Proposal for Regulations on PFOS-Related Substances

Partial Regulatory Impact Assessment

prepared for
Department for Environment,
Food and Rural Affairs

Chemicals and GM Policy Division

RPA

in association with

BRE Environment

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prepared for

Department for Environment, Food and Rural Affairs (Defra)

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TABLE OF CONTENTS

Page

1. TITLE OF PROPOSAL 1

2. PURPOSE AND INTENDED EFFECT OF MEASURE 1
2.1 The Issues and Objectives 1
2.2 The Background 3
2.3 Risk Assessment 6

3. OPTIONS 11
3.1 Option 1: Do Nothing 11
3.2 Option 2: Self Regulation/Co-regulation of PFOS Uses and Emissions 11
3.3 Option 3: Extend Scope of Existing Exposure and Emissions Controls 13
3.4 Option 4: Cessation of Emissive Uses 14

4. BENEFITS 19
4.1 Option 4b 20

5. COSTS 22
5.1 Compliance Costs 22
5.2 Costs for a Typical Business 25

6. CONSULTATION WITH SMALL BUSINESS – THE SMALL FIRMS IMPACT TEST 26

7. SIMPLE COMPETITION ASSESSMENT 27
7.1 Overview 27
7.2 Chromium Plating Industry 27
7.3 Semiconductor Industry 28
7.4 Photographic Industry 28
7.5 Remaining Industries 29

8. ENFORCEMENT AND SANCTIONS 29
8.1 Enforcement of Emissions and Emissions Controls for Derogated Uses 29
8.2 Enforcement of Action in Respect of Fire Authorities 29

9. MONITORING AND REVIEW 29

10. CONSULTATION 30

11. SUMMARY AND RECOMMENDATION 30

ANNEX 1: LIST OF CONSULTEES 32

1. Title of Proposal

National Action to Phase-Out the use of Perfluorooctane Sulphonate (PFOS) and PFOS-related Substances

2. Purpose and Intended Effect of Measure

2.1 The Issue and Objectives

The Regulatory Context

Regulation of chemical substances that were placed on the European Union (EU) market prior to 1981 is under the Existing Substances Regulation (ESR – Council Regulation (EEC) 793/93) on the evaluation and control of existing substances. Although some 140 substances have been prioritised for comprehensive risk assessment under ESR, no new substances have been added to the priority lists recently. This is in part due to the slow progress that has been made in addressing the 140 plus priority substances, but also in response to the future introduction of a new chemicals policy (referred to as REACH) at the EU level.

Although substances are not being added to the ESR priority lists, Member State Competent Authorities are able to bring forward their own proposals for the risk management of chemicals deemed to be of concern. These proposals can be introduced at the national level through the Technical Standards Directive (98/48/EC), or can be adopted at the EU level should there be support for such measures by other Member States.

The Risk Management Issue

Perfluorooctane sulphonate (hereafter referred to as PFOS) is a fully fluorinated anion, the related compounds of which, are members of the large family of perfluoroalkyl sulphonate substances (PFAS). The majority of PFOS-related substances[1] are polymers of high molecular weights in which PFOS is only a fraction of the polymer and final product (OECD, 2002).

On 16 May 2000, 3M (the major global producer of PFOS based in the United States) announced that the company would phase-out the use of PFOS voluntarily from 2001 onwards[2]. At a meeting of the Task Force on Existing Chemicals a few days after this announcement (29-30 May 2000), several OECD countries agreed to informally work together to collect information on the effects of PFOS to the environment and to human

[1] The term 'PFOS related substances' is used in this document to represent any substance that can be degraded to PFOS in the environment. A draft list of 96 substances which could degrade to PFOS has been compiled through literature review and consultation and is provided in the PFOS Risk Reduction Strategy – Final Report prepared for Defra by RPA & BRE (2004a).

[2] According to the OECD Hazard Assessment and consultation, the production of PFOS by 3M has now ceased.

health to produce a hazard assessment. The United Kingdom and the United States assumed the lead in the collection of information from both OECD countries and non-member countries through the Intergovernmental Forum on Chemical Safety (IFCS).

At the 31st Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (7-10 November 2000), it was agreed that, since this was a matter of sufficient interest to all Member countries, it should be carried out under the OECD's Existing Chemicals Programme[3] and overseen by the Task Force. The final draft of the OECD Hazard Assessment was endorsed at the 34th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (5-8 November 2002).

With regard to human health, the OECD Hazard Assessment concluded that:

- PFOS is persistent, bioaccumulative and toxic in mammals;
- PFOS has been detected in the serum of occupational and general populations;
- there is a statistically significant association between PFOS exposure and bladder cancer; and
- there appears to be an increased risk of episodes for neoplasms of the male reproductive system, the overall category of cancers and benign growths, and neoplasms of the gastrointestinal tract.

With regard to environmental effects, the OECD Hazard Assessment indicates that:

- PFOS is persistent and bioaccumulative;
- PFOS is highly toxic (acute) to honey bees and bioconcentrates in fish; and
- it has been detected in tissues of wild birds and fish, in surface water and sediment, in wastewater treatment plant effluent, sewage sludge and in landfill leachate.

In 2003, the Environment Agency for England and Wales, which is the Competent Authority for risk assessment work under ESR, commissioned a study to review the environmental risks arising from uses of PFOS-related substances. The UK Review of Environmental Risks (RER – RPA & BRE, 2004b) of PFOS-related substances concluded that PFOS meets the criteria for classification as a Persistent, Bioaccumulative and Toxic (PBT) substance. In addition, environmental risks were identified for all uses of PFOS-related substances.

The Department for Environment, Food and Rural Affairs (Defra) contracted RPA to prepare a Risk Reduction Strategy (RRS) for PFOS, including an analysis of the advantages and drawbacks of potential risk reduction options. Preparation of the Risk Reduction Strategy (finalised in May 2004) followed the provisions set out under ESR according to which, where controls on the marketing and use of the substances in question are proposed, an analysis of the advantages and drawbacks of the substance should be undertaken. It should be noted that the environmental Risk Reduction Strategy is in accordance with not only the provisions of the existing EU ESR, but also conforms

[3] It should be noted that PFOS related substances are not high production volume (HPV) substances and as such cannot be dealt with under the OECD HPV programme.

with the current European Commission proposals for REACH. Risks to humans in the workplace have not been calculated.

Under REACH[4], if a Member State (and/or the Commission) considers that the manufacture, placing on the market, or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it can initiate the Restrictions Process. Proposals for restrictions can be prepared by either Member States or the Commission in the form of a structured dossier (in this case, the Risk Reduction Strategy report); the dossier is required to demonstrate that there is a risk to human health or the environment (see also the Draft Environmental Risks Evaluation Report (RER), RPA & BRE, 2004) that needs to be addressed at Community level and to explore the options for managing that risk. The proposals for restrictions may consist of conditions for the manufacture, use(s) and/or placing on the market of a substance or of the prohibition of these activities if necessary. The restrictions provisions are intended to ensure that action is taken where required as rapidly as possible, to provide a sound scientific basis for any restriction and to enable all interested parties to participate in the procedure.

The Proposed UK Action

The objective of the proposed Action is to achieve a reduction/elimination of the environmental risks associated with the use of PFOS-related substances. The Action draws on the findings of the Risk Reduction Strategy and additional consultation within Government Departments. The Action would apply to those uses and activities giving rise to the emissions of concern within the UK.

It is proposed that risk reduction is achieved through an immediate cessation of the use of PFOS and PFOS-related substances in all activities (historical and current) at and above 0.1% by mass where suitable substitutes and/or alternative processes are already available, with a number of time limited derogations for the development of acceptable substitutes in fire fighting foams; critical applications in photography, semiconductors and photolithography; and with a transition phase for use in chrome plating applications.

2.2 The Background

2.2.1 Uses

Known Historical Applications

3M was the major global producer of PFOS and its voluntary withdrawal from the manufacture of PFOS from 2001 onwards has resulted in a phase-out of the use of PFOS-

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4 Under the proposed REACH regulations (COM(2003) 644 final), a Member State is allowed to bring forth proposals for the reduction of risks to human health or the environment from chemicals that are not adequately controlled, as long as the proposals follow the EU guidance set out in the TGD, which would make the proposals to be easily adapted at the Community level.

related substances in consumer applications within the UK[5] (although some on-going use may take place across these sectors in the EU). These (now historical) consumer uses include applications in:

- carpets;
- leather/apparel;
- textiles/upholstery;
- paper and packaging;
- coatings and coating additives;
- industrial and household cleaning products; and
- pesticides and insecticides.

It is very important to note that, while there is no evidence of current demand in the UK for these historical uses of PFOS- related substances, this phase out has been driven largely by the relative unavailability of PFOS since the 3M withdrawal. In other words, the cessation in use has been driven by a lack of supply rather than technological innovation or an industry initiative. As such, there remains a potential market for the resumed use of PFOS-related substances in these sectors. As PFOS is still manufactured in the EU this potential market must be considered in any regulatory proposals.

If allowed to resume, these types of consumer applications would act as diffuse sources of PFOS-related emissions and are therefore a particular source of concern. The RER has indicated that it is likely that the emissions from these historical uses, if allowed to re-occur, would be several orders of magnitude higher than the emissions from current uses. The RER thus concludes that any risk reduction measures that are implemented in relation to known current uses should be accompanied by measures to prevent further use in any historical applications.

Current Applications

The following sectors have been identified as representing current or continuing uses of PFOS-related substances in the UK (and EU); these applications are supplied by manufacturers of PFOS-related substances in other EU countries, the US, Japan or elsewhere. The continuing uses and estimated current demand for PFOS-related substances in these sectors are described in Table 1.

Table 1: Estimated Current Demand for PFOS-Related Substances

Industry Sector	**EU Use (kg/year)**	**UK Use (kg/year)**
Photographic industry	1,000	270
Photolithography and semi-conductors	470	94*
Hydraulic fluids	730	146*
Metal plating	10,000	500 to 2,500*
* Assuming the UK represents 20% of the EU.		

5 Note that there is uncertainty as to whether use in all of these applications has ceased in the UK although the general view is that it has.

It should be noted that three of the four industry sectors listed in Table 1 are globally integrated industry sectors (i.e. their activities cannot be restricted to one country or another). As a result, it is difficult to disaggregate demand for PFOS-related substances to a country level. The figures therefore reflect demand across the UK rather than just for continuing uses within the UK. In addition, the figures quoted in Table 1 are based on the assumption that 20% of EU demand occurs in the UK, with this being based on the Draft RER (BRE & RPA, 2004b) referred to above.

In addition to the continuing uses of PFOS-related substances set out in Table 1, there remains a substantial quantity of PFOS-based fire fighting foam in serviceable condition in the UK (although PFOS is no longer used in the manufacture of aqueous film forming foams (AFFFs)). Available best estimates of the size of the total UK stock of AFFFs and PFOS-based AFFFs are provided in Table 2. This total stock equates to around 24.4 tonnes of PFOS.

Table 2: Estimates of Quantities and Use of Fire Fighting Foams in the UK

	All AFFF Concentrates (Litres)	**PFOS-based AFFF Concentrates (Litres)**
Estimated current quantities in Fire Authority (FA) Inventories	986,350	76,190
Estimated current emergency stores at Hazardous Installations as part of Industry/FA Mutual Aid agreements	2,959,040	2,367,220
Total Estimated Inventory	**3,945,390**	**2,443,420**

It is important to note that the figure of 24.4 tonnes represents the total amount of PFOS that could enter the environment from use of these foams in the future. In contrast, the figures given in Table 1 represent the amount of PFOS consumed per annum by the other four industry sectors, and thus may enter the environment on a per annum basis.

2.2.2 Existing Regulations

There is currently no legislation on the use of PFOS-related substances in the UK (or EU) that is directly relevant to their (potential) environmental and/or human health effects. None of the 96 PFOS-related compounds identified when preparing the Risk Reduction Strategy for PFOS (RPA & BRE, 2004) are included in Annex I of the Dangerous Substances Directive 67/548/EEC (Danish EPA, 2001-2).

Although there are no specific requirements in relation to the use of PFOS related substances in the workplace, such uses are covered by the Control of Substances Hazardous to Health 2002 (COSHH).

The Integrated Pollution Prevention and Control (IPPC) Directive 96/61/EC includes fluorine and its compounds in the indicative list of the main polluting substances to be taken into account if they are relevant for fixing emission limit values (Annex III to the Directive). However, no specific emission limits currently exist for PFOS-related substances. Furthermore, IPPC would only cover two sectors of use (photographic and semiconductor applications). The chromium plating industry will also soon be covered by IPPC, but under the terms of the Directive only around 20% of chromium platers will be covered by IPPC. Use of fire fighting foams would also not be covered by IPPC.

In conclusion, the current legislative framework does not provide the necessary coverage or emissions controls to regulate the use of PFOS-related substances and associated environmental risks. The substances and their uses can be regarded, therefore, as being largely unregulated.

2.3 Risk Assessment

2.3.1 Overview

The conclusions of the OECD Hazard Assessment[6] (2002) were reported in Section 2.1 above, with these being the reason for the UK undertaking further work on PFOS. Also noted in Section 2.1, a Draft UK Review of Environmental Risks of PFOS (RPA & BRE, 2004) has been prepared, under the auspices of the Environment Agency for England and Wales. The findings of this further work are reported below, as they indicate the risks arising from a failure to take action with regard to the continued use of PFOS-related substances.

2.3.2 Summary of UK Environmental PBT Assessment

The assessment carried out as part of the Draft Review of Environmental Risks (RER) included determining whether PFOS met the EU criteria for persistence, bioaccumulation and toxicity (PBT). The EU criteria were adopted as the basis for this assessment to ensure that the conclusions would be consistent with the approach to risk assessment under ESR. However, the EU criteria are also similar to the criteria adopted by the UK Chemical Stakeholder Forum, for identifying PBT substances. The conclusions of this assessment are as follows.

- PFOS meets the EU Persistent (P) and very Persistent (vP) criteria. It is of note that no degradation of PFOS has been observed in any study;

- Bioconcentration Factor (BCF) values up to 2800 have been measured in laboratory studies, and this meets the EU (B) or 'Bioaccumulative' criterion. The occurrence in a range of biota supports this; PFOS has been found in a wide range of higher organisms in Europe, including seals, dolphins, whales, cormorants, eagles, swordfish, tuna and salmon. The Global Biophase Monitoring Programme found PFOS in livers, blood and other tissues of animals, especially in fish-eating animals; and

- Various toxicity studies have been conducted to determine the toxicity of PFOS-related substances. The severity of the effects seen at doses around 5.0 mg/kg/day in 90-day toxicity studies warrant classification as 'Toxic' and PFOS should carry the

[6] It should be noted that the OECD Hazard Assessment identifies the need for further information to be gathered on a national and regional scale for a more accurate risk characterisation.

Risk Phrase R48 (danger of serious damage to health by prolonged exposure)[7]. PFOS therefore meets the (T) or 'Toxicity' criterion for PBT classification.

When a substance is classified as a PBT, the Environment Agency (in accordance with its Chemical Strategy) has an obligation to act, and the complete cessation of emissions or zero emissions is the broad target or aim. Where complete cessation of emissions is not feasible, a cessation of use constitutes the main target of any risk reduction strategy. It should be noted that Defra shares this same position with the Environment Agency; chemicals which exhibit PBT characteristics should be phased out. This position has been established as part of Defra's work programme for the Chemical Stakeholder Forum and it is also an agreed Government position in bringing forward the new EU chemicals regulations (REACH).

A draft dossier has been prepared which may be used to nominate PFOS for inclusion in the Stockholm Convention and the UNECE-LRTAP[8] Protocol. The draft dossier (KemI, 2004) indicates that PFOS fulfils the UNECE criteria for PBT and L (long range transport).

2.3.3 Environmental Emissions

The Draft RER also predicted the environmental risks associated with emissions from the current and historic uses of PFOS-related substances. These predictions followed the processes applied under ESR and used the relevant risk assessment model. The findings of this work are presented in Table 3, overleaf, with a tick indicating an unacceptable risk to the environment (according to the EU models).

As can be seen from the Table, risks are predicted at both the local and regional/continental level, with secondary poisoning risks (i.e. risks to the various food chains) arising for all current uses.

The calculated background concentrations are sufficiently high to indicate a risk for secondary poisoning without the local contributions from the specific use patterns. However, the local releases also make a significant contribution in most cases. Calculations performed for each use area (i.e. without the contributions from the other uses) give results substantially the same as those above, the main exception being photography (developing) for which no risks are identified.

With regard to historic uses, emission estimates show that releases from continuing uses in textile are significantly higher than those from the existing fire fighting foams. Given the likely relative magnitude of emissions from such historical uses, any risk reduction measures that are implemented in relation to known current uses should be accompanied by measures to prevent further use in historical use sectors.

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7 PFOS may also have classification for carcinogenicity and reproductive toxicity (development), but the data require more expert review.

8 UNECE-LRTAP: United Nations Economic Commission for Europe - Long-range Trans-boundary Air Pollution Convention.

Table 3: Summary of Risks from Various Use Sectors of PFOS						
Industry Sector			**Risk of Secondary Poisoning**			
	Local Risk to the Terrestrial Compartment	**Local Risk to the Aquatic Compartment**	**Risk to Freshwater Food Chain**	**Risk to Marine Predator (feeding on fish)**	**Risk to Marine Top Predator**	**Risk to Terrestrial Food Chain**
Chromium Plating			✓	✓	✓	
Fire Fighting Foams (formulation)	✓	✓	✓	✓	✓	✓
Fire Fighting Foams Use (no containment of the foam and water)[1]	✓	✓	✓	✓	✓	✓
Photography (formulation)[2]			✓	✓	✓	✓
Photography (developing)			✓	✓	✓	
Photolithography[3]			✓	✓	✓	✓
Aviation[4]			✓	✓	✓	✓

[1] Fire fighting foams Use (containment of foam and water and treatment in WWT plant): Risks to the aquatic compartment, terrestrial compartment and terrestrial food chain (secondary poisoning).
[2] Photography (formulation): Risk of secondary poisoning under some scenarios.
[3] Photolithography: Risk of secondary poisoning assumes instant breakdown of PFOS-substances to PFOS.
[4] Aviation: Risk of secondary poisoning is for one scenario.

2.3.4 Human Health Effects of Concern based on OECD Hazard Assessment

The above environmental risks are in addition to the concerns for human health, which were considered in detail in the OECD Hazard Assessment. Key findings of the OECD Hazard Assessment are as follows.

PFOS has been measured and detected in human blood samples of the general population, with mean levels of 30-53 ppb having been reported for serum available from blood banks and commercial sources. In individual serum samples obtained from adults and children in various regions of the US, the mean levels of PFOS were approximately 43 ppb.

PFOS levels in the general public have also been measured in Europe; samples of serum were taken from blood banks in Belgium, the Netherlands and Germany. Of these sample groups, the highest PFOS levels were observed in serum from the Netherlands (a mean value of 53 ppb) and the lowest in serum from Belgium (a mean value of 17 ppb) (OECD, 2002).

In a study undertaken by the World Wildlife Fund (WWF), PFOS and six other perfluorinated chemicals were found in the blood samples of forty three people from various EU Member States (including the new EU countries) (WWF, 2004).

Persistence and Bioaccumulation

PFOS has been found to be persistent and its bioaccumulative potential indicates cause for concern. According to animal studies, PFOS is well absorbed following ingestion and is distributed mainly in the serum and the liver. No further metabolism is expected.

Elimination of PFOS from the body is slow and occurs via the urine and faeces. Urinary excretion is the primary route of elimination for PFOS in the rat. The elimination half-life of PFOS varies among species. Available data are presented in Table 4 below which indicates that PFOS has a significantly higher half-life in humans than in rats or monkeys.

Table 4: Elimination Half-lives of PFOS in Mammals	
Species	**Half-life**
Adult rat	7.5 days
Cynomolgus monkey	200 days
Workers (3M plant, 9 retired workers)	Mean value: 8.67 years (range: 2.29-21.3 years)
Source: OECD (2002)	

Toxicity

There have been various studies to determine the acute toxicity of PFOS. PFOS demonstrated acute toxicity to aquatic organisms such as the fathead minnow, and aquatic invertebrates such as *Daphnia magna* and shrimp species.

PFOS has shown moderate acute toxicity by the oral route; a rat LD_{50} of 251 mg/kg and a 1-hr LC_{50} of 5.2 mg/L in rats has been reported. PFOS was also found to be mildly irritating to the eyes, but non-irritating to the skin of rabbits.

In 90-day rat studies, observed signs of toxicity include: increases in liver enzymes, hepatic vacuolisation and hepatocellular hypertrophy, gastrointestinal effects, haematological abnormalities, weight loss, convulsions, and death. These effects were reported at doses of 2 mg/kg/day and above.

Repeat dose studies have also been conducted in monkeys. Adverse signs of toxicity observed in *Rhesus* monkey studies include: anorexia, emesis, diarrhoea, hypoactivity, prostration, convulsions, atrophy of the salivary glands and the pancreas, marked decreases in serum cholesterol, and lipid depletion in the adrenals. The dose range for these effects was reported between *1.5* - 300 mg/kg/day. No monkeys survived beyond three weeks into treatment at 10 mg/kg/day or beyond seven weeks into treatment at doses as low as *4.5* mg/kg/day. In a 6-month study of *Cynomolgus* monkeys, low food consumption, excessive salivation, laboured breathing, hypoactivity, ataxia, hepatic vacuolisation and hepatocellular hypertrophy, significant reductions in serum cholesterol levels, and death were observed at *0.75* mg/kg/day. No effects were observed at doses of 0.15 or 0.03 mg/kg/day.

Carcinogenicity

PFOS has been shown to be non-genotoxic in a variety of assay systems.

The results of a study into the carcinogenicity of PFOS-related substances in rats showed that PFOS is both hepatotoxic and carcinogenic. A significant increase in cancerous growths associated with the liver, thyroid and mammary glands was observed at the highest dose of 20 ppm.

In a mortality study which spanned 37 years, there was a statistically significant association between PFOS levels in workers and bladder cancer. Workers that died of bladder cancer had been employed by the 3M plant in Decatur, Alabama, for at least 20 years and had also been involved in high exposure jobs for at least 5 years. Statistical analysis of the mortality data indicated that workers who were employed in high exposure jobs were approximately 13 times more likely to die of bladder cancer than the general population of Alabama. Given the magnitude of the risk estimate (approximately 13-fold), it was considered that these effects would not be due to chance, as many years of follow up without another death from bladder cancer would have to occur before there would no longer be an appreciable risk.

It is unclear, considering the paucity of data, whether fluorochemicals are responsible for the excess of bladder cancer deaths or whether other carcinogens may be present in the plant. At a facility where fluorochemicals were manufactured, five bladder cancer deaths were reported, with four of these deaths occurring in employees who did not work primarily in the chemicals division. The study, however, reports that these employees worked mostly in maintenance jobs or at the incinerator and wastewater treatment plant and could have been exposed to many chemicals in addition to fluorochemicals. The OECD Hazard Assessment indicates the need for further work on this issue in order to gain a better understanding of the mortality experience of workers exposed to fluorochemicals.

In order to screen for morbidity outcomes, an ‘episode of care’ analysis was undertaken for employees who had worked at the plant between 1993 and 1998. Increased incidences of other conditions such as cancers and non-malignant growths (that have been investigated through the years) were not found to be of significance and no mortality risks were reported for most of the cancer types. However, an increased risk of episodes for neoplasms of the male reproductive system, the overall category of cancers and benign growths and neoplasms of the gastrointestinal tract was indicated. Risk ratios were, however, found to be highest in the employees with the highest and longest exposures to fluorochemicals (OECD, 2002).

In conclusion, cancer of the bladder is considered a potentially significant but yet uncertain end-point in the analysis of risks from PFOS-related substances.

3. OPTIONS

The options presented draw on those identified as being the most feasible by the work undertaken for Defra to develop a risk reduction strategy for PFOS-related substances (RPA & BRE, 2004a). As a starting point, this work considered 22 possible different types of risk reduction, covering measures applicable to industrial/professional uses, domestic and consumer uses and waste management. All of these possible measures were assessed with regard to their ease of implementation, coverage and effectiveness. The most applicable measures were then further assessed against four criteria[9]: effectiveness, practicality, economic impact and monitorability. A Steering Group was established to oversee the progress of the risk reduction strategy, with this including representatives of Government, industry and a non-governmental organisation. Members of the Steering Group were able to comment on the strategy as it was developed, including on the applicability of specific measures. Formal comments were sought at four different points during development of the strategy, as it became more detailed and refined in scope.

It should be noted that, although these options are based on the research carried out for the Risk Reduction Strategy, they reflect on-going consultation activities and discussions carried out for and by Defra. They, therefore, represent Defra's proposals rather than those of RPA.

3.1 Option 1: Do Nothing

Under this option, no action would be taken to further regulate uses and emissions of PFOS-related substances. As such, PFOS would remain unregulated and the identified risks would not be addressed. This would result in the build up of a PBT chemical in the environment, increasing risks to the aquatic environment and throughout the various food chains of concern. It would also contravene Government policy in relation to the phase-out of such chemicals owing to their long term potential to cause harm to man and the environment.

As a result, the 'do nothing' option is not an appropriate response and is not considered further in this RIA.

3.2 Option 2: Self-regulation/Co-regulation of PFOS Uses and Emissions

The voluntary phase-out of PFOS by 3M has already had a significant effect on the use of PFOS-related substances in the UK, reducing it across all of the identified consumer applications (referred to above as historic uses as they no longer take place). While this suggests that self-regulation may have a role to play in reducing the risks posed by PFOS- related substances, it is very important to note that for these historical uses of PFOS- related substances cessation of use in the UK has been driven largely by the unavailability of PFOS. In other words, demand for the PFOS-related substances could not be met by the relatively small volumes produced by manufacturers other than 3M.

9 These are the criteria specified in the Technical Guidance Document on the Development of Risk Reduction Strategies under the Existing Substances Regulation.

Thus, cessation in use was driven by a lack of supply rather than technological innovation or an industry initiative. As such, there remains a potential market for the use of PFOS-related substances in these sectors.

To date, there are no voluntary agreements in place at present for any of the sectors that are relevant to the use of PFOS-related substances and emissions. The potential use of such agreements was examined as part of the work undertaken to develop a risk reduction strategy. In theory, sector specific agreements could be developed to secure a cessation in use, maintain a cessation in sectors where PFOS is not used at present, or agree conditions of use and associated emissions. In practice, however, the main drawbacks of this type of approach relate to ensuring that most companies within the relevant industry sector are signed up to the voluntary agreements, developing a sufficiently robust monitoring and enforcement regime, and putting in place appropriate penalties for non-compliance. This would be particularly difficult to achieve in those sectors characterised by large numbers of firms (e.g. metal plating, textiles, cleaning products, etc.) or where a significant proportion of firms are not members of trade associations which can act as the focal point for agreeing and implementing such agreements.

More specifically, for the chromium metal plating sector, a voluntary agreement is considered unlikely to succeed on the basis that there have been a number of industry and regulator (e.g. HSE) led initiatives to promote a shift to Cr (III) technology in the past that have had limited effectiveness. This is partly because they cannot readily address the issue of customers' specifications stipulating the use of Cr (VI) plating processes. It is also due to the fact that there are a large number of small platers, who are reluctant to adopt new processes.

For the more globally integrated industry sectors of aviation, photographic and semiconductors/photolithography, the willingness to participate in a voluntary agreement will depend upon the actions taken in other countries (highlighting the importance of action at the EU level). This is particularly the case for aviation hydraulic fluids, where action is required at the global level due to the nature of the aviation sector. With regard to the photographic and semiconductor sectors, both indicated during the development of the risk reduction strategy that they were willing to meet strict processing and waste disposal requirements (with these already being in place under IPPC)[10]. These actions alone, however, would not be sufficient to cease emissions of PFOS to the environment. Furthermore, no commitments were made by the sectors to reduce the future use of PFOS, other than to carry on with current research and development activities.

As a result, it has been concluded that with regard to PFOS-related substances, voluntary or co-regulatory agreements to regulate use have no advantages over regulatory approaches. They are very unlikely to deliver the necessary certainty that either the risks associated with continuing use and emissions of PFOS-related substances have been addressed or that these substances are no longer used.

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[10] It is of note that neither sector came forward with its own additional proposals for a voluntary agreement.

Self-regulation/co-regulation, therefore, is not considered further here as an option on its own. However, depending on the regulatory approaches taken and the time required to implement these, it may be useful as an interim measure. For example, there is the option of developing voluntary agreements for sectors where there are continuing uses of PFOS-related substances as an interim measure to reduce risks, where there is a delay in introducing UK and/or EU legislation to limit the risks from PFOS-related substances.

Such a voluntary agreement would be aimed at ensuring effective emissions control and incineration of wastes containing PFOS-related substances to smooth the transition and provide for swifter and more effective risk management. The voluntary agreement would also be supplemented by reinforcing the duty of care provisions under the Environmental Protection Act (1990), the Waste Management Licensing Regulations (1994), the Special Waste Regulations (1996) and the Waste Incineration Directive (2000).

It is of note though that the experience of the Chemical Stakeholder Forum is that unless regulations are expected to be introduced in the near future, companies acting within an industry are reluctant to join into a voluntary agreement in the interim period.

3.3 Option 3: Extend Scope of Existing Exposure and Emissions Controls

A third option would involve the extension of available existing legislative instruments to cover uses and emissions of PFOS; relevant legislation include the:

- IPPC Directive (96/61/EC);
- Water Framework Directive (2000/60/EC);
- Waste Incineration Directive (2000/76/EC); and
- Directive on Hazardous Waste (91/689/EEC).

The specific issues (i.e. advantages and drawbacks) associated with measures adopted under the above legislation were analysed alongside the other options as part of the development of the formal risk reduction strategy (RRS) prepared for Defra.

As a PBT giving rise to unacceptable environmental risks at the continental and local level from all current uses, establishing what constitutes an acceptable level of emissions other than zero emission is a difficult issue. However, even if it were possible, setting emission limits under IPPC may only be theoretically possible for photographic (but possibly not development of film/paper and PFOS migration as this is not a process covered under IPPC) and semiconductor applications. Emission limits could not be set for aircraft maintenance and the associated use of hydraulic fluids within IPPC. Only a limited coverage (20% of companies) in the chromium plating industry would be possible under IPPC (where this could not be instituted until 2007 when certain sectors of the chromium industry will be covered by IPPC). No controls over use of the remaining stocks of fire fighting foams or losses of PFOS from aviation hydraulic fluids would be possible under IPPC as these processes are not covered by IPPC.

For the photography and semiconductors/photolithography sectors, there is the theoretical possibility of using emissions control technology to reduce emissions. However, sophisticated emissions control is currently in place in these sectors under

IPPC. The RER, however, concludes that residual emissions (which include emissions associated with all on-going applications) result in unacceptable environmental risks. For example, for the semiconductor industry, even with the removal of some applications (i.e. developer related applications), emissions would continue within the aqueous developer waste streams from photoresists and anti-reflecting coatings and it is not clear that these emissions would be reduced. Because IPPC is focused on processes rather than on substances, the control of particular substances cannot be guaranteed under this legislation. Furthermore, because implementation of IPPC takes account of site specific factors, unless strict requirements that cannot be deviated from are set within the IPPC BREF notes, then consistent application of any proposed restrictions cannot be guaranteed across the EU.

With regard to the Water Framework Directive, PFOS is not on either the Priority Substance (PS) or Priority Hazardous Substance (PHS) list. Even if limits could be established, it would take some time before environmental quality standards (EQSs) could be included or enforced for PFOS.

In relation to wastes, it is theoretically possible to stipulate that PFOS-containing wastes must be disposed of by high temperature incineration above a certain temperature (with this applying to wastes with greater than 1% organohalon content, which would include PFOS-containing wastes). However, emissions from wastes with less than 1% PFOS content have been found to be significant from a risk perspective; for example, the concentration of PFOS-related substances in aviation hydraulic fluids is of the order of 500ppm (0.05%), but the RER has found that this represents an unacceptable environmental risk. In terms of effluents, discharge consents are generally only set for organohalogen concentrations of greater than 0.1% by mass, with this then giving rise to the same issues as for incineration, as PFOS may be present in lower concentrations. As a result, actions under the relevant waste and effluent treatment instruments extended to cover PFOS will not address risks.

An extension of existing exposure and emission based legislation alone will therefore not address the risks associated with use and emissions of PFOS-related substances. It can be concluded that either new regulation will be required to control uses and emissions effectively and/or existing legislation controlling the marketing and use of PFOS (at EU level under the Marketing and Use Directive or, at UK level through provisions under the Technical Standards Directive - TSD) would be required.

3.4 Option 4: Cessation of Emissive Uses

3.4.1 Overview

The conclusion of the RRS is that the extension of existing emissions and waste based legislation and self-regulation/co-regulation will not address the risks adequately. The alternative then is to introduce legislation to control the marketing and use of PFOS-related substances within the UK using powers under the Environmental Protection Act Section 140 and subsequently under the Technical Standards Directive; within the EU more generally, such restrictions would be introduced under the Marketing and Use Directive, supplemented if necessary by a new regulation on the incineration of PFOS-containing waste streams (c.f. the PCB Regulations).

In order to address the unacceptable environmental risks arising from the potential re-establishment of historic uses and the current continuing uses, such legislation would have to place tight and explicit controls on the use of PFOS-related substances. There are two sub-options here, which vary in terms of regulatory simplicity, benefits and their timing, and costs to industry.

3.4.2 Option 4a: Immediate Cessation of all Uses

The first option is to introduce an immediate cessation of all uses (current and historical) of PFOS-related substances. This would also require that the existing stock of PFOS-based fire fighting foams be incinerated and replaced with the (already available) alternatives. Use would also be required to cease in the chromium plating, photographic, semiconductor/photolithography, and aviation sectors.

Under this option, risks to human health and the environment from PFOS-related substances would be substituted by potential risks from the use of alternative substances[11].

There are significant issues with achieving such immediate substitution, associated both with the fact that there are no technically feasible substitutes currently available for a number of the current applications (semiconductors, photography and aviation) and that, where chemical substitutes do exist (for fire fighting foams) at present, the risks from these alternative substances cannot be predicted with any certainty.

With regard to the latter, the RRS has identified that there are significant uncertainties as to whether the substitute fire fighting foams provide a significantly better environmental option compared with PFOS-based foams. As such, purely from a risk perspective, an immediate cessation as required by Option 4a is unlikely to be an acceptable option for this application use. The RRS recommends a delay in the phase out of PFOS-based fire fighting foams until there is greater certainty concerning the safety of substitutes.

As regards other uses, as noted above, there are no substitutes that are currently available for a number of applications, namely semiconductors, photography and aviation. All of these represent economically important uses and, in the case of aviation hydraulic fluids, relate to significant aviation and public safety benefits.

[11] Chromium plating involves substitution with alternative processes rather than a substitute chemical, and substitutes for photographic, semiconductor and aviation applications have yet to be identified.

Given these facts, it can be concluded that an immediate cessation is not an appropriate action and some lead in time may be required to establish the identity and safety of substitutes. For this reason this option not considered further.

3.4.3 Option 4b: Immediate Cessation in Historical Uses and on Current Uses with Conditional Derogations for Critical Applications

Overview

Option 4b provides an integrated approach to the identification of technically feasible substitutes and the uncertainties associated with the safety of available substitutes. As such, it seeks to address the limitations and drawbacks of Option 4a by promoting an immediate cessation in all uses of PFOS-related substances and preparations where technically feasible and demonstrably safer alternative substances or processes currently exist.

Where technically feasible alternative substances or processes do not currently exist, Option 4b allows a period of five years for their identification and the reporting of any on-going efforts to identify such alternatives.

Where there are uncertainties concerning whether existing substitutes are safer, Option 4b also provides time to address these uncertainties. To harmonise the requirements across applications, the time periods for identification of substitutes and elimination/reduction of uncertainties concerning existing substitutes are the same, namely five years. This will promote the flow of information concerning substitutes and their safety.

Because there are several different process applications of PFOS-related substances in each use sector, some prioritisation of efforts to identify and introduce substitutes may be required. Owing to the complex chemistry of PFOS and PFOS-related substances and associated emissions, Option 4b seeks to achieve such prioritisation by applying a standard 0.1% by mass presence of a substance of concern in formulations and preparations. This is consistent with previous provisions under the EU Marketing and Use Directive and the new EU Chemicals Strategy (REACH).

In summary, Option 4b requires that, where PFOS-related substances are present as a substance in a preparation at concentrations of equal to or above 0.1% by mass, there will be an immediate phase-out of use in processes where demonstrably safer alternative processes/substances exist. Where demonstrably safer alternative processes/substances do not currently exist (and where above and equal to the 0.1% threshold), a delay of five years is permitted to identify substitutes and address risks and uncertainties surrounding these substitutes, after which time there will be a cessation in use in these processes.

Anticipated Action - Prohibition of Historical and Future New Uses

Under Option 4b, the use of PFOS-related substances at any concentration would be prohibited for all historical applications and possible future new uses not yet identified. As such, there would be an immediate prohibition on the use of PFOS-related substances in the following known historical applications (including outside the UK):

- carpets;
- leather/apparel;
- textiles/upholstery;
- paper and packaging;
- coatings and coating additives;
- industrial and household cleaning products;
- pesticides and insecticides;
- medical applications;
- flame retardants;
- mining and oil surfactants; and
- adhesives.

Anticipated Action - Immediate Phase-out where ≥0.1% and Suitable and Safer Alternatives Available

It is anticipated that under Option 4b, the requirements for an immediate cessation in uses where PFOS-related substances are present as a substances or in a preparation at a concentration of 0.1% and above by mass and where suitable and demonstrably safer alternatives exist will result in actions in the following applications:

- *Chromium Plating Applications*
  The restrictions on chromium plating would apply to all uses of PFOS-related substances as mist suppressants on the basis that the following alternative processes are available to substitute the use of PFOS-related substances:
  - in 'decorative' chromium plating applications, the use of PFOS-related substances can be substituted by a move from the use of Chromium (VI) to Chromium (III) processes which avoid the generation of the toxic and harmful Chromium (VI) mists that would otherwise need to be controlled;
  - for 'hard' plating applications and plating on plastics, Chromium (III) processes are not a technically feasible alternative to the use of Chromium (VI). As such, a discontinuation in the use of PFOS-related substances would require some platers to install improved ventilation, extraction and enclosure processes to control toxic Chromium (VI) mists.

  As alternatives are available a two year transitional period (from the time the regulations enter into force) is proposed for this sector to give them time to comply with the new requirements.

- *Developers used in semiconductors (where above 0.1% by critical mass)*
  Technically feasible substitutes also exist for PFOS-related substances used in developers by the semiconductor industry; as a result, this application cannot be considered a critical application of these substances (i.e. an application where substitutes do not exist) and alternatives would have to be used where the concentration of PFOS-related substances is 0.1% or above.

Anticipated Action - Delayed Phase-out where ≥0.1% and Suitable and Safer Alternatives Uncertain

In the case of Fire Fighting Foams, the relative safety of the available substitutes is uncertain and the RRS has concluded that a time delay is required to ensure that the available substitutes represent a better environmental option. The following action is anticipated:

- *PFOS-based Stocks of Fire Fighting Foams*
  Usage of the current stocks of PFOS-based foams would be granted a five year derogation, for use of these foams on Class B fires, as classified in British Standard BS EN 2 published by the British Standards Institute (December, 1992), whilst the efficacy and safety of alternatives was fully explored. A cessation of the import into the UK and the marketing in the UK of PFOS-based foams would also be required. Transferral of these foams between members of a mutual aid group would however be permitted, in the case of a fire emergency. The derogation would last for a maximum of five years, after which all remaining PFOS-based stock would be disposed of by high temperature incineration. At the end of the five year period, those who wish to retain their PFOS-based foams will be required to apply for approval from the relevant authorities at least 18 months before the end of the derogation. The applicant will be required to demonstrate that the risk from the storage and use of PFOS-based foams is adequately controlled and that there are no suitable alternative substances or technologies. It should be noted that an approval decision could be amended or withdrawn at any time when there are a change of circumstances (for instance, changes in the scientific basis for an approval decision).

  Within the five year period, individuals or companies who believe that they have an alternative chemical or technology which presents a lower risk compared to the PFOS-based foams and is as (or more) effective than the PFOS-based fire fighting foams may present a risk assessment to Defra. This risk assessment should follow the assessment requirements within the Existing Substances Regulation (EC 793/93) and accompanying TGD. In the interim, the disposal of unwanted PFOS-based stocks would also be through high temperature incineration.

Anticipated Action - Derogated Phase-out where >0.1% and No Currently Available Alternatives

For the remaining applications, a cessation of use would apply with time limited derogations for applications using PFOS-related substances at concentrations of greater than 0.1% by mass either as a substance or in a preparation. These applications would be granted an initial period of five years (subject to review). Derogations and associated conditions are as set out below for the potentially affected uses:

- *Photographic, Photolithography and Semiconductor Applications*
  These sectors would be granted a conditional time limited derogation from phase-out of five years in current critical applications only, where no alternatives are currently known to exist.

The applications to be covered by a derogation for the *photographic sector* are:

- surfactants for mixtures used in coatings applied to films, papers and printing plates;
- electrostatic charge control agents for mixtures used coatings applied to films, papers and printing plates;
- friction control and dirt repellent agents for mixtures used on coatings applied to films, papers and printing plates; and
- adhesion control agents for mixtures used in coatings.

The applications to be covered by a derogation for the *photolithography/ semiconductor* sector are:

- antireflective coatings; and
- photoresists.

The development of future applications would not be permitted. At the end of the five year period, any request for an extension to the derogation must be made to the relevant authorities at least 18 months before the end of the derogation and would be subject to a review of industry's progress in finding substitute chemicals or processes. The applicant will also be required to demonstrate that risks from the use of PFOS-related substances are adequately controlled. All PFOS-containing stocks, held for the purpose of derogated photolithography and semiconductor applications, must also be disposed of appropriately once the derogation and any subsequent approvals come to an end.

- *Aviation Hydraulic Fluids*
  The use of PFOS-related substances in aviation hydraulic fluids would be generally derogated from the Action, as these substances are used below the 0.1% level (circa 0.05%). This also reflects the highly significant public safety dimension associated with the use of these fluids and the fact that no substitutes are currently available.

4. BENEFITS

The benefits of introducing controls on the use of PFOS-related substances translate to:

- avoidance of continued emissions of a PBT substance into the environment, particularly given the indications that PFOS does not degrade in the environment (in other words it is very persistent) and may meet the UNECE-LRTAP Protocol criteria for classification as a substance subject to long range transport;
- reductions in risks to the environment, for the aquatic compartment and across all foodchain compartments (freshwater, marine and terrestrial); and
- reductions in risks to human health associated with the release of PFOS into the environment.

As a PBT, the impacts of the historical emissions of PFOS may continue for some time. The benefits of the proposed restrictions are thus associated with reducing the potential for these impacts to become more severe (and permit them to reduce over time). As such, there is no specific dose-response function on which to model the economic value of reductions in current emissions. Benefits can, therefore, only be described in relation to reductions in the unacceptable risks to human health and the environment (as determined by EU criteria) described in Section 2.

It should be noted that a proactive approach to chemicals in which the accumulation of potential pollutants in the environment is prevented, is one of the objectives of the new EU chemicals policy (REACH).

4.1 Option 4b

Resumption of Historical and Unidentified Uses

Option 4b would eliminate the possibility of further environmental and human health impacts by preventing any resumption of historic consumer uses of PFOS-related substances; this includes any uses that are currently on-going but were not identified when preparing the RRS. It would also prevent the use of PFOS-related substances in new applications, thereby ensuring that risks to the environment and human health do not arise in the future.

Chromium Plating

With regard to continuing (identified) uses, the risks associated with the use of PFOS-related substances in chromium plating would be eliminated (at the end of the two year transition period), and their re-occurrence in the future would be prevented. There would therefore be benefits in terms of reducing the impact that this PBT substance would have on the environment, specifically in relation to the freshwater and marine predator foodchains. Impacts on human health related to exposure to PFOS would be reduced, but there is the potential for exposure to and risks from Chromium VI to increase. Given that this application accounts for between 75% and 94% of the total annual PFOS emissions attributed to current uses in the UK RER, the benefits would be significant.

Photographic Sector

Within the photographic sector, the concentration of PFOS tends to vary from 5% to 77% in the PFOS-related substances of concern, which themselves are reported to be significantly diluted. The regulations are applied to the raw materials before dilution and this will have the effect of reducing the risks to the freshwater and marine foodchains associated with emissions from the estimated 270 kg per year consumption of PFOS-related substances in the UK. If the raw materials are affected, this would result in a reduction of around 0.2% in the total annual UK PFOS emissions attributed to current uses in the UK RER[12].

12 Although the photographic sector uses more PFOS-related substances, emissions to the environment are predicted to be lower than those for photolithography and semiconductor applications in the UK RER.

Photolithography and Semiconductors

PFOS-related substances are generally used in photolithography and semiconductor applications in concentrations below 0.1%[13]. For developer applications (which make up in excess of 41% by mass of total annual use of PFOS-related substances in semiconductor/ photolithography), whilst there are substitutes currently available, concentrations of PFOS-related substances in developers are reported to be around 0.01% and are thus unlikely to be affected either by the immediate phase-out (for applications where substitutes are available) or after the five year derogation unless the regulations are specifically applied to the raw materials before they are diluted for use in the process. As such, the proposed restrictions on use would have little or no direct impact on the semiconductor sector in the short or longer-term as regards substitution. If there was a complete cessation after five years, the emission reduction would represent between 2% and 7% of total emissions based on current levels of usage reported in the RER.

PFOS-based Stocks of Fire Fighting Foams

Although emissions from the use of the existing PFOS-based fire fighting foam stock will continue within the five year derogation period, this is considered essential for health and safety and environmental protection reasons on the basis that these foams are used for the most severe fire emergencies and there is uncertainty over the risks associated with the substitutes. However, ensuring that use continues only on approval after this period should help ensure that future releases from the existing stock are minimised to the benefit of the aquatic environment at both the local and continental levels.

The UK RER identifies emissions of 57 kg/year, representing between 5.3% and 18% of total PFOS emissions in the UK. In the initial five years it is expected that these emissions would be reduced slightly through more careful use of the foams. After five years, use of the remaining PFOS-based fire fighting foam stock would no longer be permitted unless given specific authorisation. Use of the foams may cease sooner should a manufacturer come forward with an alternative that is both equally efficacious and represents a lower risk. In general, it is expected that following the five year derogation, PFOS emissions from fire fighting foams would be significantly reduced (if not eliminated) and substituted by substances known to have significantly better environmental performance than PFOS-related substances.

13 The only semiconductor application reported to use concentrations that may be above the 0.1% threshold is for antireflective coatings, where the concentration of PFOS-related substances is reported as circa 0.1%, which implies that lower concentrations than the 0.1% threshold are effective.

5. COSTS

5.1 Compliance Costs

5.1.1 Option 4b

Option 4b involves the phase-out of emissive activities across all uses of PFOS-related substances where present above 0.1% by mass either as a substance or in the final product where suitable substitutes and/or alternative processes are already available. Conditional derogations would be granted to critical photographic applications, critical photolithography and semiconductor applications, and use of PFOS-based fire fighting foam stocks.

Chromium Plating

Costs on chromium plating sector might come from:

- a move away from Chromium VI to Chromium III (for decorative chromium plating applications); and
- installation of improved ventilation, extraction and enclosure processes (for hard plating applications and plating onto plastic)

Move away from Chromium VI to Chromium III

Data collected from companies within the decorative chromium plating sector indicates that the move away from Chromium VI to Chromium III processes can be of financial benefit and should be possible for the majority of decorative plating activities. Thus, there should be no net cost to this sector of the industry, as indicated in Case Study 1 overleaf.

Installation of Improved Ventilation, Extraction and Enclosure

For hard plating applications and decorative plating onto plastics, through consultation, the cost of upgrading ventilation extraction systems has been estimated by a UK Trade Association as £40,000 for a medium sized operation by a UK trade association. Equivalent annual costs over 12 years (to be consistent with the remaining natural life of the stock of fire fighting foams and at the UK social discount rate of 3.5%) equate to a maximum of £4,100 per medium sized company per year.

It should be noted, however, that this figure does not include the operational savings from no longer purchasing chemical mist suppressants (containing PFOS-related substances). The US EPA estimates operational costs of chemical mist suppressants as being between £750 and £12,700 per year depending on the size of operation. If these cost savings are subtracted from the equivalent annual costs of £4,100 per company per year (calculated above), then this is reduced to a cost of between £3,350 per year to a net benefit of £8,600 per year.

Case Study 1: Costs and Benefits for Chromium Platers of moving from Cr VI to Cr III

Information received from industry groups and regulatory authorities suggests that the substitution of Cr (VI) with Cr (III) in decorative plating processes, whilst requiring some initial capital expenditure, provides significant operational cost savings.

Initial one-off costs and capital expenditure are required for disposal of the Cr (VI) solution, re-lining the process tank with PVD (after removing and disposing the contaminated lead), and replacing the lead/antimony anodes with carbon, plus an ion exchange system (BREF, 2003; SEA, 2003). However, according to the Surface Engineering Association (SEA), improvements in ion exchange resin technology have recently resulted in much lower operating costs (though these savings have only been reported qualitatively).

Operating cost savings for the Cr (III) plating process are associated with both improvements in the production process and product quality (e.g. pitting), and with reduced regulatory compliance costs and associated controls. These cost advantages include:

- reduction in the need for air scrubbers and mist suppressants;
- reduction of up to 90% in the cost of treating rinse water;
- significantly lower costs of treating and disposing of waste. The use of Cr (III) renders the need for a tank for storing the waste Cr (VI) prior to it being taken off the site redundant;
- lower health surveillance requirements. One company has reported that as a result of using Cr (III), its work force is required to be seen by the medical profession once a year rather than four times a year when using Cr (VI);
- greater system efficiency and increased production yield. Cr (III) has better throwing power, a higher current capacity, greater plating efficiency (up to 50% better) and about 30% less energy consumption than Cr (VI); and
- possibility of lower insurance premiums (given that the number of workers seeking compensation for health problems in general is rising).

The net effect is that, although the base chemicals are more expensive (about the same as a nickel process), the costs are more than offset by the savings made due to reduced waste treatment costs, reduced air monitoring costs, record keeping, and the reduced reject rate. The major benefit however relates to the significantly reduced risk of employee ill health induced by working with hexavalent chromium. Trivalent processes may require more effort to operate (i.e. regular monitoring of ampere-hours, pH, density, electrolyte cooling, and electrolyte samples must be sent away for analysis), but industry indications are that the labour costs are the same for Cr (III) and Cr (VI).

However, for the remainder of this analysis, these cost savings will not be included on the basis that there may be some additional operational costs associated with implementing improved extraction ventilation/tank enclosure. It is therefore assumed that these are of the same order of magnitude as the cost savings from no longer using chemical mist suppressants. The equivalent annual costs per medium sized company of the option are therefore taken as **£4,100** per year and this figure will be applied to the number of companies (regardless of size of operation).

Assuming that upgraded ventilation is not part of the emissions control systems maintained at present, the costs of additional extraction could be incurred by all platers (300 companies). The total equivalent annual costs across all platers are estimated at just over £1.2 million per year in the UK. However, in practice decorative platers are likely to switch to the use of Cr (III) to avoid the costs and take up the potential net financial benefits from moving to this process (as highlighted above). In this case, the costs would only be incurred by hard platers who cannot (at present) take up Cr (III) technology or alternative processes. There are estimated to be 100 such companies that cannot move to alternative plating technologies. On this basis, the total equivalent annual costs of all hard (Cr (VI)) platers adopting improved ventilation for chemical mist suppressants are around **£410,000 per year**. This is accompanied by the total elimination of PFOS-related emissions of between 500 and 2,500 kg per year.

Photographic Industry

Through consultation, Industry reports that efforts to replace PFOS-related substances have resulted in a reduction of 83% in the total amount of PFOS-related substances used in imaging products since 2000. The costs of achieving this 83% reduction across the EU since 2000 have been estimated as £12-24 million (€20-40 million). The remaining imaging products/applications where no substitution has yet been made (which account for the current 1,000 kg/year usage in the EU and 270kg in the UK) are reported to be as:

- surfactants for mixtures used in coatings applied to films, papers, and printing plates;
- electrostatic charge control agents for mixtures used in coatings applied to films, papers, and printing plates;
- friction control and dirt repellent agents for mixtures used in coatings applied to films, papers, and printing plates; and
- adhesion control agents for mixtures used in coatings.

The cost to be incurred from further work on replacements across the EU is expected to be no less (and probably significantly higher) than the estimated figure of €20-40 million (£12-24 million) spent on successful replacements to date. Assuming that 20% of this is relevant to UK industry, this translates to a further £2.4-4.8 million in research and process related expenditure. As noted in Section 4, depending on the concentrations of PFOS-related substances present in the raw materials or formulations used in photographic applications (in relation to the 0.1% threshold by mass), the proposed restrictions may or may not require any action on the part of the photographic industry. As such, these costs may or may not be attributable to the regulation itself, but rather to efforts to find alternatives before existing stocks of PFOS-related substances are used up.

Industry reports that environmental emissions control and waste incineration already takes place (with the exception of some waste streams that may currently go through water treatment). The costs to industry of such emission control are therefore assumed to be negligible. The EPCI, however, notes that if the restrictions are written in such a way which requires the incineration of large amounts of effluent rather than only PFOS-containing wastes, the costs of fuel consumption may be significant.

Photolithography and Semiconductors

In developer applications, strippers and etch mixtures, there are surfactants which are not PFOS-based which could serve as alternatives (although the identity of these is not known). For the 'newer' shorter wavelength technologies used in the manufacture of semiconductors, there are no substitutes currently available for photoresists and anti-reflective coatings (ARCs). Within the UK, recent consultation has indicated that PFOS-related substances are also used in photoresists and etching processes.

In relation to uses in photoresists, consultation has indicated that the majority of the semiconductor industry in the UK uses 'older' technologies which do not involve this application.

As noted in Section 4, because semiconductor applications use PFOS-related substances at concentrations below the 0.1% threshold by mass, the proposed restrictions may or may not formally require any action on the part of the semiconductor industry as regards substitution (depending on the concentration of PFOS-related materials in the raw materials or formulations used in the applications). As such, any costs of future substitution may or may not be attributable to the regulation itself; instead, they may relate to efforts to find alternatives before the stockpiles retained by the industry are used up.

PFOS-based Stocks of Fire Fighting Foams

Option 4b involves a five year derogation in the destruction and replacement of PFOS-based fire fighting foam stocks to allow time to address the uncertainties associated with all substitutes.

All PFOS-based stock would be maintained as part of a Mutual Aid Agreement at hazardous installations. The costs, therefore, are only associated with new requirements for incineration of out of date stocks which will occur every year between years 0 and 4, and the costs of bringing forward the replacement of the remaining stock, which will also have to be incinerated at high temperature. The resulting total NPV and equivalent annual costs for Option 4b are provided in Table 5, overleaf.

Consideration of the above cost estimates should take into account the wider context of the legal requirements concerning contamination of groundwater by fluorocarbons (including PFOS and telomer replacements) that already exist under the 1998 Groundwater Regulations and the damage costs of the incidents themselves.

Table 5: Option 4b: Conditional Maintenance of Existing Foam Stocks for 5 Years (@ 3.5%)

		Costs (£)
NPV Costs FA	Incineration	£41,040
	Replacement	£14,700
	Total	**£55,740**
NPV Costs Private/MA	Incineration	£1,275,130
	Replacement	£456,650
	Total	**£1,731,780**
Total NPV Costs		**£1,787,520**
Equivalent Total Annual Costs (over 12 Years)		**£185,100**

5.2 Costs for a Typical Business

Given the wide range of use sectors, the costs for a 'typical' business will not clarify issues concerning the incidence of any cost impacts. Indicative cost estimates developed for individual sectors have been provided above.

6. CONSULTATION WITH SMALL BUSINESS – THE SMALL FIRMS IMPACT TEST

Consultation undertaken during the preparation of the risk reduction strategy for Defra involved UK (and EU) trade associations and companies in a detailed and systematic process.

At the start of the study, national trade associations (and, in many cases, EU-wide associations) were contacted and provided with the details of this study. This initial contact was intended to gain clarification on the uses of PFOS-related substances and to provide a contact point for collection of further information during the study. Two separate questionnaires were then prepared and sent to these trade associations; one of the questionnaires was for producers and suppliers, while the other questionnaire was for users of these substances. For some of the sectors, we approached relevant companies (i.e. manufacturers, downstream user companies, formulators, etc.) directly to seek information for this study. Upon receipt of a completed questionnaire, all responses received were followed up by either a phone call and/or email to seek clarification or further information. A list of consultees contacted for this study is attached as Annex 1.

Consultation with companies (SMEs or otherwise) for this study has relied more on trade associations (as the intermediary as well as main source of information) for a number of reasons, including:

- in a number of sectors, users of PFOS-related substances were not aware that they were using these substances and, in the few cases in which the users were aware that they were using perfluorinated compounds in their products, they did not know the exact PFOS-related substance being used;
- majority of the companies contacted lacked the technical expertise (and manpower) at company level to address the issues surrounding PFOS-related substances; and
- some companies were reluctant to provide any direct information due to concerns over commercial confidentiality. In some instances, trade associations have themselves not provided information due to members' concerns over commercial confidentiality.

It should be noted that the above points also applied to a number of trade associations contacted. In some cases:

- trade associations appeared to have no information on the use of PFOS-related substances. This was the case for PFOS-based paper protection products where, despite reportedly representing a significant part of the market (at least before 3M's voluntary action), none of the trade associations contacted were able to identify UK applications or possible users; while
- in other cases, the national trade associations referred (or deferred) to the EU trade association, probably because they did not have a proper understanding of the technical issues involved.

The only sector with a substantial SME component that may be affected by the proposed regulations is the chromium plating industry. According to a 2002 Health & Safety Executive (HSE) research report[14] concerning the metal plating industry, companies with less than 250 employees represent 99% of total businesses, with 38% in the size range 10-249 employees and micro firms (those with up to 9 employees) representing about 60% of all businesses and employing 56% of all employees. Some 30% of the UK's surface engineering activity is based in the Midlands.

Consultation with the relevant trade association (the Surface Engineering Association - SEA) confirmed that the vast majority of sub-contract metal finishing enterprises are small companies, typically employing between 15 and 30 people with annual turnovers of between £0.5 and £2.5 million. The SEA also indicates that the sector does not have access to capital for plant and equipment, and often lack the resources to cope with any changes in regulatory burden. It is thus, of the opinion that the Government should assist companies in setting up the necessary improved ventilation extraction/tank enclosure systems when PFOS-containing fume suppressants are withdrawn from the market.

The actions to either switch to Chromium (III) processes or to adopt improved extraction/enclosure that would be required under the proposed strategy will initially require significant levels of investment for such companies; although a switch to Chromium (III) technology should improve financial returns over time according to SEA and HSE data. Thus, while the actions may be self-financing in the longer term (as described in section 5.1.1, Case Study 1), it is possible that assistance may be required to enable the smaller companies to make the necessary transition. The two year transition period proposed under option 4b should enable those who need financial and technical support from government, regulators or associations to receive such assistance.

It should be noted that based on advice from the Small Business Service, further analysis is needed to better assess the implications of the proposals on SMEs in the sectors affected. Further consultation with industry, such as semiconductor manufacturers and those in the chrome plating sector will be undertaken, as part of an ongoing consultation process.

7. SIMPLE COMPETITION ASSESSMENT

7.1 Overview

The competition filter test has been completed and the results suggest that a detailed competition analysis is not required. A simple assessment is therefore provided below.

7.2 Chrome Plating Industry

14 HSE (2002): Research Report 400/2002: Development of a Methodology to Design and Evaluate Effective Risk Messages: Electroplating Case Study, London, HSE Books.

For this sector it is possible that a single firm affected by the proposed strategy may account for >10% of the market share. However, it is very unlikely that any single company has a market share of greater than 20%.
As has been discussed in Section 6, the industry is comprised of a very large number of SMEs and, although the investments required to comply with the proposed strategy are likely to be self-financing in the medium to long term, the magnitude of initial investments is likely to affect the smaller companies to a greater degree than the larger companies.

It is also possible that the regulation would affect the ability of firms to choose the price, quality and range of their products. There is a perception that a switch to Chromium (III) in decorative plating will affect the quality of the product. However, it is reported that whilst there may be a slight change in the colour of the finished product, the quality is not affected. It has been reported that it is the customers for decorative chromium plating and their subsequent specifications that is the market issue here, rather than one of product quality.

7.3 Semiconductor Industry

It is possible that there are one or more companies with greater than a 20% market share and more likely that one or more companies has a share of 10% or greater. It is unlikely that market shares exceed the 50% threshold (particularly given the international nature of this sector).

The proposed national Action with associated derogation (Option 4b) is unlikely to affect the number and size of companies within the UK, given the conditions relating to presence by mass within products and emissions, the fact that there are substitutes for use of PFOS-related substances in developers exist, and that only a sub-set of companies will rely on the critical uses that would be affected by the conditional derogations. At the EU level, a similar cessation of use with derogations is also unlikely to affect the number and size of companies, unless one company invents and employs a substitute for PFOS-based chemicals within the derogated time period and maintains this in commercial confidence.

More generally, the sector is characterised by rapid technological change and, indeed, the industry reports that there are new processes and standards in the pipeline that could eliminate the need for PFOS-related substances depending on their relative performance to the other options that are available. Derogations have been included in the proposed strategy to ensure that firms continue to be able to choose the price, quality, range or location of their products.

7.4 Photographic Industry

There are an estimated 38 companies operating with the photographic chemicals material sector in the UK. Additional companies within the more general photographics sector may also be affected. It may be the case that one company has a greater than 20% market share and it may be the case, though is more unlikely, that the three largest firms have at least 50% of the market share.

The proposed strategy, however, is unlikely to affect the number and size of companies unless one company invents and employs a substitute for PFOS-based chemicals within the derogated time period and maintains this in commercial confidence. Derogations have been included in the proposed regulations to ensure that firms continue to be able to choose the price, quality, range or location of their products.

7.5 Remaining Industries

Competition effects of the proposed national Action are not expected in relation to the aviation and fire fighting foam industries. For aviation, this is because there appears to be only one major manufacturer/importer and the proposed restrictions will not require substitution in hydraulic fluids given that PFOS-related substances are present at much less than 0.1% by mass. For fire fighting foams, PFOS-based foams are no longer manufactured. There are, then, no manufacturers or agent companies that will be affected. Competition effects should also not arise in relation to the historic use sectors, given that use is not considered to take place in the relevant applications.

8. ENFORCEMENT AND SANCTIONS

8.1 Enforcement of Emissions and Emissions Controls for Derogated Uses

Controls in the photographic and semiconductor sectors will be enforced by the Environment Agency in England and Wales and by the devolved authorities in Scotland and Northern Ireland (hereafter referred to collectively as the Environment Agencies) under the relevant existing or new regulations.
Monitoring and enforcement of the cessation in the chromium plating industry would also be undertaken by the Environment Agencies, probably under Part A Pollution Prevention and Control Regulations.

The conditions on the safe treatment and disposal of contained fire waters in the event of incidents at Hazardous Installations will be administered by the Environment Agencies on a case by case basis as appropriate, as will oversight of the incineration of remaining PFOS-based stock.

8.2 Enforcement of Action in Respect of Fire Authorities

The Office of the Deputy Prime Minister (OPDM) is the relevant statutory authority regulating the Fire Authorities (FAs). As such, the ODPM is the Competent Authority for enforcing restrictions within the Fire Authorities.

9. MONITORING AND REVIEW

The effectiveness of the legislation is to be monitored by Defra and the Environment Agency in relation to progress in implementing the necessary controls and consideration of the associated reductions in emissions.

The review of derogations that is already timetabled to occur before the end of the five year time limited period should provide the opportunity to examine the success of arrangements regarding control of emissions and the success of the national Action in achieving its objectives.

10. CONSULTATION

Extensive consultation was undertaken as part of the development of the Risk Reduction Strategy. This included consultation with other Government Departments, non-governmental organisations (such as the World Wide Fund for Nature), industry trade associations and individual companies in the affected sectors. A full list of consultees is provided as Annex 1 (RPA & BRE, 2004). Wider consultation with UK companies in the affected sectors has been initiated.

11. SUMMARY AND RECOMMENDATION

Following the announcement by 3M (16 May 2000) that the company would phase-out the use of PFOS voluntarily from 2001, the OECD conducted a Hazard Assessment of PFOS, identifying a range of environmental and human health issues of concern.

In 2003, the Environment Agency for England and Wales, commissioned a study to review the environmental risks arising from current uses of PFOS-related substances. The UK Review of Environmental Risks (RER) of PFOS-related substances concluded that PFOS meets the criteria for classification as a Persistent, Bioaccumulative and Toxic (PBT) substance. In addition, risks have been identified for all uses.

In response to these findings, a Risk Reduction Strategy was prepared for Defra, following the requirements of the Existing Substances Regulations to ensure EU acceptability. The objective of the proposed strategy was to achieve a reduction/ elimination of the risks associated with PFOS-related substances. The measures proposed here draw on this strategy, but vary in what would be required.

The proposals are based on Option 4b, which require that a cessation is required on the use of PFOS-related substances in emissive applications at and above 0.1%, which would cover all historic uses. Such restrictions on historical uses should result in no costs to UK companies.

The national Action would apply immediately for the following applications:

- all known historical applications (including carpets; leather/apparel; textiles/upholstery; paper and packaging; coatings and coating additives; industrial and household cleaning products; and pesticides and insecticides);

- on-going chromium plating applications (after the expiry of a two year transition period); and
- use in semiconductor developer applications.

An immediate cessation should be delayed, however, for the following applications with time limited derogations applying to:

- use of remaining PFOS-based stocks of fire fighting foams;
- aviation hydraulic fluids;
- critical applications in the photographic sector; and
- critical applications in photolithography and semiconductors

Over a 12 year time period, the proposed strategy has estimated equivalent annual costs of around £410,000 the UK chromium plating sector. For Fire Authorities and private companies holding PFOS-based fire fighting foam stocks, the costs are estimated at around £185,100 in equivalent annual costs. Additional costs may be incurred by the photographic sector in carrying out R&D and potentially by the UK semiconductor industry in moving away from PFOS-related substances in certain applications.

ANNEX 1: LIST OF CONSULTEES

These are the organisations that were contacted in developing the Risk Reduction Strategy for PFOS. Note that six organisations requested not to be included in the list below. An asterisk indicates organisations that have responded either by providing information or by completing questionnaire that was subsequently passed to RPA.

Trade Associations

Alliance for Beverage Cartons & Environment (ACE)

Asociacion de Investigacion de las Industrias del Cvurtido y Anexas, Spain (AIICA)*

Association Internationale de la Savonnerie de la Detergence et des Produits d'Entretien (AISE)*

Association of Plastic Manufacturers in Europe (APME)

Association of Master Upholsterers*

British Adhesives and Sealants Association (BASA)*

British Association for Chemical Specialities (BACS)

British Carpet Technical Centre

British Cleaning Council

British Coatings Federation (BCF)*

British Fire Protection Systems Association (BFPSA)*

British Footwear Association (BFA)*

British Furniture Manufacturers (BFM)

British Interior Textiles Association (BITA)

British Leather Confederation (BLC)

British Leather Technology Centre Ltd.

British Lubricants Federation (BLF)*

British Luggage and Leather Goods Association (BLLA)

British Plastics Federation (BPF)

British Wood Preserving and Damp Proofing Association

Carpet Foundation

CEFIC – European Committee of Surfactants and their Organic Intermediates (CESIO)

CEFIC – European Photographic Chemicals Industry

CEFIC – Fluorocarbon Technical Committee

Centre Technique Cuir, France (CTC)

Centro Technologico das Industrias do Couro, Portugal (CTIC)

Commission on Engineering & Technical Systems (CETS)

Confederation of European Paper Industries (CEPI)

The Confederation of National Associations of Tanners & Dressers of the European Community (COTANCE)*

CIA-Organic Surfactants Group

Trade Associations

Construction Products Association
Crop Protection Association
Dutch Federation of Tanneries (FNL)
European Apparel and Textile Organisation (Euratex)*
European Automobile Manufacturers Association
European Carpets Association*
European Carton Makers Association (ECMA)
European Council of the Paint, Printing Ink & Artists' Colours Industry (CEPE)*
European Crop Protection Association (ECPA)
European Information and Communication Technology Industry Association (EICTA)
European Oilfield Speciality Chemicals Association (EOSCA)
European Semiconductors Industry Association (ESIA)*
European Textile Finishers Association (CRIET)*
Europen
Federation of the Sporting Goods Industry (FESI)
Fire Industry Research Association (FIRA)
Hellenic Leather Centre
Industry Council for Packaging & Environment (INCPEN)
Institute of Packaging
Lederinstitut Reutlingen Gerberschule, Germany (LGR)
Liquid Food Carton Manufacturers Association (LFCMA)
Metal Packaging Manufacturers Association (MPMA)*
Ministry of Defence*
National Carpet Cleaning Association
National Health Service, Purchasing and Supply Agency (PASA)*
Paper Chemicals Association (PCA)*
Paper Federation of Great Britain*
Paper Industry Research Association (PIRA)
Paper Industry Technical Association (PITA)
Photo Imaging Council (PIC)*
Rovesta Environment
Semiconductors Equipment & Materials International (SEMI)*
Society of Motor Manufacturers and Transporters (SMMT)
Society of British Aerospace Companies (SBAC)
Stazione Sperimentale per l'Industria del. Pelli et del. Materie Concianti, Italy (SSIP)
Surface Engineering Association*
Swedish Association of Industrial and Hygiene Products

Trade Associations

TEGEWA*
Textile Finishers Association (TFA)*
UK Cleaning Products Industry Association (UKCPI)
UK Fire Service*
UK Offshore Operators Association (UKOOA)
Veersuchsanstallt fur lederindustrie, Austria (VAL)*
Wood Panels Industries Federation

Companies

3M
Akzo Nobel*
Alekos Chemicals*
Angus Fire*
Apollo Scientific*
Aquados (UK) Ltd.
Asahi Glass Fluorochemicals UK*
Asahi Glass Japan
Atofina*
Atotech UK Ltd.*
Axminster Carpets
Basildon Chemical Co*
BASF plc, Agricultural Division
Baker Engineering Ltd.*
Bayer Crop Science plc*
Bayer plc*
Belchim Crop Protection Ltd., Agricultural Products Group
BIP Allchem*
Boeing
Borchers
Breaks
Brunner Mond Ltd.
Catomance Technologies*
Carpets International Ltd.
Carter-Lyne Ltd.
Causeway Carpets
Certis Europe BV
CHT Group*

Companies

Ciba Speciality Chemicals*
Clariant*
Colgate-Palmolive Ltd.
Crompton Europe Ltd.
Cussons
Daikin Chemical Europe *
Delrivados Del Fluor
Delta Fire
Dianippon
Doff Portland Ltd.
Dow AgroSciences Ltd.
Dr Petry UK*
DuPont Belgium*
DuPont (UK) Ltd.
East Lancs Chemicals
Ecolab
Enthone
Fisher Research Ltd.
Fisher Scientific*
Flexalan Products Ltd*
Fluorochem
Fluorine Technology Ltd.
Forsheda
Global Research & Development
GWP Group
Headland Agrochemicals Ltd.*
Hugh Mackay (Carpets)
Huntsman
Gibson*
Ilford Imaging Switzerland GmbH*
Ineos Chlor*
Jeyes*
John Drury & Co. Ltd.
Joseph Metcalf Ltd.
Kemira Chemicals*
Kodak UK*
Lancaster Synthesis*

Companies

Lever Feberge
London Oil Refining Co.
Louis De Poortere
Luxan (UK) Ltd.
Makhteshim-Agan (UK) Ltd.
Mandops (UK) Ltd.*
Mcdermid
Millchem
Miteni S.p.a
Monochrome Plating Co. Ltd.*
Monsanto Agriculture
My Cartons*
N2N Enviro Ltd.*
Nexus Chemicals
Nufarm UK Limited*
Nu Swift Ltd*
P and M
PBI Home & Garden Ltd.
Pelchem
Pownall Carpets
PPG*
Procter and Gamble
Protex International
Reckitt Benckiser
Robert McBride
Rudolf Chemicals Ltd
Ryalux
Sainsbury's
Sasol*
SB Chemicals Ltd.
SC Johnson*
Senzora
Silvani Fire
Solberg*
Solutia*
Solvay Fluor
South West Metal Finishing Ltd.*

Companies

Stephenson Thompson*
Sthamer
Svanen*
Syngenta Crop Protection UK Ltd.*
Synquest Labs
Texchem*
Ulster Carpets
Unilever
Uniqema
United Phosphorus*
Universal Crop Protection Ltd.
Vitax Ltd.
Westex Carpets
White Peak Fine Chemicals Ltd.*
Wools of New Zealand
Zschimmer

Competent Authorities and Academia

Environment Agency for England and Wales*
Environment Canada*
UK Civil Aviation Authority*
UK Health and Safety Executive*
Pesticides Safety Directorate (PSD)*
Swedish National Chemicals Inspectorate (KemI)*
University of Michigan*
University of Manchester Institute of Science and Technology (UMIST)*
US Environmental Protection Agency*

Fire Authorities

Northumberland Fire and Rescue Service*
West Midlands Fire Service*
Humberside Fire and Rescue Service*
Leicestershire Fire and Rescue Service*
Tyne & Wear Fire and Rescue Service*
Staffordshire Fire and Rescue Service*
Shropshire Fire and Rescue Service*

Cumbria Fire Service*
Devon Fire and Rescue Service*
London Fire & Emergency Planning Authority*
Dumfries & Galloway Service HQ*
Northamptonshire Service HQ*
North Yorkshire Brigade HQ*
Dorset Fire and Rescue Service*
Buckinghamshire Fire and Rescue Service*
Manchester Fire and Rescue Service*
Hereford and Worcester Fire Brigade*
Durham & Darlington Fire and Rescue Service*
Norfolk Fire Service*
Hampshire Fire and Rescue Service*
Essex County Fire and Rescue Service*
Surrey Fire and Rescue Service*
South Wales Fire Service*
Lancashire Fire and Rescue Service*
Avon Fire Brigade*
Lothian and Borders Fire Brigade*
Bedfordshire & Luton Fire and Rescue Service*
Kent Fire and Rescue Service*