COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.01.2001
COM(2001) 12 final

2001/0018 (COD)

.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether)

(presented by the Commission)

EXPLANATORY MEMORANDUM

INTRODUCTION AND CONTEXT

Pentabromodiphenyl ether (pentaBDE) is a brominated flame retardant almost exclusively used in the manufacture of flexible polyurethane foam for furniture and upholstery. It belongs to a group of ten substances, the polybrominated diphenyl ethers. Three polybrominated diphenyl ether flame-retardants are available on the market. The other two, decaBDE and octaBDE, are used in applications other than polyurethane foam. The proposed Directive would introduce harmonised provisions on the marketing and use of pentaBDE.

The risks to the environment of PentaBDE have been assessed under Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances. The risk assessment identified a need for reducing risks of pentaBDE to the environment from production and use of polyurethane foam containing pentaBDE. In its opinion of 4 February 2000, the Scientific Committee on toxicity, ecotoxicity and the environment (CSTEE) confirmed the conclusions of the assessment of pentaBDE on the need to reduce risks to protect the environment. Furthermore, the CSTEE confirmed, in its opinion of 19 June 2000, the concern about exposure of breast-fed children to pentaBDE and that the increasing levels of pentaBDE in breast milk might be the result of a use not yet identified.

The Commission adopted on xx.xx.2001 a Recommendation in the framework of Regulation (EEC) 793/93 on a risk reduction strategy providing for restrictions on marketing and use of pentaBDE and of articles containing pentaBDE to control risk to the environment from the production and use of polyurethane foams. It also recommended that any measures take account of the concerns about infants exposed via milk.

On the basis of the risk assessment and recommended risk reduction strategy in the framework of Regulation (EEC) 793/93 and taking account of the Precautionary Principle (Communication from the Commission on the precautionary principle, COM/2000/0001) the Commission proposes to restrict the marketing and use of pentaBDE and of articles containing pentaBDE.

The commercially available, technical grade, diphenyl ethers are mixtures and contain molecules with different numbers of bromine atoms. PentaBDE is also present in technical grade octabromodiphenyl ether (octaBDE) in low concentrations. The potential risks of (technical grade) octaBDE is currently assessed in the framework of Regulation (EEC) 793/93 and risk reduction measures may be recommended, if appropriate, following completion.

Analytical techniques, such as GC-MS (gas chromatography-mass spectrometry) are available for the quantification of pentaBDE and these techniques can also distinguish between technical grades of octaBDE and pentaBDE.

JUSTIFICATION FOR PROPOSAL AND CONSIDERATIONS OF SUBSIDIARITY

What are the objectives of the proposal in relation to the Community's obligations?
The objectives of the proposal are to preserve the Internal Market and to protect human health and the environment by taking account of the findings of the risk assessment.

What are the courses of action available to the Community?
The only course of action available is a proposal to amend for the 24th time Directive 76/769/EEC.

Are uniform rules necessary?
Is it not sufficient to establish targets to be implemented by Member States?
The proposed 24th amendment establishes uniform rules on pentaBDE to preserve the Internal Market. It also guarantees a high level of protection of health and the environment. The proposed 24th amendment is the only way to meet these goals. Targets would be insufficient.

RATIONALE OF THE PROPOSAL

The risk assessment in the framework of Regulation (EEC) 793/93 identifies risks of pentaBDE and a strategy to reduce these risks. The Commission's proposal implements, in a harmonised way, the risk reduction strategy envisaged under Regulation (EEC) 793/93 and prevents fragmentation of the Internal Market through unilateral actions by Member States.

COSTS AND BENEFITS

Costs
The proposed Directive should only pose minor problems to the industry or trade. Suitable alternative flame-retardants, both in technical and economical terms, are available. Costs are insignificant both in terms of one-off reformulation costs and annual costs in comparison to the turnover of the sectors concerned.

Benefits
The benefits of the proposal are to preserve the Internal Market and to protect health and the environment. The proposal will not result in greater risks from fires or greater risks to the environment given availability of suitable alternative flame-retardants.

PROPORTIONALITY

The 24th amendment will yield benefits in terms of a Single Market and of protecting health and the environment. These will be achieved at little cost.

CONSULTATIONS PERFORMED IN PREPARING THE DRAFT 24TH AMENDMENT

Advice on the preparation of the proposal was sought through meetings involving experts from Member States and industry, represented by CEFIC (European Chemical Industry Council).

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 health and the environment and is therefore in conformity with Article 95 (3) of the Treaty.

CONSULTATION OF THE EUROPEAN PARLIAMENT AND THE ECONOMIC AND SOCIAL COMMITTEE

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

2001/0018 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether)

(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[1],

Having regard to the opinion of the Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

(1) Under article 14 of the Treaty, an area without internal frontiers is to be established, in which the free movement of goods, persons, services and capital is ensured.

(2) The risks to the environment of pentabromodiphenyl ether (pentaBDE) have been assessed under Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[4]. The risk assessment identified a need for reducing risks of pentaBDE to the environment. In its opinion of 4 February 2000, the Scientific Committee on toxicity, ecotoxicity and the environment (CSTEE) confirms the conclusions of the assessment of pentaBDE on the need to reduce risks to protect the environment. Furthermore, the CSTEE confirmed, in its opinion of 19 June 2000, the concern about exposure of breast-fed children to pentaBDE and that the increasing levels of pentaBDE in breast milk might be the result of a use not yet identified.

(3) The Commission has adopted a Recommendation[5] in the framework of Regulation (EEC) 793/93 on a risk reduction strategy for pentaBDE providing for restrictions on marketing and use to control risk to the environment. It also recommended that any measures should take account of the concerns about infants exposed via milk.

---

1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ L 84, 5.4.1993, p. 1.
5 OJ C , , p. .

(4) In order to protect health and the environment the placing on the market and the use of pentaBDE and the placing on the market of articles containing pentaBDE should be prohibited.

(5) The commercially available, technical grade, diphenyl ethers are mixtures and contain molecules with different numbers of bromine atoms. Technical grade octabromodiphenyl ether (octaBDE) contains pentaBDE, in addition to mainly octaBDE and heptaBDE. OctaBDE is currently the subject of risk assessment under Regulation (EEC) 793/93. This risk assessment is not yet complete and though risk reduction measures may be recommended in the future the present proposal should not have the effect of restricting technical grade octaBDE.

(6) Presence of pentaBDE in concentrations higher than 0.1 % can be identified using standard analytical techniques such as GC-MS (gas chromatography-mass spectrometry). These techniques can distinguish between technical grades of octaBDE and pentaBDE.

(7) Whereas this Directive does not affect Community legislation laying down minimum requirements for the protection of workers contained in 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 work[6], and in individual directives based thereon, in particular Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)[7] and Council Directive 98/24/EC on protection of health and safety of workers from the risk related to chemical agents at work.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

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

Article 2

Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive no later than 31 December 2002 [*one year after the date of its entry into force*]. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 July 2003 [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.

---

[6] OJ L 183, 29.6.1989, p. 1.
[7] OJ L 196, 26.7.1990, p. 1.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Communities.*

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

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

"[XX] diphenylether, pentabromo derivative $C_{12}H_5Br_5O$	1. May not be placed on the market or used as a substance or as a constituent of preparations in concentrations higher than 0.1 % by mass. 2. Articles may not be placed on the market if they, or flameretarded parts thereof, contain this substance in concentrations higher than 0.1% by mass. 3. By way of derogation these provisions do not apply to technical grade octabromodiphenyl ether provided it contains less than 5% diphenylether, pentabromo derivative by mass."