1. Conclusions and recommendations

1.1 The proposal follows an announcement by the leading manufacturer of perfluorooctane sulfonates (PFOS) that it would cease to manufacture and market consumer products based on these entities. This decision was based on the manufacturer’s determination of possible risks to human health and the environment. Since then these risks have been quantified and the decision confirmed as being correct for the end-use in question. The major risk has been eliminated and action here is to ensure no recurrence of the problem. Meanwhile the needs of other users need to be protected until alternative materials or processes become available and/or until full impact assessments are undertaken.

1.2 The EESC supports the proposal, with particular reference to the restriction on marketing and use of PFOS-related substances, the derogations for the specified residual end-uses, and the need for continuing research.

1.3 The EESC notes that the end-uses to which derogations must be given differ significantly in the quantities used, in the likelihood and extent of human or environmental exposure, and in the time required to identify, develop and gain acceptance for, suitable and safer materials or processes. The EESC therefore believes that the derogations should be subject to review by the Commission on a case-by-case basis on the advice of the Scientific Committee on Health and Environmental Risks (SCHER). Indications of the factors affecting these reviews are given in the specific comments. The timing of any risk or impact assessments should be consistent with the increasing demand for chemicals risk assessment under REACH. It is essential that the Commission maintains sufficient in-house resource to enable it to fulfil these obligations in a timely and informed manner.

1.4 The EESC notes that the actions described above, in reaction to an unexpected change in external circumstances, contrast with the normal process of risk management where measures are defined following risk assessments by the competent authorities in the Member States of previously identified priority substances. This approach is however likely to be, and indeed is specifically intended to be, a more frequent occurrence under REACH. A proportionate, acceptable and effective outcome for PFOS should provide a model for the future application of REACH.

2. Summary of the Commission’s proposal

2.1 The Commission bases its proposal on an OECD hazard assessment completed in November 2002 and on a UK risk evaluation report finalised in July 2005. These and other studies, primarily in the US, were prepared following the announcement on 16 May 2000 by 3M of a voluntary withdrawal of PFOS-related substances from their principal application in providing grease, oil and water resistance to textiles, carpets, paper and general coatings.

2.2 The Commission accepts the SCHER Opinion of 18 March 2005 that, despite limitations in the available methodology for testing these entities, the data so far available indicate PFOS to be very persistent, very bio-accumulative and potentially toxic and that risk reduction measures are justified to prevent any recurrence of wide-scale use.

2.3 The Commission and SCHER also agree that there are specific low volume applications where effective substitute products or processes are not yet available. Given that the continued use of PFOS-related products in these residual applications does not appear to pose any additional risks to human health and the environment, derogations from the overall restriction on marketing and use should be given. The end uses to which derogations must be given are set out and discussed in the proposal.

2.4 Further work is required under the Research Framework Programme (PERFORCE) on exposures, sources, routes and physico-chemical parameters of these PFOS-related substances.
2.5 The proposal is intended to guarantee a high level of protection for health and the environment. The Internal Market in such products will be preserved. The costs to the affected sectors are believed to be minimal. Considerable consultation has taken place.

3. General comments

3.1 Fluorinated chemicals were developed in the late 1940s and have been used in increasing quantities to generate inert liquids with low surface tension (very spreadable) or solid surfaces with specific (usually non-stick) properties. A subgroup of these, PFOS-related products, were developed by companies such as 3M to provide grease, oil and water resistance in a range of industrial and consumer applications. By the year 2000, approximately 4 500 tonnes per year were being manufactured and marketed worldwide in products such as 3M Scotchgard™ carpet and fabric conditioner. Following the withdrawal of PFOS-related substances, these products have been reformulated around other fluorinated chemicals with similar surfactant properties but with reduced impacts on health and the environment.

3.2 As the name ‘PFOS’ suggests, these are products where all ‘per’ the hydrogen atoms on an eight-member ‘octane’ carbon chain have been replaced by fluorine ‘fluoro’ atoms and one SO₃ — ‘sulfonate’ group to form a stable negatively charged entity ‘anion’ which can in turn form a water-soluble, crystalline salt with metals such as lithium, sodium or potassium, or with other positively charged groups ‘cations’ such as NH₄⁺ ‘ammonium’. ‘PFOS’ is not a single ‘substance’ but refers to components ‘entities’ or ‘moieties’ of ‘substances’ under EU laws on ‘substances’ and ‘preparations’. PFOS-related substances are made by a specific chemical process called ‘electro-chemical fluorination’.

3.3 The combination of ‘organic’ (carbon-based, oil soluble) and ‘inorganic’ (metal salt, water soluble) properties makes PFOS-related substances extremely effective as surface active agents (‘surfactants’) in a range of specialist applications. The entities resist oxidation (are inert and do not burn) or any other environmental breakdown (are stable and therefore persistent). Given their solubility in both oil and water, they are likely to bio-accumulate. They may or may not be toxic to different species under different conditions of exposure. Their unusual physical and chemical properties mean that, as SCHER noted, laboratory test methods may prove unreliable in determining their effects in the environment as a whole.

3.4 Fully fluorinated short-chain polymers with similar properties to PFOS-related substances as surfactants but with lower or negligible impacts on human health and the environment can be made by a process known as ‘telomerisation’. These products (telomers) are not the subject of this proposal.

3.5 According to an OECD estimate in 2004, later quoted by SCHER, total annual usage of PFOS-related substances in the EU in 2000 was approximately 500 tonnes, of which 98 % was used to treat fabrics, paper or coatings. Annual emissions were believed to be around 174 tonnes. By 2004, worldwide usage had dropped significantly. Annual emissions in the EU were by then estimated in the worst case at 10 tonnes, assuming 9 tonnes from unrecovered waste water from metal plating. According to more recent German data, much of this too can be recovered.

3.6 SCHER also noted that it is only in recent years that analytical techniques have become sufficiently sophisticated to detect and reliably determine PFOS concentrations in environmental samples. It is therefore difficult to track changes due to the above reductions. SCHER could however conclude that emissions from the ongoing uses for which derogations are proposed will affect PFOS concentrations only on the local level and will insignificantly affect the overall concentration in the environment. More specifically, SCHER concluded that the overall risks for the environment and the general public were negligible with regard to their continuing use in the photographic, semiconductor and aviation industries. Usage in the plating industry was however a cause for concern and should be restricted.

3.7 Occupational hazards for each of the sectors require separate assessments. However, in the case of the photographic, semiconductor and aviation industries, given the nature of the industries involved and the high levels of protection already in place, it is difficult to see how the use of PFOS-related substances would present any additional hazards in the workplace. Usage in the chromium plating industry is however again a cause for concern. In the case of fire-fighting foams, the health and environmental risks of the proposed substitutes must be assessed before any decision is taken. Proper disposal routes for existing stocks and for run-off from major fires must also be agreed.

3.8 The EESC endorses the above and trusts that the necessary actions will be included in the work plans of the Commission.

4. Specific comments

4.1 The EESC supports the two restrictions on PFOS-related substances as defined in the proposal, i.e. (1) they may not be placed on the market or used as a substance or constituent of preparations equal or higher than 0.1 % by mass and (2) they may not be placed on the market in products or parts thereof in a concentration equal or higher than 0.1 % by mass.

4.2 The EESC also supports the derogation in paragraph (3) that paragraphs (1) and (2) above shall not apply in the six specific cases set out in the proposal and discussed in the paragraphs following.
4.2.1 Photolithography: this is, broadly, the process by which computer chips are patterned. New developments in semiconductor manufacture require specialised process fluids to allow the patterning to take place with very high reliability, density and uniformity. The PFOS-related substances provide unique electrochemical and surfactant properties and are regarded as ‘mission critical’ by the semiconductor industry. The process fluids, which do not remain in the finished products, are subject to rigorous specification and testing for each technology at each plant of every manufacturer. Used in ‘clean room’ manufacturing environments where all contamination must be eliminated, there is no possibility of workplace exposure. According to a 2002 mass balance for the industry, total emissions were below 45 kg per year. Product development times are up to 10 years. Despite extensive global R&D, no substitutes have been identified for these remaining uses. The most probable route for the removal of PFOS-related substances could be a new method of chip manufacture, yet to be invented. In the absence of this derogation, manufacture could not take place in the EU, although it could be continued without difficulty elsewhere. Given all of the above, and in the absence of any new evidence for concern, the EESC recommends that no time limit should be set for the removal of this derogation.

4.2.2 Photographic coatings: PFOS-related substances are purchased in concentrated solutions then extensively diluted to provide a range of properties essential for both workplace health and safety and overall product performance control in specialist photo imaging applications. These desired properties include electrostatic charge control, friction and adhesion control, dirt repellence and other surfactant properties for high performance imaging. Production techniques require as many as 18 imaging layers to be applied on to a fast moving film base to provide a uniform layer typically less than 0.11 mm thick. The fluids used must not be photoactive but must allow even spreading and good adhesion of subsequent layers. The antistatic properties are essential to minimise the risk of fire or explosion and subsequent injury to employees or to operating equipment. Usage of PFOS-related substances has been reduced by at least 60% in recent years by substitution in less critical applications and by the overall decline in film usage v. digital for many consumer, health and industrial applications. The remaining usages contribute less than 8 kg to the environment per year. It is likely that further moves towards digital will result in continuing decreases in the quantities required for film manufacture, although demand for photographic paper, for instance, for printing digital images, is expected to continue. Despite extensive research, no replacements have been identified for these few remaining uses of PFOS-related substances. New processes, not yet invented, requiring 10 years or more to develop, implement, test and accredit, will be required to complete the process. In the absence of this derogation, manufacture could not take place in the EU although could be continued without difficulty elsewhere. Given all of the above, and in the absence of any new evidence for concern, the EESC recommends that no time limit should be set for the removal of this derogation.

4.2.3 Mist suppressants for chromium plating: PFOS-related substances in dilute solution protect the health and safety of workers engaged in the decorative and protective chromium plating of metal or plastic substrates for the automobile and other consumer-driven industries. They also act as surface tension reducers and wetting agents, in particular in plastics etching. The working environment for chromium plating is recognised to be harsh and potentially dangerous, in particular in processes based on Cr(VI), a known carcinogen. The suppression of mists and increased human exposure is therefore essential. The situation can be improved through the use of processes based on Cr(III) but these are not yet fully available. Only PFOS-based surfactants have so far proved to be stable in either of these circumstances. Annual usage in Europe in 2000, according to SCHER, was around 10 tonnes. Estimates of the total annual release to the environment differ considerably, depending on the processes used and the degree to which these are controlled with respect to emissions, recycling and waste incineration. A German industry estimate, based on local best practice, suggests that total emissions could be as low as 500 kg per year if extrapolated across Europe. If less good technology and controls are used, the emissions could be higher. Given that chromium plating is the largest remaining ongoing use of PFOS-related substances, and that the technology is evolving and to some extent alternatives are already available, it seems appropriate that a time limit should be set for this proposed derogation and further, that, as suggested by SCHER, occupational exposure analyses and longer term assessments of the risk to the environment should be conducted without delay. These should be undertaken in cooperation with the industry to ensure that manufacturing can continue in the EU. There is no incentive to drive out one critical stage of automobile manufacture, with the obvious risk that the remaining production would eventually follow. Neither should any premature removal of PFOS-related mist suppressants lead to increased risks for worker health. The EESC recommends that this derogation should apply for a period of five years only before review by the Commission and SCHER.

4.2.4 Hydraulic fluids for aviation: these are the fluids used to drive the control surfaces and other components of commercial, military and general aviation aeroplanes. They are used, and must continue to function on a daily basis to the highest possible operating standards to maintain aircraft and passenger safety, under the most extreme conditions of temperature and pressure. The business is global, and products, components and systems are subject to extensive testing and certification by aircraft manufacturers and by relevant national and international bodies. A typical approval cycle for a new formulation can take up to 20 years. PFOS-related substances are used in small quantities (around 0.1% by mass) to provide erosion resistance for mechanical parts, valves, tubes and orifices. Despite extensive testing, no substitutes or, to date, any indications of possible substitutes, have been found. They are used in closed systems under tightly controlled conditions. Total releases to soil and water were estimated by SCHER to be below 15 kg per year. Given all of the above, and in the
absence of any new evidence for concern, the EESC recommends that no time limit should be set for the removal of this derogation.

4.2.5 Fire-fighting foams: fluorinated surfactants have been used in high-specification fire-fighting foams for many years. PFOS-related substances have been largely replaced in new foams manufactured to replace stocks used to extinguish actual fires or to provide stocks for new developments, airports, petroleum refineries and chemical plants, marine vessels and tank farms. However, the health and environmental impact of these alternative products has not yet been fully assessed. All foams have to be sold with 15-20 year guarantees, as ideally they are never used. Significant stocks of PFOS-containing foams therefore still exist and disposal of these stocks is now the key issue. The surfactants must allow water-based foams to spread quickly on the surface of the burning hydrocarbons, rather than sinking below them, in order to cut off the supply of oxygen and prevent burn-back. Both surfactants and foams must be stable under intense conditions of use and both must resist oxidation. Performance standards for foams for different fire scenarios are set by national and international bodies. Stocks of 3 % or 6 % concentrates are stored in central depots, for distribution and dilution on site when a fire occurs. Large volumes may be required and the problems of waste disposal of the run-off after the fire may be considerable. The run-off is inevitably contaminated by the products that were on fire, by the by-products of uncontrolled low temperature carbon incineration (polyaromatic hydrocarbons (PAHs) and dioxins) and by the components of the foams. The recent fire in a storage depot in Buncefield, UK, for instance, has left a residue of 20 million litres of contaminated waste. High temperature incineration is the only assured approach, but this is inefficient and costly where the bulk of the material is water. Annual emissions to the environment are therefore hard to determine, being dependent on the number, scale and circumstances of each fire, and critically on the extent to which the run-off can be contained by bund walls. SCHER quoted an annual release in the EU of under 600 kg and noted that this could overstate actual releases. The EESC agrees with SCHER that the existing stocks of PFOS-based foam concentrates should not be incinerated until the alternatives have been fully evaluated. The EESC therefore recommends that the necessary impact and risk assessments should be undertaken as quickly as possible and that remaining PFOS-based foams should be used only where essential on performance grounds and where the run-off can be contained by bund walls. The Commission should work with the industry and with national competent authorities to ensure that there are adequate disposal routes for the large volumes of waste generated. Given the many uncertainties, the EESC believes that there is no point in setting a time limit for the removal of this derogation, but every point in resolving the outstanding questions as fast as possible.

4.2.6 Other controlled closed systems: this is, or should be, a standard derogation for the majority of substances subject to EU marketing and use restrictions. Provided that raw materials can be safely delivered to the system, and products and waste products safely removed, then very low emission systems allow continuing manufacture of essential intermediates with minimal risk to human health or the environment. Workplace reviews of the operating conditions should be undertaken under routine health and safety inspection. In the absence of any new evidence of concern, the EESC recommends that no time limit should be set for the removal of this derogation.

4.3 The Commission will continue to have a key role in ensuring a satisfactory outcome in each of the above sectors. A continuing programme of research will be required, in and outside the affected sectors to develop alternative products and processes. The Directives affecting these sectors should be modified when necessary to reflect changes in current or proposed global practice.


The President
of the European Economic and Social Committee

Anne-Marie SIGMUND