

EN

ENTR 2001/xxx/E3 yy

WORKING DOCUMENT

For a Proposal for a

DIRECTIVE 200x/xx/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of [...]

amending, for the twenty-sixth 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

(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 health of 2-(2butoxyethoxy)ethanol (DEGBE) and 2-(2-methoxyethoxy)ethanol (DEGME) have been assessed under Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances⁴. The risk assessment identified a need for reducing the risks from DEGBE and DEGME to health. In its opinion of 27th November 1998, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed the conclusions of the assessment of these substances and the need to reduce risks to health.

¹ OJ C xx.

² OJ C xx.

³ Opinion of the European Parliament of 14 November 2000 (not yet published in the Official Journal), Council Common Position of 12 March 2001 (OJ C 142, 15.5.2001, p. 1) and European Parliament Decision of 16 May 2001.

⁴ OJ L 84, 5.4.1993, p. 1.

- (3) The Commission has adopted a Recommendation⁵ in the framework of Regulation (EEC) 793/93 on a risk reduction strategy for DEGBE and DEGME providing for restrictions on marketing and use to control risk to the health.
- (4) In order to protect health, the placing on the market and the use of DEGBE and DEGME should be restricted to specific uses.
- (5) An assessment of the risks to health from Dichloromethane (DCM) identified a need for reducing risks⁶. In its opinion of 5th September 2000, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed the conclusions of the assessment and the need to reduce risks to health.
- (6) In order to protect health, the placing on the market and the use of DCM in formulations used for paint strippers should be prohibited.
- (7) The risks to the environment of Nonylphenol (NP) and Nonylphenol ethoxylate (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. The risk assessment identified a need for reducing risks of NP and NPE to the environment. In its opinion of 6/7 March 2001, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) confirmed the conclusions of the assessment of NP and NPE and the need to reduce risks to the environment.
- (8) The Commission has adopted a Recommendation⁷ 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 risk to the environment.
- (9) In order to protect the environment the placing on the market and the use of NP and NPE should be restricted to specific uses.
- (10) It is known that cement preparations containing chromium (VI) may cause allergic reactions in certain circumstances, if there is a direct and prolonged contact to the human skin⁸.
- (11) The risks to the health of chromate-rich cement and cement preparations have been identified in the framework of the risk assessment on Chromium compounds under Council Regulation (EEC) 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances.
- (12) In order to protect health, the placing on the market and the use of chromate-rich cement and cement preparations should be restricted in the case of certain manual activities where there is a risk of contact to the skin.
- (13) 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 work⁹, and in individual directives based thereon, in

⁵ OJ L 292, 13.11.1999, p. 42.

⁶ TNO-Report ("Methylene chloride: Advantages and drawbacks of possible market restrictions in the EU", STB-99-53)

⁷ OJ C , , p. .

⁸ Acta Dermato-Venerologica Supplementum 179 (1992), Contact Dermatitis 1998, 38: 329-31.

⁹ OJ L 183, 29.6.1989, p. 1.

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 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 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.

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

¹⁰ OJ L 196, 26.7.1990, p. 1.

ANNEX

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

<p>“[XX]. 2-(2butoxyethoxy)ethanol CAS No. 112-34-5</p>	<p>May not be placed on the market or used as a substance or constituent of preparations in a concentration equal or higher than 5 % by mass¹¹ in paints intended for spray applications for sale to the general public.</p>
<p>[XX]. 2-(2-methoxyethoxy)ethanol CAS No. 111-77-3</p>	<p>May not be placed on the market or used as a substance or constituent of preparations in a concentration equal or higher than 1.0 % by mass in paints and paint strippers intended for sale to the general public¹².</p>
<p>[XX]. Dichloromethane CAS No. 75-09-2</p>	<p>May not be placed on the market or used as a substance or constituent of preparations in a concentration equal or higher than 1.0 % by mass in paint strippers or products used in the cleaning of facades.¹³</p> <p>However, this provision shall not apply to preparations</p> <p>- supplied in containers of a capacity not greater than 1000 ml intended for professional uses, or</p> <p>- formulated such that the vaporisation compared to pure dichloromethane is reduced by a minimum of 95% based on weight loss above an equilibrated surface.</p>
<p>[XX]. 1. Nonylphenol $C_6H_4(OH)C_9H_{19}$</p> <p>2. Nonylphenol ethoxylate $(C_2H_4O)_n C_{15}H_{24}O$</p>	<p>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 %¹⁴ by mass Nonylphenol ethoxylate for the following purposes:</p>

¹¹ D, NL: 10% is too high; Fr: “feasible” is too open; Industry: maintain the wording of the Community strategy.

¹² Agreement in principle

¹³ D: substance caused fatal accidents and there is limited sale to the general public;
A: substance is banned for all uses in A;
D, F, SW: extend ban to also cover professional users;
Fr: reserve on extension to professional users;
Industry: concerns on substitutes; vapour retarding additives are available

¹⁴ F, SW: 1% is too high; UK: 1% is appropriate

<p>[XX]. Cement</p>	<p>1) industrial and institutional cleaning except</p> <ul style="list-style-type: none"> - controlled closed dry cleaning systems where the washing liquid is recycled or incinerated¹⁵ - cleaning systems with special treatment where the washing liquid is recycled or incinerated <p>2) domestic cleaning</p> <p>3) textiles and leather processing except</p> <ul style="list-style-type: none"> - 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 sheepskin¹⁶) <p>4) emulsifier in agricultural teat dips</p> <p>5) metal working except</p> <ul style="list-style-type: none"> - uses in controlled closed systems <p>6) manufacturing of pulp and paper</p> <p>7) cosmetics including shampoos</p> <p>8)¹⁷ other personal care products except</p> <ul style="list-style-type: none"> - spermicides. <p>9)¹⁸</p> <p>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)¹⁹ of the total dry weight of the cement, for manual activities, where there is a risk of contact to the skin, such as²⁰</p> <ul style="list-style-type: none"> - brick laying
-------------------------	---

¹⁵

proposed by F

¹⁶

COTANCE: no substitutes are available

¹⁷

separate numbered entry suggested by NL

¹⁸

F prefers to add pesticides; D: pesticides pose low risk for aquatic environment;

¹⁹

Most of the Member States agree in principle; DK: in DK since 1980 no new cases of Cr VI-induced skin diseases

²⁰

SW, UK: we should avoid example list

	<ul style="list-style-type: none">- floor construction- tile laying- maintenance and repair work. <p>In addition, if Ferrous sulfate is used as a reducing agent:</p> <p>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.^{21,}</p>
--	--

²¹ DK, SW, UK request further labelling provisions to address the stability of ferrous sulfate