COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 16.8.2002 COM(2002) 459 final 2002/0206 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

relating to restrictions on the marketing and use of nonylphenol, nonylphenol ethoxylate and cement (twenty-sixth amendment of Council Directive 76/769/EEC)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. INTRODUCTION AND CONTEXT

Nonylphenol (NP) is used as an intermediate in the production of nonylphenol ethoxylates (NPE) (e.g. for use in detergents and paints), in the production of resins, plastics, stabilisers in the polymer industry, in the manufacture of phenolic oximes, and in some speciality paints.

The risks to the health and environment of NP and NPE have been assessed under Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ¹. The risk assessment identified a need for reducing the risks from NP and NPE to the environment. In its opinion of 6/7 March 2001, the CSTEE confirmed the conclusions of the assessment and the need to reduce risks to the environment.

The Commission adopted on 7 November 2001 a Recommendation in the framework of Regulation (EEC) 793/93 on a risk reduction strategy for NP and NPE providing for restrictions on marketing and use to control risks to the environment².

On the basis of the risk assessments and recommended risk reduction strategies in the framework of Regulation (EEC) 793/93, the Commission proposes to restrict the marketing and use of NP and NPE and of preparations containing them.

Cement is widely used in the construction industry. It can contain small amounts of water-soluble chromium VI, which is classified as carcinogenic and sensitising. Chromium VI in cement can induce painful, disabling, allergic eczema in people exposed to wet cement preparations. A technique for reducing chromium VI is available and has been shown to reduce the adverse health effect. In Member States where this technique has already been introduced, the number of eczema cases resulting from exposure to cement has been dramatically reduced. In its opinion of 27 June 2002, the CSTEE confirmed the scientific findings. On the basis of existing scientific evidence, the Commission proposes to restrict the marketing and use of cement containing more than 2 ppm chromium VI.

The proposed Directive would introduce harmonised provisions on the marketing and use of NP, NPE and cement.

2. JUSTIFICATION FOR THE PROPOSAL

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

The objective of the proposal is to introduce harmonised provisions with regard to NP, NPE and cement and thus preserving the Internal Market, as required by Article 95 of the Treaty. The objective is also, as set out in Article 95(3) of the Treaty, to ensure a high level of protection to health and the environment.

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

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OJ L 84, 5.4.1993, p. 1.

OJ L 319, 4.12.2001, p. 30.

the functioning of the Internal Market to the benefit of the protection to 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, the twenty-sixth amendment, providing for harmonised rules on the use of NP, NPE and cement.

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

The proposed twenty-sixth amendment establishes uniform rules for the circulation of NP, NPE and cement. It also guarantees a high level of protection of health and the environment. The proposed twenty-sixth amendment is the only way to meet these goals. Targets would be insufficient.

3. RATIONALE OF THE PROPOSAL

The proposed twenty-sixth amendment would extend Annex I to Directive 76/769/EEC by adding the NP, NPE and cement. The use of NP, NPE and cement is thus restricted.

4. COSTS AND BENEFITS

4.1. Costs

The proposed Directive should pose only minor problems to the industry or trade, as the use of NP and NPE is declining. In fact, companies have already developed substitutes or alternative techniques. With regard to the chromium VI in cement, the proposed Directive should pose only minor problems to the industry or trade as the technology for reducing chromium VI is available at low costs and is already applied by numerous enterprises in several Member States.

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 ban will ensure that for certain uses which pose a risk to human health or to the environment NP, NPE, and cement containing more than 2 ppm chromium VI, are no longer on the market.

5. PROPORTIONALITY

The twenty-sixth amendment would yield benefits in terms of protecting human health and environment. This will be achieved at little cost.

6. CONSULTATIONS PERFORMED IN PREPARING THE DRAFT TWENTY-SIXTH AMENDMENT

Advice on the preparation of the proposal was sought through meetings involving experts from Member States, the European Chemical Industry Council (CEFIC), Eurométaux, the European Cement Association, the European Federation of Building and Woodworkers. The European Consumers' Organisation BEUC also gave its opinion.

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

8. EUROPEAN PARLIAMENT AND ECONOMIC AND SOCIAL COMMITTEE

In compliance with Article 95 of the Treaty, the Codecision Procedure with the European Parliament is applicable. The 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 Commission³,

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

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁵,

Whereas:

- (1) The risks posed to the environment by nonylphenol (NP) and nonylphenol ethoxylate (NPE) have been assessed in accordance with Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁶. The assessment identified a need to reduce those risks and, in its opinion of 6/7 March 2001, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed that conclusion.
- (2) Commission Recommendation 2001/838/EC⁷, adopted within the framework of Regulation (EEC) No 793/93, proposed a risk limitation strategy for NP and NPE, recommending in particular that restrictions be placed on their marketing and use.
- (3) In order to protect the environment, it therefore appears necessary that the placing on the market and the use of NP and NPE should be restricted to specific uses.
- (4) Scientific studies have also shown that cement preparations containing chromium VI may cause allergic reactions in certain circumstances, if there is direct and prolonged contact with the human skin.
- (5) The CSTEE has confirmed the adverse health effects of chromium VI in cement.

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⁵ OJ C ...

OJ L 84, 5.4.1993, p. 1.

OJ L 319, 4.12.2001, p. 30.

- (6) In order to protect human health, it therefore appears necessary to restrict the placing on the market and the use of cement. In particular, the placing on the market and the use of cement or cement preparations containing more than 2 ppm chromium VI should be restricted in the case of manual activities where there is a risk of contact with the skin.
- (7) 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 preparations⁸ should therefore be amended accordingly.
- (8) The objective of this Directive is to introduce harmonised provisions with regard to NP, NPE and cement, thus preserving the internal market whilst ensuring a high level of protection for health and the environment, as required by Article 95 of the Treaty.
- (9) This Directive does not affect 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 work ⁹, and 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] ¹⁰ and Council Directive 98/24/EC on the protection of the health and safety of workers from the risks 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 xx xx 200x [one year after the date of its entry into force]. They shall forthwith inform the Commission thereof.

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.

⁸ OJ L 262, 27.9.1976, p. 201.

⁹ OJ L 183, 29.6.1989, p. 1.

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 The President

For the Council The President

ANNEX

The following points [XX] and [XX] are added to Annex I of Directive 76/769/EEC:

The following points [222] and [222] are added to finite it of Birective following.			
"[XX] (1) (2)	Nonylphenol C ₆ H ₄ (OH)C ₉ H ₁₉ Nonylphenol ethoxylate	May not be placed on the market or used as a substance or constituent of preparations in concentrations equal or higher than 0,1% by mass nonylphenol or 1% by mass nonylphenol ethoxylate for the following purposes:	
	$(C_2H_4O)_nC_{15}H_{24}O$	(1)	industrial and institutional cleaning except:
			 controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,
			 cleaning systems with special treatment where the washing liquid is recycled or incinerated;
		(2)	domestic cleaning;
		(3)	textiles and leather processing except:
			 processing with no release into waste water and where the NPE is fully bound in the polymer matrix (finishing agents, textile printing, dyestuffs),
			 systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);
		(4)	emulsifier in agricultural teat dips;
		(5)	metal working except:
			 uses in controlled closed systems where the washing liquid is recycled or incinerated;
		(6)	manufacturing of pulp and paper;
		(7)	cosmetics including shampoos;
		(8)	other personal care products except:
			spermicides.
[XX]. Cement		May not be placed on the market or used as a substance or constituent of preparations, if it contains more than 0,0002 % soluble chromium VI of the total dry weight of the cement, for manual activities, where there is a risk of contact to the skin.	
		In addition, if ferrous sulphate is used as a reducing agent, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement preparations shall be legibly and indelibly marked with information on the packing date and storage period during which the content of soluble chromium VI is below 0,0002 % of the total dry weight of the cement."	