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SCIENTIFIC COMMITTEE ON HEALTH AND ENVIRONMENTAL RISKS

SCHER

Opinion on

"RPA´s report "Perfluorooctane Sulphonates Risk reduction strategy and analysis of advantages and drawbacks"

(Final report - August 2004)

Adopted by the SCHER
during the 4th plenary of 18 March 2005

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1. BACKGROUND

Perfluorooctane sulfonate is a fully fluorinated moiety which is found in a large family of PFOS related substances. Most members of this group are polymers of high molecular weights in which PFOS constitutes only a small fraction of the total polymer molecule and of the final product.

On 16 May 2000, the major global producer of PFOS (3M) announced a voluntary phase out from 2001 onwards. An OECD hazard assessment was produced according to which the production of PFOS has now ceased, apart from a small-scale uses.

A study has been undertaken by RPA in association with the British authorities. The report recommends a risk reduction strategy to be taken forward.

2. TERMS OF REFERENCE

The SCHER is requested to examine the following issues:

1. To assess the overall scientific quality of the RPA report, and in considering this, to comment on the methodology, findings, conclusions and recommendation of the report.

2. To evaluate the contribution of the ongoing uses to the overall risks for the environment and to human health.

    a. Does the SCHER think it likely that all PFOS derivatives would fulfil the criteria for classification as PBT and whether they would qualify for the classification under POP criteria?

    b. How rapidly and to what level does the SCHER think that the concentrations of PFOS found in the environment will reduce as a consequence of the recent phase out of numerous uses of PFOS?

    c. Does the SCHER expect that the concentrations of PFOS in the environment will reduce to the extent that they will reach a level at which there is no risk?

    d. Does the SCHER think that the current emissions into the environment from ongoing uses have a significant influence on the rate of reduction of the concentrations of PFOS found in the environment?

3. OPINION

3.1. Overall considerations

The proposed Risk Reduction Strategy by Risk & Policy Analysts Limited (RPA, 2004) applies to PFOS, its salts and related substances including polymers, which contain one or more perfluorooctylsulphonate groups (i.e. $C_8F_{17}SO_2$) and may potentially degrade or metabolise to PFOS under certain conditions. This strategy thus does not include perfluoroalkylsulphonates with other chain lengths than eight carbons, or perfluorocarboxylates. Several of these substances have similar properties as PFOS, and may be used as substitutes.

PFOS is not on an EU priority list and there is no EU Risk Assessment Report available. It was undergoing a national environmental risk assessment by the UK in 2004 (RER, 2004). Further to preliminary indications of persistence and toxicity, the Organisation for Economic Co-operation and Development (OECD) performed in 2002 an assessment of the hazards associated with PFOS. With regard to the environmental fate, the OECD concluded that PFOS is persistent and bioaccumulative; the OECD reports toxicity studies on several aquatic and terrestrial species. PFOS has been detected in tissues of a number of species of wildlife (including marine mammals), in surface water and sediment, in wastewater treatment plant effluent, sewage sludge and in landfill leachate.

The RPA report is based on the UK Risk Evaluation Report (RER, 2004) which has mainly taken the information provided in the OECD (2002) report on PFOS. In this RER, risk characterisation is performed according to the procedures suggested in the TGD (2003) and using the EUSESv2 model. The SCHER is of the opinion that considering the particular properties of PFOS and related substances this approach is not suitable for these particular compounds. The physico-chemical properties including surface-tension activity produce an unusual environmental behaviour. Therefore the conventional partitioning approaches cannot be applied and consequently the PEC calculations cannot be supported by the SCHER. It is noted that the PECs are not sufficiently validated (including assessment of uncertainties) against the available monitoring data. The SCHER is particularly concerned on the way bioaccumulation data is used in the assessment of secondary poisoning. The SCHER is of the opinion that the procedure used in the RER is not suitable for PFOS and related substances. The reasons for this are: (1) the bioaccumulation potential of PFOS is not related to the typical mechanisms associated with accumulation in lipid-rich tissues observed for other organic chemicals, (2) in fact, the bioaccumulation is associated with a rapid assimilation, low elimination rate and protein binding, (3) the toxico-kinetic information indicates multi-compartmental kinetics and therefore the bioaccumulation/bioconcentration potential is related to the exposure level and cannot be reduced to a single BAF.

Based on the concerns expressed above, the SCHER cannot support the conclusions of the environmental risk characterisation for the present and possible future uses of PFOS (and related substance) proposed in the RER. However, concentrations in some aquatic and terrestrial organisms have been reported in several areas, indicating a potential concern for secondary poisoning even at regional level. Due to the contribution of historical emissions, the relevance of the proposed PEC/PNEC ratios for assessing the potential risk of current and future uses cannot be established.

The SCHER has also reservations regarding the conclusions reached by RPA on the risks of PFOS and related substances to human health. RPA used the 3M Risk Assessment Report (2003) as basis, where "adequate margins of exposure" were claimed for the general population, and medical surveillance data were used to demonstrate the absence of adverse effects in workers. As PFOS has been detected in the serum of occupational and general populations with elimination half-lives in the order of years, and because the lowest serum effect levels found in animal long-term repeated-dose studies were in the same range as the serum levels of some workers, a scientific human health risk assessment should be performed, taking into account the substantial differences in elimination kinetics between animal species and man.

Use of PFOS and PFOS related substances in consumer applications such as carpets, leather/apparel, textiles/upholstery, paper and packaging, coatings, industrial and household cleaning products, pesticides and insecticides has been largely abandoned following the announcement of the main global producer (3M) to voluntarily phase out manufacture and use of PFOS consumer applications. Continued use in some of these applications is, however, reported from single European countries. According to RPA, there is no evidence of use in Europe in medicinal products or medical devices, flame retardants, mining/oil surfactants and adhesives. These uses were therefore not considered any further in the RPA risk reduction strategy.

Ongoing industrial/professional usage of PFOS and PFOS-related substances has been confirmed for five sectors in the EU (current demand):

- Metal (chromium) plating (8,600 - 10,000 kg/year)
- Fire fighting foams (estimated quantity held in current stock: 122 tonnes)
- Photographic industry (approximately 850 kg PFOS-related substances/year)
- Semiconductor industry (436 kg/year)
- Aviation industry (hydraulic fluids; approximately 730 kg/year).

3.2. Question 1

The SCHER is asked to assess the overall scientific quality of the RPA report and in considering this, to comment on the methodology, findings, conclusions and recommendation of the report.

In response to this question, the SCHER will focus its comments on the scientific basis used for the management strategy, but will not comment on the risk reduction strategy itself:

As pointed out earlier in this document, some fundamental assumptions made in the RPA report lack substantiation, and the SCHER cannot therefore support the estimations presented in the environmental risk characterisation for present and possible future uses of PFOS (and related substance) proposed in the RER, and taken over into the RPA report. However, the SCHER agrees, that measured concentrations in some aquatic and terrestrial organisms indicate a potential concern for secondary poisoning, even at the regional level.

The SCHER has reservations also with regard to RPA's conclusion on the risks to human health, which were uncritically taken from the 3M Risk Assessment Report (2003). In particular, the summary statement that "…the observed levels of PFOS in human serum demonstrate adequate margins of exposure and should not be associated with increased health risk" cannot be supported by the SCHER.

The SCHER acknowledges that no consistent associations between exposure to PFOS and haematological, hormonal, or biochemical parameters were found in surveys of occupationally exposed workers with serum levels of up to 10 µg/ml, and that no conclusions with regard to human carcinogenicity can be drawn from the available epidemiology data, including a retrospective cohort study with a reported increased risk of bladder cancer in workers who were highly exposed to fluorochemicals, but also other chemicals, primarily in non-production jobs, including maintenance and incinerator and wastewater treatment plant operations (SMR 12.77; 95% CI 2.63-37.3; Alexander et al.. 2003).

The toxicity profile of PFOS is, however, fairly consistent across different animal species, and includes liver toxicity, hypolipidemia, liver tumours, and toxicity to the developing organism. As PFOS has not shown a genotoxic activity in a wide variety of tests, it is justified to assume a non-genotoxic mechanism for the development of liver, thyroid and mammary gland tumours. The key health hazards identified in animal studies were therefore repeated dose and developmental toxicity, with the lowest effect level found in a chronic dietary toxicity study on rats at 2 ppm (corresponding to ~17 µg/ml serum; mild hepatocellular centrilobular hypertrophy in males). The NOAEL in this study was at 0.5 ppm (4 µg PFOS/ml serum). Dose-dependent mortality was seen in rodent offspring after exposure of dams to PFOS in postnatal, reproductive and developmental toxicity studies. Exposure to 3 mg/kg bw/day (rat, corresponding to 72 µg/ml serum) and 10 mg/kg bw/day (mouse) resulted in the death of 50% of the offspring within four days, possibly related to an interference of the chemical with lung maturation. In this study, the benchmark dose that predicts a 5% increase in pup mortality over background was estimated at 0.58 mg/kg bw/day. In a rat 2-generation reproductive study the NOAEL and LOAEL for second generation offspring (F2 pups) were 0.1 mg/kg bw/day and 0.4 mg/kg bw/day based on reductions in pup weight.

Substantial differences exist in the elimination kinetics between animal species and man. These differences have to be taken into account in order to judge whether or not "…the observed levels of PFOS in human serum demonstrate adequate margins of exposure". No such information is presented in the RPA report. Whilst simply comparing serum levels in the general population (0.030 – 0.040 µg/ml, geometric mean) with the no effect level in the chronic rodent studies (4 µg/ml serum) indeed reveals Margins of Exposure ≥100, indicating a low risk for the general population, serum levels of workers (up to 13 µg/ml) are already in the range of those levels at which toxicity has been observed in animal studies. The SCHER is therefore of the opinion that a full human health risk assessment should be performed.

Potential risk reduction measures that were examined by RPA were those of the TGD document. These measures were assessed against the following decision criteria (in accordance with the TGD): a) effectiveness, b) practicality, c) economic impact, and d) monitorability. Where controls on the marketing and use of PFOS and PFOS containing substances were proposed, an analysis of the advantages and drawbacks of the substance itself and its substitutes was undertaken by RPA. The recommended risk reduction measures included: manufacturing process changes, environmental emission control, exposure control, provision of information and guidance, waste disposal, marketing and use restrictions, and measures for "previous uses" to prevent re-introduction. Additionally, classification and labelling were proposed (R51/R53; R48).

3.2.1. Findings and recommendations for on-going uses:

- Metal (chromium) plating

PFOS is used as mist suppressant in hard, decorative and plastic chromium plating. According to the RPA report, there are no means of reducing emissions from its use in these applications to near zero level. Alternative processes/operations and/or emission controls for hard and plastic chromium platers include additional extraction ventilation and tank enclosure; and for decorative chromium platers alternatively also a move away from Cr(VI) processes to Cr(III) processes. A voluntary agreement with the plating industry was considered unlikely to succeed given that previous initiatives to promote a shift to Cr(III) technology have had little effect. Therefore, RPA proposed marketing and use restrictions through national regulations in accordance with EU Directive 76/769/EEC.

The SCHER notes that the risk reduction strategy assumes 100% release into the environment, without taking into consideration recycling measures and waste disposal by incineration. For Europe, Industry has calculated a total emission of only 517 kg based on data from a German plant and extrapolated to the European situation.

- Fire fighting foams

PFOS based substances are no longer used in the manufacture of fire fighting foams. The RPA report notes that 95% of the substitute foams that are currently available in the UK are based on perfluorocarboxylates and telomer sulphonates with unknown long-term effects on the environment. Further toxicity data has also to be generated on the fluorine-free alternative foams.

Given these uncertainties, the immediate destruction and replacement of PFOS based foams is not recommended in the RPA report. Instead, a five year delay in destruction of the remaining foams is suggested to allow for provision of better data on the impact of the substitutes. The ongoing use of remaining stocks should be subject to a number of conditions, such as that they are not used at incidents where firewater containment is not possible.

RPA proposes marketing and use restrictions through national regulations in accordance with EU Directive 76/769/EEC.

The SCHER notes, that releases into the environment were estimated to be 570 kg PFOS-acid/year (based on a use rate of 15%/year and a PFOS-concentration of 1% in the foams). This is probably overstating the actual releases, because a use rate of only 0.5% for PFOS-based foams is reported elsewhere (UK Environment Agency, 2004: Risk Evaluation Report, p. 21).

- Photographic industry

PFOS itself is not used in the photographic industry. The use of PFOS related substances in the photographic industry has been reduced by more than 80% through replacement by telomer products. It is noted, that telomers are currently under review in various countries. If restrictions will be placed on telomers, it may become more difficult to further reduce or eliminate PFOS in this sector. Furthermore, for a few applications no alternatives are currently available, including electrostatic charge control, which may affect workers safety. Current releases into the environment were estimated to be about 6.75 kg PFOS-related substances/year from film development, and 1.02 kg PFOS-acid/year into waste water and 0.051 kg PFOS-acid/year into air from the manufacturing of films.

RPA proposes marketing and use restrictions through national regulations in accordance with EU Directive 76/769/EEC with a conditional derogation period of 5 years for the critical photographic applications where no replacement is currently available. Conditions for permitted use should include that PFOS related substances are only used in closed systems, and high temperature incineration of all PFOS containing waste. Any prolongation of the 5-year-derogation period would need detailed justification (e.g. providing evidence of research progress). Efforts to secure an industry voluntary agreement aimed at ensuring effective emissions control and high temperature incineration of wastes containing PFOS related substances are also suggested by RPA.

- Semiconductor industry

Substitutes (of unknown identity) are available only for developer applications. There are currently no alternatives available for anti-reflective coatings. For photoresists alternative processes are in the early stages of development.

RPA proposes marketing and use restrictions through national regulations in accordance with EU Directive 76/769/EEC with a conditional derogation period of 5 years for the critical applications where no replacement is currently available. Conditions for permitted use should include that PFOS related substances are only used in closed systems, and high temperature incineration of all PFOS containing waste. Any prolongation of the 5-yr-derogation period would need detailed justification (e.g. providing evidence of research progress). Efforts to secure an industry voluntary agreement aimed at ensuring effective emissions control and high temperature incineration of wastes containing PFOS related substances are also suggested by RPA.

The SCHER notes that waste incineration with high destruction and removal efficiency was not taken into account when estimating current releases. If complete elimination of the use in developers is assumed (as indicated by industry), about 43 kg PFOS-related substance/year are estimated to be released into the environment (use in developers: 195 kg/year; incineration of 83% of the remaining 241 kg/year with 99.99% destruction and removal efficiency).

- Aviation industry

According to the RPA report, there are no current alternatives to the PFOS related substances in hydraulic fluids for aircraft systems. In recognition of the long time frames involved in replacing this use this application should be derogated from marketing and use restrictions with no set deadline for phase-out but with continuing review. PFOS related substances should be subject to conditions of permitted use, involving provisions for the collection and disposal of aviation hydraulic fluids via high temperature incineration. Efforts to secure an industry voluntary agreement are suggested.

Releases into waste water were estimated to be 3.94 kg PFOS-acid/year, and to soil 9.2 kg PFOS-acid/year.

3.2.2. Former uses

The risk reduction strategy proposes marketing and use restrictions through national regulations and EU Directive 76/769/EEC for all former uses in order to prevent the re-introduction and re-use of PFOS related substances in these applications. The SCHER supports this recommendation, but notes that high uncertainty exists on the actual versus “historical” uses. Certain EU member countries have indeed confirmed that single applications that were classified “historical” in the UK are still on-going in their country.

In conclusion, in order to answer to Question 1, it is opinion of the SCHER that:

- the RPA report suffers from a lack of scientific detail to substantiate the recommendations, and the information presented does not appear to be a sufficient basis for decision-making. The RPA report is based on the UK Risk Evaluation Report, which used the methodology of the TGD (2003). The SCHER is of the opinion that considering the particular properties of PFOS and related substances, this approach is not suitable for a science-based risk characterisation and consequently the PEC calculations cannot be supported by the SCHER, nor can the SCHER support the conclusions for the present and possible future uses of PFOS (and related substance). Concentrations in some aquatic and terrestrial organisms in several areas indicate a potential concern for secondary poisoning even at regional level.

- the SCHER has reservations also with regard to RPA's conclusion on the risks to human health. The data as presented in the RPA report is not sufficient to adequately judge the risk of PFOS and PFOS related substances to human health.

3.3. Question 2

The SCHER was asked "to evaluate the contribution of the ongoing uses to the overall risks for the environment and to human health"

a. *Does the SCHER think it likely that all PFOS derivatives would fulfil the criteria for classification as PBT and whether they would qualify for the classification under POP criteria*

b. *How rapidly and to what level does the SCHER think that the concentrations of PFOS found in the environment will reduce as a consequence of the recent phase out of numerous uses of PFOS?*

c. *Does the SCHER expect that the concentrations of PFOS in the environment will reduce to the extent that they will reach a level at which there is no risk?*

d. *Does the SCHER think that the current emissions into the environment from ongoing uses have a significant influence on the rate of reduction of the concentrations of PFOS found in the environment?*

Given that risks are not properly characterized (Question1) the SCHER cannot address this question relating to the contribution to risk. The following therefore relates only to the contribution to exposure reduction.

In order to respond to these questions, the SCHER compared exposures from former and ongoing uses:

Environmental and human exposure assessment before phase out of major applications, including the contribution of other sources like formation of PFOS from degradation of PFOS related compounds

Before their phase out PFOS and PFOS-related substances were mainly used in the textile and leather industry, in household cleaning products, in pesticides and insecticides, in paper, packaging, and coatings. According to the RPA report, in the UK alone more than 100 tonnes of PFOS were used in these applications in 2000 (>25 tonnes for paper and packaging protecting, >25 tonnes for carpet protection, >10 tonnes for coatings (additives), >10 tonnes for apparel and leather protection, >10 tonnes for fabric and upholstery protection, and >1 tonne for fire fighting foams. Additives for household products, chemical intermediates, electroplating/etching bath surfactants and others accounted for less than 1 tonne each). For Europe, the ECB noted 10 PFOS-related raw chemicals in trade (imported and/or manufactured) since 1996 or 2000, each in volumes less than 1000 tonne/year (OECD, 2004). According to the 3M Company, U.S. production and import of these chemicals in 2000 was estimated at 2,950 metric tons (OECD, 2004). The global consumption in 2000 was estimated based on data from the 3M Company to be ≈ 4,500 metric tons (OECD, 2002).

The OECD survey (2004) also gives the following estimates for the use in the EU, largely describing the situation before the PFOS products were removed from the market:

Table 1: EU uses of PFOS related substances in 2000 (OECD, 2004)

Use	**Substance Type**	**EU quantity (tonnes/year)**	**Note**
Chromium plating	acid	10	Estimate from Germany
Photolithography	substance	0.47	ESIA/SEMI estimate
Photography	acid	0.85	EPCI estimate
	polymer	0.75	EPCI estimate, use of film
Aviation	acid	0.73	One third of world use estimate
Fire fighting foams	acid	0.57	From UK estimate of foam use
Fabric treatment	polymer	240	From UK estimate of 48 tons, assuming UK is 20% of EU
Paper treatment	substance	160	From UK estimate of 32 tons, assuming UK is 20% of EU
Coatings	substance	90	From UK estimate of 18 tons, assuming UK is 20% of EU
Total		**≈ 500 tonnes/year**	

For major former uses emission estimates have been made by RPA on basis of EU emission scenarios and information from industry (relating to the year 2000). These are summarised in the following:

Table 2: EU emissions estimates for the year 2000

	Compartment	EU emissions per year
PFOS-related substances		
Fabrics treatment	Waste water	30 kg
Fabrics service life	Water	1,018 kg
	Soil	599 kg
Paper treatment	Waste water	7,200 kg
Coating	Waste water	405 kg
PFOS-polymers		
Fabrics treatment	Waste water	3,024 kg
Fabrics service life	Water	101,800 kg
	Soil	59,900 kg
Total		**174 tonnes / year**

PFOS was found in surface water and sediment, downstream of production sites, waste water treatment plant effluents, sewage sludge, landfill leachate, and in wildlife species all over the world, including very remote areas in the Arctic. At present, it is unclear which exposure pathways are responsible for the small quantities of PFOS (and several other perfluorinated compounds) now found in the serum of the general population around the world. Surveys of American adults, children, and elderly subjects showed geometric mean serum concentrations in the range of 30-40 ng/ml with no correlation with age, and liver concentrations of PFOS from < 4.5 to 57 ng/g in human organ donors from the general population (Olsen, 2003a). In other studies (e.g. Kärrman et al., 2004; Kannan et al., 2004) serum concentrations of <1 to 82 ng/ml were found, with values greater than 30 ng/ml in samples from the United States and Poland, the highest of the countries surveyed. PFOS concentrations in samples from Japan, Korea, Malaysia, Belgium, and Brazil averaged between 10 and 25 ng/ml, and samples from Italy and Colombia were between 4 and 10 ng/ml. The lowest concentration was found in samples from India (on average less than 3 ng/ml).

Mean serum PFOS levels of 1-2 ppm (range 0.1 – 13 µg/ml) were reported in 3M fluorochemical production workers in 1999; later, geometric means in random sample of

126 3M chemical plant employees were reported as 0.941 µg/ml (95% confidence interval: 0.787-1.126; Olsen et al.,1999; 2003b).

Evaluation of present and possible future exposure (after phasing out of previous uses)

3M´s voluntary phase-out of PFOS production has led to a significant reduction in the use of PFOS and PFOS-related substances in the EU, as PFOS has been substituted by other perfluoroalkylates or other chemicals in most of the former major uses. PFOS and PFOS-related chemicals are however still manufactured by a few countries, including Germany (20 – 60 tonnes in 2003), Italy (< 22 tonnes in 2003) and Japan (< 1000 tonnes), mostly for industrial uses. The total volume is not known (OECD, 2004).

Products containing PFOS and related chemicals are also still imported and/or manufactured in the EU. The total volume of PFOS and related chemicals reported in these products is imprecise but is likely to be at least 30 tonnes/year worldwide (OECD, 2004). As PFOS and PFOS-related chemicals may not always be listed on MSDS for products/mixtures, importers may not be aware of the presence of PFOS and related chemicals within products/mixtures and so these products/mixtures may not have been always be reported.

There is no precise quantitative assessment of the emissions from on-going uses into the different environmental departments available; nevertheless the following emissions can be estimated:

Table 3: Emission estimates for on-going uses (2004)

	Compartment	Emissions
PFOS		
Metal plating	Waste water	9,000 kg[1]
Fire-fighting foams	Surface water	257 kg[2]
	Soil	257 kg[2]
Photographic industry	Air	0.051 kg
	Waste water	1.02 kg
Aviation	Waste water	3.94 kg
	Soil	9.2 kg
PFOS related substances		
Photographic industry	Waste water	6.75 kg
Semiconductor industry	Waste water	43 kg [3]
Total		9578 kg (without metal plating: 576

	Compartment	Emissions
		kg)

[1] This figure assumes that all used material is released into the environment; according to industry calculations the emissions are only 517 kg, based on German data extrapolated for Europe

[2] Based on a use rate of 15%/year and a PFOS-concentration of 1% in the foams; with a more realistic use rate of 0.05%/year, only 17 kg instead of 514 kg would be released from fire-fighting foams

[3] Based on new information from industry; the figure given in the RPA report is 226 kg

Emissions from ongoing uses in the photographic, semiconductor and aviation industry amount to 64 kg, i.e. less than 0.3% of the emissions caused by the former uses. A possibly relevant environmental exposure is to be expected by the on-going use in metal plating, potentially accounting for >5% of the previous major uses, if re-cycling of the material is not taken into account (industry calculations indicate a total of only 517 kg for the EU). If allowed to re-occur, emissions from the previous uses would be orders of magnitude higher than the emissions from on-going uses. The RPA report, therefore, rightly points to the fact that any risk reduction measures that are implemented in relation to known current uses should be accompanied by measures to prevent re-occurrence of previous uses, should alternative sources of PFOS become available again.

According to the recent OECD survey, PFOS chemicals are now present in products in concentrations ranging between 0.001% and 50%. For uses in electronic etching or metal plating, PFOS or related chemicals were noted as present at 5% to 25% (OECD, 2004). A typical use concentration in hydraulic fluids for the aviation industry is 0.05%.

Only in recent years the analytical techniques have become sufficiently sophisticated to detect and to reliably determine PFOS concentrations in environmental samples and biological materials. Some efforts have been undertaken to re-construct the PFOS concentrations in environmental and tissue samples over the course of time from archived samples.

a. *Does the SCHER think it likely that all PFOS derivatives would fulfil the criteria for classification as PBT and whether they would qualify for the classification under POP criteria*

As previously expressed by the CSTEE, there are several scientific concerns with regard to the criteria applied for the classification of substances as PBT. The SCHER considers that the criteria are particularly problematic for substances with properties such as PFOS, particularly related to bioaccumulation and toxicity. The bioaccumulation potential of PFOS should not be based on the BCF but on scientifically sound information on the toxicokinetics of this chemical. Considering the oral assimilation in fish and mammals and the low elimination rate, the SCHER concludes that PFOS has similar environmental concerns for bioaccumulation than those associated to vB substances. The toxicity associated to the oral exposure route is confirmed as well as a high persistency. Therefore a scientifically based assessment of Persistence-Bioaccumulation and Toxicity should indicate that PFOS fulfils the criteria for vP, vB and T.

To be considered as a POP under the Stockholm Convention a substance has to be persistent, bioaccumulative, have a potential for long range environmental transport and have the potential to give adverse effects. PFOS fulfils the criteria for all these properties given in Annex D of the Convention.

b. How rapidly and to what level does the SCHER think that the concentrations of PFOS found in the environment will reduce as a consequence of the recent phase out of numerous uses of PFOS?

At present, there is insufficient data available to respond to this question. On-going and future monitoring of PFOS-concentrations in the environment, biota and humans will be necessary to elucidate the kinetics of distribution, accumulation, and elimination.

PFOS concentration may initially increase even if all productions ceases due to degradation of precursors already in the environment.

c. Does the SCHER expect that the concentrations of PFOS in the environment will reduce to the extent that they will reach a level at which there is no risk?

If re-occurrence of former major uses is not allowed, the concentrations of PFOS in the environment may eventually diminish.

d. Does the SCHER think that the current emissions into the environment from ongoing uses have a significant influence on the rate of reduction of the concentrations of PFOS found in the environment?

Current emissions from ongoing uses will most likely influence the rate of reduction of the PFOS concentrations in the environment only on a local level, and will insignificantly affect the overall concentration found in the environment. Local contributions from metal platters, airports, and from the use of PFOS-containing fire fighting foam may still be significant.

In conclusion, in order to answer to Question 2, it is opinion of the SCHER that:

- The contribution of the confirmed on-going industrial/professional uses to the overall risks for the environment and for the general public are probably negligible with regard to the sectors photographic industry, semiconductor industry, and aviation industry. Emissions from the plating industry must however be restricted. With regard to human health, occupational exposure analyses should be performed, and a scientific risk assessment be performed. Regarding environmental risks, a long-term assessment of the risk associated to secondary poisoning considering the specificities of these chemicals and covering historical and on-going uses is required.

4. CONCLUSIONS

Because PFOS and PFOS related substances pose potential risk to human health and the environment, the SCHER agrees that risk reduction measures might be necessary. These measures should be substantiated by scientific risk assessment, taking into account the exceptional physico-chemical and toxicological properties of PFOS and PFOS-related substances, and the considerable reduction in production volume after the phase-out of PFOS by the major producer the SCHER agrees that the re-occurrence of former uses (e.g. textile industry) must not be allowed, and that significant new uses must not be introduced in the future. The SCHER also agrees with the proposed restrictions for the plating industry, if there are no other measures available that could be applied to reduce emissions during metal plating to a significantly lower level. On-going critical uses in the aviation industry, the semiconductor industry, and the photographic industry do, however, not appear to pose a relevant risk to the environment or human health, if releases into the environment and workplace exposure are minimised. With regard to fire-fighting foams, the SCHER agrees that health and environmental risks of the proposed substitutes must be assessed before a final decision is taken.

5. LIST OF ABBREVIATIONS

BAF	Bio-accumulation factor
BCF	Bio-concentration factor
ECB	European Chemical Bureau
EUSES	European Union System for the Evaluation of Substances
LOAEL	Lowest Observed Adverse Effect Level
MSDS	Material Safety Data Sheets
NOAEL	No Observed Adverse Effect Level
OECD	Organization for Economic Cooperation and Development
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted Environmental Concentration
PFOS	Perfluorooctane sulfonate
POP	Persistent Organic Pollutant
RER	Risk Evaluation Report
RPA	Risk & Policy Analysts Limited
SMR	Standardized Mortality Rate
TGD	Technical Guidance Document

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