



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 5.12.2005
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2005/0244 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**relating to restrictions on the marketing and use of perfluorooctane sulfonates
(amendment of Council Directive 76/769/EEC)**

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION AND CONTEXT

Perfluorooctane sulfonates (PFOS) are anions that are commercially available in the form of salts, derivatives and polymers. The major uses for PFOS-related substances were in providing grease, oil and water resistance to materials such as textiles, carpets, paper and in general coating. The substances used in these areas were largely PFOS-polymers for fabrics and PFOS-substances for paper treatment and coatings. Other smaller volume uses are in chromium plating, photography, photolithography, fire fighting foams and in hydraulic fluids for aviation.

The proposal is primarily based on the following studies:

- An 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). According to this assessment PFOS is persistent in the environment, bio accumulative and toxic to mammalian species.
- A risk evaluation report and a risk reduction strategy ***which includes an impact assessment*** have been prepared by the United Kingdom in accordance with the principles of Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances¹.
- *The Scientific Committee on Health and Environmental Risks (SCHER) examined the scientific aspects of the above mentioned risk reduction strategy and confirmed in its opinion adopted on 18 March 2005 that the data indicate that PFOS was very persistent, very bio-accumulative and toxic.*

Estimates of emissions from each use area have been made. The risk assessment identified a need for reducing the risks to health and the environment from PFOS. The risk reduction strategy recommended marketing and use restrictions for certain uses. ***The proposed Directive would cover the great part of the exposure risks by preventing the use of PFOS in carpets, textiles, upholstery, leather, apparel, paper, packaging and other applications. These uses seem already to be phased out and the proposal would prevent their reintroduction. There are some further smaller and specific uses in chromium plating, photography, photolithography, fire fighting foams and in hydraulic fluids for aviation. The volumes used in these limited areas, and the emissions into the environment, would need to be further assessed, but they are currently expected to be very small. The advantages and disadvantages of regulating these uses would have to be subject to impact assessment.***

An ongoing research project PERFORCE (<http://www.science.uva.nl/perforce/>) which is financed by the Research Framework Programme is generating new data, e.g. on exposures, sources and routes and physico-chemical parameters of PFOS.

¹ OJ L 84, 5.4.1993, p. 1.

Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations² should therefore be amended accordingly.

The objective of the Directive would be to introduce harmonised provisions with regard to PFOS, thus preserving the internal market whilst ensuring a high level of protection of human health and the environment, as required by Article 95 of the Treaty.

2. JUSTIFICATION FOR PROPOSAL

What are the objectives of the proposal in relation to the Community's obligations?

Due to the fact that certain uses of chemicals cannot be controlled under certain conditions, safety for health and the environment can only be ensured by prohibiting such uses of the substances and preparations concerned.

The aim of the proposal is to preserve the Internal Market. When Member States adopt national provisions restricting the marketing and use of dangerous substances and preparations there will be obstacles to trade because of differences in legislation between Member States. The Draft Proposal aims to improve the conditions for the functioning of the Internal Market to the benefit of the protection of health and the environment.

What are the courses of action available to the Community?

The only course of action available is to make a proposal for an amendment to Directive 76/769/EEC providing for harmonised rules on the use of PFOS.

Are uniform rules necessary? Is it not sufficient to establish targets to be implemented by Member States?

The proposed Directive would establish uniform rules for the circulation of PFOS. It also guarantees a high level of protection of health and the environment. The proposed amendment to Directive 76/769/EEC is the only way to meet these goals. Targets would be insufficient.

3. RATIONALE OF THE PROPOSAL

The proposed Directive would extend Annex I to Directive 76/769 by adding the substance PFOS. Marketing and use of this substance would thus be restricted.

4. COSTS AND BENEFITS

4.1. Costs

The proposed Directive should pose only minor problems to the industry or trade, as the uses of PFOS are declining in the concerned cases, and companies have already developed alternatives.

² OJ L 262, 27.9.1976, p. 201.

4.2. Benefits

The benefits of the proposal are to establish an Internal Market as well as to protect human health and the environment. The proposed restriction will ensure that for certain uses which pose a risk to human health or the environment PFOS are no longer on the market.

5. PROPORTIONALITY

The proposed Directive would yield benefits in terms of protecting human health and the environment. This will be achieved at little cost.

6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT AMENDMENT

Advice on the preparation of the proposal was sought through meetings involving experts from Member States and the European Chemical Industry Council (CEFIC), the outcome of which is reflected in the proposal. The European Consumers' Organisation BEUC has also been invited to give comments.

7. CONFORMITY WITH THE TREATY

This proposal is intended to preserve the Internal Market and at the same time ensure a high level of protection of human health and the environment. It is therefore in conformity with Article 95(3) of the Treaty.

8. EUROPEAN PARLIAMENT AND EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 95 of the Treaty, the Codecision Procedure with the European Parliament is applicable. The European Economic and Social Committee has to be consulted.

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission ³,

Having regard to the opinion of the European Economic and Social Committee ⁴,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁵,

Whereas:

- (1) An OECD hazard assessment has been done on the basis of information that was available by July 2002. This assessment concluded that the potential hazards of perfluorooctane sulfonates (PFOS) indicate cause for concern.
- (2) The risks posed to health and environment by PFOS have been assessed in accordance with the principles of Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁶. The risk assessment identified a need to reduce the risks to health and environment.
- (3) The Scientific Committee on Health and Environmental Risks (SCHER) has been consulted. ***The SCHER has seen a need for further scientific risk assessment of PFOS but it also agreed that risk reduction measures might be necessary to avoid the re-occurrence of former uses. According to SCHER, on-going critical uses in the aviation industry, the semiconductor industry, and the photographic industry do not appear to pose a relevant risk to the environment or human health, if releases into the environment and workplace exposure are minimised. With regard to fire-fighting foams, the SCHER agrees that health and environmental risks of substitutes must be***

³ OJ C [...], [...], p. [...].

⁴ OJ C [...], [...], p. [...].

⁵ OJ C [...], [...], p. [...].

⁶ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 57, 25.2.2003).

assessed before a final decision can be taken. With regard to chromium plating measures to reduce the emissions should be assessed.

- (4) In order to protect health and the environment, it therefore appears necessary that the placing on the market and the use of PFOS should be restricted. ***The proposed Directive would cover the major part of the exposure risks. Other minor uses of PFOS do not seem to pose a risk and they are therefore currently exempted. They will be further examined and they will be the subject of a specific impact assessment.***
- (5) ***The products containing PFOS should also be restricted in order to protect the environment. The present directive should only restrict new products and should not apply to products already in use or on the second hand market.***
- (6) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations⁷ should be amended accordingly.
- (7) The objective of this Directive is to introduce harmonised provisions with regard to PFOS, thus preserving the internal market whilst ensuring a high level of protection of human health and the environment, as required by Article 95 of the Treaty.
- (8) This Directive is without prejudice to the Community legislation laying down minimum requirements for the protection of workers, such as Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁸ and individual directives based thereon, in particular Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version)⁹ and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)¹⁰,

⁷ OJ L 262, 27.9.1976, p. 201. Directive as last amended by Commission Directive 2004/21/EC (OJ L 57, 25.2.2004, p. 4).

⁸ OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁹ OJ L 158, 30.4.2004, p. 50.

¹⁰ OJ L 131, 5.5.1998, p. 11.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by xx xx 200x [*one year after the date of its entry into force*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from xx xx 200x [*eighteen months after the entry into force of this Directive*].

When Member States adopt those provisions, the provisions shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

The following point [XX] is added to Annex I of Directive 76/769/EEC:

<p>“[XX]. Perfluorooctane sulfonates $C_8F_{17}SO_2X$ (X = OH, Metal salt, halide, amide, and other derivatives including polymers)</p>	<p>(1) May not be placed on the market or used as a substance or constituent of preparations in a concentration equal or higher than 0.1 % by mass.</p> <p>"(2) May not be placed on the market in products or parts thereof in a concentration equal or higher than 0.1% by mass"</p> <p>(3) <i>By way of derogation, paragraphs 1 and 2 shall not apply to</i></p> <ul style="list-style-type: none">- <i>photoresists or anti reflective coatings for photolithography processes,</i>- <i>industrial photographic coatings applied to films, papers, or printing plates,</i>- <i>mist suppressants for chromium plating,</i>- <i>hydraulic fluids for aviation,</i>- <i>fire fighting foams,</i>- <i>controlled closed systems where the concentration of PFOS released into the environment is less than 1µg per kg, and where that release corresponds to less than 0.1% by mass of the PFOS used in the system.</i>
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