REPORT

Proposal for new Normative Values for PFOS and PFOA in contaminated soil

FORSLAG TIL NYE NORMVERDIER FOR PFOS OG PFOA I FORURENSET GRUNN

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Summary

The Norwegian Geotechnical Institute (NGI) has reviewed the existing data that are used to derive the Norwegian soil normative values for Perfluorooctanesulfonic acid (PFOS) and Perfluorooctanoic acid (PFOA) on behalf of the Norwegian Environment Agency (Miljødirektorat). Soil normative values (in Norwegian *normverdier*) are used to assess the unrestricted handling of soil in the case of soil contamination. For PFOS a soil normative value was derived in 2007, while no value exists for PFOA. Significant new knowledge and insight has been gained concerning the environmental fate and toxicity of per- and polyfluorinated alkyl substances (PFAS) during recent years. This report reviews the latest advances with regard to human and ecological risk assessment for PFOS and PFOA in the terrestrial environment. This includes the recently published proposal concerning risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food by the European Food Safety Authority (EFSA, 2018a). These data have been reviewed and used in the Norwegian risk assessment framework to derive soil quality standards for human health and the ecosystem as basis for normative values for PFOS and PFOA in soil.

A critical aspect in the suggested revised soil normative values is that human health quality standards, derived using the Norwegian risk assessment model, are strongly dominated by the exposure route drinking water from local wells. The contribution of this exposure route to the total modelled human exposure is > 80% for PFOS and > 90% for PFOA. Inclusion of this exposure route, as well as secondary poisoning in the terrestrial food web, results in soil normative values in the low µg/kg dryweight range.

The recommended normative values for PFOS and PFOA are above the current limit of quantification (LOQ) used by commercial chemical laboratories operating in the Norwegian market (0.1 µg/kg d.w.).

An overview of the derived quality standards for soil (QS_{soil}) and proposed revised soil normative values for PFOS and PFOA is presented in Table S1. The table includes a comparison with the existing legal values.

Table S1. An overview of the quality standards for soil (QS_{soil} in mg/kg d.w.) and proposed soil normative values for PFOS and PFOA including a comparison with the existing normative values.

QS values (mg/kg d.w.)	PFOS	PFOA	Remark
$QS_{soil, human}$	0.0025	0.00018*	Based on proposed Maximum Tolerable Daily Intake (MTDI) values from EFSA (2018), alternative MTDI values result in: PFOS: RIVM* (2019) = 0.0083 mg/kg PFOA: RIVM* (2016) = 0.0026 mg/kg
$QS_{soil, human}$ (excl. drinking water)	0.015	0.0029	Based on proposed MTDI values from EFSA (2018), alternative MTDI values result in: PFOS: RIVM* (2019) = 0.051 mg/kg PFOA: RIVM* (2016) = 0.042 mg/kg
$QS_{soil, ecotox}$	0.016	0.5	
$QS_{soil, EqP}$	*0.0000065***	0.011	PFOS; AA-EQS (0.00065 µg/l) x K_D (10 l/kg)** PFOA: AA-EQS (9.1 µg/l) x K_D (1.25 l/kg)
$QS_{soil, sec.poisoning}$	0.003	0.007	
Normative Value 2007	**0.1**	**-**	No existing normative value for PFOA
Proposed Normative Value 2019	**0.003**	**0.003**	Quality standard used for proposed normative value: PFOS: Human health and Secondary poisoning PFOA: Human health

* EFSA and National Institute for Public Health and the Environment, the Netherlands (RIVM) propose different MTDI values; (based on Zeilmaker et al. 2018 and Zeilmaker et al. 2016);

** not used in the establishment of the normative value for reasons explained in the text.

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1 Introduction

1.1 Background

The Norwegian Environment Agency (Miljødirektorat) first introduced a system for assessing normative values for soil concentrations in the 1999 guideline "Veiledning om risikovurdering av forurenset grunn" (TA-1629/1999, English version TA-1691/1999 (Miljødirektoratet, 1999a, b)). These normative values, referred to in Norwegian as *normverdier*, are essentially soil quality criteria that can be used to determine whether a Norwegian soil is polluted. If the normative values are not exceeded, the soil is considered to be acceptable (or without risk) for all applications.

In 2007, a revision of the 1999 normative values was carried out based on the latest available data at that time. This included a new list of substances, such as brominated flame retardants, perfluorooctanesulfonic acid (PFOS), chlorinated paraffins, alkyl-phenols and phthalates (Aquateam, 2007). The derived values were later put into effect and are legally binding in Norway (Forskrift om begrensning av forurensning, *forurensningsforskriften*, chapter 2, appendix 1 (Lovdata, 2013)).

Following the introduction of the European Union's Water Framework Directive, environmental quality standards (EQS) for water, sediment and biota were derived and implemented (Miljødirektoratet, 2014; 2016). This included EQS for PFOS and PFOA, as both chemicals are listed in the Water Framework Directive. Since 2016, significant new knowledge and insight has been gained concerning the environmental fate and toxicity of per- and polyfluorinated alkyl substances (PFAS). This report reviews the latest advances with regard to human and ecological risk assessment for PFOS and PFOA in the terrestrial environment. This includes the recently published proposal concerning risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food by the European Food Safety Authority (EFSA, 2018a). In addition, a recent assessment carried out for the National Institute for Public Health and the Environment in the Netherlands (RIVM) was also used. Discussions with key persons involved in this: Arjen Wintersen, Eric Verbruggen and Els Smit, as well as acess to the extensive data complitaion were crucial in the work presented here. These more recent data sources have been reviewed and used in the Norwegian risk assessment framework (Miljødirektoratet, 1999a, b) to derive normative values for PFOS and PFOA in soil.

A short overview over the used methodology is presented in this chapter followed by separate chapters for PFOS and PFOA. NGI report 20160648-03-R rev 1 (NGI, 2019) describes the methodology in detail.

1.2 Methodology

The work and decision tree for deriving the normative values used in this report is an extension of the methodology provided previously (Miljødirektoratet, 1999a, b; Aquateam, 2007), and is presented in Figure 1.

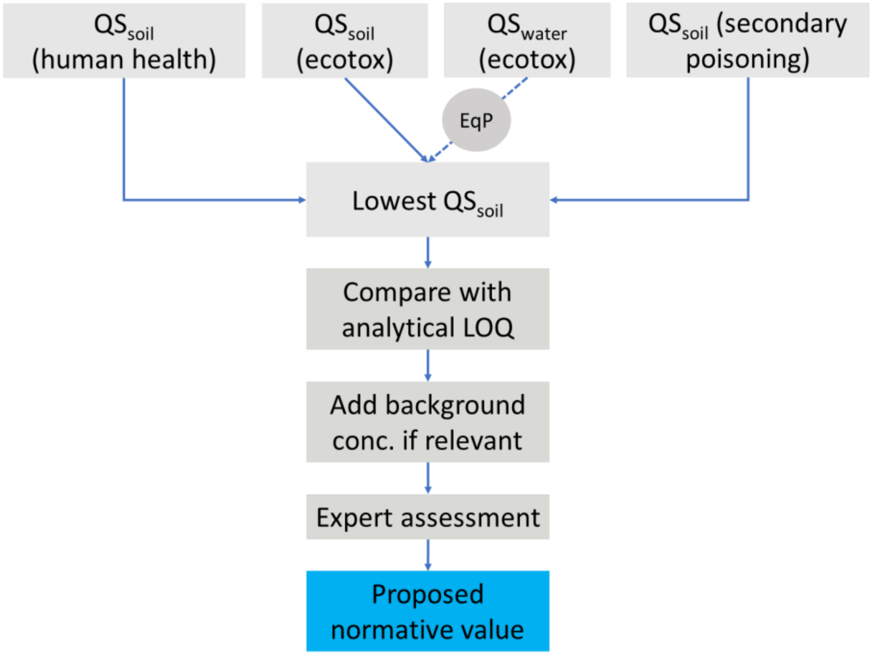

Figure 1. Flow chart for the evaluation of suitable normative values for soil based on the lowest quality standard for human health, ecotoxicity and secondary poisoning. If no QS_{soil} (ecotox) data are available QS_{water} (ecotox) can be used with equilibrium partitioning (EqP).

A presented in Figure 1, the first step in deriving a normative value for soil is to derive three types of quality standards that are protective of the soil environment. The first is protective of human health QS_{soil}(human health), the second is protective of soil ecology, and is based on soil ecotox studies QS_{soil}(ecotox), and the third is protective of predators in the terrestrial foodweb QS_{soil}(secondary poisoning). The inclusion of QS_{soil} (secondary poisoning) is unique to this report compared to previously derived normative values (Miljødirektoratet, 1999a, b; Aquateam, 2007), since more data have become available. The inclusion represents are stronger focus on the ecotoxicological effects of the contaminants.

As presented in the description of Figure 1, an alternative to a $QS_{soil,ecotox}$ is the equilibrium partitioning method $QS_{soil,EQP}$. The $QS_{soil,EqP}$ derivation is based on the assumption that interspecies Predicted No Effect Concentration (PNEC) for chronic toxicity for freshwater organisms, such as the Annual Average-Environmental Quality Standard (AA-EQS) value in the Water Framework Directive (2013/39 EU), can be related to the PNEC for chronic toxicity in soil dwelling organisms via a soil-water partition coefficient, K_D.:

$$QS_{soil,EqP} = AA - EQS_{freshwater} \times K_D \quad (1)$$

Where $AA\text{-}EQS_{freshwater}$ is the Annual Average-EQS value for freshwater (e.g. from the Water Framework Directive - Directive 2013/39 EU). Generally and historicaly in Norway, $QS_{soil,ecotox}$ values are favoured over $QS_{soil,EqP}$ values for deriving soil normative values, as $QS_{soil,ecotox}$ values more directly apply to soil dwelling organisms. In this report, it was considered important to derive both $QS_{soil,ecotox}$ and $QS_{soil,EqP}$. Although no ecological effects are observed in soil, there may be situations where the soil is a contaminant source to nearby freshwater recipients. This approach is particularly favoured for environmentally persistent and mobile substances, and where the mode of toxicity is similar for soil dwelling organisms and freshwater organisms.

After all QS_{soil} values are derived, the lowest value is compared with the current analytical limit of quantification (LOQ) used by commercial chemical laboratories operating in the Norwegian market. This value does not refer to limits of quantification that can be achieved by cutting edge techniques (e.g. in universities), as most site managers and consultants will not have access to these laboratories on a routine basis. Following this, a typical Norwegian background concentration is identified as some contaminants, such as heavy metals, appear in a soil as a result of natural geological processes. This value is then added to the lowest QS_{soil} (or the LOQ if it is higher than the lowest QS_{soil}). However in the case of PFOS and PFOA, this is not considered to be relevant due to their anthropogenic nature.

Finally, an expert assessment is conducted to assign a normative value considering the lowest QS_{soil}, LOQ, background concentrations and additional compound specific considerations These considerations might comprise formation of transformation products, unique vulnerabilities of exposed ecosystems or human populations in Norway, management considerations such as practicality in relation to available technology or cost to society, and conformity with other guideline values.

These steps are explained in detail in Miljødirektoratet (1999a, b) and Aquateam (2007) and are applied in this report to derive soil normative values for PFOS and PFOA. Where relevant, specific calculations following this methodology are presented to guarantee transparency and allow for future revision given the rapid development of knowledge related to the environmental impact of PFAS.

Internationally there are several, relevant on-going studies expected to be published early 2020. The outcome of these studies may result in updated or different data than those used here to derive the normative values, in this case further refinement of the soil normative values suggested in this report may be required.

2 Perfluorooctanesulfonic acid (PFOS)

2.1 Compound properties

The critical properties of PFOS that determine the environmental fate, transport and risk are presented in Table 1. For apolar organic compounds log K_{OW} would be indicative of sorption of the contaminant to the organic matter in the soil matrix. This sorption increases with the organic carbon content in the soil. For PFOS, log K_{OW} is a problematic parameter because PFOS is dissociated (in ionic form) under normal environmental conditions, and sorption is therefore dependant on pH. Further, the K_{OW} does not capture ionic interactions that can occur with soil organic carbon and minerals. These interactions affect how strongly PFOS binds to different fractions of the soil, and thus has an influence on the environmental fate. There is also discussion in the literature whether the distribution coefficient (K_D) for PFOS is systematically increasing with soil carbon content (Verbruggen et al. in prep.), and therefore how suitable K_{OC} is to predict sorption. Measurements of K_D and K_{OC} for PFOS are spread over several orders of magnitude (Zareitalabad et al., 2013), which is broader than most organic chemicals, and it is due to the complex sorption interactions that can exist between PFOS and different types of soil, sediment and sludge. Therefore the use of the average measured K_{OC} value from the literature is recommended. The K_D value is then derived from the literature K_{OC} using a default TOC content of 1% for Norwegian soil (Miljødirektoratet, 1999a, b). This approach is in accordance with quality standards derived for aquatic sediments (Miljødirektoratet, 2016).

Uptake in organisms is estimated using biota concentration factors (BCF) that relate the concentration in specified biota to the concentration in the aqueous phase (surface or porewater). For terrestrial species, these values can be transformed to biota to soil accumulation factors (BSAF) relating the biota concentration directly to the soil concentration using the following formula:

$$BSAF = \frac{C_{biota}}{C_{soil}} = \frac{C_{biota}}{C_{water}} \times \frac{C_{water}}{C_{soil}} = \frac{BCF}{K_D} \qquad (2)$$

Further accumulation to higher trophic levels in the ecosystem is expressed with a biota magnification factor (BMF):

$$BMF = \frac{C_{biota,2}}{C_{biota,1}} \qquad (3)$$

Table 1 Overview of compound properties used in environmental risk assessment of PFOS

Parameter	Unit	Value	Definition	Comments
M.W.	g/mol	500.13	Molecular weight	undissociated form
S	mg/l	2400	Aqueous solubility	Campbell et al. (2009)
Vp	Pa	3.36	Vapour pressure	Arp et al. (2006)
log K_{OW}	l/l	6.4 to -5.0	Octanol-water partition coefficient	6.4 in Neutral form. -5.0 at pH 8 (Wang et al. 2011)
K_{OC}	l/kg d.w.	1000	Organic carbon-water partition coefficient	Zareitalabad et al. (2013)
K_D	l/kg d.w.	10	Soil-water distribution coefficient	assuming 1% TOC in soil (Miljødirektoratet 2016).
Henry constant	-	$8.7x10^{-10}$ (pH =4)	Dimensionless Henry's law coefficient	log Kaw = -1.7 (neutral form). -13.1 at pH 8 (Wang et al., 2011).
BCF_{fish}	l/kg w.w.	2796	Bioconcentration factor in fish	EU dossier PFOS (2011)
$BSAF_{leaf/soil}$	kg d.w./ kg w.w.	0.017	Bioconcentration factor in plant leaves	empirical conc. leaf/conc. soil (Wintersen et al., 2019)*
$BSAF_{root/soil}$	kg d.w./ kg w.w..	0.001	Bioconcentration factor in plant roots	empirical conc. root/conc. soil (Wintersen et al., 2019)**
$BSAF_{soil/worm}$	kg d.w./ kg w.w..	1.92	Bioconcentration factor in earthworms	(Verbruggen et al., in preparation.)
$BMF_{worm/mammal}$	kg w.w./ kg w.w..	6.74	Biomagnification factor in mammals and birds	(Verbruggen et al., in preparation.)

* value applicable for other vegetables (Wintersen et al., 2019)

** value applicable for potatoes (Wintersen et al., 2019)

2.2 Existing environmental quality standards

An overview of existing environmental quality standards (EQS) for PFOS in soil, sediment and water in Norway are presented in Table 2.

Table 2. Overview existing environmental quality standards for PFOS in different environmental compartments in Norway.

Environmental Quality Standard	**Value**	**Reference**
Normative value soil	0.1 mg/kg d.w.	Lovdata, 2013
EQS freshwater sediment (chronic)	0.0023 mg/kg d.w.	Miljødirektoratet, 2016
EQS marine sediment (chronic)	0.00023 mg/kg d.w.	Miljødirektoratet, 2016
EQS freshwater sediment (acute)	0.36 mg/kg d.w.	Miljødirektoratet, 2016
EQS marine sediment (acute)	0.072 mg/kg d.w.	Miljødirektoratet, 2016
Annual average EQS freshwater	6.5×10^{-4} µg/l	Miljødirektoratet, 2016
Annual average EQS seawater	1.3×10^{-4} µg/l	Miljødirektoratet, 2016
Max. acceptable conc. EQS freshwater	36 µg/l	Miljødirektoratet, 2016
Max. acceptable conc. EQS seawater	7.2 µg/l	Miljødirektoratet, 2016
EQS biota (whole fish)	9.1 µg/kg w.w.	Miljødirektoratet, 2016

The values for the aquatic environment presented in Table 2 are related to the European Water Framework Directive and based on human fish consumption using the MTDI values from EFSA (2008). The EFSA (2018a) MTDI values are considerably lower and are not reflected in the quality standards presented in Table 2.

2.3 Human health risk

2.3.1 Maximum tolerable daily intake

Human health effects are focused on liver hypertrophy as the most sensitive end point. Maximum tolerable daily intake values (MTDI) for PFOS have changed over time as more data have become available. The latest Health Based Guidance Values (HBGVs) proposed by EFSA (2018a) are significantly lower than recommended in previous studies (Table 3). These values are presently under discussion as several European environmental authorities have divergent opinions related to how the latest EFSA values were derived (EFSA, 2018b). Work on establishing new HBGVs is expected to continue in 2020.

Table 3. Overview of MTDI values for PFOS presented in various studies in chronological order.

Source	**MTDI PFOS (ng/kgbw/d)**
European Food Safety Authority (EFSA, 2008)	150
US Environmental Protection Agency (USEPA, 2016a)	20
Agency for Toxic Substances and Disease Registry, US (ATSDR, 2018)	20
National Institute for Public Health and the Environment, the Netherlands (RIVM 2019, based on Zeilmaker et al. 2018)	6.25
European Food Safety Authority (EFSA, 2018a)*	1.86*

* original reference states TWI 13 ng/kg b.w./week

2.3.2 Human exposure estimation

The MTDI values presented in Table 3 can be used in the Norwegian human risk assessment framework (Miljødirektoratet, 1999a, b) using the latest version of the model tool (Miljødirektoratet, 2013). Calculations were performed using both PFOS compound properties from 2013 and the revised parameters (2019) presented in Table 1.

Table 4. Estimated soil concentrations of PFOS that would not result in exceedance of MTDI values.

Parameter	**Unit**	**Compound properties (Miljødirektoratet, 2013)**	**Revised compound properties (2019)**
K_{OC}	l/kg d.w.	2690	1000
K_D	l/kg d.w.	26.9	10
Dimensionless Henry constant (K_{aw})	-	$3.2x10^{-8}$	$8.7x10^{-10}$
BCF fish	l/kg w.w.	2796	2796
BCF leaf	l/kg d.w.	-	0.17*
BCF root	l/kg d.w.	-	0.01*
Soil quality standard human (including drinking water)			
$QS_{soil,\ human}$ ($MTDI_{EFSA2008}$)	µg/kg d.w.	540	200
$QS_{soil,\ human}$ ($MTDI_{RIVM2019}$)	µg/kg d.w.	23	8.3
$QS_{soil,\ human}$ ($MTDI_{EFSA2018a}$)	µg/kg d.w.	6.7	2.5
Soil quality standard human (excluding drinking water)			
$QS_{soil,\ human}$ ($MTDI_{EFSA2008}$)	µg/kg d.w.	3600	1200
$QS_{soil,\ human}$ ($MTDI_{RIVM2019}$)	µg/kg d.w.	150	51
$QS_{soil,\ human}$ ($MTDI_{EFSA2018a}$)	µg/kg d.w.	44	15

* Recalculated to $BCF_{plant/water}$ (l/kg w.w.); BCF = K_D·x $BSAF_{plant/soil}$ (kg d.w./kg w.w.)

Calculations were performed with and without the inclusion of drinking water from a local well as a human exposure route. Results of the model calculation indicate that soil concentrations varying from 2.5 (EFSA, 2018a) to. 23 µg/kg d.w (RIVM, 2019) will not result in exceedance of the respective MTDI values if drinking water exposure is included. Without drinking water the respective values are 15 (EFSA, 2018a) and 150 µg/kg d.w (RIVM, 2019). Showing that exposure through drinking water is dominating human exposure (Figure 2). Exposure through drinking water is responsible for more than 80% of the estimated exposure if all exposure routes in the Norwegian human risk assessment framework are included (Miljødirektoratet, 1999a, b). Groundwater concentrations that are estimated in the human risk exposure model and used as drinking water concentrations are strongly dependent (almost proportionally) on the distribution coefficient (K_D) that is used.

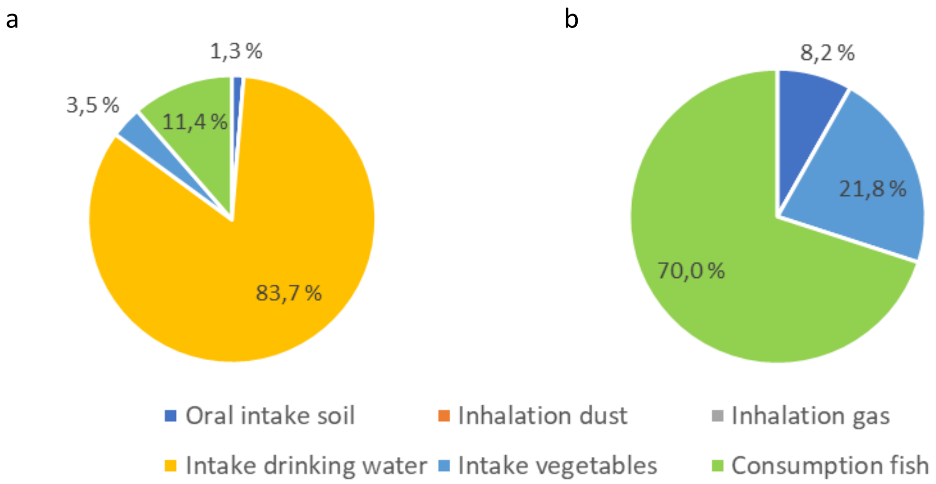

Figure 2. Contribution of the different exposure routes to human exposure of PFOS including exposure through drinkingwater (a) and excluding exposure through drinking water (b).

2.3.3 Drinking water limits

The human risk assessment model (Miljødirektoratet, 1999a, b) used here assumes a human intake of drinking water of 2 liter/day for adults (7-64 yrs, 70 kg body weight) and 1 liter/day for children (0-6 yrs, 15 kg body weight). Resulting in a life time integrated exposure of 1.9 liters/day. The World Health Organisation states that 20% of the MTDI can come from drinking water when guidelines for drinking water quality are derived (WHO, 2017). An estimate of concentrations in drinking water using the various MTDI values (Table 3) is presented in Table 5.

Drinking water limits were calculated as follows:

$$C_{drinking\ water} = \frac{MTDI \cdot BW_{lifetime} \cdot 0.2}{IL_{dw}} \qquad (4)$$

Where:
$BW_{lifetime}$, body weight life time integrated = 65 kg
IL_{dw}, Lifetime intake drinking water = 1.9 L/day

Exposure via drinking water is now a well established concern for PFOS and many other PFAS. These substances are found near ubiquitously in water based on their high mobility in the aquatic environment (Kabore et al. 2018). In addition, a recent study found clear correlations between drinking water concentrations and blood serum concentrations in children (Gyllenhammer et al. 2019).

Table 5. Estimated PFOS concentrations in drinking water that would not result in exceedance of 20% of the respective MTDI values.

MTDI value reference	**PFOS MTDI value ($ng/kg_{bw}/d$)**	**PFOS drinking water limit (ng/l)**
EFSA, 2008	150	1030
USEPA, 2016a	20	137
RIVM, 2019 (based on Zeilmaker et al. 2018)	6.25	43
EFSA, 2018a	1.86*	13

* original reference states TWI 13 ng/kg b.w./week

It is relevant to compare this data to drinking water limits for PFOS recommended in different parts of the world (Table 6).

Table 6. Published drinking water limits for PFOS.

Information source	**Drinking water limit (ng/l)**
WHO (2017)	400
USEPA drinking water advisory (2016b)	70 (for PFOS and PFOA combined)
EU Drinking water directive proposal (2018a)	100 single PFAS, 500 for sum PFAS

Compared to these limits, the estimated drinking water limits based on the PFOS MTDI of RIVM (2019) and USEPA (2016a) values are within the range of the EU and USEPA drinking water limits, but the EFSA (2018a) would be relatively conservative.

2.4 Ecological effects

Quality standards for soil biota ($QS_{soil,\ ecotox}$) exposed to PFOS were derived by Bodar (2011) and have been revised and supplemented by Verbruggen et al. (in preparation.). These values are used and discussed in this report. The quality standards are based on no-observed-effect concentrations (NOEC) or effect concentration for 10% of organisms (EC_{10}) as a chronic endpoint according van Vlaardingen and Verbruggen (2007); and the EU-technical guidance document (EU, 2018b). Results from tests using different plants and soil organisms were assessed. Geometric mean values of studies that were considered of sufficient quality were calculated. The dataset that forms the basis for the derived $QS_{soil,\ ecotox}$ is presented in Table 7

Table 7. Overview of chronic toxicity data (NOEC/EC_{10}) for plants and soil organisms used to derived QS_{ecotox} (see Verbruggen et al. (in preparation) for a detailed evaluation).

Taxonomic group	Species	Criterium	Value (mg/kg d.w.)
Plants	*Allium cepa*	EC_{10}	2.3
	Brassica rapa chinensis	EC_{10}	72
	Glycine max	EC_{10}	75
	Lactuca sativa	EC_{10}	0.81
	Linum usitatissimum	EC_{10}	28
	Lolium perenne	EC_{10}	0.79
	Medicago sativa	EC_{10}	18
	Lycopersicum esculentem	EC_{10}	3.2
Invertebrates	*Eisenia fetida*	NOEC	3.8
	Folsomia candida	EC_{10}	90
	Oppia nitens	EC_{10}	8.6
Geometric mean			9.1

This geometric mean value of 9.1 mg/kg d.w. is proposed as hazard concentration 50% (HC_{50}) a concentration where a negative effect of PFOS exposure to 50% of the soil dwelling species cannot be excluded. To derive a value that is considered protective for the soil ecosystem the lowest value (0.79 mg/kg d.w.) is used and an assessment factor of 50 is applied following the methodology of Van Vlaardingen and Verbruggen (2007). This results in a value of 0.016 mg/kg d.w. that is considered protective of 95% of soil living organisms and equivalent to HC_5.

This $QS_{soil,EqP}$ value can be calculated using the AA-EQS value for freshwater from Table 2 as:

$$QS_{soil,EqP} = \text{AA-EQS } (6.5 \times 10^{-4}\ \mu g/l) \times K_D\ (10\ l/kg) = 0.0065\ \mu g/kg \qquad (5)$$

This value is considerably lower than the toxicity to soil living organisms, as it is based on the low QS value for human health from fish consumption, based on the EFSA (2008) value of 150 $ng/kg_{bw}/d$ and an assessment factor of 200 (EU 2011). It is noted that the

AA-EQS for freshwater may change in future based on either the new TWI values from EFSA or RIVM data, and any corresponding update in the assessment factor.

2.5 Secondary poisoning

Exposure of higher organisms such as birds and mammals to PFOS comes as a result of bioaccumulation in prey organisms and subsequent biomagnification with increasing trophic level. This is referred to as secondary poisoning. Verbruggen (2014) has developed a methodology to estimate biomagnification in the terrestrial ecosystem based on the energy content of the prey consumed by higher organisms like birds and mammals. Based on toxicity data for birds and mammals soil quality standards can be derived by back calculation from levels in mammals to concentration in prey organisms using BMF and subsequent concentration in soil using BSAF as follows:

$$QS_{soil,\ sec.poisoning} = \frac{Risk\ limit_{mammals}}{BMF_{worm,mammal} \cdot BSAF_{soil,worm}} \qquad (6)$$

The derivation of the risk limits, equivalent to HC_5 and HC_{50} values for PFOS for predators of earthworm consuming animals is explained in detail in Verbruggen et al. (in prep.). The dataset contains toxicity data for duck, quail, mouse, rat, rabbit, Java monkey and rhesus monkey. Applying corrections for length of the study (subchronic vs. chronic) and an assessment factor following Verbruggen (2014), risk limits were derived and are presented in Table 8. The biota-soil accumulation factor (BSAF) values are not corrected for soil properties like organic carbon content but based on a geometric mean of observed values (Verbruggen et al. in preparation).

Table 8. Overview ecological risk limits for earth worm eating animals for PFOS (µg/kg$_{dw}$) derived from Wintersen et al. (2016).

Risk limit	**Mammals/birds (mg/kgbw)**	**$BMF_{worm,\ mammal}$***	**$BSAF_{soil,\ worm}$**	$QS_{soil,\ sec.pois.}$ **(mg/kg soil)**
Equiv. to HC_5	0.038	6.74	1.92	0.003
Equiv. to HC_{50}	1.35	6.74	1.92	0.106

* Miljødirektoratet (2014) and EU (2011) use a BMF of 5.0 for biomagnification from aquatic organisms to mammals used to derive the values presented in Table 2. Following the methodology in Verbruggen (in preparation) a BMF of 3.7 from aquatic organisms to mammals would be derived.

2.6 Proposed soil quality standards

To derive new normative values for soil in Norway the methodology in Figure 1 was followed using the data presented in the previous sections. The quality standards for human, ecological risk and secondary poisoning are presented in Table 9

Table 9. Overview of quality standards for soil (QS_{soil}) for PFOS and proposed normative value (µg/kg_{dw}).

Risk	**Value (µg/kg d.w.)**	**Comment**
$QS_{soil, human}$	8.6	based on $MTDI_{RIVM\ 2018}$
$QS_{soil, human}$	2.5	based on $MTDI_{EFSA2018}$
$QS_{soil, ecotox}$	16	equiv.to HC_5 value plants and soil organisms
$QS_{soil, EqP*}$	*0.0065**	Freshwater AA-EQS (6.5 x 10^{-4} µg/l) x K_D (10 l/kg)
$QS_{soil, sec.\ poisoning}$	3	equiv. to HC_5 value birds and mammals
Proposed Normative value	**3**	based on $QS_{soil, human}$ and $QS_{soil, sec.\ poisoning}$

*not considered in final derivation

At present there is still uncertainty related to the MTDI value that will be adopted by EFSA after comments received during the public hearing (EFSA, 2018b). Considering this uncertainty, a Normative value of 3 µg/kg d.w. is proposed as it covers both the lower human toxicity value and secondary poisoning in the ecosystem. This value is within the current limit of quantification (LOQ) used by commercial chemical laboratories operating in the Norwegian market (0.1 µg/kg d.w.).

Despite PFOS being persistent and mobile, the *$QS_{soil,\ EqP}$* is not used to derive the proposed normative value for PFOS for the following reasons:

- high quality $QS_{soil,ecotox}$ data for PFOS are available;
- there is a large variability in the K_D and K_{OC} values reported for PFOS (Zareitalabad et al., 2013)); further, they may not describe sorption in unsaturated soil, which appears much stronger than in saturated soil, potentially due to enhanced sorption on pore air-water interfaces (Brusseau, 2018). This makes the available K_D values problematic for estimating leaching behaviour for unsaturated soils.
- the dependence of the AA-EQS for freshwater on human health TDI values and the related assessment factor, which are currently under discussion (EFSA, 2018 a, b). Therefor run-off to near by resipients is not included in the proposed normative values.
- EqP based limit is very conservative and below the current limit of quantification (LOQ) used by commercial chemical laboratories operating in the Norwegian market (0.1 µg/kg d.w.), making it problematic for implementation.

3 Perfluorooctanoic acid (PFOA)

3.1 Compound properties

The critical properties of PFOA that determine the environmental fate, transport and risk are presented in Table 10. For apolar organic compounds log K_{OW} would be indicative of sorption of the contaminant to the organic matter in the soil matrix. This sorption increases with the organic carbon content in the soil. For PFOA, log K_{OW} is a problematic parameter because PFOA is dissociated (in ionic form) under normal environmental conditions, and sorption is therefore dependant on pH. Further, the K_{OW} does not capture ionic interactions that can occur with soil organic carbon and minerals. Potentially complicating matter further, is the fact that PFOA can dimerize at elevated concentratons (Cheng et al., 2009). There is also discussion in the literature whether the distribution coefficient (K_D) is systematically increasing with soil carbon content (Lijzen et al. 2018) and therefore how suitable K_{OC} is to predict sorption.

Table 10 Overview of compound properties used in human health risk assessment of PFOA

Parameter	Unit	Value	Definition	Comments
M.W.	g/mol	414.07	Molecular weight	undissociated form
S	mg/l	9500	Aqueous solubility	Campbell et al. (2009)
Vp	Pa	4	Vapour pressure	Kaiser et al. (2005)
log K_{OW}	l/l	2.2	Octanol-water partition coefficient	5.3 in Neutral form, -1.8 at pH 8, 2.2 at pH 4 (Wang et al. 2011)
K_{OC}	l/kg d.w.	125	Organic carbon-water partition coefficient	Zareitalabad et al. (2013)
K_D	l/kg d.w.	1.25	Soil-water distribution coefficient	assuming 1% TOC in soil
Henry constant	-	1.0×10^{-3}	Henry's law coefficient	log Kaw = -3.0 (Li et al. 2007), calculated -1.9 neutral form, -9.0 at pH 8
BCF_{fish}	l/kg w.w.	4.0	Bioconcentration factor in fish	1.8-8.0 for different fish species (ECHA, 2013)*
$BSAF_{leaf/soil}$	kg d.w./ kg w.w.	0.035	Bioconcentration factor in plant leaf	empirical conc. leave/conc. soil (Lijzen et al. 2018)
$BSAF_{root/soil}$	kg d.w./ kg w.w..	0.012	Bioconcentration in plant roots	empirical conc. root/conc. soil (Lijzen et al. 2018)
$BSAF_{soil/worm}$	kg d.w./ kg w.w.	0.56	Bioconcentration factor in earthworms	(Verbruggen et al., in preparation.)
$BMF_{worm/mammal}$	kg w.w./ kg w.w.	7.71	Biomagnification factor in mammals and birds	(Verbruggen et al., in preparation.)

* an extensive review of BCF data for fish is presented in Verbruggen et al. (2017)

As with PFOS, measurements of K_D and K_{OC} of PFOA are spread over several orders of magnitude (Zareitalabad et al., 2013), which is broader than most organic chemicals, and it is due to the complex sorption interactions that can exist between PFOA and different types of soil, sediment and sludge. Here we derive the K_D from literature K_{OC} (Zareitalabad et al., 2013) using a default TOC content of 1% for Norwegian soil (Miljødirektoratet, 1999a, b).

3.2 Existing environmental quality standards

PFOA has not previously been included in the human risk assessment for the terrestrial environment (Aquateam, 2007), but has been included in the guidelines for water, sediment and aquatic biota (Miljødirektoratet, 2016). An overview of existing environmental quality standards for PFOA in soil, sediment and water in Norway are presented in Table 11.

Table 11. Overview of existing environmental quality standards for PFOA in different environmental compartments in Norway.

Environmental Quality Standard	**Value**	**Reference**
Normative value soil	-	
EQS freshwater sediment (chronic)	0.713 mg/kg d.w.	Miljødirektoratet, 2016
EQS marine sediment (chronic)	0.071 mg/kg d.w.	Miljødirektoratet, 2016
EQS freshwater sediment (acute)	-	
EQS marine sediment (acute)	-	
Annual average EQS freshwater	9.1 µg/l	Miljødirektoratet, 2016
Annual average EQS seawater	9.1 µg/l	Miljødirektoratet, 2016
Max. acceptable conc. EQS freshwater	-	
Max. acceptable conc. EQS freshwater	-	
EQS biota (whole fish)	91.3 µg/kg w.w.	Miljødirektoratet, 2016

The values for the aquatic environment presented in Table 11 are related to the European Water Framework Directive and based on human fish consumption using the MTDI values from EFSA (2008). The EFSA (2018a) MTDI values are considerably lower and are not reflected in the quality standards presented in Table 11.

3.3 Human health risk

3.3.1 Maximum tolerable daily intake

Human health effects are focused on liver hypertrophy as the most sensitive end point. MTDI values that were derived for PFOA have changed over time as more data became available. The latest Health Based Guidance Values (HBGVs) proposed by EFSA (2018a) are significantly lower (0.86 ng/kg b.w./d) than recommended in previous studies (12.5-1500 ng/kg b.w./d, see Table 12). These values are presently under discussion as several European environmental authorities have divergent opinion on how the latest EFSA values were derived (EFSA, 2018b).

Table 12. Overview of MTDI values for PFOA presented in various studies in chronological order.

Source	**PFOA (ng/kg bw/d)**
European Food Safety Authority (EFSA, 2008)	1500
US Environmental Protection Agency (USEPA 2016c)	20
National Institute for Public Health and the Environment, the Netherlands RIVM (Zeilmaker et al. 2016)	12.5
Agency for Toxic Substances and Disease Registry, US (ATSDR, 2018)	20
European Food Safety Authority (EFSA, 2018a)	0.86*

* original reference states TWI 6 ng/kg b.w./week

3.3.2 Human exposure estimation

The MTDI values presented in Table 12 can be used in the Norwegian human risk assessment framework (Miljødirektoratet, 1999a, b) using the latest version of the model tool (Miljødirektoratet, 2013). Calculations were performed using the parameters presented in Table 13.

Calculations were performed with and without the inclusion of drinking water from a local well as a human exposure route. Results of the model calculation indicate that soil concentrations varying from 0.17 (EFSA, 2018a) to 2.5 µg/kg d.w (RIVM, 2019) will not result in exceedance of the respective MTDI values if drinking water exposure is included. Without drinking water the respective values are 2.9 (EFSA, 2018a) and 42 µg/kg d.w (RIVM, 2019). Showing that exposure through drinking water is dominating human exposure (Figure 3). Exposure through drinking water is responsible for more than 90% of the estimated exposure if all exposure routes in the Norwegian human risk assessment framework are included (Miljødirektoratet, 1999a, b). Groundwater concentrations that are estimated in the human risk exposure model and used as drinking water concentrations are strongly dependent (almost proportionally) on the distribution coefficient (K_D) that is used. Variations in Henry's law constant (K_{aw}) have a minor effect on human exposure if drinking water exposure is excluded.

Table 13. Estimated soil concentrations that would not result in exceedance of MTDI values.

Parameter	**Unit**	**Compound properties (Miljødirektoratet, 2013)**	**Proposed compound properties (2019)**
K_{OC}	l/kg d.w.	-	125
K_D	l/kg d.w.	-	1.25
Dimensionless Henry constant (K_{aw})	-	-	$1.0x10^{-3}$
BCF fish	l/kg w.w.	-	4
BCF leaf	l/kg d.w.	-	0.044*
BCF root	l/kg d.w.	-	0.015*
Soil quality standard human (including drinking water)			
QS_{human} ($MTDI_{EFSA2008}$)	µg/kg d.w.	-	303
QS_{human} ($MTDI_{RIVM2016}$)	µg/kg d.w.	-	2.5
QS_{human} ($MTDI_{EFSA2018a}$)	µg/kg d.w.	-	0.17
Soil quality standard human (excluding drinking water)			
QS_{human} ($MTDI_{EFSA2008}$)	µg/kg d.w.	-	5100
QS_{human} ($MTDI_{RIVM2016}$)	µg/kg d.w.	-	42
QS_{human} ($MTDI_{EFSA2018a}$)	µg/kg d.w.	-	2.9

* Recalculated to $BCF_{plant/water}$ (l/kg w.w.); BCF = K_D·x $BSAF_{plant/soil}$ (kg d.w./kg w.w.)

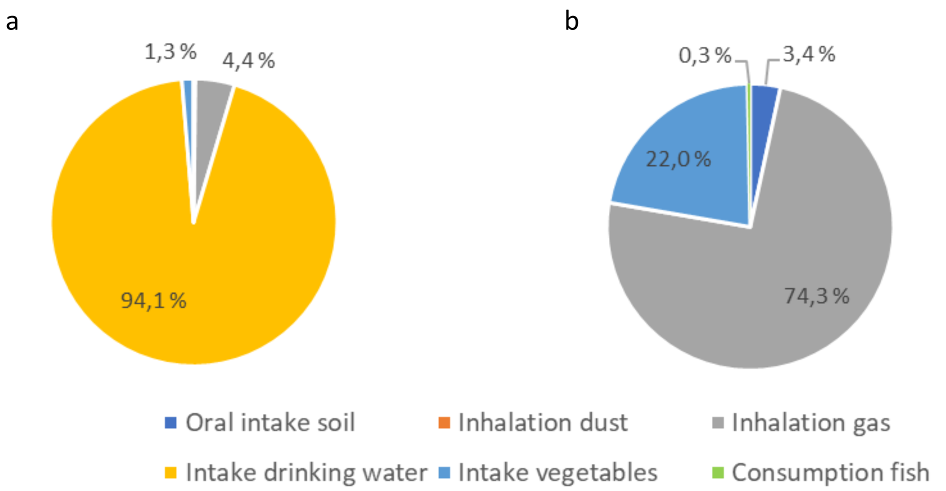

Figure 3. Contribution of the different exposure routes to human exposure of PFOA including exposure through drinkingwater (a) and excluding exposure through drinking water (b).

3.3.3 Drinking water limits

The human risk assessment model (Miljødirektoratet, 1999a, b) used here assumes a human intake of drinking water of 2 liter/day for adults (7-64 yrs, 70 kg body weight) and 1 liter/day for children (0-6 yrs, 15 kg body weight). Resulting in a life time integrated exposure of 1.9 liters/day. The World Health Organisation states that 20% of the MTDI can come from drinking water when guidelines for drinking water quality are derived (WHO, 2017). An estimate of concentrations in drinking water using the various MTDI values (Table 12) is presented in Table 14. Drinking water limits were calculated as follows:

$$C_{drinking\ water} = \frac{MTDI \cdot BW_{lifetime} \cdot 0.2}{IL_{dw}} \tag{7}$$

Where:
$BW_{lifetime}$, body weight life time integrated = 65 kg
IL_{dw}, Lifetime intake drinking water = 1.9 L/day

Table 14. Estimated PFOA concentrations in drinking water that would not result in exceedance of 20% of the respective MTDI values..

Information source	MTDI value ($ng/kg_{bw}/d$)	Drinking water limit (ng/l)
EFSA 2008	1500	10300
USEPA 2016c	20	137
RIVM 2016 (Zeilmaker et al. 2016)	12.5	85
EFSA 2018a	0.86*	5.9

* original reference states TWI 6 ng/kg b.w./week

It is relevant to compare this data to drinking water limits for PFOA recommended in different regions (Table 15).

Table 15. Proposed drinking water limits for PFOA.

Information source	Drinking water limit (ng/l)
WHO (2017)	4000
USEPA drinking water advisory (2016b)	70 (for PFOS and PFOA combined)
EU Drinking water directive proposal (2018a)	100 ng/L single PFAS, 500 ng/L for sum PFAS

Compared to these limits, the estimated drinking water limits based on the PFOA MTDI of RIVM 2016 (Zeilmaker et al. 2016) and USEPA (2016b) are within range of the EU proposal, but the value based on EFSA (2018a) would be relatively conservative.

3.4 Ecological effects

Quality standards for soil biota ($QS_{soil,\ ecotox}$) exposed to PFOA were derived by Lijzen et al. (2018). These values are used and discussed in this report. The quality standards are based on no-observed-effect concentrations (NOEC) or effect concentration for 10% of organisms (EC_{10}) as a chronic endpoint according to van Vlaardingen and Verbruggen (2007); and the EU-technical guidance document (EU, 2018b). Both plant studies and results from test with soil living organisms where compiled. Values of studies that were considered of sufficient quality were assessed (Table 16). Only 2 studies presented NOEC or EC_{10} values that could be used to derive a chronic end-point. The geometric mean of these studies forms the basis for the derived $QS_{soil,\ ecotox}$ (Table 16). This geometric mean value of 50 mg/kg d.w. is proposed as HC_{50}, a concentration where a negative effect of PFOA exposure to 50% of the soil living species cannot be excluded.

Table 16. Overview over toxicity data for plants and soil living organisms used to derived $QS_{soil,\ ecotox}$ (see Lijzen et al. 2018, for a detailed evaluation).

Taxonomic group	**Species**	**Criterium**	**Value (mg/kg d.w.)**
Soil enzyme activity	dehydrogenase	EC_{50}	66.2
	urease	EC_{50}	87.7
Plants	*Brassica chinensis*	EC_{10}	99.8*
		EC_{50}	163
Earthworm	*Eisenia fetida*	NOEC	25.0*
		LC_{50}	872
*Geometric mean for chronic end-point (NOEC or EC_{10})			50

To derive a value that is considered protective for the soil ecosystem the lowest value (25 mg/kg d.w.) is used and an assessment factor of 50 is applied following the methodology of Van Vlaardingen and Verbruggen (2007). This results in a value of 0.50 mg/kg d.w. that is considered protective of 95% of soil organisms and equivalent to HC_5.

A $QS_{soil,EqP}$ value can be calculated using the AA-EQS value for freshwater from Table 11 as:

$$QS_{soil,EQP} = \text{AA-EQS } (9.1\ \mu g/l) \times K_D\ (1.25\ l/kg) = 11.4\ \mu g/kg \quad (8)$$

This valule is considerably lower than the toxicity to soil living organisms, as it is based on the low QS value for human health from fish consumption, based on the EFSA (2008) value of 1500 $ng/kg_{bw}/d$. It is noted that the AA-EQS for freshwater may change in future based on either the new TDI values from EFSA or RIVM data, and any corresponding update in the assessment factor.

3.5 Secondary poisoning

Exposure of higher organisms such as birds and mammals to PFOS comes as a result of bioaccumulation in prey organisms and subsequent biomagnification with increasing trophic level. This is referred to as secondary poisoning. Verbruggen (2014) has developed a methodology to estimate biomagnification in the terrestrial ecosystem based on the energy content of the prey consumed by higher organisms like birds and mammals. Based on toxicity data for birds and mammals soil quality standards can be derived by back calculation from lvels in mammals to concentration in prey organisms using BMF and subsequent concentration in soil using BSAF as follows:

$$QS_{soil,\ \ sec.poisoning} = \frac{Risk\ limit_{mammals}}{BMF_{worm,mammal} \cdot BSAF_{soil,worm}} \quad (9)$$

The derivation of the risk limits, equivalent to HC_5 and HC_{50} values for PFOA for predators of earthworm consuming animals is in detail explained in Lijzen et al. (2018). The dataset contains toxicity data for mouse, rat, rabbit and monkey. Applying corrections for length of the study (subchronic vs. chronic) and an assessment factor following Verbruggen (2014) risk limits were derived presented in

Table 17. The BAF values are not corrected for soil properties like organic carbon content but based on a geometric mean of observed values (Lijzen et al. 2018).

Table 17. Overview ecological risk limits for earth worm eating animals for PFOA (µg/kg$_{dw}$) derived by Lijzen et al. (2018).

Risk limit	**Mammals/birds (mg/kgbw)**	**$BMF_{worm,\ mammal}$***	**$BSAF_{soil,\ worm}$**	**$QS_{soil,\ sec.\ pois.}$ (mg/kg soil)**
Equiv. to HC5	0.030	7.71	0.56	0.007
Equiv. to HC50	4.9	7.71	0.56	1.137

* Miljødirektoratet (2014) uses a BMF of 2.5 for biomagnification from aquatic organisms to mammals to derive the values presented in Table 11.

3.6 Proposed soil quality standards

To derive new normative values for soil in Norway the methodology in Figure 1 was followed using the data presented in the previous sections. The quality standards for human, ecological risk and secondary poisoning are presented in Table 18

Table 18. Overview of soil risk limits for PFOA and proposed normative value (µg/kg$_{dw}$).

Risk	**Value (µg/kgdw)**	**Comment**
$QS_{soil,\ human}$	2.6	based on $MTDI_{RIVM\ 2016}$
$QS_{soil,\ human}$	0.18	based on $MTDI_{EFSA2018}$
$QS_{soil,\ ecotox}$	500	equiv. to HC_5 value plants and soil living organisms
$QS_{soil,\ EqP*}$	*11*	Freshwater AA-EQS (9.1 µg/l) x K_D (1.25 l/kg)
$QS_{soil,\ sec.\ poisoning}$	7	equiv. to HC_5 value birds and mammals
Proposed Normative value	**3**	based on $QS_{soil,\ human}$

At present there is still uncertainty related to the MTDI value that will be adopted by the EFSA after comments received during the public hearing (EFSA, 2018b). Considering this uncertainty, a Normative value of 3 µg/kgdw is proposed covering both the human toxicity value and secondary poisoning in the ecosystem.

This value is within the current limit of quantification (LOQ) used by commercial chemical laboratories operating in the Norwegian market (0.1 µg/kg d.w.). For PFOA the $QS_{soil,EqP}$ is subject to change if EFSA(2018) or RIVM (2016) is used in its derivation.

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