





Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2005/0244(COD) Procedure completed
Restrictions on the marketing and use of perfluorooctane sulfonates	
Subject 3.40.01 Chemical industry, fertilizers, plastics 3.40.10 Textile and clothing industry, leathers 3.40.11 Precision engineering, optics, photography, medical 3.70.01 Protection of natural resources: fauna, flora, nature, wildlife, countryside; biodiversity 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 4.20 Public health 4.60.04.02 Consumer security	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Environment, Public Health and Food Safety		21/02/2006
		Vers/ALE SCHLYTER Carl	
	Committee for opinion	Rapporteur for opinion	Appointed
	 Industry, Research and Energy	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Transport, Telecommunications and Energy	2772	11/12/2006
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events			
05/12/2005	Legislative proposal published	COM(2005)0618	Summary
13/12/2005	Committee referral announced in Parliament, 1st reading		
13/07/2006	Vote in committee, 1st reading		Summary
19/07/2006	Committee report tabled for plenary, 1st reading	A6-0251/2006	
24/10/2006	Debate in Parliament		
25/10/2006	Results of vote in Parliament		
25/10/2006	Decision by Parliament, 1st reading	T6-0444/2006	Summary
11/12/2006	Act adopted by Council after Parliament's 1st reading		
12/12/2006	Final act signed		
12/12/2006	End of procedure in Parliament		

Technical information	
Procedure reference	2005/0244(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/32396

Documentation gateway					
Legislative proposal		COM(2005)0618	05/12/2005	EC	Summary
Committee draft report		PE372.192	02/05/2006	EP	
Economic and Social Committee: opinion, report		CES0731/2006	17/05/2006	ESC	
Amendments tabled in committee		PE374.361	07/06/2006	EP	
Amendments tabled in committee		PE376.358	05/07/2006	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0251/2006	19/07/2006	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0444/2006	25/10/2006	EP	Summary
Commission response to text adopted in plenary		SP(2006)5316/2	23/11/2006	EC	
Draft final act		03660/1/2006	12/12/2006	CSL	

Additional information	
European Commission	EUR-Lex

Final act
Directive 2006/122 OJ L 372 27.12.2006, p. 0032-0034 Summary

Restrictions on the marketing and use of perfluorooctane sulfonates

PURPOSE : to place restrictions on the marketing and use of perfluorooctane sulfonates and amend Council Directive 76/769/EEC.

PROPOSED ACT : Directive of the European Parliament and of the Council.

CONTENT : 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.

Recent studies have shown PFOs to be persistent in the environment, bio accumulative and toxic to mammalian species.

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.

Council Directive 76/769/EEC 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 preparations 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.

Restrictions on the marketing and use of perfluorooctane sulfonates

The committee adopted the report by Carl SCHLYTER (Greens/EFA, SE) amending - under the 1st reading of the codecision procedure - the proposed directive on restrictions on the marketing and use of perfluorooctane sulfonates (PFOS):

- the title was amended so that the directive would also apply to perfluorooctanoic acid (PFOA), which has a similar structure and toxicity to PFOS,
- PFOS should not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0.005% by mass (as opposed to 0.1% by mass proposed by the Commission). Nor should it be placed on the market in articles or parts thereof in a concentration equal to or higher than 0.005% by mass in a homogenous material that cannot be mechanically disjointed into different materials. These two conditions would apply to PFOA three years after the directive's entry into force;
- the proposed derogations for certain products using PFOS should be time-limited: 8 years for photoresists or anti-reflective coatings for photolithography processes; 6 years for industrial photographic coatings applied to films, papers or printing; and 10 years for hydraulic fluids for aviation. These time-limited derogations may be extended on a case-by-case basis if no safer alternatives have become available;
- the proposed derogations for mist suppressants for chromium plating and for fire-fighting foams were deleted, but the committee proposed that fire-fighting foams may be used up to 18 months after the directive's entry into force;
- the committee proposed a tighter definition of controlled closed systems ("where the concentration of PFOS released into the environment and the workplace is less than 1 µg per kg of the PFOS used in the system processes") and imposed a time-limit of six years;
- Member States should establish inventories of uses of PFOS and PFOA on their own, in preparations or in articles, and take steps to prevent discharges, emissions and loss of PFOS and PFOA from the inventoried products.

Restrictions on the marketing and use of perfluorooctane sulfonates

The European Parliament adopted the resolution drafted by Carl SCHLYTER (Greens/EFA, SE) and confirmed a first-reading agreement between Parliament and Council. The resolution was adopted by 632 votes to 10 with 20 abstentions.

Under the agreement, the directive will ban the placing of PFOS on the market and their use as a substance or constituent of preparations in a concentration equal to or higher than 0.005% by mass. It will also outlaw the sale of PFOS or their use in semi-finished products or articles, or parts thereof, if the concentration of PFOS is equal to or higher than 0.1% by mass or, for textiles or other coated materials, if the amount of PFOS is equal to or higher than 1 µg/m² of the coated material. Under the directive, substances and preparations needed to produce photoresists or anti-reflective coatings for photolithography processes, photographic coatings applied to films, papers, or printing plates may contain PFOS in larger quantities. The same applies to suppressants for non-decorative hard chromium (VI) plating and wetting agents for use in controlled electroplating systems as well as hydraulic fluids for aviation.

Regarding fire-fighting foams, the initially proposed derogation was dropped. All new foams must be free of PFOS. Foams that have been placed on the market before the directive enters into force can be used until 54 months after its entry into force. Two years after entry into force, Member States must compile and send to the Commission an inventory listing the processes for chromium plating subject to derogation, the amounts of PFOS used in and released into the environment, and existing stocks of fire-fighting foams.

When reviewing derogations in the light of new information, the Commission must ensure that: the uses of PFOS are phased out as soon as the use of safer alternatives is technically and economically feasible; a derogation is only continued for essential uses for which safer alternatives do not exist and where it has been reported what has been undertaken to find safer alternatives; releases of PFOS into the environment have been minimised, by applying best available techniques.

Lastly, the Commission will keep under review the ongoing risk assessment activities and the availability of safer alternative substances or technologies related to the uses of perfluorooctanoic acid (PFOA) and related substances and propose any measures needed to reduce identified risks, including restrictions of marketing and use, in particular when safer alternative substances or technologies which are technically and economically feasible are available.

Member States will have 18 months to enact the directive in national law, i.e. up to mid-2008.

Restrictions on the marketing and use of perfluorooctane sulfonates

PURPOSE: to place restrictions on the marketing and use of perfluorooctane sulfonates and to amend Council Directive 76/769/EEC accordingly.

LEGISLATIVE ACT: Directive 2006/122/EC of the European Parliament and of the Council amending for the 30th time Council Directive 76/769/EEC 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 preparations (perfluorooctane sulfonates).

BACKGROUND: an OECD assessment of perfluorooctane sulfonates (PFOs) concluded that they are persistent, bio accumulative and toxic to mammalian species. The EU's Scientific Committee on Health and Environmental Risks (SCHER) formed similar conclusions to that of the OECD and noted that PFOs could be considered persistent organic pollutants (POPs). As a result the SCHER noted that:

- measures might be needed to avoid the re-occurrence of former PFO uses;
- on-going critical uses in the aviation industry, the semiconductor industry and the photographic industry did not appear to pose a relevant risk ? on condition that exposures be minimised;
- that alternatives to PFOs in fire-fighting foam should be assessed, from an environmental point of view, before a final decision can be taken;
- the use of PFOs in the plating industry should be restricted.

CONTENT: based on the above analysis this Directive restricts the placing on the market, and the use of, PFOs in the EU. It covers all major ?exposure? risks. Thus, PFOs may not be placed on the market or used as a substance or constituent of preparations in concentrations equal to or higher than 0,005% of the mass. The use of PFOs that are deemed to carry a ?minor? risk are, currently, exempted from the Directive (for example, photographic coatings applied to films, papers or printing plates). The derogations are, however, subject to regular reviews.

In other areas the Directive:

- gives special attention to the plating processes that rely on PFOs and the releases from those process through the application of best available techniques (BATs);
- restricts the use of semi-finished products and articles containing PFOs in order to protect the environment. The restrictions will cover all products and articles to which PFOs are intentionally added;
- will apply only to new products and not to products already in use or on the second hand market. However, existing stocks of fire-fighting foams containing PFOs will need to be identified and their use only allowed for a limited period;
- requires the Commission to review each derogation once new information on safer alternatives becomes available;
- requires that perfluorooctanic acid (PFOA), which has similar qualities to PFOs, to be kept under review.

ENTRY INTO FORCE: 27 December 2006.

TRANSPOSITION: 27 December 2007.

APPLICATION: 27 June 2008.