOAEL of 6.4 mg/kg bw per day for reduced body weight/body weight gain from the 2-generation reproductive toxicity study in rats and applying the standard uncertainty factor (UF) of 100. The acute reference dose (ARfD) is 0.15 mg/kg bw based on the maternal NOAEL of 15 mg/kg bw per day for reduced body weight gain in the first days of dosing from the rabbit developmental toxicity study, 100 UF applied. The acceptable operator exposure level (AOEL) is 0.64 mg/kg bw per day on the same basis as the ADI: NOAEL of 6.4 mg/kg bw per day observed in the 2-generation reproductive toxicity study, 100 UF applied and no correction regarding oral absorption.

Based on human skin *in vitro* dermal absorption study, dermal absorption values for the representative SL formulation containing 200 g flupyradifurone/L is 0.4 % for the concentrate, 3 % for 0.625 g/L dilution, 8 % for 0.1 g/L dilution and, based on *pro rata* extrapolation, 17 % for the most diluted in-use field dilution of 0.045 g/L. Estimated operator, worker, bystander and residential exposures were below the AOEL even when the use of personal protective equipment (PPE) is not considered for operators and workers, with the exception of hand-held scenario on lettuce according to the UK POEM model, where PPE (gloves during mixing and loading operations and gloves and impermeable coveralls during applications) have to be considered to ensure that operator exposure does not exceed the AOEL.

3. Residues

The assessment in the residue section is based on the guidance documents listed in the document 1607/VI/97 rev.2 (European Commission, 1999), the EC guideline document on MRL setting (European Commission, 2011), the JMPR recommendations on livestock burden calculations (JMPR, 2004, 2007) and OECD publication on MRL calculations (OECD, 2011).

3.1. Representative uses

Flupyradifurone metabolism in primary crops was investigated in four crop groups either by foliar applications (apple, cotton, rice), by soil granule/drench applications (tomato, potato, rice) and by seed dressing (potato). Studies were conducted using ^{14}C-flupyradifurone labelled on the pyridinyl or furanone moiety and using application rates representative of the supported uses. One study on tomato using soil drench application and a ^{14}C-labelling on the difluoroethyl amino group was also submitted.

The metabolism in primary crops was seen to be similar in all plant groups investigated. Flupyridafurone was consistently observed as the major component of the radioactive residues, accounting for *ca.* 25% to 88% TRR in all plant parts analysed. Besides flupyradifurone, the following metabolites were identified in different plant matrices:

- the conjugate flupyradifurone-hydroxy-glycoside, up to 36%TRR in apple leaves,
- the conjugate CHPM-diglycoside, up to 37% TRR (0.06 mg/kg) and the metabolite 6-CNA in the range of 13% to 22% TRR in tomato fruit, potato tuber and cotton seed at ca. 0.02 mg/kg, both resulting from the cleavage of the molecule at ethylamine bond and containing the pyridinyl moiety.

In contrast, metabolites containing the furanone moiety were almost not detected and the radioactivity in the ^{14}C-furanone studies was mostly recovered as incorporated in natural glucoside and carbohydrate components, indicating an extensive degradation of the furanone counterpart. In addition, information was given by the study conducted on tomato with the ^{14}C-labelling on the difluoroethyl amino group that, following soil drench application, significant proportions (87% TRR) and levels (0.17 mg/kg) of difluoroacetic acid (DFA) are present in tomato fruits. Samples from the radiolabelled studies were therefore re-analysed for non-radiolabelled DFA and residues, expressed as DFA equivalent, were measured in the range of 0.04 to 0.23 mg/kg in apple fruits, potato tuber, cotton seed and rice grain, irrespective of the mode of application.

A similar metabolic profile was observed in the confined rotational studies conducted with a ^{14}C-pyridinyl and ^{14}C-furanone labelling, where flupyradifurone and its metabolites flupyradifurone-hydroxy, 6-CNA and their conjugates were seen to be the major components of the radioactive residues. These radiolabelled studies are however incomplete as they did not include a labelling on the difluoroethyl amino group. Information provided by rotational crop field studies, indicates that DFA is the major component of the residues in rotational crops. The presence of DFA is mostly the result of a preferential uptake from soil, where this metabolite was identified as a major metabolite (see section 4).

In primary crops, flupyradifurone is not extensively degraded and the metabolism in plant proceed via the hydroxylation of the furanone ring leading to the M8 metabolite and its glycoside conjugates and via the cleavage of the parent molecule at the ethylamine bond resulting in the formation of metabolites containing the pyridinyl moiety (CHMP-diglycoside, 6-CNA free and conjugated). The furanone counterpart is extensively metabolised and incorporated in natural glycoside or carbohydrate components. In rotational crops, residues were identified as mostly composed of the DFA metabolite and resulting from a preferential uptake from the soil, where DFA was identified as major metabolite.

Based on these studies, and considering the outcome of the Peer Review Meeting 122 on toxicology where it was concluded that the toxicological reference values set for flupyradifurone are also applicable to DFA, the residue definition for risk assessment was proposed as ‘sum of flupyradifurone and DFA expressed as flupyradifurone’. For enforcement, the residue definition was intensively discussed in the teleconference meeting 107, where the three following different proposals were considered:

1) **Residue definition limited to flupyradifurone only**: This definition was concluded to be inappropriate, since unable to consider the significant DFA residue levels in rotational crops, where parent flupyradifurone is almost not present. Moreover for primary crops, the setting of reliable conversion factors (CF) for risk assessment is not possible for some plant commodities, since the ratio (flupyradifurone + DFA)/flupyradifurone is constantly changing with the PHI (e.g. CF 2 and 10 respectively, at 3 and 14 day PHI on cucurbits).
2) **Residue definition proposed as sum of flupyradifurone and DFA:** This residue definition was indeed concluded to be inappropriate to monitor flupyradifurone residues, since the MRLs derived from the uses of flupyradifurone on primary crops would be covered by the default MRL values proposed for rotational crops and resulting from the significant presence of DFA in rotational crops.
3) **Two separate residue definitions for monitoring, as flupyradifurone and DFA expressed as DFA, respectively**: It was finally agreed that two separate residue definitions would be required, as ‘flupyradifurone’; to consider the residues resulting from the uses of the active substance on primary crops, and as ‘DFA, expressed as DFA’; to consider DFA residues in rotational crops.

Sufficient residue trials were submitted to propose MRLs for the representative uses on lettuce and hops. However, the GAP proposed for the uses of flupyradifurone under indoor conditions results in an exceedance of the ARfD and therefore, the MRL proposal of 5 mg/kg for lettuce was based on the outdoor field uses. Numerous field rotational crop studies conducted at dose rates of 200 to 250 g/ha were provided (*ca* 1N indoor use on lettuce, 1N outdoor uses in MRL application). The setting of MRL in rotational crops was discussed in the Pesticides Peer Review expert meeting TC 107. Since flupyradifurone is a persistent compound, the experts were of the opinion that sufficient information was not provided to conclude whether these field trials were conducted at rates reflecting the expected plateau concentrations in soil reached following several years of consecutive applications. Moreover, most of the studies were conducted with a single plant back interval (PBI) of 30 days (crop failure) which seems an unrealistic situation for several crops. It was therefore concluded that further studies conducted at realistic PBIs and providing information on the flupyradifurone and DFA residue levels in soil are required. Provisionally and since significant DFA residues are expected in rotational crops, it was agreed to derive the default MRLs values for rotational crops from the available trials conducted at a dose rate of 200 g/ha and considering the plant back interval of 30 days and the highest residue values.

Residue trial data are supported by the storage stability studies showing flupyradifurone and DFA residues stable at least 18 months in high water-, high acid-, high-oil-, high protein- and high starch-content matrices, when stored frozen at approximately -18°C.

Flupyradifurone was seen to be stable under standard hydrolysis conditions. Processing studies were submitted and processing and conversion factors were proposed for flupyradifurone and DFA respectively, for lettuce, hops, and for the crops included in MRL application (apple, grape, tomato and cucumber).

Livestock metabolism studies conducted with ^{14}C-flupyradifurone labelled on the pyridinyl or furanone moiety at the dose rate of *ca.* 1 mg/kg bw over 5-6 days (goat) or 14 days (hen) were submitted. In ruminant, the degradation of the parent compound was limited, flupyradifurone accounting for 24%-35% in milk and kidney up to 81%-99% in fat. The metabolism was more extensive in hen, and flupyradifurone almost not detected in any poultry matrices in the ^{14}C-furanone study (<3% TRR) and in the range of 1% (liver) to 20% TRR (eggs) in the ^{14}C-pyridinyl study. The main components identified in hen were the hydroxy-flupyradifurone metabolites (18% TRR in eggs) and its sulphate conjugated in fat and liver (16-23% TRR) and the acetyl-AMCP metabolite in egg, fat and muscle (23 to 40% TRR). As for plants, the metabolic picture given by these studies is incomplete as the ^{14}C labelling on the difluoroethyl amino group is missing. The feeding studies conducted with animals dosed with flupyradifurone alone, revealed that DFA is a major marker of the residues in poultry matrices and in a lesser extent, in ruminant matrices. Based on these studies the residue definitions were proposed as ‘sum of flupyradifurone and DFA expressed as flupyradifurone’ for risk assessment and as flupyradifurone and as DFA as for plant two separate residue definitions were proposed for enforcement respectively. Cow and poultry feeding studies were provided where animals were dosed with the parent flupyradifurone only while, considering the residues anticipated in rotational crops, animals are expected to be mostly exposed to the DFA metabolite. The experts in the expert meeting TC 107 were therefore of the opinion that further feeding studies where animals are dosed with the DFA metabolite should be requested to derive reliable MRLs for products of animal origin. Provisionally and pending the submission of the requested data, MRL for animal products were derived from the feeding studies conducted with the parent flupyradifurone alone and considering a transfer factor approach proposed by the applicant.

The consumer risk assessment was conducted using the EFSA PRIMo rev.2 model and considering the STMRs and HRs derived from the residue trials on primary crops and from the field rotational crops studies. Having regard to the indoor use of flupyradifurone on lettuce, an acute risk cannot be excluded for the consumers since, based on the HR of 6.04 mg/kg observed in the indoor trials, the acute intake was calculated to be 108% of the ARfD (DE, child). This acute intake is reduced to 94% of the ARfD when a processing factor of 0.87 considering the removal of the outer leaves is applied. EFSA therefore proposes to set the MRL for lettuce on the outdoor GAP described in the MRL application, where the HR value of 3.18 mg/kg results in an acute intake of 57% of the ARfD. No acute exceedance was observed for the other crops. No chronic consumer concern was identified, the maximum international estimated daily intake (IEDI) was estimated to be 15% of the ADI (WHO, cluster B).

Based on WHO consumption figures (WHO, 2011), the additional contribution to the consumer intakes, resulting from the presence of the DFA metabolite in groundwater above 0.75 µg/l is negligible, and estimated to be less than 0.5 % of the ADI for infant, child and adult.

3.2. Maximum residue levels

An MRL application to set additional MRL and import tolerances was included in the DAR. The request for import tolerances was not considered in the framework of this peer review as evidence of the registration of flupyradifurone in the exporting countries (USA, Canada) was not provided. Sufficient residue trials conducted according to the EU GAPs were submitted to derive MRL proposals for flupyradifurone and DFA in pome fruits, grapes, tomatoes, peppers, eggplants, watermelons and cucurbit edible peel. Median processing factors listed in the list of end points and derived from at least two processing studies, are recommended for inclusion in Annex VI of Regulation (EC) 396/2005.

4. Environmental fate and behaviour

Flupyradifurone was discussed at the Pesticides Peer Review Meeting 121 in November 2014.

In soil laboratory incubations under aerobic conditions in the dark, flupyradifurone exhibited moderate to high persistence, forming the major (>10% applied radioactivity (AR)) metabolites difluoroacetic acid (DFA, max 33.9%) and 6-chloronicotinic acid (6-CNA, max 17.1%), which exhibited moderate to medium persistence and very low to moderate persistence, respectively. Mineralisation of the pyridinyl-methyl-, pyridine-2,6-, furanone-4-, ethyl-1- ^{14}C radiolabel to carbon dioxide accounted for 29.4-58.6% AR, 20.2-57.4% AR, 12.3-38.9% AR and 25.9-42.3%, respectively, after 100 days. The formation of unextractable residues (not extracted by acetonitrile/water) for the pyridinyl-methyl-, pyridine-2,6-, furanone-4-, ethyl-1- ^{14}C radiolabel accounted for 12.5-16.8% AR, 11.3-25.5% AR, 16.4-34.1% and 14.3-17.9% AR, respectively, after 100 days. In anaerobic soil incubations flupyradifurone was essentially stable. Flupyradifurone exhibited high mobility in soil. Metabolite DFA exhibited high soil mobility and metabolite 6-CNA exhibited very high soil mobility. It was concluded that the adsorption of flupyradifurone and the metabolites DFA and 6-CNA was not pH-dependent. In satisfactory field dissipation studies carried out at three sites in Germany, one site in UK, one site in Italy and one site in Spain flupyradifurone exhibited low to high persistence. Sample analyses were only carried out for the parent flupyradifurone. Field study DT_{50} values were not used for the PEC calculations.

In laboratory incubations in dark aerobic natural sediment water systems, flupyradifurone exhibited high persistence, forming the metabolite DFA (max. 6.9% AR in both water and sediment, exhibiting high persistence). The unextractable sediment fraction (not extracted by acetonitrile/water) was the major sink for pyridine-2,6-, furanone-4-, ethyl-1- ^{14}C radiolabel, accounting for 13.6-25.0 % AR, 17.9-22.6 % AR and 15.2-26.6 %, respectively, at the study end (120 days). Mineralisation of these radiolabels accounted for only 6.8-8.5 % AR, 3.9-5.5 % AR and 0.9-1.5 % AR, respectively, at the end of the study. The rate of decline of flupyradifurone in laboratory sterile aqueous photolysis experiment was fast relative to that occurred in the aerobic sediment water incubations. The reaction products flupyradifurone-succinamide and flupyradifurone-azabicyclosuccinamide was accounted for > 10%. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for the metabolites 6-CNA, DFA, flupyradifurone-succinamide and flupyradifurone-azabicyclosuccinamide, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach. For the active substance flupyradifurone, appropriate step 3 (FOCUS 2001) and step 4 calculations were available[7]. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones up to 20m being implemented

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[7] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7

for the drainage scenarios (representing a 93 – 95 % spray drift reduction) combined with low drift nozzles and combined no-spray buffer zones with vegetative buffer strips of up to 20m (reducing solute flux in run-off by max. 80%) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2000 mL/g (i.e. flupyradifurone), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds. It should also be noted that according to the GAP-table the representative crop hops (field use) is restricted to an application every second year only and the representative crop lettuce (field use) is restricted to max. 1 application every 24 months and max. 1 application every 12 months depending on the growth stage at the application time.

For the representative protected use, the predicted environmental concentrations calculated in soil (PECsoil) were higher than for the outdoor uses. The surface water exposure assessment (PECsw) for glasshouses was calculated using 0.2 % emissions from glasshouses (FOCUS, 2008) to 30cm deep static water body.

In the Pesticides Peer Review expert Meeting 121 the groundwater modelling was discussed considering time dependent sorption input parameters for both the active substance and relevant metabolites. The experts agreed that the kinetic sorption experiments were performed following the draft guidance by Beulke (Beulke *et al*, 2012) and the calculations of the model input parameters and the ground water modelling required were provided. However the experts concluded that there are doubts on the acceptability of the TDS scheme as in the draft guidance by Beulke (Beulke *et al*, 2012) due to uncertainties in the validation of the scheme against accepted (and not completely clear) protection goals, experts considered that at this stage the results of these simulations should not be included in the list of endpoints, see Appendix A. Furthermore the experts also discussed the use of a plant uptake factor of 0.5 for the parent and the relevant metabolites. They concluded that a plant uptake factor of 0.5 was acceptable for the parent since uptake from soil via the root has been proven. However, for the metabolites no evidence was available and therefore calculations should be based on a plant uptake factor of 0.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4 and PELMO 4.4.3[8] for the active substance flupyradifurone and the metabolites 6-CNA and DFA. The potential for groundwater exposure by flupyradifurone above the parametric drinking water limit of 0.1 µg/L was concluded high in 4 out of 7 scenarios for the biennial application on hops; in 4 out of 7 scenarios for annual field application on lettuce; 4 out of 7 scenarios for biennial field application on lettuce and in 6 out of 7 scenarios for glasshouse application on lettuce. For the metabolite 6-CNA the potential for groundwater exposure for all representative uses above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all FOCUS groundwater scenarios. The potential for groundwater exposure by the metabolite DFA above the parametric drinking water limit of 0.1 µg/L was concluded high in all the scenarios for all representative uses. The metabolite DFA was not considered to be toxicological relevant, see section 2.

The applicant provided a statement that concentrations in groundwater or surface water of flupyradifurone and its metabolites at raw water abstractions points will be clearly below 0.1 µg/L so information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater are abstracted for drinking water would not be needed. Whilst the RMS agreed with this consideration, EFSA considered that the argumentation provided was too qualitative in nature, so has included a data gap regarding this in section 7.As the RMS could not assess the potentially relevant studies published in the open literature, a data gap was set for a transparent study-by-study justification of the relevant studies found

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[8] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

by the applicant during the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

5. Ecotoxicology

The risk assessments considered the following documents: European Commission 2002a and 2002b, SETAC 2001, and EFSA (2009).

The ecotoxicological assessment is supported by the technical specifications.

As discussed in section 2, available data were not sufficient to exclude an endocrine-mediated mode of action of flupyradifurone for fish and birds. Therefore a data gap was identified for this issue (see section 7).

On the basis of the available data and assessments, a low risk to birds (acute and long-term) and mammals (acute) was indicated for all representative uses. For long-term risk assessment to mammals and all representative uses a high risk was indicated at first tier. The mammalian long-term risk assessment was discussed at the Pesticides Peer Review Expert Meeting 124 (December 2014). During the meeting it was decided that the NOAEL of 100 ppm (6.4 mg a.s./kg bw/d) should be used for the assessment. It was also concluded that based on the available residue decline data, fTWA could be refined in the risk assessment for the representative uses. On the basis of an assessment using the NOAEL of 100 ppm and the refined fTWA values a low long-term risk for mammals was indicated for the representative use on hops, however for the representative use on lettuce a high risk for small herbivorous mammal was still indicated. Therefore, a data gap was identified (see section 7).

The risk assessment for flupyradifurone (including the product ‘Sivanto SL 200’) and metabolites BYI 02960-succinamide, flupyradifurone-azabicyclosuccinamide, 6-CNA and DFA indicated for all representative uses a low risk for fish (acute for parent and metabolites and chronic for the parent), a low risk for algae and a low risk for aquatic plants using FOCUS step 2 PECsw. For fish, algae and aquatic plants studies were not available for all the metabolites, however assuming that the metabolites were ten times more toxic than the parent a low risk can be shown for all the representative uses according to the GAP. The aquatic invertebrate risk assessment was discussed at the Pesticides Peer Review Expert Meeting 124 (December 2014). It was discussed if mayflies (*Ephemeroptera*) should be considered in the aquatic invertebrate risk assessment since mayflies seem to have a high sensitivity to a group of pesticides that flupyradifurone is related to. The experts concluded that not enough evidence was available to support such a requirement. The acute and chronic risk assessment for the metabolites BYI 02960-succinamide, flupyradifurone-azabicyclosuccinamide, 6-CNA and DFA using FOCUS step 2 indicated a low risk for all representative uses for aquatic invertebrates. For the metabolites the field use was considered to cover the glasshouse use. A low risk for aquatic invertebrates and flupyradifurone was also concluded for the representative use in lettuce in glasshouse. A high risk to aquatic invertebrates both acute and chronic for all field representative uses was indicated for flupyradifurone using FOCUS step 3. Further refinements were performed using FOCUS step 4, assuming drift reducing nozzles (90 % drift reduction and no non-spray buffer zone) or assuming drift reducing nozzles (75 % drift reduction) in combination with non-spray drift buffer zone and/or non-spray vegetated filter strips. These exposure mitigations indicated a low risk for flupyradifurone for the representative use in hops. The risk assessment for flupyradifurone for the representative field uses in lettuce still indicated a high risk at FOCUS step 4 level. Therefore a data gap was identified (see section 7).

A number of laboratory and higher tier studies were available for honey bees. In addition to the acute tests, chronic toxicity studies (10-day feeding test) were available for the active substance and for the metabolites difluoroacetic acid (DFA), difluoroethyl-amino-furanone (DFEAF), 6-chloronicotinic acid (6-CNA), 6-chloro-picolylalcohol and BYI02960-hydroxy. In addition, a chronic toxicity study on honeybee larvae was available for flupyradifurone with a 3-day exposure period. Although some uncertainties for the chronic toxicity studies (adult and larvae) were noted during the peer-review, the following conclusions could be made: The acute and the chronic toxicity of flupyradifurone is comparable, the sensitivity of adult bees and larvae to flupyradifurone is comparable, and it is likely that the above mentioned metabolites are less toxic to bees than flupyradifurone. The risk assessment – considering the acute toxicity (HQ approach with a trigger of 50) – resulted in a low risk from contact exposure for the representative uses. However a high risk from the oral route of exposure could not be excluded. The available higher tier studies (5 reliable semi-field, 2 field studies and a feeding study under semi-field/field conditions) were discussed at the Pesticides Peer Review Expert Meeting 124 (December 2014). In the feeding study the bees were foraging on spiked food for a 6-week period and in the other studies the bees were foraging on an attractive crop during full flowering. The spray applications were made in the flowering period. With the exception of two semi-field studies, the application rate was higher (about 200 g flupyradifurone/ha) than the application rates for the representative uses in lettuce and hop. Moreover, they were combined with several other applications in earlier crop stages. Some deviations from the control in forager mortality, flight intensity, brood development or in hive weight were noted in some studies. The experts agreed that these observations indicated that some slight, transient treatment related effects might occur. Some sub lethal effects (intoxicated bees) were also observed in some studies. However, as an overall conclusion, the experts agreed that the data set indicated no adverse acute or long-term effects to honey bee colonies including assessments for over-wintering. Therefore the risk to honey bees was considered as low for the representative uses of flupyradifurone.

An acute contact test was available on bumble bees, which, compared to the data available for honey bees, did not indicate higher sensitivity to flupyradifurone. However, this single study was not considered to be robust enough to underpin a conclusion for wild pollinators.

On the basis of the standard tier 1 laboratory tests and the available extended laboratory tests, a high in-field and off-field risk to non-target arthropods was indicated for the representative uses. Aged residue studies on two sensitive species were also available. The results of these studies indicated a potential for re-colonisation of the in-field area within one year. However, a low off-field risk could not be demonstrated with the laboratory data for the representative uses. Therefore two field studies, designed to investigate the potential for recovery of off-field habitats were available. These field studies and the risk assessments were discussed in the Pesticides Peer Review Expert Meeting 124. Although some uncertainties related to the methodology used in these studies were noted, the experts agreed on a NOER value derived from these field studies. The off-field risk assessments were updated using this agreed NOER. These assessments indicated that no adverse effect on off-field populations is expected with appropriate risk mitigation measures (i.e. spray drift mitigation). Therefore, a low risk to non-target arthropods was concluded for the representative uses provided that an appropriate risk mitigation measures is applied.

Laboratory studies on earthworms, soil mites, collembola and soil microorganisms were available. In addition, two field litter bag tests were also available. Based on the results of these studies, the risk to earthworms and non-target soil macro and microorganisms was assessed as low for the representative uses of flupyradifurone.

A low risk was concluded for non-target terrestrial plants and organisms involved in biological methods for sewage treatment on the basis of the available data and assessments.

As the RMS could not assess the potentially relevant studies published in the open literature, a data gap was set for a transparent study-by-study justification of the relevant studies found by the applicant during the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites

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**
flupyradifurone	Moderate to high persistence DT_{50} 40.5 – 210.3 days (20°C, pF 2 soil moisture, 40 % MWHC) European field dissipation studies DT_{50} 8.3 – 251 days.	The risk to soil dwelling organisms was assessed as low.
6-chloronicotinic acid (6-CNA)	Very low to moderate persistence DT_{50} 2.2 – 22.4 days (20°C, pF 2 soil moisture, 40 % MWHC	The risk to soil dwelling organisms was assessed as low.
difluoroacetic acid (DFA)	Moderate to medium persistence DT_{50} 32.0 - 73.6 days (20°C, pF 2 soil moisture, 40 % MWHC	The risk to soil dwelling organisms was assessed as low.

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**
flupyradifurone	High mobility in soil K_{Foc} 74.9 -132.2 mL/g	Yes (in 4 out of 7 scenarios for biennial application on hops; in 4 out of 7 scenarios for field annual application on lettuce; 4 out of 7 scenarios for field biennial application on lettuce and in 6 out of 7 scenarios for glasshouse application on lettuce)	Yes	Yes	A low risk to aquatic organisms was indicated in the situations where groundwater becomes surface water.
6-chloronicotinic acid (6-CNA)	High mobility in soil K_{Foc} 70 -129 mL/g	No	No data available, however no further assessments are triggered.	Insufficient data available, however assessment not triggered. Negative Ames test Rat oral LD_{50} > 5000 mg/kg bw	A low risk to aquatic organisms was indicated in the situations where groundwater becomes surface water.

Compound (name and/or code)	**Mobility in soil**	**>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)**	**Pesticidal activity**	**Toxicological relevance**	**Ecotoxicological activity**
difluoroacetic acid (DFA)	Very high mobility in soil K_{Foc} 1.7 -9.5 mL/g	Yes (in 7/7 scenarios for all representative uses and above 0.75 µg/L in 1 out of 7 scenarios for biennial application on hops; in 2 out of 7 scenarios for field annual application on lettuce; 4 out of 7 scenarios for field biennial application on lettuce and in 7 out of 7 scenarios for glasshouse application on lettuce.	No pesticidal activity.	No Negative Ames test, *in vitro* mammalian cells gene mutation and chromosome aberration tests Rat oral LD_{50} > 300 < 2000 mg/kg bw 14-d, rat NOAEL 51 mg/kg bw per day 90-d, rat NOAEL 12.7 mg/kg bw per day Reference values of parent are applicable to the metabolite	A low risk to aquatic organisms was indicated in the situations where groundwater becomes surface water.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
flupyradifurone	Risk assessment not finalised for aquatic organisms for the representative field uses in lettuce
6-chloronicotinic acid (6-CNA)	The risk to aquatic organisms was assessed as low.
difluoroacetic acid (DFA)	The risk to aquatic organisms was assessed as low.
BYI 02960-succinamide	The risk to aquatic organisms was assessed as low.
flupyradifurone-azabicyclosuccin-amide	The risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	**Toxicology**
flupyradifurone	Rat LC_{50} inhalation > 4.7 mg/L air/4h (nose-only), no classification required

7. Data gaps

This is a complete list studies to be generated, still ongoing or available but not peer reviewed that were 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 56 of the Regulation concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- Transparent study-by-study justification of the relevant studies found by the applicant during the search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2, 4 and 5).

- Assessment of the relevance of the individual impurities present in the technical specification in comparison with the toxicological profile of the parent compound (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2).

- Level 2 tests currently indicated in the OECD Conceptual Framework, noting that further tests might be necessary pending on the outcome, to address the potential for endocrine-mediated mode of action regarding the reproductive effects observed in a 2-generation reproductive toxicity in rats (reduced number of implantation sites and oestrus cycle, reduced litter size -reduced number of pups born and higher number of stillborn) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 2 and 5).

- Field rotational crop studies considering realistic plant back intervals for the crops considered and providing information on the flupyradifurone and DFA residue levels in soil are required. (relevant for the representative use on lettuce; submission date proposed by the applicant: unknown; see Section 3).

- Animal feeding studies conducted with the DFA metabolite are required (relevant for the representative use on lettuce; submission date proposed by the applicant: unknown; see Section 3).

- Information on the effect of water treatment processes on the nature of residues of the active substance and metabolites when surface water is abstracted for drinking water and metabolites when groundwater is abstracted for drinking water to address Article 4 (approval criteria for active substances) 3(b) of Regulation (EC) No 1107/2009 is needed. Probably in the first instance, a consideration of the processes of ozonation and chlorination would appear appropriate (relevant for all representative use evaluated; no submission date proposed by the applicant; see Section 4).

- Further information is required to address the long-term risk to small herbivorous mammals from dietary routes in lettuce (relevant for the representative field uses on lettuce; submission date proposed by the applicant: unknown; see Section 5).

- Further information is required to address the chronic risk to aquatic invertebrates (relevant for the representative field uses on lettuce; submission date proposed by the applicant: unknown; see Section 5).

7.2. Data gaps identified for the MRL application

- Documentation evidencing that an authorisation has been granted for the active substance by the national authorities in the exporting countries and GAPs and MRL values effectively adopted in the exporting countries should be provided. The assessment of the import tolerance proposals in the Evaluation Report (ER) part III is pending the submission of the information requested here above (relevant for all uses reported in the ER part III; submission date proposed by the applicant: unknown; see section 3.2).

- Field rotational crop studies considering realistic plant back intervals for the crops considered and providing information on the flupyradifurone and DFA residue levels in soil are required. (relevant for the uses on lettuce, tomato, pepper, eggplant, cucurbit edible peel and watermelon; submission date proposed by the applicant: unknown; see section 3).

- Animal feeding studies conducted with the DFA metabolite are required (relevant for the use on pome fruits and non-perennial crops listed in the MRL application; submission date proposed by the applicant: unknown; see section 3).

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

8.1. Particular conditions proposed for the representative uses evaluated

- Personal protective equipment (PPE) such as gloves during mixing and loading operations and gloves and impermeable coverall during applications have to be considered to ensure that operator exposure does not exceed the AOEL according to the UK POEM model for hand-held applications on lettuce (see section 2).

- Residue levels in animal matrices and in rotational crops not fully addressed and pending the submission of feeding studies conducted with the DFA metabolite and further rotational crop studies (see data gap).

- Mitigation measures comparable to a total reduction of 95 % (i.e. spray drift and runoff) were needed to address the risk for aquatic organisms for the representative use in hops (see Section 5).

- Mitigation measures comparable to the effects of a 30-metres non-spray buffer zone for hops or 5-metres non-spray buffer zone for field uses lettuce were needed to address the risk for non-target arthropods (see Section 5).

8.2. Particular conditions proposed for the MRL application

- Having regard to the application rates recommended for the uses under consideration in the MRL application (up to 2x 100 g/ha on grapes, 2x 125 g/ha on lettuce, 2x 200 g/ha on pome fruits and 2x 225 g/ha on fruiting vegetables), potential for active substance flupyradifurone to exceed the parametric drinking water limit of 0.1µg/L in groundwater should be evaluated for all uses reported in the MRL application.

- Residue levels in animal matrices and in rotational crops not fully addressed and pending the submission of feeding studies conducted with the DFA metabolite and further rotational crop studies (see data gap).

9. Concerns

9.1. Concerns for the representative uses evaluated

9.1.1. 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 in accordance with Article 29(6) of the Regulation and as set out in

Commission Regulation (EU) No 546/2011[9] 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. Flupyradifurone is not classified or proposed to be classified as carcinogenic or toxic for the reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008 (no harmonised classification is currently available), and therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. However, an endocrine-mediated mode of action could not be ruled out regarding the reproductive effects observed in the multigeneration toxicity study (reduced number of implantation sites and oestrus cycle, reduced litter size -reduced number of pups born and higher number of stillborn) and the potential for endocrine disrupting effects of flupyradifurone could not be finalised (see sections 2 and 5).

2. The consumer risk assessment is not finalised with regard to the unknown nature of residues that might be present in drinking water consequent to water treatment following abstraction of surface water that might contain the active substance or metabolites and groundwater that might contain metabolites.

3. The long-term risk to small herbivorous mammals from the field uses in lettuce could not be finalised

4. The chronic risk to aquatic invertebrates from the field uses in lettuce could not be finalised

9.1.2. 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 in accordance with Article 29(6) of the Regulation and as set out in Commission Regulation (EU) No 546/2011, 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.

5. The active substance flupyradifurone has a high potential to exceed the parametric drinking water limit of 0.1µg/L in groundwater as represented by the 80th percentile annual average concentration moving below 1m depth, in geoclimatic situations represented by the FOCUS scenarios in hops (4 out of 7 scenarios), field lettuce (4 out of 7 scenarios) and protected lettuce (6 out of 7 scenarios).

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[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.

9.1.3. 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.)

Representative use		**Hops field Biennial application**	**Lettuce field Biennial application** (1 application per 24 months)	**Lettuce field** (1 application per 12 months)	**Lettuce glasshouse** (2 applications per 12 months)
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				X
	Assessment not finalised	X^{2}	X^{2}	X^{2}	
Risk to wild non target terrestrial vertebrates	Risk identified				
	Assessment not finalised		X^{3}	X^{3}	
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^{4}	X^{4}	
Groundwater exposure active substance	Legal parametric value breached	X (4/7)^{5}	X (4/7)^{5}	X (4/7)^{5}	X (6/7)^{5}
	Assessment not finalised				
Groundwater exposure metabolites	Legal parametric value breached				
	Parametric value of 10µg/L breached				
	Assessment not finalised				
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.

9.2. Concerns for the MRL applications

9.2.1. Issues that could not be finalised

- None

9.2.2. Concerns relating to identified consumer risk

No chronic or acute risks have been identified for consumers, with regard to the EU uses under consideration in the MRL application.

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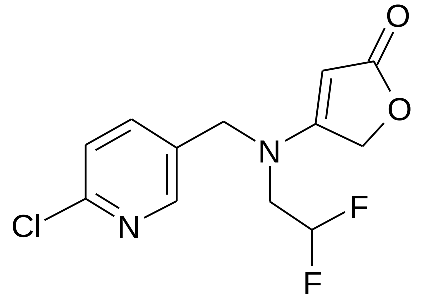
APPENDICES

Appendix A – List of end points for the active substance and the representative formulation

Active substance (ISO Common Name)	Flupyradifurone
Function (e.g. fungicide)	Insecticide

Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	4-[(6-chloro-3-pyridylmethyl)(2,2-difluoroethyl)amino]furan-2(5H)-one
Chemical name (CA)	4-[[(6-chloro-3-pyridinyl)methyl](2,2-difluoroethyl)amino]-2(5H)-furanone
CIPAC No	not allocated
CAS No	951659-40-8
EEC No (EINECS or ELINCS)	not assigned
FAO Specification (including year of publication)	not applicable
Minimum purity of the active substance as manufactured (g/kg)	Min. 960 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	open
Molecular formula	C12 H11Cl F2 N2 O2
Molar mass	288.68 g/mol
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity)	69.0 °C (99.4%)
Boiling point (state purity)	No boiling point; decomposition occurred at 270°C (99.4%)
Temperature of decomposition	Decomposition occurred at the temperature range 270 – 355 °C (99.4%)
Appearance (state purity)	white powder with weak, not characteristic odour (99.4%)
Relative density (state purity)	D420 = 1.43 (99.4%)
Surface tension	69.1 mN/m at 20°C (97.6%)

Vapour pressure (in Pa, state temperature)	9.1 x 10-7 Pa at 20 °C 1.7 x 10-6 Pa at 25 °C 2.6 x 10-5 Pa at 50 °C (extrapolated, 99.9%)

<table>
<tr><td>Henry’s law constant (Pa m3 mol-1)</td><td>8.2 x 10-8 Pa x m3 x mol-1 at 20 °C</td></tr>
<tr><td>Solubility in water (g/L or mg/L, state pH and temperature)</td><td>pH 4 (buffer) 3.2 g/L at 20°C
pH 9 (buffer) 3.0 g/L at 20°C
In distilled water:
pH 7 3.2 g/L at 20°C (99.4%)</td></tr>
<tr><td>Solubility in organic solvents (in g/L or mg/L, state temperature)</td><td>
<table>
<tr><td></td><td>[g/L at 20 °C] (99.4%)</td></tr>
<tr><td>methanol</td><td>> 250</td></tr>
<tr><td>heptane</td><td>0.0005</td></tr>
<tr><td>toluene</td><td>3.7</td></tr>
<tr><td>dichloromethane</td><td>> 250</td></tr>
<tr><td>acetone</td><td>> 250</td></tr>
<tr><td>ethylacetate</td><td>> 250</td></tr>
<tr><td>dimethyl sulfoxide</td><td>> 250</td></tr>
</table>
</td></tr>
<tr><td>Partition coefficient (log POW, state pH and temperature)</td><td>At 25 °C, pH7 (99.4%)
<table>
<tr><td>Pow</td><td>log Pow</td></tr>
<tr><td>16</td><td>1.2</td></tr>
</table>
</td></tr>
<tr><td>Hydrolytic stability (DT50, state pH and temperature)</td><td>hydrolytically stable at ambient temperature in the range of pH 4 to pH 9.</td></tr>
<tr><td>Dissociation constant</td><td>No dissociation occurs in aqueous solutions in the pH-range 1< pH <12</td></tr>
<tr><td>UV / VIS absorption (max.) (if absorption >290 nm state ε at wavelength)</td><td>UV/Vis-spectrum: MeOH
<table>
<tr><td>pH</td><td>λmax</td><td>ε</td></tr>
<tr><td>7.0</td><td>213</td><td>9615.06</td></tr>
<tr><td></td><td>259</td><td>25800.49</td></tr>
<tr><td>2.0</td><td>214</td><td>9388.74</td></tr>
<tr><td></td><td>259</td><td>26576.75</td></tr>
<tr><td>10.0</td><td>213</td><td>9996.41</td></tr>
<tr><td></td><td>259</td><td>25954.64</td></tr>
</table>
ε: molar absorption coefficient, L/(mol x cm) (99.4%)</td></tr>
<tr><td>Flammability</td><td>not highly flammable</td></tr>
<tr><td>Explosive properties</td><td>not explosive</td></tr>
</table>

Classification and proposed labelling (Annex IIA, point 10) with regard to physical and chemical data	No classification is proposed

List of representative uses evaluated

Crop and/or situation (a)	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)	BBCH stage & season (j)	number min-max (k)	interval between applications (min)	g as/hL min-max	Water L/ha min-max	g as/ha min max		
Representative uses															
Hops	N-EU (residue zone)	Sivanto SL 200	F	Aphids Phorodon humuli	SL	200	spray	31-75 May-July.	1	n.a.	4.5-7.5	2000-3300	150	21	Biennial application proposed
Lettuce	N/S-EU (residue zone)	Sivanto SL 200	F	Aphids, Nasonovia ribisnigri	SL	200	spray	12-49 May-Oct	1	n.a.	12.5-25	500-1000	125	10	Max 1 application per 24 months
Lettuce	N/S-EU (residue zone)	Sivanto SL 200	F	Aphids, Nasonovia ribisnigr	SL	200	spray	41-49 May-Oct	1	n.a.	12.5-25	500-1000	125	3	Max 1 application per 12 months
Lettuce (soil bound)	N/S-EU (residue zone)	Sivanto SL 200	G	Aphids, Nasonovia ribisnigri,	SL	200	spray	12-49	2	10	12.5-25	500-1000	125	3	Max 2 applications per 12 months

Crop and/or situation (a)	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)	Con. as (i)	method kind (f-h)	BBCH stage & season (j)	number min-max (k)	interval between applications (min)	g as/hL min-max	Water L/ha min-max	g as/ha min-max		
MRL application															
Pome fruits (apple, pear)	NEU	Sivanto	F	Aphids, (psyllids)	SL	200	Spray	10 - 79	1	na	12-24	250-500 /mCH*	60 /mCH* max 180	14	Biennial application (Germany, Poland)
	NEU	Sivanto	F	Aphids, (psyllids)	SL	050	Spray	60 - 79	1-2	14	13.5-27	250-500 /mCH*	67.5 /mCH* max 200	14	Home & Garden use, treatment of only a small area of garden
	SEU	Sivanto	F	aphids, (psyllids)	SL	050	Spray	60 - 79	1	na	13.5-27	250-500 /mCH*	67.5 /mCH* max 200	14	Home & Garden use, treatment of only a small area of garden
Grapes	NEU	Sivanto	F	Leaf hoppers	SL	200	Spray	59 - 81	1	na	10-100	100-1000	100	14	Annual application
	SEU	Sivanto	F	Leaf hoppers	SL	200	Spray	57 - 81	1	na	10-100	100-1000	100	14	Annual application
	NEU & SEU	Sivanto	F	Leaf hoppers	SL	050	Spray	58 - 81	1-2	14	n.a.	n.a.	100		Home & Garden use, treatment of only a small area of garden

Crop and/or situation (a)	**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)	**Con. as (i)**	**method kind (f-h)**	**BBCH stage & season (j)**	**number min-max (k)**	**interval between applications (min)**	**g as/hL min-max**	**Water L/ha min-max**	**g as/ha min-max**		
Fruiting vegetables (tomatoes, eggplant, peppers)	n.a.	Sivanto	G	Aphids, Whiteflies	SL	200	Spray	12 - 87	1-2	10	15	750 /mCH* max. 1500	112.5 /mCH* max. 225	n.a.	Annual application
	SEU	Sivanto	F	Aphids, Whiteflies	SL	200	Spray	21 - 87	1	na	15-22.5	500-750	112.5	3	Annual application
	SEU	Sivanto	F	Aphids, Whiteflies	SL	050	Spray	12 - 87	1-2	14	15-22.5	500-750	112.5	3	Home & Garden use, treatment of only a small area of garden, annual application
Cucurbits (cucumbers, zucchini)	n.a.	Sivanto	G	Aphids, Whiteflies	SL	200	Spray	12 - 87	1-2	10	15	750/mCH* max. 1500	112.5/mCH* max. 225	3	Annual application
	SEU	Sivanto	F	Aphids	SL	200	Spray	21 - 87	1	na	15-22.5	500-750	112.5	3	Annual application
	SEU	Sivanto	F	aphids	SL	050	Spray	12 - 87	1-2	14	15-22.5	500-750	112.5	3	Home & Garden use, treatment of only a small area of garden, annual application
Watermelon	n.a.	Sivanto	G	Aphids, Whiteflies	SL	200	Spray	12 - 87	1-2	10	10-20	max 1500	112.5/mCH* max. 225	3	Annual applications
	SEU	Sivanto	F	Aphids	SL	200	Spray	21 - 87	1	na	15-22.5	500-750	112.5	3	Annual application
Lettuce	NEU SEU	Sivanto	F	Aphids	SL	050	spray	12 - 49	1-2	10	12.5-25	500-1000	125	3	Home & Garden use, treatment of only a small area of garden, annual applications

Remarks

in case of group of crops the Codex classification should be used	Kind, e.g. overall, broadcast aerial spraying, row, individual plant, between the plants
Outdoor of field use (F), or glasshouse application (G)	g/l or g/L
e.g. biting and sucking in insects, soil born insects, foliar fungi	Growth stage at last treatment
e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)	The minimum and maximum number of application possible under practical conditions of use must be provided
Use CIPAC/FAO Codes where appropriate	
All abbreviations used must be explained	PHI - Pre Harvest Interval
Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	Remarks may include: Extent of use/ economic importance/restrictions

*: mCH: meter canopy height

Methods of Analysis

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

Technical as (principle of method)	HPLC-UV at 225 nm
Impurities in technical as (principle of method)	HPLC-UV at 210/256 nm
Plant protection product (principle of method)	HPLC-UV at 280 nm

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Two separate residue definitions: 1) Flupyradifurone 2) DFA, expressed as DFA
Food of animal origin		Two separate residue definitions: 1) Flupyradifurone 2) DFA, expressed as DFA
Soil		Flupyradifurone
Water	surface	Flupyradifurone
	drinking/ground	Flupyradifurone
Air		Flupyradifurone

Monitoring/ Enforcement methods

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-MS/MS method 01330 with acetonitrile/water (4/1, v/v) with 2.2 mL/L formic acid extraction. LOQ 0.01 mg/kg for flupyradifurone for lettuce, wheat, orange, rape seed potato, and wheat. LOQ 0.05 mg/kg for hop. LOQ 0.02 mg/kg for DFA for lettuce, wheat, orange, rape seed potato, and wheat. LOQ 0.10 mg/kg for hop.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-MS/MS acetonitrile/water (4/1, v/v), with the addition of heptane in the cases of fat and milk. LOQ 0.01 mg/kg for flupyradifurone and LOQ 0.02 mg/kg for DFA in fat, liver, kidney, muscle, egg and milk.
Soil (principle of method and LOQ)	HPLC-MS/MS after extraction with acetonitrile. LOQ of 5 µg/kg for flupyradifurone
Water (principle of method and LOQ)	HPLC-MS/MS LOQ for flupyradifurone is 0.05 µg/L in drinking and surface water.
Air (principle of method and LOQ)	HPLC/MS-MS after extraction with acetonitrile. LOQ for flupyradifurone 7 µg /m3
Body fluids and tissues (principle of method and LOQ)	No methods required.

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	> 80 % based on comparison of patterns of excretion after oral and iv administrations, almost completely absorbed within 48 h
Distribution ‡	Widely distributed with highest concentrations in liver and kidney. Higher concentration also detected in GIT, blood, myocardium and several glands. Maximum plasma concentration was reached approx. 1 h after administration of a single low dose
Potential for accumulation ‡	No evidence for accumulation, supported by the low Pow of 1.2. A fast decline was observed for all organs and tissues (<LOQ seven days after administration)
Rate and extent of excretion ‡	Excretion was fast, mainly renal and almost completed after 24 h (approx. 77 – 97 % within 24 h and 82 – 100 % within 48 h); 75 – 90 % was excreted via urine within 48 h and 7 – 26 % was excreted via faeces
Metabolism in animals ‡	Moderately metabolised in the rat. The parent compound represents the predominant part of the radioactivity in urine. Main metabolites detected in urine (accounting for > 10 % of the dose administered) were BYI 02960-OH and BYI 02960-hippuric acid (only high dose male). Metabolites 6-CNA and DFA were detected in urine at levels > 5 % of the dose administered. Metabolic reactions: • hydroxylation followed by conjugation with glucuronic acid or sulfate, • cleavage of the difluoroethyl group forming BYI 02960-des-difluoroethyl, and difluoroacetic acid (DFA), • cleavage of the molecule at the pyridinylmethylene bridge forming 6-CNA, which was further conjugated with glycine to BYI 02960-hippuric acid and BYI 02960-difluoroethyl-amino-furanone. 6-CNA is considered a major metabolite in male rat but not in females
Toxicologically relevant compounds ‡ (animals and plants)	Flupyradifurone
Toxicologically relevant compounds ‡ (environment)	Flupyradifurone

Acute toxicity (Annex IIA, point 5.2)

Rat LD50 oral ‡	> 300 < 2000 mg/kg bw	H302
Rat LD50 dermal ‡	> 2000 mg/kg bw	
Rat LC50 inhalation ‡	> 4.7 mg/L air/4 h (nose only)	
Skin irritation ‡	Non irritating	
Eye irritation ‡	Slight redness of the conjunctivae, reversed	

	within 48 hours	
Skin sensitisation ‡	Not sensitising (LLNA)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Rat: ↓ bw gain, thyroid weight Mouse: ↓ bw gain, liver (↑ weight, clinical chemistry changes and histopathology) and kidney (↓ weight and histopathology) Dog: ↓ bw gain, clinical chemistry changes, ↑ relative kidney weight and skeletal muscles myofiber atrophy/degeneration	
Relevant oral NOAEL ‡	90-day, rat: 6.0 mg/kg bw per day 90-day, mouse: 81 mg/kg bw per day 90-day & 1-year, dog: 12 mg/kg bw per day	
Relevant dermal NOAEL ‡	28-day, rat: 500 mg/kg bw per day (highest dose tested)	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Flupyradifurone has no genotoxic potential	

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

Target/critical effect ‡	Rat: ↓ bw, bw gain, liver (hepatocellular centrilobular hypertrophy), and thyroid (colloid alterations) Mouse: liver (↑ weight and hepatocellular vacuolation/macrovacuolation) and kidney (↓ weight, atrophic/small)	
Relevant NOAEL ‡	15.8 mg/kg bw per day (2-year rat) 43 mg/kg bw per day (18-month mouse)	
Carcinogenicity ‡	Not carcinogenic in both rats (up to 80 mg/kg bw per day) and mice (up to 224 mg/kg bw per day)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental toxicity: decreased bw, body weight gain Reproductive toxicity: ↓ oestrous cycle number, ↓ litter size (reduced number of pups born and higher number of stillborn) and ↓ number of implantation sites Offspring toxicity: effects on pup weight, physical development	
Relevant parental NOAEL ‡	6.4 mg/kg bw per day	
Relevant reproductive NOAEL ‡	32 mg/kg bw per day	
Relevant offspring NOAEL ‡	6.4 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Maternal toxicity: decreased bw; increased liver weight Developmental toxicity:↑ short 13th costal cartilage (variation) Rabbit: Maternal toxicity: decreased bw gain No effects observed on the development	
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw per day Rabbit: 15 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rat: 50 mg/kg bw per day Rabbit: 40 mg/kg bw per day (highest dose tested)	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL: 35 mg/kg bw, based on piloerection and dilated pupils (m/f rats)	
Repeated neurotoxicity ‡	90-day, rat: Systemic toxicity: NOAEL: 29.4 mg/kg bw per day, based on ↓ body weight and food consumption, enlarged liver Neurotoxicity: No adverse effects, NOAEL: 143 mg/kg bw per day (highest dose tested)	
Delayed neurotoxicity ‡	No data available – not required	
Developmental neurotoxicity	Maternal and developmental toxicity NOAEL: 42.4 mg/kg bw per day based on decreased body weight gain Developmental neurotoxicity NOAEL: 42.4 mg/kg bw per day, based on slightly increased motor/locomotor activity and startle habituation	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Biokinetic study in the plasma of rats following 7-day exposure through the diet: Plasma concentrations were considered similar between the three times of blood collection for both sexes.
	28-day, rat immunotoxicity study: Systemic NOAEL of 50 mg/kg bw per day, based on ↓ bw and food consumption Immunotoxic NOAEL of 230 mg/kg bw per day (highest dose tested)

Studies performed on metabolites or impurities ‡	DFA (Difluoroacetic acid, BCS-AA56716, M44) Ames test: negative In vitro CHO/HGPRT: negative In vitro CA: negative Rat oral LD50: > 300 < 2000 mg/kg bw 14-day dietary rat: NOAEL = 51 mg/kg bw per day based on ↓ bw gain, 90-day dietary rat: NOAEL = 12.7 mg/kg bw per day, based on ↓ bw gain, slightly ↓ haematological parameters (Hb, MCV, Hct, MCH) and focal glandular erosion/necrosis of the stomach DFA unlikely to have genotoxic potential; Reference values of the parent are applicable to DFA DFEAF (difluoroethyl-amino-furanone (BCS-CC98193, M34) Ames test: negative In vitro CA: positive in absence of metabolic activation In vitro CHO/HGPRT: negative In vivo MNT: negative In vivo UDS: negative Rat, oral LD50 > 2000 mg/kg bw 14-day dietary rat: NOAEL = 135 mg/kg bw per day, based on reduced bw gain and clinical chemistry changes (↑ Chol) 28-day dietary rat: NOAEL = 243 mg/kg bw per day (highest dose tested) DFEAF unlikely to have genotoxic potential; Reference values of the parent are applicable to DFEAF CHMP (6-chloropyridin-3-ylmethanol, IM-O, M21) Ames test: negative Rat, oral LD50 in females = 1483 mg/kg bw 90-day dietary rat: NOAEL = 48.9 mg/kg bw per day, based on eosinophilic intranuclear inclusions in the proximal tubular epithelium of kidneys 6-CNA (6-chloronicotinic acid, IC-0, M27) Ames test: negative Rat, oral LD50 > 5000 mg/kg bw
Medical data ‡ (Annex IIA, point 5.9)	Limited as this is a new active ingredient

Summary (Annex IIA, point 5.10)	Value	Study	Uncertainty factor
ADI ‡	0.064 mg/kg bw per day	Rat, two-generation study	100
AOEL ‡	0.064 mg/kg bw per day	Rat, two-generation study	100*

ARfD ‡	0.15 mg/kg bw	Rabbit, developmental study	100

*oral absorption is >80%, correction for oral absorption not necessary.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Sivanto SL 200 (200 g flupyradifurone/L SL formulation)	Based on human in vitro absorption values corrected for the large variation: 0.4 % at 200 g/L 3 % at 0.625 g/L 8 % at 0.1 g/L 17 % at 0.045 g/L (calculated pro rata)

Exposure scenarios (Annex IIIA, point 7.2)

Operators

	% AOEL without PPE	% AOEL with PPE
Hops (application rate: 0.150 kg flupyradifurone/ha) Mechanical upward spraying, field		
UK-75th	42.9 %	29.0 %
DE-GM	53.1 %	49.7 %
Lettuce (application rate: 0.125 kg flupyradifurone/ha) Mechanical downward spraying, field		
UK-75th	50.5 %	7.7 %
DE-GM	20.0 %	15.9 %
Lettuce Manual downward spraying, field		
UK-75th	119.3 %	21.8 %
Lettuce Manual downward spraying, (indoor)		
Dutch greenhouse model	97.7	12.3

Workers	exposure up to 46.1 % of the AOEL, without PPE (EUROPOEM II)
Bystanders	exposure up to 5.8 % of the AOEL (EUROPOEM II)
Resident	Exposure up to 0.58 % of the AOEL (German model for the child)

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

Substance	Flupyradifurone
Harmonised classification - Annex VI of Regulation (EC) No 1272/2008[10] (CLP Regulation)	Currently not listed

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[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

RMS/peer review proposal [11]	Warning, GHS07: Acute Tox. 4, H302 'harmful if swallowed'

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

Plant groups covered	**Foliar application:** - Fruit apple, - Pulses/oilseeds cotton - Cereals rice **Soil application:** - Fruit Tomato (soil drench) - Root/tuber Potato (in furrow spray at planting) - Cereals Rice (soil granule at planting) **Seed treatment:** - Root/Tuber Potato
Rotational crops	Turnips, wheat, Swiss chard
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Hydrolysis (pasteurisation/boiling/sterilisation)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Parent flupyradifurone is stable, no information on major metabolites DFA and DFEAF
Plant residue definition for monitoring	Two separate residue definitions : 1) Flupyradifurone 2) DFA (expressed as DFA)
Plant residue definition for risk assessment	Sum flupyradifurone and DFA expressed as flupyradifurone
Conversion factor (monitoring to risk assessment)	not appropriate

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

Animals covered	Laying hen, lactating goat
Time needed to reach a plateau concentration in milk and eggs	Eggs: 6 days, confirmed by feeding study Milk: 9 days, confirmed by cattle feeding study
Animal residue definition for monitoring	Two separate residue definitions : 1) Flupyradifurone 2) DFA (expressed as DFA)
Animal residue definition for risk assessment	sum of flupyradifurone and DFA, expressed in flupyradifurone
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

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

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

Field rotational crop studies in N & SEU at 200 g/ha on bare soil (25-30 day PBI) or on lettuce as primary crop (61-145 and 266-329 day PBI). Flupyradifurone (F; mg/kg flupyradifurone equivalent) and DFA (D; mg/kg DFA equivalent) residue levels in rotational crops at maturity:

25 to 30 day PBI

carrot/turnip root:	F: 4 <0.01 D: 0.01, 0.02, 0.02, 0.03
Lettuce:	F: 2< 0.01, 0.01, **0.03** D: <0.01, 0.01, 0.02, **0.04**
Barley grain:	F: 3x <**0.01** D: 0.03, 0.11, **0.21**
Barley straw:	F: <0.01, 0.01, 0.02, 0.04 D: <0.02, 0.02, 0.04, 0.11

65 to 145 day PBI:

carrot/turnip root:	F: 4 <0.01 D: <0.01, 3x 0.01
Lettuce:	F: 3< 0.01, 0.01 D: 3x <0.01, 0.03
Barley grain:	F: 4x <0.01 D: 0.01, 0.03, 0.03, 0.09
Barley straw:	F: 3x <0.01, 0.02 D: 3x <0.02, 0.03

266 to 329 day PBI

carrot/turnip root:	F: 4 <0.01 D: <0.01, 3x 0.01
Lettuce:	F: 4< 0.01 D: 3x <0.01, 0.02
Barley grain:	F: 4x <0.01 D: 0.02, 0.03, 0.03, 0.12
Barley straw:	F: 4x <0.01 D: 3x <0.02, 0.06

Field rotational crop trials in NEU and SEU at 2x 125 g/ha on bare soil at 30 day PBI. Flupyradiforone <0.01 mg/kg in all plant matrices. DFA levels (DFA equivalent):

- Potato:	0.01, 0.01, 0.06, **0.08**
- Leek:	0.01, 0.01, 0.03, **0.08**
- Cucumber:	0.02, 0.09, 0.11, **0.14**
- Onion:	0.01, 0.02, 0.02, **0.05**
- Bean (legume):	0.09, 0.13, 0.19, **0.37**
- Peas (pulses):	0.22, 0.33, 0.70, **0.77**
- Winter rape:	0.02, 0.02, 0.03, **0.05**

Default MRLs for rotational crops, based on the HR values highlighted in bold.

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

Flupyradifurone DFEAF, and DFA stable when stored frozen (≤-20°C) for at least 18 months in :

- high acid (orange)
- high water (spinach, sugar cane and tomato)
- high starch (wheat grain)
- high protein (bean seed)
- and high oil matrices (soybean seed)
- specific matrix (coffee bean)

DFA is stable in animal fat, kidney, liver, and muscle for at least 43 days, when stored frozen at (≤-20°C).

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

	Ruminant:	**Poultry:**	**Pig:**
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	Yes Flup.: 0.20/0.20 DFA: 2.05/2.40(a) dairy/beef cattle (mg/kg DM)	Yes Flup.: 0.06 DFA: 1.27(a) mg/kg DM	Yes Flup.: 0.19 DFA: 2.36(a) mg/kg DM
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues.	Yes	Yes	Yes
	Feeding studies **Ruminants (lactating cow):** - Flupyradifurone: 4.8 mg /kg DM (16N) - DFA(b): 3.9 mg/kg DM (1.4N) **Laying hens**: - Flupyradifurone : 1.5 mg /kg DM (28N) - DFA(c): 0.5 mg/kg DM (0.4N) Residue levels in matrices: Mean (max) **expressed as mg/kg flupyradifurone equivalent.**		
Muscle	F: 0.04 (0.05) DFA: 0.39 (0.47)	F: <0.01 (<0.01) DFA: 0.08 (0.10)	-
Liver	F: 0.15 (0.17) DFA: 0.39 (0.51)	F: <0.01 (<0.01) DFA: 0.10 (0.11)	-
Kidney	F: 0.16 (0.22) DFA: 0.56 (0.69)	No data	-
Fat	F: 0.02 (0.03) DFA: 0.39 (0.56)	F: <0.01 (<0.01) DFA: 0.03 (0.04)	-
Milk	F: 0.02 (0.026) DFA: 1.43 (0.241)		
Eggs		F: <0.01 (<0.01) DFA: 0.047 (0.051)	

(a): DFA expressed as flupyradifurone equivalent

(b): Animals dosed with flupyradifurone at a level of 135 mg/kg DM, supposed by the applicant to be equivalent to a DFA feeding rate of 3.9 mg/kg (expressed as fluopyradifurone), assuming that animal exposure to DFA is related to the absolute ratio DFA/flupyradifurone of 2.9% observed in tissues, organs and excreta.

(c): Animals dosed with flupyradifurone at a level of 6.5 mg/kg DM, supposed by the applicant to be equivalent to a DFA feeding rate of 2.1 mg/kg (expressed as fluopyradifurone), assuming that animal exposure to DFA is related to the absolute ratio DFA/flupyradifurone in tissues, organs and excreta of 32.1%.

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 **(Trial GAPs)**	Region/ Indoor	Supervised residue trials results **(mg/kg)** F: **flupyradifurone (expressed as flupyradifurone)** D: **difluoroacetic acid (expressed as DFA)** S: **Flupyradifurone + DFA (expressed as flupyradifurone)**	Recommendations/Comments	MRL proposals		HR **(mg/kg)**	STMR **(mg/kg)**
				Flupyr	**DFA**		
Representative uses							
Lettuce **(2x 125 g/ha, PHI 3 d)**	**Indoor**	**F**: 0.73; 1.4; 1.8; 2.0; 2.1; 2.5; 2.6; 3.5; 6.0 **D:** 0.020; <0.007; 0.007; <0.007; 0.007; 0.010; 0.012; <0.007; 0.010, 0.012 **S:** 0.79; 1.42; 1.82; 2.02; 2.12; 2.53; 2.64; 3.52; 6.04	MRL_{OECD}: 8.6/9 Open leaf varieties underlined MRL_{OECD}: 0.06/0.07 Acute concern (108 % ARfD). MRLs not proposed	**-**	**-**	6.04	2.12
Lettuce (1x 125 g/ha, PHI 10 d)	NEU	**F:** 0.08; 0.11; 0.13; 0.19 0.20; 0.25; 0.37; 0.57; 0.80 **D:** 5x <0.007, 0.009, <0.007, 0.016, <0.007 **S:** 0.10; 0.13; 0.15; 0.21; 0.22; 0.28; 0.39; 0.62; 0.82	**Similar trials as above (samples collected 9-11 days after the 1st application, just before the 2nd application). NEU and SEU datasets similar (U-Test, 5%), MRL derived from merged data.** **MRL_{OECD}: 1.3/1.5** **MRL_{OECD}: 0.03/0.03 (DFA)**	1.5	0.03	0.82	0.25
	SEU	**F:** 2x 0.04; 0.05; 0.11; 0.29; 0.38; 0.43; 0.55; 0.80 **D:** 2< 0.007, 0.010, 0.010, <0.007, 0.010, 0.015, 0.017, 0.007 **S:** 2x 0.06; 0.08; 0.14; 0.31; 0.41; 0.48; 0.60; 0.82					
Lettuce (1x 125 g/ha, PHI 3 d)	N & SEU	No trials submitted in support to the representative use defined in NEU and SEU as 1 application at 125 g/ha, (BBCH 41-49), PHI 3 days					
Hops (dry cones) (1x120 g/ha, PHI 21 d)	NEU	**F:** 0.31, 0.43, 0.48, 0.77, 0.90, 1.10, 1.80, 2.0 **D:** 3x <0.07; 0.09; 0.07; 0.13; 0.17 ; 0.09 **S:** 0.51, 0.63, 0.68, 1.05, 1.11, 1.50, 2.27, 2.30	**MRL_{OECD}: 3.7/4** **MRL_{OECD}: 0.24/0.3 (DFA)**	**4**	**0.3**	**2.3**	**1.08**

Crop **(Trial GAP)**	Region/ Indoor **(a)**	Supervised residue trials results **(mg/kg)**[(b)] F: **flupyradifurone (expressed as flupyradifurone)** D: **difluoroacetic acid (expressed as DFA)** S: **Flupyradifurone + DFA (expressed as flupyradifurone)**	Recommendations/Comments[(c)]	MRL proposals		HR[(d)] **(mg/kg)**	STMR[(e)] **(mg/kg)**
MRL application (EU uses)							
Lettuce **(2x 125 g/ha, PHI 3 d)**	**NEU**	**F:** 0.11; 0.37; 0.43; 0.58; 0.68; 0.83; 1.0; 1.5; 2.9 **D:** 2x <0.007;0.009; 4x <0.007; 0.008; 0.032 **S:** 0.13; 0.39; 0.46; 0.60; 0.70; 0.83; 1.02; 1.52; 3.00	NEU and SEU datasets not significantly different (U-Test, 5%). MRL derived from the merged data MRL_{OECD}: 4.3/5 MRL_{OECD}: 0.04/0.05(DFA)	**5**	**0.05**	**3.18**	**0.80**
	SEU	**F:** 0.35; 0.40; 0.48; 0.72; 1.1; 1.5; 2.1; 2.7; 3.1 **D:** 0.010; 0.007; 0.017; 0.012; <0.007; 0.026; 0.017; 0.010; 0.028 **S:** 0.38; 0.42; 0.53; 0.76; 1.1 2; 1.58; 2.15; 2.73; 3.18					
Apple (2x 68 g/mCH PHI 14 d)	NEU	**F:** 0.051, 0.060, 0.064, 0.070, 0.070, 0.090, 0.120, 0.140, 0.140, 0.320 **D:** 0.023, <0.007, 0.007, 0.007, <0.007, <0.007, 0.009, 0.010, 0.010, 0.015 **S:** 0.120, 0.080, 0.084, 0.090, 0.090, 0.110, 0.141, 0.170, 0.170, 0.359	6 SEU trials (out of 10) were not conducted according to the SEU GAP (1x 68 g/mCH) but according to the NEU GAP. Since NEU and SEU datasets (2 applications) are not significant different (U-Test, 5%), both were pooled together to derive the MRL proposal for apple: MRL_{OECD}: 0.37/0.4 MRL_{OECD}: 0.03/0.03 (DFA)	**0.4**	**0.03**	**0.359**	**0.115**
	SEU	**F:** 0.040, 0.050, 0.060, 0.070, 0.100, 0.110 **D:** 0.010, 0.013, 0.010, 0.007, 0.013, 0.017 **S:** 0.060, 0.090, 0.080, 0.090, 0.140, 0.160					
Grape (2x 100 g/ha, PHI 14 d)	NEU	**F:** 0.11; 0.18; 0.18; 0.20; 0.21; 0.26; 0.38; 0.42; 0.46 **D:** 0.010; 3x 0.020; 0.023; 0.030; 0.031; 0.037; 0.040 **S**: 0.17, 0.25, 0.23, 0.22, 0.24, 0.33, 0.45, 0.50, 0.51	MRL_{OECD}: 0.8/0.8 MRL_{OECD}: 0.08/0.08 (DFA) Residue levels significant higher in NEU (U-Test, 5%)	**0.8**	0.08	**0.51**	**0.25**
	SEU	**F:** 0.05, 0.06, 0.07, 0.10, 0.10, 0.11, 0.12, 0.22 **D:** 0.007, 0.019, 0.037, 0.086, 0.033, 0.020, 0.027, 0.017 **S:** 0.07, 0.11, 0.15, 0.16, 0.18, 0.18, 0.24, 0.27	MRL_{OECD}: 0.32/0.4 MRL_{OECD}: 0.13/0.15 (DFA)	0.4	**0.15**		

Crop **(Trial GAP)**	Region/ Indoor **(a)**	Supervised residue trials results **(mg/kg)**[b] F: **flupyradifurone (expressed as flupyradifurone)** D: **difluoroacetic acid (expressed as DFA)** S: **Flupyradifurone + DFA (expressed as flupyradifurone)**	Recommendations/Comments[c]	MRL proposals		HR[d] **(mg/kg)**	STMR[e] **(mg/kg)**
MRL application (EU uses)							
						0.27	0.17
Tomato (2x 113 g/mCH, PHI 3 d)	indoor	**F:** 0.060, 0.070, 0.080, 0.082, 0.120, 0.250, 0.270, 0.360 **D:** 5x <0.007, 0.009, 0.018, 0.037 S: 0.080, 0.090, 0.100, 0.102, 0.140, 0.270, 0.304, 0.470	MRL$_{OECD}$: 0.62/0.7 MRL$_{OECD}$: 0.05/0.06 (DFA)	**0.7**	**0.06**	**0.47**	**0.121**
Tomato (2x 113 g/ha, PHI 3 d)	SEU	**F:** 0.010, 0.033, 0.034, 0.050, 0.050, 0.057, 0.062, 0.080 **D:** <0.007, <0.007, 0.009, 0.007, <0.007, 0.012, 0.013, 0.010 **S:** 0.030, 0.053, 0.054, 0.070, 0.070, 0.086, 0.085, 0.100	MRL$_{OECD}$: 0.13/0.15 MRL$_{OECD}$: 0.02/0.02 (DFA)	0.15	0.02	0.10	0.07
Pepper (2x 113 g/mCH, PHI 3 d)	Indoor	**F:** 0.09, 0.12, 0.14, 0.15, 0.20, 0.24, 0.31, 0.57 **D:** 0.013, 0.033, 0.011, 0.053, 0.029, 0.012, 0.047, 0.018 **S:** 0.108, 0.146, 0.173, 0.212, 0.263, 0.260, 0.331, 0.592	MRL$_{OECD}$: 0.85/0.9 MRL$_{OECD}$: 0.09/0.1 (DFA)	**0.9**	**0.1**	**0.592**	**0.236**
Pepper (2x 113 g/ha, PHI 3 d)	SEU	**F:** 0.02, 0.03, 0.08, 0.08, 0.09, 0.12, 0.21, 0.22 **D:** 0.007, 0.011, 0.010, 0.007, 0.015, 0.015, 0.010, 0.007 **S:** 0.040, 0.067, 0.110, 0.100, 0.133, 0.165, 0.240, 0.240	MRL$_{OECD}$: 0.4/0.4 MRL$_{OECD}$: 0.09/0.1 (DFA)	0.4	0.08	0.24	0.12
Cucumber (2x 113 g/mCH PHI 3 d)	indoor	**F:** 0.100, 0.120, 0.130, 0.150, 0.160, 0.180, 0.190, 0.190 **D:** 0.050, 0.050, 0.073, 0.070, 0.156, 0.086, 0.123, 0.033 **S:** 0.163, 0.230, 0.280, 0.320, 0.460, 0.320, 0.310, 0.270	MRL$_{OECD}$: 0.46/0.5 MRL$_{OECD}$: 0.24/0.0.3 (DFA)	0.5	0.3	0.46	0.30
Cucumber & gherkin (2x 113 g/ha, PHI 3 d)	SEU	**F:** 0.020, 0.030, 0.042, 0.046, 0.060, 0.060, 0.270, 0.310 **D:** 0.023, 0.067, 0.043, 0.033, 0.047, 0.067, 0.073, 0.223 **S:** 0.060, 0.090, 0.106, 0.091, 0.150, 0.260, 0.358, 0.660	MRL$_{OECD}$: 0.57/0.6 MRL$_{OECD}$: 0.33/0.4 (DFA) Trials on gherkins underlined	**0.6**	**0.4**	**0.660**	**0.13**
Melons (2x 113 g/ha PHI 3 d)	indoor	**F:** 0.014, 0.027, 0.033, 0.033, 0.037, 0.049 (0.09, 0.12, 0.13) **D:** 0.037, 0.027, 0.037, 0.093, 0.040, 0.080, (0.03, 0.02, 0.06) **S** (pulp): 0.050, 0.054, 0.068, 0.071, 0.093, 0.100 (0.14, 0.16, 0.21)	Within brackets, trials on climbing melons conducted at 250 g/ha (eq. to 113 g/mCH x 2 m), not considered as MRL requested for watermelons only and climbing varieties not relevant for	0.1	0.1	(pulp) 0.10	(pulp) 0.07

Crop **(Trial GAP)**	Region/ Indoor **(a)**	Supervised residue trials results **(mg/kg)**[(b)] F: **flupyradifurone (expressed as flupyradifurone)** D: **difluoroacetic acid (expressed as DFA)** S: **Flupyradifurone + DFA (expressed as flupyradifurone)**	Recommendations/Comments[(c)]	MRL proposals		HR[(d)] **(mg/kg)**	STMR[(e)] **(mg/kg)**
MRL application (EU uses)							
			watermelons.				
Melon (2x 113 g/ha, PHI 3 d)	SEU	**F**: <0.01, 0.010, 0.020, 0.021, 0.022, 0.027, 0.040, 0.050, 0.069 D: 0.027, 0.010, 0.010, 0.043, 0.037, 0.047, 0.027, 0.043, 0.083 S (pulp): 0.030, 0.030, 0.050, 0.063, 0.065, 0.069, 0.093, 0.100, 0.199	MRL for watermelons derived from SEU trials on melon. MRL_{OECD}: 0.11/0.15 MRL_{OECD}: 0.13/0.15 (DFA) Indoor and SEU datasets (excluding climbing varieties) similar (U-Test, 5%)	**0.15**	**0.15**	**(pulp) 0.199**	**(pulp) 0.065**

(a): NEU (Outdoor Northern Europe), SEU (Outdoor Southern Europe), Indoor or Import (country code).

(b) Individual residue levels considered for MRL calculation are reported in ascending order as following: 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.10, 0.15, 0.17
F: flupyradifurone residues levels expressed as flupyradifurone equivalent (mg/kg)
D: DFA residues levels (mg/kg) expressed as DFA equivalent (mg/kg)
S: Sum flupyradifurone + DFA expressed as flupyradifurone (residue definition for risk assessment)

(c): Statistical estimation of MRLs according to according to OECD methodology (unrounded/rounded values; OECD, 2011), extrapolations and any other useful information.

(d): HR: Highest value of the individual trial results according to the residue definition for risk assessment (Sum flupyradifurone + DFA expressed as flupyradifurone).

(e): STMR: Median value of the individual trial results according to the residue definition for risk assessment (Sum flupyradifurone + DFA expressed as flupyradifurone)..

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

Including representative uses and uses related to the MRL application

ADI	**0.064 mg/kg bw/d**
TMDI (% ADI) according to	
TMDI (% ADI) according to	
IEDI (% ADI) according EFSA PRIMo rev.2	Highest IEDI: 17% ADI ((WHO, cluster B)
NEDI (specify diet) (% ADI)	Not required
Factors included in IEDI	- STMR for primary crops - PF for beer (hops), - Default MRLs for rotational crops
ARfD	**0.15 mg/kg bw**
IESTI (% ARfD)	Highest IESTI: 57 % ARfD (Lettuce, DE Child) based on HR of 3.18 mg/kg in outdoor SEU trials.
NESTI (% ARfD) according to national (to be specified) large portion consumption data	See IESTI
Factors included in IESTI and NESTI	- HR for primary crops - PF for beer (hops), - Default MRL values for rotational crops

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

Crop (RAC) /processed product	**Number of studies**	**Processing factor** (PF)			**Conversion Factor**
		Individual values	**median PF**(a)		
			Flup.	DFA	
Lettuce/outer leaves	4	**F:** 1.6, 1.8, 1.8, 2.2 **D:** ≤LOQ	1.8	-	not applicable
Lettuce/inner head parts	4	**F:** 0.6, 0.7, 0.7, 0.8 **D:** ≤LOQ	0.7	-	
Lettuce/inner leaves	4	**F:** 0.1, 0.8, 1.0, 1.2, **D:** ≤LOQ	0.9	-	
Lettuce/washed inner leaves	4	**F:** 0.5, 0.6, 0.7, 0.8, **D:** ≤LOQ	0.6	-	
Hops/Beer	2	**F:** 0.005, 0.005 **D:** 0.03, 0.03	0.005	0.03	
Apple/Wet pomace	4	**F:** 1.4, 1.5, 1.7, 3.3 **D:** <LOQ	1.6	-	
Apple/Dry pomace	4	**F:** 4.6, 4.9, 5.0, 12 **D:** <LOQ	4.9	-	
Apple/Juice	4	**F:** 0.3, 0.4, 0.7, 1.5 **D:** <LOQ	0.5	-	
Apple/Sauce	4 1	**F:** 0.7, 0.8, 0.8, 1.8 **D:** 1.5	0.8	-	
Apple/Dry peeled fruit	1 1	**F:** 2.0 **D:** 1.5	-	-	
Grape/Red wine	2 1	**F:** 0.7, 0.7 **D:** 1.0	0.7	-	

Crop (RAC) /processed product	**Number of studies**	**Processing factor** (PF)			**Conversion Factor**
		Individual values	**median PF**[(a)]		
			Flup.	DFA	
Grape/White wine	2 1	**F:** 0.3, 0.4 **D:** 1.0	0.3	-	
Grape/Juice (pasteurised)	2	**F:** 0.5, 0.9 **D:** 1.0, 1.0	0.7	1.0	
Grape/Jelly	2	**F:** 0.2, 0.4 **D:** 0.7, 0.7	0.3	0.7	
Grape/Raisin	2 1	**F:** 2.1, 2.9 **D:** 2.3	2.5	-	
Tomato/Juice	3	**F:** 0.5, 0.6, 1.0 **D:** <LOQ	0.6	-	
Tomato/Puree	3 2	**F:** 1.4, 1.4, 3.0 **D:** 1.5, 2.0	1.4	1.8	
Tomato/Paste	3	**F:** 2.0, 4.0 **D:** 2.0, 1.5	3.0	1.8	
Tomato/Preserve	3	**F:** 0.4, 0.6, 1.4 **D:** <LOQ	0.6	-	
Tomato/Dried fruit	2	**F:** 2.0, 4.0 **D:** 2.5, 1.0	3.0	1.8	
Cucumber/Preserve	2	**F:** 0.5, 0.70 **D:** 0.8, 1.0	0.6	0.9	

(a): Median processing factors recommended for inclusion in Annex VI of Regulation (EC) No 396/2005

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

Code[(a)]	Commodity/Group	MRL proposals		Comments
		Flup.	DFA	
Plant commodities				
Representative uses				
0251020	Lettuce	5	0.05	Oudoor N & SEU
0700000	Hops	4	0.3	NEU
MRL application (MRL proposals based on the on uses of flupyradifurone on primary crops)				
0130000	Pome fruits	0.4	0.03	N & SEU
0151000	Grapes	0.8	0.15	N & SEU (wine and table grapes)
0231010	Tomatoes	0.7	0.06[(b)]	Indoor and SEU
0231020	Peppers	0.9	0.1[(b)]	Indoor and SEU
0231030	Eggplants	0.7	0.06[(b)]	Extrapolation from tomato
0232000	Cucurbits edible peel	0.6	0.4	Indoor and SEU
0233030	Watermelons	0.15	0.15	Indoor and SEU
0252010	Spinaches	no proposal		No GAP proposed in the application form
Rotational crops (default MRL proposals based on residues in rotational crops)				
0210000	Root/tuber vegetables	0.01 *	0.09	**Provisionally**, pending the submission of additional rotational crop field studies.
0220000	Bulb vegetables	0.01 *	0.06	
0230000	Fruiting vegetables	0.01 *	0.15	
0250000	Leafy vegetables	0.03	0.04	
0260000	Legume vegetables	0.01 *	0.4	
0270000	Stem vegetables	0.01 *	0.08	
0300000	Pulses	0.01 *	0.8	
0401000	Oilseeds	0.01 *	0.05	
0500000	Cereals	0.01 *	0.3	
Animal commodities				
101X010	Muscle	0.01 *	0.1	MRLs for swine, bovine, sheep, goat and horse products
101X020	fat	0.01 *	0.1	
101X030	Liver	0.01 *	0.1	
101X040	Kidney	0.01	0.15	

		*		
101X050	Edible offal	0.01 *	0.15	
1016010	poultry muscle	0.01 *	0.05	**All MRLs for animal products set Provisionally**, pending the submission of feeding studies on lactating cow and laying hen dosed with DFA and field rotational crop studies.
1016010	poultry fat	0.01 *	0.03	
1016010	poultry liver	0.01 *	0.1	
1020000	Milk	0.01 *	0.03	
1030000	Eggs	0.01 *	0.03	

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): Default rotational crop MRL of 0.15 mg/kg to be considered for tomatoes, peppers and eggplants

MRLs proposed at the LOQ, are annotated by an asterisk (*) after the figure.

Fate and behaviour

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

Mineralization after 100 days *	29.4-58.6% (n=4, PYM-14C BYI 02960) 20.2-57.4% (n=3, PYR-14C BYI 02960) 12.3-38.9% (n=6, FUR-14C BYI 02960) 25.9-42.3% (n=3, ETH-14C BYI 02960)
Non-extractable residues after 100 days *	12.5-16.8% (n=4, PYM-14C BYI 02960) 11.3-25.5% (n=3, PYR-14C BYI 02960) 16.4-34.1% (n=6, FUR-14C BYI 02960) 14.3-17.9% (n=3, ETH-14C BYI 02960)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	difluoroacetic acid (DFA, max. 33.9%) 6-chloronicotinic acid (6-CNA, max. 17.1%)

PYM (= pyrindinyl-methyl-14C-label), PYR (= pyridine-2,6-14C-label), FUR (= furanone-4-14C-label) and ETH (= ethyl-1-14C-label)
* at the end of the experiment at 120 days; n = number of soils tested

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

Mineralization after 100 days*	6.0-26.6% (n=3, PYR-14C BYI 02960) 15.9% (n=1, FUR-14C BYI 02960) 6.9% (n=1, ETH-14C BYI 02960) Formed at the aerobic phase
Non-extractable residues after 100 days*	12.9-17.2% (n=3, PYR-14C BYI 02960) 30.1% (n=1, FUR-14C BYI 02960) 15.2% (n=1, ETH-14C BYI 02960)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	DFA (max. 26.2%; mainly during aerobic phase) 6-CNA (max. 14.2%; mainly during aerobic phase)

* duration experiment 120 days, value at the end of the experiment; n = number of soils

Soil photolysis

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	no major metabolites mineralization 0.1-2.2% 8 d cont. irradiation bound residues 0.8-0.9% 8 d cont. irradiation DT50 (SFO) 99.6-109.3 d 8 d cont. irradiation 419.2->1000 d 8 d dark control

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

Parent	Aerobic conditions							
Soil type1 (Origin)	BYI 02960 label	pH (CaCl2)	t. oC / % MWHC	DT50 (d)	DT90 (d)	DT50 (d) 20˚C pF 2	χ2	Method of calculation
Sandy loam (AX)	PYM	6.4	20 / 55	63.4	443.3	169.1 *a	1.2	DFOP
Sandy loam (AX)	FUR	6.1	20 / 55	62.2	390.6	141.5 *b	1.6	DFOP

Loamy sand (AX)	ETH	6.2	20 / 55	62.0	538.1	210.3 *c	1.6	DFOP
Ax geometric mean				62.5	453.3	171.3		
Silt loam (HF)	PYM	6.5	20 / 55	52.4	209.3	54.4 **	0.6	DFOP
Silt loam (HF)	FUR	6.5	20 / 55	33.2	229.5	40.5 **	1.7	DFOP
Silt loam (HF)	ETH	6.5	20 / 55	34.1	329.8	43.0 **	2.3	DFOP
Silt loam (HF)	PYR	6.5	20 / 55	33.0	221.3	90.0 **	2.0	DFOP
HF geometric mean				37.4	243.3	54.0		
Loam (HN)	PYM	5.4	20 / 55	120.0	489.7	157.5 *d	1.2	DFOP
Silt loam (HN)	FUR	4.8	20 / 55	98.3	462.5	157.5 *e	2.0	DFOP
HN geometric mean				108.6	475.9	157.5		
Clay loam (DD)	PYM	7.4	20 / 55	56.4	265.1	60.1 **	1.7	DFOP
Silty clay (DD)	FUR	7.1	20 / 55	49.3	303.1	55.1 **	2.3	DFOP
Clay loam (DD)	ETH	7.1	20 / 55	33.9	649.6	38.6 **	1.9	DFOP
DD geometric mean				45.5	373.7	50.4		
Silt loam (SF)	FUR	6.5	20 / pF2.0-2.5	228	757	179.7 **	1.3	SFO
Silt loam (SF)	PYR	6.5	20 / pF2.0-2.5	242	898	166.4 **	0.7	DFOP
SF geometric mean				234.9	824.5	172.9		
Sandy loam (S)	FUR	7.0	20 / pF2.0-2.5	58.3	273	58.8 **	1.1	DFOP
Sandy loam (S)	PYR	7.0	20 / pF2.0-2.5	56.3	324	55.5 **	1.8	FOMC
Sanger (S) geometric mean				56.8	522.5	57.1		
Overall geometric mean				73.2	405.0	94.8		
Overall median				59.7	413.5	107.3		

1 USDA classification; * DFOP slow fase DT50 ; ** SFO for modelling DT50

Ax = Laacher Hof, HF = Hofchen an Hohenseh, HN = , DD = Dollendorf II SF = Springfield, S = Sanger soil

PYM (= pyrindinyl-methyl-14C-label), PYR (= pyridine-2,6-14C-label), FUR (= furanone-4-14C-label) and ETH (= ethyl-1-14C-label); a: k1 0.0438, k2: 0.0041, g 0.3822; b: k1 0.0650, k2: 0.0049, g 0.3312; c: k1 0.0546, k2: 0.0033, g 0.4023; d: k1 0.1031 , k2: 0.0044, g 0.1571; e: k1 0.1079, k2: 0.0044, g 0.2280

6-CNA	Aerobic conditions							
Soil type1	pH (CaCl2)	t. oC / % MWHC	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2	f.f.	χ2	Method of calculation
Sandy loam	5.8	20 / 45	2.9	9.7	2.9	-	8.5	SFO
Clay	7.4	20 / 45	2.2	7.4	2.2	-	6.9	SFO
Loam	7.0	20 / 45	5.3	17.5	5.3	-	8.5	SFO
Silt loam	6.5	20 / 55	3.1 3.0*	10.4 9.9*	- 3.0	- 0.266	17.0 15.4	FOMC-SFO DFOP-SFO
Sandy loam	7.0	20 / pF2.0-2.5	36.6 24.8*	121 82.4 *	- 22.4#	- 0.694	13.8 15.1	DFOP-SFO SFO-SFO
Geometric mean			5.2	17.4	4.7			
Arithmetic mean						0.480		

1 USDA classification; f.f. = formation fraction; # normalised to pF2 ; * not included in the geometric mean

DFA	Aerobic conditions							
Soil type1	pH (CaCl2)	t. oC / % MWHC	DT50 (d)	DT90 (d)	DT50 (d) 20°C pF2	f.f.	χ2	Method of calculation
Clay loam	7.1	20 / 55	44.9 32.0*	149.0 106.2 *	- 32.0	- 0.909	5.4 5.2	DFOP-SFO SFO-SFO
Loamy sand	6.2	20 / 55	73.6	244.5	73.6	0.590	8.4	SFO-SFO
Silt loam	6.5	20 / 55	67.4 37.8*	223.9 125.7 *	- 37.8	- 1.00	7.4 4.0	FOMC-SFO SFO-SFO
Geometric mean			60.6	201.3	44.7			
Arithmetic mean						0.833		

1 USDA classification; f.f. = formation fraction; # normalised to pF2 ; * not included in the geometric mean

Field studies

BYI 0960	Aerobic conditions									
Soil type (bare soil)	Location (country or USA state)	pH 1	Depth (cm)	DT50 (d) actual	DT90 (d) actual	χ2	Method of calculation	DT50 (d) Norm.	χ2	Method of calculation
Sandy loam	Germany	6.3	0-30	41.0a	749	7.5	DFOP	n.c.	n.r.	n.r.
Clay laom	UK	5.8	0-30	251b	>1000	7.5	DFOP	n.c.	n.r.	n.r.
Silt loam	Germany	6.3	0-30	42.8c	484	6.3	DFOP	n.c.	n.r.	n.r.
Clay loam	Italy	7.4	0-30	8.3d	279	7.1	DFOP	n.c.	n.r.	n.r.
Loam	Spain	5.9	0-30	22.6e	215	6.6	DFOP	n.c.	n.r.	n.r.
Loam	Germany	5.5	0-30	39.0f	579	11.3	DFOP	n.c.	n.r.	n.r.
Geometric mean								n.c.		

1 pH CaCl2; n.c. not calculated; n.r. not relevant

a: k1 0.0547, k2: 0.0021, g 0.5144; b: k1 31.6805, k2: 0.0015, g 0.2716; c: k1 0.0646, k2: 0.0035, g 0.4518; d: k1 0.1984 , k2: 0.0050, g 0.5989; e: k1 0.3350, k2: 0.0084, g 0.3960; f: k1 0.0295, k2: 0.0019, g 0.6993

pH dependence (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration	0.080 mg/kg PECplateau and 0.160 mg/kg PECplateau + PIEC for hops over 5 cm for perennial crops without tillage 0.0618 mg/kg PECplateau for lettuce over 20 cm and 0.2766 mg/kg PECplateau + PIEC for lettuce over 20 cm+5cm for the final year.

Laboratory studies

Parent	Anaerobic conditions							
Soil type	BYI 02960 label	pH (CaCl2)	t. oC / % MWHC	DT50	DT90 (d)	DT50 (d) 20°C pF2/10kPa	χ2	Method of calculation
Silt loam	PYR	6.4	20 / 55 *	581.8	>1000	n.c.	1.4	SFO

Silt loam	FUR	6.4	20 / 55 *	693.2	>1000	n.c.	1.3	SFO
Silt loam	ETH	6.4	20 / 55 *	631.0	>1000	n.c.	0.9	SFO
Silt loam geometric mean				633.7	>1000	n.c.		
Loamy sand	PYR	6.7	20 / 55 *	152	506	n.c.	11.9	SFO
Sandy clay loam	PYR	6.5	20 / 55 *	>1000**	>1000**	n.c.	n.r.	n.r.
Geometric mean				458.4	796.8	n.c.		

PYR (= pyridine-2,6-14C-label), FUR (= furanone-4-14C-label) and ETH (= ethyl-1-14C-label); n.c. not calculated; not relevant

* %MWHC before flooding at aerobic stage; ** no degradation observed DT50 and DT90 not calculated

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent BYI 02960					
Soil Type1	OC %	Soil pH (CaCl2)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam *	2.1	6.2	2.077	98.9	0.8445
Loam *	2.4	6.6	2.213	92.2	0.8682
Loam *	2.2	5.3	2.354	107.0	0.8643
Loam *	5.1	7.2	3.822	74.9	0.8648
Sandy loam	0.7	6.8	0.597	85.2	0.9021
Silt loam	1.9	6.5	2.512	132.2	0.8505
Arithmetic mean				98.4	0.8657
pH dependence, Yes or No			No		

1 USDA classification; * soils used for determination of 1/n in the time dependent sorption

Metabolite 6-CNA					
Soil Type1	OC %	Soil pH (CaCl2)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy Sand	2.54	6.2	1.027	70	1.0069
Silt loam	0.76	6.6	0.569	129	0.9706
Clay	2.05	7.5	0.833	70	0.8941
Clay loam	1.41	8.3	0.690	84	0.9262
Arithmetic mean				88.3	0.9495
pH dependence (yes or no)			No		

1 USDA classification

Metabolite DFA					
Soil Type1	OC %	Soil pH (CaCl2)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.4	6.5	1.74	9.5	0.9053
Loam	2.9	5.8	1.07	7.8	0.8013
Clay loam	4.5	7.4	1.78	8.2	0.9579
Sandy Loam	0.5	6.0	0.594	6.7	0.6902
Silty clay loam	1.7	6.5	0.274	1.7	0.8194
Arithmetic mean				6.8	0.8348
pH dependence (yes or no)			No		

1 USDA classification

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

Column leaching	Performed for Brazilian registration, not required for EU registration
Aged residues leaching ‡	Not performed, not required Leaching assessment based on batch adsorption values
Lysimeter/ field leaching studies ‡	Not performed, not required For parent substance and metabolites leaching based on batch adsorption values

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT50 (d): 0.02 (fast) and 462 (slow) Kinetics: DFOP (k1=34.66; k2=0.0015; g=0.27) Field or Lab: Field
Application data	Crop: hops lettuce (biennial application) lettuce (annual application) lettuce glasshouse(annual application) Depth of soil layer: 5 cm Soil bulk density: 1500 kg/m3 % plant interception: 60 for hops (BBCH stage 31-75) 25 for lettuce (BBCH stage 12-49) (biennial and glasshouse) 70 for lettuce (BBCH stage 41-49) (annual) Number of appl.: 1 field, 2 glasshouse Interval (d): 10 days for glasshouse lettuce Application rate(s): 150 g as/ha for hops 125 g as/ha for lettuce (field application and glasshouse)

PECsoil of BYI 02960 after application

		Hops		Lettuce (biennial)		Lettuce (annual)	
	Time* [d]	PECsoil,act [mg kg-1]	PECsoil,twa [mg kg-1]	PECsoil,act [mg kg-1]	PECsoil,twa [mg kg-1]	PECsoil,act [mg kg-1]	PECsoil,twa [mg kg-1]
Initial	0	0.080	-	0.125	-	0.050	-
Short-term	1	0.058	0.069	0.091	0.108	0.036	0.043
	2	0.058	0.066	0.091	0.102	0.036	0.041
	4	0.058	0.063	0.091	0.098	0.036	0.039
Long-term	7	0.058	0.061	0.090	0.095	0.036	0.038
	14	0.057	0.059	0.089	0.093	0.036	0.037
	21	0.057	0.058	0.088	0.091	0.035	0.037
	28	0.056	0.058	0.087	0.091	0.035	0.036
	50	0.054	0.057	0.085	0.089	0.034	0.035
	100	0.050	0.054	0.079	0.085	0.031	0.034

*Time: days after maximum concentration (PECsoil,act) or time interval (PECsoil,twa)

Long term PECsoil of BYI 02960

	Residues distributed over … [cm]	Seasonal PECs, max, max. soil residue in 1st year [mg/kg]	Long-term plateau / background conc. Cmin [mg/kg]	Long-term maximum conc. Cmax [mg/kg]	Background Cmin + max. of 1 year in 5 cm [mg/kg]
Hops 1 x 150 g/ha	5	0.080	0.080	0.160	-
	10	0.040	0.040	0.080	0.120
	20	0.020	0.020	0.040	0.100
Lettuce 1 1) 1 x 125 g/ha	5	0.125	0.046	0.171	-
	10	0.063	0.023	0.085	0.148
	20	0.031	0.011	0.043	0.136
Lettuce 2 2) 1 x 125 g/ha	5	0.050	0.050	0.100	-
	10	0.025	0.025	0.050	0.075
	20	0.013	0.013	0.025	0.063
Lettuce glasshouse 2 x 125 g/ha	5				
	10				
	20		0.0618		0.2766

1) Max 1 application per 24 months (biennial)
2) Max 1 application per 12 months (annual)
In bold: Generally, for long-term assessments the substance distribution in soil for annual crops with tillage should be assumed over a depth of 20 cm (lettuce) and for perennial crops without tillage over a depth of 5 – 10 cm (e.g. hops).

Metabolites Method of calculation	6-CNA Molecular weight: 157.6 g/mol Molecular weight relative to the parent: 0.546 DT50 (d): 36.6 Kinetics: SFO Field or Lab: Lab DFA Molecular weight: 96.0 g/mol Molecular weight relative to the parent: 0.333 DT50 (d): 73.6 Kinetics: SFO Field or Lab: Lab
Application data	6-CNA Maximum occurrence: 17.1% DFA Maximum occurrence: 33.9%

Initial PECsoil of BYI 02960 metabolites after application (5 cm soil)

		Hops	Lettuce (biennial)	Lettuce (annual)
	Time* [d]	PECsoil,act [mg kg-1]	PECsoil,act [mg kg-1]	PECsoil,act [mg kg-1]
6-CNA	0	0.007	0.012	0.005
DFA	0	0.009	0.014	0.006

Long term PECsoil of BYI 02960 metabolite 6-CNA

	Residues distributed over … [cm]	Seasonal PECs, max, max. soil residue in 1st year [mg/kg]	Long-term plateau / background conc. Cmin [mg/kg]	Long-term maximum conc. Cmax [mg/kg]
Hops 1 x 150 g/ha	5	0.015	<0.001	0.015
Lettuce 1 1) 1 x 125 g/ha	20	0.004	<0.001	0.004
Lettuce 2 2) 1 x 125 g/ha	20	0.002	<0.001	0.002

1) Max 1 application per 24 months (biennial); 2) Max 1 application per 12 months (annual)

Long term PECsoil of BYI 02960 metabolite DFA

	Residues distributed over … [cm]	Seasonal PECs, max, max. soil residue in 1st year [mg/kg]	Long-term plateau / background conc. Cmin [mg/kg]	Long-term maximum conc. Cmax [mg/kg]
Hops 1 x 150 g/ha	5	0.018	0.001	0.019
Lettuce 1 1) 1 x 125 g/ha	20	0.005	<0.001	0.005
Lettuce 2 2) 1 x 125 g/ha	20	0.003	<0.001	0.003

1) Max 1 application per 24 months (biennial); 2) Max 1 application per 12 months (annual)

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

Hydrolytic degradation of the active substance and metabolites above 10 %	pH 4, 7 and 9, 50 ºC: stable no metabolites >10%
Photolytic degradation of active substance and metabolites above 10 %	Tested BYI 02960 furanone-4-14C-label Parent DT50 : 13.8 hours (under study conditions) Estimated DT50 at 33.3°N: 1.75 days Estimated DT50 at 38.03°N: 2.7 days Estimated DT50 at 51.32°N: 3.4 days Reaction products >10%: BYI 02960-succinamide and BYI 02960-azabicyclosuccinamide
Quantum yield of direct photo transformation in water at Σ > 290 nm	1.38 x 10 -4 mol · Einstein -1
Readily biodegradable (yes/no)	Test not performed, active substance classified as not ready biodegradable.

Degradation in water / sediment

Parent BYI 02960	Distribution in water decreased to 11.4% (Sandy loam), 22.3% (Loamy sand) 14.1-14.3% (Loam) and 35.6-36.8% (Sand) at termination of the studies. Maximum sediment 59.4% (Sandy loam) at 59 d, 49.5% (Loamy sand) at termination, 58.3-58.7% (Loam) after 45-60 d and 37.6-38.9 % (Sand) at termination.								
Water / sediment system	pH water phase	pH sed.	t. oC	DegT50 / DegT90 whole system	χ2	Method of calc.	DT50 / DT90 water	χ2	Method of calc.
Sandy loam	7.4	5.2	20±2	193.1 / 641.3	1.2	SFO	8.5 / 174.6	1.6	FOMC
Loamy sand	7.7	6.7	20±2	246.9 / 820.1	1.3	SFO	34.5 / 181.8	4.4	DFOP
Loam	6.5	4.8	20±1	208.2 / 691.6	1.5	SFO	48.5 / 161.0	47.1	DFOP
Sand	6.9	6.8	20±1	246.1 / 817.4	1.3	SFO	123.8 / 411.2	2.9	DFOP
Loam	6.5	4.8	20±1	202.4 / 672.2	1.6	SFO	50.2 / 116.9	4.9	DFOP
Sand	6.9	6.8	20±1	285.0 / 946.9	1.0	SFO	117.5 / 390.3	2.4	DFOP
Geometric mean				228.1 / 757.7					

BYI 02960 Mineralization and non extractable residues				
Water / sediment system	BYI 02960 label	Mineralization x % after n d. (end of the study)	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. x % after n d (end of the study)
Sandy loam	PYR	6.8	25.0 after 119 d	25.0 after 119 d
Loamy sand	PYR	8.5	13.6 after 119 d	13.6 after 119 d
Loam	FUR	3.9	22.6 after 120 d	22.6 after 120 d
Sand	FUR	5.5	17.9 after 120 d	17.9 after 120 d
Loam	ETH	1.5	26.6 after 120 d	26.6 after 120 d
Sand	ETH	0.9	15.2 after 120 d	15.2 after 120 d

PYR (= pyridine-2,6-14C-label), FUR (= furanone-4-14C-label) and ETH (= ethyl-1-14C-label)

DFA	Distribution in water decrease to 32.3% (Loam) at termination of the study and 72.3% (Loamy sand) at 79 d. Maximum sediment 25.2% (Loam) and 16.5% (Loamy sand) both after 79 d								
Water / sediment system	pH water phase	pH sed.	t. oC	DegT50 / DegT90 whole system	χ2	Method of calc.	DT50 / DT90 water	χ2	Method of calc.
Loam	6.9	5.2	19.2±0.1	109.0 / 362.2	2.9	SFO	75.3 / 250.3	1.6	DFOP
Loamy sand	7.5	7.0	19.2±0.1	567.2 / >1000	3.0	SFO	371.5 / >1000	4.8	SFO
Geometric mean				248.6 / 601.8					

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

Parent Parameters used in FOCUSsw step 1 and 2, 3 and 4	Version control no. of FOCUS calculator: FOCUS step 1 and 2 version 1.1. Swash verion 3.1 (step 3) and Swan version 1.1.4 (step 4) Molecular weight (g/mol): 288.7 Water solubility (mg/L): 3200 at 20ºC Vapour pressure (Pa): 9.1 x 10-7 KOC (L/kg): 98.4 Freudlich exponent (1/n): 0.8657 Geometric mean DT50 soil (d): 94.8 Geometric mean DT50 water/sed (d): 228 DT50 water (d): 228 DT50 sediment (d): 228 (STEP 1 and 2) DT50 sediment (d): 1000 (STEP 3 an 4) Crop interception (%): 50 for hops (biennial) 25 for lettuce (biennial) 50 for lettuce (annual)
Application rate	Crop: hops Number of applications: 1 Interval (d): n.a. Application rate(s): 150 g as/ha Application window: NE- March-May SE- March-May Crop: leafy vegetables (lettuce) Number of applications: 1 (for field application) Interval (d): n.a. Application rate(s): 125 g as/ha Application window: NE- March-May SE- March-May

FOCUS STEP 1 Scenario	crop	PECsw,max (µg/L)	PECsed,max (µg/kg)
		Actual	Actual
	Hops	53.86	43.49
	Lettuce (biennial)	53.86	43.49
	Lettuce (annual)	53.86	43.49

FOCUS STEP 2 Scenario	Crop	PECsw,max (µg/L)	PECsed,max (µg/kg)
		Actual	Actual
	Hops (NE)	13.07	12.49
	Hops (SE)	17.36	16.70
	Lettuce (NE - biennial)	6.41	6.25
	Lettuce (SE - biennial)	11.88	11.51
	Lettuce (NE - annual)	3.19	3.09
	Lettuce (SE - annual)	5.34	5.20

FOCUS STEP 3 Hops Scenario	Entry route	PECsw, max (µg/L)	PECsed, max (µg/kg)
R1, pond	Spray drift	0.394	0.795
R1, stream	Spray drift	5.531	0.362

Time dependent PEC values or time-weighted average concentrations are not included in the LoEP, because they were not used in the risk assessment.

FOCUS STEP 3 Lettuce (biennial) Scenario	Entry route	PECsw, max (µg/L)	PECsed, max (µg/kg)
D3 (ditch, 1st)	Spray drift	0.830	0.380
D3 (ditch, 2nd)	Spray drift	0.840	0.460
D4 (pond, 1st)	Drainage	1.035	4.545
D4 (stream, 1st)	Spray drift	0.794	1.772
D6 (ditch, 1st)	Drainage	1.268	1.766
R1 (pond, 1st)	Run-off	0.060	0.162
R1 (stream, 1st)	Run-off	0.858	0.211
R1 (pond, 2nd)	Run-off	0.097	0.254
R1 (stream, 2nd)	Run-off	1.186	0.334
R2 (stream, 1st)	Run-off	1.586	0.521
R2 (stream, 2nd)	Run-off	0.940	0.342
R3 (stream, 1st)	Run-off	2.226	0.469
R3 (stream, 2nd)	Run-off	3.570	1.011
R4 (stream, 1st)	Spray drift	0.522	0.054
R4 (stream, 2nd)	Run-off	4.808	1.255

Time dependent PEC values or time-weighted average concentrations are not included in the LoEP, because they were not used in the risk assessment.

FOCUS STEP 4
Hops, 1 x 150 g/ha

Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		25%	50%	75%	90%	25%	50%	75%	90%
0m (drift)	R1 (pond, 1st) R1 (stream, 1st)	0.296 4.149	0.197 2.766	0.099 1.383	0.039 0.553	0.607 0.273	0.415 0.184	0.218 0.093	0.094 0.072
5m (drift)	R1 (pond, 1st) R1 (stream, 1st)	0.445 4.515	0.223 2.258	0.111 1.129	0.045 0.452	0.891 0.297	0.465 0.151	0.244 0.076	0.105 0.071
10m (drift & run-off)	R1 (pond, 1st) R1 (stream, 1st)	0.253 2.354	0.126 1.177	0.063 0.589	0.025 -	0.522 0.157	0.273 0.080	0.142 0.04	0.061 0.031
15m (drift & run-off)	R1 (pond, 1st) R1 (stream, 1st)	0.141 1.554	0.071 0.777	0.035 0.388	-	0.302 0.104	0.158 0.053	0.083 0.032	0.036 0.03
20m (drift & run-off)	R1 (pond, 1st) R1 (stream, 1st)	0.078 0.708	0.039 0.354	- -	- -	0.174 0.048	0.091 0.025	0.048 0.017	0.021 0.016

The mitigation from 10 m onwards includes spray drift and concurrent run-off buffer. However, as can be seen from the linear decrease of PECsw values with increasing drift reduction, the PECsw is always drift dominated and the run-off buffer does not drive the PECsw.

FOCUS STEP 4
Lettuce, 1 x 125 g/ha (biennial)

Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		25%	50%	75%	90%	25%	50%	75%	90%
0m (drift)	D3 (ditch, 1st)	0.632	0.434	0.235	0.117	0.335	0.334	0.333	0.332
	D3 (ditch, 2nd)	0.643	0.446	0.249	0.130	0.419	0.399	0.398	0.397
	D4 (pond, 1st)	1.034	1.034	1.033	1.033	4.538	4.531	4.524	4.520
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.766	1.765	1.765	1.764
	R1 (pond, 1st)	0.055	0.050	0.045	0.043	0.148	0.134	0.119	0.111
	R1 (stream, 1st)	0.858	0.858	0.858	0.858	0.210	0.208	0.207	0.206
	R1 (pond, 2nd)	0.092	0.087	0.082	0.079	0.240	0.225	0.210	0.201
	R1 (stream, 2nd)	1.186	1.186	1.186	1.186	0.333	0.332	0.330	0.330
	R2 (stream, 1st)	1.586	1.586	1.586	1.586	0.520	0.520	0.519	0.518
	R2 (stream, 2nd)	0.940	0.940	0.940	0.940	0.342	0.341	0.341	0.340
	R3 (stream, 1st)	2.226	2.226	2.226	2.226	0.466	0.462	0.459	0.456
	R3 (stream, 2nd)	3.570	3.570	3.570	3.570	1.006	1.000	0.995	0.991
	R4 (stream, 1st)	0.392	0.261	0.131	0.074	0.041	0.027	0.025	0.024
	R4 (stream, 2nd)	4.808	4.808	4.808	4.808	1.253	1.251	1.249	1.248

FOCUS STEP 4
Lettuce, 1 x 125 g/ha (biennial)

Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m (drift)	D3 (ditch, 1st)	0.252	0.145	0.091	-	0.333	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.265	0.158	0.105	-	0.398	0.397	0.397	0.396
	D4 (pond, 1st)	1.035	1.034	1.033	1.033	4.541	4.529	4.523	4.520

FOCUS STEP 4 Lettuce, 1 x 125 g/ha (biennial)									
Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.765	1.764	1.764	1.764
	R1 (pond, 1st)	0.057	0.049	0.045	0.042	0.154	0.130	0.117	0.11
	R1 (stream, 1st)	0.858	0.858	0.858	0.858	0.208	0.207	0.206	0.206
	R1 (pond, 2nd)	0.094	0.086	0.082	0.079	0.247	0.221	0.208	0.201
	R1 (stream,2nd)	1.186	1.186	1.186	1.186	0.331	0.330	0.33	0.329
	R2 (stream, 1st)	1.586	1.586	1.586	1.586	0.519	0.518	0.518	0.518
	R2 (stream,2nd)	0.940	0.940	0.940	0.940	0.341	0.341	0.34	0.34
	R3 (stream, 1st)	2.226	2.226	2.226	2.226	0.460	0.458	0.456	0.455
	R3 (stream,2nd)	3.570	3.570	3.570	3.570	0.997	0.993	0.991	0.99
	R4 (stream, 1st)	0.191	0.095	0.074	0.074	0.025	0.025	0.024	0.024
	R4 (stream,2nd)	4.808	4.808	4.808	4.808	1.250	1.248	1.247	1.247
10m (drift and run-off)	D3 (ditch, 1st)	0.151	0.094	-	-	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.165	0.108	-	-	0.397	0.397	0.396	0.396
	D4 (pond, 1st)	1.034	1.033	1.033	1.033	4.534	4.526	4.522	4.519
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.029	0.022	0.019	0.018	0.083	0.064	0.055	0.049
	R1 (stream, 1st)	0.389	0.389	0.389	0.389	0.097	0.097	0.097	0.096
	R1 (pond, 2nd)	0.043	0.037	0.034	0.032	0.122	0.103	0.094	0.088
	R1 (stream,2nd)	0.540	0.540	0.540	0.540	0.157	0.157	0.157	0.156
	R2 (stream, 1st)	0.716	0.716	0.716	0.716	0.228	0.228	0.228	0.228
	R2 (stream,2nd)	0.422	0.422	0.422	0.422	0.151	0.151	0.151	0.151
	R3 (stream, 1st)	1.009	1.009	1.009	1.009	0.219	0.217	0.216	0.216
	R3 (stream,2nd)	1.630	1.630	1.630	1.630	0.452	0.450	0.449	0.448
	R4 (stream, 1st)	0.101	0.051	0.034	0.034	0.012	0.012	0.012	0.011
	R4 (stream,2nd)	2.184	2.184	2.184	2.184	0.585	0.584	0.584	0.584
15m (drift	D3 (ditch, 1st)	0.115	0.076	-	-	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.129	0.090	-	-	0.397	0.396	0.396	0.396

FOCUS STEP 4 Lettuce, 1 x 125 g/ha (biennial)									
Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
and run-off)	D4 (pond, 1st)	1.034	1.033	1.033	1.033	4.531	4.524	4.521	4.519
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.018	0.013	0.011	0.009	0.055	0.039	0.032	0.027
	R1 (stream, 1st)	0.204	0.204	0.204	0.204	0.053	0.052	0.052	0.052
	R1 (pond, 2nd)	0.025	0.021	0.018	0.017	0.076	0.060	0.052	0.047
	R1 (stream,2nd)	0.283	0.283	0.283	0.283	0.086	0.085	0.085	0.085
	R2 (stream, 1st)	0.375	0.375	0.375	0.375	0.122	0.122	0.122	0.122
	R2 (stream,2nd)	0.220	0.220	0.220	0.220	0.081	0.081	0.081	0.081
	R3 (stream, 1st)	0.528	0.528	0.528	0.528	0.119	0.118	0.117	0.117
	R3 (stream,2nd)	0.856	0.856	0.856	0.856	0.245	0.243	0.242	0.242
	R4 (stream, 1st)	0.069	0.035	0.018	0.018	0.008	0.006	0.006	0.006
	R4 (stream,2nd)	1.144	1.144	1.144	1.144	0.318	0.317	0.317	0.316
20m (drift and run-off)	D3 (ditch, 1st)	0.097	-	-	-	0.332	0.332	0.332	0.332
	D3 (ditch, 2nd)	0.110	-	-	-	0.397	0.396	0.396	0.396
	D4 (pond, 1st)	1.033	1.033	1.033	1.033	4.529	4.523	4.520	4.518
	D4 (stream, 1st)	0.721	0.721	0.721	0.721	1.771	1.771	1.771	1.771
	D6 (ditch, 1st)	1.268	1.268	1.268	1.268	1.764	1.764	1.764	1.764
	R1 (pond, 1st)	0.016	0.012	0.010	0.009	0.050	0.037	0.03	0.026
	R1 (stream, 1st)	0.204	0.204	0.204	0.204	0.052	0.052	0.052	0.052
	R1 (pond, 2nd)	0.024	0.020	0.018	0.016	0.071	0.057	0.05	0.046
	R1 (stream,2nd)	0.283	0.283	0.283	0.283	0.086	0.085	0.085	0.085
	R2 (stream, 1st)	0.375	0.375	0.375	0.375	0.122	0.122	0.122	0.122
	R2 (stream,2nd)	0.220	0.220	0.220	0.220	0.081	0.081	0.081	0.081
	R3 (stream, 1st)	0.528	0.528	0.528	0.528	0.118	0.117	0.117	0.117
	R3 (stream,2nd)	0.856	0.856	0.856	0.856	0.244	0.243	0.242	0.242
	R4 (stream, 1st)	0.053	0.026	0.018	0.018	0.007	0.006	0.006	0.006
	R4 (stream,2nd)	1.144	1.144	1.144	1.144	0.317	0.317	0.317	0.316

FOCUS STEP 4 Lettuce, 1 x 125 g/ha (annual)									
Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
5m (drift)	D3 (ditch, 1st)	0.234	0.127	0.073	-	0.188	0.187	0.187	0.186
	D3 (ditch, 2nd)	0.234	0.127	0.073	-	0.177	0.173	0.172	0.172
	D4 (pond, 1st)	0.982	0.978	0.976	0.975	3.750	3.732	3.723	3.718
	D4 (stream, 1st)	0.969	0.969	0.969	0.969	1.395	1.394	1.394	1.394
	D6 (ditch, 1st)	1.206	1.206	1.206	1.206	1.958	1.958	1.958	1.958
	R1 (pond, 1st)	0.334	0.325	0.320	0.317	0.744	0.723	0.712	0.706
	R1 (stream, 1st)	2.827	2.827	2.827	2.827	0.694	0.693	0.692	0.692
	R1 (pond, 2nd)	0.137	0.130	0.127	0.125	0.404	0.379	0.367	0.359
	R1 (stream,2nd)	2.189	2.189	2.189	2.189	0.411	0.410	0.409	0.409
	R2 (stream, 1st)	1.215	1.215	1.215	1.215	0.510	0.509	0.508	0.508
	R2 (stream,2nd)	1.044	1.044	1.044	1.044	0.243	0.242	0.242	0.241
	R3 (stream, 1st)	3.698	3.698	3.698	3.698	0.780	0.775	0.772	0.771
	R3 (stream,2nd)	3.297	3.297	3.297	3.297	0.949	0.945	0.942	0.941
	R4 (stream, 1st)	0.830	0.830	0.830	0.830	0.239	0.238	0.238	0.238
	R4 (stream,2nd)	2.954	2.954	2.954	2.954	0.797	0.796	0.795	0.794
10m (drift and run-off)	D3 (ditch, 1st)	0.133	0.076	-	-	0.187	0.187	0.186	0.186
	D3 (ditch, 2nd)	0.133	0.077	-	-	0.173	0.172	0.172	0.172
	D4 (pond, 1st)	0.980	0.977	0.976	0.975	3.740	3.727	3.720	3.717
	D4 (stream, 1st)	0.969	0.969	0.969	0.969	1.394	1.394	1.394	1.394
	D6 (ditch, 1st)	1.206	1.206	1.206	1.206	1.958	1.958	1.958	1.958
	R1 (pond, 1st)	0.143	0.135	0.132	0.130	0.339	0.323	0.314	0.309
	R1 (stream, 1st)	1.270	1.270	1.270	1.270	0.294	0.293	0.293	0.292
	R1 (pond, 2nd)	0.060	0.055	0.052	0.051	0.196	0.177	0.168	0.162
	R1 (stream,2nd)	0.954	0.954	0.954	0.954	0.193	0.193	0.192	0.192
	R2 (stream, 1st)	0.553	0.553	0.553	0.553	0.207	0.206	0.206	0.206
	R2 (stream,2nd)	0.469	0.469	0.469	0.469	0.108	0.108	0.108	0.108
	R3 (stream, 1st)	1.683	1.683	1.683	1.683	0.367	0.365	0.363	0.362
	R3 (stream,2nd)	1.506	1.506	1.506	1.506	0.403	0.400	0.399	0.398
	R4 (stream, 1st)	0.379	0.379	0.379	0.379	0.112	0.112	0.111	0.111
	R4 (stream,2nd)	1.345	1.345	1.345	1.345	0.373	0.372	0.372	0.372

FOCUS STEP 4 Lettuce, 1 x 125 g/ha (annual)									
Buffer Width & Type	FOCUS Scenario	PECsw [µg/L] Drift Reduction				PECsed [µg/kg] Drift Reduction			
		0%	50%	75%	90%	0%	50%	75%	90%
15m (drift and run-off)	D3 (ditch, 1st)	0.097	-	-	-	0.187	0.186	0.186	0.186
	D3 (ditch, 2nd)	0.098	-	-	-	0.173	0.172	0.172	0.172
	D4 (pond, 1st)	0.979	0.977	0.976	0.975	3.734	3.724	3.719	3.716
	D4 (stream, 1st)	0.969	0.969	0.969	0.969	1.394	1.394	1.394	1.394
	D6 (ditch, 1st)	1.206	1.206	1.206	1.206	1.958	1.958	1.958	1.958
	R1 (pond, 1st)	0.140	0.134	0.131	0.129	0.332	0.319	0.313	0.309
	R1 (stream, 1st)	1.270	1.270	1.270	1.270	0.293	0.293	0.293	0.292
	R1 (pond, 2nd)	0.058	0.054	0.052	0.051	0.188	0.173	0.166	0.161
	R1 (stream,2nd)	0.954	0.954	0.954	0.954	0.193	0.193	0.192	0.192
	R2 (stream, 1st)	0.553	0.553	0.553	0.553	0.207	0.206	0.206	0.206
	R2 (stream,2nd)	0.469	0.469	0.469	0.469	0.108	0.108	0.108	0.107
	R3 (stream, 1st)	1.683	1.683	1.683	1.683	0.366	0.364	0.363	0.362
	R3 (stream,2nd)	1.506	1.506	1.506	1.506	0.401	0.399	0.398	0.398
	R4 (stream, 1st)	0.379	0.379	0.379	0.379	0.112	0.111	0.111	0.111
	R4 (stream,2nd)	1.345	1.345	1.345	1.345	0.373	0.372	0.372	0.372
20m (drift and run-off)	D3 (ditch, 1st)	0.078	-	-	-	0.187	0.186	0.186	0.186
	D3 (ditch, 2nd)	0.079	-	-	-	0.172	0.172	0.172	0.172
	D4 (pond, 1st)	0.978	0.976	0.976	0.975	3.731	3.723	3.718	3.716
	D4 (stream, 1st)	0.969	0.969	0.969	0.969	1.394	1.394	1.394	1.394
	D6 (ditch, 1st)	1.206	1.206	1.206	1.206	1.958	1.958	1.958	1.958
	R1 (pond, 1st)	0.074	0.069	0.067	0.066	0.185	0.173	0.167	0.164
	R1 (stream, 1st)	0.662	0.662	0.662	0.662	0.156	0.155	0.155	0.155
	R1 (pond, 2nd)	0.032	0.028	0.027	0.026	0.111	0.097	0.091	0.087
	R1 (stream,2nd)	0.500	0.500	0.500	0.500	0.104	0.104	0.104	0.104
	R2 (stream, 1st)	0.290	0.290	0.290	0.290	0.109	0.108	0.108	0.108
	R2 (stream,2nd)	0.244	0.244	0.244	0.244	0.058	0.057	0.057	0.057
	R3 (stream, 1st)	0.882	0.882	0.882	0.882	0.199	0.198	0.197	0.196
	R3 (stream,2nd)	0.790	0.790	0.790	0.790	0.214	0.212	0.212	0.211
	R4 (stream, 1st)	0.199	0.199	0.199	0.199	0.060	0.060	0.060	0.060
	R4 (stream,2nd)	0.705	0.705	0.705	0.705	0.202	0.202	0.202	0.202

Glasshouse PECSW

Parent Parameters used	0.2% emission to a 1m wide 30cm deep static water body having a volume of 300L per 1m of length adjacent to a protected cropping structure (eg. glasshouse or poly tunnel)
Application rate	Crop: lettuce Number of applications: 2x125 g/ha calculated as a single loading of 250 g/ha Interval (d): n.a.

FOCUS AIR Scenario	crop	PECsw,max (µg/L)
		Actual
	Lettuce (annual)	0.1667

Parameters used in FOCUSsw step 1 and 2 Metabolite 6-CNA	Molecular weight (g mol-1): 157.6 Water solubility (mg/L): 1430 at 20ºC Soil or water metabolite: soil Koc (L/kg): 88 Geometric mean DT50 soil (d): 4.7 at 20ºC/pF2 Geometric mean DT50 water/sed (d): 1000 DT50 water (d): 1000 (system value) DT50 sediment (d): 1000 (system value) Crop interception (%): see parent Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 0 Soil: 17.1
Parameters used in FOCUSsw step 1 and 2 Metabolite DFA	Molecular weight (g mol-1): 96.0 Water solubility (mg/L): 500000 at 20ºC Soil or water metabolite: soil and water Koc (L/kg): 6.8 Geometric mean DT50 soil (d): 44.7 at 20ºC/pF2 Geometric mean DT50 water/sed (d): 249 DT50 water (d): 249 (system value) DT50 sediment (d): 249 (system value) Crop interception (%): see parent Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 6.9 Soil: 33.9
Parameters used in FOCUSsw step 1 and 2 Metabolite BYI 02960-succinamide	Molecular weight (g mol-1): 306.7 Water solubility (mg/L): 120000 at 20ºC Soil or water metabolite: water Koc (L/kg): 0 DT50 soil (d): 0.1 DT50 water/sed (d): 1000 DT50 water (d): 1000 DT50 sediment (d): 1000 Crop interception (%): see parent

	Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 39.6 (photolysis) Soil: 0
Parameters used in FOCUSsw step 1 and 2 Metabolite BYI 02960-azabicyclo succinamide	Molecular weight (g mol-1): 288.3 Water solubility (mg/L): 180000 at 20ºC Soil or water metabolite: water Koc (L/kg): 0 DT50 soil (d): 0.1 DT50 water/sed (d): 1000 DT50 water (d): 1000 DT50 sediment (d): 1000 Crop interception (%): see parent Maximum occurrence observed (% molar basis with respect to the parent) Water/sediment: 25.9 (photolysis) Soil: 0
Application rate	See parent
Main routes of entry	Drift of parent

Crop	FOCUS STEP	Difluoroacetic acid		6-Chloronicotinic acid		BYI 02960-succinamide		BYI 02960-azabicyclo-succinamide	
		PECsw (µg/L)	PECsed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)	PECsw (µg/L)	PECsed (µg/kg)
Hops 1 x 150 g/ha	1	5.810	0.380	4.177	3.675	4.065	<0.001	2.499	<0.001
	2 N-EU	0.743	0.050	0.232	0.204	4.065	<0.001	2.499	<0.001
	2 S-EU	1.268	0.086	0.463	0.408	4.065	<0.001	2.499	<0.001
Lettuce (biennial) 1 x 125 g/ha	1	4.683	0.317	3.481	3.063	0.484	<0.001	0.297	<0.001
	2 N-EU	0.682	0.046	0.289	0.255	0.484	<0.001	0.297	<0.001
	2 S-EU	1.339	0.091	0.579	0.509	0.484	<0.001	0.297	<0.001
Lettuce (annual) 1 x 125 g/ha	1	4.683	0.317	3.481	3.063	0.484	<0.001	0.297	<0.001
	2 N-EU	0.551	0.037	0.193	0.170	0.484	<0.001	0.297	<0.001
	2 S-EU	1.076	0.073	0.386	0.340	0.484	<0.001	0.297	<0.001

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)	For FOCUS gw modeling, values used – Modeling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Models used: FOCUS-PEARL 4.4.4 PELMO 4.4.3 Scenarios (list of names): seven for hops all nine for lettuce Crop: hops leafy vegetables for lettuce

Flupyradifurone (BYI 02960)	Molecular weight (g/mol): 288.7 Water solubility (mg/L): 3200 at 20ºC Vapour pressure (Pa): 9.1 x 10-7 Geometric mean DT50 (d): 94.8 (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58; Tier 1) DT50 (d): 33.4 (fast; Tier 2a (DFOP)) 94.8 (slow; Tier 2a (DFOP)) g 0.43 (Tier 2a (DFOP)) Arithmetic mean Kom (L/kg): 57.1 (Tier 1 and 2a (DFOP)) Arithmetic mean Koc (L/kg): 98.4 (Tier 1 and 2a (DFOP)) Freundlich exponent (1/n): 0.8657 (Tier 1 and 2a(DFOP)) Plant uptake factor: 0.5 (systemic active substance) Q10: 2.58 Molar activation energy (kJ/mol): 65.4
Metabolite 6-CNA	Molecular weight (g/mol): 157.6 * Water solubility (mg/L): 1430 Vapour pressure (Pa): 1.0 x 10-10 Geometric mean DT50 (d): 4.7 (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58) Arithmetic mean Kom (L/kg): 51 Arithmetic mean Koc (L/kg): 88 Freundlich exponent (1/n): 0.949 Kinetic formation fraction: 0.478 from parent ** Plant uptake factor: 0.0 Q10: 2.58 Molar activation energy (kJ/mol): 65.4
Metabolite DFA	Molecular weight (g/mol): 96.0 Water solubility (mg/L): 500000 Vapour pressure (Pa): 1.0 x 10-10 Geometric mean DT50 (d): 44.7 (normalisation to 10kPa or pF2, 20°C with Q10 of 2.58) Arithmetic mean Kom (L/kg): 3.9 Arithmetic mean Koc (L/kg): 6.8 Freundlich exponent (1/n): 0.835 Kinetic formation fraction: 0.833 from parent ** Plant uptake factor: 0.0 Q10: 2.58 Molar activation energy (kJ/mol): 65.4

Application rate	Application rate (g/ha): 150 (hops, annual and biennial) 125 (lettuce, field annual and biennial) 125 (lettuce, glasshouse) Number of applications: 1 (hops annual and biennial) 1 (lettuce, field annual and biennial) 2 (lettuce, glasshouse) Interval (d): n.a. (hops and lettuce field) 10 (lettuce, glass) Time of application: BBCH 31-75 (hops annual and biennial) BBCH 41-49 (lettuce annual) BBCH 12-49 (lettuce biennial) (month or season) BBCH 12-49 (lettuce, glasshouse) Plant interception (%): 60 (hops annual and biennial) 70 (lettuce annual) 25 (lettuce biennial)) 25 (lettuce, glasshouse)

* The sum of formation fractions of both metabolites is > 1. In order to run the modeling with PELMO, the molar mass of 6-CNA was set to 451 g/mol, resulting from Mauxiliary (6-CNA) = M (6-CNA) × 0.478 / (1-0.833) = 451 g/mol
** Kinetic formation fraction used for PEARL, values used for PELMO see DAR;
Additional higher Tier PECgw calculations with time dependent sorption are presented in the DAR.

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

Scenario	PECgw BYI02960 (µg/L) annual			
	Tier I		Tier 2a (DFOP)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.457	0.409	0.275	0.247
Hamburg	0.567	0.591	0.338	0.358
Kremsmünster	0.409	0.461	0.246	0.277
Piacenza	0.377	0.458	0.224	0.275
Porto	0.214	0.275	0.130	0.166
Sevilla	0.219	0.060	0.134	0.037
Thiva	0.178	0.154	0.108	0.094

In italics: values pass the trigger of 0.1 µg/L

Scenario	PECgw BYI02960 (µg/L) biennial			
	Tier I		Tier 2a (DFOP)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.197	0.169	0.119	0.103
Hamburg	0.271	0.230	0.164	0.140
Kremsmünster	0.169	0.189	0.102	0.114
Piacenza	0.162	0.210	0.097	0.126
Porto	0.091	0.115	0.055	0.069
Sevilla	0.090	0.022	0.055	0.014
Thiva	0.073	0.058	0.045	0.036

In italics: values pass the trigger of 0.1 µg/L

Scenario	PECgw 6-CNA (µg/L)			
	Tier I annual		Tier I biennial	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.010	0.009	0.005	0.004
Hamburg	0.011	0.012	0.006	0.005
Kremsmünster	0.009	0.010	0.004	0.004
Piacenza	0.008	0.009	0.004	0.005
Porto	0.006	0.007	0.002	0.003
Sevilla	0.005	0.002	0.002	0.001
Thiva	0.004	0.004	0.002	0.002

In italics: values pass the trigger of 0.1 µg/L

Scenario	PECgw DFA (µg/L) annual			
	Tier I		Tier 2a (DFOP parent)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	1.554	1.377	1.459	1.299
Hamburg	1.699	1.830	1.631	1.771
Kremsmünster	1.064	1.228	1.020	1.189
Piacenza	1.059	0.957	0.953	0.904
Porto	0.696	0.758	0.608	0.691
Sevilla	0.976	0.776	0.916	0.715
Thiva	0.912	0.916	0.817	0.838

In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) biennial			
	Tier I		Tier 2a (DFOP parent)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.754	0.697	0.722	0.681
Hamburg	0.793	0.852	0.772	0.836
Kremsmünster	0.525	0.596	0.515	0.592
Piacenza	0.511	0.448	0.473	0.439
Porto	0.318	0.350	0.277	0.315
Sevilla	0.479	0.428	0.459	0.424
Thiva	0.450	0.426	0.415	0.395

In bold: values pass the trigger of 0.75 µg/L

Lettuce field annual

Scenario	PECgw BYI02960 (µg/L) annual (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.106	0.065	0.065	0.040
Hamburg	0.259	0.212	0.156	0.129
Jokionen	0.095	0.080	0.059	0.050
Kremsmünster	0.175	0.149	0.106	0.090
Porto	0.106	0.130	0.064	0.078
Sevilla	0.002	0.001	0.002	0.001
Thiva	0.043	0.031	0.027	0.020

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) annual (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.135	0.089	0.083	0.056
Hamburg	0.319	0.286	0.193	0.175
Kremsmünster	0.216	0.185	0.130	0.113
Porto	0.211	0.253	0.128	0.155
Sevilla	0.004	0.001	0.003	0.001

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) annual			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.003	0.002	0.003	0.003
Hamburg	0.005	0.005	0.007	0.006
Jokionen	0.003	0.002	-	-
Kremsmünster	0.004	0.004	0.005	0.004
Porto	0.003	0.004	0.005	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.001	0.002	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) annual (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.691	0.554	0.657	0.543
Hamburg	1.165	0.990	1.141	0.987
Jokionen	1.064	0.961	1.037	0.974
Kremsmünster	0.670	0.613	0.650	0.618
Porto	0.412	0.393	0.373	0.374
Sevilla	0.237	0.179	0.211	0.164
Thiva	0.280	0.261	0.252	0.238

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) annual (2st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.691	0.567	0.654	0.558
Hamburg	1.179	1.082	1.153	1.088
Kremsmünster	0.671	0.632	0.651	0.638
Porto	0.456	0.435	0.479	0.472
Sevilla	0.362	0.272	0.376	0.291

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Lettuce field biennial

Scenario	PECgw BYI02960 (µg/L) biennial (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.154	0.106	0.065	0.040
Hamburg	0.379	0.288	0.156	0.129
Jokionen	0.110	0.084	0.059	0.050
Kremsmünster	0.242	0.203	0.106	0.090
Porto	0.138	0.169	0.064	0.078
Sevilla	0.006	0.002	0.002	0.001
Thiva	0.111	0.065	0.027	0.020

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) biennial (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.207	0.137	0.126	0.083
Hamburg	0.443	0.398	0.270	0.237
Kremsmünster	0.291	0.244	0.177	0.149
Porto	0.253	0.302	0.153	0.178
Sevilla	0.009	0.002	0.006	0.002

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) biennial			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.004	0.003	0.005	0.003
Hamburg	0.008	0.006	0.009	0.008
Jokionen	0.003	0.003	-	-
Kremsmünster	0.005	0.005	0.006	0.006
Porto	0.004	0.004	0.006	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.003	0.002	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) biennial (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.847	0.668	0.801	0.651
Hamburg	1.393	1.169	1.357	1.168
Jokionen	1.393	1.197	1.372	1.207
Kremsmünster	0.852	0.778	0.823	0.769
Porto	0.461	0.394	0.397	0.365
Sevilla	0.295	0.236	0.258	0.219
Thiva	0.626	0.519	0.668	0.561

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) biennial (2nd cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.946	0.748	0.955	0.783
Hamburg	1.517	1.411	1.546	1.462
Kremsmünster	0.892	0.880	0.906	0.906
Porto	0.660	0.626	0.688	0.653
Sevilla	0.379	0.290	0.369	0.293

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Lettuce glasshouse

Scenario	PECgw BYI02960 (µg/L) Glasshouse (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	1.132	0.786	0.682	0.474
Hamburg	2.179	1.879	1.310	1.125
Jokionen	0.985	0.769	0.598	0.473
Kremsmünster	1.503	1.330	0.898	0.797
Porto	0.877	0.980	0.524	0.576
Sevilla	0.078	0.018	0.050	0.012
Thiva	0.997	0.717	0.606	0.438

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) Glasshouse (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	1.543	1.073	0.927	0.684
Hamburg	2.843	2.540	1.706	1.534
Kremsmünster	1.819	1.654	1.089	0.991
Porto	1.691	1.787	1.008	1.070
Sevilla	0.116	0.024	0.076	0.016

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) Glasshouse			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.022	0.016	0.029	0.021
Hamburg	0.038	0.036	0.050	0.048
Jokionen	0.021	0.018	-	-
Kremsmünster	0.028	0.026	0.034	0.031
Porto	0.020	0.022	0.035	0.038
Sevilla	0.002	0.001	0.003	0.001
Thiva	0.019	0.015	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) Glasshouse (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	3.511	2.857	3.605	2.894
Hamburg	6.305	5.095	6.353	5.297
Jokionen	6.390	5.751	6.230	5.829
Kremsmünster	3.573	3.331	3.685	3.402
Porto	1.863	1.703	2.059	1.833
Sevilla	1.098	0.827	1.185	0.917
Thiva	3.020	2.649	2.727	2.416

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) Glasshouse (2st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	4.267	3.627	4.127	3.474
Hamburg	7.008	6.341	6.836	6.244
Kremsmünster	3.970	3.761	3.948	3.647
Porto	2.959	2.773	2.760	2.650
Sevilla	1.669	1.283	1.589	1.280

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Application rate	Application rate (g/ha): 150 (hops biennial) 125 (lettuce, field annual and biennial) 125 (lettuce, glasshouse) Number of applications: 1 (hops biennial) 1 (lettuce, field annual and biennial) 2 (lettuce, glasshouse) Interval (d): n.a. (hops and lettuce field) 10 (lettuce, glasshouse) Time of application: BBCH 31-75 (hops biennial) BBCH 41-49 (lettuce annual) BBCH 12-49 (lettuce biennial) (month or season) BBCH 12-49 (lettuce, glasshouse) Plant interception (%): 60 (hops biennial) 70 (lettuce annual) 25 (lettuce biennial)) 25 (lettuce, glasshouse)

* The sum of formation fractions of both metabolites is > 1. In order to run the modeling with PELMO, the molar mass of 6-CNA was set to 451 g/mol, resulting from Mauxiliary (6-CNA) = M (6-CNA) × 0.478 / (1-0.833) = 451 g/mol

** Kinetic formation fraction used for PEARL, values used for PELMO see DAR

Additional higher Tier PECgw calculations with time dependent sorption are presented in the DAR.

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

Scenario	PECgw BYI02960 (µg/L) biennial			
	Tier I		Tier 2a (DFOP)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.197	0.169	0.119	0.103
Hamburg	0.271	0.230	0.164	0.140
Kremsmünster	0.169	0.189	0.102	0.114
Piacenza	0.162	0.210	0.097	0.126
Porto	0.091	0.115	0.055	0.069
Sevilla	0.090	0.022	0.055	0.014
Thiva	0.073	0.058	0.045	0.036

In italics: values pass the trigger of 0.1 µg/L

Scenario	PECgw 6-CNA (µg/L)			
			Tier I biennial	
			Hops PEARL	Hops PELMO
Châteaudun			0.005	0.004
Hamburg			0.006	0.005
Kremsmünster			0.004	0.004
Piacenza			0.004	0.005
Porto			0.002	0.003
Sevilla			0.002	0.001
Thiva			0.002	0.002

In italics: values pass the trigger of 0.1 µg/L

Scenario	PECgw DFA (µg/L) biennial			
	Tier I		Tier 2a (DFOP parent)	
	Hops PEARL	Hops PELMO	Hops PEARL	Hops PELMO
Châteaudun	0.754	0.697	0.722	0.681
Hamburg	0.793	0.852	0.772	0.836
Kremsmünster	0.525	0.596	0.515	0.592
Piacenza	0.511	0.448	0.473	0.439
Porto	0.318	0.350	0.277	0.315
Sevilla	0.479	0.428	0.459	0.424
Thiva	0.450	0.426	0.415	0.395

In bold: values pass the trigger of 0.75 µg/L

Lettuce field annual

Scenario	PECgw BYI02960 (µg/L) annual (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.106	0.065	0.065	0.040
Hamburg	0.259	0.212	0.156	0.129
Jokionen	0.095	0.080	0.059	0.050
Kremsmünster	0.175	0.149	0.106	0.090
Porto	0.106	0.130	0.064	0.078
Sevilla	0.002	0.001	0.002	0.001
Thiva	0.043	0.031	0.027	0.020

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) annual (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.135	0.089	0.083	0.056
Hamburg	0.319	0.286	0.193	0.175
Kremsmünster	0.216	0.185	0.130	0.113
Porto	0.211	0.253	0.128	0.155
Sevilla	0.004	0.001	0.003	0.001

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) annual			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.003	0.002	0.003	0.003
Hamburg	0.005	0.005	0.007	0.006
Jokionen	0.003	0.002	-	-
Kremsmünster	0.004	0.004	0.005	0.004
Porto	0.003	0.004	0.005	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.001	0.002	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) annual (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.691	0.554	0.657	0.543
Hamburg	1.165	0.990	1.141	0.987
Jokionen	1.064	0.961	1.037	0.974
Kremsmünster	0.670	0.613	0.650	0.618
Porto	0.412	0.393	0.373	0.374
Sevilla	0.237	0.179	0.211	0.164
Thiva	0.280	0.261	0.252	0.238

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) annual (2st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.691	0.567	0.654	0.558
Hamburg	1.179	1.082	1.153	1.088
Kremsmünster	0.671	0.632	0.651	0.638
Porto	0.456	0.435	0.479	0.472
Sevilla	0.362	0.272	0.376	0.291

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Lettuce field biennial

Scenario	PECgw BYI02960 (µg/L) biennial (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.154	0.106	0.065	0.040
Hamburg	0.379	0.288	0.156	0.129
Jokionen	0.110	0.084	0.059	0.050
Kremsmünster	0.242	0.203	0.106	0.090
Porto	0.138	0.169	0.064	0.078
Sevilla	0.006	0.002	0.002	0.001
Thiva	0.111	0.065	0.027	0.020

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) biennial (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.207	0.137	0.126	0.083
Hamburg	0.443	0.398	0.270	0.237
Kremsmünster	0.291	0.244	0.177	0.149
Porto	0.253	0.302	0.153	0.178
Sevilla	0.009	0.002	0.006	0.002

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) biennial			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.004	0.003	0.005	0.003
Hamburg	0.008	0.006	0.009	0.008
Jokionen	0.003	0.003	-	-
Kremsmünster	0.005	0.005	0.006	0.006
Porto	0.004	0.004	0.006	0.007
Sevilla	<0.001	<0.001	<0.001	<0.001
Thiva	0.003	0.002	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) biennial (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.847	0.668	0.801	0.651
Hamburg	1.393	1.169	1.357	1.168
Jokionen	1.393	1.197	1.372	1.207
Kremsmünster	0.852	0.778	0.823	0.769
Porto	0.461	0.394	0.397	0.365
Sevilla	0.295	0.236	0.258	0.219
Thiva	0.626	0.519	0.668	0.561

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) biennial (2st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.946	0.748	0.955	0.783
Hamburg	1.517	1.411	1.546	1.462
Kremsmünster	0.892	0.880	0.906	0.906
Porto	0.660	0.626	0.688	0.653
Sevilla	0.379	0.290	0.369	0.293

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Lettuce glasshouse

Scenario	PECgw BYI02960 (µg/L) Glasshouse (1st cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	1.132	0.786	0.682	0.474
Hamburg	2.179	1.879	1.310	1.125
Jokionen	0.985	0.769	0.598	0.473
Kremsmünster	1.503	1.330	0.898	0.797
Porto	0.877	0.980	0.524	0.576
Sevilla	0.078	0.018	0.050	0.012
Thiva	0.997	0.717	0.606	0.438

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw BYI02960 (µg/L) Glasshouse (2nd cropping)			
	Tier I		Tier 2a (DFOP)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	1.543	1.073	0.927	0.684
Hamburg	2.843	2.540	1.706	1.534
Kremsmünster	1.819	1.654	1.089	0.991
Porto	1.691	1.787	1.008	1.070
Sevilla	0.116	0.024	0.076	0.016

In italics: values pass the trigger of 0.1 µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw 6-CNA (µg/L) Glasshouse			
	Tier I (1st cropping)		Tier I (2nd cropping)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	0.022	0.016	0.029	0.021
Hamburg	0.038	0.036	0.050	0.048
Jokionen	0.021	0.018	-	-
Kremsmünster	0.028	0.026	0.034	0.031
Porto	0.020	0.022	0.035	0.038
Sevilla	0.002	0.001	0.003	0.001
Thiva	0.019	0.015	-	-

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) Glasshouse (1st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	3.511	2.857	3.605	2.894
Hamburg	6.305	5.095	6.353	5.297
Jokionen	6.390	5.751	6.230	5.829
Kremsmünster	3.573	3.331	3.685	3.402
Porto	1.863	1.703	2.059	1.833
Sevilla	1.098	0.827	1.185	0.917
Thiva	3.020	2.649	2.727	2.416

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

Scenario	PECgw DFA (µg/L) Glasshouse (2st cropping)			
	Tier I		Tier 2a (DFOP parent)	
	Lettuce PEARL	Lettuce PELMO	Lettuce PEARL	Lettuce PELMO
Châteaudun	4.267	3.627	4.127	3.474
Hamburg	7.008	6.341	6.836	6.244
Kremsmünster	3.970	3.761	3.948	3.647
Porto	2.959	2.773	2.760	2.650
Sevilla	1.669	1.283	1.589	1.280

In italics: values pass the trigger of 0.1µg/L
In bold: values pass the trigger of 0.75 µg/L

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	1.38 x 10-4 mol/Einstein in water
Photochemical oxidative degradation in air	DT50 of 4.4 hours (0.18 d) derived by the Atkinson model (AOPWIN version 1.92a). OH (12 h) concentration assumed = 1.5 x 10-6 OH/cm3
Volatilisation	From plant surfaces (BBA guideline): no data Vapour pressure: 9.1 x 10-7 Pa at 20°C
	From soil surfaces (BBA guideline): no data
Metabolites	No data

PEC (air)

Method of calculation	Expert judgement, based on Vapour pressure 9.1 x 10-7 Pa at 20°C, Henry's Law Constant 4.13 x 10-7 Pa m3 mol-1 Atmospheric half life 4.4 – 13.1 hours residues in air are expected to be negligible.

PEC(a)

Maximum concentration	No data provided - none requested

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: BYI 02960, 6-CNA, DFA Surface Water: BYI 02960, 6-CNA, DFA, BYI 02960-succinamide, BYI 02960-azabicyclosuccinmaide Sediment: BYI 02960, 6-CNA, DFA

	Ground water: BYI 02960, 6-CNA, DFA Air: BYI 02960

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

Soil (indicate location and type of study)	New active substance, not applicable
Surface water (indicate location and type of study)	New active substance, not applicable
Ground water (indicate location and type of study)	New active substance, not applicable
Air (indicate location and type of study)	New active substance, not applicable

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

Not readily biodegradable; candidate for chronic (long term) aquatic hazard

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				
Bobwhite quail (Colinus virginianus)	a.s.	Acute	LD50 232	
Canary (Serinus canaria)	a.s.	Acute	LD50 330	
Bobwhite quail (Colinus virginianus)	BYI 02960 SL 2001	Acute	LD50 431 mg a.s. /kg bw	
Hen (Gallus domesticus)	BYI 02960 SL 2001	Acute	LD50 >342 mg a.s. /kg bw	
Mallard duck (Anas platyrhynchos)	a.s.	Short-term	LC50 >825	>4741
Bobwhite quail (Colinus virginianus)	a.s.	Short-term	LC50 >470	>4876
Mallard duck (Anas platyrhynchos)	a.s.	Long-term	NOAEL 83 (measured)	845
Bobwhite quail (Colinus virginianus)	a.s.	Long-term	NOAEL 14 (nominal)	111
Mammals				
Rat	a.s.	Acute	LD50 2000 (cut-off)	
Rat	a.s.	Acute neurotoxicity	LD50 >800	
		Combined acute endpoint :	LD50 1607	
Rat	BYI 02960 SL 200 g/L1	Acute	LD50 > 2000 mg form/kg bw (>5000 cut-off)	
Rat	a.s.	Long-term	NOAEL 6.4	100
Rat	DFA, DFEAF, BYI 02960-CHMP, 6-CNA	see LoE mamtox		
Additional higher tier studies ‡				
-				

1 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

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

Crop (BBCH stage) / Generic focal species	Time scale	DDD	TER1	Annex VI Trigger³
Tier 1 – uptake via diet (Birds)				
Hops (BBCH 31-75) – 1x 0.150 g a.s./ha				
Hops (≥ 20)– Small insectivorous bird ‘finch’				
	Acute	3.80	61	10
	Long-term	0.84	17	5
Hops (20-39)– Small granivorous bird ‘finch’				
	Acute	1.85	126	10

Crop (BBCH stage) / Generic focal species	Time scale	DDD	TER1	Annex VI Trigger³
	Long-term	0.45	32	5
Lettuce (BBCH 12-49) – 1x 0.125 g a.s./ha				
Lettuce (10-19)– Medium herbivorous/granivorous bird ‘pigeon’				
	Acute	6.94	33	10
	Long-term	1.50	9.3	5
Lettuce (10-49)– Small granivorous bird ‘finch’				
	Acute	3.43	68	10
	Long-term	0.83	17	5
Lettuce (10-49)– Small omnivorous bird ‘lark’				
	Acute	3.0	77	10
	Long-term	0.72	19	5
Lettuce (10-19)– Small insectivorous bird ‘wagtail’				
	Acute	3.35	69	10
	Long-term	0.75	19	5

Crop (BBCH stage) / Generic focal species	Time scale	DDD	TER1	Annex VI Trigger³
Tier 1 – uptake via diet (mammals)				
Hops (BBCH 31-75) – 1x 0.150 g a.s./ha				
Hops (≥ 20)– Small insectivorous mammal ‘shrew’				
	Acute	0.81	1984	10
	Long-term	0.151	42	5
Hops (≥ 40)– Small herbivorous mammal ‘vole’				
	Acute	6.14	262	10
	Long-term	1.73	3.7	5
Hops (20-39)– Small omnivorous mammal ‘mouse’				
	Acute	1.29	1246	10
	Long-term	0.31	21	5
Lettuce (BBCH 12-49) – 1x 0.125 g a.s./ha				
Lettuce (≥ 20) - Small insectivorous mammal ‘shrew’				
	Acute	0.68	2381	10
	Long-term	0.13	51	5
Lettuce (40-49)– Small herbivorous mammal ‘vole’				
	Acute	17.05	94	10
	Long-term	4.79	1.3	5
Lettuce (all season)– Large herbivorous mammal ‘lagomorph’				
	Acute	4.39	366	10
	Long-term	0.95	6.8	5
Lettuce (10-49)– Small omnivorous mammal ‘mouse’				
	Acute	2.15	747	10
	Long-term	0.52	12.4	5
Tier 2 – uptake via diet (mammals). Refined ftwa of 0.164 can be used for all weed types and lettuce crop plants for the representative uses.				
Hops (≥ 40)– Small herbivorous mammal ‘vole’				
	Long-term	0.53	12	5
Lettuce (40-49)– Small herbivorous mammal ‘vole’				
	Long-term	1.48	4.3	5

Tier 1– uptake via drinking water (Birds and mammals)				
	Time scale	DDD	TER1	Annex VI Trigger³

Leaf scenario (use in lettuce, 1x0.125 kg a.s./ha) (birds only)	Acute	23	10.1	10
Puddle scenario (birds and mammals)	Not relevant based on escape clause			
Tier 1 – secondary poisoning (Birds and mammals): not relevant, logPow <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	Toxicity1 (mg/L)
Laboratory tests ‡				
Fish				
Rainbow trout (Oncorhynchus mykiss)	a.s.	96 h (static)	Mortality, LC50	>74.2 (mm)
Fathead minnow (Pimephales promelas)	a.s.	96 h (static)	Mortality, LC50	>70.5 (mm)
Common carp (Cyprinus carpio)	a.s.	96 h (static)	Mortality, LC50	>100 (nom)
Sheepshead minnow (Cyprinodon variegatus) (saltwater species)	a.s.	96 h (static)	Mortality, LC50	>83.9 (mm)
Fathead minnow (Pimephales promelas)	a.s.	ELS, 35 d (flow-through)	Survival NOEC	4.41 (mm)
Rainbow trout (Oncorhynchus mykiss)	BYI 02960 SL 200 G2	96 h (static)	Mortality, LC50	>585 (form, nom) >100 (a.s.,nom)
Common carp (Cyprinus carpio)	BYI 02960 SL 200 G2	96 h (static)	Mortality, LC50	>585 (form, nom) >100 (a.s.,nom)
Rainbow trout (Oncorhynchus mykiss)	BYI 02960-succinamide	96 h (static)	Mortality, EC50	>100 (nom)
Rainbow trout (Oncorhynchus mykiss)	DFA (BCS-AB60481 (tech.) = sodium difluoroacetate)	96 h (static)	Mortality, EC50	>10 (nom)
Amphibians				
Frog (Xenopus laevis)	a.s.	96 h (static)	Mortality, LC50	>80 (nom)
Aquatic invertebrates				
Daphnia magna	a.s.	48 h (static)	Mortality, EC50	>77.6 (mm)
Eastern oyster (Crassostrea virginica) (saltwater species)	a.s.	96 h (static)	Inhibition of shell growth, EC50	>29 (mm)
Mysid (Americamysis bahia) (saltwater species), juveniles3	a.s.	96 h (static)	Mortality, EC50	0.26 (mm)
Daphnia magna	a.s.	21 d (semi-static)	Reproduction, NOEC	3.2 (nom)

Group	Test substance	Time-scale (Test type)	End point	Toxicity1 (mg/L)
Mysid (Americamysis bahia) (saltwater species), juveniles	a.s.	28 d (semi-static)	life-cycle toxicity, NOEC	0.0132 4 (mm)
Daphnia magna	BYI 02960 SL 200 G2	48 h (static)	Mortality, EC50	684 (form, nom) 117 (a.s., nom)
Daphnia magna	DFA (BCS-AB60481 (tech.) = sodium difluoroacetate)	48 h (static)	Mortality, EC50	>10 (nom)
Daphnia magna	6-CNA (IC-0)	48 h (static)	Mortality, EC50	>95.1 (mm)
Daphnia magna	BYI 02960-succinamide	21 d (semi-static)	Reproduction, NOEC	43.3 (nom)
Sediment dwelling organisms				
Chironomus riparius	a.s.	48 h (static; water-spiked)	Mortality, EC50	0.0617 (nom)
Chironomus riparius	a.s.	28 d (static; water-spiked)	NOEC	0.00681 (mm)
Chironomus riparius	BYI 02960-succinamide	48 h (static; water-spiked)	Mortality, EC50	>100 (nom)
Chironomus riparius	BYI 02960-azabicyclosuccinamide, sodium salt	48 h (static; water-spiked)	Mortality, EC50	>100 (nom)
Chironomus tentans	6-CNA	96 h (static; water-spiked)	Mortality, EC50	>1 (nom)
Chironomus riparius	DFA (BCS-AB60481 (tech.) = sodium difluoroacetate)	28 d (static; water-spiked)	NOEC	100 (nom)
Chironomus riparius	6-CNA (IC-0)	28 d (static; water-spiked)	NOEC	100 (nom)
Chironomus riparius	BYI 02960 SL 200 G2	28 d (static; water-spiked)	NOEC	0.012 0.00989 mg a.s./L (nom mm)
Algae				
Pseudokirchneriella subcapitata	a.s.	72 h (static)	Biomass: EbC50, Growth rate: ErC50 & Yield: EyC50	>80 (nom)
Pseudokirchneriella subcapitata	BYI 02960 SL 200 G2	72 h (static)	Biomass: EbC50 & Growth rate: ErC50	>250 (form, nom) >42.8 (a.s., nom)

Group	Test substance	Time-scale (Test type)	End point	Toxicity1 (mg/L)
Pseudokirchneriella subcapitata	DFA (BCS-AB60481 (tech.) = sodium difluoroacetate)	72 h (static)	Growth rate: ErC50 and Yield: EyC50	>10 (nom)
Pseudokirchneriella subcapitata	BYI 02960-succinamide	72 h (static)	Growth rate: ErC50 and Yield: EyC50	>10 (nom)
Pseudokirchneriella subcapitata	6-CNA (IC-0)	72 h (static)	Growth rate: ErC50 Yield: EyC50	>100 (nom) 85 (nom)
Aquatic higher plants				
Lemna gibba	a.s.	7 d (static)	Biomass: EbC50, Growth rate: ErC50 and Yield: EyC50	>67.7 (mm)
Microcosm or mesocosm tests				
Not required				

1 indicate whether based on nominal (nom) or mean measured concentrations (mm). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

2 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto = 200 g/L flupyradifurone (nominal), 201 g/L flupyradifurone (analysed) ;

3 Unknown if juveniles are the most sensitive life stage, see B.9

4 ~30% difference on average from the control, but this is considered not biologically relevant - see detailed discussion in DAR

Maximum PECsw values and TER values – application to hops at 1 × 0.150 g as/ha

TERA calculations for fish based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	P. promelas	LC50	> 70 500	17.36	> 4 061	100
BYI 02960 – succinamide	O. mykiss	LC50	> 100 000	4.065	> 24 600	
DFA*	O. mykiss	LC50	> 10 000	1.268 (1.421*)	>7 886 (> 7 037*)	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERLT calculations for fish based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERLT	Trigger
Crop: Hops						
BYI 02960	P. promelas	NOEC	4410	17.36	254	10

TERA calculations for aquatic invertebrates based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	C. riparius	EC50	61.7	17.36	3.53	100

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
DFA*	D. magna	EC50	> 10 000	1.268 (1.421*)	> 7 886 (> 7 037*)	
6-CNA	C. tentans	EC50	> 1 000	0.463	> 2 160	
BYI 02960-succinamide	C. riparius	EC50	> 100 000	4.065	> 24 600	
BYI 02960-azabicyclosuccinamide, sodium salt	C. riparius	EC50	> 100 000	2.499	>40 016	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERLT calculations for aquatic invertebrates based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERLT	Trigger
Crop: Hops						
BYI 02960	C. riparius	NOEC	6.81	17.36	0.39	10
BYI 02960 –succinamide	D. magna	NOEC	43 300	4.065	10 652	
DFA*	C. riparius	NOEC	100 000	1.268 (1.421*)	78 864 (70 373*)	
6-CNA	C. riparius	NOEC	100 000	0.463	215 983	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERA calculations for C. riparius based on FOCUS Step 3 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Hops							
BYI 02960	C. riparius	EC50	61.7	0.394	R1, pond	157	100
				5.531	R1, stream	11	

TERLT calculations for C. riparius based on FOCUS Step 3 for application in hops

Compound	Species	Endpoint [µg a.i./L]		PECsw,max [µg/L]	Scenario	TERLT	Trigger
Crop: Hops							
BYI 02960	C. riparius	NOEC	6.81	0.394	R1, pond	17	10
				5.531	R1, stream	1.23	

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Hops; 90 % drift reduction (no buffer zone)							
BYI 02960	C. riparius	EC50	61.7	0.553	R1, stream	112	100
Crop: Hops; 75 % drift reduction and 10 m buffer zone							
BYI 02960	C. riparius	EC50	61.7	0.589	R1, stream	105	100

TERLT calculations for C. riparius based on FOCUS Step 4 for application in hops with exposure mitigation measures

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Scenario	TERLT	Trigger
Crop: Hops; no buffer zone 90% drift reduction						
BYI 02960	C.riparius	NOEC 6.81	0.553	R1, stream	12.3	10
5 m distance (spray drift buffer) and 90 % drift reduction						
BYI 02960	C.riparius	NOEC 6.81	0.452	R1, stream	15.1	10
15 m distance (spray drift buffer & VFS*) and 75 % drift reduction						
BYI 02960	C.riparius	NOEC 6.81	0.388	R1, stream	17.6	10

*VFS: vegetated filter strip

TERA calculations for algae based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	P. subcapitata	EC50	>42 800	17.36	>2 465	10
DFA	P. subcapitata	EC50	>10 000	1.268	>7 886	10
BYI 02960 – succinamide	P. subcapitata	EC50	>10 000	4.065	>2 460	10
6-CNA	P. subcapitata	EC50	85 000	0.463	183 585	10

TERA calculations for lemna based on FOCUS Step 2 for application in hops

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	L. gibba	EC50	>67 700	17.36	>3 890	10

Maximum PECsw values and TER values – application to lettuce at 1 × 0.125 g as/ha- biennial use (once every two years, at BBCH 12-49) and annual use (use once per year, at BBCH 41-49)

TERA calculations for fish based on FOCUS Step 2 for application in lettuce – biennial (covers annual use)

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Lettuce						
BYI 02960	P. promelas	LC50	> 70 500	11.88	> 5 934	100
BYI 02960 – succinamide	O. mykiss	LC50	> 100 000	0.484	> 206 612	
DFA*	O. mykiss	LC50	> 10 000	1.339 (5.599*)	> 7 468 (> 1 786*)	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERLT calculations for fish based on FOCUS Step 2 for application in lettuce – biennial (covers annual use)

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERLT	Trigger
Crop: Lettuce						
BYI 02960	P. promelas	NOEC	4410	11.88	371	10

TERA calculations for aquatic invertebrates based on FOCUS Step 2 for application in lettuce – biennial (covers annual use)

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	EC50	61.7	11.88	5.20	100
DFA*	D. magna	EC50	> 10 000	1.339 (5.599*)	> 7 468 (> 1 786*)	
6-CNA	C. tentans	EC50	> 1 000	0.579	> 1 727	
BYI 02960-succinamide	C. riparius	EC50	> 100 000	0.484	> 206 612	
BYI 02960-azabicyclosuccinamide, sodium salt	C. riparius	EC50	> 100 000	0.297	> 336 700	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERA for aquatic invertebrates based on Glasshouse PEC SW for application in lettuce in glasshouse

Compound	Species	Endpoint [µg/L]	PECsw,max Glasshouse [µg/L]	TERA	Trigger
Crop: Lettuce					
BYI 02960	C. riparius	EC50 61.7	0.1667	370	100

TERLT calculations for aquatic invertebrates based on FOCUS Step 2 for application in lettuce– biennial (covers annual use)

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERLT	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	NOEC	6.81	11.88	0.57	10
BYI 02960 –succinamide	D. magna	NOEC	43 300	0.484	89 463	
DFA*	C. riparius	NOEC	100 000	1.339 (5.599*)	74 683 (17 860*)	
6-CNA	C. riparius	NOEC	100 000	0.579	172 712	

*) In a worst-case approach, exposure concentrations for DFA are based upon groundwater calculations; however, dilution will occur during transport to surface waters.

TERLT for aquatic invertebrates based on Glasshouse PEC SW for application in lettuce in glasshouse

Compound	Species	Endpoint [µg/L]	PECsw,max Glasshouse [µg/L]	TERLT	Trigger
Crop: Lettuce					
BYI 02960	C. riparius	NOEC 6.81	0.1667	41	10

TERA calculations for C. riparius based on FOCUS Step 3 for application in lettuce – biennial use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	EC50 61.7	0.830	D3 (ditch, 1st)	74	100
			0.840	D3 (ditch, 2nd)	74	
			1.035	D4 (pond, 1st)	60	
			0.794	D4 (stream, 1st)	78	
			1.268	D6 (ditch, 1st)	49	
			0.060	R1 (pond, 1st)	1028	
			0.858	R1 (stream, 1st)	72	
			0.097	R1 (pond, 2nd)	636	
			1.186	R1 (stream, 2nd)	52	
			1.586	R2 (stream, 1st)	39	
			0.940	R2 (stream, 2nd)	66	
			2.226	R3 (stream, 1st)	28	
			3.570	R3 (stream, 2nd)	17	
			0.522	R4 (stream, 1st)	118	
			4.808	R4 (stream, 2nd)	13	

TERA calculations for C. riparius based on FOCUS Step 3 for application in lettuce – annual use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	EC50 61.7	0.813	D3 (ditch, 1st)	76	100
			0.811	D3 (ditch, 2nd)	76	
			0.983	D4 (pond, 1st)	63	
			0.969	D4 (stream, 1st)	64	
			1.206	D6 (ditch, 1st)	51	

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Scenario	TERA	Trigger
			0.337	R1 (pond, 1st)	183	
			2.827	R1 (stream, 1st)	22	
			0.139	R1 (pond, 2nd)	444	
			2.189	R1 (stream, 2nd)	28	
			1.215	R2 (stream, 1st)	51	
			1.044	R2 (stream, 2nd)	59	
			3.698	R3 (stream, 1st)	17	
			3.297	R3 (stream, 2nd)	18	
			0.83	R4 (stream, 1st)	74	
			2.954	R4 (stream, 2nd)	21	

TERLT calculations for C.riparius based on FOCUS Step 3 for application in lettuce – biennial use

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Scenario	TERLT	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	NOEC 6.81	0.830	D3 (ditch, 1st)	8.20	10
			0.840	D3 (ditch, 2nd)	8.11	
			1.035	D4 (pond, 1st)	6.58	
			0.794	D4 (stream, 1st)	8.58	
			1.268	D6 (ditch, 1st)	5.37	
			0.060	R1 (pond, 1st)	114	
			0.858	R1 (stream, 1st)	7.94	
			0.097	R1 (pond, 2nd)	70.2	
			1.186	R1 (stream, 2nd)	5.74	
			1.586	R2 (stream, 1st)	4.29	
			0.940	R2 (stream, 2nd)	7.24	
			2.226	R3 (stream, 1st)	3.06	
			3.570	R3 (stream, 2nd)	1.91	
			0.522	R4 (stream, 1st)	13.1	
			4.808	R4 (stream, 2nd)	1.42	

TERLT calculations for C.riparius based on FOCUS Step 3 for application in lettuce – annual use

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Scenario	TERLT	Trigger
Crop: Lettuce						
BYI 02960	C. riparius	NOEC 6.81	0.830	D3 (ditch, 1st)	8.38	10

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Scenario	TERLT	Trigger
			0.811	D3 (ditch, 2nd)	8.40	
			0.983	D4 (pond, 1st)	6.93	
			0.969	D4 (stream, 1st)	7.03	
			1.206	D6 (ditch, 1st)	5.65	
			0.337	R1 (pond, 1st)	20.2	
			2.827	R1 (stream, 1st)	2.41	
			0.139	R1 (pond, 2nd)	49.0	
			2.189	R1 (stream, 2nd)	3.11	
			1.215	R2 (stream, 1st)	5.60	
			1.044	R2 (stream, 2nd)	6.52	
			3.698	R3 (stream, 1st)	1.84	
			3.297	R3 (stream, 2nd)	2.07	
			0.830	R4 (stream, 1st)	8.20	
			2.954	R4 (stream, 2nd)	2.31	

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce – biennial use* (drift reducing nozzles)

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Drift reduction [%]	Scenario	TERA	Trigger
Crop: Lettuce; 50% drift reduction (No buffer)							
BYI 02960	C. riparius	EC50 61.7	0.434	50	D3 (ditch, 1st)	143	100
			0.446	50	D3 (ditch, 2nd)	139	
			1.033	90	D4 (pond, 1st)	60	
			0.721	90	D4 (stream, 1st)	86	
			1.268	90	D6 (ditch, 1st)	49	
			0.858	90	R1 (stream, 1st)	72	
			1.186	90	R1 (stream, 2nd)	52	
			1.586	90	R2 (stream, 1st)	39	
			0.940	90	R2 (stream, 2nd)	66	
			2.226	90	R3 (stream, 1st)	28	
			3.570	90	R3 (stream, 2nd)	17	
			4.808	90	R4 (stream, 2nd)	13	

*The PECsw calculated with only drift reducing nozzles are not available for the annual use in lettuce

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (5 m distance) – biennial use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Lettuce; 5 m drift buffer (no drift reduction)						
BYI 02960	C. riparius	EC50 61.7	1.035	D4 (pond, 1st)	59.7	100
			0.721	D4 (stream, 1st)	85.6	
			1.268	D6 (ditch, 1st)	48.7	
			0.858	R1 (stream, 1st)	71.9	
			1.186	R1 (stream, 2nd)	52.0	
			1.586	R2 (stream, 1st)	38.9	
			0.940	R2 (stream, 2nd)	65.6	
			2.226	R3 (stream, 1st)	27.7	
			3.570	R3 (stream, 2nd)	17.3	
			4.808	R4 (stream, 2nd)	12.8	

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (5 m distance) – annual use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Scenario	TERA	Trigger
Crop: Lettuce; 5 m drift buffer (no drift reduction)						
BYI 02960	C. riparius	EC50 61.7	0.234	D4 (pond, 1st)	264	100
			0.234	D4 (stream, 1st)	264	
			0.982	D4 (pond, 1st)	59.7	
			0.969	D4 (stream, 1st)	85.6	
			1.206	D6 (ditch, 1st)	48.7	
			2.827	R1 (stream, 1st)	71.9	
			2.189	R1 (stream, 2nd)	52.0	
			1.215	R2 (stream, 1st)	38.9	
			1.044	R2 (stream, 2nd)	65.6	
			3.698	R3 (stream, 1st)	27.7	
			3.297	R3 (stream, 2nd)	17.3	
			0.830	R4 (stream, 1st)	74.34	
			2.954	R4 (stream, 2nd)	12.8	

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (10 m distance) – biennial use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 10 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							
BYI 02960	C. riparius	EC50 61.7	1.034	S	D4 (pond, 1st)	59.7	100
			0.721	S	D4 (stream, 1st)	85.6	
			1.268	S	D6 (ditch, 1st)	48.7	
			0.389	R	R1 (stream, 1st)	159	
			0.540	R	R1 (stream, 2nd)	114	

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
			0.716	R	R2 (stream, 1st)	86.2	
			0.422	R	R2 (stream, 2nd)	146	
			1.009	R	R3 (stream, 1st)	61.2	
			1.630	R	R3 (stream, 2nd)	37.9	
			2.184	R	R4 (stream, 2nd)	28.3	

*VFS: vegetated filter strip

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (10 m distance) – annual use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 10 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							
BYI 02960	C. riparius	EC50 61.7	0.975	S	D4 (pond, 1st)	63.3	100
			0.969	S	D4 (stream, 1st)	63.7	
			1.206	S	D6 (ditch, 1st)	51.2	
			1.270	R	R1 (stream, 1st)	48.6	
			0.954	R	R1 (stream, 2nd)	64.7	
			0.553	R	R2 (stream, 1st)	112	
			0.469	R	R2 (stream, 2nd)	132	
			1.683	R	R3 (stream, 1st)	36.7	
			1.506	R	R3 (stream, 2nd)	41.0	
			1.345	R	R4 (stream, 1st)	45.9	
			0.705	R	R4 (stream, 2nd)	87.5	

*VFS: vegetated filter strip

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (15 m distance) – biennial use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 15 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							
BYI 02960	C. riparius	EC50 61.7	1.034	S	D4 (pond, 1st)	59.7	100
			0.721	S	D4 (stream, 1st)	85.6	
			1.268	S	D6 (ditch, 1st)	48.7	
			0.375	R	R2 (stream, 1st)	165	
			0.528	R	R3 (stream, 1st)	117	
			0.856	R	R3 (stream, 2nd)	72.1	
			1.144	R	R4 (stream, 2nd)	53.9	

*VFS: vegetated filter strip

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (15 m distance) – annual use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 15 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
BYI 02960	C. riparius	EC50 61.7	0.975	S	D4 (pond, 1st)	63.3	100
			0.969	S	D4 (stream, 1st)	63.7	
			1.206	S	D6 (ditch, 1st)	51.2	
			1.270	R	R1 (stream, 1st)	48.6	
			0.954	R	R1 (stream, 2nd)	64.7	
			1.683	R	R3 (stream, 1st)	36.7	
			1.506	R	R3 (stream, 2nd)	41.0	
			1.345	R	R4 (stream, 1st)	163	
			0.705	R	R4 (stream, 2nd)	45.9	

*VFS: vegetated filter strip

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (20 m distance) – biennial use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 20 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							
BYI 02960	C. riparius	EC50 62	1.033	S	D4 (pond, 1st)	59.7	100
			0.721	S	D4 (stream, 1st)	85.6	
			1.268	S	D6 (ditch, 1st)	48.7	
			0.856	R	R3 (stream, 2nd)	72.1	
			1.144	R	R4 (stream, 2nd)	53.9	

*VFS: vegetated filter strip

Refined TERA calculations for C. riparius based on FOCUS Step 4 for application in lettuce (20 m distance) – annual use

Compound	Species	Endpoint [µg/L]	PECsw,max [µg/L]	Buffer type	Scenario	TERA	Trigger
Crop: Lettuce; 20 m distance (spray drift mitigation only (S) or spray drift mitigation + VFS* (R))							
BYI 02960	C. riparius	EC50 61.7	0.975	S	D4 (pond, 1st)	63.3	100
			0.969	S	D4 (stream, 1st)	63.7	
			1.206	S	D6 (ditch, 1st)	51.2	
			0.662	R	R1 (stream, 1st)	93.2	
			0.500	R	R1 (stream, 2nd)	123	
			0.882	R	R3 (stream, 1st)	70.0	
			0.790	R	R3 (stream, 2nd)	78.1	
			0.705	R	R4 (stream, 2nd)	87.5	

*VFS: vegetated filter strip

Table B.9.2.5.5-11 TERLT calculations for C. riparius based on FOCUS Step 4 for biennial application in lettuce (drift reducing nozzles)

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Drift reduction [%]	Scenario	TERLT	Trigger
Crop: Lettuce; drift reduction (no buffer)							

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	Drift reduction [%]	Scenario	TERLT	Trigger
BYI 02960	C.riparius	NOEC 6.81	0.434	50%	D3 (ditch, 1st)	15.7	10
			0.446	50%	D3 (ditch, 2nd)	15.3	
			1.033	90%	D4 (pond, 1st)	6.59	
			0.721	90%	D4 (stream, 1st)	9.45	
			1.268	90%	D6 (ditch, 1st)	5.37	
			0.858	90%	R1 (stream, 1st)	7.94	
			1.186	90%	R1 (stream, 2nd)	5.74	
			1.586	90%	R2 (stream, 1st)	4.29	
			0.940	90%	R2 (stream, 2nd)	7.24	
			2.226	90%	R3 (stream, 1st)	3.06	
			3.570	90%	R3 (stream, 2nd)	1.91	
			4.808	90%	R4 (stream, 2nd)	1.42	

TERLT calculations for C.riparius based on FOCUS Step 4 for biennial application in lettuce**

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	% drift reduction	buffer zone	Scenario	TERLT	Trigger
Crop: Lettuce; D scenarios: buffer (spray drift only) + drift reduction (nozzles); R scenarios: buffer (spray drift + VFS*) + drift reduction								
BYI 02960	C.riparius	NOEC 6.81	1.033	90%	20	D4 (pond, 1st)	6.59	10
			0.721	90%	20	D4 (stream, 1st)	9.45	
			1.268	90%	20	D6 (ditch, 1st)	5.37	
			0.389	0%	20	R1 (stream, 1st)	17.5	
			0.540	0%	10	R1 (stream, 2nd)	12.6	

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	% drift reduction	buffer zone	Scenario	TERLT	Trigger
			0.375	0%	10	R2 (stream, 1st)	18.2	
			0.422	0%	10	R2 (stream, 2nd)	16.1	
			0.528	90%	15	R3 (stream, 1st)	12.9	
			0.856	90%	20	R3 (stream, 2nd)	7.96	
			1.144	90%	20	R4 (stream, 2nd)	5.95	

*VFS: vegetated filter strip
** per subscenario, the minimum required mitigation measure is shown to reach a TER < trigger. If this cannot be reached, the TER is shown at the strictest mitigation measure

TERLT calculations for C.riparius based on FOCUS Step 4 for annual application in lettuce**

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	% drift reduction	buffer zone	Scenario	TERLT	Trigger
Crop: Lettuce; D scenarios: buffer (spray drift only) + drift reduction (nozzles); R scenarios: buffer (spray drift + VFS*) + drift reduction)								
BYI 02960	C.riparius	NOEC 6.81	0.234	0%	5	D3 (ditch, 1st)	29.1	10
			0.234	0%	5	D3 (ditch, 2nd)	29.1	
			0.975	90%	20	D4 (pond, 1st)	6.98	
			0.969	90%	20	D4 (stream, 1st)	7.03	
			1.206	90%	20	D6 (ditch, 1st)	5.65	
			0.662	0%	20	R1 (stream, 1st)	10.29	
			0.500	0%	20	R1 (stream, 2nd)	13.62	
			0.553	0%	10	R2 (stream, 1st)	12.31	

Compound	Species	Endpoint [µg a.i./L]	PECsw,max [µg/L]	% drift reduction	buffer zone	Scenario	TERLT	Trigger
			0.469	0%	10	R2 (stream, 2nd)	14.52	
			0.882	90%	20	R3 (stream, 1st)	7.72	
			0.790	90%	20	R3 (stream, 2nd)	8.62	
			0.379	0%	10	R4 (stream, 1st)	17.97	
			0.705	90%	20	R4 (stream, 2nd)	9.66	

*VFS: vegetated filter strip

** per subscenario, the minimum required mitigation measure is shown to reach a TER < trigger. If this cannot be reached, the TER is shown at the strictest mitigation measure

TERA calculations for algae based on FOCUS Step 2 for application in lettuce

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	P. subcapitata	EC50	>42 800	11.88	>3 603	10
DFA	P. subcapitata	EC50	>10 000	1.339	>7 468	10
BYI 02960 –succinamide	P. subcapitata	EC50	>10 000	0.484	>20 661	10
6-CNA	P. subcapitata	EC50	85 000	0.579	146 805	10

TERA calculations for lemna based on FOCUS Step 2 for application in lettuce

Compound	Species	Endpoint [µg/L]		PECsw,max [µg/L]	TERA	Trigger
Crop: Hops						
BYI 02960	L. gibba	EC50	>67 700	11.88	>5 699	10

Bioconcentration						
	Active substance	BYI 02960-succinamide	BYI 02960-azabicyclo-succinamide	DFA	BYI 02960-DFEAF	6-CNA
logPO/W	1.2	-1.3	-2.7	-3.1	-0.2	1.52
Bioconcentration factor (BCF)1 ‡	not required					
Annex VI Trigger for the bioconcentration factor	100 (a.s. not readily biodegradable)					

Bioconcentration	
Clearance time (days) (CT50)	-
(CT90)	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-

1 only required if log PO/W >3.

Effects on honeybees (Annex IIA, point 8.7, Annex IIIA, point 10.4)

Acute toxicity studies on adult honeybees		
Test substance	Acute oral toxicity (LD50 µg/bee)	Acute contact toxicity (LD50 µg/bee)
a.s.	1.2	122.8
Flupyradifurone SL 200 G1	3.2 (a.s.)	15.7 (a.s.)
BYI02960-difluoroethyl-amino-furanone (BYI02960-DFEAF)	>81.5	>100
BYI02960 - hydroxy	>105.3	>100
Difluoroacetic acid	>107.9	>100
6-chloronicotinic acid (6-CNA = IC-0);	>107.1	>100
6-chloro-picolylalcohol	>106.7	>100

1 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

Chronic toxicity studies on adult honeybees*		
Test substance	LC50 µg/L	LC50 µg/bee/d
a.s.	61100 µg/kg	1.83
BYI02960-difluoroethyl-amino-furanone (BYI02960-DFEAF)	>10000	>0.435
BYI02960 - hydroxy	>10000	>0.420
Difluoroacetic acid	>10000	>0.379
6-chloronicotinic acid (6-CNA = IC-0);	>10000	>0.418
6-chloro-picolylalcohol	>10000	>0.413

* These studies were performed in 2012/2013. Some uncertainties were noted during peer review arising from the lack of toxic standard, the lack of information on the history of the used bees, the lack of experience of conducting these kind of tests and the lack of experience for the interpretation of these tests. However, it is noted that currently no harmonised guideline is available, nor an agreed reference performance for any potential toxic standard. The studies were used in the risk assessment as additional information only.

Chronic toxicity studies on honeybee larvae*		
Test substance	NOEC µg/diet	NOEC µg/larvae
a.s.	≥ 10000 (nominal)	1.32 µg a.s./larvae (nominal) (accumulated exposure on day +4, +5 and +6 after grafting of the larvae)

* This study was performed in 2010. Some uncertainties were noted during peer review arising the lack of experience of conducting these kind of tests and the lack of experience for the interpretation of these tests. The study was used in the risk assessment as additional information only.

Acute toxicity studies on adult bumblebees	
Test substance	Acute contact toxicity (LD50 µg/bee)
Flupyradifurone SL 200 G1	>100 (a.s.)

1 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

Field or semi-field tests
Five acceptable semi-field (gauze tunnel) studies are available, where BYI 02960 formulations were applied to Phacelia tanacetifolia with honey bees actively foraging on the crop (i.e. during bee flight) with different application regimes (ranging from 1x 75 g a.s. foliar spray to 1x 300 g a.s./ha soil application + 2x 200 g a.s./ha. Furthermore, two field studies are available in oil seed rape where BYI 02960 formulations were applied with honey bees actively foraging on the crop (i.e. during bee flight) at 2x 200 g a.s./ha with preceding 1x 300 g a.s./ha soil application and 10 g a.s./kg seed seed treatment. In the semi-field and field studies, the only clearly treatment-related effects seen were short-term reduced flight intensity (one to at most seven days after application) and behaviour anomalies in some bees (one day after application) after the foliar application during full flowering. Furthermore some slight, transient, potential effects were observed on other parameters. However this did not lead to reduced colony performance or survival. Also, a large residue package is available with a.o. residues measured in pollen and nectar taken both from foragers and from hives, from studies in Phacelia and oil seed rape. Lastly, a long-term feeding study was submitted in which colonies were forced to feed on up to 10 mg/kg diet for six weeks. This did not lead to collapse of the colonies, including overwintering. The overall data package shows that the spraying of 2x 200 g a.s./ha on a bee-attractive crop during full flowering and active foraging of honey bees may have caused some slight transient treatment related effects, but does not result in adverse acute or long-term (including overwintering) effects on honey bee colonies. Therefore, the risk to honey bees from application on the non-bee attractive crops hops and lettuce is clearly covered.

Hazard quotients for honey bees (Annex IIIA, point 10.4)
Application rate: 0.150 kg a.s./ha (hops, worst case for lettuce)

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	1.22	50
a.s.	oral	125	50
Flupyradifurone SL 200 G	Contact	9.6	50
Flupyradifurone SL 200 G	oral	47	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)
Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR50 g a.s./ha)
Typhlodromus pyri	BYI 02960 SL200 G 1	Mortality	17
Aphidius rhopalosiphi	BYI 02960 SL200 G 1	Mortality	<0.5

1 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

Hops, 1 x 0.150 g a.s./ha

Test substance	Species	Effect (LR50 g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
BYI 02960 SL200 G	Typhlodromus pyri	17	8.8	1.7	2
	Aphidius rhopalosiphi	<0.5	>300	>58	2

[1] at distance of 3 m and drift rate of 19.33%

Lettuce, 1 x 0.125 g a.s./ha

Test substance	Species	Effect (LR50 g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
BYI 02960 SL200 G	Typhlodromus pyri	17	7.4	0.2	2
	Aphidius rhopalosiphi	<0.5	>250	>6.9	2

[1] at distance of 1 m and drift rate of 2.77% for vegetables < 50 cm.

Further laboratory and extended laboratory studies

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	End point	% effect[1]	Trigger value
Extended laboratory test						
Aphidius rhopalosiphi	adults, < 48 h	BYI 02960 SL200[3] Initial residues on barley seedlings	0.5, 0.89, 1.58, 2.81, 5.0	Mortality Reproduction	LR50: 2.02 g a.s./ha ER50: >0.89 and <1.58 g a.s./ha	50 %
Typhlodromus pyri	protonymphs	BYI 02960 SL200[3] Initial residues on bean leaf discs	15, 32, 67, 142, 300	Mortality Reproduction	LR50: 177 g a.s./ha ER50: >142 g a.s./ha	50%
Coccinella semtempunctata	larvae 4 d	BYI 02960 SL200[3] Initial residues on bean leaves	8, 17, 35, 72, 100, 150, 160, 250, 380, 600	Mortality Reproduction	LR50: 273.9 g a.s./ha No effects up to 250 g a.s./ha	50%
Aleochara bilineata	adults	BYI 02960 SL200[3] Initial residues sprayed on soil	10, 21, 45, 95, 200, 300	Reproduction	ER50: >300 g a.s./ha	50%
Aphidius rhopalosiphi	adults, < 48 h	BYI 02960 SL200 G[3] Semi-field aged residues on maize seedlings	2x 250 with 10d interval; ageing up to 56 d	Mort. / Repr. 0 DAA 14 DAA 28 DAA 42 DAA 49 DAA 56 DAA	100* / n.a. 90* / n.a. 76.7* / n.a. 29.6* / 89.9* 20.0* / 37.6 6.7 / 0.6	50 %

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	End point	% effect1	Trigger value
Orius laevigatus	nymphs, 4-5 d	BYI 02960 SL200 G 3 Semi-field aged residues on apple trees	2x 250 with 10d interval; ageing up to 42 d	Mort. / Repr. 0 DAA 14 DAA 28 DAA 42 DAA	 100* / n.a. 76* / n.a. 25* / -6.5. 9.8 / 13	50 %

1 Corrected mortality / reduction of reproduction relative to control. Positive percentages relate to adverse effects (e.g. a negative value for reproduction means an increase compared to the control).
* statistically significant; DAA = day after last application; n.a. = not assessed.
3 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

Field or semi-field tests
Two NTA field studies were performed with BYI 02960 SL 200 (200 g flupyradifurone/L) on grassland to similate an off-crop community. Soil-surface and plant-dwelling arthropod communities were sampled just before application and 1, 2, 4 and 8 weeks after application. Netherlands: NTA full fauna off-crop field study. Spray application rates: 1x 0.51, 1.7, 5.1, 21 g a.i./ha Community level NOER = 21 g a.i./ha Population level NOER = 5.1 g a.i./ha Population level NOEAER = 21 g a.i./ha, effect class 2 (two taxa adversely affected on one sampling moment shortly after application in the highest treatment rate, but both populations recovered withtin the next sampling moment one or two weeks later). SW France: NTA full fauna off-crop field study. Spray application rates: 1x 0.51, 1.7, 5.1, 21 g a.i./ha Community level NOER = 21 g a.i./ha Population level NOER = 1.7 g a.i./ha Population level NOEAER = 5.1 g a.i./ha effect class 2 (two taxa adversely affected on one sampling moment, recovery at next sampling moment). Population level NOEAER = 21 g a.i./ha effect class 3a (three taxa adversely affected, of which one on two sampling moments; effects no longer statistically significant on the last two sampling dates) NOER: No Observed Effect Rate NOEAER: No Observed Ecologically Adverse Effect Rate The underlined value is used in the off-field risk assessment (without SF)

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 point1
Earthworms			
	a.s.	Acute 14 days	LC50 185.6 mg a.s./kg d.w.soil (10% organic matter)
	BYI 02960 SL 200 G 3	Acute 14 days	LC50 709 mg form/kg d.w.soil = 121 mg a.s./kg d.w.soil (5% organic matter)

Test organism	Test substance	Time scale	End point1
	BYI 02960 SL 200 G 3	Chronic 56 days	NOEC 8.9 mg form/kg d.w.soil = 1.5 mg a.s./kg d.w.soil (10% organic matter)
	BYI 02960-difluoroacetic acid	Acute 14 days	LC50 > 958 mg /kg d.w.soil (10% organic matter)
	BYI 02960-difluoroacetic acid	Chronic 56 days	NOEC 59 mg /kg d.w.soil (10% organic matter)
	IC-0 = 6-CAN	Acute 14 days	LC50 > 1000 mg /kg d.w.soil (10% organic matter)
	IC-0 = 6-CAN	Chronic 56 days	NOEC 95 mg /kg d.w.soil (5% organic matter)
Other soil macro-organisms			
Hypoaspis aculeifer	BYI 02960 SL 200 G 3	Chronic 28 days	NOEC 1000 mg form/kg d.w.soil = 170 mg a.s./kg d.w.soil (5% organic matter)
	BYI 02960-difluoroacetic acid	Chronic 14 days	NOEC 958 mg /kg d.w.soil (5% organic matter)
	IC-0 = 6-CAN	Chronic 14 days	NOEC 100 mg /kg d.w.soil (5% organic matter)
Collembola			
Folsomia candida	BYI 02960 SL 200 G 3	Chronic 28 days	NOEC 8.47 mg form/kg d.w.soil = 1.44 mg a.s./kg d.w.soil (5% organic matter)
	BYI 02960-difluoroacetic acid	Chronic 28 days	NOEC 95.8 mg /kg d.w.soil (5% organic matter)
	IC-0 = 6-CAN	Chronic 28 days	NOEC 90 mg /kg d.w.soil (5% organic matter)
Soil micro-organisms			
Nitrogen mineralisation	a.s.		< 25% effect at day 28 at 3.8 mg a.s/kg soil
	BYI 02960 SL 200 G 3		< 25% effect at day 28 at 16.59 µL form/kg d.w.soil (3.335 mg a.s/kg soil)
	IC-0 = 6-CAN		< 25% effect at day 28 at 1.33 mg /kg d.w.soil
Carbon mineralisation	a.s.		< 25% effect at day 28 at 3.8 mg a.s/kg soil
	BYI 02960 SL 200 G 3		< 25% effect at day 28 at 16.59 µL form/kg d.w.soil (3.335 mg a.s/kg soil)
Field studies2			
Litter bag study (overspray): Soil treated with 150 g a.i./ha for plateau concentration (incorporated) + the annual rate of 300 g a.i./ha (oversprayed), both with product BYI 02960 SL 200 G 3. At a measured initial concentration of 237 µg as/kg dry soil no statistically significant effects were found on soil litter degradation 217 d after treatment. Litter bag study (seed treatment): Soil treated with 150 g a.i./ha for plateau concentration (incorporated, product BYI 02960 SL 200 G 3) + the annual rate of 265 g a.i./ha (by sowing of treated wheat seed, product BYI 02960 FS 480 G). At a measured initial concentration of 243 µg as/kg dry soil no statistically significant effects were found on soil litter degradation 217 d after treatment.			

1 Correction of endpoints not necessary due to log Pow <2.0

2 litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies (a previously included earthworm field study was removed because it was considered invalid in the pesticide peer review meeting)
3 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

Toxicity/exposure ratios for soil organisms
Hops, 1 x 0.150 kg a.s./ha (annual use, covers biennial)

Test organism	Test substance	Time scale	Soil PEC1	TER	Trigger
Earthworms					
	a.s.	Acute	0.160	1.16E+3	10
	BYI 02960 SL 200 G	Acute	0.160	7.6E+2	10
	DFA	Acute	0.019	5.2E+04	10
	6-CNA	Acute	0.015	6.7E+04	10
	BYI 02960 SL 200 G	Chronic	0.160	9.4	5
	DFA	Chronic	0.019	3.1E+03	5
	6-CNA	Chronic	0.015	6.3E+03	5
Other soil macro-organisms					
Soil mite	BYI 02960 SL 200 G	Chronic	0.160	≥ 1.1E+3	5
	DFA	Chronic	0.019	≥5.0E+04	5
	6-CNA	Chronic	0.015	≥6.7E+03	5
Collembola	BYI 02960 SL 200 G	Chronic	0.160	9.0	5
	DFA	Chronic	0.019	5.0E+03	5
	6-CNA	Chronic	0.015	6.0E+03	5

1 For the a.s., the PECinitial + PECaccumulation is used.

Lettuce, 1 x 0.125 kg a.s./ha (biennial use, covers annual use)

Test organism	Test substance	Time scale	Soil PEC1	TER	Trigger
Earthworms					
	a.s.	Acute	0.136	1.4E+03	10
	BYI 02960 SL 200 G	Acute	0.136	8.9E+02	10
	DFA	Acute	0.014	>7.0E+04	10
	6-CNA	Acute	0.012	≥ 83E+3	10
	BYI 02960 SL 200 G	Chronic	0.136	11	
	DFA	Chronic	0.014	4.2E+3	5
	6-CNA	Chronic	0.012	7.9E+3	5
Other soil macro-organisms					
Soil mite	BYI 02960 SL 200 G	Chronic	0.136	≥1.3E+03	5
	DFA	Chronic	0.014	≥ 68E+3	5
	6-CNA	Chronic	0.012	≥ 8.3E+3	5
Collembola	BYI 02960 SL 200 G	Chronic	0.136	10.6	5
	DFA	Chronic	0.014	6.8E+3	5
	6-CNA	Chronic	0.012	7.5E+3	5

1 For the a.s., the PECinitial + PECaccumulation is used.

Effects on non target plants (Annex IIA, point 8.12, Annex IIIA, point 10.8)
Preliminary screening data

Not required as ER50 tests are provided

Laboratory dose response tests

Most sensitive species	Test substance	ER50 (g a.s./ha) vegetative vigour	ER50 (g a.s./ha) seedling emergence	Exposure1 (g a.s./ha)	TER	Trigger
11 species: Cucumber (Cucumis sativa), buckwheat (Fagopyrum esculentum), oilseed rape (Brassica napus), sugar beet (Beta vulgaris), soybean (Glycine max), lettuce (Lactuca sativa), tomato (Lycopersicon esculentum), onion (Allium cepa), oat (Avena sativa), ryegrass (Lolium perenne), corn (Zea mays)	BYI 02960 SL 200 g/L2	>410 (g a.s./ha)	>410 (g a.s./ha)	30 g a.s./ha	>14	5

1 for the worst case use in hops, 150 g a.s./ha, at distance of 3 m and drift rate of 19.77%
2 BYI 02960 SL 200 G = BYI 02960 SL 200 g/L = Flupyradifurone SL 200 G = Sivanto

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

Not required

Effects on biological methods for sewage treatment (Annex IIA 8.15)

Test type/organism	end point
Activated sludge	>962 mg a.s./L

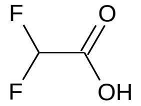
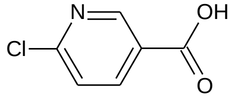
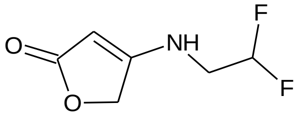
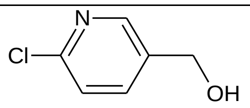
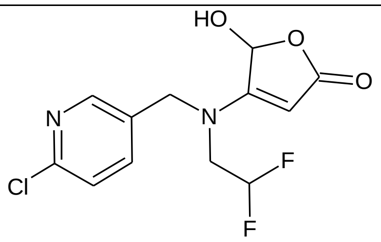
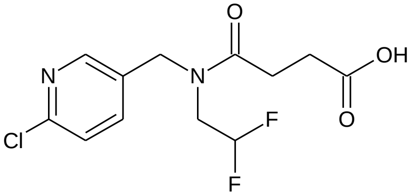
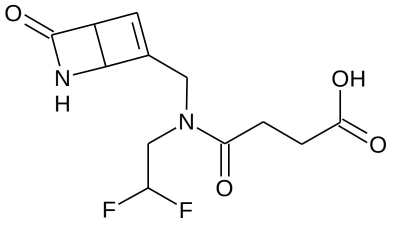
Ecotoxicologically relevant compounds
Active substance (in terms of compound under consideration, e.g. a variant such as an ester) must always be included in the soil, water and groundwater compartment. Ecotoxicological relevance of metabolites should be based on risk assessment.

Compartment	
soil	Parent
water	Parent
sediment	Parent
groundwater	Parent

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	1999/45/EC: R50/53
Active substance	EC 12725/2008: Acute 1 and Chronic 1; GHS09; H400 and H410

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name/SMILES notation**	Structural formula**
DFA	difluoroacetic acid FC(F)C(=O)O	
6-CNA	6-chloronicotinic acid OC(=O)c1cnc(Cl)cc1	
DFEAF	4-[(2,2-difluoroethyl)amino]furan-2(5*H*)-one FC(F)CNC1=CC(=O)OC1	
CHMP 6-CPA (6-chloro-picolylalcohol)	(6-chloropyridin-3-yl)methanol OCc1cnc(Cl)cc1	
BYI 02960-hydroxy flupyradifurone-hydroxy M8	4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl)amino}-5-hydroxyfuran-2(5*H*)-one OC2OC(=O)C=C2N(CC(F)F)Cc1ccc(Cl)nc1	
BYI 02960-succinamide flupyradifurone-succinamide	4-{[(6-chloropyridin-3-yl)methyl](2,2-difluoroethyl)amino}-4-oxobutanoic acid Clc1ccc(CN(CC(F)F)C(=O)CCC(=O)O)cn1	
flupyradifurone-azabicyclosuccin-amide BYI 02960-azabicyclosuccinamide	4-{(2,2-difluoroethyl)[(3-oxo-2-azabicyclo[2.2.0]hex-5-en-6-yl)methyl]amino}-4-oxobutanoic acid O=C1NC2C(CN(CC(F)F)C(=O)CCC(=O)O)=CC12	

* The metabolite name in bold is the name used in the conclusion.
** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

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
BUN	blood urea nitrogen
bw	body weight
CA	chromosome aberration
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CHO	Chinese hamster ovary cells
Chol	cholesterol
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
CLP	classification, labelling and packaging
cm	centimetre
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DDD	daily dietary dose
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
GHS07	hazard pictogram (exclamation mark) according to globally harmonized system
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
H302	hazard statement for acute oral toxicity according to Reg. (EC) No. 1272/2008
ha	hectare
Hb	haemoglobin
Hct	haematocrit
HGPRT	hypoxanthine-guanine phosphoribosyl transferase
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UV	high performance liquid chromatography with ultra violet detector
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
iv	intravenous
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_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LLNA	local lymph node assay
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	meter Canopy Height
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
µg	microgram
mL	millilitre
mm	millimetre

mN	milli-newton
MNT	micronucleus test
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})
POEM	Predictive Operator Exposure Model
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
REACH	Registration, Evaluation, Authorisation of CHemicals
RMS	rapporteur Member State
RPE	respiratory protective equipment
RUD	residue per unit dose
SANCO	Directorate-General for Health and Consumers
SL	soluble concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
SWAN	Surface Water Assessment eNabler
$t_{1/2}$	half-life (define method of estimation)
TDS	time dependent sorption
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
UF	uncertainty factor
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WHO	World Health Organization
wk	week
yr	year
↓	decrease
↑	increase