CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance spirotetramat[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 Austria, for the pesticide active substance spirotetramat are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative uses of spirotetramat as an insecticide and acaricide on citrus and lettuce. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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KEY WORDS

Spirotetramat, peer review, risk assessment, pesticide, insecticide, acaricide

[1] On request from the European Commission, Question No EFSA-Q-2009-00345, approved on 27 May 2013.

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[3] Following consideration of the position paper submitted by the applicant but not evaluated during the peer review, the data gap concerning the toxicological profile of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy has been removed. Related texts in sections 2 and 3 have also been amended. Corrections have been made to pages 2, 8, 9, 10 and 17.

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SUMMARY

Spirotetramat is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC Austria (hereinafter referred to as the 'RMS') received an application from Bayer CropScience AG for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/560/EC of 2 August 2007.

The RMS provided its initial evaluation of the dossier on spirotetramat in the Draft Assessment Report (DAR), which was received by the EFSA on 5 May 2008. In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of addenda and an updated Volume 1 of the DAR, which were received on 29 March 2012. The peer review was initiated on 4 May 2012 by dispatching the DAR and addenda for consultation of the Member States and the applicant Bayer CropScience AG in accordance with Article 11(7) of Commission Regulation (EU) No 188/2011.

Following consideration of the comments received on the DAR and its addenda, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology, and EFSA should adopt a conclusion on whether spirotetramat can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of spirotetramat as an insecticide and acaricide on citrus (outdoor) and lettuce (indoor and outdoor), as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the area of identity, physical/chemical/technical properties and methods of analysis a data gap was identified for a confirmatory method/data for the analysis of residues in water.

In the mammalian toxicology area it was not possible to confirm the compliance of the batches tested with the proposed specification (a critical area of concern was identified). A data gap was identified for toxicological data to establish the relevance of impurities in the technical specification.

Based on the available data, residue definitions for monitoring and risk assessment were proposed for plant and animal commodities. No chronic or acute risks were identified for the consumers.

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. The potential for groundwater exposure above the parametric drinking water limit of 0.1µg/L, consequent to these representative uses, by spirotetramat and its soil transformation products spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-MA-amide and 4-methoxy-cyclohexanone was concluded to be low.

In the ecotoxicology section, the potential for endocrine disruptor effects in birds and fish could not be finalised with the available data. In addition, a data gap was identified to further address the long-term risk to insectivorous birds for the representative use in citrus.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[4] Council Directive 91/414/EEC[5] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[6] (hereinafter referred to as 'the Regulation') lays down the detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant 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 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of upto 8 months where additional information is required to be submitted by the applicant(s) in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC Austria (hereinafter referred to as the 'RMS') received an application from Bayer CropScience AG for approval of the active substance spirotetramat. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2007/560/EC of 2 August 2007[7].

The RMS provided its initial evaluation of the dossier on spirotetramat in the DAR, which was received by the EFSA on 5 May 2008 (Austria, 2008). In accordance with Article 11(6) of Commission Regulation (EU) No 188/2011 additional information was requested from the applicant. The RMS's evaluation of the additional information was provided in the format of addenda and an updated Volume 1 of the DAR, which were received by EFSA on 29 March 2012. The peer review was initiated on 4 May 2012 by dispatching the DAR and addenda to the Member States and the applicant Bayer CropScience AG for consultation and comments in accordance with Article 11(7) of the Regulation. 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 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 4 September 2012. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was

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

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.

[6] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51-55.

[7] Commission Decision 2007/560/EC of 2 August 2007 recognising in principle the completeness of the dossiers submitted for detailed examination in view of the possible inclusion of chlorantraniliprole, heptamaloxyglucan, spirotetramat and Helicoverpa armigera nucleopolyhedrovirus in Annex I to Council Directive 91/414/EEC. OJ No L 213, 15.8.2007, p. 29-31.

concluded that additional information should be requested from the applicant, and that the EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in April – May 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as an insecticide and acaricide on citrus (outdoor) and lettuce (indoor and outdoor), as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) 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 and its addenda,
- the Reporting Table (6 September 2012),
- the Evaluation Table (27 May 2013),
- the reports 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 addendum (compiled version of March 2013 containing all individually submitted addenda (Austria, 2013)) 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

Spirotetramat is the ISO common name for *cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one (IUPAC). It has been clarified during the peer review that due to the presence of a plane of symmetry in the molecule the parent spirotetramat is optically inactive (see also Evaluation Table, data requirement 1.2; EFSA, 2013).

The representative formulated product for the evaluation was 'Movento® 150 OD', an oil dispersion (oil-based suspension concentrate, OD) containing 150 g/L spirotetramat.

The representative uses evaluated comprise field use spray applications against scales, aphids, mealy bugs and mites on citrus, and field and greenhouse applications against aphids on lettuce. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), Sanco/10597/2003 – rev. 8.1 (European Commission, 2009) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of the active substance is 970 g/kg. The reference specification is based on industrial scale production. No FAO specification exists.

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 spirotetramat or the representative formulation. The main data regarding the identity of spirotetramat and its physical and chemical properties are given in Appendix A.

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

The compounds in the residue definition for monitoring purposes in food and feed of plant origin can be monitored by LC-ESI-MS/MS with a LOQ for each analyte of 0.01 mg/kg for high water content, high acid content and high oil content matrices, and with a LOQ of 0.1 mg/kg for dry and difficult matrix types. Appropriate methods exist to enforce the residue definitions for monitoring purposes in food of animal origin, soil and air. Validation with a single transition has been provided for the analytical method (LC-MS/MS) for spirotetramat in water therefore a data gap was identified for a confirmatory method/data. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

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

Spirotetramat was discussed at the Pesticides Peer Review Experts' Meeting 98 held in Parma in November 2012.

An area of concern was identified as the information reported in the confidential addendum (January 2013; Austria, 2013) is not sufficient to conclude on the compliance of the toxicological batches with the specification, since the levels of some impurities in key studies are significantly different compared to the specification and no data were provided on their toxicological potential (the submitted

data did not allow the relevance of the impurities in the proposed specification to be defined). A data gap is identified for toxicological data to establish the relevance of impurities in the technical specification.

Spirotetramat is rapidly and extensively absorbed after oral administration; it is widely distributed with the highest concentrations found in plasma, liver and kidney. It metabolises through cleavage of the ester group and O-demethylation of the 8-methoxy group; it is rapidly excreted, mainly via urine. Spirotetramat is not acutely toxic via the oral, inhalation and dermal routes; it is not a skin irritant, but it is an eye irritant (R36* "Irritating to eyes" to be considered by ECHA) and a skin sensitiser (R43* "May cause sensitisation by skin contact" to be considered by ECHA). After repeated administration in subacute and subchronic studies, spirotetramat mainly affected thymus (involution) and brain (dilatation) in dogs, with a No Observed Adverse Effect Level (NOAEL) of 5 mg/kg bw per day in a 52-week study. The occurrence of brain effects and the neurotoxic potential of spirotetramat in dogs were discussed in the Pesticides Peer Review Experts' Meeting: the RMS considered that brain dilatation is a congenital anomaly, however in the historical control data (provided only in 6 studies out of 43) there were incidences of brain dilatation (one finding per study). For spirotetramat, there are three incidences and no clear dose-response relationship. The experts concluded that, based on the concurrent control and historical control data, it cannot be excluded that brain dilatation is treatment-related.

The critical effects in a 2-year study in rats were decreased body weight and body weight gain, increased liver and kidney weight, spermatid degeneration in testes, and germ cell exfoliated debris in epididymis. The presence of alveolar macrophages and interstitial pneumonia in females already at the NOAEL was discussed in the meeting: No dose-response relationship was observed. According to the applicant, aggregation of macrophages was noted with or without interstitial pneumonia, which was interpreted as a continuum of morphological changes and as such, they were evaluated together. In the study report macrophages were mentioned when observed as a single finding, and not specifically mentioned in the case of pneumonia (being included in the sum of the findings leading to the identification of pneumonia). Therefore pneumonia was regarded as a more severe effect. Combining the incidences of macrophages and pneumonia for females, they were only statistically significant at the high dose level. Therefore the relevant NOAEL of 12.5 mg/kg bw per day was confirmed, based on kidney effects.

Spirotetramat did not show genotoxic or carcinogenic potential. Tested in a multigeneration study in rats, spirotetramat caused decreased body weight and body weight gain, decreased kidney weight, tubular dilatation, abnormal sperm cells and decreased reproductive performance. These findings resulted in no pregnancies at high dose in rats. Furthermore, testicular effects were seen in different studies, other than reproductive; no mechanistic data were available to demonstrate that spirotetramat acts through the hormonal chain. The experts agreed that this warrants R62* ("Possible risk of impaired fertility", to be considered by ECHA). The agreed relevant parental, reproductive and offspring NOAELs are 70 mg/kg bw per day. In the rat teratogenicity study, at the high dose, several malformations (dysplasia of forelimb bone, altered appearance of the sacral vertebral arch and pelvic shift) were observed outside of historical control data, which were considered to trigger a proposal for classification as R63* ("Possible risk of harm to the unborn child", to be considered by ECHA). The agreed maternal and developmental NOAELs are 140 mg/kg bw per day. In rabbits the maternal and developmental NOAELs are 10 mg/kg bw per day and 160 mg/kg bw per day, respectively.

Based on the 1-year dog study, the agreed Acceptable Daily Intake (ADI) is 0.05 mg/kg bw per day, with an Uncertainty Factor (UF) of 100. (It is noted that the Pest Management Regulatory Authority of Canada recommended an ADI of 0.02 mg/kg bw per day based on the same NOAEL derived from the same dog study, with an UF of 100 plus an extra factor of 3: the *Pest Control Products Act* requires the application of an additional factor to take into account completeness of the data with respect to the

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

exposure of, and toxicity to, infants and children, as well as potential prenatal and postnatal toxicity.) It was agreed that the 1-year dog study was also appropriate to derive the Acceptable Operator Exposure Level (AOEL), applying an UF of 100, which results in the same value as the ADI (no need to correct for oral absorption). For the Acute Reference Dose (ARfD), it was agreed to use the acute neurotoxicity study, applying an UF of 100, resulting in an ARfD of 1 mg/kg bw. The estimated exposure of operators, workers and bystanders are below the AOEL even without the use of Personal Protective Equipment (PPE).

The following metabolites were not found in rats:

- spirotetramat-monohydroxy (Rat oral LD_{50} > 2000 mg/kg bw, Ames: negative)
- spirotetramat-dihydroxy (Rat oral LD_{50} > 2000 mg/kg bw, Ames: negative)
- spirotetramat-enol-Glc

The results of the available toxicological data are in line with the parent data; however, the repeated dose toxicity effects have not been investigated.

As for the rat metabolites:

- spirotetramat-enol (53 - 87 % of the administered dose).
- spirotetramat-desmethyl-enol (5 - 37 % of the administered dose)
- spirotetramat-ketohydroxy (0.5 - 1.1 % of the administered dose) (Rat oral LD_{50} > 2000 mg/kg bw, Ames: negative)
- spirotetramat-desmethyl-ketohydroxy (0.1 - 0.7 % of the administered dose) (Rat oral LD_{50} > 2000 mg/kg bw, Ames: negative)
- spirotetramat-enol-GA (0.2 - 0.8 % of the administered dose)
- spirotetramat-enol-alcohol (0.4 - 1.6 % of the administered dose)

it can reasonably be assumed that they have been tested in the toxicological assays; this holds true in particular for spirotetramat-enol, for which the reference values of spirotetramat are considered to apply, as well as for its glucuronic conjugate (spirotetramat-enol-Glc) and for spirotetramat-enol-GA (both metabolism and structure related); however, for the other metabolites, present in the metabolism in very low amounts, in principle it cannot be excluded that effects of concern shown by spirotetramat could be caused by one of these metabolites with very high potency. However, considering the information reported in the position paper submitted by the applicant, it is unlikely that the metabolites spirotetramat-monohydroxy and spirotetramat-ketohydroxy (included in the residue definition) are more toxic than spirotetramat.

3. Residues

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

The metabolism in plants was investigated in 4 different plant groups; on oilseeds/pulses (cotton), leafy crops (lettuce), root vegetables (potato) and fruit crops (apple), using ^{14}C-spirotetramat labelled on a single position in the azaspirodecenyl moiety. Studies were conducted with a total of 2 or 3 foliar applications and using experimental designs representative of the supported uses. On apples however, samples were collected 63 days after the last application while PHIs of less than 21 days are requested on fruiting crops.

Unchanged spiroteramat was the predominant component of the radioactive residues accounting for 20 % to 72 % TRR in most of the samples, except in cotton seeds and potato tubers where it was almost not detected and residues were mainly composed of the metabolite spirotetramat-enol (40 % to 66 % TRR). The metabolite spirotetramat-enol and its glucuronic conjugate was also identified as a major metabolite in lettuce (*ca* 0.9 mg/kg), cotton gin trash and apple leaves (*ca* 10 to 30% TRR). The

remaining radioactivity was composed of numerous minor metabolites, each accounting for less than 5 % TRR, with the exception of the metabolite spirotetramat-ketohydroxy, which was detected in all plant matrices and represented up to 9 % TRR in cotton seed, lettuce and apple, and up to 30 % TRR in cotton gin trash and potato leaves. In addition, but in apple only, the metabolite spirotetramat-monohydroxy was also identified in significant proportions, amounting to 16 % TRR in fruits (0.10 mg/kg). A similar metabolic pathway was observed in all plant groups. The major metabolic reactions involved first the hydrolytic cleavage of the ethyl carbonate group to form the metabolite spirotetramat-enol, which is further degraded by oxidation or reduction to form the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy. Additional hydroxylation, oxidation, demethylation and glucoside conjugations result in several supplementary minor metabolites.

Based on these studies, the residue definition for risk assessment was proposed as "**sum of spirotetramat, spirotetramat-enol, spirotetramat-enol-Glc, spirotetramat-ketohydroxy and spirotetramat-monohydroxy, expressed as spirotetramat**" assuming that all metabolites are of similar toxicity as the parent. A data gap was however identified to address the impact of the possible changes in the stereochemistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy on the consumer risk assessment (see Evaluation Table, data requirement 3.3; EFSA, 2013). For monitoring, the residue definition was limited to the "**sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat**" as both represent the major part of the residues. Moreover, as spirotetramat residues are not stable under frozen storage conditions and degraded to spirotetramat-enol, the inclusion of this metabolite in the residue definition for monitoring is necessary.

Numerous residue trials conducted on a large number of crops were submitted and evaluated in the DAR, in addition to the representative uses on citrus and lettuce. All data were taken into account in the course of the peer review. The samples were analysed for spirotetramat and its 4 metabolites included in the residue definition for risk assessment. MRLs were derived for a total of 20 plant commodities and an overall conversion factor of 2 was proposed for risk assessment. Standard hydrolysis studies were conducted with spirotetramat and its 4 major metabolites. Under sterilisation conditions, spirotetramat and spirotetramat-enol-Glc were significantly degraded to spirotetramat-enol, and spirotetramat-ketohydroxy was almost entirely converted to spirotetramat-MA-amide. In contrast, spirotetramat-enol and spirotetramat-monohydroxy were seen to remain stable under all conditions. As for primary crops, the metabolite spirotetramat-enol appears to represent an adequate marker for the residues in processed commodities, since spirotetramat and spirotetramat-enol-Glc are degraded to spirotetramat-enol, whereas the latter remains stable under all process conditions. A large dataset of processing studies was provided, and processing and conversion factors were proposed for citrus, pome fruits, stone fruits, grapes, tomato, bean and hop.

Spirotetramat and spirotetramat-enol residues were seen not to be stable under frozen conditions at -18 °C and were significantly degraded in some matrices to spirotetramat-enol and spirotetramat-ketohydroxy, respectively. However, when analysed for both spirotetramat and spirotetramat-enol, the total residues are stable in high water-, high starch- and high oil-content matrices for at least 18 months. Therefore, it can be concluded that the samples from the residue trials were stored under conditions for which the integrity of the total residues (sum of spirotetramat and spirotetramat-enol) was demonstrated.

A confined rotational crop study conducted at the dose rate of 406 g/ha was provided. The parent spirotetramat and its main primary crop metabolite spirotetramat-enol were nearly not detected in rotational crop matrices, where residues were mostly composed of the metabolites spirotetramat-ketohydroxy and spirotetramat-desmethyl-ketohydroxy and their conjugates. Field rotational crop trials were submitted to confirm that no significant residues are expected to be present in rotational crops when spirotetramat is applied on a primary crop according to the representative GAPs.

Livestock intakes were calculated to be up to 1.9 mg/kg DM in ruminants and 0.27 mg/kg DM in poultry, and therefore metabolism studies were provided. In all goat and poultry matrices, radioactive

residues were shown to be almost completely composed of the metabolite spirotetramat-enol and its glucuronic acid conjugate spirotetramat-enol-GA, accounting both together for 65 % to 95 % TRR, except in poultry fat, where spirotetramat-enol represented only 18 % TRR. The residue definition was therefore proposed as the "**sum of spirotetramat-enol and spirotetramat-enol-GA expressed as spirotetramat**" for risk assessment and limited to the metabolite spirotetramat-enol for monitoring. Based on the feeding study, MRLs were proposed at 0.02 mg/kg in kidney and at the LOQ for the other ruminant and pig products. A feeding study was not provided and MRLs were not proposed for poultry products, as it was clear from the metabolism study that no residues are expected in poultry matrices.

No acute or chronic risks were identified for the consumers. Using the EFSA PRIMo model and considering the STMR and HR values derived from the supervised residue trials and the MRLs proposed for animal products, the highest IEDI is 7 % of the ADI (WHO, Cluster B) and the highest IESTI, 6 % of the ARfD (lettuce).

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, spirotetramat exhibited very low persistence, forming the major metabolites (>10 % applied radioactivity (AR)) spirotetramat-enol (max. 100 % AR) and spirotetramat-ketohydroxy (24 % AR), which exhibited very low to moderate and low to moderate persistence, respectively. The metabolite spirotetramat-MA-amide was formed at levels triggering consideration for groundwater exposure (5.2 % AR) and exhibited low persistence. Mineralisation of the azaspirodecenyl-3- ^{14}C radiolabel to carbon dioxide accounted for 10 - 19 % AR after 50 days (range from 4 soils), and reached 12.1 % after 126 days in the single soil where the incubation continued beyond 50 days. The formation of unextractable residues (not extracted by formic acid acidified acetonitrile / water followed by acetonitrile / 1N hydrochloric acid then acetonitrile) for this radiolabel accounted for 21 – 31 % AR after 50 days, and 28 % after 126 days in the single soil where the incubation continued beyond 50 days. In an anaerobic soil incubation spirotetramat also exhibited very low persistence forming the same metabolites as under aerobic conditions, with spirotetramat-MA-amide being formed at a slightly higher level than in aerobic incubations at up to 7.2 % AR. In a laboratory soil photolysis study, a novel transformation product 4-methoxy-cyclohexanone was formed at up to 10 % AR. Spirotetramat exhibited medium mobility in soil. The metabolites spirotetramat-enol and spirotetramat-ketohydroxy exhibited very high to high soil mobility and spirotetramat-MA-amide exhibited very high soil mobility. Soil adsorption measurements were not available for 4-methoxy-cyclohexanone, therefore the groundwater exposure assessment was completed using the worst case assumption that this metabolite has no soil adsorption potential. The available data indicate that soil mobility is not pH dependent for these compounds. In satisfactory field dissipation studies carried out at 4 sites in the USA (New York, Florida, California and Washington, spray application to the soil surface on bare soil plots in late spring and at three sites to bare soil where previously seeded crops (bush beans, tomatoes and onions) subsequently emerged) spirotetramat exhibited very low persistence. Sample analyses were carried out for spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy and spirotetramat-MA-amide. During sample handling and extraction spirotetramat-enol was not stable, it converted to spirotetramat-ketohydroxy. When residues were expressed as the sum of these 4 compounds, the total residue exhibited low to moderate persistence (the DT_{90} were 19 to 78 days).

In laboratory incubations in dark aerobic natural sediment water systems, spirotetramat exhibited very low persistence, forming the major metabolites spirotetramat-enol (max. 79 % AR in water and 36 % AR in sediment, exhibiting moderate persistence) and spirotetramat-ketohydroxy (max. 13 % AR in water and 28 % in sediment, which was stable). The unextractable sediment fraction (not extracted by formic acid acidified acetonitrile / water followed by acetonitrile / 1N hydrochloric acid then acetonitrile) for the azaspirodecenyl-3- ^{14}C and azaspirodecenyl-5- ^{14}C radiolabels accounted for 33 – 36 % AR at study end (120 days). Mineralisation of these radiolabels accounted for 6 - 24 % AR at the end of the study. Under the conditions of a laboratory sterile aqueous natural water photolysis study,

spirotetramat-enol as well as the major transformation products 4-methoxy-cyclohexyl-aminocarboxylic acid (max 11 % AR) and 4-methoxy-cyclohexanone (max 17 % AR) were formed.

The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) were carried out for spirotetramat and the transformation products spirotetramat-enol, spirotetramat-ketohydroxy, 4-methoxy-cyclohexanone and 4-methoxy-cyclohexyl-aminocarboxylic acid, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator). For the active substance spirotetramat, appropriate step 3 (FOCUS, 2001) and step 4 calculations were available[8]. The step 4 calculations that were only completed for the use on citrus appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented. Vegetated buffer strips to mitigate run-off input have not been implemented in this step 4 modelling. For the representative protected lettuce use, specific PEC in surface water and sediment were not calculated. However, emissions from glasshouses are usually assumed to be 0.2 % (FOCUS, 2008). This emission level is within that which would be calculated at FOCUS step 3 for leafy vegetables and step 4 for citrus with a 20 m spray drift buffer zone. Therefore these field PEC estimates can be used to conclude on the aquatic risk from the glasshouse use.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the FOCUS tool PEARL 4.4.4[9] for the active substance spirotetramat and its soil transformation products spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-MA-amide and 4-methoxy-cyclohexanone. For spirotetramat-enol, the PEARL tool was parameterised to implement a single first-order reversible binding (SFO-RB) model[10]. For the photolysis product 4-methoxy-cyclohexanone the simulations were run, applying this metabolite at the soil surface as if it was an active substance. The results of this modelling indicate that the potential for groundwater exposure from the representative uses by spirotetramat and its soil transformation products spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-MA-amide and 4-methoxy-cyclohexanone above the parametric drinking water limit of 0.1 µg/L can be concluded to be low, in geoclimatic situations that are represented by all 7 pertinent FOCUS groundwater scenarios.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

Information on the potential for racemisation of enantiomers of the metabolite spirotetramat-ketohydroxy in soil and natural water systems and spirotetramat-MA-amide in soil was not available to the peer review. As spirotetramat-MA-amide reached levels in soil that only triggered consideration for groundwater exposure, and for the representative uses being assessed the potential for groundwater exposure above the parametric drinking water limit was assessed as low, there is no concern in relation to the representative uses and enantiomers of spirotetramat-MA-amide. The impact of the enantiomer composition of spirotetramat-ketohydroxy on the environmental risk assessment needs to be considered. This has been done in section 5.

5. Ecotoxicology

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

Spirotetramat was discussed during the Pesticides Peer Review Experts' Meeting 100 (11-15 February 2013).

[8]Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7
[9]Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA PPR, 2007) and Walker equation coefficient of 0.7
[10]This model is described in FOCUS kinetics (FOCUS, 2006) guidance where it is termed the 'SFORB model'.

An area of concern was identified as regards the compliance of the toxicological batches with the specification, since the levels of some impurities in key studies are significantly different compared to the specification and no data were provided on their ecotoxicological potential.

As no mechanistic data were submitted in the mammalian toxicology section to demonstrate that spirotetramat acts through the hormonal chain, a concern was raised for birds and fish. The available data did not specifically address this issue, therefore a general data gap was identified to further address the potential for endocrine disruptor effects in birds and fish for the field uses. No further data were deemed necessary for mammals because the NOAEL used for risk assessment for wild mammals was considered sufficient to cover such potential effects.

A low risk was indicated for **birds** (acute and short-term) and **mammals** (acute and long-term) at the first-tier risk assessment, while the long-term risk for birds was indicated high for the representative field uses. A refined risk assessment was performed for the representative use in lettuce (field use) by considering the wood pigeon (*Columba palumbus*, as herbivorous birds) and yellow wagtail (*Motacilla flava*, as insectivorous birds) as focal species as well as related ecological data. A refinement was also performed for the representative use in citrus by considering the great tit (*Parus major*, insectivorous) as focal species and the related ecological data. These risk refinements were discussed at the Pesticides Peer Review Experts' Meeting 100. The experts agreed that the PD value for wood pigeon was not reliable because it was not supported by robust data. Therefore the risk assessment was amended by assuming the standard PD value of 1. The TER, including measured residue data, was still below the trigger (TER = 4.1). However the experts agreed that the available information support a weight of evidence approach to conclude a low risk for herbivorous birds, i.e. lettuce is of low energy content and therefore it is not the major part of the diet for birds. The PD and PT for yellow wagtail were considered sufficiently conservative for the representative use in lettuce. The TER was above the trigger, indicating a low risk. Overall, the long-term risk for birds for the representative use in lettuce was concluded to be low. As regards the risk refinement for the representative use in citrus, no concerns were raised except that the PT of 0.61 for great tit was derived from literature data. It was noted that therefore this value is considered obsolete. A new value of 0.79 is recommended by the authors of the above literature data for great tit in orchards. The risk assessment was therefore amended accordingly, however the resulting TER was below the trigger (TER = 4). Since no further information was available to address the long-term risk to insectivorous birds for the representative use in citrus, a data gap was identified. The risk for birds and mammals was considered low for the glasshouse uses.

Toxicity data were available for fish, aquatic invertebrates, sediment-dwelling organisms and algae with the active substance, the formulated product (except for aquatic invertebrates), and the metabolites spirotetramat-enol and 4-methoxy-cyclohexanone. In addition, for chironomids, studies were also available with the metabolites spirotetramat-ketohydroxy and 4-methoxy-cyclohexyl-aminocarboxylic acid. For aquatic plants studies were available with spirotetramat and spirotetramat-enol. *Chironomus riparius* was the most sensitive species based on an acute study with the formulation and on a chronic study with the active substance. Therefore, the acute and chronic risk assessments for **aquatic organisms** were driven by endpoints derived for *Chironomus riparius*. The chronic risk to aquatic organisms was assessed as low at FOCUS step 3, while the acute risk was assessed as low at FOCUS step 4 with mitigation measures comparable to a 5 m no-spray buffer zone for the use in citrus. The risk was assessed as low for the representative uses in lettuce (field and glasshouse). The risk from the relevant metabolites was also considered as low. The large margin of safety on the TER trigger for *Chironomus riparius* from exposure to the metabolite spirotetramat-ketohydroxy means that for the representative uses assessed the uncertainty in relation to the enantiomer composition of what was tested in the available ecotoxicology study and the enantiomer composition to which aquatic organisms would be exposed (see section 4) is not of concern.

The risk assessment based on the calculation of HQ values for honey **bees** indicated a low risk. Spirotetramat is a systemic active substance and according to its mode of action as a lipid biosynthesis inhibitor, it is particularly effective against the juvenile stages of aphids, whereas adults are strongly

affected in their fecundity. Therefore, to address such potential effects on honey bees and honey bee larvae, several higher tier tests were made available. These higher tier studies were considered at the Pesticides Peer Review Experts' Meeting 100 and overall, a low risk to honey bees was concluded for all representative uses.

The first-tier risk assessment for **non-target arthropods** based on the calculation of HQ values was performed for the two standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi*. The in-field and off-field risk was indicated high for *T. pyri* for both representative field uses. The in-field risk was indicated as high also for *A. rhopalosiphi* for the representative use in citrus. Higher tier studies with additional species were available. At the Pesticides Peer Review Experts' Meeting 100 it was concluded that overall the available data package indicated that the in-field recovery of predatory mite fauna is possible within one year. Therefore, the overall risk assessment for non-target arthropods is considered addressed for all representative uses.

A low risk was assessed for **earthworms, soil macro and microorganisms** (including the risk from the relevant metabolites), **terrestrial non-target plants** (based on semi-field study) and **biological methods for sewage treatment plants**. The large margin of safety on the TER trigger for earthworms from exposure to the metabolite spirotetramat-ketohydroxy means that for the representative uses assessed the uncertainty in relation to the enantiomer composition of what was tested in the available ecotoxicology study and the enantiomer composition to which soil organisms would be exposed (see section 4) is not of concern.

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
spirotetramat	Very low persistence Biphasic DT_{50} 0.09 - 0.3 of a day (DT_{90} 0.34 - 1.26 days, 20ºC, above pF 2 soil moisture) USA field studies: Single first-order DT_{50} 0.3 - 1 day	Low risk
spirotetramat-enol	Very low to moderate persistence Biphasic DT_{50} 0.02 - 0.18 of a day (DT_{90} 10.9 - 40.9 days, 20ºC, above pF 2 soil moisture)	Low risk
spirotetramat-ketohydroxy	low to moderate persistence Single first-order DT_{50} 1.5 - 14.2 days (20ºC, above pF 2 soil moisture)	Low risk
4-methoxy-cyclohexanone (formed via photolysis at the soil surface)	Very low persistence DT_{50} < 1 day (20ºC, above pF 2 soil moisture)	Low risk

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
spirotetramat	medium mobility K_{Foc} 159 - 435 mL/g	No	yes	Yes	Low risk to aquatic organisms in surface water
spirotetramat-enol	Very high to high mobility K_{doc} 27 - 99 mL/g	No	No data, not needed	Yes	Low risk to aquatic organisms in surface water
spirotetramat-ketohydroxy	Very high to high mobility K_{Foc} 41 - 99.1 mL/g	No	No data, not needed	Yes	Low risk to aquatic organisms in surface water
spirotetramat-MA-amide	Very high mobility K_{Foc} 4.4 - 25.5 mL/g	No	No data, not needed	No data, not needed	No data, not needed
4-methoxy-cyclohexanone (formed via photolysis at the soil surface)	Data not available but a conservative assessment was completed assuming no soil adsorption.	No	No data, not needed	No data, not needed	Low risk to aquatic organisms in surface water

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
spirotetramat	Low risk to aquatic organisms
spirotetramat-enol	Low risk to aquatic organisms
spirotetramat-ketohydroxy	Low risk to aquatic organisms (based on data with chironomids)
4-methoxy-cyclohexyl-aminocarboxylic acid (water only aqueous photolysis product)	Low risk to aquatic organisms (based on data with chironomids)
4-methoxy-cyclohexanone (water only photolysis product)	Low risk to aquatic organisms

6.4. Air

Compound (name and/or code)	Toxicology
spirotetramat	Not acutely toxic via inhalation
spirotetramat-enol	No data available

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

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

- Confirmatory method/data for the analysis of spirotetramat residues in water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Toxicological data to establish the relevance of impurities in the technical specification (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 2).
- Data to address the impact of the possible changes in the stereochemistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy on the consumer risk assessment (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).
- Further data to address the potential for endocrine disruptor effects in birds and fish (relevant for the field representative uses evaluated; submission date proposed by the applicant: unknown; see section 5).
- To further address the long-term risk to insectivorous birds (relevant for the representative in citrus; submission date proposed by the applicant: unknown; see section 5).

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

- Mitigation measures comparable to a 5 m no-spray buffer zone are necessary to address the acute risk to aquatic organisms for the representative use in citrus.

9. Concerns

9.1. Issues that could not be finalised

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

1. The potential for endocrine disruptor effects in birds and fish could not be finalised with the available data.

9.2. Critical areas of concern

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

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level

does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

2. The toxicological compliance of the proposed specification with the batches tested in the toxicological and ecotoxicological data package could not be demonstrated.

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

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

In addition to the issues identified in the table, all columns are grey as the technical material specification proposed was not demonstrated to be comparable to the material used in the testing that was used to derive the toxicological reference values.

Representative use		**Citrus**	**Lettuce** (field)	**Lettuce** (protected)
Operator risk	Risk identified			
	Assessment not finalised			
Worker risk	Risk identified			
	Assessment not finalised			
Bystander risk	Risk identified			
	Assessment not finalised			
Consumer risk	Risk identified			
	Assessment not finalised			
Risk to wild non target terrestrial vertebrates	Risk identified	X		
	Assessment not finalised	X[1]	X[1]	
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[1]	X[1]	
Groundwater exposure active substance	Legal parametric value breached			
	Assessment not finalised			
Groundwater exposure metabolites	Legal parametric value breached			
	Parametric value of 10µg/L[(a)] breached			
	Assessment not finalised			
Comments/Remarks				

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

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APPENDICES

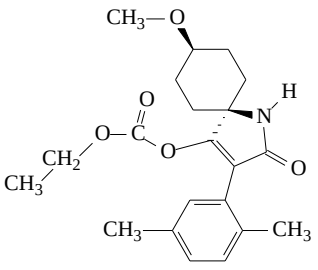
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	Spirotetramat
Function (*e.g.* fungicide)	Insecticide/Acaricide

Rapporteur Member State (EU)	Austria
Co-rapporteur Member State	-
OECD Joint Review Project:	USA (US EPA): Lead country, Toxicology Canada (PMRA): Physical and Chemical Properties, Identity & Methods of Analysis, Residues Austria (AGES): Residues, Fate and Behaviour, Ecotoxicology UK (CRD): Import tolerances

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	*cis*-4-(ethoxycarbonyloxy)-8-methoxy-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-2-one
Chemical name (CA) ‡	*cis*-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl ethyl carbonate
CIPAC No ‡	795
CAS No ‡	203313-25-1
EC No (EINECS or ELINCS) ‡	Not allocated
FAO Specification (including year of publication) ‡	Not applicable
Minimum purity of the active substance as manufactured ‡	970 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Open
Molecular formula ‡	$C_{21}H_{27}NO_5$
Molecular mass ‡	373.45 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	142 °C (99.2 %)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	235 °C (99.2 %)
Appearance (state purity) ‡	Pure material: light beige powder (99.1 %) Technical material: white powder (97.5 %)
Vapour pressure (state temperature, state purity) ‡	Purity 99.2% 5.6×10^{-9} Pa for 20 °C 1.5×10^{-8} Pa for 25 °C 1.5×10^{-6} Pa for 50 °C
Henry's law constant ‡	at pH 4: 6.24×10^{-8} Pa x m^3 x mol^{-1} at pH 7: 6.99×10^{-8} Pa x m^3 x mol^{-1} at pH 9: 1.09×10^{-7} Pa x m^3 x mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	Purity 99.1 % at pH 4: 33.5 mg/L at 20°C at pH 7: 29.9 mg/L at 20°C at pH 9: 19.1 mg/L at 20°C In distilled water, purity 99.4 % at pH 6.0 – 6.3: 33.4 mg/L at 20°C
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C in g/L (99.1 %) Ethanol 44 n-hexane: 0.055 toluene: 60 dichloromethane: > 600 acetone: 100 – 120 ethyl acetate: 67 dimethyl sulfoxide 200 - 300
Surface tension ‡ (state concentration and temperature, state purity)	61.65 mN/m at 20 °C (99.1 %) (90 % saturated solution) 60.5 mN/m at 20 °C (97.5 %) (90 % saturated solution)
Partition co-efficient ‡ (state temperature, pH and purity)	Purity 99.1 % log $P_{O/W}$ = 2.51 at 20 °C (pH 4) log $P_{O/W}$ = 2.51 at 20 °C (pH 7) log $P_{O/W}$ = 2.50 at 20 °C (pH 9)
Dissociation constant (state purity) ‡	pKa = 10.7 (99.1 %)

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Purity 99.2 % λ_{max} (nm) ε (1000cm^2/mol) 211 22.0 x 10^3 276 0.8 x 10^3 ε = 74.1 L/mol*cm at 290 nm <u>at pH 2</u>: λ_{max} [nm] molar absorptivity [1000 cm²/mol] 201 26823.64 213 20704.35 ε = 750.63 L/mol*cm at 290 nm <u>at pH 10</u>: λ_{max} [nm] molar absorptivity [1000 cm²/mol] 212 22417.81 no absorbance at 290 nm	
Flammability ‡ (state purity)	not highly flammable Auto-flammability: no self-ignition up to 401 °C	(97.5 %) (97.5 %)
Explosive properties ‡ (state purity)	not explosive	(97.5 %)
Oxidising properties ‡ (state purity)	not oxidizing	(97.5 %)

Summary of representative uses evaluated (*spirotetramat*)

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 a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	Interval between appl. (min)	kg a.s./hL min-max	water L/ha min-max	kg a.s./ha min-max		
Citrus all types	EU-S	Movento® 150 OD	F	scales, aphids, mealy bugs, mites	OD	150 g/L	spray	BBCH 78 at last application; first application not earlier than mid of May	2	21	0.0096	1000 L/ha and m CH*, max 3000 L/ha	0.096 kg a.s./ha and m CH*, max 0.288 kg a.s./ha (3 metres)	14	representative use for the EU-evaluation
Lettuce head and leafy	EU-N EU-S	Movento® 150 OD	F	aphids	OD	150 g/L	spray	BBCH 48 at last application	max 2	14	0.0072 - 0.0144	500-1000	0.072	7	representative use for the EU-evaluation
Lettuce, head and leafy	EU-N EU-S	Movento® 150 OD	G	aphids	OD	150 g/L	spray	BBCH 48 at last application	max 2	14	0.0072 - 0.0144	500-1000	0.072	7	representative use for the EU-evaluation

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

* CH: Canopy Height

(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr).
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	HPLC-UV , GC-FID and Karl Fischer
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat
Food of animal origin		Spirotetramat-enol expressed as spirotetramat
Soil		Spirotetramat
Water	surface	Spirotetramat
	drinking/ground	Spirotetramat
Air		Spirotetramat

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-ESI-MS/MS (method 01084) for each analyte stated in the current residue definition. confirmation: two transitions monitored ILV available LOQ: 0.01 mg/kg tomato (high water content), avocado (high oil content), orange (high acid content), potato (high water and high starch content) LOQ: 0.1 mg/kg hop cone dried (matrix difficult to analyse)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-ESI-MS/MS (method 00969/M001) for spirotetramat-enol confirmation: two transitions monitored ILV available LOQ of 0.005 mg/kg for milk; LOQ of 0.01 mg/kg for fat, liver, kidney, muscle, and egg.
Soil (analytical technique and LOQ)	LC-ESI-MS/MS; LOQ = 5 µg/kg
Water (analytical technique and LOQ)	LC-MS/MS (one transition), LOQ = 0.05 µg/L In drinking water and surface water or HPLC-UV, LOQ = 5.0 µg/L in surface water Confirmatory method/data is required.
Air (analytical technique and LOQ)	LC-UV, LOQ = 10 µg/m^3

Body fluids and tissues (analytical technique and LOQ)	Not relevant since spirotetramat in neither classified as toxic (T) or very toxic (T^+)

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

	Peer review proposal
Active substance	None

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	95 % absorbed (rat study, 2 mg/kg bw)
Distribution ‡	highest levels found in plasma, liver and kidney
Potential for accumulation ‡	no evidence for bioaccumulation
Rate and extent of excretion ‡	rapid, mainly via urine (90 % within 24 hours)
Metabolism in animals ‡	Cleavage of ester group and O-demethylation of 8-methoxy group
Toxicologically relevant compounds ‡ (animals and plants)	Spirotetramat
Toxicologically relevant compounds ‡ (environment)	Spirotetramat

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	Rat LD_{50} oral ‡	> 2000 mg/kg bw
Rat LD_{50} dermal ‡	Rat LD_{50} dermal ‡	> 2000 mg/kg bw
Rat LC_{50} inhalation ‡	Rat LC_{50} inhalation ‡	> 4.183 mg/L air/4h
Skin irritation ‡	Skin irritation ‡	not irritant
Eye irritation ‡	Eye irritation ‡	Irritant **Xi, R 36**
Skin sensitisation ‡	Skin sensitisation ‡	Sensitiser **Xi, R 43**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Thymus involution, brain dilatation, decreased T3, T4
Relevant oral NOAEL ‡	52-week dog: 5 mg/kg bw per day
Relevant dermal NOAEL ‡	28-day rat: 1000 mg/kg bw per day
Relevant inhalation NOAEL ‡	no data, not required

Genotoxicity ‡ (Annex IIA, point 5.4)

no genotoxic potential

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

Target/critical effect ‡	body weight decrease, body weight gain decrease, liver and kidney weight ↑, alveolar macrophages in lungs, spermatid degeneration in testes, germ cell exfoliated debris in epididymis

Relevant NOAEL ‡	2-year oral rat: 250 ppm (12.5 mg/kg bw per day males); 250 ppm (16.8 mg/kg bw per day females)
Carcinogenicity ‡	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Bodyweight decrease, body weight gain decrease, kidney weight decrease, tubular dilatation, abnormal sperm cells, reproductive performance decrease **Xn, R 62**
Relevant parental NOAEL ‡	1000 ppm (70 mg/kg bw per day)
Relevant reproductive NOAEL ‡	1000 ppm (70 mg/kg bw per day)
Relevant offspring NOAEL ‡ (AGES/EPA) Relevant offspring NOAEL (PMRA)	1000 ppm (70 mg/kg bw per day) 250 ppm (17 mg/kg bw per day)

Developmental toxicity

Developmental target / critical effect ‡	rats: skeletal malformations and skeletal deviations at maternal toxic doses **Xn, R 63**
Relevant maternal NOAEL ‡	rat: 140 mg/kg bw per day, rabbit: 10 mg/kg bw per day
Relevant developmental NOAEL ‡	rat: 140 mg/kg bw per day, rabbit: 160 mg/kg bw per day

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	locomotor activity decrease, clinical signs; no evidence of neurotoxicity; NOAEL (systemic toxicity) 100 mg/kg bw
Repeated neurotoxicity ‡	no data, not required
Delayed neurotoxicity ‡	no data, not required

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	-
Studies performed on metabolites or impurities ‡	Spirotetramat ketohydroxy, spirotetramat-desmethyl-ketohydroxy, spirotetramat-monohydroxy, spirotetramat -dihydroxy: Rat LD_{50} oral > 2000 mg/kg bw no genotoxic potential (bacterial reverse mutation test)

Medical data ‡ (Annex IIA, point 5.9)

-

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	0.05 mg/kg bw per day	1-year dog study	100
AOEL ‡	0.05 mg/kg bw per day	1-year dog study	100
ARfD ‡	1.0 mg/kg bw	Acute neurotoxicity study rat	100

Dermal absorption ‡ (Annex IIIA, point 7.6)

Formulation Movento 150 OD	Concentrate: 0.5 % Spray dilutions: 3 % and 10 % Rat in *vivo* and comparative *in vitro* (human/rat skin)

Exposure scenarios (Annex IIIA, point 7.3 – 7.6)

Operator	Without PPE Citrus: 45 % of the AOEL - German model, hand-held application 78 % of the AOEL - German model, tractor broadcast air assisted (high crop) Lettuce: 9 % of the AOEL - German model, tractor boom applications (low crop) Glasshouse use: 0.6 % of the AOEL - German model, spray gun/lance connected to a tank (low crop)
Workers	Without PPE 21.7 % of the AOEL (crop inspection) Glasshouse use: < 1 % of the AOEL
Bystanders	Without PPE 3.5 % of the AOEL (for glasshouse: not relevant)

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 9)

Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:

Peer review proposal*:

Active substance	Xn, R 36; R43; R 62, R 63
Preparation	Xn, R43, R 62, R 63

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 or Regulation (EU) No 188/2011 are not formal proposals.

Residues

Metabolism in plants (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.2 and 8.7)

Plant groups covered	Fruit crops: (apple) Oilseeds/Pulses (cotton) Leafy crops (lettuce) Roots/Tubers (potato) Foliar applications
Rotational crops	Cereals (wheat), leafy vegetables (Swiss chard) and Root/tuber crops (turnip)
Metabolism in rotational crops similar to metabolism in primary crops?	Metabolism more extensive in rotational crops than in primary crops. Parent spirotetramat not observed and spirotetramat-enol only detected in wheat grain (3 % TRR). Residues mainly composed of the ketohydroxy-, desmethyl-ketohydroxy and desmethyl-dihydroxy-metabolites and their conjugates, each accounting mostly for less than 15 % TRR.
Processed commodities	Standard hydrolysis studies were conducted with spirotetramat, spirotetramat-enol, spirotetramat-enol-Glc, spirotetramat-ketohydroxy and spirotetramat-monohydroxy respectively. - **spirotetramat** is stable under pasteurization but degraded to spirotetramat-enol under baking (15 % AR) and sterilization (85 % AR). - **spirotetramat-enol, spirotetramat-monohydroxy** are stable under all test conditions. - **spirotetramat-enol-Glc** is stable under pasteurization but degraded to spirotetramat-enol under baking (*ca.*10 % AR) and sterilization (*ca.* 40 % AR) - **spirotetramat-ketohydroxy** is stable under pasteurization and slightly degraded to spirotetramat-MA-amide under baking (5 % AR), but almost completely under sterilization (99 % AR).
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Qualitatively similar. The residue definitions proposed for plants are also applicable to processed commodities. Spirotetramat-enol and spirotetramat-ketohydroxy residues increase slightly in some processed commodities under hydrolytic conditions.
Plant residue definition for monitoring	Sum of spirotetramat, spirotetramat-enol expressed as spirotetramat.
Plant residue definition for risk assessment	Sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-Glc, expressed as spirotetramat.
Conversion factor (monitoring to risk assessment)	**2** (An overall conversion factor of 2 has been considered adequate to cover all intended crops investigated).

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.2 and 8.7)

Animals covered	Laying Hens, Lactating Goat
Time needed to reach a plateau concentration	Eggs: 7 days; Milk: 2 days
Animal residue definition for monitoring	Spirotetramat-enol expressed as spirotetramat
Animal residue definition for risk assessment	Sum of spirotetramat-enol and spirotetramat-enol-GA expressed as spirotetramat
Conversion factor (monitoring to risk assessment)	1.5 for ruminants and pigs (an overall CF of 1.5 is derived from the highest feeding level in the cow study)
Metabolism in rat and ruminant similar (yes/no)	Yes.
Fat soluble residue: (yes/no)	No (Log P_{ow} 2.5 and residue levels in muscle/fat and in whole milk/mik fat similar).

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.6)

Confined rotational crop study (2.7N Lettuce GAP): Spiroteramat and spirotetramat-enol ≤ 0.001 mg eq/kg in all plant matrices and for all plant back intervals:

- For the 135 and 260 day plant back intervals, all individual identified compounds < 0.010 and < 0.007 mg eq./kg respectively.
- For the 30 day plant back interval, residues above 0.05 mg eq/kg only observed in cereal hay and straw.

Field rotational crop study (USA, *ca.* 1N rate) Residues of spirotetramat, spirotetramat-ketohydroxy, spirotetramat-desmethyl-ketohydroxy, spirotetramat-desmethyl-dihydroxy and spirotetramat-ketohydroxy-alcohol, all < LOQ in mustard green, turnip and wheat, sown as rotational crops 30 days after the last application of spirotetramat.to a primary crop.

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

When stored frozen at -18°C residues of **spirotetramat** should be considered

- not stable more than:
- 1 month in high oil content matrices (nut)
- 3 months in high starch content matrices (potato).
- 6 months in high water content matrices (lettuce, bean with pods)

- stable at least:
- 5 months in orange juice and prune
- 18 months in tomato (high water content matrice).

In several matrices, spirotetramat is not stable and degraded **to spirotetramat-enol** under frozen conditions.

When stored frozen at -18°C residues of **spirotetramat-enol** should be considered:

- not stable more than:
- 6 months in high water content matrices (lettuce, bean with pods).

- 12 months in high starch content matrices (potato). **- stable at least:** - 5 months in orange juice and prune - 12 months in tomato paste - 18 months in high starch and high oil content matrices and in tomato. In several matrices spirotetramat-enol is not stable and degraded to spirotetramat-ketohydroxy under frozen conditions. **Residues of spirotetramat should be considered stable** for at least 18 months in high-water, high starch and high oil content matrices **when analysed for the sum of spirotetramat and spirotetramat-enol.** **Spirotetramat-ketohydroxy**, **spirotetramat-enol-Glc and spirotetramat-mono hydroxy** stable for at least 18 months in high-water, high starch and high oil content matrices, and 5 and 12 months in orange juice, prune and tomato past, respectively.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.4)

	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 1.9 mg/kg DM	Yes 0.27 mg/kg DM	Yes 0.82 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/no)	No.	No.	No.
	Feeding study with spirotetramat at the dose rate of 3.0 mg./kg DM* (lowest feeding rate, *ca.* 2N) Residue levels in matrices : Mean (max)[mg/kg]		
Muscle	<0.01	---	---
Liver	<0.01	---	---
Kidney	0.02 (0.024)	---	---
Fat	<0.01	---	---
Milk	<0.005		
Eggs		---	

* Using a transfer factor of 0.0075 for kidney, the resulting concentration in kidney for the dietary burden of 1.9 mg a.s./kg is 0.014 mg/kg. Based on the results of the livestock feeding study, a MRL of 0.02 mg/kg is proposed for bovine, sheep, goat and swine kidney. For other edible tissues MRL is set at the LOQ (0.01* mg/kg and 0.005* mg/kg for milk).

Summary of residues data according to the representative uses on raw agricultural commodities and feeding stuffs (Annex IIA, point 6.3, Annex IIIA, point 8.3)

Representative uses are on citrus and lettuce only. The other crops, highlighted in grey, have been included in the risk assessment as effectively authorised within the EU and considering that all the data have been included and evaluated in the DAR.

Commodity (cGAP)	**Region** (a)	**Individual trial results** (mg/kg) **RM:** according to residue definition for monitoring **RA:** according to residue definition for risk assessment	Recommendation/comments	**MRL proposal** (mg/kg)	**STMR** (mg/kg) (b)	**HR** (mg/kg) (c)	**Median CF** (d)
Mandarin (2x 288 g/ha PHI, 14 d)	SEU	**RM:**-0.069, 0.085; 0.096, 0.109, 0.133, 0.160, 0.177, 0.23, 0.24 **RA:** 0.101, 0.140, 0.146, 0.173, 0.185, 0.213, 0.232, 0.273, 0.331 **RA pulp:** <0.054, 3x 0.064, 0.074, 0.095, 0.105, 0.14	Residues in mandarin significantly higher than in orange (U-test, 5%), MRL for citrus derived from the mandarin dataset: R_{ber}: 0.41 OECD: 0.43 R_{max}: 0.33	**0.5**	(0.13) Pulp 0.07	(0.24) Pulp 0.14	1.4
Orange (2x 288 g/ha PHI, 14 d)	SEU	**RM** 3x 0.032, 0.037, 0.045, 0.081, 0.089, 0.19 **RA:** 3x 0.064, 0.069, 0.077, 0.114, 0.122, 0.233 **RA pulp:** 4x <0.054, 0.057, 0.076	R_{ber}: 0.17 OECD: 0.29 R_{max}: 0.24		(0.04)	(0.19)	1.8
Lettuce (2x 72 g/ha PHI, 7 d)	Indoor	**RM:** 0.106, 0.268, 0.29, 0.96, 1.26, 1.65, 1.73, 2.18 **RA:** 0.163, 0.387, 0.374, 1.057, 1.406, 1.756, 1.835, 2.327	MRL fot lettuce derived from the indoor trials as residue levels significantly higher than in outdoor trials: R_{ber}: 3.4 OECD: 4.2 R_{max}: 3.5	**5**	(1.11) 1.23	(2.18) 2.33	1.1
	NEU	**RM:** 0.065, 0.078, 0.22, 0.27 **RA:** 0.117, 0.151, 0.341, 0.441	Outdoor trials conducted with 3 applications, while cGAP defined 2 applications only. R_{ber}: 0.41 OECD: 0.45 R_{max}: 0.38		(0.11)	(0.27)	1.8
	SEU	**RM:** 0.053, 0.081, 0.128, 0.16 **RA:** 0.106, 0.155, 0.188, 0.265					
Pome Fruit (2x 216 g/ha PHI, 21 d)	NEU + SEU	**RM:** 0.022, 0.022, 0.032, 0.032, 0.032, 0.032, 0.032, 0.032, 0.051, 0.062, 0.062, 0.062, 0.063, 0.064, 0.074, 0.082, 0.092, 0.102, 0.102, 0.112, 0.112, 0.115, 0.122, 0.173, 0.173 **RA:** 0.054, 0.054, 0.069, 0.064, 0.064, 0.064, 0.074, 0.066, 0.094, 0.094, 0.098, 0.096, 0.095, 0.099, 0.115, 0.114, 0.129, 0.14, 0.144, 0.156, 0.151, 0.192, 0.155, 0.254, 0.249	Residue levels in Northern and Southern trials not significantly different (U-test. 5%). MRL, HR and STMR derived from the merged datasets. R_{ber}: 0.21 OECD: 0.25 R_{max}: 0.17	**0.3**	(0.063) 0.10	(0.173) 0.25	1.6

Commodity (cGAP)	**Region** (a)	**Individual trial results** (mg/kg) **RM:** according to residue definition for monitoring **RA:** according to residue definition for risk assessment	Recommendation/comments	**MRL proposal** (mg/kg)	**STMR** (mg/kg) (b)	**HR** (mg/kg) (c)	**Median CF** (d)
Peach and Apricot (2x 216 g/ha PHI, 21 d)	NEU	**RM:** 0.200, 0.220, 0.235, 0.310, 0.330 **RA:** 0.314, 0.438, 0.511, 0.520, 0.696	Residue levels in Northern trials significantly higher than in Southern (U-test. 5%). MRL, HR and STMR derived from the Northern dataset. R_{ber}: 0.64 OECD: 0.77 R_{max}: 0.50	**0.8**	(0.24) 0.51	(0.33) 0.70	1.5
	SEU	**RM:** 0.077, 0.081, 0.101, 0.113, 0.150, 0.183, 0.210, 0.230, 0.250 **RA:** 0.115, 0.170, 0.236, 0.275, 0.286, 0.307, 0.346, 0.679, 0.687			(0.15) 0.29	(0.25) 0.69	
Plum (2x 216 g/ha PHI, 21 d)	NEU + SEU	**RM:** 0.044, 0.063, 0.073, 0.094, 0.122, 0.150, 0.168, 0.22, 0.22, 0.23, 0.33, 0.37 **RA:** 0.135, 0.159, 0.181, 0.193, 0.119, 0.416, 0.448, 0.353, 0.395, 0.485, 0.529, 0.751	Residue levels in Northern and Southern trials not significantly different (U-test. 5%). MRL, HR and STMR derived from the merged datasets R_{ber}: 0.46 OECD: 0.59 R_{max}: 0.46	**0.6**	(0.16) 0.37	(0.37) 0.75	2.0
Cherry Sweet & sour (2x 216 g/ha PHI, 21 d)	NEU + SEU	**RM:** 0.16, 0.22, 0.22, 0.24, 0.28, 0.33, 0.36, 0.38, 0.39, 0.55, 0.60 **RA:** 0.248, 0.285, 0.295, 0.417, 0.721, 0.679, 0.583, 0.826, 0.629, 1.045, 0.939	Residue levels in Northern and Southern trials not significantly different (U-test. 5%). MRL, HR and STMR derived from the merged datasets R_{ber}: 0.78 OECD: 1.02 R_{max}: 0.73	**1.0**	(0.33) 0.63	(0.60) 1.05	1.6
Grapes NEU: 2x72 g/ha SEU: 2x96 g/ha PHI, 21 d	NEU	**RM:** 0.105, 0.115, 0.158, 0.172, 0.185, 0.194, 0.213, 0.221 **RA:** 0.142, 0.135, 0.189, 0.2, 0.242, 0.22, 0.284, 0.26	R_{ber}: 0.42 OECD: 0.51 R_{max}: 0.31	(0.6)	(0.18)	(0.22)	1.2
	SEU	**RM:** 0.095, 0.101, 0.172, 0.172, 0.185, 0.19, 0.212, 0.22, 0.37, 0.517 **RA:** 0.183, 0.167, 0.218, 0.204, 0.282, 0.26, 0.476, 0.348, 0.573, 0.641	MRL for grapes derived from the Southern dataset: R_{ber}: 0.52 OECD: 0.74 R_{max}: 0.60	**0.8**	(0.19) 0.27	(0.52) 0.64	1.5
Strawberries (2x 96 g/ha PHI, 3 d)	Indoor	**RM:** 0.17, 0.20, 0.20, 0.25, 0.25, 0.26, 0.27, 0.29 **RA:** 0.205, 0.239, 0.234, 0.282, 0.282, 0.292, 0.303, 0.328	Residue levels from indoor dataset significantly higher than from outdoor trials (NEU+SEU). MRL for strawberry derived from the indoor dataset: R_{ber}: 0.54 OECD: 0.71	**0.7**	(0.25) 0.28	(0.29) 0.33	1.1
	NEU	**RM:** 0.13, 0.15, 0.18, 0.22 **RA:** 0.162, 0.182, 0.212, 0.258			(0.13)	(0.22)	1.3

Commodity (cGAP)	**Region** (a)	**Individual trial results** (mg/kg) **RM:** according to residue definition for monitoring **RA:** according to residue definition for risk assessment	Recommendation/comments	**MRL proposal** (mg/kg)	**STMR** (mg/kg) (b)	**HR** (mg/kg) (c)	**Median CF** (d)
	SEU	**RM:** 0.081, 0.10, 0.11, 0.12 **RA:** 0.113, 0.136, 0.143, 0.152	R_{max}: 0.37				
Onion (4x 72 g/ha PHI, 7 d)	NEU	**RM:** 0.22, 0.052, 0.060, 0.065, 0.077, 0.081, 0.13, 0.17 **RA:** 0.054, 0.084, 0.092, 0.097, 0.113, 0.109, 0.162, 0.202	Residue levels in Northern and Southern trials not significantly different (U-test. 5%). MRL, HR and STMR derived from the merged datasets R_{ber}: 0.21 OECD: 0.25 R_{max}: 0.18	**0.3**	(0.07) 0.10	(0.17) 0.20	1.6
	SEU	**RM:** <0.022, 0.034, 0.044, 0.057, 0.066, 0.091, 0.110, 0.140 **RA:** <0.054, 0.066, 0.076, 0.094, 0.098, 0.123, 0.143, 0.172					
Tomato (4x 144 g/ha PHI, 3 d)	Indoor	**RM:** 0.163, 0.19, 0.26, 0.28, 0.32, 0.45, 0.48, 0.49 **RA:** 0.215, 0.257, 0.336, 0.442, 0.436, 0.514, 0.677, 0.703	Residue levels in indoor trials significantly higher than in Southern trials. MRL, HR, STMR derived from the indoor dataset: R_{ber}: 0.95 OECD: 0.99 R_{max}: 0.74	**1.0**	(0.30) 0.44	(0.49) 0.70	1.4
	SEU	**RM:** 0.065, 0.101, 0.128, 0.16 **RA:** 0.12, 0.144, 0.188, 0.209	R_{ber}: 0.30 OECD: 0.34 R_{max}: 0.32		(0.11)	(0.16)	1.5
Pepper (4x 144 g/ha PHI, 3 d)	Indoor	**RM:** 0.23, 0.25, 0.27, 0.30, 0.36, 0.40, 0.42, 0.46, 0.47, 0.49, 0.50, 0.50 **RA:** 0.261, 0.268, 0.311, 0.351, 0.426, 0.48, 0.483, 0.536, 0.546, 0.574, 0.565, 0.581	Residue levels in indoor trials significantly higher than in Southern trials. MRL, HR, STMR derived from the indoor dataset: R_{ber}: 0.97 OECD: 1.16 R_{max}: 0.67	**1.5**	(0.41) 0.48	(0.50) 0.58	1.2
	SEU	**RM:** 0.079, 0.102, 0.14, 0.14, 0.17, 0.22, 0.31, 0.68 **RA:** 0.113, 0.139, 0.172, 0.172, 0.206, 0.266, 0.353, 0.817	R_{ber}: 0.58 OECD: 1.0 R_{max}: 0.85		(0.16)	(0.68)	1.2
Cucumber (4x 144 g/ha PHI, 3 d)	SEU	**RM:** 3x <0.022, 0.022, 0.032, 0.032, 0.087 **RA:** 3x <0.054,0.055, 0.064, 0.064, 0.119	MRL, STMR and HR derived from the Southern trials: R_{ber}: 0.06 OECD: 0.13 R_{max}: 0.12	**0.15**	(0.02) 0.06	(0.09) 0.12	2.5
	Indoor	**RM:** <0.022, <0.022, <0.022, 0.022, 0.032, 0.032, 0.032, 0.042 **RA:** <0.054, 0.055, 0.057,0.059, 0.075, 0.070, 0.074, 0.077	R_{ber}: 0.06 OECD: 0.0.6 R_{max}: 0.05		(0.03)	(0.04)	2.4

Commodity (cGAP)	**Region** (a)	**Individual trial results** (mg/kg) **RM:** according to residue definition for monitoring **RA:** according to residue definition for risk assessment	Recommendation/comments	**MRL proposal** (mg/kg)	**STMR** (mg/kg) (b)	**HR** (mg/kg) (c)	**Median CF** (d)
Melon (4x 72 g/ha PHI, 3 d)	SEU	**RM:** 3x <0.022, <0.022, 0.022, 0.024, 0.027, 0.052, 0.056 **RA:** 3x <0.054, 0.079,0.054, 0.056, 0.059, 0.084, 0.088 **Pulp (RA):** 8x <0.054, 0.075	MRL, STMR and HR derived from the Southern trials R_{ber}: 0.08 OECD: 0.09 R_{max}: 0.07	**0.09**	(0.02) Pulp 0.05	(0.06) Pulp 0.08	2.5
	Indoor	**RM:** 4x <0.022, 0.022, 0.024, 0.029, 0.032 **RA:** 4x <0.054, 0.054, 0.056, 0.061, 0.064 **Pulp (RA):** 8x <0.054	R_{ber}: 0.06 OECD: 0.05 R_{max}: 0.04		(0.02)	(0.03)	2.5
Flowering brassica (2x 72 g/ha PHI, 3 d)	NEU	**RM:** 0.058, 0.065, 0.16, 0.16, 0.19, 0.19, 0.27, 0.32, 0.37 **RA:** 0.11, 0.427, 0.241, 0.22, 0.384, 0.308, 0.578, 0.369, 0.521	Residue in Northern and Southern datasets not significantly different (U-test. 5%). MRL, HR and STMR are derived from the merged datasets R_{ber}: 0.59 OECD: 0.60 R_{max}: 0.46	**0.6**	(0.16) 0.31	(0.37) 0.58	1.6
	SEU	**RM:** 0.094, 0.14, 0.14, 0.33 **RA:** 0.13, 0.26, 0.196, 0.439					
Brussels sprouts (2x 72 g/ha PHI, 3 d)	NEU	**RM:** 0.039, 0.051, 0.051, 0.063, 0.074, 0.078, 0.079, 0.140 **RA:** 0.089, 0.088, 0.089, 0.106, 0.128, 0.110, 0.131, 0.218	R_{ber}: 0.16 OECD: 0.22 R_{max}: 0.17	**0.30**	(0.07) 0.11	(0.14) 0.22	1.7
Head cabbage (2x 72 g/ha PHI, 3 d)	NEU + SEU	RM: 0.027, 0.035, 0.041, 0.042, 0.044, 0.047, 0.070, 0.072, 0.072, 0.075, 0.081, 0.102, 0.141, 0.200 **RA:** 0.091, 0.067, 0.092, 0.077, 0.082, 0.097, 0.151, 0.104, 0.186, 0.107, 0.113, 0.134, 0.261, 0.232	Residue in Northern and Southern datasets not significantly different (U-test. 5%). MRL, HR and STMR are derived from the merged datasets R_{ber}: 0.17 OECD: 0.26 R_{max}: 0.20	**0.30**	(0.07) 0.11	(0.20) 0.26	1.9
Leafy brassica (2x 72 g/ha PHI, 3 d)	NEU	**RM:** 0.178, 0.23, 0.49, 0.62 **RA:** 0.24, 0.301, 0.62, 0.765	Northern and Southern datasets not significantly different (U-test. 5%). MRL, HR and STMR derived from the merged datasets R_{ber}: 0.97 OECD: 1.03 R_{max}: 0.89	**1.0**	(0.31) 0.43	(0.62) 0.77	1.4
	SEU	**RM:** 0.16, 0.20, 0.39, 0.46 **RA:** 0.212, 0.289, 0.556, 0.631					
Kohlrabi (2x 72 g/ha	NEU	**RM:** 0.12, 0.20, 0.50, 0.53	R_{ber}: 1.05 OECD: 1.17 R_{max}: 1.41	**1.5**	(0.35)	(0.53)	1.2

Commodity (cGAP)	**Region** (a)	**Individual trial results** (mg/kg) **RM:** according to residue definition for monitoring **RA:** according to residue definition for risk assessment	Recommendation/comments	**MRL proposal** (mg/kg)	**STMR** (mg/kg) (b)	**HR** (mg/kg) (c)	**Median CF** (d)
PHI, 3 d)		**RA:** 0.152, 0.232, 0.554, 0.67			0.39	0.67	
Green bean (with pods) (4x 144 g/ha PHI, 14 d)	indoor	**RM:** 0.025, 0.076, 0.10, 0.18, 0.27, 0.41, 0.42, 0.42 **RA:** 0.082, 0.116, 0.208, 0.303, 0.401, 0.564, 0.566, 0.624	R_{ber}: 0.84 OECD: 0.90 R_{max}: 0.76	**0.9**	(0.23) 0.35	(0.42) 0.62	1.5
Hops (1x 150 g/ha PHI, 14 d)	NEU	**RM:** 0.73, 0.81, 1.06, 1.29, 1.69, 1.82, 1.85, 2.92 **RA:** 1.11, 1.64, 1.74, 2.62, 2.01, 3.11, 4.02, 4.34	R_{ber}: 3.7 OECD: 4.6 R_{max}: 3.8	**5**	(1.49) 2.32	(2.92) 4.34	1.7

Note: grey marked data are only intended for MRL setting (not supported uses)**.**

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
NEU+SEU: Since residue levels in Northern and Southern datasets are not significantly different (U-test, 5%); MRL, HR and STMR are derived from the merged datasets.
(b): **STMR:** Median value of the individual trial results according to the **residue definition for risk assessment** (median value according residue definition for enforcement given in brackets)
(c): **HR:** Highest value of the individual trial results **according to the residue definition for risk assessment** (Highest value according residue definition for enforcement given in brackets)
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(*): Indicates that the MRL is set at the limit of analytical quantification

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.10)

ADI	**0.05 mg/kg bw per day**
TMDI (% ADI) according to EFSA PRIMo model	Highest TMDI: 42 % ADI (DE, child)
TMDI (% ADI) according to national diets	Not relevant.
IEDI (% ADI)according to EFSA PRIMo model	Highest IEDI: 7 % ADI (WHO, Cluster B)
NEDI (specify diet) (% ADI)	Not relevant.
Factors included in IEDI and NEDI	TMDI: CF of 2 for plant and 1.5 for animal commodities IEDI: STMR (according definition for risk assessment)
ARfD	**1.0 mg/kg bw**
IESTI (% ARfD):**EFSA PRIMo-rev. 2**	Highest IESTI: 6 % ARfD (Lettuce)
NESTI (% ARfD) according to national data	Not relevant
Factors included in IESTI and NESTI	HR (according definition for risk assessment)

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.5)

Crop/processed product	**Number of Studies**[a]	**Processing factor (PF)**		Amount transferred (%)
		Median PF[b] (individual values)	**Correction Factor (CF)**[c]	
Orange/Peeled fruit	17 EU	**0.6** (range 0.2 to 0.9)	2.0	
Orange/Pomace (wet)	4 EU	**0.5** (0.3, 0.3, 0.6, 0.7)	2.2	
Orange/Pomace (dry)	4 EU	**0.8** (0.6, 0.8, 0.8, 1.5)	1.9	
Orange/Juice (pasteurised)	4 EU+1 US	**0.3** (0.2, 0.2, 0.3, 0.6, 0.7)	2.3	
Orange/Marmelate	4 EU	**0.5** (0.3, 0.3, 0.6, 0.7)	2.2	
Orange/Orange oil	1 US	**17**	1.0	
Apple/Washed fruit	4 EU+1 US	**0.6** (0.5, 0.5, 0.6, 1.2, 1.5)	1.7	
Apple/Pomace (wet)	1 US	**1.9**	1.3	
Apple/Pomace (dry)	4 EU	**7.5** (4.3, 7.2, 7.9, 11.5)	1.1	
Apple/Juice (pasteurised)	4 EU+1 US	**0.4** (0.2, 0.3, 0.4, 0.4, 1.0)	2.4	
Apple/Sauce	4 EU+1 US	**0.7** (0.1, 0.6, 0.7, 0.8, 1.2)	1.8	
Cherry/Washed fruit	4 EU	**0.9** (0.8, 0.9,0.9, 1.0)	1.6	
Cherry/Preserved	4 EU	**0.5** (0.4, 0.5, 0.5, 0.6)	1.4	
Grape/Wine (*red* and white)	4 EU	**0.5** (*0.4*, 0.4, 0.6, 0.9)	1.5	
Grape/Raisin	2 EU+1 US	**2.5** (1.5, 2.5, 3.0)	1.4	
Grape/Juice	1 US	**0.6**	1.3	
Grape/Jelly	1 US	**0.3**	1.3	
Tomato/Washed fruit	4 EU+1 US	**0.6** (0.5, 0.5, 0.6, 0.7, 0.7)	1.4	
Tomato/Juice	4 EU+1 US	**0.6** (0.5, 0.6, 0.6, 0.7, 0.9)	1.3	
Tomato/Preserve	4 EU+1 US	**0.6** (0.3, 0.4, 0.6, 0.7, 1.1)	1.4	
Tomato/Puree	4 EU+1 US	**1.0** (0.5, 0.7, 1.0, 1.2, 3.4)	1.2	
Tomato/Fruit dried	1 US	**11**	1.1	
Bean/Cooked (with pods)	4 EU	**0.6** (0.5, 0.6, 0.6, 0.8)	1.2	
Hops/Beer	4 EU	**0.02** (0.01, 0.01, 0.03, 0.03)	2.2	

(a): US value refers to the mean of 3 replicates (PF derived from US study are underlined)

(b): PF calculated as the ratio "residue level in processed commodity/residue level in RAC" the residue levels being expressed according to the residue definition for monitoring.
(c): CF calculated as the ratio "residue level in processed commodity according to the definition for RA/residue level in processed commodity according to the definition for monitoring".

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.7) 1)

Plant commodities

Citrus	0.5
Lettuce	5
Pome fruit	0.3
Peach/Apricots	0.8
Cherries	1
Plums	0.6
Grapes	0.8
Strawberries	0.7
Onions	0.3
Tomatoes	1
Peppers	1.5
Cucumbers	0.15
Melons	0.09
Flowering brassica	0.6
Brussels sprouts	0.3
Head cabbage	0.3
Leafy brassica	1.0
Kohlrabi	1.5
Green beans	0.9
Hops	5

Animal Commodities

Kidney (bovine, goat, sheep, swine)	0.02
Milk	0.005*
Other products (bovine, goat, sheep, swine)	0.01*

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

Environmental fate and behaviour

Route of degradation (aerobic) in soil (OECD Annex IIA, point 7.1)

Mineralisation after 100 days ‡	12.1 % after 126 days, [3-^{14}C]-label (n[1]= 1) 9.7– 19.4 % after 50 days, [3-^{14}C]-label (n= 4)
Non-extractable residues after 100 days ‡	27.6 % after 126 days, [3-^{14}C]-label (n = 1) 21.5 – 31.0 % after 50 days, [3-^{14}C]-label (n = 4)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Spirotetramat study, [3-^{14}C]-label: Study was not considered valid for estimation of maximum occurrence of metabolites owing to analytical reasons (instability of metabolites during acidic extraction) Spirotetramat-enol study, [3-^{14}C] and [5-^{14}C]-label: Spirotetramat-enol: 100 % (worst case assumption) Spirotetramat-ketohydroxy: 16.6 – 24.0 % after 0.25 - 1 day (n = 4) Spirotetramat-MA-amide: 2.5 – 5.2 % after 1 – 4 days (n = 4)

Route of degradation in soil - Supplemental studies (OECD Annex IIA, point 7.1.2 and 7.1.3)

Anaerobic degradation ‡

Mineralization after 100 days	0.1 % after 120 days, [3-^{14}C]-label (n = 1)
Non-extractable residues after 100 days	10.7 % after 120 days, [3-^{14}C]-label (n = 1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	[3-^{14}C]-label: Spirotetramat-enol: 54.6 % after 180 days (n = 1) Spirotetramat-ketohydroxy: 19.3 % after 1 day (n = 1) Spirotetramat-MA-amide: 7.2 % after 180 days (n = 1)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	[3-^{14}C]-label: Spirotetramat-enol: 5.3 % after 7 days (n = 1) Spirotetramat-ketohydroxy: 12.3 % after 7 days (n = 1) [5-^{14}C]-label: Spirotetramat-enol: 10.1 % after 1 days (n = 1) Spirotetramat-ketohydroxy: 20.9 % after 2 days (n = 1) 4-methoxy-cyclohexanone: 10.0 % after 2 days (n = 1)

[1] n corresponds to the number of soils.

Rate of degradation in soil (OECD Annex IIA, point 7.2 and 7.3, Annex IIIA, point 9.1 and 9.2)									
Laboratory studies ‡									
Spirotetramat				Aerobic conditions					
Soil type	OC %	pH (H_2O)	Temperature / moisture content	DT_{50} / DT_{90} (d)	SFO-DT_{50} recalc[a] (d)	SFO-DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	chi^2 error [%]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 50 % MWHC	0.21 / 0.69 0.24 / 0.89 0.25 / 1.04	nc 0.27 0.31	0.20 0.25 0.29	> 0.99 > 0.99 < 0.99	8.5 1.4 6.5	SFO[b] DFOP[c] FOMC
Silt loam	0.83	7.4	20 °C / 50 % MWHC	0.23 / 0.77 0.26 / 0.97 0.23 / 1.09	nc 0.29 0.33	0.18 0.23 0.26	> 0.99 > 0.99 > 0.99	8.8 0.8 7.5	SFO DFOP FOMC
Silt	2.11	7.6	20 °C / 50 % MWHC	0.08 / 0.28 0.09 / 0.34 0.01 / 0.44	nc 0.10 0.13	0.08 0.10 0.13	> 0.99 > 0.99 > 0.99	9.5 4.0 3.6	SFO DFOP FOMC
Sandy loam	0.93	6.1	20 °C / 75 % of 1/3 bar	0.33 / 1.09 0.30 / 1.26 0.26 / 2.61	nc 0.38 0.79	0.26 0.30 0.63	0.99 > 0.99 > 0.99	21.8 6.1 16.5	SFO DFOP FOMC
Geometric mean (EU)				**0.19 / 0.63** **nc** **nc**	**nc** **nc** **0.32**	**0.17** **0.20** **0.28**	-	-	SFO DFOP FOMC
80th percentile (PMRA)				**0.27 / 0.90** **nc**	**nc** **0.33**	**nc** **nc**	-	-	SFO DFOP
90th percentile of confidence interval on arithmetic mean (US-EPA)				**0.30 / 0.98** **nc**	**nc** **0.36**	**nc** **nc**	-	-	SFO DFOP

[a] SFO-DT_{50} recalculated from DFOP-DT_{90} or FOMC-DT_{90}, divided by 3.32

[b] Single first order (used for modelling, EU risk assessment)

[c] Double first-order in parallel (best fit kinetics)

nc: not calculated

Spirotetramat				Aerobic conditions (DFOP kinetics, additional information)						
Soil type	OC %	pH (H_2O)	Temperature / moisture content	DT_{50} / DT_{90} (d)	Fast-phase DT_{50} (d)	Slow-phase DT_{50} (d)	g-value (-)	Slow-phase DT_{50} (d) 20°C pF2/10kPa	chi ^{2} error [%]	Meth-od of calcu-lation
Sandy loam	1.02	7.2	20 °C / 50 % MWHC	0.24 / 0.89	0.23	69.3	0.85	64.5	1.4	DFOP
Silt loam	0.83	7.4	20 °C / 50 % MWHC	0.26 / 0.97	0.25	630	0.96	492	0.8	DFOP
Silt	2.11	7.6	20 °C / 50 % MWHC	0.09 / 0.34	0.09	47.2	0.96	47.2	4.0	DFOP
Sandy loam	0.93	6.1	20 °C / 75 % of 1/3 bar	0.30 / 1.26	0.27	248	0.94	198	6.1	DFOP
Geometric mean				-	-	-	-	**131**	-	DFOP

Spirotetramat-enol (parent in study)				Aerobic conditions					
Soil type	OC %	pH (H_2O)	Temperature / moisture content	DT_{50} / DT_{90} (d)	SFO-DT_{50} recalc[a] (d)	SFO-DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	chi ^{2} error [%]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 60 % MWHC	0.02 / 0.07 0.02 / 0.07 0.02 / 28.9 0.02 / 9.8	nc nc 12.3 3.0	0.02 0.02 12.3 3.0	0.98 > 0.99 0.99 0.97	37.4 6.8 5.6 16.0	SFO[b] SFO-RB[c] DFOP[d] FOMC[e]
Silt loam	0.83	7.4	20 °C / 60 % MWHC	0.22 / 0.73 0.16 / 0.53 0.18 / 40.9 0.12 / 5.8	nc nc 5.1 1.8	0.19 0.14 4.4 1.5	0.98 > 0.99 0.99 0.99	20.9 11.0 2.4 5.6	SFO SFO-RB DFOP FOMC
Silt	2.11	7.6	20 °C / 60 % MWHC	0.02 / 0.07 0.02 / 0.06 0.02 / 16.8 0.02 / 2.6	nc nc 3.3 0.8	0.02 0.02 3.3 0.79	0.99 > 0.99 0.99 0.98	31.3 6.4 5.2 16.9	SFO SFO-RB DFOP FOMC
Sandy loam	0.93	6.1	20 °C / 80 % of 1/3 bar	0.10 / 0.33 0.05 / 0.17 0.06 / 10.9 0.06 / 3.6	nc nc 8.7 1.1	0.08 0.04 7.4 0.94	0.98 > 0.99 0.99 0.97	28.8 6.8 5.5 19.0	SFO SFO-RB DFOP FOMC
Geometric mean (EU)				**0.06 / 0.18** **0.04 / 0.14** **nc** **nc**	**nc** **nc** **6.5** **1.5**	**0.05** **0.04** **6.0** **1.4**	-	-	SFO SFO-RB DFOP FOMC
80th percentile (PMRA)				**0.15 / 0.49** **0.09 / 0.31** **nc** **nc**	**nc** **nc** **10.1** **2.2**	**nc** **nc** **nc** **nc**	-	-	SFO SFO-RB DFOP FOMC
90th percentile of confidence interval on arithmetic mean (US-EPA)				**0.17 / 0.56** **0.12 / 0.39** **nc** **nc**	**nc** **nc** **10.6** **2.4**	**nc** **nc** **nc** **nc**	-	-	SFO SFO-RB DFOP FOMC

[a] SFO-DT_{50} recalculated from DFOP-DT_{90} or FOMC-DT_{90}, divided by 3.32

[b] Single first-order

[c] Single first-order – reversible binding (used for higher tier modelling, EU risk assessment)

[d] Double first-order in parallel (best fit kinetics)

[e] First order multi compartment (recalculated SFO-DT_{50} used for 1st tier modelling, EU risk assessment)

Spirotetramat-enol (parent in study)				Aerobic conditions (DFOP kinetics, additional information, not used for EU-risk assessment)						
Soil type	OC %	pH (H_2O)	Temperature / moisture content	DT_{50} / DT_{90} (d)	Fast-phase DT_{50} (d)	Slow-phase DT_{50} (d)	g-value (-)	Slow-phase DT_{50} (d) 20°C pF2/10kPa	chi ^{2} error [%]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 60 % MWHC	0.02 / 28.9	0.02	63.0	0.863	53.6	5.6	DFOP
Silt loam	0.83	7.4	20 °C / 60 % MWHC	0.18 / 40.9	0.13	69.3	0.851	69.3	2.4	DFOP
Silt	2.11	7.6	20 °C / 60 % MWHC	0.02 / 16.8	0.02	23.1	0.833	20.1	5.2	DFOP
Sandy loam	0.93	6.1	20 °C / 80 % of 1/3 bar	0.06 / 10.9	0.04	63.0	0.888	63.0	5.5	DFOP
Geometric mean				-	-	-	-	**46.6**	-	DFOP

Spirotetramat-enol (parent in study)				Aerobic conditions (SFO-RB kinetics, additional information)		
Soil type	OC %	pH (H_2O)	Temperature / moisture content	f_{NE} (-)[a]	K_d (d^{-1})[b]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 60 % MWHC	693	0.012	SFO-RB[c]
Silt loam	0.83	7.4	20 °C / 60 % MWHC	28.9	0.037	SFO-RB
Silt	2.11	7.6	20 °C / 60 % MWHC	594	0.012	SFO-RB
Sandy loam	0.93	6.1	20 °C / 80 % of 1/3 bar	193	0.016	SFO-RB
Geometric mean (EU)				-	**0.016**	-
Arithmetic mean (EU)				**377**	-	-

[a] Ratio between non-equilibrium and equilibrium sorption sites (used for higher tier modelling, EU risk assessment)

[b] Kinetic sorption rate constant (used for higher tier modelling, EU risk assessment)

[C] Single first-order – reversible binding (used for higher tier modelling, EU risk assessment)

Spirotetramat-ketohydroxy				Aerobic conditions					
Soil type	OC %	pH (H_2O)	Temperature/ moisture content	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Formation fraction[a] [0 … 1]	St. (r^2)	chi ^{2} error [%]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 60 % MWHC	4.2 / 13.9	4.2	0.223	0.956	17.7	SFO[b]
Silt loam	0.83	7.4	20 °C / 60 % MWHC	5.1 / 16.9	4.4	0.356	0.874	27.2	SFO
Silt	2.11	7.6	20 °C / 60 % MWHC	1.5 / 5.1	1.5	0.243	0.889	33.8	SFO
Sandy loam	0.93	6.1	20 °C / 80 % of 1/3 bar	16.7 / 55.6	14.2	0.206	0.859	22.3	SFO
Geometric mean (EU)				**4.8 / 16.1**	**4.5**	**nc**	-	-	SFO
80th percentile (PMRA)				**9.7 / 32.3**	**nc**	**nc**	-	-	SFO
90th percentile of confidence interval on arithmetic mean (US-EPA)				**12.4 / 41.2**	**nc**	**nc**	-	-	SFO
Arithmetic mean (EU)				**nc**	**nc**	**0.257**	-	-	SFO

[a] From spirotetramat-enol

[b] Single first-order (multi-compartment model)

Spirotetramat-MA-amide				Aerobic conditions					
Soil type	OC %	pH (H_2O)	Temperature/ moisture content	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	Formation fraction[a] [0 … 1]	St. (r^2)	chi ^{2} error [%]	Method of calculation
Sandy loam	1.02	7.2	20 °C / 60 % MWHC	1.1 / 3.6	1.1	1.00[b]	0.866	27.4	SFO[c]
Silt loam	0.83	7.4	20 °C / 60 % MWHC	1.8 / 6.3	1.6	1.00[b]	0.913	29.6	SFO
Silt	2.11	7.6	20 °C / 60 % MWHC	0.3 / 1.0	0.3	1.00[b]	0.823	40.0	SFO
Sandy loam	0.93	6.1	20 °C / 80 % of 1/3 bar	5.4 / 18.1	4.6	1.00[b]	0.771	29.6	SFO
Geometric mean (EU)				**1.3 / 4.5**	**1.2**	**nc**	-	-	SFO
80th percentile (PMRA)				**3.2 / 11.0**	**nc**	**nc**	-	-	SFO
90th percentile of confidence interval on arithmetic mean (US-EPA)				**4.0 / 13.4**	**nc**	**nc**	-	-	SFO
Arithmetic mean (EU)				**nc**	**nc**	**1.00**	-	-	SFO

[a] From spirotetramat-ketohydroxy

[b] Fixed to 1.00 during kinetic evaluation

[c] Single first-order (multi-compartment model)

4-methoxy-cyclohexanone (parent in study)				Aerobic conditions				
Soil type	OC %	pH (H_2O)	Temperature / moisture content	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	chi ^{2} error [%]	Method of calculation
Silt loam	2.4	6.8	20 °C / 55 % MWHC	< 1 / < 1	-	-	-	not evaluated[a]
Loam	1.0	7.0	20 °C / 55 % MWHC	< 1 / < 1	-	-	-	not evaluated[a]
Loamy sand	0.7	6.7	20 °C / 55 % MWHC	0.6 / 1.8	-	-	11.2	SFO[b]

[a] No DT_{50} / DT_{90} values could be calculated due to the very fast dissipation and lack of data points after the treatment

[b] Single first-order

Field studies ‡

Spirotetramat	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used)	Location (USA state)	OC %	pH H_20	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm	Method of calculation
Loamy sand / bare ground	New York	0.75	6.3	0-15	0.5	1.6	0.94	-	SFO[a]
Sand / bare ground	Florida	0.23	7.1	0-15	0.9	2.9	0.96	-	SFO
Sand / cropped	Florida	0.23	7.1	0-15	1.0	3.3	0.96	-	SFO
Sandy loam / bare ground	California	0.29	6.8	0-15	1.0	3.5	0.98	-	SFO
Sandy loam / cropped	California	0.29	6.8	0-15	1.0	3.4	0.97	-	SFO
Sandy loam / bare ground	Washington	0.41	8.1	0-15	0.4	1.4	0.99	-	SFO
Sandy loam / cropped	Washington	0.41	8.1	0-15	0.3	1.1	0.99	-	SFO
Geometric mean (EU)					**0.7**	**2.2**			
80th percentile (PMRA)					**1.0**	**3.4**			
90th percentile of confidence interval on arithmetic mean (US-EPA)					**0.9**	**3.0**			

[a] Single first-order

Sum of spirotetramat-enol + spirotetramat-ketohydroxy[a]	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used)	Location (USA state)	OC %	pH H_20	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm	Method of calculation
Loamy sand / bare ground	New York	0.75	6.3	0-15	31.6	105	nc	-	SFO[b]
Sand / bare ground	Florida	0.23	7.1	0-15	6.6	21.9	nc	-	SFO
Sand / cropped	Florida	0.23	7.1	0-15	4.8	16.0	nc	-	SFO
Sandy loam / bare ground	California	0.29	6.8	0-15	7.6	25.4	0.94	-	SFO
Sandy loam / cropped	California	0.29	6.8	0-15	8.7	28.9	0.90	-	SFO
Sandy loam / bare ground	Washington	0.41	8.1	0-15	5.2	17.4	0.98	-	SFO
Sandy loam / cropped	Washington	0.41	8.1	0-15	4.6	15.4	0.98	-	SFO
Geometric mean (EU)					**7.7**	**25.6**			
80th percentile (PMRA)					**8.5**	**28.2**			
90th percentile of confidence interval on arithmetic mean (US-EPA)					**15.2**	**50.4**			

[a] Owing to the low storage stability of spirotetramat-enol (degrading to spirotetramat-ketohydroxy) only combined residues are considered valid

[b] Single first-order (multi-compartment model, formation fraction set to 100 %)

Sum of total residues[a]	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used)	Location (USA state)	OC %	pH H_20	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm	Method of calculation
Loamy sand / bare ground	New York	0.75	6.3	0-15	23.4	77.8	0.93	-	SFO[b]
Sand / bare ground	Florida	0.23	7.1	0-15	7.6	25.3	0.86	-	SFO
Sand / cropped	Florida	0.23	7.1	0-15	5.7	19.0	0.90	-	SFO
Sandy loam / bare ground	California	0.29	6.8	0-15	8.4	27.9	0.95	-	SFO
Sandy loam / cropped	California	0.29	6.8	0-15	10.2	33.9	0.91	-	SFO
Sandy loam / bare ground	Washington	0.41	8.1	0-15	6.3	21.0	0.98	-	SFO
Sandy loam / cropped	Washington	0.41	8.1	0-15	5.0	16.7	0.98	-	SFO
Geometric mean (EU)					**8.3**	**27.7**			
80th percentile (PMRA)					**9.8**	**32.7**			
90th percentile of confidence interval on arithmetic mean (US-EPA)					**13.0**	**43.2**			

[a] Sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy and spirotetramat-MA-amide

[b] Single first-order

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not studied - no data requested

Laboratory studies ‡

Spirotetramat	Anaerobic conditions							
Soil type	OC %	pH (H_2O)	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	chi ^{2} error [%]	Method of calculation
Sandy loam	0.4	7.4	20°C / 50 % MWHC	0.25 / 0.83 0.06 / 1.33 0.22 / 0.87	- - -	nc 0.993 nc	18.0 5.27 9.23	SFO[a] FOMC[b] DFOP[c]
Spirotetramat	Soil photolysis							
Soil type	OC %	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	chi ^{2} error [%]	Method of calculation
Sandy loam	0.7	6.3	20 °C / 75 % of 1/3 bar / sterile conditions / **irradiated**	[3-^{14}C]: 12.0 / 39.9 [5-^{14}C]: 7.1 / 23.7	- -	- -	6.9 7.4	SFO[a] SFO[a]
Sandy loam	0.7	6.3	20 °C / 75 % of 1/3 bar / sterile conditions / **dark**	[3-^{14}C]: 5.2 / 17.1 [5-^{14}C]: 4.9 / 16.2	- -	- -	2.6 1.4	SFO[a] SFO[a]

[a] Single first-order

[b] First order multi compartment

[c] Double first-order in parallel

Soil adsorption/desorption (OECD Annex IIA, point 7.4.1 and 7.4.2)							
Spirotetramat							
Soil Type	OC %	Soil pH ($CaCl_2$)	Freundlich isotherm			Linear isotherm	
			Kf (mL/g)	Kfoc (mL/g)	1/n	Kd (mL/g)	Koc (mL/g)
Loamy sand	2.38	6.1	4.79	201	1.001	4.38	184
Sandy loam	0.87	6.8	3.78	435	0.892	3.80	437
Silt loam	2.33	5.9	4.10	176	0.945	4.69	201
Sandy loam	0.93	5.4	4.05	435	0.823	3.58	385
Loam	2.33	4.7	3.70	159	1.042	5.52	237
Arithmetic mean (EU)			**nc**	**281**	**0.941**	-	-
20th percentile (PMRA)			-	-	-	**nc**	**198**
pH dependence, Yes or No			No				

nc: not calculated

Spirotetramat-enol – unstable in the adsorption/desorption test system, adsorption data from soil column study							
Soil Type	OC %	Soil pH ($CaCl_2$)	Freundlich isotherm			Linear isotherm	
			Kf (mL/g)	Kfoc (mL/g)	1/n	Kd (mL/g)	Koc (mL/g)
Sandy loam	2.0	6.1	-	-	-	0.54	27
Loam	1.2	6.5	-	-	-	0.78	65
Silt loam	2.4	6.4	-	-	-	0.70	29
Sandy loam	0.8	5.4	-	-	-	0.79	99
Arithmetic mean (EU)			**-**	**-**	**1.0[a]**	**nc**	**55**
20th percentile (PMRA)			**-**	**-**	**-**	**nc**	**28**
pH dependence, Yes or No			No				

[a] Set to 1.0 by default

nc: not calculated

Spirotetramat-ketohydroxy							
Soil Type	OC %	Soil pH ($CaCl_2$)	Freundlich isotherm			Linear isotherm	
			Kf (mL/g)	Kfoc (mL/g)	1/n	Kd (mL/g)	Koc (mL/g)
Sandy loam	1.30	6.0	0.533	41.0	0.920	0.560	43.1
Silt loam	1.10	6.4	0.516	46.9	0.929	0.529	48.1
Silt loam	2.62	6.1	1.08	41.2	0.927	1.10	42.0
Sandy loam	0.87	6.2	0.862	99.1	0.918	0.867	99.7
Clay loam	2.44	5.5	2.21	90.4	0.915	2.28	93.4
Arithmetic mean (EU)			**nc**	**63.7**	**0.922**	**-**	**-**
20th percentile (PMRA)			**-**	**-**	**-**	**nc**	**42.9**
pH dependence, Yes or No			No				

nc: not calculated

Spirotetramat-MA-amide							
Soil Type	OC %	Soil pH ($CaCl_2$)	Freundlich isotherm			Linear isotherm	
			Kf (mL/g)	Kfoc (mL/g)	1/n	Kd (mL/g)	Koc (mL/g)
Sandy loam	1.7	6.3	0.08	4.4	1.07	0.071	4.2
Silt loam	0.91	6.7	0.06	6.5	0.96	0.064	7.0
Silt loam	2.07	6.5	0.10	5.0	0.80	0.116	5.6
Loamy sand	0.7	5.7	0.18	25.5	0.98	0.179	25.6
Loam	2.3	5.4	0.12	5.1	0.93	0.126	5.5
Arithmetic mean (EU)			**nc**	**9.3**	**0.95**	**-**	**-**
20th percentile (PMRA)			**-**	**-**	**-**	**nc**	**5.2**
pH dependence, Yes or No			No				

nc: not calculated

Mobility in soil (OECD Annex IIA, point 7.4, Annex IIIA, point 9.3)

Column leaching ‡	Spirotetramat-enol: Eluation (mm): 1000 mm of 0.01 M $CaCl_2$ solution Time period (d): 5 d
	Leachate: Total radioactivity: 2.6 – 17.0 % (n = 4) Spirotetramat-enol: 0.1 – 2.8 % (n = 4) Spirotetramat-ketohydroxy: 0.2 – 7.5 % (n = 4) Spirotetramat-MA-amide: 0.8 – 1.9 % (n = 4) Soil: Total radioactivity (0 – 6 cm): 64.2 – 77.6 % (n = 4) Total radioactivity (6 – 30 cm): 5.8 – 15.8 % (n = 4) Spirotetramat-enol Koc: 27 - 99 L kg^{-1}
Aged residues leaching ‡	Not studied - no data requested
Lysimeter/ field leaching studies ‡	Not studied - no data requested

PEC (soil) (OECD Annex IIIA, point 9.4 and 9.5)

EU risk assessment

Spirotetramat Method of calculation	DT_{50} (d): 0.33 days Kinetics: SFO Representative worst case from lab studies, non-normalized
Spirotetramat-enol Method of calculation	DT_{50} (d): 2.95 days Kinetics: SFO (recalculated from FOMC-DT_{90}/3.32) Representative worst case from lab studies, non-normalized Maximum occurrence in soil: 100 % Molecular ratio: 0.807
Spirotetramat-ketohydroxy Method of calculation	DT_{50} (d): 16.7 days Kinetics: SFO Representative worst case from lab studies, non-normalized Maximum occurrence in soil: 24.0 % Molecular ratio: 0.850
4-methoxy-cyclohexanone Method of calculation	DT_{50} (d): 0.6 days Kinetics: SFO Representative worst case from lab studies, non-normalized Maximum occurrence in soil: 10.0 % (soil photolysis) Molecular ratio: 0.343
Application data	**Citrus** Application rate: 288 g a.s. ha^{-1} (assuming a tree height of 3 m) Number of applications: 2 Interval (d): 21 % plant interception: 70 % Depth of soil layer: 5 cm Soil bulk density: 1.5 g cm^{-3} **Leafy vegetables** Application rate: 72 g a.s. ha^{-1} Number of applications: 2 Interval (d): 14 % plant interception: 70 % Depth of soil layer: 5 cm Soil bulk density: 1.5 g cm^{-3}

$PEC_{(s)}$ (mg/kg)		Citrus / spirotetramat			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.115	
Short term	24 h	nc	nc	0.014	0.048
	2 d	nc	nc	0.002	0.027
	4 d	nc	nc	< 0.001	0.014
Long term	7 d	nc	nc	< 0.001	0.008
	14 d	nc	nc	< 0.001	0.004
	21 d	nc	nc	< 0.001	0.003
	28 d	nc	nc	< 0.001	0.002
	42 d	nc	nc	< 0.001	0.001
	50 d	nc	nc	< 0.001	0.001
	100 d	nc	nc	< 0.001	< 0.001
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Citrus / spirotetramat-enol			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.094	
Short term	24 h	nc	nc	0.074	0.083
	2 d	nc	nc	0.059	0.075
	4 d	nc	nc	0.037	0.061
Long term	7 d	nc	nc	0.018	0.046
	14 d	nc	nc	0.003	0.027
	21 d	nc	nc	< 0.001	0.019
	28 d	nc	nc	< 0.001	0.014
	42 d	nc	nc	< 0.001	0.009
	50 d	nc	nc	< 0.001	0.008
	100 d	nc	nc	< 0.001	0.004
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Citrus / spirotetramat-ketohydroxy			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.033	
Short term	24 h	nc	nc	0.032	0.033
	2 d	nc	nc	0.031	0.032
	4 d	nc	nc	0.028	0.031
Long term	7 d	nc	nc	0.025	0.029
	14 d	nc	nc	0.019	0.025
	21 d	nc	nc	0.014	0.022
	28 d	nc	nc	0.010	0.020
	42 d	nc	nc	0.006	0.016
	50 d	nc	nc	0.004	0.014
	100 d	nc	nc	< 0.001	0.008
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Citrus / 4-methoxy-cyclohexanone			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.004	
Short term	24 h	nc	nc	0.001	0.002
	2 d	nc	nc	< 0.001	0.002
	4 d	nc	nc	< 0.001	< 0.001
Long term	7 d	nc	nc	< 0.001	< 0.001
	14 d	nc	nc	< 0.001	< 0.001
	21 d	nc	nc	< 0.001	< 0.001
	28 d	nc	nc	< 0.001	< 0.001
	42 d	nc	nc	< 0.001	< 0.001
	50 d	nc	nc	< 0.001	< 0.001
	100 d	nc	nc	< 0.001	< 0.001
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Leafy vegetables / spirotetramat			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.029	
Short term	24 h	nc	nc	0.004	0.012
	2 d	nc	nc	< 0.001	0.007
	4 d	nc	nc	< 0.001	0.003
Long term	7 d	nc	nc	< 0.001	0.002
	14 d	nc	nc	< 0.001	< 0.001
	21 d	nc	nc	< 0.001	< 0.001
	28 d	nc	nc	< 0.001	< 0.001
	42 d	nc	nc	< 0.001	< 0.001
	50 d	nc	nc	< 0.001	< 0.001
	100 d	nc	nc	< 0.001	< 0.001
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Leafy vegetables / spirotetramat-enol			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.024	
Short term	24 h	nc	nc	0.019	0.021
	2 d	nc	nc	0.015	0.019
	4 d	nc	nc	0.009	0.016
Long term	7 d	nc	nc	0.005	0.012
	14 d	nc	nc	< 0.001	0.007
	21 d	nc	nc	< 0.001	0.005
	28 d	nc	nc	< 0.001	0.004
	42 d	nc	nc	< 0.001	0.002
	50 d	nc	nc	< 0.001	0.002
	100 d	nc	nc	< 0.001	0.001
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Leafy vegetables / spirotetramat-ketohydroxy			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		0.009	
Short term	24 h	nc	nc	0.009	0.009
	2 d	nc	nc	0.008	0.009
	4 d	nc	nc	0.008	0.008
Long term	7 d	nc	nc	0.007	0.008
	14 d	nc	nc	0.005	0.007
	21 d	nc	nc	0.004	0.006
	28 d	nc	nc	0.003	0.005
	42 d	nc	nc	0.002	0.004
	50 d	nc	nc	0.001	0.004
	100 d	nc	nc	< 0.001	0.002
Plateau concentration		Not considered to accumulate			

$PEC_{(s)}$ (mg/kg)		Leafy vegetables / 4-methoxy-cyclohexanone			
		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		nc		< 0.001	
Short term	24 h	nc	nc	< 0.001	< 0.001
	2 d	nc	nc	< 0.001	< 0.001
	4 d	nc	nc	< 0.001	< 0.001
Long term	7 d	nc	nc	< 0.001	< 0.001
	14 d	nc	nc	< 0.001	< 0.001
	21 d	nc	nc	< 0.001	< 0.001
	28 d	nc	nc	< 0.001	< 0.001
	42 d	nc	nc	< 0.001	< 0.001
	50 d	nc	nc	< 0.001	< 0.001
	100 d	nc	nc	< 0.001	< 0.001
Plateau concentration		Not considered to accumulate			

Route and rate of degradation in water (OECD Annex IIA, point 7.5, 7.6, 7.7 and 7.8)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Spirotetramat, [3-^{14}C] and [5-^{14}C]-label: DT_{50} (pH 4, 25 °C): 32.5 d (SFO, r^2 = 1) DT_{50} (pH 7, 25 °C): 8.6 d (SFO, r^2 = 1) DT_{50} (pH 9, 25 °C): 0.32 d (SFO, r^2 = 1) Metabolites: Only spirotetramat-enol (max. 93 % at pH 9, 25 °C) Spirotetramat-enol, [3-^{14}C] and [5-^{14}C]-label: Hydrolytically stable at pH 4, 7 and 9 Spirotetramat-ketohydroxy, [3-^{14}C]-label: DT_{50} (pH 4, 25 °C): No degradation observed DT_{50} (pH 7, 25 °C): 82.7 d (SFO, chi^2-error = 0.8) DT_{50} (pH 9, 25 °C): 4.9 d (SFO, chi^2-error = 4.9)
Photolytic degradation of active substance and metabolites above 10 % ‡	Spirotetramat, [3-^{14}C] and [5-^{14}C]-label: **Sterilized natural water** DT_{50} (pH 7.9, 25 °C, irradiated): 0.19 d (SFO) DT_{50} (pH 7.9, 25 °C, dark): 1.54 d (SFO) DT_{50} (pH 7.9, 25 °C, net): 0.22 d (SFO) Converted to natural summer light: Athens (Greece, EU): DT_{50} 1.15 days Phoenix (AZ, USA): DT_{50} 0.74 days Edmonton (Alberta, Canada): DT_{50} 1.05 days Photolysis-metabolites: Spirotetramat-enol: 81.9 % (1 d) 4-methoxy-cyclohexyl-aminocarboxylic acid: 11.3 % (10 d) 4-methoxy-cyclohexanone: 17.5 % (8 d)
Quantum yield of direct phototransformation in water at Σ > 290 nm	Spirotetramat: Φ = 0.00571 DT_{50} under natural late spring to summer light, Central Europe: approx. 0.5 – 1 days (GC-SOLAR, Frank & Klöpffer) Spirotetramat-enol: Φ = 0.000252 DT_{50} under natural late spring to summer light, Central Europe: approx. 9 – 16 days (GC-SOLAR, Frank & Klöpffer)
Readily biodegradable ‡ (yes/no)	No (based on data)

Degradation in water / sediment

Spirotetramat	Distribution (Max. in sediment: 3.2 % after 1 d)									
Water / sediment system	pH water phase	pH sed. $CaCl_2$	t. °C	DT_{50} / DT_{90} Whole system (d)	St. (r^2)	DT_{50} / DT_{90} Water (d)[a]	St. (r^2)	DT_{50} / DT_{90} Sediment (d)	St. (r^2)	Method of calculation
'Hönninger Weiher'	6.7	5.6	20	0.86 / 2.85	0.99	0.82 / 2.73	0.99	nc	-	SFO[b]
'Anglerweiher'	7.2	6.8	20	0.70 / 2.34	0.97	0.74 / 2.45	0.97	nc	-	SFO
Geometric mean				**0.78 / 2.58**		**0.78 / 2.59**		**nc**		

[a] Dissipation
[b] Single first-order
nc: not calculated

Spirotetramat-enol	Distribution (max in water: 78.8 % after 7 d, max. sediment: 36.6 % after 60 d, mean of both labels)									
Water / sediment system	pH water phase	pH sed. $CaCl_2$	t. °C	DT_{50} / DT_{90} Whole system (d)	St. (r^2)	DT_{50} / DT_{90} Water (d)[a]	St. (r^2)	DT_{50} / DT_{90} Sediment (d)	St. (r^2)	Method of calculation
'Hönninger Weiher'	6.7	5.6	20	59.0 / 196	0.93	nc	-	nc	-	SFO[a]
'Anglerweiher'	7.2	6.8	20	37.9 / 126	0.93	nc	-	nc	-	SFO
Geometric mean				**47.3 / 157**		**nc**		**nc**		

[a] Single first-order (multi-compartment model)
nc: not calculated

Spirotetramat-ketohydroxy	Distribution (max in water: 12.7 % after 120 d, max. sediment: 27.8 % after 120 d, mean of both labels)									
Water / sediment system	pH water phase	pH sed. $CaCl_2$	t. °C	DT_{50} / DT_{90} Whole system (d)	St. (r^2)	DT_{50} / DT_{90} Water (d)[a]	St. (r^2)	DT_{50} / DT_{90} Sediment (d)	St. (r^2)	Method of calculation
'Hönninger Weiher'	6.7	5.6	20	Stable	-	nc	-	nc	-	-
'Anglerweiher'	7.2	6.8	20	Stable	-	nc	-	nc	-	-
Geometric mean				**Stable**		**nc**		**nc**		**-**

nc: not calculated

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed. $CaCl_2$	Mineralization (end of the study)	Non-extractable residues in sediment (maximum)	Non-extractable residues in sediment (end of the study)
'Hönninger Weiher'	6.7	5.6	[3-^{14}C]: 11.0 % after 120 d [5-^{14}C]: 5.9 % after 120 d	[3-^{14}C]: 32.9 % after 120 d [5-^{14}C]: 40.7 % after 91 d	[3-^{14}C]: 32.9 % after 120 d [5-^{14}C]: 36.3 % after 120 d
'Anglerweiher'	7.2	6.8	[3-^{14}C]: 24.0 % after 120 d [5-^{14}C]: 13.5 % after 120 d	[3-^{14}C]: 32.3 % after 120 d [5-^{14}C]: 33.9 % after 120 d	[3-^{14}C]: 32.3 % after 120 d [5-^{14}C]: 33.9 % after 120 d

PEC (ground water) (OECD Annex IIIA, point 9.6)

EU risk assessment

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model, with appropriate FOCUSgw scenarios, according to FOCUS guidance Model(s) used: FOCUS PEARL 4.4.4 Scenarios (list of names): All if appropriate Crops: Citrus, leafy vegetables **Spirotetramat:** Geometric mean DT_{50}: 0.17 d (*lab, SFO, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) K_{FOC}: 281 L kg^{-1} (*arithmetic mean*) $^1/_n$ = 0.94 (*arithmetic mean*) Water solubility: 29.9 mg L^{-1} Vapour pressure: 5.6 × 10^{-9} Pa Plant uptake: 0.5 **Spirotetramat-enol** (*implementing kinetic sorption approach*): Geometric mean DT_{50}: 0.04 d (*lab, SFO, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58, minimum value possible (i.e. 0.1 d) used for modelling*) K_{OC}: 55 L kg^{-1} (*arithmetic mean, column leaching study*) $^1/_n$: 1.0 (*unknown, conservative default value*) k_d: 0.016 d^{-1} (*lab, SFO, non-normalized, geometric mean*) f_{NE}: 377 (*lab, arithmetic mean, maximum value possible (i.e. 99) used for modelling*) Formation fraction (from parent): 1.00 Water solubility: 2700 mg L^{-1} Vapour pressure: 3.64 × 10^{-10} Pa Plant uptake: 0.5 **Spirotetramat-ketohydroxy:** Geometric mean DT_{50}: 4.5 d (*lab, SFO, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) K_{FOC}: 63.7 L kg^{-1} (*arithmetic mean*) $^1/_n$ = 0.92 (*arithmetic mean*) Formation fraction (from spirotetramat-enol): 0.26 (*arithmetic mean*)

	Water solubility: 288 mg L^{-1} Vapour pressure: 2.21 × 10^{-10} Pa Plant uptake: 0.5 **Spirotetramat-MA-amide:** Geometric mean DT_{50}: 1.2 d (*lab, SFO, normalisation to 10kPa or pF2, 20 °C with Q_{10} of 2.58*) K_{FOC}: 9.3 L kg^{-1} (*arithmetic mean*) $^1/_n$ = 0.95 (*arithmetic mean*) Formation fraction (from spirotetramat-ketohydroxy): 1.00 (*fixed*) Water solubility: 69.7 mg L^{-1} Vapour pressure: 1.56 × 10^{-11} Pa Plant uptake: 0.5 **4-methoxy-cyclohexanone:** DT_{50}: 0.6 d (*lab, SFO, non-normalized, maximum*) K_{FOC}: 0.0 L kg^{-1} (*unknown, worst case*) $^1/_n$ = 0.9 (*unknown, default value*) Water solubility: 53200 mg L^{-1} (*estimate*) Vapour pressure: 70.8 Pa (*estimate*) Maximum occurrence in soil: 10.0 % (*Soil photolysis*) Plant uptake: 0.5 For all these compounds simulations used a Q10 of 2.58 and Walker equation coefficient of 0.7
Application rate	**Citrus** Application rate(s): 288 g a.s. ha^{-1} (assuming a tree height of 3 m) Number of applications: 2 Interval (d): 21 Crop interception: 70 % Application time: November, 7th and 28th **Leafy vegetables** Application rate(s): 72 g a.s. ha^{-1} Number of applications: 2 Interval (d): 14 Crop interception: 70 % Application time: 30 and 44 d after emergence

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

PEARL 4.4.4/ **Citrus**	Scenario	Spirotetramat (µg/L)	Metabolite (µg/L)			
			Spirotetramat -enol	Spirotetramat -ketohydroxy	Spirotetramat -MA-amide	4-methoxy-cyclohexanone
	Piacenza	< 0.001	< 0.001	< 0.001	0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	0.002	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
PEARL 4.4.4/ **Leafy vegetables**	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

PEC (surface water) and PEC sediment (OECD Annex IIIA, point 9.7 and 9.8)

EU risk assessment

Spirotetramat Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 373.45 Water solubility (mg/L): 29.9 K_{FOC} / K_{FOM} (L/kg): 281 / 163 (*arithmetic mean*) DT_{50} soil (d): 0.16 *(lab, geometric mean, in accordance with FOCUS SFO)* DT_{50} water/sediment system (d): 0.78 *(geometric mean)* DT_{50} water (d): 0.78 *(value from entire system)* DT_{50} sediment (d): 0.78 *(value from entire system)*
Parameters used in FOCUSsw step 3 and 4	Version control no. of FOCUS software: SWASH 3.1, MACRO 4.4.2, PRZM 1.1.1, TOXSWA 3.3.1 & SWAN 1.1.4 Vapour pressure (Pa): 5.6×10^{-9} 1/n: 0.94 (*arithmetic mean*) DT_{50} water (d): 0.78 *(value from entire system)* DT_{50} sediment (d): 1000 *(default value)* Simulations used a Q10 of 2.58 and Walker equation coefficient of 0.7
Spirotetramat-enol Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 301.38 Water solubility (mg/L): 2700 K_{FOC} / K_{FOM} (L/kg): 55 / 32 (*arithmetic mean*) DT_{50} soil (d): 1.16[a] *(SFO-DT_{50} recalculated from FOMC-DT_{90}, lab, geometric mean, in accordance with FOCUS SFO)* DT_{50} water/sediment system (d): 47.3 *(geometric mean)* DT_{50} water (d): 47.3 *(value from entire system)* DT_{50} sediment (d): 47.3 *(value from entire system)* Max. in soil (%): 100.0 Max. in entire water/sediment (%): 97.5 [a] Correct value is 1.35 days
Spirotetramat-ketohydroxy Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 317.38 Water solubility (mg/L): 288 K_{FOC} / K_{FOM} (L/kg): 63.7 / 36.9 (*arithmetic mean*) DT_{50} soil (d): 3.8[a] *(lab, geometric mean, in accordance with FOCUS SFO)* DT_{50} water/sediment system (d): 1000 (*unknown, default value*) DT_{50} water (d): 1000 (*unknown, default value*) DT_{50} sediment (d): 1000 (*unknown, default value*) Max. in soil (%): 24.0 Max. in entire water/sediment (%): 40.5 [a] Correct value is 4.5 days
4-methoxy-cyclohexanone Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 128.17 Water solubility (mg/L): 53200 K_{FOC} / K_{FOM} (L/kg): 2.6 / 1.5 (*unknown, estimated, EPIWINNT*) DT_{50} soil (d): 0.6 *(lab, worst case, in accordance with FOCUS SFO)*

	DT_{50} water/sediment system (d): 1000 (*unknown, default value*) DT_{50} water (d): 1000 (*unknown, default value*) DT_{50} sediment (d): 1000 (*unknown, default value*) Max. in soil (%): 10.0 (*soil photolysis*) Max. in entire water/sediment (%): 17.5 (*water photolysis*)
4-methoxy-cyclohexyl-aminocarboxylic acid Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: 1.1 Molecular weight (g/mol): 173.21 Water solubility (mg/L): 26570 K_{FOC} / K_{FOM} (L/kg): 10 / 5.8 (unknown, *estimated, EPIWINNT*) DT_{50} soil (d): 1000 *(unknown, default value)* DT_{50} water/sediment system (d): 1000 (*unknown, default value*) DT_{50} water (d): 1000 (*unknown, default value*) DT_{50} sediment (d): 1000 (*unknown, default value*) Max. in soil (%): 0.0 Max. in entire water/sediment (%): 11.3 (*water photolysis*)
Application rate	**Citrus** Application rate(s): 288 g a.s./ha (assuming tree height of 3 m) Number of applications: 2 Interval (d): 21 Crop interception: 70 % Application window: STEP 1 & 2: South EU, October – February STEP 3 & 4: November, 1st, 51 days window **Leafy vegetables** Application rate(s): 72 g a.s./ha Number of applications: 2 Interval (d): 14 Crop interception: 70 % Application window: STEP 1 & 2: South/North EU, March - May STEP 3 & 4: March, 24th – September, 23rd (*depends on scenario*), 44 days window
Mitigation at FOCUSsw step 4	Only drift mitigation and drift reducing nozzels considered, no mitigation of run-off or drainage for citrus. Step 4 calculations were not completed for leafy vegetables.

FOCUS STEP 1 Scenario	Substance	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
Citrus / no scenario defined	Spirotetramat	84.9	196
	Spirotetramat-enol	168	90.2
	Spirotetramat-ketohydroxy	46.5	29.1
	4-methoxy-cyclohexanone	8.38	0.218
	4-methoxy-cyclohexyl-aminocarboxylic acid	1.58	0.156
Leafy vegetables / no scenario defined	Spirotetramat	18.1	49.1
	Spirotetramat-enol	37.1	20.1
	Spirotetramat-ketohydroxy	9.48	6.01
	4-methoxy-cyclohexanone	1.72	0.043
	4-methoxy-cyclohexyl-aminocarboxylic acid	0.069	0.007

FOCUS STEP 2 Scenario	Substance	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
Citrus / South EU	Spirotetramat	11.6	6.53
	Spirotetramat-enol	15.6	8.00
	Spirotetramat-ketohydroxy	8.59	5.34
	4-methoxy-cyclohexanone	1.39	0.036
	4-methoxy-cyclohexyl-aminocarboxylic acid	1.21	0.119
Leafy vegetables / North EU	Spirotetramat	0.585	0.328
	Spirotetramat-enol	0.850	0.452
	Spirotetramat-ketohydroxy	0.519	0.324
	4-methoxy-cyclohexanone	0.071	0.002
	4-methoxy-cyclohexyl-aminocarboxylic acid	0.061	0.006
Leafy vegetables / South EU	Spirotetramat	0.585	0.328
	Spirotetramat-enol	0.950	0.505
	Spirotetramat-ketohydroxy	0.662	0.415
	4-methoxy-cyclohexanone	0.071	0.002
	4-methoxy-cyclohexyl-aminocarboxylic acid	0.061	0.006

FOCUS STEP 3 Scenario	Spirotetramat			
	Citrus		**Leafy vegetables**	
	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
D3 – ditch	Not defined	Not defined	0.399	0.122
D4 – pond	Not defined	Not defined	0.0129	0.006
D4 – stream	Not defined	Not defined	0.296	0.009
D6 – ditch	8.43	4.16	0.398	0.109
R1 – pond	Not defined	Not defined	0.0129	0.007
R1 – stream	Not defined	Not defined	0.261	0.033
R2 – stream	Not defined	Not defined	0.350	0.028
R3 - stream	Not defined	Not defined	0.368	0.071
R4 - stream	6.51	0.753	0.261	0.057

FOCUS STEP 4 Scenario (5 m buffer zone, spray drift reduction only)	Spirotetramat			
	Citrus		**Leafy vegetables**	
	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
D6 – ditch	5.86	2.94	nc	nc
R4 - stream	5.18	0.61	nc	nc

nc: not calculated

FOCUS STEP 4 Scenario	Spirotetramat			
	Spray drift mitigation		**Citrus**	
	Distance (m)	Drift reducing nozzels (%)	PEC_{SW} (µg/L) – global maximum	PEC_{SED} (µg/kg) – global maximum
D6 – ditch	5	0	5.86	2.94
		50	2.93	1.50
	10	0	2.82	1.44
	15	0	1.38	0.72
	20	0	0.80	0.42
R4 - stream	5	0	5.18	0.61
		50	2.59	0.31
	10	0	2.49	0.29
	15	0	1.22	0.15
	20	0	0.71	0.08

Fate and behaviour in air (OECD Annex IIA, point 7.10, Annex III, point 9.9)

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Spirotetramat: Φ = 0.00571 (in water) Spirotetramat-enol: Φ = 0.000252 (in water)
Photochemical oxidative degradation in air ‡	Spirotetramat: DT_{50} of 1.69 hours derived by the Atkinson model (version 1.9), OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3} Spirotetramat-enol: DT_{50} of 1.72 hours derived by the Atkinson model (version 1.9), OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3} 4-methoxy-cyclohexanone: DT_{50} of 4.36 hours derived by the Atkinson model (version 1.9), OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3} 4-methoxy-cyclohexyl-aminocarboxylic acid: DT_{50} of 2.80 hours derived by the Atkinson model (version 1.9), OH (12 h) concentration assumed = 1.5 x 10^6 cm^{-3}
Volatilisation ‡	From plant surfaces: not studied - no data requested
	From soil surfaces: not studied - no data requested
Metabolites	See above

PEC (air)

Method of calculation	Not relevant, because of low vapor pressure; same is true for the major metabolite spirotetramat-enol, being more polar (i.e. less volatile) than the parent

$PEC_{(a)}$

EU risk assessment

Maximum concentration	Negligible

Residues requiring further assessment (OECD Annex IIA, point 7.11)

EU risk assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and /or requiring consideration for groundwater exposure	Soil: Spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, 4-methoxy-cyclohexanone (the latter from soil photolysis) Surface water: Spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, 4-methoxy-cyclohexyl-aminocarboxylic acid, 4-methoxy-cyclohexanone (the two latter from water photolysis) Sediment: Spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy Ground water: Spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-MA-amide, 4-methoxy-cyclohexanone (the latter from soil photolysis) Air: Spirotetramat, spirotetramat-enol

Monitoring data, if available (OECD Annex IIA, point 7.12)

Soil (indicate location and type of study)	No monitoring data, new active substance
Surface water (indicate location and type of study)	No monitoring data, new active substance
Ground water (indicate location and type of study)	No monitoring data, new active substance
Air (indicate location and type of study)	No monitoring data, new active substance

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data (OECD Annex IIA, point 9)

Not readily biodegradable

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	a.s.	Acute	> 2000	/
Mallard duck	Preparation	Acute	/	
Bobwhite quail	a.s.	Short-term	> 475	> 6050
Mallard duck	a.s.	Long-term	4	30
Mammals ‡				
Rat	a.s.	Acute	> 2000	/
Rat	Spirotetramat OD150	Acute	> 2000	/
Rat f	Spirotetramat-ketohydroxy	Acute	> 2000	/
Rat f	Spirotetramat - desmethyl-ketohydroxy	Acute	> 2000	/
Rat f	Spirotetramat - dihydroxy	Acute	> 2000	/
Rat f	Spirotetramat - monohydroxy	Acute	> 2000	/
Rat	a.s.	Long-term	70	1000
Additional higher tier studies ‡				
Long-term Mallard duck dermal exposure study				
Semi-field study on the effects of dermal and dietary exposure in Mallard ducks				
Generic field monitoring study of birds in potato / Northern Europe				
Study on insectivorous birds / focal species in Southern European citrus plantation				
Study on residues in potential wildlife feed items				
Study on residues of spirotetramat in arthropods – magnitude and time course of decline				

m: male
f: female

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

EU risk assessment

Indicator species/Category	Time scale	ETE	TER[1]	Annex VI Trigger[2]
Tier 1 (Birds)				
Lettuce, 72 g a.s./ha				
Medium herbivorous bird	Acute	5.7	> 350	10
Small insectivorous bird	Acute	3.9	> 514	10
Medium herbivorous bird	Short-term	3.1	> 155	10
Small insectivorous bird	Short-term	2.2	> 219	10
Medium herbivorous bird	Long-term	1.6	**2.5**	5
Small insectivorous bird	Long-term	2.2	**1.8**	5
Citrus, 288 g a.s./ha				
Small insectivorous bird	Acute	5.2	> 128	10
Small insectivorous bird	Short-term	2.9	> 55	10
Small insectivorous bird	Long-term	2.9	**0.5**	5
Higher tier refinement (Birds)				
Lettuce, 72 g a.s./ha: herbiv: residue decline on plants considered; insectiv: PD, PT considered				
Wood Pigeon (herbiv.)	Long-term	0.99	4.1[#]	5
Yellow Wagtail (insectiv.)	Long-term	0.25	16	5
Citrus, 288 g a.s./ha: PD: foliage + ground-dwelling arthropods, measured residues on arthropods considered, PT considered (Final Addendum; Austria, 2013):				
Great Tit (insectiv.)	Long-term	1	4	5
Tier 1 (Mammals)				
Lettuce, 72 g a.s./ha				
Medium herbivorous mammal	Acute	2.1	> 950	10
Medium herbivorous mammal	Acute form.	2.1	> 145	10
Medium herbivorous mammal	Long-term	0.6	117	5
Citrus, 288 g a.s./ha				
Small herbivorous mammal	Acute	41	> 49	10
Small herbivorous mammal	Acute form.	41	> 7.5**	10
Small herbivorous mammal	Long-term	12	5.8	5
Higher tier refinement (Mammals)				
None required				

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

[2] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

* effective application rate with regard to oversprayed insects per meter canopy height

** figure is considered acceptable, because based on a "bigger than" LD_{50} with no mortality

[#] this TER was considered acceptable based on a weight-of-evidence argumentation

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)	Endpoint	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Cyprinodon variegatus	Spirotetramat	96 hr (flow-through)	Mortality, EC_{50}	1.96 (mm)
Pimephales promelas	Spirotetramat	33 d (flow-through)	Fry survival, NOEC	0.534 (mm)
Oncorhynchus mykiss	OD 150 (formulation)	96 hr (flow-through)	Mortality, EC_{50}	9.48 (nom) (1.41 mg as/L)
Oncorhynchus mykiss	Spirotetramat-enol	96 hr (static, limit)	Mortality, EC_{50}	> 100 (nom)
Danio rerio	4-methoxycyclo-hexanone	96 hr (static, limit)	Mortality, EC_{50}	> 100 (nom)
Aquatic invertebrate				
Daphnia magna	Spirotetramat	48 h (static)	Mortality, EC_{50}	> 42.7 (mm)
Crassostera virginica	Spirotetramat	96 h (static)	Shell deposition, EC_{50}	0.85 (mm)
Daphnia magna	Spirotetramat	21 d (static)	Mortality adults, NOEC	2.0 (nom)
Daphnia magna	Spirotetramat-enol	48 hr (static, limit)	Mortality, EC_{50}	> 100 (nom)
Daphnia magna	4-methoxycyclo-hexanone	48 hr (static, limit)	Mortality, EC_{50}	> 100 (nom)
Sediment dwelling organisms				
Chironomus riparius	Spirotetramat	48 h (static, water only)	Mortality, EC_{50}	1.3 (mm)
Chironomus riparius	Spirotetramat	21 d (static, spiked water)	Emergence, NOEC	0.1 (nom)
Chironomus riparius	OD 150 (formulation)	48 h (static, water only)	Mortality, EC_{50}	4.41 (mm) (0.66 mg as/L)
Chironomus riparius	Spirotetramat-enol	48 hr (static, water only)	Mortality, EC_{50}	74.9 (nom)
Chironomus riparius	Spirotetramat-ketohydroxy	48 hr (static, water only)	Mortality, EC_{50}	> 100 (nom)
Chironomus riparius	4-methoxycyclo-hexanone	48 hr (static, water only)	Mortality, EC_{50}	> 100 (nom)
Chironomus riparius	4-methoxycyclo-hexylamino carcoxylic acid	48 hr (static, water only)	Mortality, EC_{50}	> 100 (nom)
Algae				
Skeletonema costatum	Spirotetramat	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.36 (mm) 0.96

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Pseudokirch subcap.	OD 150 (formulation)	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	43.3 $_{(mm)}$ (6.56 mg as/L) > 54.3 (> 8.2 mg as/L)
Pseudokirch subcap.	Spirotetramat-enol	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 $_{(mm)}$ > 100 $_{(mm)}$
Desmodesmus subcap.	4-methoxycyclo-hexanone	72 h (static, limit)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 100 $_{(nom)}$ > 100 $_{(nom)}$
Higher plant				
Lemna gibba	Spirotetramat	7 d (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	4.49 $_{(mm)}$ 6.21 $_{(mm)}$
Lemna gibba	Spirotetramat-enol	7 d (static)	Yield: E_yC_{50} Growth rate: E_rC_{50}	5.4 $_{(mm)}$ 19.3 $_{(mm)}$
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 endpoints are presented as units of preparation or a.s.

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

FOCUS Step1

Citrus (worst case), 2 x 288 g/ha

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger
Spirotetramat	*Cyprinodon variegatus*	1.96	Acute	0.0849	**23**	100
Spirotetramat	*Pimephales promelas*	0.534	Chronic	0.0849	**6**	10
OD 150 (formulation)	*Oncorhynchus mykiss*	1.41	Acute	0.0849	**17**	100
Spirotetramat-enol	*Oncorhynchus mykiss*	> 100	Acute	0.1680	> 595	100
4-methoxycyclo-hexanone	*Danio rerio*	> 100	Acute	0.0084	> 11933	100
Spirotetramat	*Daphnia magna*	> 42.7	Acute	0.0849	> 503	100
Spirotetramat	*Crassostera virginica*	0.85	Acute	0.0849	**10**	100
Spirotetramat	*Daphnia magna*	2.0	Chronic	0.0849	24	10
Spirotetramat-enol	*Daphnia magna*	> 100	Acute	0.1680	> 595	100
4-methoxycyclo-hexanone	*Daphnia magna*	> 100	Acute	0.0084	> 11933	100
Spirotetramat	*Chironomus riparius*	1.3	Acute	0.0849	**15**	100
Spirotetramat	*Chironomus riparius*	0.1	Chronic	0.0849	**1**	10
OD 150 (formulation)	*Chironomus riparius*	0.66	Acute	0.0849	**8**	100
Spirotetramat-enol	*Chironomus riparius*	74.9	Acute	0.1680	446	100
Spirotetramat-ketohydroxy	*Chironomus riparius*	> 100	Acute	0.0465	> 2151	100
4-methoxycyclo-hexanone	*Chironomus riparius*	> 100	Acute	0.0084	> 11933	100
4-methoxycyclo-hexylamino carcoxylic acid	*Chironomus riparius*	> 100	Acute	0.0016	> 63291	100
Spirotetramat	*Skeletonema costatum*	0.36	Chronic	0.0849	**4**	10
OD 150 (formulation)	*Pseudokirch subcap.*	6.56	Chronic	0.0849	77	10
Spirotetramat-enol	*Pseudokirch subcap.*	> 100	Chronic	0.1680	> 595	10
4-methoxycyclo-hexanone	*Desmodesmus subcap.*	> 100	Chronic	0.0084	> 11933	10

Lettuce, 72 g a.s./ha

Organism	Test substance	Toxicity endpoint (mg a.s./L)	Time scale	PEC (mg/L)	TER	Annex VI Trigger
Fish						
Cyprinodon variegatus	Spirotetramat	1.96	96 h	0.0181	108	100
Pimephales promelas	Spirotetramat	0.534	33 d	0.0181	30	10
Oncorhynchus mykiss	OD 150 formulation	1.41	96 h	0.0181	**78**	100
Oncorhynchus mykiss	Spirotetramat-enol	> 100	96 h	0.0371	> 2695	100
Danio rerio	4-methoxy-cyclohexanone	> 100	96 h	0.0017	> 58140	100
Aquatic invertebrates						
Daphnia magna	Spirotetramat	> 42.7	48 h	0.0181	> 2359	100
Crassostrea virginica	Spirotetramat	0.85	48 h	0.0181	**47**	100
Daphnia magna	Spirotetramat	2.0	21 d	0.0181	110	10
Daphnia magna	Spirotetramat-enol	> 100	48 h	0.0371	> 2695	100
Daphnia magna	4-methoxy-cyclohexanone	> 100	48 h	0.0017	> 58140	100
Sediment dwelling organisms						
Chironomus riparius	Spirotetramat	1.3	48 h	0.0181	**72**	100
Chironomus riparius	Spirotetramat	0.1	21 d	0.0181	**6**	10
Chironomus riparius	OD 150 formulation	0.66	48 h	0.0181	**36**	100
Chironomus riparius	Spirotetramat-enol	74.9	48 h	0.0371	2019	100
Chironomus riparius	Spirotetramat-ketohydroxy	> 100	48 h	0.0095	10549	100
Chironomus riparius	4-methoxy-cyclohexanone	> 100	48 h	0.0017	> 58140	100
Chironomus riparius	4-methoxycyclohexyl-amino-carboxylic acid	> 100	48 h	0.00007	> 14.4 x 10^5	100
Algae						
Skeletonema costatum	Spirotetramat	0.36/0.96	72 h	0.0181	20/53	10
P. subcapitata	OD 150 formulation	6.56/>8.2	72 h	0.0181	362/>453	10
P. subcapitata	Spirotetramat-enol	> 100	72 h	0.0371	> 2695	10
Desmodesmus subcapitata	4-methoxycyclohexanone	> 100	72 h	0.0017	> 58140	10
Higher plant						
Lemna gibba	Spirotetramat	4.49/6.21	7 d	0.0181	248/343	10
Lemna gibba	Spirotetramat-enol	5.4/19.3	7 d	0.0371	146/520	10

FOCUS Step 2

Citrus (worst case), 2 x 288 g/ha, BBCH 71 – 78, Southern Europe

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger
Spirotetramat	*Cyprinodon variegatus*	1.96	Acute	0.0116	169	100
Spirotetramat	*Pimephales promelas*	0.534	Chronic	0.0116	46	10
OD 150 (formulation)	*Oncorhynchus mykiss*	1.41	Acute	0.0116	122	100
Spirotetramat	*Crassostera virginica*	0.85	Acute	0.0116	**73**	100
Spirotetramat	*Chironomus riparius*	1.3	Acute	0.0116	112	100
Spirotetramat	*Chironomus riparius*	0.1	Chronic	0.0116	**9**	10
OD 150 (formulation)	*Chironomus riparius*	0.66	Acute	0.0116	**57**	100
Spirotetramat	*Skeletonema costatum*	0.36	Chronic	0.0116	31	10

Lettuce, 72 g a.s./ha

Organism	Test substance	Toxicity endpoint (mg a.s./L)	Time scale	PEC (mg/L)	TER	Annex VI Trigger
Fish						
Oncorhynchus mykiss	OD 150 formulation	1.41	96 h	0.00059	2410	100
Aquatic invertebrates						
Crassostrea virginica	Spirotetramat	0.85	48 h	0.00059	1453	100
Sediment dwelling organisms						
Chironomus riparius	Spirotetramat	1.3	48 h	0.00059	2222	100
Chironomus riparius	Spirotetramat	0.1	21 d	0.00059	171	10
Chironomus riparius	OD 150 formulation	0.66	48 h	0.00059	1128	100

Refined aquatic risk assessment using higher tier FOCUS modelling

FOCUS Step 3

Citrus (worst case), 2 x 288 g/ha

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Toxicity endpoint (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI trigger
Spirotetramat	D6	ditch	*Crassostera virginica*	0.85	Acute	0.0084	101	100
Spirotetramat	D6	ditch	*Chironomus riparius*	0.1	Chronic	0.0084	12	10
OD 150 (formulation)	D6	ditch	*Chironomus riparius*	0.66	Acute	0.0084	**78**	100

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 2.

FOCUS Step 4

Citrus (worst case), 2 x 288 g/ha

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Toxicity endpoint (mg/L)	Time scale	Buffer zone	PEC_{max} (mg/L)	TER	Annex VI trigger
BYI 08330 OD 150 (formulation)	D6	ditch	*Chironomus riparius*	0.66	Acute	5 m	0.0059	113	100

[1] drainage (D1-D6) and run-off (R1-R4)

[2] ditch/stream/pond

[3] include critical groups which fail at Step 3.

Bioaccumulation					
	Spirotetramat	Spirotetramat-enol	Spirotetramat-ketohydroxy	4-methoxy-cyclo-hexanone	4-methoxy-cycylo-hexyl-amino carboxylic acid
logPow	2.51	0.3 (pH 7)	1.3 (pH 7)	-0.04 – 0.74*	-2.49 – 1.0*
Bioconcentration factor (BCF)[1] ‡	-	-	-	-	-
Annex VI Trigger for the bioconcentration factor	-	-	-	-	-
Clearance time (days) (CT_{50})	-	-	-	-	-
(CT_{90})	-	-	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-	-	-	-	-

[1] only required if log Pow >3.

* estimated by RMS using computer program ALOGPS 2.1

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

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
a.s. ‡	> 107.3	> 100
Preparation Spirotetramat OD150	91.7	162
Field or semi-field tests		
Feeding study in the field with 2 formulations and treatment with a sucrose solution containing 0.0144 % a.s.: Spirotetramat OD100: Slightly increased mortality of adults and pupae. No effects on flight activity and behaviour of bees. Brood development: High termination rate in two out of three colonies. Spirotetramat SC240: Increased adult mortality, termination of brood development with tendency to recover. No effects on flight activity and behaviour of bees. Feeding studies with spiked pollen/semi-field with spirotetramat and spirotetramat-enol (Final Addendum,		

Test substance	Acute oral toxicity (LD_{50} µg a.s./bee)	Acute contact toxicity (LD_{50} µg a.s./bee)
Austria, 2013): 1. Doering *et al.* 2007: Small colonies in tunnels were fed with pollen spiked with spirotetramat + spirotetramat-enol at concentrations of 0.05 - 10 mg/kg for 22 days. A slight transient effect to larval abundance in the highest treatment group cannot be excluded, though data are not unequivocal. In the other treatment groups, no consistent effects were seen in this endpoint. There were no adverse effects to other brood-related endpoints, comb development, hive weight development, honey and pollen storage behaviour, foraging activity and mortality by foraging on and consumption of pollen containing up to 10 mg spirotetramat + spirotetramat-enol/kg pollen. 2. Doering *et al.* 2008b: same test design, 23 days exposure, concentrations of 2 - 20 mg/kg pollen. No effect on brood and brood development was found. There were no adverse effects on comb development, hive weight development, honey and pollen storage behaviour and foraging activity. No effect on adult or pre-imaginal mortality. Semi-field study with Spirotetramat OD100: 2 applications on crop before flowering at 72 g a.s./ha + 2 x 72 g a.s./ha or 1 x 96g a.s./ha: no adverse effect on adult and brood mortality, flight activity and behaviour of bees. Semi-field study (tunnel design) with Spirotetramat OD100: 3 applications on crop before flowering at 72 g a.s./ha + 2 x 96 g a.s./ha after flowering or 1 x 96g a.s./ha: no adverse effects on adult and brood mortality, condition of the colonies, flight activity and behaviour of bees. Irritation of brood development in the earlier assessments in one of 3 colonies of the 5x treatment, no clear treatment relation, recovery. Additional non-GLP tunnel tests with different spirotetramat formulations and application scenarios: The proportion of the larval cell comb area appeared to be reduced from about 3 up to 14 days after application. In all cases the effects were transient; i.e. recovery was seen and the overall survival of the affected colonies was not endangered. <u>Field studies with Spirotetramat OD150</u> (Final Addendum; Austria, 2013): 1. Field study, *Phacelia*, Spain (Schur, 2006): 2 applications on crop before flowering at 72 g a.s./ha + 2 x 72 g a.s./ha during flowering or 2 x 96 g a.s./ha. No adverse effects on adult and brood mortality, condition of the colonies, flight activity and behaviour of bees. 2. Field study, citrus, Spain (Bocksch, 2008): Application: 2 x 192 g as/ha (≙ 96 g as/ha/m canopy height) pre-flowering and flowering. No effects on brood development, storage behaviour, activity, condition of the colonies, mortality, hive weight or other parameters. Only few citrus pollen was collected by the bees, in spite of high activity in the field. Whilst this may be a realistic situation, it is probably not a worst case situation. 3. Field study, melon, Argentina (Stadler et al., 2008): Application: T2: 4 x 72 g as/ha; T3: 4 x 88 g as/ha. No effects on brood development, storage behaviour, activity, condition of the colonies, mortality, hive weight or other parameters. But: Because of low flower density, the attractiveness of the crop and hence the significance of the study was diminished. 4. Field study, melon, Argentina (Doering *et al.*, 2008a): Application: T2: 4 x 75 g as/ha, T3: 2 x 88 g as/ha. No effects on brood development, storage behaviour, activity, condition of the colonies, mortality, hive weight or other parameters. 5. Field study, citrus, Argentina (Stadler *et al.*, 2010): Application: 2 x 172.8 g a.s./ha to 278.4 g a.s./ha, depending on respective tree height (≙ 96 g as/ha/m canopy height) flowering. No effects on brood development, storage behaviour, activity, condition of the colonies, mortality, hive weight or other parameters.		

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

Lettuce, 72 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 0.72	50
a.s.	oral	< 0.67	50
Spirotetramat OD150	Contact	0.44	50
Spirotetramat OD150	oral	0.79	50

Citrus, 288 g a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	< 2.9	50
a.s.	oral	< 2.7	50
Spirotetramat OD150	Contact	1.8	50
Spirotetramat OD150	oral	3.1	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g a.s./ha)
Typhlodromus pyri ‡	Spirotetramat OD150	Mortality	0.333
Aphidius rhopalosiphi ‡	Spirotetramat OD150	Mortality	114.7

Lettuce, 72 g a.s./ha

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
Spirotetramat OD150	*Typhlodromus pyri*	0.333	259	7	2
Spirotetramat OD150	*Aphidius rhopalosiphi*	114.7	0.75	0.02	2

[1] 1 m distance

Citrus, 288 g a.s./ha

Test substance	Species	Effect (LR_{50} g a.s./ha)	HQ in-field	HQ off-field[1]	Trigger
Spirotetramat OD150	*Typhlodromus pyri*	0.333	951	150	2
Spirotetramat OD150	*Aphidius rhopalosiphi*	114.7	2.8	0.4	2

[1] 3 m distance

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g a.s./ha)	Endpoint	% adverse effect[1]	Trigger value
Aphidius rhopalosiphi	adults	Spirotetramat OD150, contact with dried residues on treated barley plants, 2+11 d	22 42 80 151 288	Corrected mortality / reproduction	3.3 / n.p. 3.3 / n.p. 0 / -28.1 6.7 / -7 0 / 27.8	50 %
Typhlodromus pyri	protonymphs	Spirotetramat OD150, contact with dried residues on treated bean leaves, 14 d	0.15 0.51 1.7 5.9 20	Corrected mortality / reproduction	4.1 / 43.2 1.4 / 48.7 56.8 / n.d. 98.6 / n.d. 100 / n.d.	50 %
Typhlodromus pyri	protonymphs	Spirotetramat OD150, contact with dried residues (acute and aged) on treated apple leaves, 7 d	4 x 72 (7d) Aged res.	Corrected mortality Residue aging in days	0d: 93.7 7d: 100 14d: 90.5 21d: 92.8 28d: 100 42d: 58.3 49d: 50.5 56d: 10.8 no red. of reproduction on DAA 49+56	50 %
Chrysoperla carnea	larvae	Spirotetramat OD150, contact with dried residues on treated bean leaves, until pupation+43 d	44 72 112 184 288	Corrected mortality	5.3 7.9 2.6 0 5.3 no effect on reproduction	50 %
Coccinella septempunctata	larvae	Spirotetramat OD150, contact with dried residues on treated bean leaves, feeding with treated aphids, until pupation	33 57 97 168 288	Corrected mortality	-14.8 -22.2 0 22.2 25.9 no effect on reproduction	50 %

[1] negative figures indicate a positive effect compared to the control
n.d. - not determined
n.p. - no assessment performed

Field or semi-field tests
Field study in grapevines, France: Effects on the predatory mite fauna after application of 2 x 96 g a.s./ha (Spirotetramat OD150) and different drift rates were assessed by leaf sampling method. No effects were found.

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	Endpoint[1]
Earthworms			
Eisenia fetida	Spirotetramat	Acute 14 days	LC_{50} (corr) > 500 mg a.s./kg d.w.soil
Eisenia fetida	Spirotetramat-ketohydroxy	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	4-methoxy-cyclohexanone	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
Eisenia fetida	Spirotetramat-enol	Chronic 8 weeks	NOEC (reproduction): 32 mg a.s./kg d.w.soil
Other soil macro-organisms			
Hypoaspis aculeifer	Spirotetramat-enol	28 days	NOEC (mortality): 316 mg a.s./kg d.w. soil LC_{50} (mortality, reproduction): > 1000 mg a.s./kg d.w.soil
Collembola			
Not required			
Soil micro-organisms			
Nitrogen mineralisation	Spirotetramat	28 days	16 % effect at day 28 at 1.3 mg a.s./kg d.w.soil (0.99 mg a.s/ha)
Carbon mineralisation	Spirotetramat	28 days	7 % effect at day 28 at 1.3 mg a.s./kg d.w.soil (0.99 mg a.s/ha)
Field studies			
Not required			

[1] Corrections of endpoints are not necessary because test with the active substance was performed using an artificial soil containing 5 % sphagnum and log Pow values of all metabolites are < 2.0.

Toxicity/exposure ratios for soil organisms

Citrus (worst case), 2 x 288 g/ha

Test organism	Test substance	Time scale	max PEC_{soil} (mg/kg)	TER	Trigger
Earthworms					
Eisenia fetida	Spirotetramat	Acute	0.115	> 4348	10
Eisenia fetida	BYI 08830-ketohydroxy	Acute	0.031	> 32258	10
Eisenia fetida	4-Methoxycyclo-hexanone	Acute	0.004	> 250000	10
Eisenia fetida	BYI 08830-enol	Chronic	0.093	344	5
Other soil macro-organisms					
Hypoaspis aculeifer	BYI 08830-enol	Chronic	0.093	3399	5

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

Preliminary screening data

Effects > 50 % were found in several species in a vegetative vigour test after application of 288 g a.s./ha Spirotetramat OD 150.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g a.s./ha) vegetative vigour	ER_{50} (g a.s./ha) emergence	Exposure[1] (g a.s./ha)	TER	Trigger
Zea mays	Spirotetramat OD150	134		Lettuce, 1 m: 2.39	56	5
				Citrus, 3 m: 50	2.7	5
				Citrus, 5 m: 27	5	5
Brassica napus	Spirotetramat OD150		> 176	/	/	5

[1] based on Ganzelmeier drift data

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

Semi field study (vegetative vigour under semi-field conditions) with Spirotetramt OD150: The most sensitive monocotyledonous species in this higher tier study, in which plants were grown and maintained under external environmental conditions, was corn (*Zea mays*). The lowest ER_{50} values were also for shoot dry weight with 152.2 g a.s./ha at the 1st harvest and 149.2g a.s./ha at the 2nd harvest. The NOER values for both shoot length and dry weight were <18 g a.s./ha at the 1st harvest, however these were 72g a.s./ha at the 2nd harvest, indicating recovery.

Most sensitive species	Test substance	ER50 (g a.s./ha) vegetative vigour	ER50 (g a.s./ha) emergence	Exposure[1] (g a.s./ha)[2]	TER	Trigger
Zea mays	Spirotetramat OD150	149		Lettuce, 1 m: 2.39	62	3
				Citrus, 3 m: 50	3	3

[1] based on Ganzelmeier drift data

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

Test type/organism	endpoint
Activated sludge	EC_{50} (3 hours) > 10000 mg/L
Pseudomonas sp	No data

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

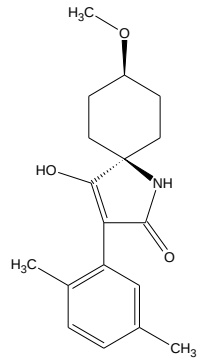
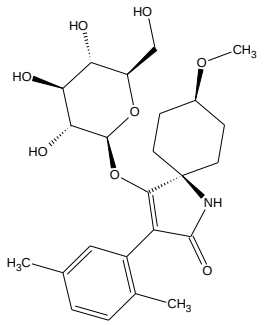
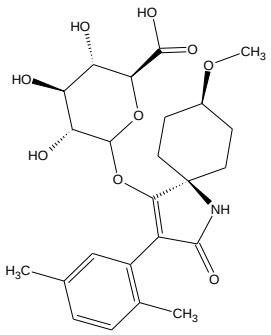
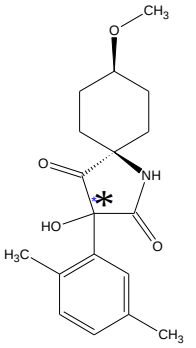
Compartment	
soil	Spirotetramat
water	Spirotetramat
sediment	Spirotetramat
groundwater	Spirotetramat

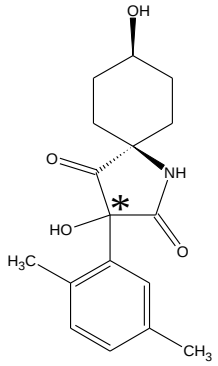
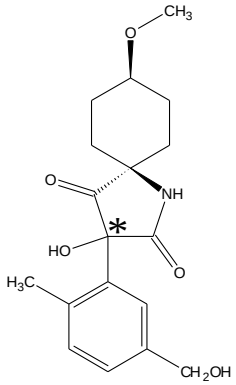
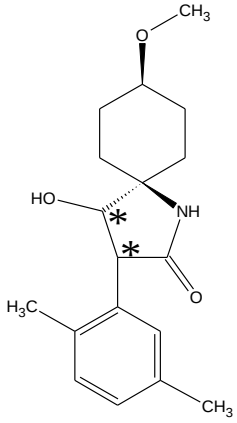
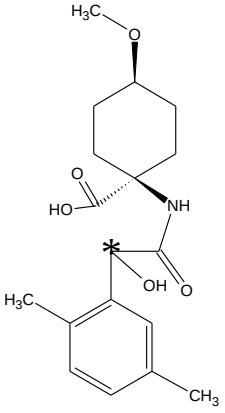
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

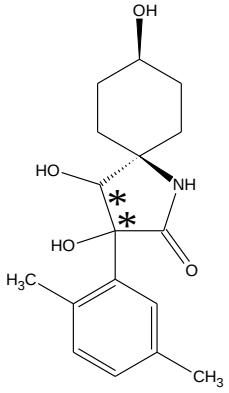
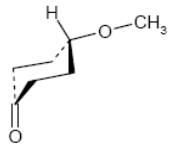
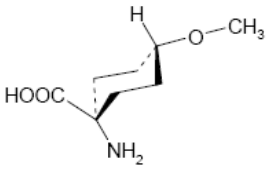
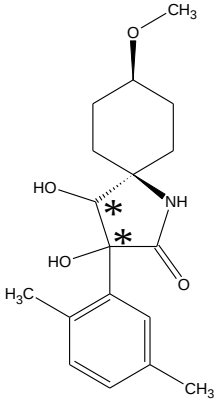
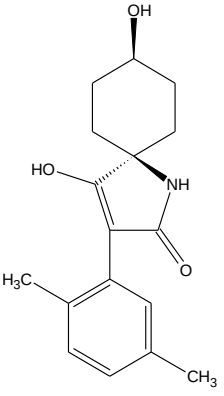
Classification according to Council Directive 67/548/EEC / Regulation (EC) No 1272/2008:	RMS (AT)/peer review proposal*
Spirotetramat	N, R 51/53

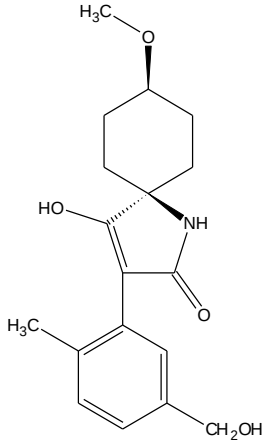
* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 or Regulation (EU) No 188/2011 are not formal proposals.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name**	Chemical name***	Structural formula***
Spirotetramat-enol BYI 08330-enol	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one	
Spirotetramat-enol-Glc BYI 08330-enol-Glc	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β-D-glucopyranoside	
Spirotetramat-enol-GA BYI 08330-enol-GA	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl D-glucopyranosiduronic acid	
Spirotetramat-ketohydroxy BYI 08330-cis-ketohydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione Enantiomer composition unspecified	

Code/Trivial name**	Chemical name***	Structural formula***
Spirotetramat-desmethyl-ketohydroxy BYI 08330-desmethyl-ketohydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione Enantiomer composition unspecified	
Spirotetramat-ketohydroxy-alcohol BYI 08330-ketohydroxy-alcohol	(5*s*,8*s*)-3-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-methoxy-1-azaspiro[4.5]decane-2,4-dione Enantiomer composition unspecified	
Spirotetramat-mono-hydroxy BYI 08330-monohydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one Isomer composition unspecified	
Spirotetramat-MA-amide BYI 08330-MA-amide	*cis*-1-{[(2,5-dimethylphenyl)(hydroxy)acetyl]amino}-4-methoxycyclohexanecarboxylic acid Enantiomer composition unspecified	

Code/Trivial name**	Chemical name***	Structural formula***
Spirotetramat-desmethyl-di-hydroxy BYI 08330-desmethyl-di-hydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-3,4,8-trihydroxy-1-azaspiro[4.5]decan-2-one Isomer composition unspecified	
4-methoxy-cyclohexanone	4-methoxy-cyclohexanone	
4-methoxy-cyclohexyl-aminocarboxylic acid	(5*s*,8*s*)-1-amino-4-methoxycyclohexanecarboxylic acid	
Spirotetramat-dihydroxy BYI 08330-dihydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-3,4-dihydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one Isomer composition unspecified	
Spirotetramat-desmethyl-enol BYI 08330-desmethyl-enol	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-4,8-dihydroxy-1-azaspiro[4.5]dec-3-en-2-one	

Code/Trivial name**	Chemical name***	Structural formula***
Spirotetramat-enol-alcohol BYI 08330-enol-alcohol	(5*s*,8*s*)-4-hydroxy-3-[5-(hydroxymethyl)-2-methylphenyl]-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one	

*chiral centre, entiomer(s) present in experiments in the dossier was not stated / may be unknown

** 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
AGES	The Austrian Agency for Health and Food Safety (Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH)
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CF	conversion factor
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
CRD	The UK Chemicals Regulation Directorate (Directorate of the Health & Safety Executive)
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFOP	double first-order in parallel kinetics
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 Chemicals 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
EPA	Environmental Protection Agency
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EU-N	Northern Europe

EU-S	Southern Europe
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first-order multi-compartment model
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FID	gas chromatography with flame ionisation detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-UV	high pressure liquid chromatography with ultraviolet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter-laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-ESI-MS/MS	liquid chromatography-electrospray ionization tandem mass spectrometry
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LC-UV	liquid chromatography with ultraviolet detection
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration

MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OD	oil-based suspension concentrate
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
PF	processing factor
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
PMRA	Pest Management Regulatory Authority of Canada
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RAC	raw agricultural commodity
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SFO-RB	single first-order reversible binding model
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure

TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year