

EUROPOS PARLAMENTAS

2004



2009

Aplinkos, visuomenės sveikatos ir maisto saugos komitetas

NEGALUTINIS
2005/0244(COD)

2.5.2006

*****I**

PRANEŠIMO PROJEKTAS

dėl pasiūlymo dėl Europos Parlamento ir Tarybos direktyvos dėl perfluoroktano sulfonātų pardavimo ir naudojimo apribojimų (Tarybos Direktyvos 76/769/EEB dalinis pakeitimas)
(KOM(2005)0618 – C6-0418/2005 – 2005/0244(COD))

Aplinkos, visuomenės sveikatos ir maisto saugos komitetas

Pranešėjas: Carl Schlyter

Procedūrų sutartiniai ženklai

- * Konsultavimosi procedūra
balsavusių narių balsų dauguma
 - **I Bendradarbiavimo procedūra (pirmasis svarstymas)
balsavusių narių balsų dauguma
 - **II Bendradarbiavimo procedūra (antrasis svarstymas)
balsavusių narių balsų dauguma pritariama bendrajai pozicijai visų Parlamento narių balsų dauguma atmetama arba taisoma bendroji pozicija
 - *** Pritarimo procedūra
visų Parlamento narių balsų dauguma, išskyrus EB sutarties 105, 107, 161 ir 300 straipsniuose bei ES sutarties 7 straipsnyje numatytus atvejus
 - ***I Bendro sprendimo procedūra (pirmasis svarstymas)
balsavusių narių balsų dauguma
 - ***II Bendro sprendimo procedūra (antrasis svarstymas)
balsavusių narių balsų dauguma pritariama bendrajai pozicijai visų Parlamento narių balsų dauguma atmetama arba taisoma bendroji pozicija
 - ***III Bendro sprendimo procedūra (trečiasis svarstymas)
balsavusių narių balsų dauguma pritariama bendram tekstui
- (Procedūra pasirenkama atsižvelgiant į Komisijos pasiūlytą teisinį pagrindą.)

Teisės akto pakeitimai

Parlamento pakeitimų tekstas paryškinamas *pusjuodžiu kursyvu*. Paryškinimas *paprastu kursyvu* parodo atitinkamiems skyriams tas teisės akto projekto vietas, kurias siūloma taisyti rengiant galutinį tekstą (pvz., tekste tam tikra kalba paliktas akivaizdžias klaidas ar praleistas vietas). Pasiūlytiems tokio pobūdžio pataisymams reikalingas atitinkamų skyrių sutikimas.

TURINYS

Puslapis

EUROPOS PARLAMENTO TEISĖKŪROS REZOLIUCIJOS PROJEKTAS.....	5
EXPLANATORY STATEMENT.....	16

EUROPOS PARLAMENTO TEISĖKŪROS REZOLIUCIJOS PROJEKTAS

dėl pasiūlymo dėl Europos Parlamento ir Tarybos direktyvos dėl perfluoroktano sulfonatų pardavimo ir naudojimo apribojimų (Tarybos Direktyvos 76/769/EEB dalinis pakeitimas)

(KOM(2005)0618 – C6-0418/2005 – 2005/0244(COD))

(Bendro sprendimo procedūra: pirmasis svarstymas)

Europos Parlamentas,

- atsižvelgdamas į Komisijos pasiūlymą Europos Parlamentui ir Tarybai (KOM(2005)0618)¹,
 - atsižvelgdamas į EB sutarties 251 straipsnio 2 dalį ir į EB sutarties 95 straipsnį, pagal kuriuos Komisija jam pateikė pasiūlymą (C6-0418/2005),
 - atsižvelgdamas į Darbo tvarkos taisyklių 51 straipsnį,
 - atsižvelgdamas į Aplinkos, visuomenės sveikatos ir maisto saugos komiteto pranešimą (A6-0000/2006),
1. pritaria Komisijos pasiūlymui su pakeitimais;
 2. ragina Komisiją dar kartą perduoti klausimą svarstyti Parlamentui, jei ji savo pasiūlymą ketina keisti iš esmės arba pakeisti jį nauju tekstu;
 3. paveda Pirmininkui Parlamento poziciją perduoti Tarybai ir Komisijai.

Komisijos siūlomas tekstas

Parlamento pakeitimai

Pakeitimas 1 PAVADINIMAS

Pasiūlymas dėl Europos Parlamento ir Tarybos direktyvos dėl perfluoroktano sulfonatų pardavimo ir naudojimo apribojimų (Tarybos Direktyvos 76/769/EEB dalinis pakeitimas)

Pasiūlymas dėl Europos Parlamento ir Tarybos direktyvos dėl perfluoroktano sulfonatų *and perfluorooctanoic acid* pardavimo ir naudojimo apribojimų (Tarybos Direktyvos 76/769/EEB dalinis pakeitimas)

Pagrindimas

The US EPA has found that perfluorooctanoic acid (PFOA) and its salts are of similar concern due to structural analogy with PFOS. An assessment from 2002 indicated potential systemic toxicity and carcinogenicity, and blood monitoring data suggested widespread exposure to the general population. Numerous studies have shown that PFOA and its salts

¹ OL C ... / Dar neskelbta Oficialiajame leidinyje.

are also highly persistent in the environment and do not biodegrade under environmental conditions. PFOA is also highly persistent in humans, is not metabolized and has a half life of several years. This Directive should therefore also restrict PFOA and its salts.

Pakeitimas 2

1 KONSTATUOJAMOJI DALIS

(1) OECD pateiktas pavojaus įvertinimas buvo atliktas remiantis 2002 m. liepos mėn. turėta informacija. Šiame įvertinime buvo padaryta išvada, kad **galimas** perfluoroktano sulfonatų (PFOS) **kenksmingumas** verčia susirūpinti.

(1) An OECD hazard assessment has been done on the basis of information that was available by July 2002. This assessment concluded that perfluorooctane sulfonates (PFOS) **are persistent, bioaccumulative and toxic to mammalian species and, therefore,** indicate cause for concern.

(1) OECD pateiktas pavojaus įvertinimas buvo atliktas remiantis 2002 m. liepos mėn. turėta informacija. Šiame įvertinime buvo padaryta išvada, kad galimas perfluoroktano sulfonatų (PFOS) kenksmingumas verčia susirūpinti.

Pagrindimas

The key hazardous properties of PFOS as given in the OECD hazard assessment should be specified.

Pakeitimas 3

1A KONSTATUOJAMOJI DALIS (nauja)

(1a) Perfluorooctanoic acid (PFOA) and its salts are of similar concern due to their structural analogy with PFOS. Studies have indicated potential systemic toxicity and carcinogenicity of PFOA and its salts as well as widespread exposure of the general population thereto based on blood monitoring data. PFOA and its salts are highly persistent in the environment and do not biodegrade under environmental conditions. PFOA is also highly persistent in humans, is not metabolized and has a half life of several years.

Pagrindimas

Given the strong similarities between PFOS and PFOA, PFOA should also be covered by this

Pakeitimas 4
3 KONSTATUOJAMOJI DALIS

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

Įvyko konsultacijos su Pavojų sveikatai ir aplinkai moksliniu komitetu (SCHER). SCHER įvardijo tolesnio mokslinio PFOS rizikos įvertinimo poreikį, tačiau taip pat sutiko, kad gali prireikti rizikos mažinimo priemonių, kad nebūtų kartojami ankstesni naudojimo būdai. Pasak SCHER, pagrindiniai šiuo metu aviacijos pramonėje, puslaidininkių pramonėje ir fotografijos pramonėje taikomi naudojimo būdai nekelia pavojaus aplinkai ar žmonių sveikatai, jeigu jų patekimas į aplinką ir poveikis darbo vietoje yra minimalus. SCHER pritaria, kad prieš priimant galutinį sprendimą dėl ugnies gesinimo putų reikia įvertinti, kokį pavojų sveikatai ir aplinkai kelia jų pakaitalai. Chromavimo atveju reikia įvertinti emisijos sumažinimo priemones.

(3) The Scientific Committee on Health and Environmental Risks (SCHER) has been consulted. **It stated that PFOS fulfil the criteria for classification as very persistent, very bioaccumulative and toxic.** 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 **finds** that health and environmental risks of substitutes must be assessed before a final decision can be taken. With regard to chromium plating, **the SCHER considers that emissions from the plating industry should be restricted.**

Įvyko konsultacijos su Pavojų sveikatai ir aplinkai moksliniu komitetu (SCHER). SCHER įvardijo tolesnio mokslinio PFOS rizikos įvertinimo poreikį, tačiau taip pat sutiko, kad gali prireikti rizikos mažinimo priemonių, kad nebūtų kartojami ankstesni naudojimo būdai. Pasak SCHER, pagrindiniai šiuo metu aviacijos pramonėje, puslaidininkių pramonėje ir fotografijos pramonėje taikomi naudojimo būdai nekelia pavojaus aplinkai ar žmonių sveikatai, jeigu jų patekimas į aplinką ir poveikis darbo vietoje yra minimalus. SCHER pritaria, kad prieš priimant galutinį sprendimą dėl ugnies gesinimo putų reikia įvertinti, kokį pavojų sveikatai ir aplinkai kelia jų pakaitalai. Chromavimo atveju reikia įvertinti emisijos sumažinimo priemones.

Pagrindimas

The PBT properties of PFOS as found by the scientific committee should be indicated. The SCHER opinion as regards chromium plating needs to be reflected correctly.

Pakeitimas 5

3A KONSTATUOJAMOJI DALIS (nauja)

(3a) PFOS as well as PFOA fulfil the criteria for classification as hazardous substances pursuant to Directive 2000/60/EC of the European Parliament and the Council establishing a framework for Community action in the field of water policy¹. Under the terms of that Directive, the European Parliament and the Council are required to adopt specific measures against pollution of water. For priority hazardous substances, such measures must aim at the cessation or phasing-out of discharges, emissions and losses. It is appropriate to take such measures in respect of PFOS and PFOA.

¹ OJ L 327, 22.12. 2000, p.1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p.1).

Pagrindimas

PFOS and PFOA clearly fulfil the criteria of hazardous substances pursuant to the Water Framework Directive. While they have not yet been added to the list of priority hazardous substances, the Community should nevertheless treat them the same way as priority hazardous substances.

Pakeitimas 6

4 KONSTATUOJAMOJI DALIS

(4) Todėl siekiant apsaugoti sveikatą ir aplinką yra būtina apriboti PFOS pateikimą į rinką ir naudojimą. ***Siūloma direktyva apims didžiąją kenksmingo poveikio dalį. Atrodo, kad kiti nedidelių PFOS kiekių naudojimo būdai nekelia pavojaus ir todėl jiems šiuo metu netaikomi apribojimai. Jie bus iširti vėliau, atliekant atskirą poveikio įvertinimą.***

(4) Todėl siekiant apsaugoti sveikatą ir aplinką yra būtina apriboti PFOS pateikimą į rinką ir naudojimą. ***Essential uses for which no alternatives are yet available should be exempted from the restriction for a limited period of time, subject to a review, where appropriate. Exemptions for essential uses as an intermediate should only be granted for use in***

controlled closed systems.

Pagrindimas

Restrictions should also be taken for PFOA. Restrictions should be guided by the objective to phase out discharges, emissions and losses as enshrined in the Water Framework Directive.

Pakeitimas 7

5 KONSTATUOJAMOJI DALIS

(5) Siekiant apsaugoti aplinką apribojimais bus taikomi ir **produktams**, kurių sudėtyje yra PFOS. Šioje direktyvoje numatyti apribojimai bus taikomi tik naujiems produktams, bet nebus taikoma jau naudojamiems produktams ar parduodant panaudotus produktus.

(5) Siekiant apsaugoti aplinką apribojimais bus taikomi ir **produktams**, kurių sudėtyje yra PFOS. Šioje direktyvoje numatyti apribojimai bus taikomi tik naujiems produktams, bet nebus taikoma jau naudojamiems produktams ar parduodant panaudotus produktus.

Pagrindimas

The Directive should use the appropriate terminology in line with Directive 76/769/EEC and the future REACH legislation. The term "product" is generic and can refer to a substance, a preparation or an article. However, this provision is meant to refer to articles, which are defined in Community legislation on chemicals, and, therefore, the term "product" should be replaced by the correct term "article".

Pakeitimas 8

5A KONSTATUOJAMOJI DALIS (nauja)

(5a) Given the specific risks of PFOS and PFOA, Member States should establish an inventory of the uses of PFOS and PFOA on their own, in preparations or in articles and take the necessary measures to ensure the cessation of discharges, emissions and losses of PFOS and PFOA from the inventoried products to the environment.

Pagrindimas

PFOS was brought onto the market in the 70's. In the year 2000, around 500 tonnes of PFOS were used in the EU. Current use has dropped significantly to around 12 tonnes per year. As such, so-called former uses - that however still exist in the real world - may represent the biggest source of emissions. To avoid that PFOS from these products is released to the environment, Member States should establish inventories of all products containing PFOS

and take the necessary measures to avoid further releases of PFOS to the environment from these products. Such an inventory should also include PFOA based products.

Pakeitimas 9

ANNEX, TABLE, RIGHT COLUMN, POINT 1
Annex I, point XX (Directive 76/769/EEC)

1) Negalima pateikti į rinką arba naudoti kaip medžiagą ar jos sudedamąją dalį preparatuose, jeigu medžiagos koncentracija lygi arba viršija **0,1** % masės.

1) Negalima pateikti į rinką arba naudoti kaip medžiagą ar jos sudedamąją dalį preparatuose, jeigu medžiagos koncentracija lygi arba viršija **0,001** % masės.

Pagrindimas

According to SCHER, referring to a recent OECD survey, PFOS chemicals are present in products in concentrations ranging between 0.001% and 50%. Given the specific properties of PFOS, it is often used in concentrations below 0.1%. The standard administrative threshold of 0.1% for restrictions is, therefore, not appropriate here. To ensure that the restriction is effective, the threshold needs to be lowered to 0.001%.

Pakeitimas 10

ANNEX, TABLE, RIGHT COLUMN, POINT 2
Annex I, point XX (Directive 76/769/EEC)

2) Negalima pateikti į rinką **produktuose** ar jų dalyse, jeigu medžiagos koncentracija lygi arba viršija **0,1** % masės.

2) Negalima pateikti į rinką produktuose ar jų dalyse, jeigu medžiagos koncentracija lygi arba viršija 0,1 % masės.

Pagrindimas

The appropriate term here is 'article', not 'product'.

According to SCHER, referring to a recent OECD survey, PFOS chemicals are present in products in concentrations ranging between 0.001% and 50%. The standard administrative threshold of 0.1% for restrictions is therefore not appropriate here. To ensure that the restriction is effective, the threshold needs to be lowered to 0.001%. In line with the approach taken for restrictions of certain hazardous substances in electrical and electronic equipment, the threshold should refer to homogenous materials.

Pakeitimas 11

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 1
Annex I, point XX (Directive 76/769/EEC)

- fotorezistams ar fotolitografijos procesuose naudojamiems

(a) photoresists or anti reflective coatings for photolithography processes **until ...***,

antirefleksiniam paviršiam,

provided that they are used in controlled closed systems in accordance with Commission Directive 2001/59/EC¹.

** Four years after entry into force of this Directive.*

¹ *Commission Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p.1).*

Pagrindimas

According to the risk reduction strategy commissioned by the UK competent authorities, the substitution process of PFOS in photolithography would take a minimum of three to four years. It is thus reasonable to set a clear timeframe for the phase out of this use. The time-limited derogation may be extended if no safer alternatives have become available (see amendment 17). The derogation should only be given when such uses take place in controlled closed systems as defined in Directive 2001/59.

Pakeitimas 12

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 2
Annex I, point XX (Directive 76/769/EEC)

- juostelėms, popieriui ar spausdinimo plokštėms naudojamiems pramoniniams fotografiniams paviršiams,

- juostelėms, popieriui ar spausdinimo plokštėms naudojamiems pramoniniams fotografiniams paviršiams,

** Four years after entry into force of this Directive.*

Pagrindimas

According to the risk reduction strategy commissioned by the UK competent authorities, more than 80% of this use of PFOS has already been successfully replaced by safer substances in the past years. Given further technology changes due to the shift to digital photography, it is reasonable to assume that the remaining uses can be substituted within four years.

Pakeitimas 13

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 3
Annex I, point XX (Directive 76/769/EEC)

- *chromavimo procese naudojamiems cheminiam rūko inhibitoriams,*

Išbraukta.

Pagrindimas

PFOS related substances are used in the following main applications: decorative chromium plating, hard chromium plating and plating onto plastics. The use of PFOS in the plating industry accounts by far for the highest releases to the environment. A restriction is supported by the SCHER. The use in decorative plating can be substituted by replacing Cr (VI) with Cr (III) with significant operational cost savings after initial one-off costs. The use of PFOS as a mist suppressant in hard chromium plating and in plating onto plastics can be replaced by mechanical mist suppression options and improved ventilation extraction. As such, there is no justification for an exemption for chromium plating.

Pakeitimas 14

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 4
Annex I, point XX (Directive 76/769/EEC)

- aviacijoje naudojamiems hidrauliniams
skysčiams,

- aviacijoje naudojamiems hidrauliniams
skysčiams,

** Ten years after entry into force of this Directive.*

Pagrindimas

There are currently no alternatives available for PFOS in hydraulic fluids. It has been suggested that the process of qualifying a new fluid for use in commercial aircraft has historically taken about 10 years from concept to actual commercial manufacture. It is, therefore, reasonable to allow a 10-year derogation from the phase-out to allow for sufficient time to develop alternatives. The time-limited derogation may be extended if no safer alternatives have become available (see amendment 17).

Pakeitimas 15

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 5
Annex I, point XX (Directive 76/769/EEC)

- *ugnies gesinimo putoms,*

Išbraukta.

Pagrindimas

PFOS containing fire fighting foams represent by far the biggest stock of PFOS-containing products. PFOS is no longer used in the manufacture of fire fighting foams. Safer organohalogen-free alternatives are readily available. In the UK stakeholder consultation on a national ban in 2005, all firefighting organisations called for an immediate cessation of use and safe disposal. Given the very dangerous properties of PFOS, it is not acceptable to allow that remaining stocks are used at the expense of the environment and health, when safer alternatives are available.

Pakeitimas 16

ANNEX, TABLE, RIGHT COLUMN, POINT 3, INDENT 6
Annex I, point XX (Directive 76/769/EEC)

- kontroliuojamoms uždaroms sistemoms, Išbraukta.
kuriose į aplinką išmetamų PFOS
koncentracija mažesnė nei 1 µg/ kg, o
emisija sudaro mažiau nei 0,1 % sistemoje
naudojamos PFOS masės.

Pagrindimas

The specifications given in the Commission proposal for a controlled closed system would allow releases and are as such contradictory to the concept of controlled closed systems. Such an exemption, especially in an unspecific generic form, is unacceptable and should therefore be deleted.

Pakeitimas 17

ANNEX, TABLE, RIGHT COLUMN, POINT 3A (new)
Annex I, point XX (Directive 76/769/EEC)

(3a) The derogations under paragraph 3(a) and (c) may be extended for a limited period of time if manufacturers can prove that they have undertaken every effort to develop safer alternatives or alternative processes, and that safer alternatives or alternative processes are still not available.

Pagrindimas

It should be possible to extend the derogation for photolithography and for hydraulic fluids in aviation, if manufacturers can prove that they failed to develop safer alternatives or alternative processes despite their best efforts. However, no such extension should be given to industrial photographic coatings, as substitution is already largely completed.

Pakeitimas 18

ANNEX, TABLE, RIGHT COLUMN, POINT 3B (new)
Annex I, point XX (Directive 76/769/EEC)

(3b) Member States shall establish an inventory of uses of PFOS on their own, in preparations or in articles. Member States shall take the necessary measures to ensure the cessation of discharges, emissions and losses of PFOS from the

inventoried products.

Pagrindimas

As only the Annex of Directive 76/769/EEC will be carried over into REACH, all supplementary provisions to the phase out have to be put into the Annex.

PFOS was brought onto the market in the 70's. In the year 2000, around 500 tonnes of PFOS were used in the EU. Current use has dropped significantly to around 12 tonnes per year. As such, so-called former uses - that however still exist in the real world - may represent the biggest source of emissions. To avoid that PFOS from these products is released to the environment, Member States should establish inventories of all products containing PFOS and take the necessary measures to avoid further releases of PFOS to the environment from these products.

Pakeitimas 19

ANNEX, TABLE, NEW ENTRY

Annex I, point XX a (new) (Directive 76/769/EEC)

left column:

***"[XXa]. Perfluorooctanoic acid
C₇F₁₅COX (X=OH, Metal salt, halide
amide, and other derivatives including
polymers)***

right column:

(1) May not be placed on the market or used as a substance or constituent of preparations in a concentration equal to or higher than 0,001 % by mass after ...^(*).

(2) May not be placed on the market in articles or parts thereof in a concentration equal to or higher than 0,001% by mass in a homogeneous material that cannot be mechanically disjointed into different materials after ...^{*}.

(3) Manufacturers may request a derogation from paragraphs 1 and 2 before ...^{**}. A derogation shall be granted for essential uses for a limited period of time, to be set on a case-by-case basis, if manufacturers can prove that they have undertaken every effort to develop safer alternatives or alternative processes, and that safer alternatives or alternative processes are still not available.

(4) Member States shall establish an

inventory of uses of PFOA on its own, in preparations or in articles. Member States shall take the necessary measures to ensure the cessation of discharges, emissions and losses of PFOA from the inventoried products."

** Three years after entry into force of this Directive.*

*** Eighteen months after entry into force of this Directive.*

Pagrindimas

The US EPA found that perfluorooctanoic acid (PFOA) and its salts are of similar concern due to structural analogy with PFOS. PFOA is persistent, bioaccumulative and toxic, and there is widespread exposure to the general population. Restrictions must therefore not be postponed any longer. A mechanism is proposed so that industry can request for time-limited derogations for essential uses for which no alternatives have been found. Member States should establish inventories of all products containing PFOA and take the necessary measures to avoid further releases of PFOA to the environment from these products.

EXPLANATORY STATEMENT

"All scientific work is incomplete -- whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone action that it appears to demand at a given time."

Sir Austin Bradford Hill, Proceedings of the Royal Society of Medicine, 1965

Introduction

Most of us are aware of the many problems linked to chlorine chemistry. Chlorine chemistry stands for a group of substances such as DDT, PCBs and CFCs that caused havoc in the environment. While the problems of such substances became known by Rachel Carson's book "The silent spring" in the 60's, it took decades to phase them out in the 80's or 90's. But they are still with us: polluting the environment, the food chain as well as our bodies, or damaging the ozone layer and contributing to climate change - because they are persistent. Many people like to see this kind of industrial chemistry as a problem of the past.

Perfluorooctane sulfonates (PFOS) - the subject of the Commission proposal - are representatives of the relatively new class of *perfluorinated compounds*. They are an example of how uncontrolled experimentation with persistent chemicals has continued despite the "chlorine experience".

PFOS stand for a double failure: the failure of current chemical legislation to protect human health and the environment, and the failure to learn from the past.

Perfluorinated compounds - and the failure of chemical legislation

Perfluorinated compounds have found numerous applications in consumer products and industrial applications due to their stability and repellent properties. They are probably best known from materials or brands like Teflon or Gore-Tex. PFOS has been a key ingredient of Scotchguard, a fabric protector produced by 3M to protect materials from stain.

According to the Scientific Committee on Health and Environmental Risks (SCHER), PFOS is very persistent, very bioaccumulative and toxic. PFOS - the production of which started in the 70's - has now become a ubiquitous contaminant. PFOS has been found in a wide variety of species across the world - from polar bears to albatrosses, from the Arctic to the mid-Pacific. It is also a common contaminant of humans - in fact, every single one of us most likely carries PFOS in his/her body. A blood monitoring study by WWF from 2004, that investigated 47 people from 17 countries, including 39 Members of the European Parliament, found PFOS and six other perfluorinated compounds in every single one of the 47 people tested.

It was the combination of PFOS contamination of a wide variety of species, including humans plus worrying toxicological data that led 3M - the global market leader - to voluntarily exit PFOS production in 2000.

In other words, the use of PFOS remained unregulated for decades, until irreversible damage was done: global contamination by a substance that is very persistent, very bioaccumulative and toxic.

Perfluorinated compounds - and the failure to learn from the past

Fluorine is one out of three halogens in the periodic system. The other two are bromine and chlorine. They share very specific properties. They are all highly reactive - but once combined with a carbon atom, they render the molecule more persistent, and in many cases also more bioaccumulative and toxic. In fact, the link between carbon and fluorine is the most stable link known in organic chemistry, causing certain perfluorinated compounds like PFOS to be virtually indestructible.

One might naïvely assume that the chemical industry learnt its lesson from the massive and ongoing environmental damage caused by chlorinated organic compounds and would stay away from brominated and fluorinated organic chemistry. Unfortunately, the contrary is true. The production of perfluorinated compounds started in the 70's and was increased significantly thereafter - while the main chlorinated compounds were being phased out.

Legislator lagging behind

While it is common place that the regulator runs behind and most often only restricts substances when they are on their way out, the story of PFOS takes this to the extreme. In this case - it was the global market leader that realised that PFOS was becoming too much of a liability and therefore decided to exit its production in 2000 - after more than 20 years of production. The UK competent authorities followed up on this in the EU and notified a national phase-out for most of the remaining uses in 2004. It took until the end of 2005 for the Commission to make a legislative proposal. However, contrary to the UK draft national ban, the Commission only proposes to restrict former uses - uses that do not exist anymore - while all remaining current uses are to receive an unlimited derogation.

And while 3M also phased out the use of perfluorooctanoic acid (PFOA), a substance that poses very similar concern due to structural analogy with PFOS, the US EPA is stuck in endless investigations on it, and the Commission does not include in its proposal.

Your rapporteur suggests the following modifications to strengthen the Commission proposal:

- 1) **Lower threshold for phase-out:** According to SCHER, PFOS chemicals are present in products in concentrations ranging between 0.001% and 50%. The standard administrative threshold for restrictions of 0.1%, as proposed by the Commission, is therefore not appropriate for PFOS. To ensure that the restriction is effective, the threshold needs to be lowered to 0.001%.
- 2) **Deletion of three exemptions:**
 - a. Chromium plating: According to SCHER, the use of PFOS in chromium plating represents by far the biggest source of emissions of PFOS to the environment. For certain chromium applications, PFOS can be substituted by replacing Cr (VI) with Cr (III) with significant cost savings. In other applications, the use of PFOS can be replaced by mechanical mist suppression

options and improved ventilation extraction. As such, there is no justification for an exemption for chromium plating.

- b. Fire fighting foams: PFOS-containing fire fighting foams represent by far the biggest stock of PFOS-containing products. PFOS is no longer used in the manufacture of fire fighting foams. Safer organohalogen-free alternatives are readily available. Given the very dangerous properties of PFOS, it is not acceptable to allow that remaining stocks are used when safer alternatives are available.
- c. Controlled closed systems: The specifications given in the Commission proposal for a controlled closed system would allow releases and are as such contradictory to the concept of controlled closed systems. Such an exemption, especially in an unspecific generic form, is unacceptable.

3) **Time-limitation of remaining three exemptions, with a possibility to extend the derogation for two applications**: Derogations from the phase-out should only be given for a limited period of time so as to give an incentive towards substitution. Time-limits should be set case-by-case. For two applications, it is justified to allow for an extension of the time-limit, if manufacturers can prove that they undertook all efforts to develop safer alternatives or alternative processes, and that safer alternatives or alternative processes are still not available.

- a. Photolithography: Studies estimate that the substitution process of PFOS in photolithography would take a minimum of 3-4 years. It is thus reasonable to set a timeframe of 4 years for the phase out of this use, with the possibility to extend this derogation as described above. This derogation should only be given when such uses take place in controlled closed systems as defined in Community legislation on chemicals.
- b. Industrial photographic coatings: More than 80% of this use of PFOS has already been successfully replaced by safer substances in the past years. Given further technology changes due to the shift to digital photography, it is reasonable to assume that the remaining uses can be substituted within 4 years.
- c. Hydraulic fluids for aviation: There are currently no alternatives available for PFOS in hydraulic fluids. The process of qualifying a new fluid for use in commercial aircraft has historically taken about 10 years. It is, therefore, reasonable to give a 10-year derogation - which may be extended (see above) - from the phase-out to allow for sufficient time to develop alternatives.

4) **Inventory of PFOS products in use**: Given the major drop in PFOS production after 2000, former uses - that however still exist in the real world - may represent the biggest source of emissions. To avoid that PFOS from these products is released to the environment, Member States should establish inventories of all products containing PFOS and take the necessary measures to avoid further releases of PFOS to the environment from these.

5) **Add PFOA to the scope of the phase-out**: Perfluorooctanoic acid (PFOA) and its salts are of similar concern due to structural analogy with PFOS. An assessment by the US EPA from 2002 indicated potential systemic toxicity and carcinogenicity, and blood monitoring data suggested widespread exposure to the general population. Numerous studies have shown that PFOA and its salts are also highly persistent in the environment and in humans. This Directive should therefore also phase out the use of

PFOA and its salts within three years after entry into force. Subject to a request within 18 months, manufacturers would be granted a derogation for essential uses, if they can prove that they undertook all efforts to develop safer alternatives or alternative processes, and that safer alternatives or alternative processes are still not available. In analogy to the provisions of PFOS, Member States should also establish inventories of all products containing PFOA and take the necessary measures to avoid further releases of PFOS to the environment from these products.

Final remarks

There are hundreds of perfluorinated compounds on the market. Their use is due to their specific properties - and as such they are likely to show at least some of the hazardous properties of PFOS and PFOA. It goes beyond the capacity and role of the rapporteur to include these substances into the scope of this Directive, all the more that the new chemical legislation REACH should soon be in place. Unfortunately, given the relatively low volume of most perfluorinated compounds, and the political compromises on REACH, your rapporteur is afraid that it may still take a long time before REACH will be able to protect human health and the environment against other perfluorinated compounds, unless specific action is taken against these.