CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

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

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

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Germany being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 9 December 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 December 2009. The EFSA collated and forwarded all comments received to the Commission on 25 January 2010

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

1 On request from the European Commission, Question No EFSA-Q-2010-00135, issued on 20 August 2010

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3 OJ L224, 21.08.2002, p.25

4 OJ L 246, 21.9.2007, p. 19

5 OJ L 333, 11.12.2008, p. 11

6 OJ L 15, 18.01.2008, p.5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of tefluthrin as an insecticide on sugar beet (seed treatment) as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

For the section on physical-chemical properties several data gaps were identified in relation to the specification and methods of analysis but there were no critical areas of concern.

In the mammalian toxicology section, there are no critical areas of concern but one data gap has been identified with regard to the identification of the ratio of isomers to which the workers handling treated seed are exposed. Pending on this, more information about the relative toxicity of the isomers may be needed and the risk assessment for the workers might be reconsidered.

For residues the risk assessment was finalised and there are no critical areas of concern. One data gap was identified for freezer storage stability data for two metabolites.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses assessed.

Since it was noted that the purity of the different batches used in the ecotoxicological tests varies from 90 to 99.7%, a data gap was identified to address the compliance of the ecotoxicological test batches with the technical specification of tefluthrin. A high risk to mammals is indicated, and a data gap was identified to provide further data to address the risk for mammals to treated sugar beet seeds. A low risk was identified for birds, aquatic organisms, bees, non-target arthropods, earthworms, non-target soil macro- and micro- organisms. For a seed treatment use no data were required for terrestrial non-target plants. No effects were observed on biological methods of sewage treatment plants.

KEY WORDS

tefluthrin, peer review, risk assessment, pesticide, insecticide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

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

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

Tefluthin is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Germany, which was received by the EFSA on 14 August 2006 (Germany, 2006).

The peer review was initiated on 4 May 2007 by dispatching the DAR to Member States and the applicant Syngenta for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS

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

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

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

In accordance with Article 18 Germany, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 9 December 2009 (Germany, 2009).

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

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 10 December 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received on the DAR under the first review and on the AR under the resubmission procedure to the Commission on 25 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation 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.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 22 February 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on tefluthrin within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 22 February 2010, the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology and ecotoxicology. Further information was not requested from the applicant.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in July 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a insecticide on sugar beet (seed treatment) 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 (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1, 22 February 2010),
- the Evaluation Table (18 August 2010)
- the reports of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of July 2010 containing all individually submitted addenda (Germany, 2010)) and the Peer

Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT.

Tefluthrin is the ISO common name for 2,3,5,6-tetrafluoro-4-methylbenzyl (1*RS*, 3*RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate (IUPAC).

The representative formulated product for the evaluation was 'Force 20 CS' a capsule suspension (CS) containing 200 g/L tefluthrin.

The representative use evaluated is as a seed treatment against soil-borne insects in sugar beet. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of tefluthrin as manufactured should be not less than 920 g/kg. Tefluthrin is a racemic mixture of *Z*-(1*R*, 3*R*) and *Z*-(1*S*, 3*S*) enantiomers, and a data gap was identified to address the biological activity of the 2 isomers. Hexachlorobenzene was considered as a relevant impurity, but a maximum content cannot be set at this time and a data gap has been identified. In general the specification for impurities proposed by the applicant was not accepted, and a data gap is identified for a revised specification. However, if the specification is changed to the RMS's proposal given in C.1.2.3 of Vol. 4 of the Additional Report then it would be acceptable. Data gaps were identified for confirmation of the identity of impurity R290116 or SYN545561 and the specificity of the method for impurity R176973.

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

It should be noted that the formulation showed poor pourability which might result in incomplete emptying of the product container. Appropriate label phrases may be needed.

The residue definition for all matrices is tefluthrin. GC-MS methods are available for plants, animals, soil, water, air, body fluids and tissues. Data gaps were identified to address the dilution prior to analysis in the ILV plant method, and for a confirmatory method for water.

2. Mammalian toxicity

The proposed technical specification of tefluthrin (as proposed by the RMS) was considered as covered by the composition of the toxicological batches, and the impurities were not considered toxicologically relevant except hexachlorobenzene. The maximum ciontent for this relevant impurity should be below 0.1% to be of no toxicological concern. Considering that the racemic mixture of *Z*-(1*R*, 3*R*) and *Z*-(1*S*, 3*S*) enantiomers has been tested in the toxicological studies, more information might be needed about the relative toxicity of the other isomers potentially formed after seed treatment, following whichthe risk assessment for workers handling treated seed might need to be reconsidered. A data gap has been identified.

During the acute toxicity tests, tefluthrin was shown to be very toxic by inhalation and if swallowed (T+, R26/28), as well as toxic in contact with skin (T, R24), but it was only slightly irritant to the skin and the eyes, and had no skin sensitisation properties. In repeated dose studies, the dog was the most sensitive species, with the nervous system and the thyroid being the main target organs. The relevant oral NOAEL for the dog studies (13 and 52-week) is 0.5 mg/kg bw/day. In a 21-day dermal study with rats, a LOAEL for local effects including paresthesia was identified at the low dose (0.1 mg/kg bw/d) whereas the systemic NOAEL was set at the high dose (50 mg/kg bw/d).

In long-term studies with rats and mice, the critical effects were observed in the liver, on the body weight gain, and as clinical signs of neurotoxicity (for the rat only). No evidence of genotoxicity or carcinogenicity was observed. The relevant long-term NOAELs are 1.5 mg/kg bw/d for the rat and

3.2 mg/kg bw/d for the mouse. In the reproductive toxicity study (3-generation), the neurological effects in the offspring were attributed to a direct systemic exposure after oral ingestion. No adverse effects were observed in the fertility parameters. The agreed parental and offspring NOAELs are 4.7 mg/kg bw/d, whereas the agreed reproductive NOAEL is 23.4 mg/kg bw/day. In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal NOAELs are 1 mg/kg bw/d for the rat and <3 mg/kg bw/d for the rabbit. Based on reduced foetal ossification (rats) and skeletal variations (rat and rabbit), the developmental NOAELs are 3 and <3 mg/kg bw/d, respectively for the rat and the rabbit. Neurotoxic effects in rats were also observed in an acute neurotoxicity study (NOAEL 2.5 mg/kg bw/d), and in a 90-day neurotoxicity study (NOAEL 11.6 mg/kg bw/d), but no signs of delayed neurotoxicity were observed in domestic hens.

The agreed Acceptable Daily Intake (**ADI**) is 0.005 mg/kg bw/d based on the 1-year dog study. The agreed Acute Reference Dose (**ARfD**) is 0.005 mg/kg bw based on the 90-day dog study. Both were derived with a safety factor of 100. The agreed Acceptable Operator Exposure Level (**AOEL**) is 0.0015 mg/kg bw/d based on the 90-day and 1-year dog studies, using a safety factor of 100 and a correction for an oral absorption value of 30%. The relevant dermal absorption value is 0.12%.

Considering the representative use in sugar beet as a seed treatment, the use of personal protective equipment (long-sleeved work jacket, long trousers, nitrile gloves) and respiratory protective equipment (with a protection factor of 90 to 98%, see details in Appendix A) is needed to protect operators, and respiratory protective equipment (dust mask) is needed to protect workers against local effects of tefluthrin, and to reduce the exposure level to an estimate below the AOEL. Estimated exposure to bystanders is below the AOEL.

3. Residues

The regulatory dossier provides no information on the behaviour of each individual tefluthrin enantiomer in plants and animals. It is not known if either isomer is degraded more quickly than the other. However, a data gap is not identified as residues above the LOQ of 0.01 mg/kg were not found. Sugar beet is highly processed and tefluthrin will not partition in to the sugar. There is a sufficient margin of safety in the consumer risk assessment.

The nature of the residue in primary crops was investigated in cabbage, maize and sugar beet with either seed treatment or soil treatment. The main components of the residue were compounds Ia and VI. Tefluthrin was not found at significant levels. It was considered whether these compounds should be included in the residue definition. The final conclusion, which is supported by residue trials where these metabolites were analysed for, is that at least for the representative use as a seed treatment in sugar beet no significant residues will be present at harvest. It was therefore accepted that the default residue definition should be tefluthrin only. This residue definition is only for seed treatment uses. The residue definition should be reassessed for other uses (e.g. spray application). It was demonstrated that residues in rotational crops will not occur at significant levels and therefore will not contribute to the consumer risk assessment. However, a data gap was identified for storage stability data for metabolites IV and XI. Metabolism studies with lactating goat were conducted even though the need for these studies was not triggered by the representative use. From this study it was proposed that the residue definition for risk assessment should be tefluthrin and metabolites Ia and VI expressed as tefluthrin, whilst for monitoring tefluthrin alone was proposed. It must be emphasised that this is a proposal and should not be considered as the final residue definitions. Eighteen residue trials were conducted in Northern Europe and 8 in Southern Europe, only two trials gave residues above the LOQ of 0.01 mg/kg at 0.01 and 0.02 mg/kg. These positive residues are probably as a result of adhering seed coat and soil, which would be removed during normal processing of sugar beet. In a further 6 trials residues of Ia and VI were sought but not found above the LOQ of 0.01 mg/kg. Storage stability data were provided that demonstrate that residues of tefluthrin are stable for 24 months in maize, sugar beet roots, soybeans and broccoli. Metabolite Ia is stable in apple, cabbage, corn fodder and forage, lettuce, tobacco, tomato, sugar, beet root, sorghum grain, peanut hulls, peanut meat, soybean seed and cotton seed for 24 months. Metabolite VI is stable in maize foliage and sugar beet for 17 months. Processing data were not required because residues are low.

The TMDI calculation using the EFSA PRIMo model rev. 2 gave a maximum intake of 70 % of the ADI. The acute risk assessment resulted in a maximum intake of 11 % of the ARfD.

4. Environmental fate and behaviour

The regulatory dossier provides no information on the behaviour of each individual tefluthrin enantiomer in the environment. It is not known if either isomer is degraded more quickly than the other in the environmental matrices or if any other conversion between isomers occurs. This is also the situation for metabolites that contain chiral carbon atoms. References made to tefluthrin and compound Ia (R119890) in section 4 therefore relate to the sum of isomers of unknown ratio. This is identified as an issue in the 'List of studies to be generated…' section of this conclusion, though further information on this is not considered necessary to finalise the environmental risk assessments for the representative use assessed (see section 5).

The aerobic route of degradation has been investigated in two soils with ^{14}C-cyclopropyl-labelled tefluthrin (in another two soils the recovery rates were not acceptable) and in 3 soils with [U-^{14}C]-phenyl-labelled tefluthrin. One of the soils was also treated with a granular formulation. Tefluthrin exhibited moderate to medium persistence in soils treated with acetone or acetonitrile solution formulation. Granule formulations provided a slow release of the active substance and tefluthrin exhibited high persistence. One minor non-transient metabolite was formed, compound Ia (also referred to as PP890 or R119890) at a maximum of 7.1% of the applied radioactivity (AR). Metabolite Ia exhibited low to moderate persistence in soil. Mineralisation of the phenyl ring radiolabel to carbon dioxide was significant accounting for 21-65 % AR after 90-94 days. The mineralisation for the cyclopropyl ring radiolabel was similar and accounted for 23-55% AR after 30-56 days. The formation of unextractable residues was also a sink for both the radiolabel positions, accounting for a maximum of 22% AR after 30-94 days. There was no mineralisation and insignificant bound residue formation under anaerobic incubation conditions. The metabolite compound III (R153946) reached 17.5% AR after 90 days. In a study under aerobic conditions, compound III exhibited very low to low persistence. Tefluthrin is immobile in soil, with compound Ia exhibiting very high to high mobility. There was no indication that adsorption of these two compounds was pH dependent. Anaerobic metabolism is not expected to play a significant role because anaerobic conditions are unlikely for the proposed use pattern as a seed treatment in sugar beet. However, a data gap was set for an environmental exposure assessment for the major anaerobic metabolite compound III, including biological activity and ecotoxicological relevance, to address situations where prolonged soil anaerobic conditions are prevalent. Soil photolysis can be considered not relevant to the representative use of tefluthrin as a pelleted seed dressing where normal agricultural practice would be to drill seed into the field to a depth of below 2 cm consequently light is excluded by the soil. Field dissipation studies where decline rates of tefluthrin residues could be reliably estimated were carried out in Germany (6 sites) using an EC formulation (single application to bare soil). In these trials, analyses were only for tefluthrin residues. As in the laboratory, tefluthrin exhibited low to medium persistence (considering the DT_{90} values estimated). Contrary to the fitting utilised in the laboratory incubations, the pattern of decline in the field was essentially fitted to first order multi compartment (FOMC) kinetics. Another series of terrestrial field dissipation studies was carried out with tefluthrin applied in-furrow (4 cm deep) as a slow release granule in 4 different locations (Germany, Italy, Spain and France). The soils were analysed for residues of tefluthrin and its main metabolite compound Ia. The granular in-furrow application resulted in a longer persistence of tefluthrin in soil (max SFO $DT_{50field}$ = 206 days) and the estimated dissipation rates can be considered as more realistic than those obtained with the soil surface application. However, as field studies with tefluthrin seed treatments are not available, a data gap was identified for data on the rate of release of tefluthrin from treated seeds after EC formulation application to sugar beet to support the representativeness of the field dissipation rates obtained from trials where tefluthrin was applied as an EC formulation.

In laboratory incubations in dark aerobic natural sediment water systems, tefluthrin dissipates very rapidly from the water phase and binds predominantly to the sediment (max 91% AR at day 3). The major metabolite compound Ia was found at levels up to 22% AR in the water phase and 7% AR in the

sediment. Metabolite compound IV was found in water at a maximum of 7% AR at 20°C, compared to a maximum of 22.6% AR at 5°C. The unextractable sediment fraction (extracted using acetonitrile:water) accounted for 8.5-22% AR and 9.8-13% AR for the phenyl and cyclopropyl C^{14} ring radiolabels, respectively. Mineralisation of these radiolabels accounted for between 1 and 48.6 % AR at 84 to 120 days. The water/sediment studies have some deficiencies e.g. low recoveries and the estimated dissipation/degradation rates should be considered with caution as it cannot be excluded that adsorption of tefluthrin to the glass vials during the experiments has taken place and that part of the active substance has been lost via volatilisation. Under irradiated conditions tefluthrin degraded in pure water to give its trans-isomer (up to 37% AR after 31 days of irradiation). Photolytic degradation is not expected to be a relevant route of degradation for a seed treatment application under normal agricultural practice and therefore no further assessment is required for the photo-degradation product trans-tefluthrin. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC)) were appropriately carried out using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator) for tefluthrin and its metabolite compound Ia. Moreover, PEC values for surface water and sediment were calculated for tefluthrin using the FOCUS step 3 approach.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2000) scenarios and FOCUS (PELMO 3.3.2 and FOCUS PEARL 3.3.3[11]). The potential for groundwater exposure from the representative use by tefluthrin or the metabolite compound Ia above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios.

The PECs in soil, surface water, sediment and groundwater for the representative use assessed can be found in Appendix A.

5. Ecotoxicology

Since it was noted that the purity of the different batches used in the ecotoxicological tests varies from 90 to 99.7%, a data gap was identified to address the compliance of the ecotoxicological test baches with the technical specification of tefluthrin.

A higher tier risk assessment was provided for both birds and mammals since in the acute, short-term and long-term first tier risk assessment the TER values were far below the Annex VI triggers. For birds the experts in the meeting (PRAPeR 77) questioned the choice of the focal species (i.e. Skylark) and the related PT value of 0.2 and PD of 0.021, derived from the study of Wolf (2005). Also the PD of 0.05 arbitrarily chosen by the RMS as a worst-case was rejected. In view of the representative use (i.e. seed treatment) a large bird was considered to be more appropriate by the RMS to refine the risk assessment on the basis of literature data. The number of seeds needed to reach the toxicity endpoints was calculated during the expert meeting, taking into account both small and large birds. A risk to small birds was identified, where 2 and 3 coated seeds were sufficient to reach the LC_{50} and LD_{50} respectively, including a safety factor of 10. The experts agreed that the acute risk assessment for small birds (15g) could be refined by using the geometric mean of LD50 from the 3 species (i.e. 919 mg/kg bw/d), resulting in 11 seeds required to reach the LD_{50} values. It was noted that availability of seeds on the surface after precision drilling was low (0.195 seeds/m2, 1.5% seeds on soil surface was identified as worst case), indicating that the exposure is likely to be low. In addition, there was some evidence on the occurrence of dehusking. Overall, and taking into consideration the outcome of the study of Wolf (2005), which indicated a low frequentation of sugar beet fields by small birds, the risk to birds from the consumption of seeds was considered as low, when a precision drilling technique was used. The experts also recommended labelling requiring removal of all spills remaining on the soil surface.

[11] Simulations correctly utilised the agreed Q10 of 2.58 and Walker equation coefficient of 0.7

To refine the risk to mammals, wood mouse was considered as the focal species. In the original DAR, PT values of 0.2 (short-term) and of 0.05 (long-term), PD of 0.3, avoidance factor of 0.8 and dehusking factor of 0.15 were used. The PT and PD values were questioned during the peer review because they were not confirmed by substantial data. A weight of evidence approach was provided in the Additional Report to support the palatability, avoidance and dehusking behaviour. On the basis of the data submitted, it was noted that wood mice completely remove the coating of the seeds before consumption, indicating a low likely exposure.However, it was not clear to what extent the exposure is reduced and therefore, this information was considered not sufficient to set a dehusking factor. The avoidance factor of 0.8 was considered not acceptable because it was derived from a toxicological study not dedicated to investigating avoidance (see report PRAPeR 77, point 5.2). The time to reach avoidance was estimated in a study which did not consider pelleted seed. The study suggested that the avoidance response time was a maximum of 15 minutes and the ingested dose was 1.9 mg a.s./kg bw/min. This was equivalent to ~28 mg a.s./kg bw/15 mins, i.e. 1.2 seeds would be consumed in 15 minutes before avoidance occurred. It was noted that 0.5 and 0.2 seeds would need to be consumed to reach the LD_{50} (21.8 mg.kg bw) and the NOEC (4.7 mg.kg bw), respectively, based on active substance data; while 7.2 seeds would be needed to reach the LD_{50} of 344 mg/kg bw/d, based on formulation data. This means that, based on the active substance data, the lethal dose could be reached before avoidance occurs. Therefore, a high risk to mammals for the active substance was identified. A data gap was identified for further data to address the exposure of mammals to treated sugar beet seeds.

The risk to earthworm-eating birds and mammals was assessed as low. The risk to fish-eating birds and mammals, and the risk from contaminated drinking water consumption, even if not assessed, could be considered as low for the representative use, due to the negligible exposure.

Teflutrin is very toxic to aquatic organisms. According to the TERs calculated with FOCUS step 3 PEC_{sw} the risk was assessed as low. The margins of safety on the risk assessments are large enough that the uncertainty on the relative toxicity and contributions to the total residue levels of the isomers of tefluthrin and pertinent metabolites does not change this conclusion of low aquatic risk.

Bees can be exposed to tefluthrin when used as seed treatment by dust drift during sowing. In a field study to establish a drift pattern, the highest emission from sowing maize seeds was 0.333 % of the field rate of 15.6 g tefluthrin/ha at 3 meters distance using unmodified pneumatic seeders. HQ calculation indicates a low risk for bees.

On the basis of studies under semi-field and field conditions the risk to non-target arthropods was considered as low. For completeness,a data gap was identified for the applicant to provide the raw data for the study Bruehl C., Halsall N. (2006): ZA0993 (Tefluthrin): Evaluation of potential side-effects of a granular formulation of Tefluthrin (A13226H) to ground and soil dwelling non-target arthropods under field conditions in maize.

The risk was assessed as low for earthworms, soil macro- and micro-organisms. For seed treatment use no data were required for terrestrial non-target plants. No effects were observed for biological methods of sewage treatment plants. The margins of safety on these risk assessments are large enough that the uncertainty on the relative toxicity and contributions to the total residue levels of the isomers of tefluthrin does not change this conclusion of low risk for organisms residing in soil.

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
tefluthrin	moderate to medium persistence single first order (SFO) laboratory DT_{50} 13-63 days (20ºC pF 2 soil moisture) granule formulation: high persistence SFO laboratory DT_{50} 151 days (20ºC pF 2 soil moisture) European Field dissipation studies SFO and biphasic kinetics DT_{50} 31-128 days (DT_{90} 98-424 days)	The risk was assessed as low for soil-dwelling organisms
compound III (R153946) (major metabolite under anaerobic conditions)	very low to low persistence SFO laboratory DT_{50} 0.8-1.6 days (20ºC pF 2 soil moisture)	The risk to soil-living organisms was not assessed. However, it could be considered addressed by the submitted long-term studies and field test with the parent.

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
tefluthrin	Immobile K_{Foc} 46000-36x10^5 mL/g	no	yes	Yes	no

compound Ia (R119890)	high to very high mobility K_{Foc} 13-93 mL/g	no	No data	No data, not required.	no

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
tefluthrin	Teflutrin was very toxic to aquatic organisms. The risk was assessed as low at FOCUS step 3. The lowest endpoint was 0.00397 µg a.s/L (observed in a chronic study with *Pimephales promelas*)
compound Ia (R119890)	The risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	**Toxicology**
tefluthrin	Very toxic by inhalation (T+, R26)

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

- The biological activity of the isomers should be addressed (relevant for all representative uses; submission date proposed by the applicant: unknown; see section 1).
- Propose a maximum content for hexachlorobenzene and support with a 5 batch analysis (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Clarify the identity of impurity R290116 or SYN545561 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Demonstrate the specificity of the method for impurity R176973 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Revised specification that is supported by the available batch data (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- In the plant ILV method Klimmek 2004 it should be clarified to what extent samples were diluted prior to analysis (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Confirmatory method for water (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- Identification of the isomers potentially formed after seed treatment, to which the workers handling treated seed are exposed. Pending on this ratio, more information about the relative toxicity of the isomers could be needed and the risk assessment for the workers might be reconsidered (relevant for all representative uses evaluated; no submission date proposed by the applicant; see section 2).
- Freezer storage stability data for metabolites IV and XI (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 3).
- Environmental exposure assessment for the major anaerobic metabolite compound III, including biological activity and ecotoxicological relevance, to address situations where prolonged soil anaerobic conditions are prevalent (not relevant for the representative uses evaluated; submission date proposed by the applicant; unknown; see section 4).
- Information about conversion / preferential degradation of isomers of tefluthrin and metabolite Ia (R119890) in the environmental compartments was not available (concluded as not being necessary to conclude on the risk to wild non target organisms (excluding mammals) for the representative uses evaluated; submission date proposed by the notifier; unknown; see sections 4 and 5)
- Information on the release rate of tefluthrin from treated seeds after EC formulation application to support the representativeness of the field dissipation rates obtained from trials where tefluthrin was applied as EC formulation (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 4).
- Data to address the risk for mammals to treated sugar beet seeds (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).
- Raw data to the study Bruehl C., Halsall N. (2006): ZA0993 (Tefluthrin): Evaluation of potential side-effects of a granular formulation of Tefluthrin (A13226H) to ground and soil dwelling non-

target arthropods under field conditions in maize (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

- Information to address the ecotoxicological relevance of the different purity of batches used in the ecotox tests needs to be provided. It was noted that the purity of the different batches varies from 90 to 99.7% (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

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

- Use of personal protective equipment as well as respiratory protective equipment is needed to reduce the estimated exposure to operators and workers to a level below the AOEL (see section 2).

- Precision drilling must be used to minimize the exposure of birds and mammals. It was also recommended to remove all the spills by label recommendations. (see section 5).

- The formulation showed poor pourability, which might result in incomplete emptying of the product container. Appropriate label phrases may be needed.

ISSUES THAT COULD NOT BE FINALISED

- Exposure of workers to other isomers potentially formed after seed treatment could not be concluded.

CRITICAL AREAS OF CONCERN

- A high risk to mammals is indicated. The need of further data was identified to address the exposure of mammals to treated seeds.

REFERENCES

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

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

Germany, 2009 Additional Report to the Draft Assessment Report on the active substance tefluthrin prepared by the rapporteur Member State Germany in the framework of Commission Regulation (EC) No 33/2008, December 2009.

Germany, 2010. Final Addendum to the Additional Report on tefluthrin compiled by EFSA, July 2010.

Guidance documents[12]:

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

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

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

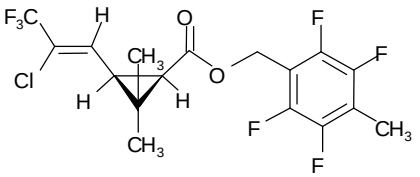
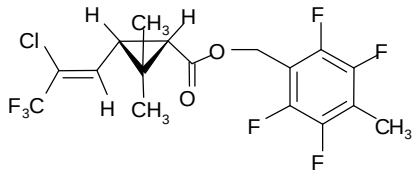
APPENDICES

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) ‡	Tefluthrin
Function (*e.g.* fungicide)	Insecticide
Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	2,3,5,6-tetrafluoro-4-methylbenzyl (1*RS, 3RS*)-3-[(*Z*)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate
Chemical name (CA) ‡	(2,3,5,6-tetrafluoro-4-methylphenyl)methyl (1R,3R)-*rel*-3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethylcyclopropanecarboxylate
CIPAC No ‡	451
CAS No ‡	79538-32-2
EC No (EINECS or ELINCS) ‡	not available
FAO Specification (including year of publication)‡	not available
Minimum purity of the active substance as manufactured ‡	920 g/kg, Tefluthrin is a 1:1 mixture of *Z*-(1*R*, 3*R*) and *Z*-(1*S*, 3*S*) enantiomers
Identity of relevant impurities (of toxicological and/or environmental concern) in the active substance as manufactured	Hexachlorobenzene; a maximum content cannot be set at this time.
Molecular formula ‡	$C_{17}H_{14}ClF_7O_2$
Molecular mass ‡	418.7 u
Structural formula ‡	 *Z*-(1*R*, 3*R*)  *Z*-(1*S*, 3*S*)

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	44.6 °C (99.1 %)
Boiling point (state purity) ‡	156 °C at 1 mm Hg (99.1 %)
Temperature of decomposition (state purity)	295 °C (99.1 %)
Appearance (state purity) ‡	white solid (99.1 %)
Vapour pressure (state temperature, state purity) ‡	8.4×10^{-3} Pa at 20 °C 2.1×10^{-2} Pa at 30 °C 5.1×10^{-2} Pa at 40 °C (all 99.1 %)
Henry's law constant ‡	2×10^{2} Pa m^3 mol^{-1} at 20 °C
Solubility in water (state temperature, state purity and pH)‡	0.016 mg/L at 20 °C (99.1 %) (purified water) 0.015 mg/L at 20 °C (99.1 %) (pH 5) 0.016 mg/L at 20 °C (99.1 %) (pH 9)
Solubility in organic solvents (state temperature, state purity) ‡	Solubility at 21 °C (94.9 %): acetone > 500 g/L dichloromethane > 500 g/L toluene > 500 g/L ethyl acetate > 500 g/L hexane > 500 g/L methanol 262 g/L
Surface tension (state concentration and temperature, state purity)	69.0 mN/m (saturated solution, 25 °C, 94.9 %)
Partition co-efficient (state, temperature, pH and purity)	6.4 at 20 °C (99.1 %), pH not stated
	pH 7: stable at 25 °C up to 30 d
	pH 9: 28 % hydrolysed after 30 d (25 °C)
Dissociation constant (state purity)‡	considered not relevant
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	$\varepsilon = 25400$ L.mol^{-1}.cm^{-1}($\lambda = 211.7$ nm) $\varepsilon = 1190$ L.mol^{-1}.cm^{-1}($\lambda = 268.3$ nm)
Flammability ‡ (state purity)	not considered highly flammable (92.6 %)
Explosive properties ‡ (state purity)	no explosive properties (theoretical assessment)
Oxidising properties ‡ (state purity)	non-oxidising (theoretical assessment)

Summary of representative uses evaluated (tefluthrin)*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks:
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max (l)	water L/ha min max	kg as/ha min max (l)		
sugar beet	Northern and Southern Europe	Force 20 CS	F	soil-borne insects	FS	200 g/L	seed treat-ment	seed	1	-	12 g as per seed unit (1 seed unit = 100000 seeds)	-	0.0156*	N/A	*using max 1.3 seed units/ha [1] [2]

[1] A high risk to mammals is identified
[2] Exposure of workers to isomers potentially formed after seed treatment could not be concluded

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

* Uses for which the risk assessment can not be concluded are marked grey.

Methods of Analysis

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

Technical as (analytical technique)	GC/FID
Impurities in technical as (analytical technique)	GC/FID
Plant protection product (analytical technique)	GC/FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		tefluthrin
Food of animal origin		tefluthrin
Soil		tefluthrin
Water	surface	tefluthrin
	drinking/ground	tefluthrin
Air		tefluthrin

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS	0.01 mg/kg (maize grain, maize straw, sugar beet roots, sugar beet leaves with tops, oranges, oil seed rape)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	GC-MS	0.002 mg/kg (muscle, fat, egg, kidney, liver) 0.001 mg/kg (milk)
Soil (analytical technique and LOQ)	GC-MS	0.01 mg/kg
Water (analytical technique and LOQ)	GC-MS	0.0002 µg/L (tap and surface water) (a validated confirmatory method is missing)
Air (analytical technique and LOQ)	GC-MS	0.15 µg/m^3
Body fluids and tissues (analytical technique and LOQ)	GC-MS	0.002 mg/kg (tissue, whole blood)

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

	RMS/peer review proposal
Active substance	none

Impact on Human and Animal Health

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

Rate and extent of absorption ‡	Oral absorption of ~ 30 % (within 96h), based on urinary excretion in dogs taking into account some biliary excretion (5-16%) observed in rats
Distribution ‡	Widely distributed, highest residues in liver, kidney and fat (rat, dog)
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	~ 90 % within 48 h in rats, via faeces (45-64%) and urine (25-39%); >90% within 4d in dogs, via faeces (66-70%) and urine (25-27%)
Metabolism in animals ‡	Extensively metabolised, oxidation of aliphatic groups in the acid and alcohol moieties, ester cleavage
Toxicologically relevant compounds (animals and plants) ‡	Tefluthrin
Toxicologically relevant compounds ‡ (environment)	Tefluthrin

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	21.8 mg/kg bw	**T+,R28**
Mouse LD_{50} oral	45.6 mg/kg bw	-
Rat LD_{50} dermal ‡	177 mg/kg bw	**T, R24**
Rat LC_{50} inhalation ‡	0.037 mg/L (4h, nose only, aerosol)	**T+,R26**
Skin irritation ‡	Slightly irritating, no classification	-
Eye irritation ‡	Slightly irritating, no classification	-
Skin sensitisation (test method used and result) ‡	Not sensitising (M & K Test)	-

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	bw gain decreased in rats and dogs, nervous system (tremor, ataxia) and thyroid (increased weight) in dogs
Relevant oral NOAEL ‡	Dog: 0.5 mg/kg bw/d (13- and 52-wk) Rat: 13.6 mg/kg bw/d (13-wk)
Relevant dermal NOAEL‡	Rat, 21 day: 50 mg/kg bw/d (systemic effects); < 0.1 ~~1.0~~ mg/kg bw/day (local effects including paresthesia)
Relevant inhalation NOAEL ‡	No data

Genotoxicity (Annex IIA, point 5.4)

No evidence of genotoxicity

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

Target / critical effect ‡	Decreased bw gain and food consumption (rat, mouse), nervous system (clinical signs) (rat), liver (clinical chemistry, organ weight, histology) (rat, mouse)
Relevant NOAEL	Rat: 1.5 mg/kg bw/d (2-yr) Mouse: 3.2 mg/kg bw/d (2-yr)
Carcinogenicity ‡	No evidence of carcinogenicity in rats and mice.

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect ‡	Parental: neurological symptoms (abnormal gait, shaking), reduced bw gain Offspring: reduced total litter weight and pup weight gain, neurological symptoms (abnormal gait, shaking) Reproductive: no adverse effect
Relevant parental NOAEL ‡	4.7 mg/kg bw/d
Relevant reproductive NOAEL ‡	23.4 mg/kg bw/d
Relevant offspring NOAEL ‡	4.7 mg/kg bw/d

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat: reduced bw gain and food consumption, subdued behaviour Rabbit: body tremor Developmental: Slight reduction of ossification in rats, increased incidence of 25 pre-sacral vertebrae in rats and of 27 pre-sacral vertebrae in rabbits No evidence of teratogenicity	
Relevant maternal NOAEL ‡	Rat: 1 mg/kg bw/d Rabbit: < 3 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 3 mg/kg bw/d Rabbit: < 3 mg/kg bw/d	

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity, Rat	Decreased landing foot splay, increased breathing rate NOAEL: 2.5 mg/kg bw/d
Subchronic neurotoxicity, Rat	90 day: increased landing foot splay, clinical signs NOAEL: 11.6 mg/kg bw/d
Delayed neurotoxicity ‡	Domestic hen, single dose of 3605 mg/kg bw: clinical signs of acute neurotoxicity, no clinical signs of delayed neurotoxicity; minimal axonal degeneration of spinal cord without damage of sciatic or tibial nerve

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Special research neurotoxicity study, 8-wk, rat: larger vacuoles in spinal cord at 5 mg/kg bw in females, limited number of animals
Studies performed on metabolites or impurities ‡	Impurities R153307, R290193 & R202752: Ames test negative

Medical data (Annex IIA, point 5.9)

Reports of paraesthesia (facial, forearms, eyes)

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor/OA
ADI ‡	0.005 mg/kg bw/d	Dog, 1 yr	100
AOEL ‡	0.0015 mg/kg bw/d	Dog, 90 d and 1 yr	100 / 30 %
ARfD ‡	0.005 mg/kg bw	Dog, 90 d	100

OA = oral absorption

Dermal absorption (Annex IIIA, point 7.3)

Tefluthrin 20CS Formulation (nominal 200 g tefluthrin/L), identical to FORCE 20CS	0.12 % (based on *in vivo* rat, and *in vitro* comparison rat vs. human skin)

Exposure scenarios (Annex IIIA, point 7.2)

Operator

Seed Tropex data (for cereal seed treatment) were used to estimate the exposure of operators during pelleting of sugar beet seed (values in % of AOEL):

Task	Without PPE	With PPE[§]
Mix/load (Fast-couple)	361	55 (+RPE[#])
Cleaning	2255	56 (+RPE[##])

Workers

SeedTropex data were used to estimate the exposure of workers during loading and drilling of pelleted seed (values in % of AOEL):

Task	No RPE	With RPE[###]
Loading and drilling (8h/d)	188	26

Bystanders

The estimated exposure for fork lift drivers in a seed treatment plant according to SeedTropex is 16% of the AOEL for a work rate of 8 hour/day.

[§]PPE: personal protective equipment (long sleeved work jacket, long trousers, nitrile gloves)
[#]RPE: respiratory protective equipment: faceshield and dust mask (90% protection)
[##]RPE: full facepiece respirator with antidust filter (class FFP3, providing 98% protection)
[###]RPE: dust mask is needed to reduce the exposure below the AOEL, but use of gloves is also needed to protect workers against local effects.

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

	RMS/peer review proposal
Substance classified with regard to toxicological data (according to the criteria in Dir. 67/548/EEC):	T+ - Very toxic R24 - Toxic in contact with skin R26 - Very toxic by inhalation R28 - Very toxic if swallowed
Substance classified with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute toxicity, cat 1 H310 - Fatal in contact with skin H330 - Fatal if inhaled H300 - Fatal if swallowed

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

Plant groups covered	root and tuber vegetables (sugar beet), cereals (maize), both granular soil treatment, and leafy vegetables (cabbage, seed treatment, drench)
Rotational crops	wheat, soybean, lettuce, sugar beet
Metabolism in rotational crops similar to metabolism in primary crops?	widely similar, however, some differences are highlighted: - one additional metabolite in soybean foliage (compound XII) - compound IV occurred in higher amounts in succeeding wheat and soybeans (up to 64.5 %) than in primary crops sugar beet and maize
Processed commodities	not applicable
Residue pattern in processed commodities similar to residue pattern in raw commodities?	not applicable
Plant residue definition for monitoring	tefluthrin
Plant residue definition for risk assessment	tefluthrin
Conversion factor (monitoring to risk assessment)	not applicable

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

Animals covered	lactating goat
Time needed to reach a plateau concentration in milk and eggs	Milk: 3 days (metabolism study with goats), 5 days (feeding study with dairy cows) eggs: not applicable
Animal residue definition for monitoring	Tefluthrin (parent compound)
Animal residue definition for risk assessment	Tefluthrin (parent compound) + compound Ia + compound VI, expr. as parent eq.
Conversion factor (monitoring to risk assessment)	not applicable
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	no

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

crops: wheat, soybean, lettuce and sugar beet, turnip, millet, collard, mustard leaves, sweet potatoes
rotation intervals: 1, 4 , 6 and 12 and 13 months

Residues in edible parts of succeeding crops (wheat grain, lettuce, soybean, sugar beet, turnip root, millet garin, collard, mustard leaves, sweet potatoes) are not likely to exceed 0.01 mg/kg when grown after tefluthrin-treated sugar beet. Residues in feeding commodities derived from succeeding crops (wheat straw, soybean foliage, sugar beet foliage, feed commodities of turnip, millet, collard, mustard leaves, sweet potatoes) are not likely to exceed 0.1 mg/kg when grown after tefluthrin-treated sugar beet.

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

Tefluthrin: stable for up to 24 months at -18 °C in maize (fodder, forage and kernels), sugar beet roots, soybeans and broccoli

Compound Ia: stable in water-, starch and oil-containing matrices for 24 months at -18 °C

Compound VI: stable in water-containing matrices (maize foliage and sugar beet) for 17 months

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	no	no	no
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 studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg Residues in animal matrices (data from low dose group feeding study with dairy cows: 0.3 mg/kg diet tefluthrin + 0.2 mg/kg diet R173204) The low dose from the study is still sixfold overdosed compared with the maximum calculated dietary burden.		
Muscle	Tefluthrin: < 0.002 mg/kg PP890/R173204: <0.01mg/kg	not required [2]	not required [2]

	Ruminant:	Poultry:	Pig:
	each[2]		
Liver	Tefluthrin: < 0.002 mg/kg PP890/R173204: <0.01mg/kg each[2]	not required [2]	not required [2]
Kidney	Tefluthrin: < 0.002 mg/kg PP890/R173204: <0.01mg/kg each[2]	not required [2]	not required [2]
Fat	Tefluthrin: 0.003-0.01 mg/kg PP890/R173204: <0.01mg/kg each[2]	not required [2]	not required [2]
Milk	Tefluthrin: < 0.002 mg/kg PP890/R173204: <0.01mg/kg each[2]		
Eggs		not required [2]	

[1] State whether intake by specified animals is ≥ 0.1 mg/kg diet/day or not, based on a dry weight basis as given in table 1 of Guidance Document Appendix G

[2] Fill in results from appropriate feeding studies at appropriate dose rates according to Guidance Document Appendix G. State 'not required' when the conditions of requirement of feeding studies according to directive 91/414/EEC are not met.

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Sugar Beet	Northern	roots: < 0.01 (18); 0.02 mg/kg foliage: < 0.01 (17) mg/kg	Residues of up to 0.07 mg/kg (whole plant) were found in immature plants. Residues of compounds Ia and VI were < 0.01 mg/kg (6 trials from Northern Region).	0.02 mg/kg	0.02	0.01
	Mediterranean	roots: < 0.01 (8) 0.01 mg/kg foliage: < 0.01 (9) mg/kg			0.01	0.01

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

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)[7]

ADI	0.005 mg/kg bw
TMDI (% ADI) according to WHO European diet	42.8 % (WHO Cluster diet B)
TMDI (% ADI) according to national (to be specified) diets	PRIMo model rev. 2 66.9 % (UK infant)
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	not required
ARfD	0.005 mg/kg bw
IESTI (% ARfD)	PRIMo model rev. 2 11.4 % (UK toddler)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not required
Factors included in IESTI and NESTI	None

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
Not required.				

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

Plant matrices	The existing EU MRL of 0.05 mg/kg according to Reg.(EC) N°149/2008 covers the expected residue situation of the representative use in sugar beet. No new MRL is proposed.
Animal matrices	-

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

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

Mineralisation after 100 days ‡	[U-^{14}C]-phenyl labelled tefluthrin: 21 - 65% AR after 90-94 days, 2 soils, For 1 of 2 soils 39% AR after 180 days [^{14}C]-cyclopropyl labelled tefluthrin: 23 - 55 % AR after 30 - 56 days, 3 soils
Non-extractable residues after 100 days ‡	[U-^{14}C]-phenyl labelled tefluthrin: 9 – 22% AR after 90-94 days, 2 soils In 1 of these soils 16% AR after 180 days [^{14}C]-cyclopropyl labelled tefluthrin: 13 - 22 % AR after 30 - 56 days, 3 soils
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Compound Ia (R119890) was formed in amounts > 5 % AR (max. 7.1 %AR after 31 d) at two consecutive time points in 1 of 8 aerobic studies.

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

Anaerobic degradation ‡

Mineralisation after 100 days	Study 1: anaerobic (^{14}C-phenyl labelled tefluthrin) 0 % AR after 90days Study 2: 30 d aerobic, 64 d anaerobic ([^{14}C]-phenyl/ [^{14}C]-cyclopropyl labelled tefluthrin) 18 %/25 % AR after 31 days, 24 %/32 % AR after 94 days,
Non-extractable residues after 100 days	Study 1: anaerobic ([^{14}C]-phenyl labelled tefluthrin) 2 % AR after 90 days Study 2: 30 d aerobic, 64 d anaerobic ([^{14}C]-phenyl/ [^{14}C]-cyclopropyl labelled tefluthrin) 15 %/11 % AR after 94 days
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	anaerobic conditions: max. 17.5 % AR compound III (R153946) after 90 days aerobic/anaerobic conditions: max. 24.7 % AR compound Ia (R119890) after 94 days max. 18.3 % AR compound III (R153946) after 94 days

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	none

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type (site)	Kind of formulation	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20 °C	St.	Model, Kinetics;

					pF2/10kPa	[1)]R^2 [2)]chi^2	Method of calculation
18 acres , sandy loam	solution	6.8	20 °C/40 % MWHC	48 / 160	48	0.970 [1)]	SFO
18 acres , sandy loam, granule	granule	6.8	20 °C/40 % MWHC	151/ -*	151	0.928[1)]	SFO
Frensham, loamy sand	solution	5.3	20 °C/40 % MWHC	63 / -*	63	0.926[1)]	SFO
18 acres , sandy loam	solution	6.5	5 °C/40 % MWHC	134 /-*		0.876[1)]	SFO
	solution	6.5	20 °C/40 % MWHC	13 / 43	(13)	0.998[1)]	SFO
	solution	6.5	20 °C/40 % MWHC	20 / 67	(20)	0.996 [1)]	SFO
	solution	6.5	20 °C/40 % MWHC	26 / 86	(26)	0.995[1)]	SFO
	solution	6.5	30 °C/40 % MWHC	17 / 58		0.988[1)]	SFO
			Mean (18 acres sandy loam, n = 3)		18.9		
Gartenacker, loam	solution	7.8	20 °C/ pF2	7/ 22	7	3.67 [2)]	SFO
Marsillargues, silty clay	solution	8.5	20 °C/ pF2	36/ 119	36	2.24 [2)]	SFO
Pappelacker, sandy loam	solution	8	20 °C/ pF2	33/ 110	33	1.15 [2)]	SFO
Geometric mean/median (DT_{50})					37[§]		
Worst case granule application					151		

* The DT_{90} values are unreliable and are not quoted since time points after 90 % degradation, necessary to obtain reliable estimates, were not available

[§] The correct value, calculated with the exclusion of the normalised DT_{50} values derived at 5°C and 30°C for the 18 Acres sandy loam soil is 35 days.

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

Laboratory studies ‡

Compound Ia (PP890)	Aerobic conditions						
Soil type (site)	X[1]	pH *in 0.01 M	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20°C pF2/10kPa	St. (chi^2)	Model, Kinetics; Method of calculation

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

		$CaCl_2$					
UK, sandy clay loam		5.4*	20 °C, pF2	3.1/ 10.2	3.1	10.9	SFO
Switzerland, loam		7.1*	20 °C, pF2	4.0/ 13.4	4.0	11.4	SFO
France, loam		7.6*	20 °C, pF2	16.0/ 53.1	16.0	6.4	SFO
Worst case					16		

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

Laboratory studies ‡

Compound III (R153946)	Aerobic conditions						
Soil type (site)	X[2]	pH 0.01 M $CaCl_2$	t. °C / % MWHC	DT_{50} /DT_{90} (d) (report)	DT_{50} (d) 20°C pF2/10kPa	St. (chi^2)	Model, Kinetics; Method of calculation
18 acres , sandy loam		6.1	20 °C, pF2	0.8/ 2.7	0.8	1.3	SFO
Gartenacker, loam		7	20 °C, pF2	1.6/ 5.4	1.6	4.8	SFO
Marsilargues, silty clay loam		7.6	20 °C, pF2	1.5/ 5	1.5	5.6	SFO
Geometric mean/median (DT_{50})					**1.2**		

Field studies ‡

Parent	Aerobic conditions							
Application as an EC formulation[1]								
Soil type	Location	X[1]	pH	Depth (cm)	DT_{50} (d) (* = FOMC DT_{90}/ 3.32)	DT_{90} (d)	St. (R^2)	Method of calculation
sandy loam	Buchen, Germany 1987		6.4	0 – 30	(14) 73*	241	0.994	FOMC

[2] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate

Field studies ‡

Parent	Aerobic conditions							
Application as an EC formulation[1]								
Soil type	Location	X[1]	pH	Depth (cm)	DT_{50} (d) (* = FOMC DT_{90}/ 3.32)	DT_{90} (d)	St. (R^2)	Method of calculation
sandy loam	Varendorf, Germany 1987		5.7	0 – 25	16	53	0.993	SFO
silt loam	Kapellen, Germany 1987		7.8	0 – 30	(9) 26*	86	0.998	FOMC
Loam	Ottersweier, Germany 1987		5.3	0 – 30	(35) 66*	219	0.942	FOMC
silty clayloam	Langenerling, Germany 1987		8.3	0 – 30	(9) 22*	74	0.998	FOMC
silty loam	Inzkofen, Germany 1987		7.2	0 – 30	9	31	0.994	SFO
Granular in–furrow application								
Soil type	Location	X[1]	pH	Depth (cm)	DT_{50} (d)	DT_{90} (d)	St. [1)]R^2/ [2)]chi^2	Method of calculation
Silty clay loam	Dußlingen, Germany		6.9	0-15	86	287	13.7 [2)]	SFO
Sandy loam	Dugliolo (IT)		7.9	0-15	56	187	9.4 [2)]	SFO
Silty clay	Alpera (ES)		7.8	0-15	156	517	16.3 [2)]	SFO
Silt loam	Meistratzheim (FR)		7.9	0-15	206	686	10.1 [2)]	SFO
Geometric mean/median (DT_{50}, n = 6). Application as an EC formulation					27.1	-		
Worst case (DT_{50}, n = 4). Granular in–furrow application					206	-		

1: Information on the release rate of tefluthrin from treated seeds after EC formulation application is not available.

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	refer to PECsoil calculations section

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d [mL/g]	K_{oc} [mL/g]	K_f [mL/g]	K_{foc} [mL/g]	1/n
Sandy clay loam	1.6	6.3	1800	112500	1200*	75000	0.93
Sandy loam	0.7	6.2	762	109000	332*	46000	0.83
Sandy loam	0.9	6.6	895	99500	2052*	228000	1.16
Silt loam	0.4	5.2	1067	267000	14400*	3600000	1.5
Sandy loam	1.7	5.8	1140	68000	1810	108000	1.08
Sandy loam	0.3	4.8	492	170000	1010	348000	1.15
Silty clay loam	2.5	4.8	1320	52700	2250	102000	1.12
Clay loam	5.1	7.2	1230	24200	4380	85700	1.23
arithmetic mean						574088	1.125
median						105000	1.135
pH dependence, Yes or No			no				

*: calculated by RMS based on K_{foc} and OC

Metabolite 1 compound Ia (PP890)							
Soil Type	OC %	Soil pH (0.01 M $CaCl_2$)	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sandy clay loam	3.23	4.45	2.969	91.9	3.011	93	1.03
Sandy loam	2.5	6.05	0.345	13.8	0.314	13	0.92
Silt clay loam	0.58	7.5	0.0079	16.2	0.079	14	0.82
Arithmetic mean/						40	0.92
pH dependence (yes or no)			no (pH dependency can not be derived from 3 soils)				

Metabolite compound III (R153946)							
Soil Type	OM %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sandy clay loam	3.5	5.9				*	
loam	5	7.1				*	
Silty clay loam	1.8	7.7				*	
Arithmetic mean/median						-	
			*) Adsorption was negligible				

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

Column leaching ‡	Eluation (mm): 393 mm Time period (d): 48 h Three soils: Speyer 2.1, 2.2 and 2.3
	Tefluthrin was not detected in leachate (LOQ < 0.54 µg/L).
Aged residues leaching ‡	Aged for (d): 1 month Time period (d): 6 weeks Eluation (mm): 660 mm in 6 weeks Two soils: Acres, Frenshem
	Radioactivity was not detected in leachate (LOD < 0.00016 µg/L). Residues in soil (LOD < 0.0016 µg/L): Tefluthrin: 72 to 74 % Compound III 0.3 to 1.8 % Compound IV: 0.4 to 0.6 % Compound V: 0.5 to 1 %
Lysimeter/field leaching studies	no data, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 206 Kinetics: SFO worst case field study
Application data	Crop: sugar beet Depth of soil layer: 5 cm % plant interception: 0 (seed drill) Number of applications: 1 Interval (d): - Application rate(s): 15.6 g as/ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Many years of application considering accumulation Actual	Many years of application Time weighted average
Initial	0.0208		not applicable	
Short term 24h	0.0207	0.0208	0.0229	0.0229
2d	0.0207	0.0207	0.0228	0.0229
4d	0.0205	0.0207	0.0227	0.0228
Long term 7d	0.0203	0.0206	0.0225	0.0227
28d	0.0189	0.0199	0.0211	0.0220
50d	0.0176	0.0191	0.0197	0.0213

100d	0.0149	0.0177	0.017	0.0198
Plateau concentration	0.023 mg/kg (0.0022 mg/kg final background concentration over 20 cm)			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5- pH 7: hydrolytically stable at 20 °C, pH 9: DT_{50} > 30 d (incubation time 30 d) pH 9: compound Ia: 34.6 %, compound II: 21.4 %
Photolytic degradation of active substance and metabolites above 10 % ‡	pH 7, intensity 260 - 370 W/m² at 25 °C (290 – 400 nm) as: residue 60 - 63 % after 31 d (DT_{50}: 11.2 d*) metabolites > trans-tefluthrin (R156944) 21.2 – 37.2 %
Quantum yield of direct phototransformation in water at λ > 290 nm	not relevant
Readily biodegradable ‡ (yes/no)	not readily biodegradable

* transferred to natural summer condition 40° N, calculation performed by RMS

Degradation in water / sediment

Note: the following dissipation/degradation rates for tefluthrin should be considered with caution as it cannot be excluded that adsorption of tefluthrin to the glass vials has taken place during the water/sediment studies and taking into consideration that part of the active substance could have been lost via volatilisation

Parent	Distribution: in sediment max of 91 % at day 3; in water max of 29 % at day 0 (aerobic conditions, 20 °C)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Kromme Rijn ^{14}C-Cyclopropyl label	8.2	7.3	20	146/520	0.996	1.3/ 4.4	0.996-	203/673	0.996	SFO, Water/ sediment together
TNO ^{14}C-Cyclopropyl label	8.8	7.4	20	60/ 246	0.995	0.6/ 2	0.995	204/678	0.995*	SFO, Water/ sediment together
Old Basing ^{14}C-Cyclopropyl label	7.6	7.6	20	58/190	0.959	0.7/ 2.3	0.959	57/189	0.959	SFO, Water/ sediment together
Old Basing ^{14}C-Phenyl label	7.6	7.6	20	51/185	0.995	0.6/ 2.1	0.959	59/195	0.995	SFO , Water/ sediment together
DT_{50} Geometric mean (DT_{50} of both labels for one system were averaged)				**78**		**0.8**		**133**		
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (chi^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (chi^2)	Method of calculation
Kromme Rijn ^{14}C-Cyclopropyl label	8.2	7.3	20	127/ 423	3.9	-	-	202/674	2.1	SFO, Sediment separate and whole system separate
Kromme Rijn ^{14}C-Phenyl label	8.2	7.3	20	145/ 482	2.9	-	-	161/ 535	3.6	SFO, Sediment separate and whole system separate

Degradation in water / sediment

Note: the following dissipation/degradation rates for tefluthrin should be considered with caution as it cannot be excluded that adsorption of tefluthrin to the glass vials has taken place during the water/sediment studies and taking into consideration that part of the active substance could have been lost via volatilisation

Parent	Distribution: in sediment max of 91 % at day 3; in water max of 29 % at day 0 (aerobic conditions, 20 °C)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
TNO ^{14}C-Cyclopropyl label	8.8	7.4	20	64/213	6.5	-	-	81/268	4.3	SFO, Sediment separate and whole system separate
TNO ^{14}C-Phenyl label	8.8	7.4	20	87/ 288	7.7	-	-	137	4.4	SFO, Sediment separate and whole system separate
Old Basing ^{14}C-Cyclopropyl label	7.6	7.6	20	50/ 167	5.5	-	-	54/ 179	4.0	SFO, Sediment separate and whole system separate
Old Basing ^{14}C-Phenyl label	7.6	7.6	20	57/ 190	4.3	-	-	61/ 203	5.6	SFO, Sediment separate and whole system separate
DT_{50} Geometric mean/ DT_{50} of both labels for one system were averaged				**82**		**-**		**104**		
Compound Ia	*Distribution: max 22 % in water (day 84, study 1 II), max 7 % in sediment (day 84, study 1 II) and 2 sequential measures > 5 %									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
Geometric mean/median										no calculation performed
Compound IV	max 7.0 % in water (day 14, study 2), and 2 sequential measures > 5 % in water at 20 °C, max. 22.6 % in water at 5 °C (day 360, study 2)									
Water / sediment	pH w	pH sed	t. °C	DT_{50}-DT_{90}	St. (r^2)	DT_{50}-DT_{90}	r^2	DT_{50}-DT_{90}	St. (r^2)	Method of calculation

Degradation in water / sediment

Note: the following dissipation/degradation rates for tefluthrin should be considered with caution as it cannot be excluded that adsorption of tefluthrin to the glass vials has taken place during the water/sediment studies and taking into consideration that part of the active substance could have been lost via volatilisation

Parent	Distribution: in sediment max of 91 % at day 3; in water max of 29 % at day 0 (aerobic conditions, 20 °C)									
Water / sediment system	pH w	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}-DT_{90} sed	St. (r^2)	Method of calculation
system				whole sys.		water		sed		
Geometric mean/median										no calculation performed

Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. x % after n d. (end of the study).	
Kromme Rijn ^{14}C-Cyclopropyl label	8.2	7.3	3 % after 84 d	10.5 % after 84 d	
Kromme Rijn ^{14}C-Phenyl label	8.2	7.3	1 % after 84 d	8.5 % after 84 d	
TNO Zuidpolder ^{14}C-Cyclopropyl label	8.8	4	6 % after 84 d	13 % after 84 d	
TNO Zuidpolder ^{14}C-Phenyl label	8.8	4	1.5 % after 84 d	10 % after 84 d	
Old Basing Phenyl label			32 % after 120 d, 53 % after 360 d	22 % after 120 d, 15.9 % after 360 d	
Old Basing Cyclopropyl label			48.6 % after 120 d, 66.8 % after 360 d	9.8 % after 120 d, 7,8 % after 360 d	

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

Parent

Parameters used in FOCUS$_{sw}$ step 1 and 2

Molecular weight (g/mol): 418.74

Water solubility (mg/L): 0.016

K_{foc} (L/kg): 105000 (Median, n = 8)

DT_{50} soil (d): 151 (Maximum), Lab

DT_{50} water/sediment system (d): 82 (worst case total system geom. mean)

DT_{50} water (d): 82 (worst case total system geom. mean)

DT_{50} sediment (d): 133 (worst case geom. mean)

Crop interception (%): 0

Crop type: sugar beets

Parameters used in FOCUS$_{sw}$ step 3 (if performed)	Vapour pressure : 0 K_{Foc}: 105000 (median) 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively): 1 Water degradation half-life: 1000 d * Sediment degradation half-life: 104 d * Soil half-live: 145 d* Q10: 2.58 Water solubility: $1.6x10^{-2}$ mg/L *) The default DT_{50} of 1000 d should be used for sediment and the $DT_{50}$of the whole system for the faster degrading compartment water. For soil the worst case DT of 151 d should be used. In this case, it does not have an impact on the result of risk assessment.
Application rate	Crop: sugar beets Crop interception: 0 Number of applications: 1 Application rate(s): 15.6 g as/ha Region and Season of Application: seed treatment D3: 10th April 1992 D4 pond: 20th April 1985 D4 stream: 20th April 1985 R1 pond: 2trh April 1984 R1 stream: 26th April 1984 R3 stream: 10th March 1980 Depth of water body: 30 cm Application window (Julian day number): D3: 101-131 D4: 110-140 R1: 92-122 R3: 65-95

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.18		38.72	
	24h	0.04	0.11	39.46	39.09
	2d	0.04	0.07	39.12	39.19
	4d	0.04	0.06	38.47	38.99
	7d	0.04	0.05	37.51	38.56
	14d	0.03	0.04	35.35	37.49
	21d	0.03	0.04	33.32	36.43
	28d	0.03	0.04	31.41	35.41
	42d	0.03	0.03	27.9	33.48

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU Mar.-May	0 h	0.14		8.6	
	24 h	0.05	0.1	8.6	8.62
	2 d	0.02	0.06	8.56	8.6
	4 d	0.01	0.04	8.47	8.56
	7 d	0.01	0.02	8.34	8.49
	14 d	0.01	0.02	8.04	8.34
	21 d	0.01	0.01	7.75	8.19
	28 d	0.01	0.01	7.47	8.04
	42 d	0.01	0.01	6.94	7.76
Southern EU Mar.-May	0 h	0.14		16.24	
	24 h	0.05	0.1	16.17	16.2
	2 d	0.02	0.06	16.08	16.16
	4 d	0.02	0.04	15.92	16.08
	7 d	0.02	0.03	15.67	15.96
	14 d	0.01	0.02	15.1	15.67
	21 d	0.01	0.02	14.56	15.39
	28 d	0.01	0.02	14.04	15.12
	42 d	0.01	0.02	13.04	14.59

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
	D3 ditch	0 h	< 0.00001		< 0.0001	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001
	D4 pond	0 h	< 0.00001		0.00009	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001
	D4 stream	0 h	< 0.00001		0.00004	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001
	R1 pond	0 h	< 0.00001		< 0.0001	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001
	R1 stream	0 h	< 0.00001		< 0.0001	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
	R3 stream	0 h	< 0.00001		< 0.0001	
		24 h-42 d	< 0.00001	< 0.00001	< 0.0001	< 0.0001

The results of the study are plausible, as drift is not a relevant entry route and it is not expected that considerable amounts of tefluthrin reach surface water via runoff or drainage.
The Freundlich exponent (1/n = 1) used by the notifier differs from the mean value found in the laboratory sorption experiments (1.14). A value of 1 was implemented in the simulation, because the median 1/n value of 1.14 is considered by some to be outside the valid range, though a range for validity is not prescribed by the guideline (FOCUS, 2001).

Two major metabolites were observed in the water sediment study (Compound Ia was found at levels up to 22 % in water, 7 % in sediment, and compound IV 7 % at 20 °C). No simulation for compound IV was performed.

Metabolite compound Ia Parameters used in $FOCUS_{sw}$ step 1 and 2	Molecular weight: 242.6 Water solubility (mg/L): 32.6 Soil or water metabolite: K_{oc}/ (L/kg): 40 DT_{50} soil (d): *16* days (worst case lab. SFO) DT_{50} water/sediment system (d): (representative worst case from sediment water studies) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%): 0 Maximum occurrence observed Water: 22 % AR Sediment: 7 % AR
Parameters used in $FOCUS_{sw}$ step 3 (if performed)	Step 3 not performed for metabolite compound Ia.
Application rate	
Main routes of entry	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.23		0.08	
	24h	0.23	0.23	0.09	0.09
	2d	0.23	0.23	0.09	0.09
	4d	0.23	0.23	0.09	0.09
	7d	0.22	0.23	0.09	0.09
	14d	0.22	0.22	0.09	0.09
	21d	0.22	0.22	0.09	0.09
	28d	0.22	0.22	0.09	0.09
	42d	0.22	0.22	0.09	0.09

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.06		0.02	
	24 h	0.06	0.06	0.02	0.02
	2 d	0.06	0.06	0.02	0.02
	4 d	0.06	0.06	0.02	0.02
	7 d	0.06	0.06	0.02	0.02
	14 d	0.06	0.06	0.02	0.02
	21 d	0.06	0.06	0.02	0.02
	28 d	0.06	0.06	0.02	0.02
	42 d	0.06	0.06	0.02	0.02
Southern EU	0 h	0.09		0.04	
	24 h	0.09	0.09	0.04	0.04
	2 d	0.09	0.09	0.04	0.04
	4 d	0.09	0.09	0.04	0.04
	7 d	0.09	0.09	0.04	0.04
	14 d	0.09	0.09	0.04	0.04
	21 d	0.09	0.09	0.04	0.04
	28 d	0.09	0.09	0.04	0.04
	42 d	0.09	0.09	0.04	0.04

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter): Modelling using FOCUS PELMO	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUS gw scenarios, according to FOCUS guidance. Model(s) used: FOCUS PELMO 3.3.2 and FOCUS PEARL 3.3.3: Scenarios (list of names): Chateaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva Crop: sugar beet interception: 0 (granules) soil depth: 4 cm Parent DT_{50}lab: 145 d* K_{foc}: 105000 L/kg (median, n = 8), 1/n = 1** Metabolite Compound 1a, max. 7.1 % Molar mass: 242.5 g/mol DT_{50}lab: 16 d (worst case) K_{foc}: 40 (arithmetic mean n = 3), 1/n = 0.92.
Application rate	Application rate: 15.6 g/ha. No. of applications:1 Time of application (month or season): Châteaudun 25th March Hamburg 1st April Jokioinen 10th May Kremsmünster 1st April Okehampton 10th April Piacenza 1st March Porto 28th February Sevilla 31th Oktober Thiva 15th April

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

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Compound 1a	-	-
FOCUS PELMO/PEARL sugarbeet, 15.6 g/ha	Châteaudaun	< 0.001	< 0.001		
	Hamburg	< 0.001	< 0.001		
	Jokioinen	< 0.001	< 0.001		
	Kremsmünster	< 0.001	< 0.001		
	Okehampton	< 0.001	< 0.001		
	Piacenza	< 0.001	< 0.001		
	Porto	< 0.001	< 0.001		
	Sevilla	< 0.001	< 0.001		
	Thiva	< 0.001	< 0.001		

	Chateaudaun	< 0.001	< 0.001		

*The notifier has used a DT_{50} of 145 d. The worst case DT_{50} of laboratory studies with granule application is 151 days. There is only one laboratory DT_{50} with granule application available, the DT_{50} of 151 days triggers field studies. Unnormalised DT_{50} in the field with granule application can be longer than 151 days.
Since the soil adsorption is extremely high for tefluthrin, it is not expected that the DT_{50} does not influence PEC_{GW}-,. So the use of a DT_{50} of 145 d can be accepted.
**The Freundlich exponent (1/n = 1) used by the notifier differs from the mean value found in the laboratory sorption experiments (1.135). Because of the high adsorption coefficients it is unlikely that the use of 1/n value of 1.135 will have an impact on the estimated PECgw.

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

Direct photolysis in air ‡	not relevant (incorporated below 4 cm of soil)
Quantum yield of direct phototransformation	not relevant (incorporated below 4 cm of soil)
Photochemical oxidative degradation in air ‡	AOP-calculations: AOP version 1.91: DT_{50} = 0.94 d (24 hr day; 0.5 x 10^6 OH/cm^3)
Volatilisation ‡	not relevant (incorporated below 4 cm of soil) Max. 15.5 % from soil (30 °C, after 60 d, soil degradation study, surface application)
Metabolites	not applicable

PEC (air)

Method of calculation	n.a.*

$PEC_{(a)}$

Maximum concentration	n.a.*

(* DT_{50} in air is shorter than 2 days, not relevant, no simulation necessary.)

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: tefluthrin, compound III (R153946) (major metabolite under anaerobic conditions) Surface Water: tefluthrin, compound Ia (R119890) Groundwater: tefluthrin, compound Ia (R119890) Air: tefluthrin

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

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	not available

Air (indicate location and type of study)	not available

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

R53 - Tefluthrin can be classified as ”not readily biodegradable”:

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

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds ‡				
Passer domesticus	Tefluthrin as	Acute	LD_{50} 267	
	Preparation	Acute	No data submitted – justification accepted	
	Metabolites	Acute		
Anas platyrhynchus	Tefluthrin as	Acute	LD_{50} > 3960	
	Tefluthrin as	**Short-term**	**LD_{50} > 179[1)]**	**LC_{50} 2317**
	Tefluthrin as	Long-term, reproduction	NOEL ≥ 3.7	NOEC = 25
Colinus virginianus	Tefluthrin as	Acute	LD_{50} = 734	
	Tefluthrin as	Short-term	LD_{50} > 735.0	LC_{50} > 10500
	Tefluthrin as	Long-term, reproduction	NOEL ≥ 2.0	NOEC ≥ 25
	Tefluthrin as	**Long-term, reproduction**	**NOEL ≥ 83.2**	**NOEC ≥1000**
Mammals ‡				
Rat	Tefluthrin as	Acute	LD_{50} 21.8	
Rat	Preparation 20 % CS	Acute	LD_{50} > 344 [2)]	
Rat	Metabolite	Acute	No data submitted - not relevant	
Rat	Tefluthrin as	Short-term, 90-day mortality	NOEL 31.8	NOEC 350
Rat	Tefluthrin as	Long-term, 3-gen. reproduction study reduced litter size, red. offspring bw	NOEL 4.7	NOEC 50
Rat	Metabolites	Long-term	No data submitted - not relevant	
Additional higher tier studies ‡ No data submitted – justification accepted				

[1)] Daily dietary dose was calculated with 793 mg as/kg feed, the highest conc. without food avoidance and mortality. This represents a conservative LD_{50}.

[2)] In common with other pyrethroid micro-encapsulated products, the CS micro-encapsulated formulation of tefluthrin is significantly less toxic than the active substance alone. Acute exposure will be to the encapsulated formulated product, rather than to the technical active substance, so the endpoint for the similar 20 % CS formulation will be used in the acute risk assessment.

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

Sugar beets, seed treatment, 0.0156 kg as/ha, 3158 mg as/kg pelleted seed fresh weight

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
Granivorous bird	Acute	1200	0.2	10
Granivorous bird	Short-term	1200	> 0.15	10
Granivorous bird	Long-term	1200	0.07	5
Higher tier refinement (Birds)				
Indicator species/Category[2]	Time scale	Number of seeds/day (approx.) that must be consumed daily to reach the ecotoxicological endpoint		
Skylark (*Alauda arvensis*) 40 g	Acute	89 seeds to reach LD_{50} [1)]		
	Short-term	60 seeds/day to reach LD_{50} [1)]		
	Long-term	28 seeds/day to reach NOEL Long-term exposure not likely, due to seed germination after 8-12 days [2)]		
Pheasant (*Phasianus colchicus*) 950 g	Acute	2114 seeds/day to reach LD_{50} [1)]		
	Short-term	1417 seeds/day to reach LD_{50} [1)]		
	Long-term	658 seeds/day to reach NOEL Long-term exposure not likely, due to seed germination after 8-12 days		
Greenfinch (*Carduelis chloris*) 28 g	Acute	62 seeds/day to reach LD_{50} [1)]		
	Short-term	42 seeds/day to reach LD_{50} [1)]		
	Long-term	20 seeds/day to reach NOEL Long-term exposure not likely, due to seed germination after 8-12 days [3)]		
Small bird 15 g	Short-term	11 seeds/day to reach LD_{50}[4]		
Bioaccumulation and food chain behaviour: TER for risk to earthworm-eating birds				
Indicator species	Time scale	PECworm (mg/kg)	TER	Annex VI Trigger
Blackbird (*Turdus merula*, 100 g)	Long-term	0.240	315	5

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 (Mammals)				
Small granivorous mammal	Acute	726	> 0.47	10
Small granivorous mammal	Short-term [3)]	726	> 0.04	10
Small granivorous mammal	Long-term	726	0.006	5
Higher tier refinement (Mammals)				
Indicator species/Category[2]	Time scale	Number of seeds/day (approx.) that must be consumed daily to reach the ecotoxicological endpoint		
Wood mouse (25 g)	Acute	7.2 seeds/day to reach $LD_{50(formulation)}$ [5)] 0.5 seeds/day to reach $LD_{50(as)}$		
	Short-term	~~0.7~~ seeds/day to reach $LD_{50(as)}$ [5)]		
	Long-term	0.2 seed/day to reach NOEL [5)]		
Bioaccumulation and food chain behaviour: TER for risk to earthworm-eating mammals				
Indicator species	Time scale	PECworm (mg/kg)	TER	Annex VI Trigger
small mammal (10 g)	Long-term	0.240	18	5

[1)] Sugar beet pills are not attractive to birds and the availability of seeds on the surface post precision drilling is low (0.195 seeds/m2; worst case: 1.5% seeds on soil surface). Considering the number of seeds required to reach the regulatory lethal dose, exposure is likely to be low and risk is considered acceptable

[2)] Risk is considered acceptable, since long-term exposure will not occur and daily uptake of seeds to reach NOEL is unlikely.

[3)] There is evidence that small birds will dehusk the pelleted sugar beet seeds, reducing the exposure. Moreover, studies are available that indicates a low frequentation of small birds to sugar beet fields. Therefore, the risk to small birds from the consumption of treated seeds is considered acceptable.

[4)] The experts agreed that the acute risk assessment for small birds (15g) could be refined by using the geometric mean of LD50 from the 3 species (i.e. 919 mg/kg bw/d), resulting in 11 seeds required to reach the LD50 values (0.12 mg tefluthrin/seed) . It was noted that availability of seeds on the surface post after precision drilling was low (0.195 seeds/m2, 1.5% seeds on soil surface was identified as worst case), indicating that the exposure is likely to be low. In addition, there was some evidence on the occurrence of dehusking. Overall, and taking into consideration the outcome of the study of Wolf (2005), which indicated a low frequentation of sugar beet fields by small birds, the risk to small birds from the consumption of seeds was considered as low, when a precision drilling technique was used.

[5)] Number of seeds per day to reach critical levels was recalculated during PRAPeR 77. Wood mice may however minimise exposure to tefluthrin by completely remove the coating of the seeds before they are consumed. There was not enough information on how dehusking/depelleting behaviour will impact exposure of wood mice. A data gap remains for further data to conclude on an acceptable risk to mammals from exposure to pelleted sugar beet seeds.

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				
Oncorhynchus mykiss	Tefluthrin	Acute, 96 h (static)	Mortality, EC_{50}	0.00006 mm

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Pimephales promelas	Tefluthrin	Chronic, 345 d (flow-through)	NOEC	0.00000397 $_{mm}$
Oncorhynchus mykiss	Preparation Tefluthrin 300 g/L CS	Acute 96 h (static)	Mortality, EC_{50}	0.00033 as $_{nom}$ 0.0012 product $_{nom}$
Oncorhynchus mykiss	Metabolite Compound Ia (PP890)	Acute 96 h (static)	Mortality, EC_{50}	> 15.8 $_{mm}$
Oncorhynchus mykiss	Metabolite Compound III (2,3,5,6-tetrafluoro-4-methyl-benzoic acid)[4]	Acute, 96 h (static)	Mortality, EC_{50}	> 100 $_{nom}$
Aquatic invertebrate				
Daphnia magna	Tefluthrin	Acute 48 h (static)	Mortality, EC_{50}	0.00007 $_{mm}$
Daphnia magna	Tefluthrin	Acute 48 h (static)	Mortality, EC_{50}	0.000064 $_{mm}$
Daphnia magna	Preparation Tefluthrin 300 g/L CS	Acute 48 h (static)	Mortality, EC_{50}	0.0079 $_{mm}$ product (0.0021 $_{mm}$ as)
Daphnia magna	Tefluthrin	Chronic 21 d (semi-static)	Reproduction, NOEC	0.00000792 $_{mm}$
Daphnia magna	Metabolite Compound Ia (PP890)	Acute 48 h (static)	Mortality, EC_{50}	> 182 $_{nom}$
Daphnia magna	Metabolite Compound III	Acute 48 h (static)	Mortality, EC_{50}	> 120 $_{nom}$
Sediment dwelling organisms				
Chironomus riparius	Tefluthrin	Acute 48 h (static)	Mortality, EC_{50}	0.0025
	Tefluthrin	Chronic 28 d (static)	Reproduction, NOEC	0.47 mg/kg sediment
Algae				
Pseudokirchneriella subcapitata	Tefluthrin	Chronic 72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	> 1.05 $_{nom}$ > 1.05 $_{nom}$
Pseudokirchneriella subcapitata	Preparation Tefluthrin 200 g/L CS	Chronic 72 hr (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	82 product $_{nom}$ (15 as) 100 product $_{nom}$ (18.3 as)
Pseudokirchneriella subcapitata	Metabolite	Chronic 72 hr (static)	no data submitted, not required	-

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity[1] (mg/L)
Higher plant				
Lemna gibba	Tefluthrin	7 d (semi-static)	no data submitted, not required	-
Lemna gibba	Preparation	7 d (static)	no data submitted, not required	-
Microcosm or mesocosm tests				
Not required, not relevant				

[1] indicate whether based on nominal ($_{nom}$ = analytically confirmed) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means concentration corresponds to test substance in column two.

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

Maximum PEC_{sw} values and TER values for tefluthrin application to sugar beet at 15.6 g a.s./ha (seed treatment)

FOCUS Step1

Sugar beets, seed treatment, 0.0156 kg as/ha

Test substance	Organism	Toxicity endpoint (mg/L)	Time scale	PECi	PECtwa	TER	Annex VI Trigger[1]
as	not performed not required						

[1]If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.
[2] only required for herbicides
[3]consider the need for PEC_{sw} and PEC_{sed} and indicate which has been used

FOCUS Step 2

Sugar beets, seed treatment, 0.0156 kg as/ha

Test substance	N/S[1]	Organism[2]	Toxicity endpoint (mg/L)	Time scale	PEC[3]	TER	Annex VI Trigger[4]
as		not performed, not required					

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

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

Sugar beets, seed treatment, 0.0156 kg as/ha

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity endpoint (µg/L)	PEC_{sw}[4] maximum µg/L	TER	Annex VI trigger[5]
as	All scenarios D3, D4, R1, R3	pond, ditch, stream	fish	acute	0.06	8×10^{-9}	7×10^{6}	100
as			fish, life cycle	long-term	0.00397	8×10^{-9}	5×10^{5}	10
Metabolite Compound Ia			fish	acute	> 15800	< 0.0001	$> 1.6 \times 10^{8}$	100
Product			fish	acute	0.33 µg as/L	8×10^{-9}	4×10^{7}	100

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] include critical groups which fail at Step 2.
[4] indicate whether PEC_{sw}, or PEC_{sed} and whether maximum or twa values used
[5] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a Trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
logPow	6.4			
Bioconcentration factor (BCF)[1] whole fish‡	1400	Not relevant	Not relevant	
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	14			
(CT_{90})	-			
Level and nature of residues (%) in organisms after the 14 day depuration phase	After 14 d depuartion: 47 % total ^{14}C. After 65 d depuartion: 14 % total ^{14}C (2.4 µg/kg fish)			

[1] only required if log Pow > 3.
* based on total ^{14}C or on specific compounds

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Tefluthrin tech.	1.88	0.28
Preparation[1]	-	-
Metabolite PP890	> 164	> 200
Metabolite R173204	> 220	> 200
Field or semi-field tests		
Honey bees can be exposed to tefluthrin when used as seed treatment by dust drift during sowing. In a field study to establish a drift pattern, the highest emission from sowing maize seeds was 0.333 % of the field rate of 15.6 g tefluthrin/ha at 3 meters distance using unmodified pneumatic seeders. HQ calculation indicates a low risk for bees. Exposure via droplets of guttation fluids excreted by sugar beets and exposure via pollen and nectar is expected negligible since tefluthrin has no systemic properties.		

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

0.05 g as/ha drift dust, sugar beet (seed treatment only)

Test substance	Route	Hazard quotient	Annex VI Trigger
as	contact	0.19	50
as	oral	0.03	50
Preparation	contact	-	50
Preparation	oral	-	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	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	---	Mortality	No laboratory study was performed, because tefluthrin is a pyrethroid insecticide, active against a broad spectrum of soil pests and effects are to be expected in Tier 1 studies. Furthermore, according to Escort 2 glass plate tests can not reasonably be performed with seed.
Aphidius rhopalosiphi ‡	---	Mortality	

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Crop and application rate: sugar beet; seed dressing: average rate of 15.6 g as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
--	*Typhlodromus pyri*	see above			2
--	*Aphidius rhopalosiphi*	see above			2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% adverse effect[3]	Trigger value
No laboratory study was performed, because tefluthrin is a pyrethroid insecticide used in coating for sugar beet seeds, active against a broad spectrum of soil pests and effects are to be expected.						50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of as or preparation
[3] indicate when the effect is not adverse

Field or semi-field tests
Application of tefluthrin as a 5 % w/w in-furrow granule at the equivalent of 50 g as/ha, and as a micro-encapsulated seed treatment on pelleted sugar beet at the equivalent of 10 g as/ha Seed treatment at 10 g as/ha: no effects Granular treatments at 50 g tefluthrin/ha: only limited, transient effects on some non-target arthropods. Positive control treatments with aldicarb, carbofuran and gamma-HCH had greater effects. Granular treatments at 183 and 233 g tefluthrin./ha, no adverse effects persisting for more than one year after application of tefluthrin up to a rate of 233 g as/ha.

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 foetida	tefluthrin (as) ‡	Acute 28 days	LC_{50corr} 1.0 mg as/kg dw soil (750 g as/ha) $NOEC_{corr}$ 0.16 mg as/kg dw soil
	tefluthrin (as) ‡	Chronic 8 weeks	Not performed
Eisenia foetida	Preparation: tefluthrin 5 % EC formulation	Acute 28 days	LC_{50corr} 0.8 mg as/kg d.w. soil (600 g as/ha) $NOEC_{corr}$ 0.16 mg as/kg dw soil
Eisenia andrei	Preparation: tefluthrin 20 %CS formulation	Chronic 8 weeks	$NOEC_{corr}$ 1.25 mg as/kg dw soil
	Metabolite Compound Ia	Acute	Not performed, not required. Covered by 28 d acute test (metabolite > 5 % from day 13)

Test organism	Test substance	Time scale	Endpoint[1]
Other soil macro-organisms			
Collembola or gamasid soil mite	Preparation: tefluthrin 20 % CS formulation	Chronic	$NOEC_{corr}$ 30 mg as/kg dw soil
	Preparation 5 % w/w in-furrow granule at the equivalent of 50 g as/ha, and as a micro-encapsulated seed treatment on pelleted sugar beet at the equivalent of 10 g as/ha	Chronic, field study on non-target arthropods	No effects on Collembola at 50 g as/ha
	Metabolite Compound Ia	Chronic	Not required, covered by field study with preparation
Soil micro-organisms			
Nitrogen mineralisation	Tefluthrin EC Formulation 104 g as/L		< 25 % effect at day 28 at 1mg as/kg d.w. soil (750 g as/ha)
	Metabolites		Not relevant
Carbon mineralisation	Tefluthrin EC Formulation 104 g as/L		< 25 % effect at day 28 at 1mg as/kg d.w. soil (750 g as/ha)
	Metabolites		Not relevant
Field studies[2]			
Field studies regarding earthworm biocoenosis were performed with two different formulations (micro-capsule suspension (20 % CS) and granular formulation). However, the study with granules is regarded non valid. Although sub-lethal effects on earthworm can not be assessed, since a reproduction study was not performed, the study with a pelleted sugar beet seed treatment demonstrates that adverse effects on earthworm populations in the field are not expected following the use of tefluthrin as a sugar beet seed treatment at 48 g as/ha, three times greater than the proposed rate of tefluthrin of 15.6 g as/ha. No further data required. Litter bag field study: both tested tefluthrin treatments (granules and seed treatment) have no significant impact on straw decomposition up to 9 months after litterbag burial in soil treated with the plateau concentration and the annual application rate. It is concluded that the use of a 200 g tefluthrin/L CS formulation as a seed treatment on sugar beet at a rate of 15.6 g tefluthrin/ha will present a negligible risk to soil microbial organisms and to the decomposition processes of organic material under field conditions.			

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

Toxicity/exposure ratios for soil organisms

Crop and application rate: sugar beet; seed dressing: average rate of 15.6 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia foetida	tefluthrin (as) ‡	Acute	PEC_i 0.0208 mg/kg	48	10
Eisenia foetida	Preparation	Acute	PEC_i 0.0208 mg/kg	39	10

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Eisenia foetida resp. *E. andrei*	Preparation	Chronic	PEC_i 0.0208 mg/kg	60	5
	Metabolite: Compound Ia Covered by 28 d acute test (metabolite > 5 % from day 13)	Acute	Not relevant	-	10
Other soil macro-organisms					
Soil mite	as ‡	Time scale	-	Not relevant	
	Preparation	-	-	Not relevant	
	Metabolite	-	-	Not relevant	
Collembola	Preparation	Chronic	PEC_i 0.0208 mg/kg	>1000	5
	Preparation	Field study	PEC_i 0.0208 mg/kg	≥ 3.2*	
	Metabolite	-	-	Not relevant	

* no effect at treatment equivalent to 50 g as/ha, 3.2 higher than maximum application rate, risk is acceptable
[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

No tests performed. Tefluthrin is an insecticide used as seed treatment.

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Not relevant due to application form						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of as or preparation

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

Not relevant

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

Test type/organism	endpoint
Activated sludge	3-hour NOEC ≥1000 mg tefluthrin/L (water solubility = 0,016 mg/L).
Pseudomonas sp	test non valid, data not required

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

Compartment	
soil	Parent (tefluthrin),
water	Parent (tefluthrin)
sediment	Parent (tefluthrin)
groundwater	Parent (tefluthrin)

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

	RMS/peer review proposal
Active substance	N, R50/R53

	ECB decision (up to 30th ATP, checked at November 8, 2005)
Active substance	Not listed

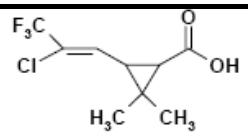
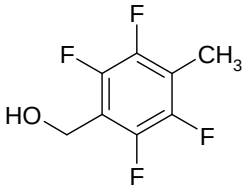
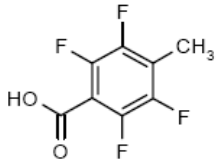
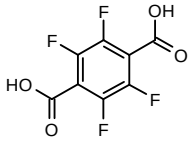
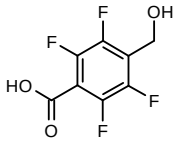
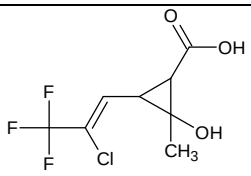
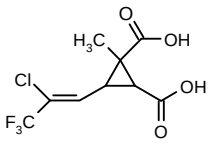
Appendix 1– Used compound code(s) in the list of end points

Appendix 2 – Abbreviations used in the list of endpoints

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstracts
CAS	Chemical Abstracts Service
CIPAC	Collaborative International Pesticides Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent degradation / dissipation
DT_{90}	period required for 90 percent degradation / dissipation
ε	decadic molar extinction coefficient
EC_{50}	effective concentration, median
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography or high pressure liquid chromatography
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{OC}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated Short Term Intake
NIR	Near-Infrared-(Spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water

PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
r^2	coefficient of determination
RMS	rapporteur Member State
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
compound Ia (R119890)	1R,3R;1S,3S)-3-((Z)-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropanecarboxylic acid	
Compound II	2,3,5,6-tetrafluoro-4-methylbenzylalcohol	
compound III (R153946)	2,3,5,6-tetrafluoro-4-methylbenzoic acid	
Compound IV	2,3,5,6-tetrafluoroterephthalic acid	
Compound VI	2,3,5,6-tetrafluoro-4-hydroxymethyl benzoic acid	
Compound XI	3-[(1Z)-2-chloro-3,3,3-trifluoroprop-1-en-1-yl]-2-hydroxy-2-methylcyclopropanecarboxylic acid	
Compound XII	3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-1-methylcyclopropane-1,2-dicarboxylic acid	

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

ABBREVIATIONS

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

GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal

PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year