Description	Reference	Reported Highest Concentrations (Max, Mean)	Location
		Arctic fox (liver, n = 10): Max: 1400 ng/g wet wt. Mean: 250 ng/g wet wt.	
Survey of fish (US, Europe, North Pacific Ocean, Antarctic)	C	Fish (muscle, n = 172): Max: 923 ng/g wet wt. Mean. 40 ng/g wet wt.	Belgian estuary
		Carp (muscle, n = 10): Max: 296 ng/g wet wt. Mean: 120 ng/g wet wt.	US Great Lakes
Survey of fish-eating birds (US, Baltic Sea, Mediterranean Sea, Japanese coast, Korean coast)	D	Bald eagle (plasma, n = 42): Max: 2570 ng/mL Mean: 520 ng/mL	Midwest US
Survey of mink and river otter in the US	E	Mink (liver, n = 77): Max: 4870 ng/g wet wt. Mean: 1220 ng/g wet wt.	US
		River otter (liver, n = 5): Max: 994 ng/g wet wt. Mean: 330 ng/g wet wt.	US
Survey of oysters in the US (Chesapeake Bay & Gulf of Mexico)	F	Oyster (Whole body, n =77) Max: 100 ng/g wet wt. Mean: 60 ng/g wet wt.	US
Fish samples upstream and downstream of 3M facility in Decatur, Alabama, US	G	Fish (whole body): Mean (upstream): 59.1 µg/kg wet wt. Mean (downstream): 1,332 µg/kg wet wt.	Decatur, US
Swedish urban and background	H	Perch: 3 - 8 ng/g (urban sites in the vicinity of	Sweden (Lake Mälaren)

Description	Reference	Reported Highest Concentrations (Max, Mean)	Location
fish samples		municipal STPs); 20-44 ng/g in Lake Mälaren and near Stockholm	

Sources: A: 3M (2003a), B: Martin *et al.* (2004a); C: Giesy and Kannan (2001c) in 3M (2003a); D: Giesy and Kannan (2001b) in 3M (2003); E: Giesy and Kannan (2001d) in 3M (2003a); F: Giesy and Kannan (2001e) in 3M (2003); G: Giesy and Newsted (2001) in OECD (2002); H: Holmström *et al.* (2003).

Concentrations of PFOS in guillemot (*Uria aalge*) eggs from Stora Karlsö in the Baltic Sea have been measured retrospectively from 1968 to 2003 (Holmström et al, 2005). The results shown in Figure 2 display a trend of increasing concentrations since 1968 (17 – 623 ng/g).

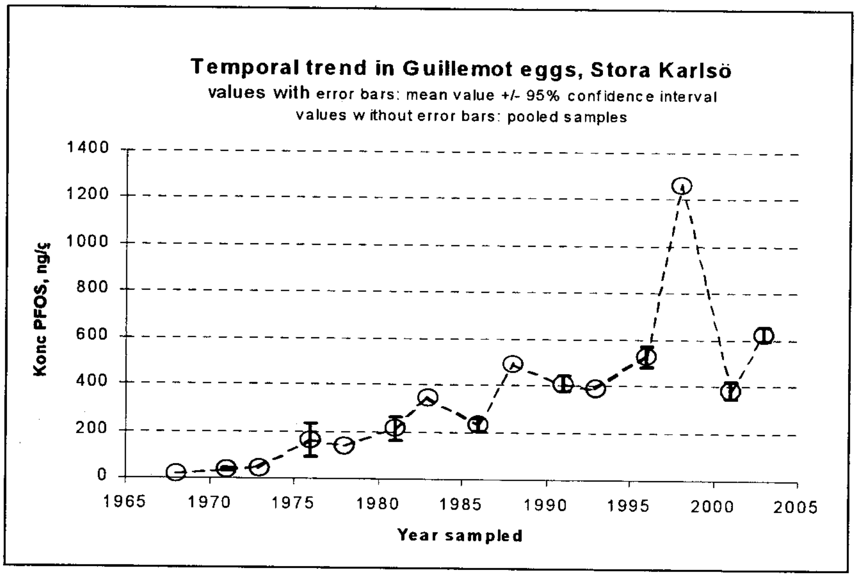

Figure 2. Measured concentrations of PFOS in Guillemot (*Uria aalge*) eggs sampled at Stora Karlsö in the Baltic Sea between the years 1968 – 2003. The graph is taken from the report "Screening av perfluorerade ämnen" by the Swedish EPA, Environmental Assessment Department (2004).

2.3.2 Bioavailability

Studies on fish have shown that PFOS has bioconcentration properties. In studies on bluegill sunfish (*Lepomis macrochirus*) and rainbow trout (*Oncorhynchus mykiss*), bioconcentration factors (BCFs) have been estimated to be 2796 (whole fish) as well as 2900 (liver) and 3100 (plasma), respectively. The major route of uptake is believed to be through the gills (Martin *et al.*, 2003).

Since PFOS is released from sewage treatment plants to the environment i.e. through water, one major route for PFOS into local food chains could be through fish. PFOS has shown a high oral uptake (95%) within 24 hours in the gastro-intestinal (GI) tract in studies on rats (OECD, 2002). Taken together, this could constitute the basis of the highly elevated levels that have been observed in top predators in food chains containing fish.

This could also be corroborated by two separate human monitoring studies on the Swedish population where the levels of PFOS in whole blood was higher (27.2 ng/g, 3.0 – 67, n = 10) in females with a high consumption of fish (Berglund, 2004) compared to samples from females in the general population (17.8 (ng/g, 4.6 – 33, n = 26) (Kärrman *et al.*, 2004).

In humans, the highest concentrations of PFOS have been detected in workers at 3M's manufacturing plant for perfluorochemicals in Decatur, US, where the levels in serum in the last year of measurement (2000) ranged between 0.06 – 10.06 ug/g (n = 263, OECD, 2002).

In a study of the general population, blood samples from families including three generations living in 12 European countries were tested for a large number of chemicals including PFOS and PFOSA. PFOS was present in 37 of 38 samples with concentrations from 0.36 to 35.3 ng/g blood, while PFOSA was present in 36 of 38 samples with concentrations from 0.15 to 2.04 ng/g blood (WWF, 2005).

Pooled serum samples from 3802 Australian residents, collected 2002-2003 and divided in relation to age, gender and region, were analysed for perfluoroalkylsulfonates, perfluoroalkylcarboxylates and PFOSA (Kärrman et al., 2006). PFOS and PFOSA were quantified in all pooled serum samples with a total range of 12.7-29.5 ng/ml (mean 17.2 ng/ml) and 0.36-2.4 ng/ml (mean 0.81 ng/ml), respectively. For PFOS, a significant correlation between age and concentration was shown. No substantial difference was found in levels of perfluorinated compounds between the urban and rural regions. According to gender some differences were shown for some of the age groups.

2.4 Hazard assessment for endpoints of concern

2.4.1 Mammalian Toxicity

Evidence of the mammalian toxicity of PFOS is available from acute, sub-chronic and chronic exposures to rats, sub-chronic exposures to monkeys, and a two-generation study on rats. Results are available from reproductive and teratogenicity studies on rats and rabbits. Details of these studies are not included here, they can be found in the assessment made by OECD (2002). The most relevant data for this risk profile are:

- A 90-day study on rhesus monkeys exposed to PFOS potassium salt via gavage at the doses 0, 0.5, 1.5 and 4.5 mg/kg bw/day. At 4.5 mg/kg bw/day all monkeys (4) died or were sacrificed in moribound condition. No deaths were observed at 0.5 or 1.5 mg/kg bw/day, but there were signs of gastrointestinal toxicity. A NOAEL could not be established since the lowest dose was a LOAEL (Goldenthal et al., 1978a).

- A 90-day oral repeated dose toxicity study in rats that were fed diets containing 0, 30, 100, 300, 1000 and 3000 mg PFOS potassium salt per kg diet. All rats died when fed diets containing 300 mg/kg PFOS and above (equivalent to 18 mg/kg bw/day and above). At 100 mg/kg (6 mg/kg bw/day), 50% (5/10) of the animals died. All rats receiving diets containing 30 mg/kg PFOS (2.0 mg/kg/day) survived until the end of the study, but small changes in body and organ weights were reported. Since the lowest dose tested was a LOAEL, a NOAEL could not be established (Goldenthal et al., 1978b).

- A two-generation reproductive toxicity study on rats that were fed PFOS potassium salt via gavage at the doses 0.1, 0.4, 1.6, and 3.2 mg/kg bw/day. At the doses 1.6 and 3.2 mg/kg bw/day a significant reduction in the viability of the F1 generation was observed. In the 1.6 mg/kg bw/day group, 34% (86/254) of the F1 pups died within four days after birth. In the 3.2 mg/kg bw/day group, 45% (71/156), of the F1 pups died within one day after delivery. None of these pups survived beyond day 4. Maternal toxicity at 1.6 and 3.2 mg/kg bw/day was manifested as reduced food consumption, body weight gain, and terminal bodyweight. Localised alopecia was also observed at 3.2 mg/kg bw/day. The LOAEL in this study was 0.4 mg/kg bw/day based on significant reductions in pup weight gain in the F1 generation animals. The NOAEL was 0.1 mg/kg bw/day (Christian et al., 1999). A new study by Luebker *et al.* (2005) supports these results.

- Cynomolgus monkeys administered PFOS for 26 weeks were observed to have thymic atrophy (females), and reduced high density lipoprotein, cholesterol, triiodothyronine, total bilirubin levels (males) (Covance Laboratories, Inc. 2002a). The LOEL dose was 0.03 $mg.kg^{-1}$ bw/day at which average mean female and male concentrations in sera and liver were 19.8 $\mu g.mL^{-1}$ and 14.5 $\mu g.g^{-1}$, respectively.
- A 2-year dietary rat study in which histopathological effects in the liver were seen in males and females at intakes as low as 0.06–0.23 mg PFOS/kg bw per day and 0.07–0.21 mg PFOS/kg bw per day, respectively (Covance Laboratories, Inc. 2002b). Average values were determined for males and females to establish LOELs of 40.8 ug/g in liver and 13.9 mg/L in serum.

A study by Grasty *et al.* (2003) concluded that exposure of pregnant rats to PFOS late in gestation, at 25 mg/kg b.w. PFOS by oral gavage on gestation day (GD) 17-20 or 50 mg/kg PFOS on GD 19-20, is sufficient to induce 100% pup mortality and that the causative factor may be inhibition of lung maturation. However, in a subsequent study by Grasty *et al.* (2005), the mechanism behind pup mortality could not be established.

2.4.2 Ecotoxicity

Environmental toxicity data for PFOS is predominantly found for aquatic organisms such as fish, invertebrates and algae, and for birds.

PFOS has shown moderate acute toxicity to fish. The lowest observed LC_{50} (96h) was estimated to be 4.7 mg/l in a study where fathead minnow (*Pimephales promelas*) were exposed to the lithium salt of PFOS. The lowest NOEC, 0.3 mg/l, has been observed in *Pimephales promelas* at prolonged exposure (42d) and was based on mortality (OECD, 2002). The lowest LC_{50} (96h) for aquatic invertebrates has been observed in the mysid shrimp (*Mysidopsis bahia)* and was estimated to be 3.6 mg/l. The lowest NOEC value has been observed in *Mysidopsis bahia* at 0.25 mg/l (OECD, 2002).

A study by Macdonald *et al.* (2004) reported a 10-day NOEC of 0.0491 mg/L for the growth and survival of the aquatic midge (Chironomous *tentans*). The authors concluded that PFOS is 2-3 orders of magnitude more toxic to chironomids than to other aquatic organisms possibly through some kind of interaction with haemoglobin, which is present at all levels of dissolved oxygen (DO) in chironomids as opposed to daphnids, where haemoglobin is produced only in response to declining DO levels.

The most sensitive algae appear to be the green algae *Pseudokirchnerilla subcapitata* with a IC_{50} (96h, cell density) of 48.2 mg/L. The lowest NOEC value for algae was determined in the same study for *Pseudokirchnerilla subcapitata*, 5.3 mg/L (Boudreau *et al.*, 2003).

Mallard and bobwhite quail were exposed to PFOS in feed for up to 21 weeks and a variety of endpoints examined including changes in adult body and organ weights, feed consumption rate, fertility, hatchability, and offspring survival. At a dose of 10 mg/kg diet PFOS, effects in male mallards (*Anas platyrhyncos)* included reduced testes size and decreased spermatogenesis (3M, 2003b). At this dose, the concentrations of PFOS in serum and liver were 87.3 ug/mL and 60.9 ug/g, respectively (3M, 2004). For quail (*Colinus virginianus*), at 10 mg/kg in diet, minor effects were observed in adults, including an increase in liver weight (females), an increase in the incidence of small testes size (males), and reduction in survivability in quail chicks as a percentage of eggs set. Concentrations in serum and liver of adult quail females was 84 μg.mL^{-1} serum (week 5, pre-reproductive phase), and 8.7 μg.mL^{-1} serum (week 21) and 4.9 μg.kg^{-1} wet weight liver; in adult quail males, concentrations were 141 μg.mL^{-1} serum and 88.5 μg.g^{-1} wet weight liver (3M, 2003c).

3 SYNTHESIS OF THE INFORMATION

Perfluorooctane sulfonate (PFOS) is a fully fluorinated anion, which is commonly used as a salt in some applications or incorporated into larger polymers. Due to its surface-active properties, it has historically been used in a wide variety of applications, typically including fire fighting foams and surface resistance/repellency to oil, water, grease or soil. PFOS can be formed by degradation from a large group of related substances, referred to as PFOS-related substances (see definition on page 4).

Due to their intrinsic properties, PFOS and its related substances have been used in a wide variety of applications. While historically, PFOS and PFOS-related substances have been used in eight different sectors as shown in Section 2.1.2. above, the present use in industrialized countries seems to be limited to five sectors, see 2.1.2. It is not known whether this also reflects the global use.

PFOS and PFOS-related substances can be released to the environment at their manufacture, during their use in industrial and consumer applications and from disposal of the chemicals or of products or articles containing them after their use.

The rate and the extent of the formation of PFOS from its related chemicals are largely unknown. Lack of data makes it very difficult to estimate the net contribution of the transformation of each of the PFOS-related substances to the environmental loadings of PFOS. However, based on its extreme stability, it is expected that PFOS is likely to be the final degradation product of all PFOS-related substances.

PFOS is extremely persistent. It has not shown any degradation in tests of hydrolysis, photolysis or biodegradation in any environmental condition tested. The only known condition whereby PFOS is degraded is through high temperature incineration.

With regard to bioaccumulation potential, PFOS meets the Annex D criteria given the highly elevated concentrations that have been found in top predators such as the polar bear, seal, bald eagle and mink. Based on the concentrations found in their prey, high BMFs have been estimated for these predators. BCF values in fish, although (rather) high do not in themselves meet the specific numeric criteria. However, due to the properties of PFOS, which binds preferentially to proteins in non-lipid tissues, application of numeric criteria for BCF or BAF, which are derived based on consideration of lipid-partitioning substances, may be inappropriate for PFOS. Most notable and alarming are the high concentrations of PFOS that have been found in Arctic animals, far from anthropogenic sources. PFOS has been detected in higher trophic level biota and predators such as fish, piscivorous birds, mink, and Arctic biota. Also, predator species, such as eagles, have been shown to accumulate higher PFOS concentrations than birds from lower trophic levels. Even with reductions in manufacturing of PFOS by some manufacturers, wildlife, such as birds, can continue to be exposed to persistent and bioaccumulative substances such as PFOS simply by virtue of its persistence and long-term accumulation.

According to available data, PFOS meets the criteria for the potential for long-range transport. This is evident through monitoring data showing highly elevated levels of PFOS in various parts of the northern hemisphere. It is especially evident in the Arctic biota, far from anthropogenic sources. PFOS also fulfils the specific criteria for atmospheric half-life.

PFOS fulfils the criteria for adverse effects. It has demonstrated toxicity towards mammals in sub-chronic repeated dose studies at low concentrations, as well as rat reproductive toxicity with mortality of pups occurring shortly after birth. PFOS is toxic to aquatic organisms with mysid shrimp and *Chironomus tentans* being the most sensitive organisms.

Table 8. POP characteristics of PFOS (studies performed with the potassium salt of PFOS, unless otherwise noted).

Criterion	Meets the criterion (Yes/No)	Remark
Persistence	Yes	Extremely persistent. No degradation recorded in chemical or biological tests
Bioaccumulation	Yes	Found in highly elevated concentrations in top predators. Calculated hypothetical BMFs = 22 - 160. BCF in fish = 2796 - 3100.
Potential for Long-Range Environmental Transport	Yes	Atmospheric half life > 2 days (estimated value based on photolytic half life > 3.7 years)
Toxicity	Yes	Sub-chronic exposure: Mortality in monkeys at 4.5 mg/kg bw/day. Reproductive toxicity: mortality in rat pups at 1.6 mg/kg bw/day. Acute toxicity to Mysid shrimp (*Mysidopsis bahia)*: LC_{50} (96h) = 3.6 mg/L Acute toxicity to fish, Fathead minnow (*Pimephales promelas*): LC_{50} = 4.7 mg/L[1]

[1]The study compound was the lithium salt of PFOS

A risk quotient analysis, where known or potential exposures are integrated with known or potential adverse environmental effects, have been performed on PFOS for the wildlife in Canada (Environment Canada, 2006). The results indicate that the higher trophic level mammals may be at risk at current environmental concentrations of PFOS.

In the risk quotient analyses for polar bear, the highest concentration was found in South Hudson Bay with a maximum concentration of 3.77 $\mu g.g^{-1}$ ww liver (range 2.00-3.77 $\mu g.g^{-1}$, mean 2.73 $\mu g.g^{-1}$ ww liver, Smithwick *et al.* 2005). In comparing this value of 3.77 $\mu g.g^{-1}$ ww liver of PFOS in polar bear with a critical toxicity value of 40.8 $\mu g.g^{-1}$ ww liver for histopathological effects in liver of rats (a 2-year study, Covance Laboratories, Inc. 2002), the difference is only about a factor 10. Using an application factor of 100[2], as was used in the Canadian Ecological Screening Assessment Report, a risk quotient of 9.2 was calculated, where values above one indicate risk. Risk quotients were also calculated on toxicological endpoints from other studies in rats and monkeys but with the same maximum exposure concentration from the south Hudson Bay polar bear, showing risk quotients from 2.1 to 19.

Concentrations in Canadian Arctic polar bear are among the highest in polar bears worldwide but the exposure concentrations are not considered an anomaly given similar concentrations in polar bears in other North America and European Arctic locations and high concentrations in other wildlife globally as shown above.

Risk quotients were also calculated for a number of bird species that are native to Canada, including many piscivorous birds and migratory species. The range of risk quotients is either above or approaching one that indicates potential for harm at concentrations observed in native species, including migratory species (Environment Canada, 2006).

4 CONCLUDING STATEMENT

PFOS is a synthetic substance of anthropogenic origin with no known natural occurrence. It can be concluded therefore that the presence of PFOS and its precursors in the environment are the result of anthropogenic activities and that PFOS found in remote areas far from possible sources has been brought there through long-range environmental transport. While PFOS related substances may be degraded to PFOS, PFOS itself is extremely persistent in all media and can bioaccumulate and biomagnify in mammals and piscivorous birds.

The voluntary phase out of PFOS production by the major producer in the USA has led to a reduction in the current use of PFOS-related substances. However, it can be assumed that it is still produced in some countries and it continues to be used in many countries. Given the inherent properties of PFOS,[3] together with demonstrated or potential environmental concentrations that may exceed the effect levels for certain higher trophic level biota such as piscivorous birds and mammals; and given the widespread occurrence of PFOS in biota, including in remote areas; and given that PFOS precursors may contribute to the overall presence of PFOS in the environment, it is concluded that PFOS is likely, as a result of its long-range environmental transport, to lead to significant adverse human health and environmental effects, such that global action is warranted.

[2] An application factor of 100 applied for extrapolation from laboratory to field conditions and for intraspecies and interspecies variations in sensitivity, and extrapolation from the observed effects level to a no-effect level.

[3] A decision on the inclusion of PFOS precursors has been postponed until the Committee has evaluated the information requested under Annex F.

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