PERFLUOROOCTANE SULPHONATE (PFOS)

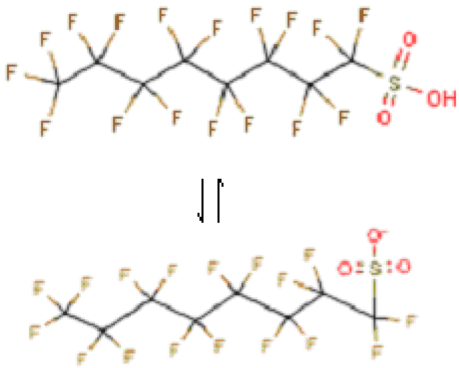
This EQS dossier was prepared by the Sub-Group on Review of the Priority Substances List (under Working Group E of the Common Implementation Strategy for the Water Framework Directive).

The dossier was reviewed by the Scientific Committee on Health and Environmental Risks (SCHER), whose comments have been addressed as follows.

The reference list has been checked and a missing original reference added. The decision to pool the freshwater and marine water data sets has been further explained, as has the magnitude of the assessment factors applied to derive the marine MAC-QS and AA-QS. Similarly, more detail has been added on the decision to use the monkey study rather than the rat study as the basis for deriving the QS $_{biota,secpois.}$ Although recent references were consulted, it was still not possible to derive standards for sediment.

1 CHEMICAL IDENTITY

Common name	PFOS
Chemical name (IUPAC)	Perfluorooctane sulphonates
Synonym(s)	
Chemical class (when available/relevant)	Perfluorinated compounds
CAS number	1763-23-1 (acid) 2795-39-3 (potassium salt) 29081-56-9 (ammonium salt) 29457-72-5 (lithium salt) 70225-39-5 (diethanolamine salt) 56773-42-3 (tetraethyl-ammonium salt) 251099-16-8 (didecyldimethyl-ammonium salt)
EU number	217-179-8 (acid) 220-527-1 (potassium salt) 249-415-0 (ammonium salt) 249-644-6 (lithium salt)
Molecular formula	$C_8F_{17}SO_3$
Molecular structure	

	
Molecular weight (g.mol^{-1})	500 (acid), 538 (potassium salt) (Environment Agency, 2004)

PFOS is the perfluorooctane sulphonate anion and is not a substance as such and therefore does not have a specific CAS number. It is commercially available in the form of salts, derivatives (PFOS-substances) and polymers (PFOS-polymers). The term 'PFOS related substances' is used to refer to any or all of the substances which contain the PFOS moiety and may break down in the environment to give PFOS (Environment Agency , 2004).

2 EXISTING EVALUATIONS AND REGULATORY INFORMATION

Annex III EQS Dir. (2008/105/EC)	Included
Existing Substances Reg. (793/93/EC)	Voluntary RAR undertaken by UK (Environment Agency, 2004)
Pesticides (91/414/EEC)	Not applicable
Biocides (98/8/EC)	Not applicable
PBT substances	Yes
Substances of Very High Concern (1907/2006/EC)	No
POPs (Stockholm convention)	Yes. PFOS has recently been identified as a POP and will be added to Annex B of the Stockholm Convention. The decision becomes effective in August 2010. Inclusion means that there is a restriction on production and use with ultimate phase out of PFOS however as a result of the international negotiations a relatively large number of specific uses are still allowed .
Other relevant chemical regulation (veterinary products, medicament, ...)	Directive 2006/122/EC placed restrictions on the marketing and use of PFOS. Limits were placed on the quantity of PFOS allowed in preparations and on finished products although there are a number of derogations including mist suppressants in electroplating systems and hydraulic fluids in aviation. Fire fighting foams containing PFOS that have been placed on the market before December 2006 can be

	used until June 2011. As a result of this Directive, PFOS has been added to Annex XVII under REACH and use restrictions apply.
Endocrine disrupter	Available data indicates that PFOS has the potential to induce adverse effects on the endocrine system of animals, including rats and fish. However the data suggest that endocrine effects appear to occur at concentrations higher than those causing effects on growth, reproduction and mortality in standard toxicity tests (Environment Agency,2008).

3 PROPOSED QUALITY STANDARDS (QS)

3.1 ENVIRONMENTAL QUALITY STANDARD (EQS)

$QS_{biota,hh}$ fis the "critical QS" for derivation of an Environmental Quality Standard

	Value	Comments
Proposed AA-EQS for biota [µg kg^{-1} $_{biota\ ww}$] Corresponding AA-EQS in [freshwater] [µg.l^{-1}] Corresponding AA-EQS in [marine water] [µg.l^{-1}]	**9.1** **0.00065** **0.00013**	**Critical QS is $QS_{biota,hh}$-.** **See section 7**
Proposed MAC-EQS for [freshwater] [µg.L^{-1}] **Proposed MAC-EQS for [marine water] [µg.L^{-1}]**	**36** **7.2**	**See section 7.1**

3.2 SPECIFIC QUALITY STANDARD (QS)

Protection objective*	**Unit**	**Value**	**Comments**
Pelagic community (freshwater)	[µg.l^{-1}]	0.23	See section 7.1
Pelagic community (marine water)	[µg.l^{-1}]	0.023	
Benthic community (freshwater)	[µg.kg^{-1} $_{dw}$]	-	e.g. EqP, see section 7.1
	[µg.l^{-1}]	-	
Benthic community (marine)	[µg.kg^{-1} $_{dw}$]	-	
	[µg.l^{-1}]	-	
Predators (secondary poisoning)	[µg.kg^{-1}$_{biota\ ww}$]	33	See section 7.5
	[µg.l^{-1}]	0.002 (freshwaters) 0.00047 (marine waters)	
Human health via consumption of fishery products	[µg.kg^{-1}$_{biota\ ww}$]	9.1	See section 7.6
	[µg.l^{-1}]	0.00065 (freshwaters) 0.00013 (marine waters)	
Human health via consumption of water	[µg.l^{-1}]	0.52	

* Please note that as recommended in the Technical Guidance for deriving EQS (Draft Version 6, February 2010), "EQSs […] are not reported for 'transitional and marine waters', but either for freshwater or marine waters". If justified by substance properties or data available, QS for the different protection objectives are given independently for transitional waters or coastal and territorial waters.

4 MAJOR USES AND ENVIRONMENTAL EMISSIONS

4.1 USES AND QUANTITIES

In 2000, 3M (a major global producer of PFOS based in the US) announced that the company would phase out the production of PFOS voluntarily from 2000 onwards. Production by 3M has now ceased (Environment Agency, 2004). Hence the use in some areas has reduced significantly or even stopped, although the potential market for use remains since there are other known suppliers.

The major uses for PFOS related substances were in providing grease, oil and water resistance to materials such as textiles, carpets, paper and in general coatings. Other smaller volume uses are in chromium plating, photolithography, photography and in hydraulic fluids for aviation. PFOS has also been used in fire fighting foams (Environment Agency 2004).

The use pattern of PFOS related substances has changed significantly however since 3M announced their intention to cease manufacture of a range of these substances. Information collected as part of the voluntary RAR indicates that their use in a number of the major areas has effectively ceased, as users have moved to different types of substances (Environment Agency, 2004).

In addition, as noted in Section 2, restrictions on the use of PFOS are in place through Annex XVII of REACH and also through the Stockholm Convention . The former places restrictions on the quantities of PFOS that can be present in preparations and also on finished articles. Some critical uses that are considered of relatively low risk or for which suitable alternatives are not available are still permitted. These include use in photolithography, photographic coatings, mist suppressants for certain electroplating activities and use in hydraulic fluids for aviation.

Use area	EU quantity	Master reference
Metal (chromium) plating	10 t/year	Environment Agency, 2004
Photolithography (semi-conductors)	0.47 t/year	Environment Agency, 2004
Photography	1.6 t/year	Environment Agency, 2004
Aviation (in hydraulic fluids)	0.73 t/year	Environment Agency,2004
Fire-fighting foams	0.57 t/year PFOS are no longer used in the manufacture of fire fighting foams. Still, storage, disposal and emergency use of stored foams may represent a continuing source of PFOS. It is estimated that the total storage of PFOS-containing fire fighting foams in EU is 122 tonnes (OSPAR, 2006).	Environment Agency, 2004

	Dir. 2006/122/EC allows the use of these stored foams until 27 June 2011	
Protective coatings for fabrics (carpets, textiles and leather)	240 t/year	Environment Agency, 2004
Paper treatment (grease proof paper, food cartons, etc.)	160 t/year	Environment Agency, 2004
Coatings (in paints)	90 t/year	Environment Agency, 2004

The above figures relate largely to the situation before some of the PFOS products were removed from the market and therefore may not reflect the current position (Environment Agency, 2004).

Simple derivatives and polymeric materials are considered to be precursors to PFOS and to have potential to lead to release of PFOS to the environment. They have apparently been taken into account in the RAR though there is little information on the breakdown of these substances in the environment (Environment Agency, 2004).

4.2 ESTIMATED ENVIRONMENTAL EMISSIONS

Estimates of emissions to waste water were calculated within the RAR. The estimated emissions for the various use scenarios are shown below. It should be noted that since these estimations were made a number of restrictions have been put in place in relation to the use of PFOS (See Section 2).

Use area	Estimated emissions to water (Local) Local (mg/day)	Estimated emissions to water (Regional) Regional (kg/year)	Estimated emissions to water (EUscale, kg/year)	Master reference
Metal (chromium) plating	180	1000	9000 (waste water)	Environment Agency, 2004
Photolithography (semi-conductors)	27	25	226 (waste water)	Environment Agency, 2004
Photography	2.27 (film production, waste water) 0.008 (film development, waste water)	0.68 (film production, waste water) 0.75 (film development, waste water)	1.02 (film production, waste water) 6.75 (film development, waste water)	Environment Agency, 2004
Aviation (in hydraulic fluids)	1.5 (waste water)	0.44 (waste water)	3.94 (waste water)	Environment Agency, 2004
Fire-fighting foams	1.14 (waste water)	28.5 (surface water)	257 (surface water)	Environment Agency, 2004
Protective coatings for fabrics (carpets, textiles and leather)		11.35 (PFOS-polymer) 114 (PFOS-substance	102 (PFOS-polymer) 1018 (PFOS-substance)	Environment Agency, 2004

Paper treatment (grease proof paper, food cartons, etc.)		800 (PFOS-substance)	7200 (waste water)	Environment Agency, 2004
Coatings (in paints)		45	405	Environment Agency, 2004

5 ENVIRONMENTAL BEHAVIOUR

5.1 ENVIRONMENTAL DISTRIBUTION

		Master reference
Water solubility (mg.l^{-1})	519mg/l at 20°C 570mg/l in pure water 370mg/l in fresh water 12.4mg/l at 22-23°C in natural seawater	Environment Agency, 2004 RIVM 2010
Volatilisation	Volatilisation from water surfaces is negligible	Environment Agency, 2008
Vapour pressure (Pa)	3.31×10^{-4} Pa (measured for the potassium salt) (may be associated uncertainties with this result as suggestion that this result may be due to volatile impurities in the substance) 1.9×10^{-9} Pa (calculated for the potassium salt) 3.1×10^{-11} Pa (calculated for the diethanolamine salt) 0.85 Pa (calculated for the acid)	Environment Agency, 2004
Henry's Law constant (Pa.m^{3}.mol^{-1})	3.19×10^{-4} Pa	Environment Agency,2004
Adsorption		
Organic carbon – water partition coefficient (K_{OC})	K_{OC} = 66 (However study considered to be of low reliability). Kd in sediment 7.42	Environment Agency,2008
Sediment – water partition coefficient($K_{sed-water}$)	5.16 (potassium salt)	Environment Agency, 2004
Bioaccumulation		
Octanol-water partition coefficient (Log Kow)	A reliable measured value is not available. The reliability of Kow prediction tools for PFOS is not	Environment Agency, 2004

	known.	
BCF (measured)	2796 (This value was chosen as the BCF for fish in the voluntary risk assessment)	Environment Agency, 2004 3M, 2003 in RIVM 2010

5.2 ABIOTIC AND BIOTIC DEGRADATIONS

		Master reference
Hydrolysis	No hydrolysis (Estimated half life of >41years at 25°C)	Environment Agency, 2004
Photolysis	No evidence of photolysis (estimated half life of >3.7years)	Environment Agency, 2004
Biodegradation	None of the available studies showed biodegradation of PFOS in the aquatic environment under either aerobic or anaerobic conditions	Environment Agency,2004

6 AQUATIC ENVIRONMENTAL CONCENTRATIONS

6.1 ESTIMATED CONCENTRATIONS

Compartment	Predicted environmental concentration (PEC)	Master reference
Freshwater	- local (worst case): 97.4 µg/L - regional (worst case): 0.088 µg/L	Environment Agency, 2004
Sediment	- local (worst case): 261 µg/kg wwt - regional (worst case): 0.386 µg/kg wwt	Environment Agency, 2004
Biota (freshwater)	- local (worst case): 807 µg/kg wwt - regional (worst case): 486 µg/kg wwt	Environment Agency, 2004
Biota (marine)	- local (worst case): 92.1 µg/kg wwt - regional (worst case): 48 µg/kg wwt	Environment Agency, 2004
Biota (marine predators)	- local (worst case): 114 µg/kg wwt - regional (worst case): 96 µg/kg wwt	Environment Agency, 2004

6.2 MEASURED CONCENTRATIONS

Compartment	Measured environmental concentration (MEC)	Master reference
Freshwater	PEC1: 7.75×10^{-2}µg/l PEC2 : 4.5×10^{-2}µg/l	James *et al.*, 2009[(1)]
	0.0003 – 0.157µg/l in Japanese freshwaters	Environment Agency, 2004
	27 European countries 2007: Average: 0.039 µg/l Median: 0.006 µg/l 90th percentile: 0.073 µg/l	Loos et al 2009 in RIVM 2010
	River Rhine, tributaries, and delta 2008 Dissolved phase 0.0009-0.025 µg/l	Möller 2009 in RIVM 2010

	Annual average 2006: 0.013 µg/l Annual average 2007: 0.0086 µg/l Lekkanaal at Nieuwegein, NL Annual average 2006: 0.014 µg/l Amsterdam-Rijnkanaal at Nieuwersluis, NL	RIWA 2007, 2008 in RIVM 2010
Marine waters (coastal and/or transitional)	0.0002 – 0.0252µg/l in Japanese coastal waters	Environment Agency, 2004
	0.00013-0.00070 µg/l Dissolved phase Dutch Bight, North Sea	Möller 2009 in RIVM 2010
WWTP effluent	0.041 – 5.29µg/l (concentrations detected in US monitoring exercise)	Environment Agency, 2004
Sediment	PEC1 : 3.12µg/kg dw PEC2 : 1.98µg/kg dw	James *et al.*, 2009[(1)]
Biota [(2)]	PEC1 (fish): 1.13×10^{2} µg/kg ww PEC2 (fish): 1.13×10^{2} µg/kg ww PEC2 (invertebrates): 1×10^{-1}µg/kg ww	James *et al.*, 2009[(1)]
	Dutch rivers and coastal waters 6-230 µg/kg ww	Bakker & Te Biesebeek 2009 in RIVM 2010
	Average levels in freshwater fish in Germany reported in the range of 12-135.7µg/l	Schuetze et al 2010
Biota (marine predators)		

[(1)] data originating from EU monitoring data collection

[(2)] PFOS has been detected in remote regions including the polar regions as well as more urban and industrial areas. PFOS has been detected in dolphins, seals, eagles, fish, otters, oysters (Environment Agency, 2004)

7 EFFECTS AND QUALITY STANDARDS

The available data on the toxicity of PFOS to aquatic life has been collated and reviewed by an number of organisations, including OECD (2002), RIVM (2010) and Environment Canada (2006). Some of the key acute and chronic toxicity studies for PFOS are outlined in the tables below.

7.1 ACUTE AND CHRONIC AQUATIC ECOTOXICITY

ACUTE EFFECTS			Master reference
	Freshwater	*Selenastrum capricornutum* /96 h EC_{50} : 71mg/l and 126mg/l	Environment Agency,2004
		Selenastrum capricornutum/96h EC_{50}: 48.2mg/l *	Environment Agency,2008
		Pseudokirchneriella subcapitata / 72 h EC_{50}: 120 mg/l	OECD, 2002 in RIVM 2010
		Navicula pelliculosa / 96 h EC_{50}: 283 mg/l	OECD, 2002 in RIVM 2010
Algae & aquatic plants (mg.l^{-1})		*Chlorella vulgaris*/96h EC_{50}: 81.6 mg/l	Environment Agency,2004 Boudreau et al, 2003 in RIVM 2010
		Anabaena flos-aquae / 96h EC_{50}: 176 mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
		Lemna gibba / 7d EC_{50}: 31.1mg/l	Environment Agency,2004 Boudreau et al, 2003 in RIVM 2010
	Marine	*Skeletonema costatum*/96 h EC_{50} : >3.2mg/l	Environment Agency,2004
Invertebrates (mg.l^{-1})	**Freshwater**	*Daphnia magna* / 48 h EC_{50} : 27 mg/l	Environment Agency,2004
		Daphnia magna / 48 h EC_{50}: 4 mg/l **	Environment Agency,2008
		Daphnia magna / 48 h EC_{50}: 48 mg/l (geometric mean of 6 values)	OECD, 2002, Boudreau et al, 2003, Ji et al 2008, and Li, 2009 in RIVM 2010
		Daphnia pulicaria / 48 h EC_{50}: 124 mg/l	Boudreau et al, 2003 in RIVM 2010
		Moina macrocopa / 48 h EC_{50}: 18 mg/l	Ji et al, 2008 in RIVM, 2010
		Neocaridina denticulate / 96 h EC_{50}: 9.3 mg/l	Li, 2009 in RIVM 2010
		Dugesia japonica / 96 hr LC_{50}: 18 mg/l (geometric mean of two values)	Li, 2008 and Li, 2009 in RIVM 2010

		Physa acuta / 96 hr LC_{50}: 165 mg/l	Li, 2009 in RIVM 2010
		Unio complamatus / 96 hr LC_{50}: 59 mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
	Marine	*Mysid shrimp (Americamysis bahia)* / 96 h EC_{50} : 3.6mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
		Brine shrimp (Artemia spp) / 48hr LC_{50}: 8.9 mg/l	Environment Agency,2004
		Artemia spp / 48 hr LC_{50}: 8.3 mg/l	OECD, 2002 in RIVM 2010
		Crassostrea virginica (Eastern oyster) 96hr EC50 >3.0mg/l (Shell deposition)	Wildlife international (2000) referenced in OECD 2002
	Sediment	No data	
Fish **(mg.l^{-1})**	**Freshwater**	*Fathead minnow (Pimephales promelas* /96 h EC_{50} : 4.7mg/l ***	Environment Agency,2004
		Fathead minnow (Pimephales promelas/96h LC50: 9.5mg/l	Environment Agency,2008
		Pimephales promelas / 96 h LC_{50}: 6.6 mg/l (geometric mean of two values)	OECD, 2002 in RIVM 2010
		Bluegill sunfish (Lepomis macrochirus) / 96 h LC_{50}: 6.9 mg/l	Environment Agency,2004
		Lepomis macrochirus / 96 h LC_{50}: 6.4 mg/l	OECD, 2002 in RIVM 2010
		Oncorhynchus mykiss / 96h LC_{50}: 7.8mg/l	Environment Agency,2008
		Oncorhynchus mykiss / 96 h LC_{50}: 13 mg/l (geometric mean of two values)	OECD, 2002 in RIVM 2010
	Marine	*Sheepshead minnow (Cyprinodon variegatus*/ 96hr EC_{50} : >15mg/l	Environment Agency,2004

		Oncorhynchus mykiss / 96h LC50: 13.7mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
Other taxonomic groups			

* Noted that this study should be considered with care as it is based on nominal concentrations and the study duration is longer than the recommended test duration.

** This value was generated in a static system with nominal concentrations and therefore the data should be treated with care.

*** This study was conducted in a static system with nominal test concentrations and should therefore be treated with care.

CHRONIC EFFECTS			Master reference
Algae & aquatic plants ($mg.l^{-1}$)	Freshwater	*Selenastrum capricornutum*/96h EC_{10}: 5.3mg/l *	Environment Agency, 2008
		Lemna gibba/7d NOEC: 15.1mg/l	Environment Agency,2004
		Lemna gibba/42d EC_{10}: 0.2mg/l **	Environment Agency,2008
		Chlorella vulgaris / 96h EC_{10}: 8.2mg/l	Environment Agency,2008 Boudreau et al, 2003 in RIVM, 2010
		Navicula pelliculosa / 96 h NOEC: 44mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
		Rhapidocelis subcapitata /96h EC_{10}: 53mg/l	OECD, 2002 in RIVM, 2010
		Anabaena flos-aqua /96h NOEC: 44mg/l	OECD, 2002 in RIVM, 2010
		Lemna gibba/7d EC_{10}: 6.6mg/l	Environment Agency,2008 Boudreau et al., 2003 in RIVM, 2010
		Myriophyllum sibiricum / 42 d NOEC: 0.092mg/l	Hanson et al, 2005 in RIVM 2010
		Myriophyllum spicatum / 42 d NOEC: 3.2mg/l	Hanson et al, 2005 in RIVM, 2010
	Marine	*Skeletonema costatum* /96h NOEC：>3.2mg/l	Environment Agency,2004 OECD, 2002 in RIVM, 2010
Invertebrates ($mg.l^{-1}$)	Freshwater	*Daphnia magna* / 21 d NOEC：12 mg/l	Environment Agency,2004
		Daphnia magna/28d NOEC: 7mg/l ***	Environment Agency,2004
		Daphnia magna/21d NOEC: 5.3mg/l ***	Environment Agency,2004
		Daphnia magna / 21/28 d NOEC: 7.0 mg/l (geomean of 4 values)	Boudreau et al, 2003, OECD, 2002 and Ji et al, 2008 in RIVM, 2010
		Moina macrocopa / 7 d EC10: 0.40mg/l	Ji et al, 2008 in RIVM 2010

		Chironomus tentans / 10d NOEC: 0.049mg	Environment Agency,2008
		Chironomus tentans / 36d NOEC: 0.049mg <0032mg/l LOEC with 32% effect	MacDonald et al, 2004 in RIVM, 2010
		Chironomus tentans / 36d NOEC: <0.002mg LOEC 0.002mg/l	MacDonald et al, 2004 in RIVM, 2010
		Enallagma cyathigerum / 120 d NOEC: <0.01mg/l LOEC with 18% effect	Bots et al, 2010 in RIVM 2010
	Marine	*Mysidopsis bahia* / 35 d NOEC：0.25mg/l	Environment Agency,2004 OECD, 2002 in RIVM 2010
	Sediment	No data	
Fish (mg.l^{-1})	**Freshwater**	Fathead minnow (*Pimephales promelas* / 42d NOEC：0.3mg/l	Environment Agency,2004
		Fathead minnow (*Pimephales promelas*) / 21d NOEC: 0.028mg/l	Environment Agency,2008 Ankley et al, 2005 in RIVM, 2010
		Oryzias latipes / 14 d NOEC: <0.01mg/l LOEC with 80% effect	Ji et al, 2008 in RIVM, 2010
		Bluegill sunfish (*Lepomis macrochirus* / 62d NOEC: <0.87mg/l	
	Marine	No data	
Other taxonomic groups		*Xenopus leavis* / 96 h NOEC: 5.0mg/l	

*Noted that the algal study needs to be treated with care as based on nominal concentrations and also of 96hr duration rather than the test recommendation of 72hrs.

** Noted that this data generated in an outdoor microcosm study and the study details are incomplete

*** Noted that these studies were undertaken with nominal concentrations and therefore should be treated with care. Lowest valid datapoint is 12mg/l.

7.2 DERIVATION OF THE MAC-$QS_{WATER,ECO}$

Short term toxicity data are available for five taxonomic groups including algae, amphibians, crustaceans, fish and molluscs (Environment Agency, 2008). According to the TGD-EQS (EC 2011) freshwater and saltwater data can be pooled unless there is evidence that sensitivity of organisms differs between freshwater and saltwater environments. The available dataset is insufficient to enable a statistical comparison of the freshwater and saltwater data to identify whether there is a significant difference. The available data however do not point to a difference in sensitivity, and therefore the freshwater and saltwater data for PFOS have been pooled. This approach has also been taken in other existing reviews of the data on PFOS, eg RIVM (2010).

7.2.1 Freshwater MAC-$QS_{freshwater,eco}$

Although acute data was available for a number of species, the range of taxonomic groups covered was insufficient to enable use of the Species Sensitivity Distribution approach to derive the MAC-QS. The assessment factor approach has therefore been used.

Acute toxicity data was available for a number of taxonomic groups including algae, crustaceans, molluscs and fish. The lowest reliable acute toxicity study from the available dataset for PFOS is a 96hr LC50 study on the marine invertebrate Mysidopsis bahia. The 96hr LC50 was 3.6mg/l. The TGD-EQS (EC 2011) notes that an assessment factor of 100 should be applied to the lowest reliable acute endpoint if acute data is available for the three trophic levels, ie fish, invertebrate and algae. An assessment factor of 100 was therefore applied to the lowest acute effect concentration of 3.6mg/l. This gives a MAC-QS for the freshwater environment of 0.036mg/l (36µg/l).

7.2.2 Saltwater MAC-$QS_{saltwater,eco}$

As noted above the lowest reliable acute toxicity study from the available dataset for PFOS is a 96hr LC50 study on the marine invertebrate Mysidopsis bahia. The 96hr LC50 was 3.6mg/l. In the case of the freshwater value an assessment factor of 100 was applied to derive the QS. The AFs for use in the derivation of $QS_{saltwater,\ eco}$ however are generally higher than for the freshwater environment as outlined in the TGD-EQS (EC 2011). The guidance notes this is justified by the need to account for the additional uncertainties associated with the extrapolation for the marine ecosystem, especially the general under representation in the experimental dataset of specific marine taxa and possibly a greater species diversity. An additional AF of 10 is therefore proposed for saltwater in the TGD-EQS, which can be lowered if data is available for additional marine taxonomic groups. The dataset for PFOS includes a reliable acute toxicity study for the marine mollusc Crassostrea virginica. The availability of this study enables the additional assessment factor to be reduced to 5 rather than 10. This results in an assessment factor of 500 being applied to the acute study on Mysidopsis bahia of 96hr LC50 3.6mg/l. This gives a proposed MAC-QS of 0.0072mg/l (ie 7.2µg/l).

7.3 DERIVATION OF THE AA-$QS_{WATER,ECO}$

Long term data are available for seven taxonomic groups including algae, cyanophyta, crustaceans, insects, fish, macrophytes, and amphibians. The lowest effect concentrations are noted in Section 7.1. Although chronic data was available for a number of species the range of taxonomic groups covered was insufficient to enable use of the Species Sensitivity Distribution approach to derive the AA-QS. The assessment factor approach has therefore been used.

7.3.1 Freshwater AA-$QS_{freshwater,eco}$

The lowest chronic NOECs for a number of invertebrates and fish are in a similar order of magnitude with a number of NOECs being reported in the range of 0.01 – 0.095mg/l. The lowest chronic NOECs however have been reported for the invertebrates Chironomus tentans and Enallagma cyathigerium. A NOEC for total emergence of Chironomus tentans (MacDonald et al 2004) indicated a NOEC of <0.0023mg/l. A NOEC for Enallagma cyathigerium (Bots et al 2009) for effects on metamorphosis indicated effects at concentrations of <0.01mg/l. Both of these NOECs relate to the study of the effect of PFOS on the emergence of invertebrates. This looks to be a particularly sensitive endpoint. In terms of the Chironomus tentans study the EC10 for total emergence was reported as 0.0893mg/l which is considerably higher than the NOEC of <0.0023mg/l. The paper by Mac Donald et al (2004) however does not indicate any reason to not consider the NOEC for this endpoint.

As chronic data is available for three trophic levels an assessment factor of 10 can be applied to the lowest reliable NOEC or EC10 value. Applying an assessment factor of 10 to the lowest NOEC of 2.3µg/l gives a AA-$QS_{freshwater,eco}$ of 0.23µg/l. It is recognised that the endpoint which has been used to derive the AA-QS is an unbounded NOEC and therefore there is uncertainty associated with the QS derived. The $QS_{biota,hh}$ however is the key driving QS for PFOS based on the available information.

7.3.2 Saltwater AA-$QS_{saltwater,\ eco}$

Chronic data was available for algae, invertebrates and fish. Data was not available for an additional marine taxonomic group and therefore, as explained in the TGD-EQS (EC 2011), an additional factor of 10 was applied to derive the AA-$QS_{saltwater,eco}$. This results in the application of an assessment factor of 100 to the lowest NOEC value of 2.3µg/l to give a AA-$QS_{saltwater,eco}$ of 0.023µg/l.

7.4 DERIVATION OF THE $QS_{SEDIMENT}$

The criteria for triggering the development of a $QS_{sediment}$ are identified in the TGD-EQS (EC 2011). The criteria include log Koc and log Kow properties, toxicity to benthic organisms and evidence of accumulation of PFOS in sediment.

A log Kow is not able to be calculated for PFOS and therefore this information is not available. Reported log Koc values for PFOS are 1.8 (RIVM, 2010) and 2.57 (EFSA, 2008). Both these values are below the threshold of 3. No data is available on the toxicity of PFOS to sediment dwelling organisms and therefore it is not possible to determine whether PFOS is of high toxicity to benthic organisms.

The final criterion relates to evidence of accumulation of PFOS in sediments. Reports have been obtained of the presence of PFOS in sediment. Monitoring data collated for the review of the Priority Substances list included data for sediment from 2 Member States which gave a PEC1 of 3.12µg/kg dw and a PEC 2 of 1.98µg/kg dw. The data was for 62 analyses within the 2 Member States of which 22 were below the limit of detection. Studies have reported rapid adsorption of PFOS to soil, sediment and sludge. Desorption studies showed that desorption took place rapidly and that river sediment s displayed the most desorption at 39% after 48hrs (Environment Canada, 2006). If released to water the distribution was expected to have 4.2% distribution to sediment and 83.18% in water (Environment Agency, 2004).

Based on the above it is felt that insufficient information is available to support a decision to derive a sediment threshold for PFOS. The lack of sediment toxicity data would mean that if a $QS_{sediment}$ was to be derived for PFOS the Equilibrium Partitioning (EqP) approach would need to be used. The validity of this approach for a substance such as PFOS has been questioned. Work undertaken by the OECD (2002) noted that for an anionic surfactant such as PFOS it is likely that interaction with inorganic substrate as well as organic substrate will be important. As a result Kp soil/sediment data was noted to be more relevant than Koc data which assumes that only the organic components of sediment or soil are important. The OECD report also noted that whilst for all substances extrapolation of PNEC from aquatic data to the terrestrial or sediment compartment is subject to uncertainty that uncertainty is compounded when the mode of uptake is different for organisms present in different environmental compartments. The mode of toxic action and the mechanism of uptake of surfactants such as PFOS were noted to be complex and therefore the use of the EqP approach is subject to considerable doubt. The OECD report concluded that on the basis of the presently available data for PFOS that the equilibrium partitioning theory can not be applied to determine a PNEC for PFOS. The following reasons were given:-

- the nature of the adsorption process can not be assumed to be linearly dependent upon concentration
- the adsorption is likely to be highly independent upon soil composition, particularly the inorganic component
- the rate at which equilibrium might be achieved is unknown.

In summary it is therefore proposed that there is insufficient data available to confirm the need for a $QS_{sediment}$ for PFOS and that in addition there would be insufficient data to derive such a threshold for PFOS.

Tentative QS_{water}	**Relevant study for derivation of QS**	**Assessment factor**	**Tentative QS**	**Reference**
$MAC_{freshwater, eco}$ *	Mysidopsis bahia/ 96hr LC50: 3.6mg/l	100	36µg/l	Environment Agency (2004)
$MAC_{marine water, eco}$		500	7.2µg/l	
$AA\text{-}QS_{freshwater, eco}$	*Chironomus tentans* / 36d NOEC : <0.0023mg.l^{-1}	10	0.23 µg.l^{-1} *	McDonald et al 2004
$AA\text{-}QS_{marine water, eco}$		100	0.023 µg.l^{-1} *	

7.5 DERIVATION OF A QS FOR SECONDARY POISONING ($QS_{BIOTA, SECPOIS}$)

The available toxicity data for PFOS has been collated and reviewed by a number of organisations, eg OECD (2002), EFSA (2008). Details of a number of the lowest reported effect concentrations are noted in the table below.

Secondary poisoning of top predators		**Master reference**
Mammalian oral toxicity	Rat / Gavage / gestation studies (AF 90) / gestation length and pup viability NOAEL : 0.37mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 7.4 mg.kg^{-1}_{feed} (CF = 20) Rat / diet / 90-d (AF 90) / Body weight NOAEL : >1.5-2 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 30 mg.kg^{-1}_{feed} (CF 15 and 13.3 from studies) Rat / Diet / Chronic (AF 30) / Carcinogenicity NOAEL : 0.14 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 2 mg.kg^{-1}_{feed} (CF 14.3from study) Rat / Gavage / two generations (AF 30) / birth weight F2 generation NOAEL : 0.1 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 2 mg.kg^{-1}_{feed} (CF 20)	Luebker et al, 2005 in RIVM, 2010 Seacat et al, 2003 and Goldenthal et al, 1978a in RIVM, 2010 Thomford, 2002 and Christian et al, 1999 in RIVM, 2010
	Mouse / Gavage / gestation studies (AF 90) / malformations (sternal defects) NOAEL : 1 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 8.3 mg.kg^{-1}_{feed} (CF = 8.3)	Thibodeaux et al, 2003 in RIVM 2010
	Rabbit / Gavage / gestation studies (AF 90) / maternal weight gain NOAEL : 0.1 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 3.33 mg.kg^{-1}_{feed} (CF = 33.3)	Case et al, 2001
	Rhesus monkey / Gavage / 90-d (AF 90) / Severe gastrointestinal effects NOAEL : 0.5 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 10 mg.kg^{-1}_{feed} (CF = 20)	Goldenthal et al, 1978b in RIVM, 2010
	Cynomolgus monkey / Intubation / 26-w (AF 30) / Body weight, survival NOAEL : 0.15 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 3 mg.kg^{-1}_{feed} (CF = 20)	Seacat et al, 2002
Avian oral toxicity	Mallard duck / Diet / 21-w (AF 30) / Body weight, reproduction NOAEL : 1.49 mg.$kg^{-1}_{bw}.d^{-1}$ NOEC : 10 mg.kg^{-1}_{feed} (CF = 6.7 from study)	Newsted et al 2007 in RIVM 2010

	Mallard duck / Diet / 21-w (AF 30) / Body weight, reproduction NOAEL : 0.77 $mg.kg^{-1}_{bw}.d^{-1}$ NOEC : 10 $mg.kg^{-1}_{feed}$ (CF = 13 from study)	Newsted et al 2007 in RIVM 2010

Both mammalian and avian toxicity data were considered. The available data indicated that mammalian species were more sensitive than avian species and therefore the QS has been based on mammalian data.

Several studies have reported NOAEL values around the 0.1mg/kg bw/day. These include:-

Species	**Test Duration**	**Endpoint**	**Effect concentration**	**Reference**
Rat	2 generation	Pup weight	NOAEL 0.1mg/kg bw	Christian et al 1999
Rabbit	Gestation day 6-20	Maternal weight gain	NOAEL 0.1mg/kg	Case et al 2001
Cynomologus monkey	183day	Body weight Hormone	NOAEL 0.15mg/kg NOAEL 0.03mg/kg	Seacat et al 2002

A two generation study in rats (Christian et al 1999) showed high sensitivity for PFOS. A NOAEL of 0.1mg/kg bw/day was reported based on significant reductions in mean pup body weight. The NOAEL for the F0 generation male and female parents was 0.1mg/kg based on reductions in body weight gain and food consumption – this was the same NOAEL for the F1 females. In addition a NOAEL of 0.1mg/kg was noted for the F2 generation offspring based on significant reductions in mean pup body weight.

Case et al (2001) administered PFOS to pregnant New Zealand white rabbits from gestation day 6-20. The NOAEL of 0.1mg/kg bw/day related to maternal toxicity (reduced weight gain).

The study by Seacat et al (2002) on the Cynomologus monkey was a 6 month study (183days) and was reported as a subchronic study. The original paper by Seacat et al (2002) noted a NOAEL of 0.15mg/kg bw day. This was due to the fact that they noted that there was uncertainty concerning the significance of the lowered HDL observed in females at 0.15mg/kg bw day. EFSA (2008) recently reviewed this study . They considered the observed changes in thyroid hormones and HDL to be treatment related and therefore concluded it was justified to consider the NOAEL of 0.03mg/kg bw/day to be valid. This endpoint was used by EFSA as the basis of the derivation of the Tolerable Daily Intake (TDI) for PFOS (EFSA, 2008). The NOAEL of 0.03mg/kg bw/day has been used by the US EPA to derive their provisional health advisory value for PFOS (2009) and has also been quoted by other regulatory bodies, eg the UK Health Protection Agency. The question arises as to the relevance of the effects observed at the NOAEL endpoint of 0.03mg/kg in relation to population level effects. Following consideration and discussion at meetings of the EU Sub-Group on the Review of Priority Substances it is proposed that the NOAEL of 0.15mg/kg should be considered in terms of the derivation of a $QS_{biota,secpois}$ due to the uncertainty around the population effects of the changes seen in relation to hormone levels.

Based on the above the lowest reported NOAEL for PFOS is therefore 0.1mg/kg bw/day which was derived in both the study by Christian et al (1999) and Case et al (2001). It is proposed that the NOAEL derived from the 2 generation rat study undertaken by Christian et al (1999) is used as the basis of the derivation of the $QS_{biota,secpois}$. This was a 2 generation study with the NOAEL of 0.1mg/kg being reported for effects observed in the F0, F1 and F2 generation. The study by Case et al (2001) on the other hand related to exposure during gestation day 6-20 and the NOAEL related solely to maternal toxicity (reduced weight gain). The NOAEL of 0.1mg/kg can be converted to a NOEC using the conversion factor of 20 taken from the REACH guidance and included in the EC TGD-EQS. This gives a NOEC of 2mg/kg. To derive a $QS_{biota,secpois}$ based on this NOEC an assessment factor of 30 has been applied to this chronic study as identified in the TGD-EQS. This gives a $QS_{biota,secpois}$ of 0.067mg/kg bw.

However it is recognised that the Cynomologus monkey study by Seacat et al (2002) is a subchronic study based on the lifespan of this species and that the chronic effects are therefore not known. A lower NOAEL of 0.03mg/kg has been reported for this study however as noted above it was proposed that the NOAEL of 0.15mg/kg should be considered in terms of the derivation of a $QS_{biota,secpois}$ due to the uncertainty around the population effects of the changes seen in relation to hormone levels. Applying a conversion factor of 20 to this NOAEL gives a NOEC of 3mg/kg food. An assessment factor of 90 is applied as this study is of 183days duration and is reported to be a subchronic study. Application of an assessment factor of 90 gives a $QS_{biota,secpois}$ of 0.033mg/kg bw.

Due to the fact that this is a subchronic study rather than a chronic study and effects have been reported at lower levels (NOAEL 0.03mg/kg for hormone changes) it is proposed that the lower value ie that derived from the Cynomologus study is used for the $QS_{biota,secpois}$ rather than that derived based on the rat study undertaken by Christian et al 1999. This gives a $QS_{biota,secpois}$ of 0.033mg/kg bw.

Conversion of the $QS_{biota,secpois}$ to a concentration in water is undertaken using the formula proposed in the TGD-EQS (see below).

$$QS_{freshwater} = QS_{biota,secpois}/(BCF x BMF)$$

$$QS_{saltwater} = QS_{biota,secpois}/(BCF x BMF1 x BMF2)$$

A range of BCF values have been reported for PFOS ranging from information on accumulation in specific fish organs/tissues, eg liver, through to BCF values for the whole organism. Information on BCFs for the whole organism are required for the above calculation. The highest, reliable BCF value for whole fish was noted to be 2796. This has been used to calculate the water concentration.

In terms of BMF1 and BMF2 values, default values are provided in the TGD-EQS (EC 2011). The default values used depend on both the log Kow and the BCF values for fish. The default values therefore apply to lipophilic, hydrophobic substances. PFOS is not lipophilic but instead binds to proteins. A log Kow cannot be derived for PFOS. Use of the default values for BMF1 and BMF2 are therefore not appropriate for PFOS. RIVM (2010) and Environment Canada (2006) have both produced reviews on PFOS which have included information on BMF values. The RIVM report notes BMF1 values in the range of 0.77 – 6 but that the reliability of these studies is either 3 or 4. In terms of BMF2 values these are reported in the range of 1.4 – 4.6 although again the reliability of the studies is noted as either 3 or 4. RIVM used values of 5 for both BMF1 and BMF2 in their derivation of risk limits for secondary poisoning. Environment Canada (2006) reported BMF values in the range of 0.4 – 5.88. This is a similar range to that reported by RIVM (2010).

As noted above RIVM note that the reliability of the studies from which the BMF values are reported is low, ie 3 or 4. Although each individual study has a low reliability score the weight of evidence may be used to determine a BMF1 for PFOS. If the BMF1 values for PFOS are averaged this gives a BMF1 value of approximately 5. It is therefore proposed that a BMF1 value of 5 is applied. In terms of the BMF2 value the values range from 1.4 – 4.6. If the same approach is applied, ie the data is used as a weight of evidence and an average is derived it gives a BMF2 value of approximately 2. Due to the uncertainties associated with the data available in relation to BMF2 however evidence of detection of PFOS in higher trophic levels it is proposed to use the same value as the BMF1, ie 5 for BMF2.

Using the formula shown above from the TGD-EQS a $QS_{biota,secpois}$ in water is derived. The BCF value used is 2796, the BMF value of 5 and a $QS_{biota,secpois}$ of 0.033mg/kg bw. This gives a freshwater concentration of 0.000002mg/l (0.002µg/l). For saltwater a QS of 0.00000047mg/l is derived (0.00047µg/l).

Tentative QS_{biota}	Relevant study for derivation of QS	Assessment factor	Tentative QS	Source
Biota	Cynomolgus monkey 183d NOAEL 0.15mg/kg (NOEC 3.3mg/kg food)	90	0.033mg/kg 0.002µg/l (freshwater) 0.00047µg/l (saltwater)	Seacat et al 2002

7.6 HUMAN HEALTH

7.6.1 Human health via consumption of fishery products <u>($QS_{biota,hh}$)</u>

Human health via consumption of fishery products		Master reference
Mammalian oral toxicity	See above	
CMR	Carc Cat 3, Repr Cat 2	RIVM 2010

Tentative $QS_{biota,\ hh}$	Relevant study for derivation of $QS_{biota,\ hh}$	Assessment Factor	Tentative $QS_{biota,\ hh}$	Source
Human health	0.03 $mg.kg^{-1}{}_{bw}.d^{-1}$	200 TDI of 150 $ng.kg^{-1}{}_{bw}.d^{-1}$ established by EFSA (2008)	9.1 $\mu g.kg^{-1}{}_{biota\ ww}$	EFSA (2008)

The $QS_{biota,hh}$ is calculated using the following equation as noted in the TGD-EQS.

$$QS_{biota,hh} = \frac{0.1 \times TL \times 70}{0.115}$$

A TDI of 0.15µg/kg bw/day was calculated by EFSA (2008). The TDI was determined by applying an uncertainty factor of 200 to the NOAEL of 0.03mg/kg bw/day (Seacat et al, 2002). This NOAEL was obtained from a subchronic study on the Cynomolgus monkey which showed changes in lipids and thyroid hormones at the next higher dose of 0.15mg/kg bw/day. The overall uncertainty factor of 200 was based on a factor of 100 to account for inter and intra-species differences and an additional factor of 2 to compensate for uncertainties in connection to the relatively short duration of the key study and the internal dose kinetics.

To convert this QS to a concentration in water the guidance provided in the TGD-EQS was followed.

$$QS_{freshwater} = QS_{biota,hh}/(BCFxBMF)$$

$$QS_{saltwater} = QS_{biota,hh}/(BCFxBMF1xBMF2)$$

A BCF of 2796 was identified. This has been identified as the most reliable BCF value for whole fish and was calculated based on a study on Bluegill sunfish. In terms of the BMF1 and BMF2 values the default value of 5 was applied as discussed under Section 7.5. Using these values and the formula shown above gives a freshwater concentration of 0.00000065mg/l (0.00065µg/l) and a saltwater concentration of 0.00000013mg/l (0.00013µg/l)

7.6.2 Human health via consumption of drinking water

Thresholds for PFOS in drinking water have been proposed by a number of countries. These are shown in the table below. However a threshold has not been derived by either the EU or WHO. Under these circumstances the TGD-EQS (EC 2011) notes that a provisional drinking water standard should be derived using the following formula:-

$$QS_{dw,hh} = \frac{0.1 \times TL_{hh} \times bw}{Uptakedw}$$

The default values for bw and uptake dw are 70kg and 2 litres respectively. The TL_{hh} refers to an available ADI or TDI. Based on the above the $QS_{dw,hh}$ for PFOS is 0.525µg/l. This value is in a similar order of magnitude as the values proposed by a number of organisations.

Human health via consumption of drinking water		**Master reference**
Existing drinking water standard(s)	No standard set in the Drinking Water Directive	
Any guideline		
0.2 µg/L	US, provisional	US EPA, 2009
0.3 µg/L	UK	HPA UK, 2007
0.3 µg/L	Germany	Roos et al., 2008
0.53 µg/L	Netherlands, proposal	Schriks et al., 2010

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