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CQC (AA-EQS) and AQC (MAC-EQS) – Proposal by the Ecotox Centre for:

Tefluthrin

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Please note that the suggested EQS and contents of this dossier do not necessarily reflect the opinion of the external reviewer.

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Executive summary

CQC (AA-EQS): 0.21 ng/L

AQC (MAC-EQS): 5.3 ng/L

The chronic quality criterion (CQC) and the acute quality criterion (AQC) were derived according to the TGD for EQS of the European Commission (EC 2018a). In order to ensure that the dossiers are internationally comparable, the English terminology of the TGD will be used in the remainder of the dossier. The AQC corresponds to the MAC-EQS ("maximum allowable concentration environmental quality standard") and the CQC corresponds to the AA-EQS ("annual average environmental quality standard"). According to the Swiss Water Protection Ordinance (The Swiss Federal Council 2020), the CQC should not be compared with an annual average value but with the averaged concentration over two weeks.

Zusammenfassung

CQK (AA-EQS): 0.21 ng/L

AQK (MAC-EQS): 5.3 ng/L

Das chronische Qualitätskriterium (CQK) und das akute Qualitätskriterium (AQK) wurden nach dem TGD for EQS der Europäischen Kommission (EC 2018a) hergeleitet. Damit die Dossiers international vergleichbar sind, wird im Weiteren die englische Terminologie des TGD verwendet. Der AQK entspricht dabei dem MAC-EQS (“maximum allowable concentration environmental quality standard”) und der CQK entspricht in der Herleitung dem AA-EQS (“annual average environmental quality standard”) soll aber gemäss Schweizer Gewässerschutzverordnung (Der Schweizerische Bundesrat 2020) nicht mit einem Jahresmittelwert sondern mit der gemittelten Konzentration über 2 Wochen verglichen werden.

Résumé

CQC (AA-EQS) : 0.21 ng/L

CQA (MAC-EQS) : 5.3 ng/L

Le critère de qualité chronique (CQC) et le critère de qualité aiguë (AQC) ont été dérivés selon le TGD for EQS de la Commission européenne (EC 2018a). Afin que les dossiers soient comparables au niveau international, la terminologie anglaise du TGD est utilisée ci dessous. La CQA correspond à la MAC-EQS (“maximum allowable concentration environmental quality standard”) ou NQE-CMA ("norme de qualité environnementale de la concentration maximale admissible") et la CQC correspond à la AA-EQS (“annual average environmental quality standard”) ou NQE-MA ("norme de qualité environnementale de la moyenne annuelle"). Selon

l'ordonnance suisse sur la protection des eaux (Le Conseil fédéral suisse 2020), la CQC ne doit cependant pas être comparée à une valeur moyenne annuelle, mais à la concentration moyenne sur deux semaines.

Sommario

CQC (AA-EQS) : 0.21 ng/L

CQA (MAC-EQS) : 5.3 ng/L

Il criterio di qualità cronica (CQC) e il criterio di qualità acuta (CQA) sono stati derivati secondo il TGD for TGD della Commissione Europea (EC 2018a). Per garantire che i dossier siano comparabili a livello internazionale, viene utilizzata la terminologia inglese del TGD. Il CQA corrisponde al MAC-EQS ("maximum allowable concentration environmental quality standard") oppure SQA-CMA ("standard di qualità ambientale a concentrazione massima ammissibile") e il CQC corrisponde al AA-EQS ("annual average environmental quality standard") oppure SQA-MA ("standard di qualità ambientale medio annuo"). Secondo l'ordinanza svizzera sulla protezione delle acque (Il Consiglio federale svizzero 2020), tuttavia, il CQC non deve essere confrontato con un valore medio annuo, ma con la concentrazione media su due settimane.

Table of content

1 General Information

Selected information on the active substance, tefluthrin, relevant for the aquatic environment is presented in this chapter. Registration information and risk assessments referred to are:

EFSA (2006) Draft Assessment Report - Tefluthrin. RMS: Germany, 1-9.

EFSA (2010) Conclusion on pesticide peer review: Conclusion on the peer review of the pesticide risk assessment of the active substance tefluthrin. EFSA Journal 8(12), 1709EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco
Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the review of the existing maximum residue levels for tefluthrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5995, 72 pp.
https://doi.org/10.2903/j.efsa.2020.5995

RIVM (Rijksinstituut voor Volksgezondheid en Milieu), Smit, CE, Keijzers, R, 2022. Risicogrenzen voor gewasbeschermingsmiddelen in oppervlaktewater.RIVM 2023. DOI 10.21945/RIVM-2022-0210

US EPA (United States Environmental Protection Agency), 2010. Housenger, J, Meléndez, JL.Environmental Fate and Ecological Risk Assessment for the Proposed New Use of Tefluthrin on Sugar Beets as a Seed Treatment.

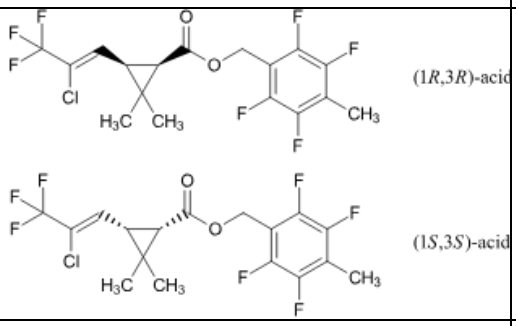
1.1 Identity and physico-chemical properties

Tefluthrin (CAS 79538-32-2, EC/List number 616-699-6) (IUPAC: 2,3,5,6-tetraluoro-4-methylbenzyl (1*RS*, 3*RS*)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate) is an insecticide that is comprised of a racemic mixture of *Z*-(1*R*,3*R*) and *Z*-(1*S*,3*S*) enantiomers. The currently available EFSA conclusion from 2010 identifies the lack of study data on the isomers as a data gap, including both the biological activity and degradation rates. For aquatic species, the EFSA conclusion (2010) does not anticipate this to be an issue because it is expected that the margins of safety in the risk assessment are large enough that the uncertainty regarding isomer-specific toxicity will not change the conclusion. Tefluthrin has a high log P_{ow} and a relatively high vapor pressure and Henry's constant, which means it is volatile and highly likely to adsorb to particulate matter. These physical chemical parameters will impact the availability for tefluthrin for aquatic organisms and could impact its behavior in sediments and soils, as well.

Table 1 summarizes identity and physical-chemical parameters for tefluthrin required for EQS derivation according to the EU TGD for EQS (EC 2018a). When not identified, no indication is available in the cited literature. Test methods are indicated in brackets when available in the cited document.

Table 1 Information required for EQS derivation according to the EU TGD for EQS (EC 2018a).

Characteristics	Values	References
Common name	Tefluthrin	
IUPAC name	2,3,5,6-tetrafluoro-4-methylbenzyl (1 *RS,*3*RS)*-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate or	EFSA DAR 2006

	2,3,5,6-tetrafluoro-4-methylbenzyl (1 *RS*)-cis-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethylcyclopropanecarboxylate	
Chemical group	Pyrethroid	EFSA DAR 2006
Structural formula		EFSA DAR 2006
Molecular formula	$C_{17}H_{14}ClF_7O_2$	EFSA DAR 2006
CAS	79538-32-2	EFSA DAR 2006
EC Number	616-699-6	
SMILES code	C(Cl)(C(F)(F)F)=CC1C(C)(C)C1C(=O)OCc2c(F)c(F)c(C)c(F)c2F	INERIS
Molecular weight [g/mol]	418.7 g/mol	EFSA DAR 2006
Melting point [°C]	44.6°C	EFSA 2010
Boiling point [°C]	156°C at 1 mm Hg	EFSA 2010
Vapour pressure [Pa]	8.4×10^{-3} Pa at 20 °C 2.1×10^{-2} Pa at 30 °C 5.1×10^{-2} Pa at 40 °C	EFSA 2010
Henry's law constant [$Pa \cdot m^3 \cdot mol^{-1}$]	2×10^2 Pa m^3 mol^{-1} at 20 °C	EFSA 2010
Water solubility [$mg \cdot l^{-1}$]	0.016 mg/L at 20 °C (purified water) 0.015 mg/L at 20 °C (pH 5) 0.016 mg/L at 20 °C (pH 9)	EFSA 2010
Dissociation constant (pK_a)	Considered not relevant	EFSA 2010
Octanol-water partition coefficient (log K_{ow})	(1) 6.4 at 20 °C (2) 6.5 at 20 °C (3) 6.5	(1) EFSA 2010 (2) US EPA 2010 (3) INERIS
Sediment/soil-water partition coefficient (K_{oc} or K_{foc} or K_p) (experimental values)	(1) Soil Kfoc: 46000-36x105 L/kg (Immobile) Soil Kfoc: 574088 L/kg (arithmetic mean, n = 8) (arithmetic mean OC%: 1.65) log Koc: 5.05 (Koc: 112500 (1.6% OC)) log Koc: 5.04 (Koc: 109000 (0.7% OC)) log Koc: 5.00 (Koc: 99500 (0.9% OC)) log Koc: 5.43 (Koc: 267000 (0.4% OC)) log Koc: 4.83 (Koc: 68000 (1.7% OC)) log Koc: 5.23 (Koc: 170000 (0.3% OC)) log Koc: 4.72 (Koc: 52700 (2.5% OC)) log Koc: 4.38 (Koc: 24200 (5.1% OC)) log Koc, est. derived from the log Kow (6.4): 3.65, Koc: 4472	(1) EFSA 2010 log Koc, est. = 0.49*log Kow+1.05 based on the equation for esters in the TGD EC (2018a)

	Soil Koc: 91240 L/kg (geomean, n=8, without estimated Koc) Soil Koc:65263 (geomean, n=9, with estimated Koc) (2) Koc: 150,000 L/kga (3) Soil Kfoc: 250,000 L/kgoc	 (2) INERIS (3) US EPA 2010
Sediment adsorption coefficient (K_d [l/kg])	Sandy Clay Loam: 1800-3200 Silt: 800-2400 England Sandy Loam: 720-1600 North Carolina Sandy Loam: 800-2100 (Analysis performed above solubility limit)	US EPA 2010
Aqueous hydrolysis DT_{50}	pH 5-7: stable at 20 °C pH 9: DT50 > 30 d pH 9: 28% hydrolyzed after 30 d (25 °C)	EFSA 2010 US EPA 2010
Aqueous photolysis DT_{50}	1000 d (stable)	US EPA 2010
Photolysis DT_{50}	11.2 d	EFSA 2010
Biodegradation in aqueous environment DT_{50} [d]	Not readily biodegradable 0.8 (geometric mean)[b]	EFSA 2010
Biodegradation in sediment DT_{50} [d]	133 (geometric mean): sediment 78 (geometric mean): whole system	EFSA 2010
Biodegradation in soil DT_{50} [d]	Single first order (SFO) laboratory: 13-63 days (20 °C pF 2 soil mixture)	EFSA 2010

[a]Value was listed as experimentally derived but no method was cited, so it is not used for calculations.
[b]DT_{50} was derived in a water/sediment study for the water compartment; this result is for the dissipation/degradation half-life.

1.2 Regulatory context and environmental limits

Table 2 summarizes existing regulation and environmental limits in Switzerland and other European countries for tefluthrin. Existing PNEC/Environmental quality standards are listed in Table 3. Please note that the information provided in Table 2 and 3 may have changed since finalization of this dossier.

Table 2 Existing regulation and environmental limits for Tefluthrin in Switzerland and Europe.

Europe	
REACH	Authorized Annex III: criteria for 1-10 ton registered substances
ECHA Classification and Labelling	Acute Toxicity Hazard Category 2 (H300) Acute Toxicity Hazard Category 2 (H310) Acute Toxicity Hazard Category 1 (H330) Aquatic Acute Hazard Category 1 (H400) Aquatic Chronic Hazard Category 1 (H410) Labelling: very toxic to aquatic life with long lasting effects
Switzerland	

SR 817.02 Lebensmittel- und Gebrauchsgegenständeverordnung (LGV)	Not listed.
PSMV	Authorized 01.07.2011

Table 3 PNEC/quality standards available from authorities and reported in the literature.

Description	Value [µg/L]	Development method	References
i-JG-MKN$_{ZOET}$	0.0004	Indicative annual average environmental quality standard for surface fresh water	Smit and Keijzers 2022
i-MAC-MKN$_{ZOET, eco}$	0.0053	Indicative maximum acceptable concentration for surface fresh water, based on ecotoxicity	Smit and Keijzers 2022

1.3 Use and emissions

The insecticide tefluthrin is registered for restricted use in soil and seed treatments, with the representative formulation used for regulatory purposes being Force 20 CS. In the United States of America (USA), tefluthrin can be used as a granular formulation and a seed treatment and is authorized for agricultural use to control insects in and on corn crops, while in the European Union (EU) it is authorized for use as either a seed or soil treatment. Its registration in Canada was also renewed as of 2020 by Health Canada's Pest Management Regulatory Agency. Tefluthrin is registered as a seed treatment to be used for the protection of early season seedlings against injury from a variety of insects, including springtails (*Collembola*), symphylids, symphylans, and millipedes (*Diplopoda*); pygmy beetle (*Atomaria linearis*); fire ants (*Solenopsis Invicta*); rootworms (*Chrysomelidae*), wireworms, and white grubs. Usage is mainly with corn and sugar beet seeds, and it is not systemically active in plants, however, it is active as an insecticide through oral or direct contact (H. Wang, Xu, and Li 2023). It has been found in surface runoff waters 1 week after planting at levels of 100 – 640 ng/L and has been detected in soil (X. Wang et al. 2022), runoff water and runoff sediment during the growing season for corn (Whiting et al. 2014).

1.4 Mode of action

Tefluthrin is an insecticide and Type I pyrethroid that induces neural dysfunction, paralysis, and death (X. Wang et al. 2022). The pyrethroid mode of action is to target voltage-sensitive sodium ion channels altering the ion flow kinetics by disrupting the sodium permeability and thus impairing nerve function. This disruption to sodium permeability specifically occurs in the neuronal membrane which is necessary for the rising phase of nerve action potential (Ahamad and Kumar 2023). Pyrethroids are neurotoxic for insects, including honeybees, and mammals. Type I pyrethroids do not have an α-cyano group while Type II pyrethroids do and this difference contributes to the differences observed in their toxicity; Type II pyrethroids are more potent neurotoxicants than Type I.

Pyrethroids have pronounced toxicity to aquatic organisms. For tefluthrin this includes toxicity to fish, aquatic invertebrates, algae, and plants (EFSA 2010). Toxicity was also observed in chronic aquatic studies at three trophic levels (algae, daphnia, and fish).

According to the EFSA conclusion from 2010, genotoxicity and carcinogenicity were not observed in mammalian studies, however, several other indicators of toxicity were identified. Notably, there were impacts in acute toxicity, developmental toxicity, neurotoxicity, and reproductive toxicity studies. In mammalian studies there were effects on body weight, behavior, abnormal neurological symptoms, reduced litter weight, neurological symptoms, and clinical signs of acute neurotoxicity as

well as developmental malformations (EFSA 2010). These studies were done with a racemic mix of tefluthrin isomers and individual isomers were not tested at the time of the 2010 submission. Endocrine activity in aquatic organisms was also not assessed at the time of submission but was identified as a data gap based on the EC 2018b guidance document for the assessment of endocrine disruption in non-target species.

In a fact sheet on endocrine disruptors (Bundesamt für Gesundheit 2019), the authors, a group of experts of Swiss BAG, BAFU, BLV, BLW, SECO, Swissmedic and Suva, refer to the WHO definition (Damstra *et al.* 2002) adapted from EC/Weybridge UK (1996):

"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."

According to the ED criteria as defined in Commission Regulation (EU) 2018/605 of 19 April 2018 (EC 2018b) and referred to in ECHA/EFSA/JRC *et al.* (2018),

"a substance shall be considered as having ED properties if it meets all of the following criteria:

a. it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population* that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

b. it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

c. the adverse effect is a consequence of the endocrine mode of action."

The EFSA "Guidance for the identification of endocrine disruptors […]" specifies that "It should be highlighted that the 'endocrine mode of action' as stated in point (b) should be interpreted as 'endocrine activity' while the term 'endocrine mode of action' in point (c) covers the link between the adverse effect and the endocrine activity identified in points a) and b), respectively." (ECHA/EFSA/JRC *et al.* 2018)

The Annex I Renewal (AIR) submission for tefluthrin will cover the potential for it to act as an endocrine disruptor based on the new regulation which went into effect in 2018. With the identification of the thyroid as a target organ in dogs from the 2010 EFSA conclusion and the observed reproductive toxicity, the evaluation of its potential to behave as an ED in the environment is necessary.

2 Environmental fate

2.1 Stability and degradation products

Currently, data are not available on the stability of individual tefluthrin enantiomers in the environment. Tefluthrin (racemic mix), does not hydrolyze at pH 5 and 7 (20 °C), while at pH 9 there is a DT_{50} > 30 d with the formation of 34.6% of the metabolite compound Ia (PP890, or R119890, or 1R,3R; (1S,3S)-3-((Z)-2-chloro-3,3,3-trifluoroprop-1-enyl)-2,2-dimethylcyclopropane-carboxylic acid) and 21.4% of the metabolite compound II (2,3,5,6-tetrafluoro-4-methylbenzyl alcohol).

In soil studies with the granular formation, a maximum of 7.1% of the applied parent compound formed one minor non-transient metabolite (compound Ia), which showed low to moderate persistence in soil. The parent compound, however, had a DT_{50} of 151 days in soil when applied as a granular formulation compared to 7-63 days when used as a solution formulation.

Aqueous photolysis is also not expected but up to 37.2% of applied tefluthrin can undergo isomerization to *trans*-tefluthrin (2,3,5,6-tetrafluoro-4-methylbenzyl (1R,3S;1S,3R)-3-[(Z)-2-chloro-3,3,3-trifluoroprop-1-enyl]-2,2-dimethyl cyclopropanecarboxylate) after 31 days of irradiation in pure water, however, as a seed treatment this is expected to be irrelevant. *Trans*-tefluthrin is considered a concern because of its structural similarity to the parent compound, and therefore total residues of the two compounds are persistent.

The DT_{50} of tefluthrin in water/sediment is 82 d and it is not considered to be readily biodegradable (EFSA 2010). For dark aerobic natural water systems, tefluthrin partitions predominantly to the sediment (maximum 91%), with the metabolite compound Ia found at up to 22% in the water phase and 7% in the sediment, based on applied radioactivity (EFSA 2010). Another metabolite, compound IV (2,3,5,6-tetrafluoroterephthalic acid), reached a maximum of 22.6% at 5°C compared to 7% at 20°C. There are limitations to the water/sediment degradation studies for need to be verified, however, because of potential losses to glassware sorption and volatilization. Tefluthrin is not classified as a persistent, bioaccumulative and toxic (PBT) compound and is not listed as a Candidate for Substitution (CfS) but further investigations are warranted (Smit and Keijzers 2022).

2.2 Bioavailability

Bioavailability is a complex process which depends on many factors including the sorption capacity of the dissolved organic carbon (DOC) in the water phase and of the sediment in the water-sediment system (e.g. OC content), the hydrophobicity of the compound, and the physiology, feeding behavior and activity of the organism considered (Warren *et al.* 2003).

As stated in the EU TGD for EQS, total and dissolved concentrations of very hydrophobic substances with Kp values above 10000 L/kg or K_{oc} values for linear partitioning into amorphous organic matter above 100000 L/kg, may differ. Thus, for compounds with log $K_p < 4$ (or, if this value is not available, log $K_{ow} < 6$, the $EQS_{water, total}$ is equivalent to the $EQS_{water,dissolved}$ (EC 2018a).

With a log K_{ow} of 6.4 and a K_{oc} of 65263 L/kg (geomean), it is expected that tefluthrin will absorb strongly to sediment and soil. According to the RIVM 2022 report, the dissolved and total concentrations of tefluthrin differ in aqueous studies, which is expected to be due to the loss to sorption processes, and means the $EQS_{water, total}$ will differ from the $EQS_{water, dissolved}$. Due to the strong sorption potential of tefluthrin with sediment, it is also recommended to consider alternative monitoring techniques including passive sampling and effect-oriented monitoring.

2.3 Bioaccumulation and biomagnification

In the following, the term “bioconcentration factor (BCF)” is used for values obtained in water-only exposure studies or exposure studies with uncontaminated food, whereas “bioaccumulation factor (BAF)” is used to refer to values from studies including a (potentially) contaminated food source.

The log K_{ow} for tefluthrin is 6.4, which triggered the need for a BCF study in fish. The subsequent study resulted in a BCF value of 1400 for whole fish and a clearance time (CT_{50}) of 14 days. After the 14 d depuration period, 47% of the total ^{14}C remained and 14% remained after 65 d (2.4 µg/kg fish) (EFSA 2010, Hamer et al. 1987). Since the BCF is ≥ 100, secondary poisoning needs to be evaluated.

In the fish full life cycle study submitted in the DAR (2006), bioconcentration of tefluthrin was also measured in adult fish and larva resulting in mean BCF values (whole fish) of 4180 and 13800, respectively. In this study, however, several points deviate from the guideline for BCF assessments which is why these BCF values were not considered. Deviations included the study duration, which was 300 days of exposure instead of the recommended 28 days, the lack of a depuration stage, the lack of lipid measurements for normalization, and the fact that maternal transfer is not considered in a BCF study. Additionally, adverse effects were observed in the fish at two of the four tefluthrin test concentrations.

The proposed residue definition in all plant commodities is at the limit of quantitation (LOQ) of 0.01 mg/kg (X. Wang et al. 2022). Foods with high oil content and acidic commodities, however, still need a validated interlaboratory study to confirm the LOQ levels for these instances (EFSA 2015). In the review of the existing MRLs for tefluthrin from (Anastassiadou et al. 2020), the available data were considered sufficient for deriving tentative values in all crops except sweet peppers, cucumbers, pumpkins, broccoli, cauliflowers, brussels sprouts, head cabbages, Chinese cabbages, kales, beans with and without pods, peas with and without pods, leeks and asparagus. EFSA proposes to include the tefluthrin metabolites Ia, IV, VI (2,3,5,6-tetrafluoro-4-hydroxymethyl benzoic acid), and XI (3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2-hydroxymethyl-2-methyl cyclopropanecarboxylic acid) in the residue definition, as well, since they are present.

No studies on biomagnification in terrestrial food chains or in fish eating mammals were submitted because tefluthrin is expected to partition directly into sediment and soil, therefore, despite the observed BCF > 100, magnification wasn't expected. Bioaccumulation may occur in benthic organisms, however, because of the strong partitioning of tefluthrin to soils.

3 Analytics

At the time of the EFSA conclusion in 2010 a validated method for tefluthrin in water was missing and identified as a data gap. Additionally, an analytical method for R and S enantiomers in water was not included at the time of the EFSA 2010 conclusion, but is currently available, and this is needed particularly for degradation and bioconcentration studies. Due to its strong affinity for organic matter, it is also expected that it will partition quickly to sediment and that the development of passive sampling methods would be necessary (RIVM 2022).

Table 4 Methods for Tefluthrin analysis and corresponding limits of detection (LOD) and limits of quantification (LOQ) (µg/L). n. a. means not reported.

LOD	LOQ	Analytical method	Reference
n.a.	$1x10^5$ ng/kg (soil)	GC-MS	EFSA 2010
n.a.	0.2 ng/L (water)	GC-MS	EFSA 2010
0.0006 ng/L (natural surface water)	0.018 ng/L (natural surface water)	Estimated SPME with GC-MS[a]	Koch et al. 2021
n.a.	0.050 ng/L (water)	GC-MS/MS	Moschet et al. 2019
n.a.	0.0125 ng/L (natural	GC-APCI-MS/MS	Rösch et al. 2019

	surface water)		
n.a.	0.005-0.05 ng/L (natural surface water)	LLE-GC-MS/MS	Daouk et al. 2022

[a]The estimated value is based on a calculated extrapolation of the signal to noise response measured directly from the calibration standard in 18 mL of blended water.

4 Effect data

A literature search was performed using Scopus on April 12, 2024 in the date range 2010-2024 which covers the period since the most recent EFSA Conclusion in 2010. The search terms included tefluthrin and ecotoxicity, ecotoxicology, and aquatic organisms, with 24, 131 and 53 hits, respectively. Once reviewed, there was only 1 relevant article for aquatic organisms.

In this study, the impacts on zebrafish embryos of a tefluthrin racemic mix and each enantiomer were evaluated at 6 hours post fertilization, 3 days post fertilization and 90 days post fertilization after 96h of exposure (Wang, Xu and Li, 2023). Enantiomeric specific measurements were done using UPLC-MS/MS and endpoints were reported based on measured values of spike solutions. The racemic mix resulted in LC_{50} values in zebrafish of 3.57 µg/L (embryo), 3.43 µg/L (larvae), and 4.07 µg/L (adult). (1R,3R)-tefluthrin was found to be more potent than (1S,3S)-tefluthrin or the racemic mix for both hatching rate and mortality but values were higher than those reported in the DAR or EFSA Conclusions. The study used Milli-Q purified water with methanol, so specific losses to organic matter weren't evaluated and the study wasn't considered reliable.

A critical aspect of studies used in the EQS derivation is the appropriate consideration of physical chemical properties and analytical measurements. Consideration of K_{oc} and K_{ow} values, as well as measurement of parent compounds, is necessary for determining study reliability. Without accurate measurements of the compound that account for potential losses to organic carbon in the system, it is impossible to determine a reliable biological endpoint, so studies that do not have analytical measurements were not used for this assessment. Additionally, studies that used concentrations above the solubility limit of tefluthrin in water (16 µg/L) should be excluded from consideration. Tefluthrin is also relatively volatile so losses from water to the gas phase are expected but adsorption to particulate matter is likely stronger.

Only reliable and relevant data should be used for EQS derivation (EC 2018a). These data are often referred to as "valid". Different approaches to assessment and classification of (eco)toxicological data have been published. An established method introduced by Klimisch *et al.* (1997) uses four levels of validity: (1) reliable, (2) reliable with restrictions, (3) not reliable, (4) not assessable. The CRED approach published by (Moermond *et al.* 2016) is based on a similar classification scheme but additionally takes into account the relevance of test results for the derivation of quality standards. Both methods are recommended in the EU TGD for EQS (EC 2018a).

Studies considered as acceptable in the EU DAR were adopted as valid/Klimisch 1 without additional assessment (face value). The US EPA Office of Pesticide Programs (OPP) Pesticide Ecotoxicity Database contains effect data that have been rated as "C" (core") or "S" (supportive) with "C"-rated studies usually being used for risk assessments by the US EPA. "S"-rated studies may be used following careful

assessment in case of lack of a "C" rated study (US EPA 2004)[1]. This classification has been adopted with "C"-rated studies being used in the same manner as Klimisch 1-rated studies and "S"-rated studies as supportive data.

Studies on formulations are considered as irrelevant due to potential effects of unknown co-formulants but are listed in Appendix 1 for comparison with active substance data. When selecting effect concentrations from algae growth inhibition tests, growth rate is preferred over growth, biomass, and cell density according to (EC 2018a), therefore values other than growth rate are in grey in Table 5. Values not deemed relevant and/or reliable for this EQS derivation are in grey.

[1] [Seite 33]: […] In some instances, a core study may not be available for a particular data requirement listed in 40 CFR 158. In this case, the risk assessment team may consider other sources of information to address the data gap (e.g., submitted studies considered to be supplemental and data from other sources not submitted as part of fulfillment of 40 CFR 158). If supplemental or non-guideline study data are available to address the type of information described by the associated guideline, then it may be used in the risk assessment after its use is carefully considered. Professional judgment is used by the risk assessment team to determine the utility of the available supplemental data for the proposed risk assessment […].

Table 5 Aquatic effect data collection for tefluthrin in µg/L. Data were evaluated for relevance and reliability according to the CRED criteria (Moermond *et al.* 2016) in case they had not been previously evaluated. Data assessed as not relevant and/or not reliable is in grey font. Data used for QS derivation is underlined. Abbreviations: n. a. = not available.

Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Validity	Reference
Acute freshwater											
Algae	*Raphidocelis subcapitata*	Biomass	96 h	EbC50	>	1050	mm	S	93	1	EFSA DAR 2006, Vol. 3 B9 p. 386
Algae	*Raphidocelis subcapitata*	Growth rate	96 h	ErC50	>	1050	mm	S	93	1	
Crustaceans	*Daphnia magna*	Immobilisation	48 h	EC50	=	0.07	mm	S	98.3	1	EFSA DAR 2006, Vol. 3 B9 p. 375
Crustaceans	*Daphnia magna*	Immobilisation	48 h	EC50	=	0.064	mm	S	99.1	1	EFSA DAR 2006, Vol. 3 B9 p. 376
Crustaceans	*Daphnia magna*	Immobilisation (geometric mean of 0.07 and 0.064 µg/L)	48 h	EC50	=	0.067					
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	LC50	=	70.8	mm – bs	S	95.5	C	US EPA MRID: 49658901
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	NOAEC	=	42	mm – bs	S	95.5	C	
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	LC50	=	2.23	mm – OCS	S	95.5	C	
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	NOAEC	=	1.3	mm – OCS	S	95.5	C	
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	LC50	=	0.552	mm – pw	S	95.5	C	
Crustaceans	*Leptocheirus plumulosus*	Mortality	10 d	NOAEC	=	0.32	mm – pw	S	95.5	C	

Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Validity	Reference
Insects	*Chironomus riparius*	Mortality	48 h	EC50	=	2.5	mm	S	91.9	1	EFSA 2010 p.55
Fish	*Oncorhynchus mykiss*	Mortality	96 h	LC50	=	0.06	mm	T	90.4	1	EFSA DAR 2006, Vol. 3 B9 p. 359
Fish	*Lepomis macrochirus*	Mortality	96 h	LC50	=	0.13	mm	T	90.4	1	EFSA DAR 2006, Vol. 3 B9 p. 358
Fish	*Cyprinus carpio*	Mortality	96 h	LC50	=	0.102	mm	T	95	1	EFSA DAR 2006, Vol. 3 B9 p. 360
Acute marine water											
Crustaceans	*Americamysis bahia*	Mortality	96 h	LC50	=	0.053	mm	T	98.5	1	EFSA DAR 2006, Vol. 3 B9 p. 377
Molluscs	*Crassostrea gigas*	Mortality	48 h	LC50	>	0.7	mm	S	93	1	EFSA DAR 2006, Vol. 3 B9 p. 378
Fish	*Cyprinodon variegatus*	Mortality	96 h	LC50	=	0.13	mm	T	94.4	1	EFSA DAR 2006, Vol. 3 B9 p. 361
Chronic freshwater											
Algae	*Raphidocelis subcapitata*	Biomass	96 h	NOEbC	<	110	mmi	S	93	1	EFSA DAR 2006, Vol. 3 B9 p. 386
Algae	*Raphidocelis subcapitata*	Growth rate	96 h	NOErC	<	110	mmi	S	93	1	
Crustaceans	*Daphnia magna*	Reproduction	21 d	NOEC	=	0.00792	mm	T	>95	1	EFSA DAR 2006, Vol. 3 B9 p. 383
Crustaceans	*Daphnia magna*	Reproduction	21 d	NOEC	=	0.0083	mm	T	99.7	2 (EFSA: only supporting)	EFSA DAR 2006, Vol. 3 B9 p. 381

Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Validity	Reference
Fish	*Pimephales promelas*	Mortality	28 d	NOEC	=	0.0096	mm	T	94.4-95	1	EFSA DAR 2006, Vol. 3 B9 p. 368
Fish	*Pimephales promelas*	Mortality	345 d	NOEC	=	0.00397	mm	T	99	1	EFSA DAR 2006, Vol. 3 B9 p. 370
Chronic marine											
Crustaceans	*Americamysis bahia*	male survival (day 28)	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	USEPA (2017)
Crustaceans	*Americamysis bahia*	female survival (day 28)	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	post-pairing survival	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	28-day survival	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	% of females producing young	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	offspring per female	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	male length	28 d	NOAEC	=	0.0023	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	female length	28 d	NOAEC	=	0.0023	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	male dry weight	28 d	NOAEC	=	0.0023	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	female dry weight	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	F1 survival (96 hours)	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	male survival (day 28)	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	female survival (day 28)	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	post-pairing survival	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	

Group	Species	Endpoint	Duration	Parameter		Value (µg/L)	Analytics	Exposure	Purity (%)	Validity	
Crustaceans	*Americamysis bahia*	28-day survival	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	% of females producing young	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	offspring per female	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	male length	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	female length	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	male dry weight	28 d	NOAEC	=	0.0042	m-twa	T	95.5	C	
crustaceans	*Americamysis bahia*	female dry weight	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	F1 survival (96 hours)	28 d	NOAEC	>	0.0042	m-twa	T	95.5	C	
Crustaceans	*Americamysis bahia*	reproduction	28 d	NOEC	=	0.0124	mm	T	98.5	2 (EFSA: only supporting)	EFSA DAR 2006, Vol. 3 B9 p. 384

Legend

Chemical analytics
M based on measured concentrationsmm based on mean measured concentrations
mm-pw based on mean measured values in the pore water
mm-bs based on mean measured values in bulk sediment
mm-OCS based on mean measured values in OC-normalized sediment
mmi based in initial mean measured values
m-twa: based on measured concentrations («time-weighted average»)
Exposure
S static
R semi-static
T flow-through
ws water-sediment study
LE entire larvae development
Purity
ag analytical grade
tg technical grade

4.1 Graphic representation of effect data

All available data have been plotted independently of their relevance and reliability (Figure 1).

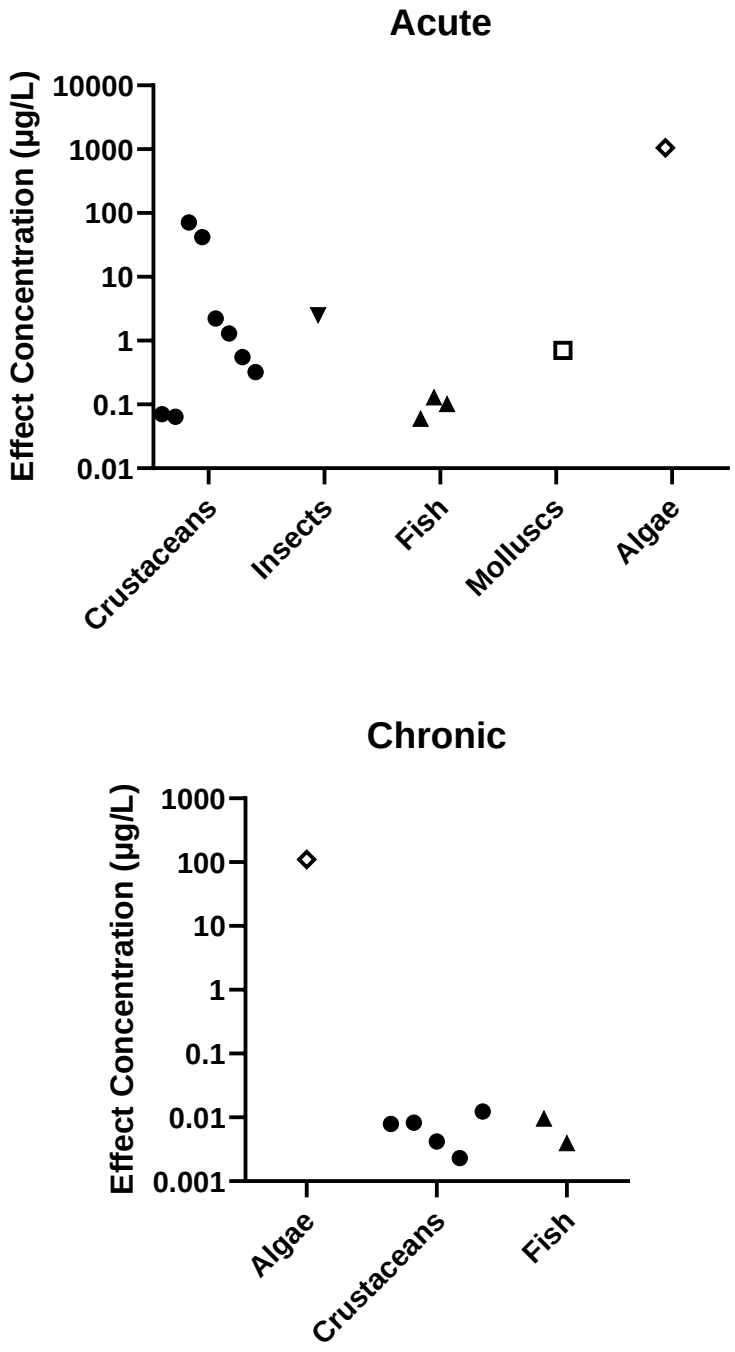


Figure 1 Graphical representation of acute and chronic effect data from aquatic toxicity tests with tefluthrin. Data are not normalized for OC. Open symbols represent unbounded data.

4.2 Comparison between marine and freshwater species

As suggested by the EU TGD for EQS (EC 2018a), for statistical comparison of marine and freshwater species, one value per species is selected, all effect data are log-transformed, and the two datasets are

compared for significant differences. For tefluthrin, only three marine studies are available for *Crassostrea gigas* (Pacific oyster), *Americamysis bahia* (Saltwater mysid) and *Cyprinodon variegatus* (sheepshead minnow tested in saltwater), therefore a statistical analysis of the differences is not possible. Notably, the freshwater fish *Lepomis macrochirus* and *Cyprinodon variegatus* both have the same LC50 value and freshwater and marine crustaceans are similarly highly sensitive. Therefore, marine and freshwater data were pooled for the derivation of the EQSs.

5 Chronic toxicity

5.1 Derivation of CQC (AA-EQS) using the Assessment Factor (AF) method

The derivation of a CQC_{AF} ($AA\text{-}EQS_{AF}$) is based on applying an assessment factor (AF) to the lowest credible datum from long-term toxicity tests.

The lowest long-term effect datum available for tefluthrin is the NOEC of 0.0023 µg/L (Table 6) for the growth (length and weight) of *Americamysis bahia.*

Table 6 Most sensitive relevant and reliable chronic data summarized from Table 5.

Group	Species	Duration	Effect concentration	Value [µg/L]	Reference
Basic data					
Algae	*Raphidocelis subcapitata*	96 h	NOEC	<110	EFSA DAR 2006, Volume 3 B9 p.386
Crustaceans	*Americamysis bahia (Saltwater)*	28 d	NOEC	0.0023	US EPA 2017
Fish	*Pimephales promelas*	345 d	NOEC	0.00397	EFSA DAR 2006, Volume 3 B9 p.370

In case of long term effect concentrations (NOEC or EC_{10}) being available for three species representing different living and feeding conditions, the EU TGD for EQS recommends the application of an assessment factor of 10 on the lowest credible datum (Table 3 in EC (2018a)).

For tefluthrin, studies are provided for all necessary species. Therefore, the suggested assessment factor is 10 in accordance with EU TGD for EQS:

$$\mathrm{CQC}_{AF}\ (\mathrm{AA}-\mathrm{EQS}_{AF}) = \frac{lowest\ EC_{10}\ or\ NOEC}{AF}$$

$$\mathrm{CQC}_{AF}\ (\mathrm{AA}-\mathrm{EQS}_{AF}) = \frac{0.0023\ \left(\frac{\mu g}{L}\right)}{10} = 0.23\ \left(\frac{ng}{L}\right)$$

According to the EU TGD for EQS, in case of substantial levels of suspended particulate matter in the test system, the effect concentration is regarded as $c_{test\ water,total}$ and needs to be corrected for OC concentration to yield $c_{water,dissolved}$.

The critical study for the chronic studies of tefluthrin was for *Americamysis bahia*, a saltwater mysid. In that case the total organic carbon was measured twice (1.1 mg/L and 1.2 mg/L) in an artificial seawater over the course of two months during testing. Tefluthrin has a log K_{ow} of 6.4 so losses caused by sorption to organic carbon are expected.

$$c_{water,dissolved} = c_{test\ water,total}\ x\ \frac{1}{1 + K_{oc} x\ TOC_{test\ result} x\ 10^{-6}}$$

$$c_{water,dissolved} = 0.0023\ \frac{\mu g}{L}\ x\ \frac{1}{1 + 65263 \frac{L}{kg} x\ 1.15\ mg/L\ x\ 10^{-6}}$$

The resulting $c_{water,dissolved}$ is 2.1 ng/L based on $c_{test\ water,total}$ of 0.0023 µg/L, maximum values of 1.15 mg/L OC and a K_{oc} of 65263 (geometric mean, see section 9).

Since the OC was measured during the duration of the study the correction for the dissolved concentration of tefluthrin is considered credible.

The application of an AF of 10 to the lowest credible chronic datum results in a **CQC_{AF} ($AA\text{-}EQS_{AF}$) = 0.21 ng/L**.

5.2 Derivation of CQC (AA-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 NOEC/EC_{10}, from different species covering at least eight taxonomic groups (EC (2018a), p. 43).

In this case, not enough data are available for applying the SSD approach.

5.3 Determination of CQC (AA-EQS) according to mesocosm/field data

No field or mesocosm studies that provide effect concentrations are available, thus, no CQC (AA-EQS) based on field data or mesocosm data has been derived.

6 Acute toxicity

6.1 Derivation of AQC (MAC-EQS) using the Assessment Factor (AF) method

The derivation of an AQC_{AF} ($MAC\text{-}EQS_{AF}$) is based on applying an assessment factor (AF) to the lowest credible datum from short-term toxicity tests.

The lowest short-term effect datum available for tefluthrin is the EC_{50} of 0.053 µg/L (Table 5) for the mortality of *Americamysis bahia*.

Table 7 Most sensitive relevant and reliable acute data summarized from Table 5

Group	Species	Duration	Effect concentration	Value [µg/L]	Reference
Basic data					
Algae	*Raphidocelis subcapitata*	96h	ErC50	>1050	EFSA DAR 2006, Volume 3 B9 p. 386
Crustaceans	*Americamysis bahia (Saltwater)*	96h	EC50	0.053	EFSA DAR 2006, Volume 3 B9 p. 377
Fish	*Oncorhynchus mykiss*	96h	LC50	0.06	EFSA DAR 2006, Volume 3 B9 p. 360
Additional data					
Mollusks	*Crassostrea gigas (Saltwater)*	48h	EC50	>0.7	EFSA DAR 2006, Volume 3 B9 p. 378

In case of short term tests being available for three species representing different living and feeding conditions, the EU TGD for EQS recommends the application of an assessment factor of 100 on the lowest credible datum (Table 5 in EC (2018a)). It can be reduced to 10 in case acute toxicity data for different species do not have a higher standard deviation than a factor of 3 in both directions (i.e., if the standard deviation of the log10 transformed L(E)C50 values is < 0.5, an assessment factor of 10 could be applied) or known mode of toxic action and representative species for the most sensitive taxonomic group included in the data set.

Since *Americamysis bahia* can be regarded as a representative species for the most sensitive taxonomic group, an assessment factor of 10 was applied. An additional assessment factor of 2 could be considered as tefluthrin is a racemic mix and the enantiomers have not been measured or individually assessed in the studies, however this is not part of the TGD for EQS derivations.

The suggested assessment factor is thus 10 in accordance with EU TGD for EQS:

$$\mathrm{AQC}_{AF}\ (\mathrm{MAC}-\mathrm{EQS}_{AF}) = \frac{lowest\ LC\ or\ EC_{50}}{AF}$$

$$\mathrm{AQC}_{AF}\ (\mathrm{MAC}-\mathrm{EQS}_{AF}) = \frac{0.053\left(\frac{\mu g}{L}\right)}{10} = 5.3\ \left(\frac{ng}{L}\right)$$

According to the EU TGD for EQS, in case of substantial levels of suspended particulate matter in the test system, the effect concentration is regarded as $c_{test\ water,total}$ and needs to be corrected for OC concentration to yield $c_{water,dissolved}$.

The critical acute toxicity study on *Americamysis bahia* was performed according to ASTM E729-80, however organic carbon content measurements were not presented in the DAR 2006 or EFSA 2010 conclusions. While loss of tefluthrin to sorption to organic carbon is expected to be high, it is not possible to add a correction for this study due to these reporting limitations.

The application of an AF of 10 to the lowest credible acute datum results in an **AQC (MAC-EQS$_{AF}$) = 5.3 ng/L**.

6.2 Derivation of AQC (MAC-EQS) using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 EC_{50}, from different species covering at least eight taxonomic groups (EC (2018a), p. 43).

In this case, not enough data are available for applying the SSD approach.

6.3 Derivation of MAC-EQS according to mesocosm/field data

No field or mesocosm studies that provide effect concentrations of tefluthrin are available, thus, no AQC (MAC-EQS) based on field data or mesocosm data has been derived.

7 Derivation of a biota standard to protect wildlife from secondary poisoning ($QS_{biota, sec\ pois, fw}$)

In the DAR 2006, it was noted that toxicokinetic and metabolism studies with rats showed extensive metabolism and elimination from the body (90% after 48h), indicating that there isn't the potential for bioaccumulation in mammals. Additionally, in fish it was concluded that there will be no exposure to fish based on the proposed use as a seed treatment and due to the high log K_{ow}, and therefore partitioning to soil. While the bioaccumulation potential was shown in the laboratory, biomagnification in the terrestrial food chain from fish-eating mammals was not expected because of the lack of exposure. However, based on the reported BCF (1400) and log K_{ow} (6.4) values for tefluthrin, a $QS_{biota, sec\ pois, fw}$ needs to be derived (see section 2.3).

A relevant food chain for the trophic transfer of tefluthrin in Swiss surface waters would be:

Algae – invertebrate (-fish) – fish/mammal/bird

The EU TGD for EQS states that the "food item that will determine the final value for the quality standard in biota is not only dependent on the energy contents of the food items, but also on the bioaccumulation characteristics of the substance through the food chain." Thus, a "critical food item" needs to be identified based on these properties. For tefluthrin, only one BCF study is available which was done for the bluegill sunfish (*Lepomis macrochirus*) resulting in a value of 1400. Field and laboratory BAF or BMF studies were not identified. Information on the accumulation in aquatic organisms other than fish and, subsequently, on trophic magnification is missing, so the

biomagnification of tefluthrin is assumed and fish were selected as the critical food item. Based on the BCF value, we assume the critical food item is predatory fish.

For the derivation of a $QS_{biota,\ sec\ pois,\ fw}$, BAF should be preferred over BCF in case of biomagnification. If reliable experimental bioaccumulation data are not available, the BAF at upper trophic level might also be estimated by QSAR (EC 2018). The BCFBAF tool of EPISuite (US EPA 2007) suggests a BAF of 5.925x 10^6 L/kg without biotransformation and 938 L/kg including biotransformation rate estimates for the upper trophic level (Table 8). The assumed rate constants are 0.32/d and 0.18/d for 10 g and 100 g fish, respectively. The fish tested in the BCF study cited in the DAR (2006) were 1.5 g at the start of the experiment and required 14 days depuration to reach 50% of the accumulated residues in the whole fish, but biotransformation was not quantified. For the EQS derivation, the estimated BAF values with and without transformation will be used.

Table 8 lists mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning. Effect data for wildlife species was not available, thus, the assessment is limited to laboratory test species. Whenever possible, long-term effect data are to be considered over acute effect data.

For the derivation of a $QS_{biota,\ sec\ pois,\ fw,}$ based on method A, the NOAEL of 0.5 mg/kg/day in dogs is selected. For the normalization of tefluthrin concentration in food to energy content, a standard energy content of 15.1 kJ/g_{dw} and a moisture fraction of 8% are assumed (Table 8, EC 27 (2018)).

$$c_{energy\ normalized}\left[\frac{mg}{kJ}\right] = \frac{0.5\left[\frac{\frac{mg}{kg}}{d}\right]}{15100\frac{kJ}{g}x\ (1-0.08)} = 0.000036\ \text{mg/kJ}$$

The result is an energy content normalized concentration of tefluthrin of 0.000036 mg/kJ.

For normalization of tefluthrin concentration in food to energy content, a standard energy content of 21.0 kJ/g_{dw} and moisture fraction of 73.7 are assumed (see Table 8, EC (2018a)) since the critical food item is fish. In order to convert the derived endpoint to the tefluthrin concentration in the critical food item, fish, the following formula is used:

$$c_{food\ item}\left[\frac{mg}{kg_{ww}}\right] = c_{energy\ nomralized}\left[\frac{mg}{kJ}\right] x\ energy\ content_{food\ item,dw} x\ (1 - moisture\ fraction_{food\ item})$$

$$c_{food\ item}\left[\frac{mg}{kg_{ww}}\right] = 0.000036\ x\ 21000\ x\ (1 - 0.737)$$

$$c_{food\ item}\left[\frac{mg}{kg_{ww}}\right] = 0.199\ \text{mg/kg}_{ww}$$

The resulting tefluthrin concentration in fish is 0.199 mg/kg_{ww}. To calculate the corresponding concentration of tefluthrin in water, the BCF in fish combined with a default BMF of 1 (for substances with a BCF <2000; Table 22, EU TGD for EQS) and the highest and lowest calculated BAF in fish are used (see section 2.3). Assuming a BAF of 5.925 x 10^6 L/kg with biotransformation, and 938 L/kg without biotransformation, and a steady state distribution of tefluthrin between water and organism, the corresponding concentration of tefluthrin in water is:

Table 8 Water concentrations of tefluthrin derived from the concentration in the critical food item

No.	Type [L/kg]	Value	Reference	Corresponding concentration in water [µg/L]
1	BCF x BMF	1400 x 1	DAR 2006	0.142
2	BAF	938	Estimated with EPISuite/BCFBAF, US EPA (2007), with biotransformation	0.212
3	BAF	5.925×10^6	Estimated with EPISuite/BCFBAF, US EPA (2007), without biotransformation	3.36E-5

In the BCF study (DAR 2006), the depuration half-life of tefluthrin in whole-body was 14 days, therefore, assuming no biotransformation (No. 3, Table 8 is not applicable. Experimental values are preferred for an EQS derivation, therefore, No.1 in Table 8 is used.

The suggested assessment factor is thus 10 in accordance with EU TGD for EQS:

$$QS_{\text{biota,sec pois,fw}} = \frac{0.199\ \text{mg/kg}_{\text{ww}}}{10} \text{ or } QS_{\text{biota,sec pois,fw}} = 0.142\ \mu\text{g/L}$$

The application of an AF of 10 to the lowest credible chronic datum results in a **$QS_{\text{Biota, sec pois, fw}}$ = 0.0199 mg/kg_{ww}** or **0.142 µg/L.**

Table 9 Mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning

Species	Exposure	Duration	Endpoint	Effect concentration	Comment	Reference
Acute toxicity to mammals						
Rat	Dietary exposure	14 days	LD_{50} LD_{50}	= 21.8 mg/kg bw (male) = 34.6 mg/kg bw (female)	5 male and 5 female rats per group Dose levels: 10.1, 25.5, 47, 100 mg/kg Single oral doses were administered after fasting 16-20 hours prior 90.4% tefluthrin	EFSA DAR 2006, Volume 3 B6 p. 95
Mouse	Dietary exposure	14 days	LD_{50} LD_{50}	= 45.6 mg/kg bw (male) = 56.5 mg/kg bw (female)	5 male and 5 female mice per group Dose levels: 9.8, 48, 97, and 125 mg/kg Test diets for 14 days 90.4% tefluthrin	EFSA DAR 2006, Volume 3 B6 p. 95
Acute toxicity to birds						
House sparrow (*Passer domesticus*)	Oral toxicity	14 days	LD_{50}	= 267 mg as/kg bw	5 male and 5 female house sparrows per group Dose levels: 26, 78, 233, 700, and 2100 mg/kg bw Single oral doses administered Positive control with two groups of 10 females dosed with either 0.5 or 5 mg carbofuran 95.4% tefluthrin	EFSA DAR 2006, Volume 3 B9 p. 350
Subchronic toxicity to mammals						
Rat	Dietary exposure	90-days	NOEC/NOEL (mortality) NOEC/NOEL (body weight)	= 350 ppm tefluthrin (male and female), daily dietary dose: 31.8 mg/kg bw/day = 150 ppm tefluthrin (male and female), daily dietary dose: 13.6 mg/kg bw/day	20 males and 20 female rats per group Dose levels: 0 (control), 50, 150, and 350 ppm Test diets for 90 days 90.4% tefluthrin	EFSA DAR 2006, Volume 3 B6 p. 106
Dog	Dietary exposure	90-days	NOAEL	0.5 mg/kg/day	Groups of 4 male and 4 female beagle dogs Dose levels: 0, 0.1, 0.5, or 1.5 mg tefluthrin/kg/day Dietary exposure for 90 days 95.1% w/w tefluthrin	EFSA DAR 2006, Volume 3 B6 p. 109
Subchronic toxicity to birds						
Mallard duck (*Anas platyhynchos*)	Dietary exposure	11 days	LC_{50} LC_{50}	> 2317 mg as/kg diet > 178.6 mg as/kg bw/day	Groups of 10 (20 at 793 mg/kg), nine day old, unsexed mallard ducks Dose levels: 0, 793, 1350, 2320, 4060, 6220, and 11200 mg tefluthrin/kg diet Dietary exposure for 5 days followed by 6 days of untreated diets	EFSA DAR 2006, Volume 3 B9, p. 337

					93% tefluthrin	
Bobwhite quail *(Colinus virginianus*)	Dietary exposure	9 days	LC_{50} NOEC	> 10500 mg/kg diet = 979 mg/kg diet	Groups of 10 juvenile bobwhite quail Dose levels: 0, 503, 915, 1664, 3025, 5500, 10000 mg tefluthrin/kg diet Dietary exposure for 11 day old birds for 5 days followed by untreated diets for 4 days 93% tefluthrin	EFSA DAR 2006, Volume 3 B9, p. 349
Chronic toxicity to mammals						
Rat	Dietary exposure	24 months	NOAEL	= 25 ppm: 1.5 mg/kg bw/day in males = 25 ppm: 1.7 mg/kg bw/day in females	50 male and 50 female mice per group Dose levels: 0, 25, 100, and 400 ppm Test diets fed for 104 weeks 95.1% tefluthrin	EFSA DAR 2006, Volume 3 B6, p. 126
Dog	Dietary exposure	52 weeks	NOAEL	**0.5 mg/kg/day**	Groups of 6 male and 6 female beagle dogs Dose levels: 0, 0.1, 0.5, or 2.0 mg tefluthrin/kg/day Dietary exposure for 1 year 95.1% w/w tefluthrin	EFSA DAR 2006, Volume 3 B6, p. 110
Effects on reproduction in mammals						
Rat	Dietary exposure	Three generation	(parental) NOAEL (pup) NOAEL	 = 50 mg/kg diet = daily dietary dose 4.7 mg/kg bw/day = 15 ppm: 1.4 mg/kg bw/day	15 male and 30 female rats per group Dose levels: 0 (control), 15, 50, 250 ppm tefluthrin Test diets fed continuously throughout the study 95.1% tefluthrin	EFSA DAR 2006, Volume 3 B6, p. 131
Effects on reproduction of birds						
Mallard duck *(Anas platyrhynchos*)	Gavage	20 weeks	NOEC	≥ 25 mg/kg diet (highest dose tested)	5 female and 2 male young adult mallard ducks per group, 6 groups total Dose levels: 0, 5, 25 mg tefluthrin/kg diet Dosed diets fed for 10 weeks prior to egg production, followed by 10 weeks during egg production. Parents were exposed *ad libitum* to treated diets and chicks fed on untreated diets 94.4% tefluthrin	EFSA DAR 2006, Volume 3 B9, p. 342
Bobwhite quail *(Colinus virginianus*)	Gavage	28 d	NOEC NOEL	≥ 25 mg/kg diet ≥ 2.0 mg as/kg bw/day (highest dose tested)	1 female and 1 male bobwhite quail per group, 2 groups total Dose levels: 0, 5, 25 mg tefluthrin/kg diet Dosed diets fed for 10 weeks prior to egg production followed by 10 weeks during egg production. Parents were exposed ad libitum to treated diets and chicks were fed on untreated diet 94.4% tefluthrin	EFSA DAR 2006, Volume 3 B9, p. 344

8 Toxicity of transformation products

Tefluthrin is known to degrade in the environment or be metabolized into several compounds including trans-tefluthrin, compounds Ia, Ib, II, III, IV, and V, VI, XI, and XII. Soil metabolism studies were conducted and included in the EFSA 2006 DAR, however, in which only compound Ia was found at above 5%. Compound III, which is expected to be in the water phase, was also detected as the most abundant metabolite at 2% in aerobic soil metabolism studies.

Two metabolites were tested with aquatic organisms, Compound Ia and Compound III, and showed far lower toxicity than the parent compound (Table 10). As a racemic compound, however, the degradation of the R and S enantiomers was not yet reported and should still be assessed.

Table 10 Metabolite studies with aquatic organisms

Study duration	Duration	Species	Endpoint	Reference
Compound Ia (PP890, OO563, cyhalothrin acid)				
Static	96 h	*Lepomis machrochirus* (bluegill sunfish)	LC_{50} > 17000 µg as/L measured	EFSA DAR 2006, Volume 3 B9, p. 394
Semi-static	96 h	*Oncorhynchus mykiss* (rainbow trout)	LC_{50} > 15800 µg as/L measured	EFSA DAR 2006, Volume 3 B9, p. 394
Static	48 h	*Daphnia magna*	EC_{50} > 120,000 µg as/L nominal	EFSA DAR 2006, Volume 3 B9, p. 380
Static	48 h	*Daphnia magna*	EC_{50} > 182,000 µg as/L nominal	EFSA DAR 2006, Volume 3 B9, p. 380
Compound III (Compound X, 2,3,5,6-tetrafluoro-4-methylbenzoic acid)				
Static	96 h	*Oncorhynchus mykiss* (rainbow trout)	LC_{50} > 100,000 µg as/L nominal	EFSA DAR 2006, Volume 3 B9, p. 394
Static	96 h	*Lepomis machrochirus* (bluegill sunfish)	LC_{50} > 100,000 µg as/L nominal	EFSA DAR 2006, Volume 3 B9, p. 394
Static	48 h	*Daphnia magna*	EC_{50} > 120,000 µg as/L nominal	EFSA DAR 2006, Volume 3 B9, p. 394

The degradation products found at the highest levels, compounds Ia and III, do not pose a risk to aquatic life based on their measured toxicities and are far less toxic than the parent compound.

9 Proposed CQC (AA-EQS) and AQC (MAC-EQS) to protect aquatic species

The different QS values for each derivation method included in the EU TGD for EQS are summarized in Table 11. According to the EU TGD for EQS, the most reliable extrapolation method for each substance should be used (EC 2018a).

For highly hydrophobic compounds the final derived EQS (which is an $EQS_{water,\ dissolved}$) should be corrected using the default concentration of suspended matter (C_{SPM}) and the partition coefficient to suspended matter ($K_{p,susp}$) (EC 2018). As discussed in section 2.2, correction is indicated for tefluthrin according to the following formula:

$$EQS_{water,total} = EQS_{water,dissolved} \times (1 + K_{p,susp} \times C_{SPM} x 10^{-6})$$

$$EQS_{water,total} = EQS_{water,dissolved} \times (1 + \left(6526 \frac{L}{kg}\ x\ 15 \frac{mg}{L} x 10^{-6}\right))$$

The partition coefficient to suspended matter ($K_{p,susp}$) may be estimated as K_{oc} x f_{oc} (organic carbon content of suspended matter), with the standard f_{oc} being 0.1. 15 mg/L is regarded as standard concentration of suspended particulate matter (C_{SPM}) in the EU but may be adapted to local conditions. Available Koc values are listed in Table 1. The corresponding geometric mean is 65263 L/kg. The resulting factor for OC correction is 1.10.

The EQS corrected based on this value as well as standard values for f_{oc} and C_{SPM} are included in Table 11.

Table 11 QS derived according to the three methodologies stipulated in the EU TGD for EQS and their corresponding AF. All concentrations expressed as ng/L.

	$EQS_{water,\ dissolved}$	$EQS_{water,\ total}$ (based on K_{oc})	AF
CQC_{AF} ($AA\text{-}EQS_{AF}$)	0.21	0.23	10
AQC_{AF} ($MAC\text{-}EQS_{AF}$)	5.3	5.8	10
$QS_{Biota,\ sec\ pois,\ fw}$	142	156	10

The $QS_{Biota,\ sec\ pois,\ fw}$ derived is several orders of magnitude higher than the CQC (AA-EQS) value so the potential for secondary poisoning to predators is considered protective.

Since tefluthrin shows a strong tendency to bind to OC and carbon content varies significantly in surface waters, the non-corrected QC values are suggested. It should be noted that the organic carbon content was only measured in the chronic study, however, so the non-corrected QC value is suggested for the $MAC\text{-}EQS_{AF}$.

An **CQC (AA-EQS) of 0.21 ng/L** and a **AQC (MAC-EQS) of 5.3 ng/L for tefluthrin** including the application of an AF of 10 and 10, respectively, are thus suggested.

10 Protection of aquatic organisms and uncertainty analysis

The assessment factor method was used to derive CQC and AQC values based on assessment factors of 10 and 10, respectively. Several limitations exist for the currently available data set. Among them, issues with differences in the purity of the tefluthrin used between ecotoxicology studies, the lack of a validated analysis method for water, the lack of data on enantiomer behavior, and no information on endocrine disruption in aquatic organisms were identified as data gaps.

The derived EQS values are based on aquatic organism data, however, tefluthrin is known to quickly partition into sediment and soil due to its high K_{ow}. Therefore, an additional ad hoc EQS_{sed} derivation has been completed and is added as an Appendix. Additionally, studies to assess the behavior of the tefluthrin enantiomers would be useful.

There were not enough species available to allow for a species-sensitive distribution (SSD) and no mesocosm data was available. The EQS values are above the most recent LOQ (Koch et al. 2021) in surface waters so there should not be any analytical detection issues.

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Appendix I

Aquatic effect data for tefluthrin formulations and metabolites. Please refer to section 4 for additional information.

Formulation/ Comopund	Species	Endpoint	Duration (h)	Parameter		Value	Units	Analytics	Exposure	Reference
Tefluthrin Preparation 300 g/L CS	Oncorhynchus mykiss	mortality	96	EC50	=	330	ng ai/L	nominal	S	(EFSA 2010)
Tefluthrin Preparation 300 g/L CS	Oncorhynchus mykiss	mortality	96	EC50		1200	ng ai/L	nominal	S	
Tefluthrin Preparation 300 g/L CS	Daphnia magna	mortality	48	EC50	=	0.0079	mg/L	measured (mean)	S	
Tefluthrin Preparation 300 g/L CS	Daphnia magna	mortality	48	EC50	=	0.0021	mg/L	measured (mean)	S	
Tefluthrin Preparation 200 g/L CS	Pseudokircheriella subcapitata	biomass	72	EbC50	=	82	mg/L	nominal	S	
Tefluthrin Metabolite Ia (PP890)	Oncorhynchus mykiss	mortality	96	EC50	>	15.8	mg/L	measured (mean)	S	
Tefluthrin Metabolite Ia (PP890)	Daphnia magna	mortality	48	EC50	>	182	mg/L	nominal	S	
Tefluthrin Metabolite Compound III (2,3,5,6-tetrafluoro-4-methyl-benzoic acid)	Oncorhynchus mykiss	mortality	96	EC50	>	100	mg/L	nominal	S	
Tefluthrin Metabolite Compound III (2,3,5,6-tetrafluoro-4-methyl-benzoic acid)	Daphnia magna	mortality	48	EC50	>	120	mg/L	nominal	S	
Tefluthrin 1.5 (Granular formulation)	Oncorhynchus mykiss	mortality	96	LC50	=	8500	ng/L	n.r.	n.r.	(Housenger and Melendez 2010b)
Tefluthrin 1.5 (Granular formulation)	Lepomis macrochirus	mortality	96	LC50	=	8000	ng/L	n.r.	n.r.	(Housenger and Melendez 2010b)

Appendix II

SQC (EQS_{sed}) – Proposal by the Ecotox Centre for: Tefluthrin.

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Summary

SQC (EQS_{sed}): 2.04 µg/kg d.w.

The Ecotox Centre develops proposals for Environmental Quality Criteria for sediment (SQC). SQC are derived applying the methodology described in the EU-Technical Guidance (TGD) for Deriving Environmental Quality Standards (EQS). In order to ensure that the dossiers are internationally comparable, the English terminology of the TGD will be used in the remainder of the dossier. These criteria provide a first screening tool to evaluate sediment chemical quality and the potential risk for the aquatic ecosystem. Based on the scientific literature available at present a preliminary SQC for tefluthrin of 2.04 µg/kg d.w. is proposed for standard sediments with 1 % OC. The SQC derivation has not been submitted to external review and is considered *ad hoc*.

Zusammenfassung

SQK (EQS_{sed}): 2.04 µg/kg TS

Das Oekotoxzentrum Vorschläge für Umweltqualitätskriterien für Sedimente (SQK). Diese Kriterien dienen als Methode für ein erstes Screening zur Bewertung der chemischen Sedimentqualität und des potenziellen Risikos für aquatische Ökosysteme. Auf der Basis von Literaturdaten für die Wirkung von Tefluthrin und unter Verwendung der Methode, die in der Technischen Richtlinie der EU zur Ableitung von Umweltqualitätsnormen beschriebenen wird, schlägt das Oekotoxzentrum einen allgemeines (PRELIMINARY) SQK für Tefluthrin von 2.04 µg/kg TS für Standardsedimente mit 1 % OC vor. The SQK derivation has not be submitted to external review and is considered *ad hoc.*

Résumé

CQS (EQS_{sed}): 2,04 µg/kg p.s.

Le Centre Ecotox élabore des propositions de critères de qualité environnementale pour les sédiments (CQS). Les CQS sont dérivés en appliquant la méthodologie décrite dans le Guide Technique de l'UE (TGD) pour la Dérivation des Normes de Qualité Environnementale (EQS). Afin que les dossiers soient comparables au niveau international, la terminologie anglaise du TGD est utilisée ci-dessous. Ces critères fournissent un premier outil de dépistage pour évaluer la qualité chimique des sédiments et le risque potentiel pour l'écosystème aquatique. Sur la base des données sur les effets existants dans la littérature un CQS préliminaire pour le téfluthrine de 2,04 µg/kg p.s. est proposé pour les sédiments

standards avec 1 % CO. La dérivation du CQS n'a pas fait l'objet d'un examen externe et est considérée comme *ad hoc*.

Sommario

CQS (EQS_{sed}): 2,04 µg/kg p.s.

Il Centro Ecotox sviluppa proposte per i criteri di qualità ambientale per i sedimenti (CQS). I CQS sono derivati applicando la metodologia descritta nella Guida Tecnica dell'UE (TGD) per la Derivazione degli Standard di Qualità Ambientale (EQS). Per garantire che i dossier siano comparabili a livello internazionale, viene utilizzata la terminologia inglese del TGD. Questi criteri forniscono un primo strumento di screening per valutare la qualità chimica dei sedimenti e il potenziale rischio per l'ecosistema acquatico. Sulla base della letteratura scientifica disponibile allo stato attuale un CQS preliminare per il treflutrin di 2,04 µg/kg p.s. è proposto per sedimenti standard con 1 % CO. Non essendo stato sottoposto a revisione esterna, il CQS viene considerato *ad hoc*.

1 General Information

Selected information on the active substance, tefluthrin, relevant for the aquatic environment is presented in chapter 1 of the main document. Selected information relevant for sediment is presented below.

1.1 Regulatory context and environmental limits

No regulatory or environmental limits for sediments for tefluthrin have been located (Dutch RIVN, French INERIS, Danish EPA). The only proposal of environmental limit for sediments is published in Nowell et al. (2016) of 0.29 µg/g-oc or 14.5 µg/kg for a standard sediment of 5% OC. This value is derived from a 10/14d spiked sediment EC/LC50 for the amphipod *Hyalella azteca* and an acute-to-chronic extrapolation factor of 10.

2 Environmental fate

2.1 Sorption/desorption processes

Tefluthrin has shown to deposit rapidly in sediments in water / sediment degradation studies (see section 2.1 main document). In dark aerobic natural water systems, tefluthrin partitions predominantly to the sediment (maximum 91% at day 3) (EFSA 2010). Sediment water partitioning coefficient (K_d) from batch equilibrium studies with freshwater sediments range from 720 to 3200 l/kg (Table 1). Normalized organic carbon water partitioning coefficients (K_{OC}) for soil from batch equilibrium studies range from 15,346 to 267,000 L/kg.

2.2 Bioavailability

No study specifically dealing with tefluthrin bioavailability in sediments could be located.

The scientific opinion of the EFSA on the effect assessment for pesticides on sediment organisms recognizes that "*the most appropriate metric for bioavailability in soils and sediments appears to be the 'freely dissolved pore water concentration' rather than the total sediment concentration, particularly for compounds with a log K_{OW} < 5*" (EFSA 2015). The mechanistic Equilibrium Partitioning model by Di Toro *et al.* (1991) considers the OC content in sediment as being the main driver of bioavailability for non-ionic organic chemicals like tefluthrin. This assumption is based among others on several studies performed with the pyrethroid cypermethrin, where a decrease in bioaccumulation was observed at increasing levels of OC (Muir *et al.* (1985), Maund *et al.* (2002)). Other sediment properties such as particle size may also influence tefluthrin bioavailability from sediments according to results with other pyrethroids (Zhang *et al.* (2018) (You *et al.* 2008), although both adsorption to fine particles and sand can play a controlling role in pyrethroid bioavailability, which in the case of sand is not taken into consideration solely by normalizing for OC. Previous authors have attributed to ingestion the difficulty in modelling bioavailability through the Equilibrium Partitioning, since this exposure route is not taken into consideration.

In conclusion, benthic organisms are likely exposed to tefluthrin through both, aqueous phase (overlying water and pore water) and ingestion. Bioavailability in the aqueous phase seems to be primarily driven by OC content but other binding surfaces might reduce bioavailability as well, in particular at increasing grain sizes.

2.3 Bioaccumulation and biomagnification

Information on the bioaccumulation and biomagnification of tefluthrin for pelagic organisms is summarised in section 2.3. Based on the reported BCF (1400) and log K_{ow} (6.4) values for tefluthrin, a $QS_{biota,\ sec\ pois,\ fw}$ needs to be derived (see section 2.3). To account for protection of top predators, a QS_{water} based on EQS_{biota} has been derived by the Ecotox Centre with a value of 51 ng/l.

No studies on biomagnification in terrestrial food chains or in fish eating mammals were submitted in the DAR (2006) because tefluthrin is expected to partition directly into sediment and soil, therefore, despite the observed BCF > 100, magnification was not expected. Bioaccumulation may occur in benthic organisms, however, because of the strong partitioning of tefluthrin to soils.

Concerning the risk of benthic invertebrates to transfer toxic and bioaccumulative substances to higher trophic levels, the EFSA scientific opinion for sediment risk assessment proposes to perform spiked sediment bioaccumulation tests with benthic invertebrates for substances that show significant bioaccumulation in fish (BCF >2000 l/kg) when the substance (1) is persistent in sediment (DT_{50} >120 d in water-sediment fate studies) and has a log K_{ow} >3; or (2) is non-persistent in sediment, log K_{ow} >3 and >10 % of the substance found in the sediment in a water-sediment fate study (EFSA 2015). The BCF for tefluthrin is below the EFSA threshold thus it is concluded that benthic invertebrates should not contribute significantly to the risk to higher organisms through trophic transfer.

3 Analytics

Tefluthrin can be analyzed together with other pyrethroids using several analytical techniques, with different limits of quantification. Limits of quantification of 0.10 µg/kg d.w. can be achieved for sediments by gas chromatography-ion trap tandem mass spectrometry (MS/MS) after accelerated solvent extraction and solid phase extraction clean-up (You et al. 2010).

Table AII.1 Methods for tefluthrin analysis in sediments and corresponding limits of detection (LOD) and limits of quantification for sediment samples (LOQ) (µg/kg d.w.). n. a. means not reported.

LOD	LOQ	Analytical method	Reference
0.10	n.a.	GC-MS/MS	You et al. (2010)
0.20	n.a.	GC- µEC	Whiting et al. (2014)

4 Environmental concentrations

A non-exhaustive search retrieved very few information on available measured environmental concentrations (MEC) of tefluthrin in sediments. Only one study reported a detection frequency of 16% of 49 urban streams from Northeast US, with average concentration of 0.234 µg/kg d.w. Other studies have targeted tefluthrin but this pyrethroid was never found above the method detection limit. These include sediments from creeks located in the three most urbanized and populated cities in China (Li et al. 2011), suspended sediment collected during storm events from a watershed dominated by agriculture (the San Joaquin River, California and tributaries) (Hladik et al. 2009) and stream sediments of soy production regions of South America (Hunt et al. 2016). None of the studies have addressed specifically corn or sugar beet usage. The study by Whiting et al. (2014) measured concentrations in run-off sediments after rain events throughout three years at a research site in central Illinois using a continuous corn, no-till agricultural system, with tefluthrin application at

planting. Measured concentrations were 294 µg/kg d.w. at the time of emergence vegetative stage of corn, decreasing to 101 µg/kg d.w. at middle vegetative state and then roughly 90 from full development of tassels until physiological maturity at end of corn growing season.

No or limited information is available on the presence of tefluthrin in sediments from Swiss water bodies.

Table AII.2 Measured environmental concentrations (MEC) of tefluthrin in Switzerland and elsewhere. All concentrations expressed as µg/kg d.w. for sediment if not indicated otherwise. n.d. not detected.

Country	MEC (min-max)	Nr sites	Comments	Reference
USA	0.234 (average) 15.2 µg/kg-OC d.w.	49	Urban stream sediment from Northeast US; detection frequency 16%	Huff Hartz et al. 2019
USA	294 (emergence vegetative stage) 101 (middle vegetative state) 91 (tassels fully developed / first reproductive stage) 91 (physiological maturity / end of season)	1	Run-off sediment from corn growing season, measured at three consecutive seasons after application at planting	Whiting et al. 2014

5 Effect data (spiked sediment toxicity tests)

The most recent EFSA Conclusion (2010) lists one toxicity test performed with a benthic organism exposed via spiked sediment (EFSA 2010). This same study is reported in the CLH report Proposal for Harmonised Classification and Labelling (2014) and reference attributed to Pfeifle, Wyeth, Dark (2005; rep. No. RJ3676B). The original study report is not available, but the study is summarised in pp. 131. The study, which was performed following GLP, was assessed as reliable, with restrictions.

A non-filtered bibliographic search was performed for tefluthrin (by CAS number) in the US Ecotox Data Base (U.S. EPA 2022) which yielded 72 entries for aquatic organisms, none on sediment exposure. A search in the German Environmental Office database ETOX did not yield any relevant results. A key word search performed on Scopus (tefluthrin AND sediment) resulted in 99 publications. Once reviewed, only one effect datum was retrieved, cited in Nowell et al. (2016).

Nowell et al. (2016) publication summarizes the derivation of sediment benchmarks for an extensive number of pesticides, including tefluthrin. For tefluthrin, one entry is reported for a LC50 or EC50 from a 9–14 days spiked sediment toxicity test with the amphipod *Hyalella azteca*. The full study report could not be retrieved.

As for surface water (section 4 main document), studies considered as acceptable in the EU DAR were adopted as valid/Klimisch 1 without additional assessment (face value). Nevertheless, an additional evaluation of relevance ("C" score in the table below) and reliability ("R" score in the table below) of all studies was completed to identify potential flaws or inconsistencies according to the CRED-criteria (Casado-Martinez et al. 2024).

According to the (EC 2018a) "*What is considered chronic or acute is very much dependent on 1) the species considered and 2) the studied endpoint and reported criterion*". According to EFSA, true

chronic tests should cover a range of 28-65 d when half-life of a pesticide in sediment is >10 d (EFSA 2015). The 28 d test for *C. riparius* is considered as “chronic” endpoints while effect LC50 and EC50 data from 9-14 d tests with *H. azteca* are considered here as acute. Only long-term endpoints should be considered for sediment EQS derivation thus the acute data for *H. azteca* was not considered for this EQS derivation (in grey).

Table AII.3 Sediment effect data collection for tefluthrin in mg/kg d.w. Data were evaluated for relevance and reliability according to the CRED criteria for sediments (Casado-Martinez et al. 2024). Data assessed as not relevant and not reliable is in grey font. Abbreviations: n. a. = not available.

Group	Species	Test compound	Exposure	Equilibration time	Endpoint	Test duration	Temperature	Effect concentration	Value (mg/kg d.w.)	Sediment type	Normalized value (mg/kg d.w., 1 %OC)	Normalized value (mg/kg d.w., 5 %OC)	Chem. Analysis	Note	Validity	References
Acute toxicity data in freshwater																
Amphipoda	*Hyalella azteca*	n.a.	n.a.	n.a.	n.a.	10 or 14 d	n.a.	EC50 or LC50	2.9 mg/kg-oc	n.a.	0.029	0.145	n.a.		R4/C1	Nowell et al. 2016
Acute toxicity data in marine water																
No data available																
Chronic toxicity data in freshwater																
Insecta	*Chironomus riparius* (First instar)	ASF611C (tefluthrin technical)	n.a.	Two hours mixing, three days of equilibration and then aerated four hours before larvae were introduced	Emergence ratio	28 d	20°C	NOEC	0.47	Artificial Sediment: 4.5 % sphagnum peat (air dried and finely ground), 20 % kaolin clay (kaolinite content >30 %), 75.5 % industrial sand (>50 % of the particles between 50 and 200 µm), Calcium carbonate (to adjust the pH). OC= 2.3 % (determined by wet oxidation), sediment moisture content 41 %	0.2043	1.022	Yes	Measured concentrations at test start (day 0) 84-92 % of the nominal values. At test end (day 28) 78-88 % of the nominal values. NOEC derived from initial measured concentrations.	R2/C1	Pfeifle, V., Wyeth, K., Dark, R. 2005. cited in Study summary in CHL 2014
					Development rate females				1.0		0.4347	2.174				
					Development rate males, females pooled				0.47		0.2043	1.022				

5.1 Graphic representation of effect data

Not enough data for graphic representation is available.

5.2 Comparison between marine and freshwater species

No marine data was available.

5.3 Overview of reliable and relevant long-term studies

According to the EC EQS TGD (EC (2018a) p. 25): "*All available data for any taxonomic group or species should be considered, provided the data meet quality requirements for relevance and reliability*".

The lowest chronic effect data are for *Chironomus riparius* (several endpoints). The study was performed following OECD 218 with nominal concentrations of 0.15, 0.3, 0.6, 1.2 and 2.4 mg ASF611C (tefluthrin technical)/kg dry weight of sediment together with a dilution water and solvent control (acetone). The results were derived from initial measured concentrations, although measured concentrations ranged from 84-92 % of the nominal values. This study was accepted as face value as from the EFSA evaluation (EFSA 2010). According to CLH report (2014), a critical point in the study is the larvae feeding with 0.5 - 1.0 mg Tetramin fish food suspension per larvae per day. Tefluthrin is strongly sorbed to the sediment and a feeding with uncontaminated food reduced the exposition of the animals. The study was also assessed as R2/C1 according to own CRED evaluation.

6 Derivation of QS_{sed}

According to the EU TGD for EQS, sediment toxicity tests, aquatic toxicity tests in conjunction with equilibrium partitioning (EqP) and field/mesocosm studies are used as several lines of evidence to derive QS_{sed} (EC 2018). Thus, in the following, the appropriateness of the deterministic approach (AF-Method), the probabilistic approach (SSD method) and the EqP approach were examined.

6.1 Derivation of $QS_{sed, AF}$ using the Assessment Factor (AF) method

The derivation of $QS_{sed, AF}$ is determined using assessment factors (AFs) applied to the lowest credible datum from long-term toxicity tests.

The lowest chronic effect datum available for tefluthrin is the NOEC of 1.022 mg/kg d.w. (5 % OC) for *C. riparius.*

Table AII.4 Most sensitive relevant and reliable chronic data summarized from Table AII.3.

Group	Species	Duration	Effect concentration	Value [mg/kg d.w.]	OC [%]	Normalised value [mg/kg d.w. 5% OC]
Insects	*Chironomus dilutus*	28d	NOEC	0.47	2.3	1.022

In case of long-term NOECs or EC_{10}s being available for one species the TGD recommends the application of an assessment factor of 100 on the lowest credible datum (Table 11 in EC (2018)).

$$QS_{sed,AF} = \frac{lowest\ EC10\ or\ NOEC}{AF}$$

$$QS_{sed,AF} = \frac{1.022\left(\frac{mg}{kg}\right)}{100} = 0.01022\ \left(\frac{mg}{kg}\right)\ (\frac{mg}{kg} d.w.\ 5\%\ OC)$$

The application of an AF of 100 to the lowest datum results in a $QS_{sed,AF}$ of 10.22 µg/kg d.w. for a standard sediment with 5% OC. This corresponds to 2.044 µg/kg d.w. for a sediment with 1% OC representing a worst case scenario in Switzerland.

6.2 Derivation of $QS_{sed,SSD}$ using the species sensitivity distribution (SSD) method

The minimum data requirements recommended for the application of the SSD approach for EQS water derivation is preferably more than 15, but at least 10 NOEC/EC_{10}, from different species covering at least eight taxonomic groups (EC (2018), p. 43). In this case, not enough data from spiked sediment toxicity tests are available for applying the SSD approach.

7 Derivation of $QS_{sed,EqP}$ using the Equilibrium Partitioning approach

If no reliable sediment toxicity data are available, the Equilibrium Partitioning (EqP) can be used to estimate the $EQS_{sed,EqP}$. This approach, developed for non-ionic substances, is used here for comparison purposes given the small data base of sediment toxicity studies.

7.1 Selection of QS for water

For the derivation of the $EQS_{sed,EqP}$, a PNEC for the aquatic freshwater environment derived with a methodology similar to the procedure described in the TGD for deriving the AA-EQS for freshwater should be used. Here, the AA-EQS of 0.21 ng/L (section 9) is used.

7.2 Selection of partition coefficient

One of the main factors influencing the application of the EqP model is the choice of the partition coefficient. It is stipulated in the ECHA 2017 guideline (p. 143, ECHA (2017)) that "To increase the reliability of PNEC sediment screen derived using the EqP, it is imperative that a conservative but realistic partitioning coefficient (e.g. K_d, K_{oc}, K_{ow}) is chosen. A clear justification must be given for the chosen coefficient and any uncertainty should be described in a transparent way."

The EU TGD for EQS requires deriving a geometric mean of all available K_{oc} values including one derived from a log K_{ow} value (EC 2018). For EqP calculations, experimentally determined values for K_{oc} are preferable. These K_{oc} values may be derived from standardised tests (e.g. OECD Guideline 106) or from other studies published in scientific literature, but those determined by the HPLC method (OECD guideline 121) are only considered as estimates and should not be used as experimental values.

EFSA (2010) reports valid log K_{oc} values for soil for tefluthrin in the range of 4.38-5.23 (Table 1), while no values for sediment or suspended matter could be retrieved that could be used for EQS derivation. Reported experimental log K_{ow} for tefluthrin is 6.4 (Table 1), estimated log K_{oc} is 4.19. The log K_{oc} of 5.71 is used for EQS derivation via EqP, calculated from all experimental log K_{oc} values for soil plus the estimated one.

7.3 Selection of OC content for a reference sediment

To account for the influence of OC content on $QS_{sed,EqP}$ development, calculations have been performed for a standard sediment according to the EU TGD for EQS with 5 % OC (EC 2018). As 5 % OC might not be representative for sediment in Switzerland, calculation was made as well for a worst-case scenario considering measurement on total sediment with 1 % OC (approx. 10^{th} percentile of OC content in Swiss Rivers).

7.4 Derivation of $QS_{sed,EqP}$

For the derivation of $QS_{sed,EqP}$ (Table 8), the partition coefficient between water and sediment has been estimated as the fraction of organic carbon multiplied by organic carbon partition coefficient ($Kp=f_{OC}*K_{OC}$) as proposed by Di Toro *et al.* (1991) for non-ionic organic chemicals. The authors considered that, for sediment with an organic fraction higher than 0.2 %, organic carbon is the main driver for chemical sorption.

An additional AF of 10 should be applied to the resulting $QS_{sed,EqP}$ for substances with log K_{ow} > 5. According to the experimental log K_{ow} > 5 the additional AF of 10 is warranted. The (rounded) $QS_{sed,EqP}$ is **0.016 µg/kg d.w. for 1% OC** or 0.079 µg/kg d.w. for 5% OC.

Table AII.5 Derived $QS_{sed,EqP}$ for a geomean K_{OC} and the CQC (AA-EQS) for water derived by the Ecotox Centre of 0.21 ng/l. The partition coefficient solid-water sediment (Kp_{sed}) is estimated for a sediment with 5 % OC (standard EC TGD sediment) and 1 % TOC (worst case scenario in Switzerland).

	K_{oc} [l/kg]	Kp_{sed} [l/kg]	$K_{sed\text{-}water}$ [m^3/m^3]	$QS_{sed,EqP}$ [µg/kg w.w.]	$QS_{sed,EqP}$ [µg/kg d.w.]	Included AF
1 % OC	74846	748.5	375.0	0.061	**0.0158**	10
5 % OC	74846	3742.3	1872.0	0.302	**0.0786**	10

8 Determination of QS_{sed} according to mesocosm/field data

No field or mesocosm studies that provide effect concentrations of tefluthrin are available on benthic invertebrates or amphibians.

9 Toxicity of degradation products

According to the low toxicity of degradation products on pelagic organisms (section 8 main document) it is expected that they do not represent a risk to benthic species.

10EQS_{sed} proposed to protect benthic species

The different QS values for each derivation method included in the EU TGD for EQS are summarized in Table AII.6. According to the EU TGD for EQS, the most reliable extrapolation method for each substance should be used (EC 2018). In all cases, data from spiked sediment toxicity tests are preferred over the EqP approach. A **EQS_{sed} of 2.04 µg/kg d.w. (1% OC)** is proposed.

Table AII.6 QS_{sed} derived according to the three methodologies stipulated in the EU TGD for EQS and their corresponding AF. All concentrations expressed as µg/kg d.w.

	Sediment 5 % TOC	Sediment 1 % TOC	AF
$QS_{sed,SSD}$	--	--	--
$QS_{sed,EqP}$	0.079	0.016	10
$QS_{sed,AF}$	10.2	2.04	100
Proposed EQS_{sed}	**10.2**	**2.04**	

11Protection of benthic organisms and uncertainty analysis

According to the high AF applied the proposed EQS_{sed} is considered preliminary. Additional long-term effect data for other benthic species, in particular for *Hyalella azteca* or other crustaceans is recommended for the derivation of a definitive value.

The proposed EQS_{sed} does not involve analytical challenges.

12 References for Appendix II

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