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

Fenpropimorph

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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): 0.016 µg/L

AQC (MAC-EQS): 3.27 µg/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

CQC (AA-EQS): 0.016 µg/L

AQC (MAC-EQS): 3.27 µg/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): 0.016 µg/L

AQC (MAC-EQS): 3.27 µg/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): 0.016 µg/L

AQC (MAC-EQS): 3.27 µg/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 fenpropimorph relevant for the aquatic environment is presented in this chapter. Registration information and risk assessments referred to are:

- Fenpropimorph as biocidal active substance: Assessment Report product-type 8 (Wood preservative), Rapporteur: Spain (EC 2009) in connection with Document IIIA (study summaries) (EC 2006a, 2006b, 2006c) and the ECHA biocidal active substance factsheet (ECHA 2021)
- Fenpropimorph as plant protection product active substance: Draft Assessment Report (DAR), Rapporteur: Germany (EC 2005) in connection with the EFSA Conclusion (EFSA 2008) and Review Report (EC 2011)
- Proposal of Environmental Quality Standards for Plant Protection Products (Kontiokari & Mattsoff 2011)
- Indicatieve MTRs voor bestrijdingsmiddelen in zoet oppervlaktewater - Beoordeling noodzaak humane route (RIVM 2014)
- Stoffdatenblatt Fenpropimorph Stand: März 2014 (UBA 2014)

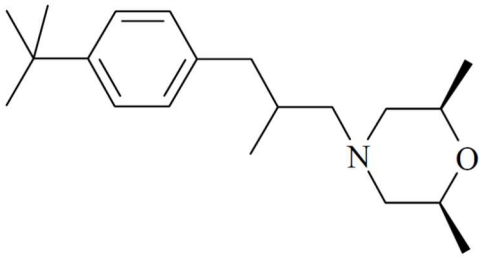
1.1 Identity and physico-chemical properties

Fenpropimorph is a morpholine derivative occurring as cis- and trans-isomer. Only the cis-isomer of fenpropimorph (CAS 67564-91-4) is used as active substance and is a mixture of its two enantiomers (R/S based on absolute configuration (EC 2005) or -/+ based on optical properties (EC 2006b)). In Document IIIA (study summaries, p. 4) for the authorisation of fenpropimorph as biocidal active substance, the applicant states that “Fenpropimorph is a racemate; both enantiomers are similarly active.”, consequently, all physical and chemical properties were reported for the racemate (EC 2006b). Isomers and potential differences are neither mentioned in the EU Assessment Report nor in the Review Report (EC 2009, 2011) or any other reference consulted. The structural formulas of the isomers were presented in the confidential appendix of the application documents (EC 2006b). Further discussion of the enantiomers is provided in section 1.4 (Mode of action).

Fenpropimorph is manufactured as racemic mixture with a minimum purity of 93 % w/w (EC 2009).

Table 1 summarizes identity and physico-chemical parameters for fenpropimorph required for EQS derivation according to the EU TGD for EQS (EC 2018). Where available, experimentally collected data is identified as (exp.) and estimated data as (est.). 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 2018).

Characteristics	Values	References
Common name	Fenpropimorph	EC (2009)
IUPAC name	(+/-)-cis-4-[3-(4-tert-butylphenyl)-2-methylpropyl]-2,6-dimethylmorpholine	EC (2009)
Chemical group	Morpholine (amine and ether functional groups) Phenylpropanes	EC (2009) HMDB (2020)
Structural formula		EFSA (2008)
Molecular formula	$C_{20}H_{33}NO$	EC (2009)
CAS	67564-91-4	EC (2009)
EC Number	266-719-9	EC (2009)
SMILES code	CC1CN(CC(O1)C)CC(C)CC2=CC=C(C=C2)C(C)(C)C	PubChem (2020)
Molecular weight [g/mol]	303.5	EC (2009)
Melting point [°C]	-47 – -41 (exp., OECD 102)	Daum* (1999) cited in EC (2006b), p. 8
Boiling point [°C]	(1) No boiling point (exp., OECD 102) (2) >250 (exp., technical material, 1 atm) (3) 120 (exp., pure active ingredient, at 0.067 mbar) (4) decomposition before boiling	(1) Daum* (1999) cited in EC (2006b), p. 8 (2) Ciba 1992 cited in FAO (1999) (3) FAO (1999) (4) (EFSA 2008), p. 43
Vapour pressure [Pa]	(1) $3.9 \cdot 10^{-3}$ (exp., 20°C) (2) $3.5 \cdot 10^{-3}$ (exp., 20°C) (3) $7 \cdot 10^{-3}$ (exp., 25°C)	(1) Kästel* (2004) cited in EC (2006b), p. 10 (2) Anonymous (1994) cited in EC (2006b), p. 10 (3) Kästel* (2004) cited in EC (2006b), p. 10
Henry's law constant [$Pa \cdot m^3 \cdot mol^{-1}$]	(1) 0.2656 (calculated) (2) 0.274 (calculated) (3) 0.2459	(1) Anonymous (1999) cited in EC (2006b), p. 11

* Author names blackened in EC (2006b) were verified based on EC (2005).

		(2) Anonymous (2004) cited in EC (2006b), p. 11 (3) Ohnsorge (2000) cited in (EC 2005), B2 p. 12
Water solubility [mg·l^{-1}]	(1) 7.3 (20°C, pH 4.4, flask, MT 157 CIPAC) (2) 4.32 (20°C, pH 7, OECD 105) (3) 3.53 (20°C, pH 9-11, OECD 105) (4) 4.32 (20°C, pH 6, column elution) (5) 3.56 (20°C, pH 10.2, column elution) (6) 5.1 (unbuffered) (1-6) exp.	(1) Redeker* (1988) cited in EC (2006b), p. 13 (2-3) Anonymous (1988) cited in EC (2006b), p. 14 [1] (4-5) Redeker (1988) cited in EC (2005), p. 13 [1] (6) Rüdel 1998 cited in FAO (1999)
Dissociation constant (pK_a)	(1) pK_b = 7.02 (exp., 20°C, OECD 112) (2) 6.98 (exp., corresponding acid, 20 °C, OECD 112) (3) 6.81 (exp., corresponding acid, 25°C, OECD 112)	(1) Anonymous (1988) cited in EC (2006b), p. 14 (2-3) Redeker (1998) cited in EC (2005), p. 15
Octanol-water partition coefficient (log K_{ow})	(1) 2.6 at 22°C, pH 5 (2) 4.1 at 22°C, pH 7 (3) 4.4 at 22 °C, pH 9 (1-3) exp., Directive 84/449/EEC, A.8 "Partition coefficient" (4) 4.93 (exp., pH-metric method, non-charged molecule) (5) 5.5 (est. EpiSuite) (6) 4.46	(1-3) Anonymous (1986) cited in EC (2006b), p. 16 (4) Chamberlain *et al.* (1996) (5) US EPA (2007) (6) geometric mean of 2-4
Soil-water partition coefficient (log K_{oc}) [a]	(1) 3.77 (K_{oc} 5943, pH 7, loam) (2) 3.44 (K_{oc} 2772, pH 7.2, loamy sand) (3) 3.65 (K_{oc} 4432, pH 7, sand) (4) 3.58 (K_{oc} 3833, pH 6.3, silty sand) (5) 3.94 (K_{oc} 8778, pH 7.3, clayey silt) (1-5) exp., batch equilibrium procedure (6) 2.94-3.65 (K_{oc} 862 – 4500) (7) 3.72 (est. based on log K_{ow} 4.46) (8) 3.68 (K_{oc} 4779)	(1-3) Redeker (1979) cited in section B8 of EC (2005) (4-5) Stockmaier (1996) cited in section B8 of EC (2005) (6) Tomlin, 1994 cited in UBA (2014), individual values not known (7) equation logKOC=0.81*logKOW+0.10 in EC (2018)[2] (8) geometric mean of 1-5, 7
Aqueous hydrolysis DT_{50} [d]	(1) stable (exp., pH 3-9, 25°C, 32 d; EPA N161-1) (2) >64 (exp., 50°C, pH 5, 7, 9) (3) >64 (exp., 70°C, pH 5) (4) 15 (exp., 70°C, pH 7, 9)	(1) Rüdel (1988) cited in EC (2005) p. 464 (2-4) BASF 1983 cited in FAO (1999)
Aqueous photolysis DT_{50} [d]	stable (exp., pH 5, 25°C, 30d; EPA N161-2)	Herrchen* (1988) cited in (EC 2006a), p. 10

Soil photolysis DT_{50} [d]	~30 (exp., 25°C, loamy sand, EPA N161-3)	Herrchen* (1988) cited in EC (2006a), p. 86
Biodegradation in aqueous environment DT_{50} [d]	(1) 1.9 (dissipation, exp., 20°C)[3] (2) 3.4 (dissipation, exp., 20°C)[3] (3) 11.7 (degradation only, 20°C)[3] (4) 4 (degradation only, 20°C)[3] (5) 6.8 (geometric mean of 3 and 4)	(1-2) Ebert* (2000) cited in EC (2006a), p. 19 (3-5) amended by RMS in (EC 2005), p. 473
Biodegradation in sediment DT_{50} [d]	(1) 83.6 (dissipation, exp., 20°C)[3] (2) no estimation possible (dissipation, exp., 20°C)[3] (3) 102.2 (degradation only, 20°C) (4) 63.4 (degradation only, 20°C) (5) 80.5 (geometric mean of 3 and 4)	(1,2) Ebert* (2000) cited in EC (2006a), p. 19 (3-5) amended by RMS in (EC 2005), p. 473
Biodegradation in soil DT_{50} [d]	(1) 12.5 (exp., 20°C, aerobic, loamy sand, mean of 11.8 and 13.2)[4] (2) 23 (exp., 20°C, aerobic, loamy sand) (3) 114 (exp., 20°C, aerobic, loamy sand) (4) 19 (exp., 20°C, aerobic, clayey sand) (5) 14 (exp., 20°C, aerobic, sandy loam) (6) 14.7 (geometric mean of 1-5 normalized to moisture) (7) 40 (field, loam, BBA IV) (8) 90 (field, loamy clay, BBA IV) (9) 10 (field, sandy loam, BBA IV) (10) 29 (field, sandy loam, BBA IV) (11) ~100 (field, loamy sand, BBA IV) (12) ~42 (6.1 weeks, filed, sandy loam) (13) >120 (exp., BBA IV 4-1, anaerobic) (1-13): dissipation studies (14) 19.6 (geometric mean, moisture normalized, used for FOCUS modelling)	(1) Anonymous (2005) cited in EC (2006a), p. 31 (2,3) Anonymous (1978) cited in EC (2006a), p. 45 (4, 5) Anonymous (1985) cited in EC (2006a), p. 55 (6) Anonymous (2005) cited in EC (2006a), p. 59 (7-8) Anonymous (1999) cited in EC (2006a), p. 64 (9-11) Anonymous (1992) cited in EC (2006a), p. 67 (12) Anonymous (1996) cited in EC (2006a), p. 72 (13) Anonymous (1998) cited in EC (2006a), p. 92 (14) EFSA (2008)

[1]potentially identical, [2]equation for morpholines or amines not available, [3]guidelines: SETAC Europe, Patt 8.2, BBA, IV 5-2, US-EPA, Subdivision N, 162-4, [4]BBA Prut IV, 4-1, 1986, OECD Guideline 307, SETAC Europe: Procedures for Assessing the Environmental Fate and Ecotoxicity of Pesticides, 1995

1.2 Regulatory context and environmental limits

In Switzerland and the EU, fenpropimorph has been authorised as wood preservative (biocide PT08); authorisation was granted till 30/06/2021 (ECHA 2021). Fenpropimorph is not included in the EU Priority Substances List under the superseded Existing Substances Regulation (ESR) (ECHA 2007) and is currently not listed for re-evaluation under the EU Rolling Action Plan.

Table 2 summarizes existing regulation and environmental limits in Switzerland, Europe and elsewhere for fenpropimorph. Existing PNEC or Environment 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 fenpropimorph in Switzerland and Europe.

Europe	
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products	PT08 (Wood Preservative) since 01.07.2011, granted till 30/06/2021
ECHA Classification and Labelling	Acute Tox. 4, H302 Skin Irrit. 2, H315 Aquatic Chronic 2, H411 Repr. 2, H361d
Switzerland	
VBP; SR 813.12	PT08 (Wood Preservative) since 01.07.2011, granted till 30/06/2021

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

Description	Value [µg/L]	Development method	References
AA-QS_{water}	0.016	*Oncorhynchus mykiss* 94 d (ELS) NOEC 0.16 µg/l; AF 10	Kontiokari & Mattsoff (2011)
MAC-QS	100	*Pseudokirchneriella subcapitata* 72 h ErC50 > 1mg/l; AF 10, since the SD (LogL/EC50) < 0.5	Kontiokari & Mattsoff (2011)
MTR*	0.22	Not described	RIVM (2014)
JD-UQN	0.016	*Oncorhynchus mykiss* 94 d (ELS) NOEC 0.16 µg/l; AF 10; TDG EQS (EC, 2011)	UBA (2014)
ZHK-UQN	21	*Lepomis macrochirus* 4 d LC50 = 2110 µg/L ; AF 100 ; TDG EQS (EC, 2011)	UBA (2014)

*Maximaal Toelaatbaar Risiconiveau

1.3 Use and emissions

In Switzerland and the EU, fenpropimorph was authorised as wood preservative (biocide PT08) till 30/06/2021. It is not part of the „Active Substance Review Programme“ (EC 2017) but is a candidate for substitution (ECHA 2021). Fenpropimorph may be used for the preservation of wood products against wood discolouring and wood destroying fungi. It is intended for the temporary preventive protection of sawn timbers in areas with temperate or tropical climate and for the preservation of structural timber for interior and exterior use without ground contact (EC 2009). Release to the environment can occur during application processes of wood preservative, during the storage of the treated wood and from wooden constructions (EC 2009).

Fenpropimorph was not re-authorised as pesticide active substance after its expiry on 30.04.2019 and is likewise not authorised for use in plant protection products in Switzerland. The last authorised date of use in plant protection products was 31.10.2020 (EC 2020). Emissions from the use as plant protection product are thus not expected.

1.4 Mode of action

Fenpropimorph is a systemic morpholine fungicide with protective, curative and eradicative effects. Only the cis-isomer of fenpropimorph is used as active ingredient as it was found to be substantially more effective than the trans-isomer (Pommer 1984).
Fenpropimorph inhibits the formation of appressoria and haustoria and controls mycelial growth and sporulation (EFSA 2008). This effect of morpholine fungicides is based on inhibition of biosynthesis of terminal fungal sterols, often ergesterol (Schwinn 1984). In particular, the enzymes sterol Δ14-reductase (ERG24), sterol Δ8→Δ7 isomerase (ERG2) and cycloeucalenol obtusifoliol isomerase (COI) are affected. As reviewed by (Mercer 1991), morpholines are protonated at physiological pH and thus structurally and electronically mimic the high-energy intermediate of all three enzymes. Consequently, they can bind to the catalytic sites of these enzymes much more tightly than the actual substrates thus inhibiting the enzymes. Inhhibition of ERG2 has been shown to decrease with increasing pH between pH 6 and pH 8.5 probably due to the deprotonation of fenpropimorph (Taton *et al.* 1987).
There is some indication that the enantiomers of the cis-isomer of fenpropimorph have different effects. It was found that the 2S-2-methyl isomer caused a greater accumulation of 9β,19-cyclopropyl sterols than A8-sterols in wheat caryopses, while the 2R-2-methyl isomer caused the reverse (Costet-Corio & Benveniste 1988). In enzyme extracts from *Saccharomyces cerevisiae*, the 2S-2-methyl isomer showed substantially stronger inhibition of sterol Δ8→Δ7 isomerase than the 2R-2-methyl isomer (Baloch & Mercer 1987). The potential specific activity of the two enantiomers in non-target organisms has not been considered in mammalian toxicology and in the environmental risk assessment for the previous authorization of fenpropimorph as active ingredient in plant protection products (EFSA 2008). With respect to the environmental risk assessment, EFSA concluded that "This adds additional uncertainty to the environmental risk assessment and needs to be addressed further" (EFSA 2008).

With regard to endocrine effects, a report for the UK HSE, it was concluded that "Adverse effects caused by an endocrine mode of action were not observed in standard toxicity tests. Therefore, fenpropimorph is not considered an endocrine disrupter based on currently available mammalian toxicology data" (Ewence *et al.* (2013), p. 180). Likewise, fenpropimorph was not listed as potential endocrine disrupter by the European Commission (identified as "false positive" or Option 1 in EC (2016)).

2 Environmental fate

2.1 Stability and degradation products

According to the data submitted for the authorization of fenpropimorph as biocidal active substance (EC 2006a, 2009), fenpropimorph was stable in aqueous hydrolysis and photolysis tests at ambient conditions. DT_{50} in soil photolysis study was ~30 days. Biodegradation tests according to OECD 301 (ready biodegradability) and OECD 302 (inherent biodegradability) were not performed for the authorisation of fenpropimorph. A study on radiolabelled fenpropimorph in two water/sediment systems with sediment taken from a pond and a small river (Germany) showed that fenpropimorph rapidly translocated from the water phase into the sediment (DT_{50} incl. sorption 1.9 and 3.4 days; Anonymous (2000) cited in EC (2006a), p. 13). Fenpropimorphic acid (BF 421-2) was the main metabolite with higher solubility in water and a weaker adsorption as compared to the parent compound. It did not exceed 10 % of the applied radioactivity in sediment but partially moved back to the water phase where it reached a maximum of 17 and 23 % of the applied radioactivity.

Mineralisation to CO_2 ranged from 6 to 8 % of the applied radioactivity. Dissipation DT_{50} in the whole systems was 18 and 54 days (EC (2006a), p. 471). According to the assessment report and the EFSA conclusion, fenpropimorph can be regarded as persistent or moderately persistent substance in the aquatic compartment (EC 2009, EFSA 2008).

In soil, aerobic degradation in laboratory tests resulted in DT_{50} of 12.5-114 days (geometric mean = 14.7, normalized to moisture) and produced fenpropimorphic acid as main metabolite and BF 421-8 (hydroxyethylamine) and BF 421-10 (dimethylmorpholine) as further metabolites. In the field, DT_{50} ranged from 10 to ~100 days with fenpropimorphic acid likewise being the main metabolite and BF 421-7 a minor metabolite. No metabolite reached > 10% of total applied radioactivity. There was no indication that adsorption of fenpropimorph to soil was pH dependent. Higher soil moisture accelerated degradation and at colder conditions (5°C) the degradation rate was slowed down (Anonymous (1985) cited in EC (2006a), p. 57). Fenpropimorph was stable in the dark and in sterilised soil. For the purpose of FOCUS modelling, a , moisture-normalized geometric mean DT50 of 19.6 for soil was used by EFSA (2008).

It was noted that the methods of analysis used in all the fate and behaviour studies were not stereoselective (EFSA 2008). EFSA thus concluded that "the regulatory dossier provides no information on the behaviour of each individual fenpropimorph enantiomer in the environment" and consequently that it "is not known if either isomer is degraded more quickly than the other in the environmental matrices studied"(EFSA 2008). A study in plants indicated enantioselective metabolism in wheat and in sugar beets, but not in grapevine (Buerge *et al.* 2016). Differences in enantiomer-degradation in other systems are thus conceivable.

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 behaviour and activity of the organism considered (Warren *et al.* 2003).

We could not identify any specific studies on the bioavailability of fenpropimorph in aquatic systems. Based on tests performed with radiolabelled fenpropimorph for the authorisation as active substance, it is rapidly translocated from the water phase into the sediment by adsorption (EC 2005). Fenpropimorph can be oxidised to the metabolite BF 421-2, which partially moves back into the water phase. 57 – 71 % of the applied radioactivity remained in the sediment within 100 d of the experiment (Ebert (2000) cited in EC (2005)). Water solubility is low and ranges from 3.53 – 7.3 mg/L depending on pH (Table 1).

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 Kp<4 (or, if this value is not available, log K_{ow} <6, the $EQS_{water,\ total}$ is equivalent to the $EQS_{water,dissolved}$ (EC 2018). Reported log K_{ow} for fenpropimorph range from 2.6 – 4.4 (pH 5 – 9) with the geometric mean of relevant log K_{ow} being 4.46. Thus, the $EQS_{water,\ total}$ can be regarded as equivalent to the $EQS_{water,\ dissolved}$ and does not need to be normalized.

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 and water. Table 4 lists BCF reported in EU assessment reports. Values estimated with EPISuite (US EPA 2007) were included. Neither BCF nor BAF nor BMF values were identified in the literature.

Table 4 BCF and BAF values reported for fenpropimorph

Species	**BCF [L/kg]**	**Tissue**	**Exposure**	**Further information**	**Reference**
Bluegill Sunfish (*Lepomis macrochirus*)	1096 (steady state)	whole fish	aqueous; 300 µg/L [phenyl-U-^{14}C] fenpropimorph (>99 %) nominal; 280 ± 40 µg/L mean measured	EPA E72-6; 28d flow through, 14d depuration phase, lipid content and TOC not measured; DT_{50} depuration 4.8 d (whole fish)	Dijk (1988a) cited in EC (2005), p. 540
Bluegill Sunfish (*Lepomis macrochirus*)	942 (steady state)	whole fish	aqueous; 300 µg/L [morpholine-U-^{14}C] fenpropimorph (> 99 %) nominal; 300 µg/L mean measured (240-340 µg/L)	EPA E72-6; 28d flow through, 14d depuration phase, lipid content and TOC not measured; DT_{50} depuration 5.9 d (whole fish)	Dijk (1988a) cited in EC (2005), p. 542
Rainbow trout (*Oncorhynchus mykiss*)	1169 (kinetic)	whole fish	aqueous; 0.2 µg/L [phenyl-U-^{14}C] fenpropimorph (>96 %) nominal; 0.2 µg/L mean measured	20d flow through, 56d depuration; TOC not measured; DT_{50} depuration 2.8 d (whole fish)	Hafemann (2003) cited in EC (2005), p. 544
	2598 (kinetic)	lipid content			
Rainbow trout (*Oncorhynchus mykiss*)	1220 (kinetic)	whole fish	aqueous; 0.2 µg/L [morpholine-U-^{14}C] fenpropimorph (>98 %) nominal; 0.22 µg/L mean measured	20d flow through, 56d depuration; TOC not measured; DT_{50} depuration 1.7 d (whole fish)	Hafemann (2003) cited in EC (2005), p. 544
	2711 (kinetic)	lipid content			
Geometric mean	1102	whole fish			
Fish	831 (regression-based estimate)	whole fish	na	including biotransformation rate estimates	Estimated with EPISuite/BCFBAF, US EPA (2007)
Fish	6986 (regression-based estimate)	whole fish	na	without biotransformation	Estimated with EPISuite/BCFBAF, US EPA (2007)
Species	**BAF [L/kg]**	**Tissue**	**Exposure**	**Further information**	**Reference**
Fish	491 (regression-based estimate)	whole fish	na	including biotransformation rate estimates	Estimated with EPISuite/BCFBAF, US EPA (2007)
Fish	82460 (regression-based estimate)	whole fish	na	without biotransformation	Estimated with EPISuite/BCFBAF, US EPA (2007)

Hafemann (2003) cited in EC (2005) reported biotransformation of fenpropimorph to yield the glucuronic acid conjugate as predominant metabolite with up to 52 % of the total radioactive residue. The RMS re-calculated depuration half-lives (whole fish) resulting in 2.8 days (phenyl label) and 1.7 days (morpholine label) corresponding to CT_{90}-values of 31 and 15.5 days, respectively. It was concluded that the BCF for the parent compound is less than 1000 (BCF-range: 421-605). The RMS concluded that "the retarded […] and incomplete depuration behaviour […] give rise to concern" (EC 2005). However, in the risk assessment for the former authorisation of fenpropimorph as pesticides active substance, EFSA concluded that "Considering that fenpropimorph dissipates rapidly from the water phase […] the risk from bioaccumulation is assumed to be low." (EFSA 2008)

Nevertheless, both primary criteria for derivation of a biota standard to protect wildlife from secondary poisoning are fulfilled (BCF (BAF) ≥100, log K_{ow} ≥ 3). The derivation is presented in section 7.

3 Analytics

As listed in Table 5, two analytical methods for the detection and quantification of fenpropimorph in water have been submitted for the authorisation, one based on GC-MS/MS detection (Ziegler 2000), the other on GC-NPD with LOQ of 0.05 µg/L (Ziegler 1999), both cited in the EC (2005).

Table 5 Methods for fenpropimorph analysis in water 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.	0.05	GC-MS/MS	Ziegler (2000) cited in EC (2005)
n.a.	0.05	GC-NPD	Ziegler (1999) cited in EC (2005)

4 Effect data

A literature search (Scopus) was performed on September 09, 2020 for the years 2010-2020 using the search terms fenpropimorph, 67564-91-4 only and in combination with ecotoxicity, ecotoxicology, aquatic toxicity, or toxicity yielding 108, 0, 0, 0 and 36 hits, respectively, with 108 unique hits. These were analysed for relevance resulting in 0 studies on effects in aquatic organisms. The studies listed in Table 6 thus originate from EU assessment reports and corresponding approval data, and databases (ETOX (UBA 2004), US EPA OPP database hosted by ECOTOX (US EPA 2014)). Studies on formulations are considered irrelevant due potential effects of unknown co-formulants.

Only reliable and relevant data should be used for EQS derivation (EC 2018). 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 separately 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 2018). Here, validity in terms of relevance ("C" in Table 6) and reliability ("R" in Table 6) of studies were evaluated according to the CRED-criteria.

Previous assessments published in EU assessment reports were adopted as valid/Klimisch 1 without additional assessment of reliability, whereas relevance was assessed according to CRED. 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)[†]. Where applicable, 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.

Overall, we noted that no new data on fenpropimorph seems to have been generated within the past 10 years with the youngest individual report (2010) being cited in UBA (2014). In many cases, original publications were not available for further assessment, e.g. of analytical methods. In some cases, several secondary references are listed for the same report as the secondary references contained complementary information. The study by Munk (1995) is listed in three lines as the secondary sources reported differently /came to different conclusions.

[†] [page 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 6 Selected effect data collection for fenpropimorph in µg/L. The full list of effect data assessed including those assessed as not relevant and not reliable is available in in Annex I. In case data had not been previously evaluated for relevance and reliability, they were evaluated according to the CRED criteria (Moermond *et al.* 2016). Data used for QS derivation are underlined. Values used to derive a geometric mean and the derived geometric mean are boxed. Abbreviations: n.r. = not reported. Supportive data (unbounded values) are in grey font.

Group	Species	Endpoint	Duration	Parameter		value[3] [µg/L]	Analytics	Exposure	Purity (%)	Validity	Reference
Acute freshwater effect data											
algae	*Chlorella fusca*	growth rate	4d	E_rC_{50}	=	2210	n.r.	n.r.	n.r.	1/C1	UBA (2014)
algae	*Pseudokirchneriella subcapitata**	biomass	72h	E_bC_{50}	=	327 (287 - 377)	nom-m	S	96.6	1/C1	Anonymous 2000 cited in EC (2006a), p. 147 Kubitza 2000 cited in EC (2005), p. 553 US EPA (2014) UBA (2004)
algae	*Pseudokirchneriella subcapitata**	growth rate	72h	E_rC_{50}	>	1000	nom-m	S	96.6	1/C1	Anonymous 2000 cited in EC (2006a), p. 147 Kubitza 2000 cited in EC (2005), p. 553
crustaceans	*Daphnia magna*	immobilisation	48h	EC_{50}	=	2380	n.r.	S	96.6	1/C1	US EPA (2014)
crustaceans	*Daphnia magna*	immobilisation	48h	EC_{50}	=	2240 (1680-2980)	nom-m	S	96.6	1/C1	Anonymous 1999 cited in (EC 2006a), p. 134 UBA (2004) Jatzek (1999) cited in EC (2005), p. 551
crustaceans	*Daphnia magna*	immobilisation	48h	LC_{50}/EC_{50}	=	2309					Geometric mean
fish	*Lepomis macrochirus*	mortality	4d	LC_{50}	=	2300 (1495-2984)	mm	S	96.6	1/C1	Zok 1999 cited in EC (2005), p. 534 Anonymous 1999 cited in (EC 2006a), p. 121
fish	*Lepomis macrochirus*	mortality	4d	LC_{50}	=	2110	n.r.	S	96.6	1/C1	US EPA (2014) UBA (2004)
fish	*Lepomis macrochirus*	mortality	4d	LC_{50}	=	2203					Geometric mean
fish	*Oncorhynchus mykiss*	mortality	4d	LC_{50}	=	3370 2260- (4573.8)	mm	S	96.6	1/C1	Zok 1999 cited in EC (2005), p. 533 Anonymous 1999 cited in (EC 2006a), p. 114
fish	*Oncorhynchus mykiss*	mortality	4d	LC_{50}	=	3460	n.r.	S	96.6	1/C1	US EPA (2014)

[3] *95 % confindence intervals are provided in brackets were available.*

Group	Species	Endpoint	Duration	Parameter		value[3] [µg/L]	Analytics	Exposure	Purity (%)	Validity	Reference
fish	*Oncorhynchus mykiss*	mortality	4d	LC_{50}	=	3415					Geometric mean
						Chronic freshwater effect data					
algae	*Chlorella fusca*	growth rate	4d	NOEC	=	80	n.r.	n.r.	n.r.	1/C1	UBA (2014)
algae	*Pseudokirchneriella subcapitata**	biomass	72h	E_bC_{10}	=	5 (4-6)	n.r.	n.r.	n.r.	1/C1	ICS Database, cited in UBA (2004) Anonymous 2000 cited in EC (2006a), p. 147 Kubitza 2000 cited in EC (2005), p. 553
algae	*Pseudokirchneriella subcapitata**	growth rate	72h	E_rC_{10}	=	58 (48-70)	n.r.	n.r.	n.r.	1/C1	UBA (2014) Anonymous 2000 cited in EC (2006a), p. 147 Kubitza 2000 cited in EC (2005), p. 553
crustaceans	*Daphnia magna*	n.r.	21d	NOEC	=	2.2	n.r.	n.r.	n.r.	1/C1	Janson, G.M. (2010) cited in UBA (2014)
insects	*Chironomus riparius*	hatching rate	20d	NOEC	>=	86	m	n.r.	n.r.	1/C1	ICS Database, cited in UBA (2004)
fish	*Oncorhynchus mykiss*	survival	60d/94d#	NOAEL	=##	0.16	nom-m	T	95.6	1/C1	Anonymous (1995) cited in EC (2006a) p. 175, A 7.4.3.2/01 and /02 Munk (1995) cited in EC (2005), p. 536
fish	*Oncorhynchus mykiss*	growth	60d/94d#	NOEC	<##	0.16	n.r.	T	95.6	1/C1	US EPA (2014)
fish	*Oncorhynchus mykiss*	weight	60d/94d#	NOEC	=##	0.16	n.r.	n.r.	n.r.	1/C1	ICS Database, cited in UBA (2004)
						Subchronic freshwater effect data					
fish	*Oncorhynchus mykiss*	mortality	21d	NOEC	=	100	m	T	95.4	1/C2	Anonymous 1998 cited in EC (2006a) p. 167

Legend

Chemical analytics

m: based on measured concentrations
mm based on mean measured concentrations
nom-m based on nominal concentrations ; recovery at the start was determined. In case recovery was 80-120 %, nominal effect concentrations are regarded as valid. In case recovery was < 80 %, effect values are regarded as invalid or, if possible, calculated (e.g. «time-weighted average»).

Exposure

S static

T flow-through

Validity

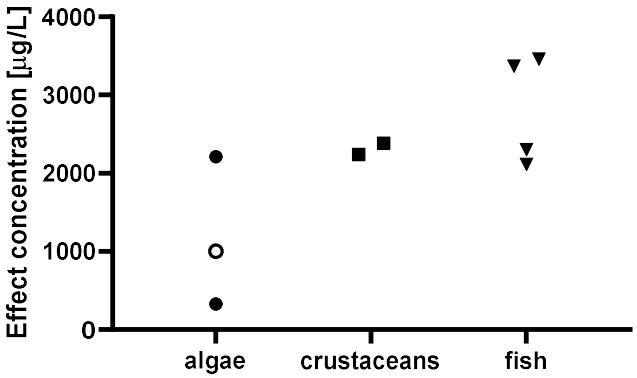
Klimisch: 1 reliable, 2 reliable with restrictions
CRES: C/R 1 reliable/relevant, C/R 2 reliable/relevant with restrictions

* *Raphidocelis subcapitata/Selenastrum capricornutum*
[#] The reported effect concentrations originate from a study by Munk (1995) also cited in EC (2005). All details are presented as in the respective secondary reference. Exposure started on the first day of hatch, i.e. day 34. Duration is given as 60 d in EC (2009) and as 94 d in all other references.
[##] The denominator has been used differently in the different references. Data was re-evaluated for the purpose of EQS derivation. Please refer to section 5.1 for discussion.

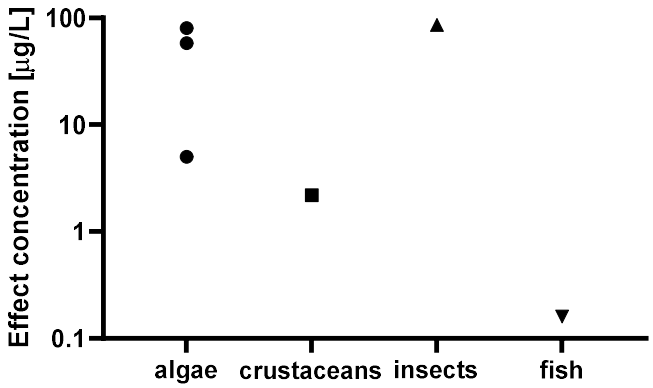
4.1 Graphic representation of effect data

All available relevant and reliable data have been plotted (Figure 1). All values are below the lowest reported water solubility of fenpropimorph (3.56 mg/L at pH 9-10; Table 1).

The ratio of acute to chronic effect concentrations for algae (*Pseudokirchneriella subcapitata)* and crustaceans (*Daphnia magna*) in this dataset are 65 and 1050, respectively. For fish, acute and chronic data are available for *Oncorhynchus mykiss* with an acute to chronic ratio of (>) 21344 based on the reported NOEC of (<)0.16 µg/L (see section 5.1).



a



b

Figure 1 Graphical representation of a) acute and b) chronic effect data from aquatic toxicity tests with fenpropimorph. Open symbols: unbounded data.

4.2 Comparison between marine and freshwater species

As suggested by the EU TGD for EQS (EC 2018), 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 fenpropimorph, no reliable and relevant marine effect data were available, thus, a comparison between marine and freshwater species is not possible.

5 Chronic toxicity

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

The CQC_{AF} ($AA\text{-}EQS_{AF}$) is determined using an assessment factor (AF) applied to the lowest credible datum from long-term toxicity tests.

The lowest long-term effect data available for fenpropimorph were obtained in an OECD 210 early life-stage toxicity test on *Oncorhynchus mykiss* by Munk (1995) submitted for authorization of fenpropimorph as active substance in plant protection products (EC (2005), p. 536) and in biocidal products (cited as "Anonymous (1995)", EC (2006a), p. 175; same document ID). The effect concentrations are also listed in the US EPA ECOTOX database (US EPA 2014) and the German EPA ETOX database (UBA 2004). The lowest nominal test concentration was 0.16 µg/L. As measured concentrations ranged from 90.5% - 106.0% of the nominal concentrations, effect concentrations were based on nominal concentrations. With respect to the NOEC/NOAEL for all three endpoints (survival, weight, length), the applicant argued that despite statistically significant differences between control and lowest test concentration, the extent of the differences was small enough to conclude that no "biologically relevant effect" occurred (survival) and that "[t]his was not considered to be detrimental for the survival of a population" (weight, length). The respective RMS agreed to this conclusion setting the NOEC/NOAEL to 0.16 µg/L. This reflects the entry for weight in the ETOX database, while the ECOTOX database lists < 0.16 µg/L for growth (not further specified). For survival, the arithmetic mean of survival in the control was lower than in the lowest test concentration (93.3% and 98.3%, respectively). The arithmetic means of weight and length at 0.16 µg/L were 89.5 % and 95.1 % of the control.

For the purpose of EQS derivation, available raw data for weight and length (Annex II) were re-analysed according to Figure 2 of the 2013 version of guideline OECD 210 (OECD 2013). Shapiro-Wilk tests were performed showing normal distribution of both datasets. Unpaired t-test, one-way ANOVA, and Welch's test indicate that there is no significant difference between control and lowest tested concentration for measured weight, but for measured length ($p = 0.05$). Based on distribution of data and statistical tests performed, a NOEC for weight of 0.16 µg/L seems supported. As an EC_{10} was not reported in the cited study, an EC_{10} of 12.8 µg/L was calculated for length (log-logistic model, GraphPad Prism; ©GraphPad Software, Inc.), reflecting the observed flat concentration-response relationship with the highest tested concentration eliciting 65.47 ± 0.75 (SD) %. Effects on weight, length and survival were statistically significant at the next higher concentration (0.8 µg/L, $p = 0.05$) using the same tests as above (results for Welch's test: $p=0.0016$, $p=0.0011$, $p=0.0217$ for weight, length, survival).

Thus, the NOEC of 0.16 µg/L for weight is regarded as lowest available effect concentration in this context (Table 7).

Table 7 Most sensitive relevant and reliable chronic data summarized from Table 6 and additional calculations.

Group	Species	Duration	Effect concentration	Value [µg/L]	Reference
Basic data					
Algae	*Pseudokirchneriella subcapitata*	72h	E_bC_{10}[4]	5	UBA (2004)
Crustaceans	*Daphnia magna*	21d	NOEC	2.2	Janson, G.M. 2010 cited in UBA (2014)
Fish	*Oncorhynchus mykiss*	60d/94d *	NOEC	0.16	Calculation based on Munk (1995) cited in EC (2005)
Additional data					
Insects	*Chironomus riparius*	20d	NOEC	>=86	UBA (2004)

* The reported effect concentrations originate from a study by Munk (1995) also cited in EC (2005). Exposure started on the first day of hatch, i.e. day 34. Duration is given as 60 d in EC (2009) and as 94 d in all other references.

In case of long-term tests (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 11 in EC (2018)).

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

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

$$\mathrm{CQC}_{AF}\ (\mathrm{AA-EQS}_{AF}) = \frac{0.16\left(\frac{\mu g}{L}\right)}{10} = 0.016\ \left(\frac{\mu g}{L}\right)$$

According to the EU TGD for EQS, in case of substantial levels of suspended particulate matter in the test system, the effect concentration of substances with log Kp<4 or alternatively log K_{ow} <6 is regarded as $c_{test\ water,total}$ and needs to be corrected for OC concentration to yield $c_{water,dissolved}$. Reported log K_{ow} of fenpropimorph range from 2.6-4.4 depending on pH (Table 1). A correction of OC concentration in the study by Munk (1995) is thus not necessary.

The application of an AF of 10 to the lowest credible chronic datum results in a **CQC_{AF} ($AA\text{-}EQS_{AF}$) = 0.016 µg/L**.

[4] As the EC_{50} could not be derived for the preferred endpoint «growth rate» and the endpoint «biomass» was used instead in the acute dataset, the E_bC_{10} is used instead of the E_rC_{10} from the same study. An EC_{10} is not considered reliable when the highest concentration did not elicite 50 % effect.

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 (2018), 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 of fenpropimorph 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 AQC_{AF} ($MAC\text{-}EQS_{AF}$) is determined using an assessment factor (As) applied to the lowest credible datum from short-term toxicity tests.

The lowest short-term effect datum available for fenpropimorph is the EbC_{50} of 327 µg/L (Table 8) for the biomass of *Pseudokirchneriella subcapitata* from an OECD 201 study. Although an effect concentration for growth rate (ErC) is considered more robust (see A1.3.2.10. in EU TGD for EQS), the ErC_{50} available from the same study is unbounded (Table 6). RMS Spain extrapolated an ErC_{50} of 16800 µg/L (10.4-27.2 mg/L 95% confidence interval). Therefore, the E_bC_{50} was used as conservative endpoint.

Table 8 Most sensitive relevant and reliable acute data summarized from Table 6

Group	Species	Duration	Effect concentration	Value [µg/L]	Reference
Basic data					
Algae	*Pseudokirchneriella subcapitata*	72h	EbC50	327	Anonymous 2000 cited in (EC 2006a), p. 147 US EPA (2014) UBA (2004)
Crustaceans	*Daphnia magna*	48h	EC50	2336	Geometric mean
Fish	*Lepomis macrochirus*	4d	LC50	2203	Geometric mean

The generic assessment factor in case of at least one short-term L(E)C50 from each of three trophic levels of the base set (fish, crustaceans and algae) being available is 100. This factor can be lowered to 10 when acute toxicity data for different species do not have a higher standard deviation than a factor

of 3 in both directions or known mode of toxic action and representative species for the most sensitive taxonomic group included in the data set (Table 5 in EC (2018)). As fenpropimorph is a fungicide, it can be expected that aquatic fungi are sensitive to the specific mode of action, however, they are not included in the data set. Fungi are not explicitly considered by the EU TGD for EQS (EC 2018), however, the Swiss Water Protection Ordinance (The Swiss Federal Council 2020) aims to protect among others microorganisms which include fungi. Further, the acute-to-chronic ratio for fish is very high (≥ 21344). Delayed effects resulting from a single peak should thus be considered (EC 2018).

The suggested assessment factor is thus 100 in accordance with EU TGD for EQS:

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

$$\mathrm{AQC}_{AF}\ (\mathrm{MAC}-\mathrm{EQS}_{AF}) = \frac{327\left(\frac{\mu g}{L}\right)}{100} = 3.27\ \left(\frac{\mu g}{L}\right)$$

According to the EU TGD for EQS, in case of substantial levels of suspended particulate matter in the test system, the effect concentration of substances with log Kp<4 or alternatively log K_{ow} <6 is regarded as $c_{test\ water,total}$ and needs to be corrected for OC concentration to yield $c_{water,dissolved}$.
The geometric mean of available log K_{ow} is 3.9 (Table 1). A correction of OC concentration in the study by Kubitza (2000) is thus not necessary.

The application of an AF of 100 to the lowest credible chronic datum results in a **MAC-EQS$_{AF}$ = 3.27 µg/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 NOEC/EC_{10}, from different species covering at least eight taxonomic groups (EC (2018), 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 fenpropimorph are available, thus, no AQC (AA-EQS) based on field data or mesocosm data has been derived.

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

Based on the reported BCF and log K_{ow} values for fenpropimorph, a $QS_{biota, sec pois, fw}$ needs to be derived (see section 2.3).

A relevant food chain for the trophic transfer of fenpropimorph 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 fenpropimorph, only guideline-based BCF studies in omnivorous (*L. macrochirus*) and predatory (*O. mykiss*) fish species are available (Table 4). Field or laboratory BAF or BMF studies were not identified. As stated in section 2.3, "retarded […] and incomplete depuration behaviour" (EC 2005) was observed. Thus, in lack of data from other trophic levels and the stated observation from fish BCF studies, we assume biomagnification of fenpropimorph. In this case, the EU TGD for EQS recommends fish that occupy trophic level 4 to be selected as basis for the biota standard.

Against this background, the critical food item is predatory fish. The geometric mean of whole-fish BCFs in *O. mykiss* are higher than in *L. macrochirus* (1175 L/kg and 1016 L/kg, respectively), the corresponding geometric mean BCF based on lipid content in *O. mykiss* is 2654. However, for derivation of $QS_{biota, sec pois, fw,}$ 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 82460 L/kg without biotransformation and 491 L/kg including biotransformation rate estimates for the upper trophic level (Table 4). The assumed rate constants are 0.5/d and 0.3/d for 10 g and 100 g fish, respectively. The fish tested by Hafemann (2003) cited in EC (2005) weighed 1.1 g at the start of the experiment and showed a depuration half-life of 1.33 d (geometric mean). Biotransformation was not separately quantified, but the parent compound was reduced to around 50 % of total radioactivity detected. Nevertheless, both estimated BAF (i.e. with and without biotransformation) will be used for EQS derivation.

Table 10 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. If available, long-term effect data are to be preferred over acute effect data.

For the derivation of a $QS_{biota, sec pois, fw}$, the lowest available NOEC of 0.3 mg/kg bw/d in male *Rattus norvegicus* (Sprague-Dawley rats) is selected, corresponding to a dietary dose-level of 10 ppm or 10 mg/kg, presumably based on food fresh weight. The average weight of the male control rats was 677 g after 92 weeks (not reported for the beginning of the study). Lower food intake was observed among females receiving 250 ppm, no further effects on feeding were observed. Fenpropimorph was mixed with Spratt's Laboratory Animal Diet No. 2 (EC (2006c), p. 201); the composition is not available. The stability of fenpropimorph in food was analytically confirmed. As daily dose and body weight are available, method A described in chapter 4.4.5.1 in EC (2018) is applied in the following. Results based on method B are in the same order of magnitude but ~2.5x higher (Annex III). The daily energy expenditure can be calculated according to the equation for mammals:

$$\log DEE[kJ/d] = 0.8136 + 0.7149 * \log bw\ [g]$$

using the weight at week 92 the log DEE can be calculated as:

$$\log DEE[kJ/d] = 0.8136 + 0.7149 * \log(677)$$

$$\log DEE[kJ/d] = \underline{2.84}$$

The diet concentration on an energy basis can then be calculated as

$$C_{energy\ normalised}[mg/kj] = dose\left[\frac{mg}{kg_{bw}}/d\right] * \frac{bw[kg]}{DEE\left[\frac{kJ}{d}\right]}$$

$$C_{energy\ normalised}[mg/kj] = 0.3 * \frac{0.677}{687} = \underline{0.00029}$$

Now the concentration in the critical food item can be calculated using the equation given in chapter 4.4.6 in EC (2018)

$$C_{food\ item}[mg/kg] = C_{ene\quad normalised}[mg/kJ] * energy\ content_{food\ item[kJ/kg]} * \left(1 - moisture\ fraction_{food\ item}\right)$$

Since the critical food item is fish, the energy content is 21.0 kJ/g_{dw} and the moisture fraction 73.7% according to table 8 in EC (2018).

$$C_{food\ item}[mg/kg] = 0.00029 * 21000 * (1 - 0.737) = 1.602$$

To calculate the corresponding concentration of fenpropimorph in water, the highest measured BCF in fish combined with a default BMF of 1 (for substances with log K_{ow} < 4.5 and a BCF_{fish} < 2000; Table 22, EU TGD for EQS) and the highest and lowest calculated BAF in fish are used (see section 2.3), assuming a steady state distribution of fenpropimorph between water, food and organism:

Table 9 Water concentrations of fenpropimorph 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	1102 x 1	Geometric mean, whole fish, see section 2.3	1.5
2	BAF	491	Estimated with EPISuite/BCFBAF, US EPA (2007), including biotransformation	3.3
3	BAF	82460	Estimated with EPISuite/BCFBAF, US EPA (2007), without biotransformation	0.02

As cited in section 2.3, about half of the applied radiolabelled fenpropimorph was metabolised in a BCF study on rainbow trout (Hafemann (2003) cited in EC (2005), p. 544). Depuration half-lives (whole fish) were 1.7-2.8 days. Assuming no biotransformation for BAF estimation is thus not justified (No. 3, Table 9). Values based on the product of the mean measured BCF and a BMF of 1 and an estimated BAF assuming biotransformation are in the same order of magnitude (No. 1 and 2, Table 9). For the purpose of EQS derivation, a value based on experimental results is preferred (No. 1, Table 9). The suggested assessment factor is 10 in accordance with EU TGD for EQS, as derivation is based on the lowest chronic value.

The application of an AF of 10 to the lowest credible chronic datum results in a $\mathbf{QS_{Biota,\ sec\ pois,\ fw}}$ **=** 1.602 mg/kg_{ww} or **0.15 µg/L** (based on BCF x BMF).

Table 10 Mammalian and avian oral toxicity data relevant for the assessment of secondary poisoning. For each type of effect, only the most sensitive study is listed. All other studies are available in the assessment reports and approval data.

Species	Exposure	Duration	Endpoint	Effect concentration	Comment	Reference
Acute toxicity to mammals						
Rattus norvegicus (Sprague-Dawley rats)	oral	Single dose, 21 d observation period	LD_{50}	1670 mg/kg bw ♀ 2830 mg/kg bw ♂	10 males and females per group Dose levels (nominal): 0, 1000, 1210, 1470, 1780, 2150, 2610, 3160 mg as/kg bw Mortalities occurred mostly between 2 d and 7 d.	Gelbke and Freisberg (1978) cited in EC (2005), p. 114
Short- and long-term toxicity to mammals						
Canus familiaris (Beagle dogs)	Oral	28 d	NOAEL	<8 mg/kg bw/d ♀ <7 mg/kg bw/d ♂	4 male and female dogs per group Dose levels (nominal): 0, 200, 400, 800 and 1600 ppm 99.1 % fenpropimorph Test substance was stable in food. No effects on alanine amino transferase activity at tested concentrations.	Kirsch (1978) cited in EC (2005), p. 145
Rattus norvegicus (Wistar rats)	Oral	90 d	NOAEL	0.8 mg/kg bw/d ♀ 0.7 mg/kg bw/d ♂	15 male and female rats (except lowest dose group: 10 each) per group Dose levels (nominal): 0, 1, 10, 100, 1000 ppm 94.3 % fenpropimorph Decreased body weight gain, increased liver weight	Mellert (1997a) cited in EC (2005), p. 151
Rattus norvegicus (Sprague-Dawley rats)	Oral	24 mo	NOAEL	0.4 mg/kg bw/d ♀ **0.3 mg/kg bw/d** ♂	75 male and female rats per group; 10 per time point/effect Dose levels (nominal): 0, 5, 10, 50, 250 ppm Exposure: 107 w (females), 114 w (males) 92.5 % fenpropimorph Decreased body weight gain, increased liver weight, histopathology liver	Hunter (1982a) cited in EC (2005), p. 171 Anonymous (1982) cited in EC (2006c), p. 200
Effects on reproduction and development of mammals						
Oryctolagus cuniculus (f. dom. Russian rabbit)	Oral	29 d	NOAEL maternal toxicity	15 mg/kg bw/d*	20 female rabbits per group Dose levels (nominal): 0, 7.5, 15, 30 mg/kg bw/d Dosage volume: 4 mL/kg bw 95.6 % fenpropimorph	Marty (1993a) cited in EC (2005), p. 198
			NOAEL embryotoxicity	15 mg/kg bw/d		
Rattus norvegicus (Wistar rats)	Oral	na (two-generation study)	NOAEL general toxicity	<2 mg/kg bw/d	25 male and female rats per group Dose levels (nominal): 0, 2, 4, 8, 16 mg/kg 95.3 % fenpropimorph General toxicity: serum choline esterase activity Reproductive effect: performance/fertility Development effect: reduced body weight	Schneider (2003 cited in EC (2005), p. 183
			NOAEL reproduction	16 mg/kg bw/d		
			NOAEL development	4 mg/kg bw/d		
Other effects in mammals						

Rattus norvegicus (Sprague Dawley)	Oral	90 d	NOAEL	0.8 mg/kg bw/d ♀ 0.7 mg/kg bw/d ♂	15 male and female rats (except lowest dose group: 10 each) per group Dose levels (nominal): 0, 1, 10, 100, 1000 ppm 94.3 % fenpropimorph Repeated neurotoxicity, effects on functional observational battery (FOB) endpoints	Mellert (1997a) cited in (EC 2005), p. 214
Toxicity to birds						
Colinus virginianus (bobwhite quail)	Intubation, single-dose	14 d	NO(A)EL mortality	2000 mg as/kg bw	5 males and 5 females (6 months, before first egg-laying) per group Dose levels (nominal): 0, 500, 1000, 2000 mg as/kg bw Dose levels (measured): > 80 % of nominal The only significant effect was a 14.1 % body weight reduction (LOEL development) in the females at 2000 mg as/kg bw	Zok (1999) cited in EC (2005), p. 509
			NO(A)EL development	2000 mg as/kg bw		
			LOEL development	1000 mg as/kg bw		
			NO(A)EL feed consumption	2000 mg as/kg bw		
Anas platyrhynchos (mallard duck)	oral	5 d 3 d post-exposure	NO(A)EL mortality	1250 mg as/kg diet	10 chicken, unsexed (6 d) per group dose levels (nominal): 0, 1250, 2500, 5000 mg as/kg diet dose levels (measured): > 80 % of nominal No clinical signs were detected during the whole study. A slight reduction in feed consumption and body weight was observed in the two highest dose groups (2500 mg as/kg diet, 5000 mg as/kg diet).	Munk (1988a) cited in EC (2005), p. 509
			LOEC mortality	2500 mg as/kg diet		
			NO(A)EL development	5000 mg as/kg diet		
			NO(A)EL feed consumption	5000 mg as/kg diet		
Effects on reproduction of birds						
Colinus virginianus (bobwhite quail)	Oral	24 w	NO(A)EL reproduction	>45 mg as/kg diet	20 pairs (37 w) per group dose levels (nominal):0, 5, 15, 45 mg as/kg diet dose levels (meas.): > 80 % of nominal *mortality, signs of toxicity, feed consumption, body weight, macroscopic post mortem examination, number of eggs laid, number of broken and cracked eggs, egg weights, egg shell thickness, number of infertile eggs, embryonic deaths, hatching, chick health and mortality, number of 14-day survivors, body weights of offspring	Roberts (1983) cited in EC (2005), p. 511
			NO(A)EL Other parameters*	>45 mg as/kg diet		

*EFSA lists a more sensitive effect concentration from a supplementary study for maternal toxicity (12 mg/kg bw/d, Merkle and Zeller 1980 cited in EC (2005), p. 194)

8 Toxicity of transformation products

As summarised in section 2.1, no abiotic transformation products are expected. The main metabolite of fenpropimorph in water-sediment systems is fenpropimorphic acid (BF 421-2). Three studies on fenpropimorphic acid are available in the BP approval data (Table 11).

Table 11 Aquatic toxicity studies on fenpropimorphic acid. Please refer to Table 6 for further explanations.

Group	Species	Endpoint	Duration	Parameter		Value (ug/L)	Analytics	Exposure	Purity (%)	Validity	Reference
Acute freshwater effect data											
algae	*Pseudokirch-neriella subcapitata*	growth rate	72 h	ErC50	>	100000	nom	S	99.8	1	Anonymous (1997b) cited in EC (2006a) p. 154; Dohmen (1997) cited in EC (2005), p. 554
crustac eans	*Daphnia magna*	immobili-sation	48 h	EC50	>	100000	nom	S	na	1	Anonymous (1997a) cited in EC (2006a) p. 141; Dohmen (1997) cited in EC (2005), p. 551
fish	Oncorhyn-chus mykiss	mortality	96 h	LC50	>	100000	nom	S	99.3	1	Anonymous (1991) cited in EC (2006a) p. 128; Munk (1997) cited in EC (2005), p. 534

Chronic aquatic toxicity studies are not available. In the EU assessment report it was concluded that "the metabolite may be considered to be ecotoxicologically non-relevant" as all L(E)C50 values were >100 mg/L and lower than those of fenpropimorph.

For the purpose of EQS derivation, no further assessment of fenpropimorphic acid is deemed necessary.

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 12. According to the EU TGD for EQS, the most reliable extrapolation method for each substance should be used (EC 2018).

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 based on OC content is not indicated for fenpropimorph.

Table 12 QS derived according to the three methodologies stipulated in the EU TGD for EQS and their corresponding AF. All concentrations expressed as µg/L. Proposed EQS are in bold letters/numbers.

	Value	AF
CQC_{AF} ($AA\text{-}EQS_{AF}$)	**0.016**	10
$QS_{Biota,\ sec\ pois,\ fw}$	0.15	10
AQC_{AF} ($MAC\text{-}EQS_{AF}$)	**3.27**	100

The suggested $QS_{Biota,\ sec\ pois,\ fw}$ is substantially higher than the suggested CQC_{AF} ($AA\text{-}EQS_{AF}$). Thus, it can be assumed that application of the suggested CQC_{AF} ($AA\text{-}EQS_{AF}$) will be protective of secondary poisoning of predators.

A **CQC (AA-EQS) of 0.016 µg/L** and a **AQC (MAC-EQS) of 3.27 µg/L for fenpropimorph** including the application of an AF of 10 and 100, respectively, are thus suggested.

10 Protection of aquatic organisms and uncertainty analysis

A complete dataset was available to derive CQC and AQC based on the assessment factor method, resulting in assessment factors of 10 and 100, respectively. The acute dataset lacks aquatic fungi as potentially sensitive group of organisms. The suggested CQC_{AF} ($AA\text{-}EQS_{AF}$) is lower than the suggested $QS_{biota,\ sec\ pois,\ fw}$ and is considered protective of exposure of wildlife via secondary poisoning

Data from a wider range of species would allow for species-sensitivity distribution modelling. Further, mesocosm studies were not available to refine the derived CQC. The derived QC can be regarded as protective of aquatic organisms, however, a larger dataset as described above would render the derived values more robust. The specific activity and degradation of the enantiomers of the cis-isomer of fenpropimorph have not been thoroughly explored.

The suggested CQC_{AF} ($AA\text{-}EQS_{AF}$) is below the LOQ of the analytical methods presented in the EU DAR EC (2005) potentially limiting the detectability of fenpropimorph around the suggested CQC_{AF}.

11 References

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Annex I

Aquatic effect data for fenpropimorph. As : active substance ; form. : formulation ; NA: not applicable. For further explanation of the table, please refer to section 4, Table 6. Results from the same study with different information in secondary references are boxed.

Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (ug/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
Acute freshwater effect data														
as	acute	algae	*Chlorella fusca*	growth rate	4d	ErC_{50}	=	2210	n.r.	n.r.	n.r.	NA	1/C1	UBA (2014)[i5]
as	acute	algae	*Pseudokirchneriella subcapitata*	biomass	72h	EbC_{50}	=	327	nom-m	S	96.6	NA	1/C1	Anonymous (2000) cited in EC (2006a), p. 147, A 7.4.1.3/01 ; Kubitza 2000 cited in EC (2005), p. 553
as	acute	algae	*Pseudokirchneriella subcapitata*	growth rate	72h	ErC_{50}	>	1000	nom-m	S	96.6	NA	1/C1	Anonymous (2000) cited in EC (2006a), p. 147, A 7.4.1.3/01; Kubitza 2000 cited in EC (2005), p. 553
as	acute	algae	*Pseudokirchneriella subcapitata*	population	72h	EC_{50}	=	327	n.r.	S	96.6	NA	1/C1	US EPA (2014)
as	acute	algae	*Pseudokirchneriella subcapitata*	biomass	72h	EC_{50}	=	327	n.r.	n.r.	n.r.	NA	1/C1	UBA (2004)
n.r.	acute	algae	*Pseudokirchneriella subcapitata*	growth rate	72h	ErC50	>	100000	nom-m	S	99.8	NA	1/C3	Anonymous (1997) cited in EC (2006a), p. 154, A 7.4.1.3/02
form.	acute	algae	*Scenedesmus subspicatus*	growth rate	72h	ErC50	=	284	m	S	n.r.	NA	1/C3	Handley 1999 cited in EC (2005), p. 554
form.	acute	algae	*Scenedesmus subspicatus*	biomass	72h	EbC50	=	171	m	S	n.r.	NA	1/C3	Handley 1999 cited in EC (2005), p. 554
as	acute	crustaceans	*Daphnia magna*	immobilisation	24h	EC_{50}	=	3500	n.r.	n.r.	n.r.	NA	1/C1	UBA (2014)
as	acute	crustaceans	*Daphnia magna*	immobilisation	48h	EC_{50}	=	2380	n.r.	S	96.6	NA	1/C1	US EPA (2014)
as	acute	crustaceans	*Daphnia magna*	immobilisation	48h	LC_{50}	=	2240	nom-m	S	96.6	NA	1/C1	Anonymous (1999) cited in EC (2006a), p. 134, A 7.4.1.2/01, Jatzek (1999) cited in EC (2005), p. 551
n.r.	acute	crustaceans	*Daphnia magna*	immobilisation	48h	LC_{50}	>	100000	nom	S	n.r.	NA	1/C3	Anonymous (1997) cited in EC (2006a), p. 141, A 7.4.1.2/02
as	acute	fish	*Cyprinus carpio*	mortality	96h	NOEC	=	680	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)
as	acute	fish	*Lepomis macrochirus*	mortality	96h	LC_{50}	n.r.	NA	mm	S	96.6	NA	1/C3	Anonymous (1999) cited in EC (2006a), p. 121, A 7.4.1.1/02
as	acute	fish	*Lepomis macrochirus*	mortality	96h	NOEL	=	196	n.r.	S	96.6	NA	1/C3	US EPA (2014)
as	acute	fish	*Lepomis macrochirus*	mortality	96h	EC_0	=	1495	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)
as	acute	fish	*Lepomis macrochirus*	mortality	96h	EC_{100}	=	2984	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)

[5] All entries retrieved from UBA (2014) that are not further specified refer to «Informationssystem Chemikaliensicherheit (ICS). Stand 2004. Umweltbundesamt, Berlin, Germany»

Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (ug/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	acute	fish	*Lepomis macrochirus*	mortality	96h	LC_{50}	=	2300	mm	S	96.6	NA	1/C1	Anonymous (1999) cited in EC (2005), p. 534
as	acute	fish	*Lepomis macrochirus*	mortality	96h	LC_{50}	=	2110	n.r.	S	96.6	NA	1/C1	US EPA (2014)
as	acute	fish	*Lepomis macrochirus*	mortality	96h	LC_{50}	=	2110	n.r.	n.r.	n.r.	NA	1/C1	UBA (2004)
as	acute	fish	*Oncorhynchus mykiss*	mortality	96h	NOEC	=	458	mm	S	96.6	NA	1/C3	Anonymous (1999) cited in EC (2006a), p. 114, A 7.4.1.1/01
as	acute	fish	*Oncorhynchus mykiss*	mortality	96h	LC_{50}	=	NA	mm	S	96.6	NA	1/C3	Anonymous (1999) cited in EC (2006a), p. 114, A 7.4.1.1/01
as	acute	fish	*Oncorhynchus mykiss*	mortality	96h	NOEL	=	460	n.r.	S	96.6	NA	1/C3	US EPA (2014)
as	acute	fish	*Oncorhynchus mykiss*	mortality	96h	LC_{50}	=	3370	mm	S	96.6	NA	1/C1	Zok 1999 cited in EC (2005), p. 533
as	acute	fish	*Oncorhynchus mykiss*	mortality	96h	LC_{50}	=	3460	n.r.	S	96.6	NA	1/C1	US EPA (2014)
n.r.	acute	fish	*Oncorhynchus mykiss*	mortality	96h	LC_{50}	>	100000	nom-m	S	99.3	NA	1/C3	Anonymous (1999) cited in EC (2006a), p. 128, A 7.4.1.1/03
Subchornic and chronic freshwater effect data														
as	chronic	algae	*Chlorella fusca*	growth rate	4d	NOEC	=	80	n.r.	n.r.	n.r.	NA	1/C1	UBA (2014)
as	chronic	algae	*Pseudokirchneriella subcapitata*	population	72h	NOEL	<	5	n.r.	S	96.6	NA	1/C3	US EPA (2014)
as	chronic	algae	*Pseudokirchneriella subcapitata*	biomass	72h	EC_{10}	=	5	n.r.	n.r.	n.r.	NA	1/C1	UBA (2004)
as	chronic	algae	*Pseudokirchneriella subcapitata*	growth rate	72h	ErC_{10}	=	58	n.r.	n.r.	n.r.	NA	1/C1	UBA (2014)
form.	chronic	algae	*Scenedesmus subspicatus*	growth rate	72h	NOEC	=	58	m	S	n.r.	NA	1/C3	Handley 1999 cited in EC (2005), p. 554
form.	chronic	algae	*Scenedesmus subspicatus*	biomass	72h	NOEC	=	58	m	S	n.r.	NA	1/C3	Handley 1999 cited in EC (2005), p. 554
n.r.	chronic	algae	*Pseudokirchneriella subcapitata*	growth rate	72h	NOEC	=	25000	nom-m	S	99.8	NA	1/C3	Anonymous (1997) cited in EC (2006a), p. 154, A 7.4.1.3/02
as	chronic	crustaceans	*Daphnia magna*	immobilisation	21d	NOEC	=	82	nom-m	T	95.4	NA	3/C3	Anonymous 1989 cited in EC (2006a), p. 224, A 7.4.3.4
as	chronic	crustaceans	*Daphnia magna*	number of offspring	21d	NOEC	=	82	nom-m	T	95.4	NA	3/C3	Anonymous 1989 cited in EC (2006a), p. 224, A 7.4.3.4
as	chronic	crustaceans	*Daphnia magna*	immobilisation	21d	NOEL	=	71	n.r.	T	95.4	NA	S/C1	US EPA (2014)
as	chronic	crustaceans	*Daphnia magna*	n.r.	21d	NOEC	=	2.2	n.r.	n.r.	n.r.	NA	1/C1	UBA (2014)
form.	chronic	crustaceans	*Daphnia magna*	number of offspring	21d	NOEC	=	32	nom-m	T	n.r.	NA	2/C3	Anonymous (1991) cited in EC (2006a), p. 233, A 7.4.3.4/02
form.	chronic	crustaceans	*Daphnia magna*	number of offspring	21d	LOEC	=	100	nom-m	T	n.r.	NA	2/C3	Anonymous (1991) cited in EC (2006a), p. 233, A 7.4.3.4/02
form.	chronic	crustaceans	*Daphnia magna*	immobilisation	21d	NOEC	<=	32	nom-m	T	n.r.	NA	2/C3	Anonymous (1991) cited in EC (2006a), p. 233, A 7.4.3.4/02
form.	chronic	crustaceans	*Daphnia magna*	immobilisation	21d	LOEC	>=	32	nom-m	T	n.r.	NA	2/C3	Anonymous (1991) cited in EC (2006a), p. 233, A 7.4.3.4/02
as	chronic	insects	*Chironomus riparius*	hatching rate	20d	NOEC	>=	86	m	n.r.	n.r.	NA	1/C1	UBA (2004)

Test item	Acute or Chronic	Group	Species	Endpoint	Duration	Parameter		Value (ug/L)	Analytics	Exposure	Purity (%)	Note	Validity	Reference
as	chronic	fish	*Lepomis macrochirus*	mortality	94d	LOEC	=	0.8	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)
as	chronic	fish	*Lepomis macrochirus*	mortality	21d	LOEC	=	300	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)
as	chronic	fish	*Lepomis macrochirus*	mortality	21d	LC0	=	1100	n.r.	n.r.	n.r.	NA	1/C3	UBA (2014)
as	chronic	fish	*Oncorhynchus mykiss*	mortality	21d	NOEC	=	100	m	T	95.4	NA	1/C2	Anonymous (1998) cited in EC (2006a), p. 167, A 7.4.3.1
as	chronic	fish	*Oncorhynchus mykiss*	survival	60d	NOAEL	=	0.16	nom-m	T	95.6	NA	1/C1	Anonymous (1995) cited in EC (2006a), p. 167, A 7.4.3.2/01 and /02
as	chronic	fish	*Oncorhynchus mykiss*	survival	94d	LOEC	=	0.8	n.r.	T	95.6	NA	1/C1	US EPA (2014)
as	chronic	fish	*Oncorhynchus mykiss*	growth	94d	LOEC	=	0.16	n.r.	T	95.6	NA	1/C3	US EPA (2014)
as	chronic	fish	*Oncorhynchus mykiss*	growth	94d	NOEC	<	0.16	n.r.	T	95.6	NA	1/C1	US EPA (2014)
as	chronic	fish	*Oncorhynchus mykiss*	weight	94d	NOEC	=	0.16	n.r.	n.r.	n.r.	NA	1/C1	UBA (2004)
form.	chronic	fish	*Oncorhynchus mykiss*	weight	49d	NOEC	=	3	nom	T	n.r.	NA	2/C3	Anonymous (2005) cited in EC (2006a), p. 190, A 7.4.3.2/04
form.	chronic	fish	*Oncorhynchus mykiss*	weight	49d	LOEC	=	9	nom	T	n.r.	NA	2/C3	Anonymous (2005) cited in EC (2006a), p. 190, A 7.4.3.2/04
form.	chronic	fish	*Leuciscus idus*	mortality	28d	NOEC	>=	12	nom-m	S	n.r.	NA	1/C3	Anonymous (2002) cited in EC (2006a), p. 184, A 7.4.3.2/03

Annex II

Raw data reported in an OECD 210 early life-stage toxicity test study on *Oncorhynchus mykiss* by Munk (1995) submitted for authorization of fenpropimorph as active substance in plant protection products (EC 2005) and in biocidal products (cited as "anonymous", EC (2009)).

Exposure concentration [µg/L]	Weight [g]				Length [cm]			
0	0.625	0.613	0.777	0.687	4.11	4.08	4.27	4.02
0.16	0.633	0.611	0.621	0.557	3.97	3.93	3.93	3.86
0.8	0.474	0.348	0.382	0.421	3.71	3.36	3.46	3.59
4	0.314	0.293	0.224	0.309	3.16	3.13	2.94	3.18
20	0.232	0.253	0.196	0.229	2.82	2.85	2.7	2.85
100	0.191	0.165	0.23	0.229	2.67	2.68	2.7	2.74

Exposure concentration [µg/L]	Absolute survival				Relative survival			
0	14	13	15	14	93.3	86.7	100	93.3
0.16	15	14	14	15	100	93.3	100	100
0.8	12	11	13	10	92.3	73.3	86.7	66.7
4	8	4	7	9	53.3	26.7	50	64.3
20	6	8	10	10	42.9	53.3	71.4	71.4
100	7	6	1	7	46.7	40	7.7	46.7

Annex III

Derivation of a biota standard to protect wildlife from secondary poisoning ($QS_{biota,\ sec\ pois,\ fw}$) based on method B:

For normalization of fenpropimorph concentration in food to energy content, a standard energy content of 15.1 kJ/g_{dw} (or and moisture fraction of 8 % are assumed (see Table 8, EC (2018)) and used to calculate the energy-normalized concentration in food:

$$0.72\ \frac{mg}{kJ} = \frac{10\ \frac{mg}{kg fw}}{15100 \frac{kJ}{kg dw} x\ (1-0.08)}$$

This results in an energy content normalized concentration of fenpropimorph of 0.00072 mg/kJ.

In order to convert the derived endpoint to fenpropimorph concentration in the critical food item, the following formula is used:

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

According to Table 7 of EU TGD for EQS, standard moisture content and energy content of fish are 73.7 % and 21 kJ/g_{dw}, respectively.

$$3.97 \frac{\boldsymbol{mg}}{\boldsymbol{kg_{ww}}} = 0.00072 \frac{\boldsymbol{mg}}{\boldsymbol{kJ}} x\ 21000 \frac{\boldsymbol{kJ}}{\boldsymbol{kg_{dw}}} x\ (1 - 0.737)$$

The resulting fenpropimorph concentration in fish is 3.97 mg/kg_{ww}. To calculate the corresponding concentration of fenpropimorph in water, the highest measured BCF in fish combined with a default BMF of 1 (for substances with log K_{ow} < 4.5; Table 22, EU TGD for EQS) and the highest and lowest calculated BAF in fish are used (see section 2.3), assuming a steady state distribution of fenpropimorph between water, food and organism:

Table 9 Water concentrations of fenpropimorph derived from the concentration in the critical food item

No.	Type [L/kg]	Value	Reference	Resulting concentration in water [µg/L]
1	BCF x BMF	1002 x 1	Geometric mean, Dijk (1988a) cited in EC (2005)	3.96
2	BAF	491	Estimated with EPISuite/BCFBAF, US EPA (2007), including biotransformation	8.1
3	BAF	82460	Estimated with EPISuite/BCFBAF, US EPA (2007), without biotransformation	0.05

As cited in section 2.3, about half of the applied radiolabelled fenpropimorph was metabolised in a BCF study on rainbow trout (Hafemann (2003) cited in EC (2005), p. 544). Depuration half-lives (whole fish) were 1.7-2.8 days. Assuming no biotransformation for BAF estimation is thus not justified (No. 3, Table 9). Values based on the product of the mean measured BCF and a BMF of 1 and an estimated BAF assuming biotransformation are in the same order of magnitude (No. 1 and 2, Table 9). For the purpose of EQS derivation, a value based on experimental results is preferred (No. 1, Table 9). The suggested assessment factor is 10 in accordance with EU TGD for EQS, as derivation is based on the lowest chronic value.

The application of an AF of 10 to the lowest credible chronic datum results in a **$QS_{Biota, sec\ pois, fw}$ =** 0.397 mg/kg_{ww} or **0.396 µg/L** (based on BCF x BMF).

[i] All entries retrieved from UBA refer to «Informationssystem Chemikaliensicherheit (ICS). Stand 2004. Umweltbundesamt, Berlin, Germany»