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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 2.10.2007  
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2007/0200 (COD)

Proposal for a

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate**

**(amendment of Council Directive 76/769/EEC)**

(presented by the Commission)

{SEC(2007) 1237}

{SEC(2007) 1238}

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE PROPOSAL

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 marketing and use of certain dangerous substances and preparations establishes a framework for harmonised rules throughout the European Union concerning the placing on the market and use of dangerous substances and preparations.

Directive 76/769/EEC is used to manage the risks to human health and the environment from dangerous substances. Dangerous substances and preparations listed in Annex I to Directive 76/769/EEC may only be placed on the market and used under specified conditions.

It is proposed to manage risks on the following five substances by listing them in Annex I of Directive 76/769/EEC:

- 2-(2-methoxyethoxy)ethanol (DEGME)
- 2-(2-butoxyethoxy)ethanol (DEGBE)
- methylenediphenyl diisocyanate (MDI)
- cyclohexane
- ammonium nitrate (AN).

Risk assessments in the framework of Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, have been carried out for DEGME, DEGBE, MDI and cyclohexane. The risk assessments identified risks to human health for consumers when using preparations containing these four substances. Commission Recommendations 1999/721/EC<sup>1</sup> and 2007/xxx/EC<sup>2</sup> adopted within the framework of Regulation (EEC) No 793/93, recommended marketing and use restrictions at Community level under Council Directive 76/769/EEC as the most appropriate strategy to limit the risks for consumers.

Ammonium nitrate is a substance that can act as an oxidant and the risk to be addressed arises from its ability to explode when mixed with certain other substances. Ammonium nitrate is widely used as a fertiliser in the EU and ammonium nitrate fertilisers should meet certain minimum safety standards before being placed on the market.

#### 1.1. Introduction to the chemical substances (chemical identities and uses)

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<sup>1</sup>Commission Recommendations 1999/721/EC of 12 October 1999 on the results of the risk evaluation and on the risk reduction strategies for the substances: 2-(2-butoxyethoxy)ethanol; 2-(2-methoxyethoxy)ethanol; Alkanes, C10-13, chloro; Benzene, C10-13-alkyl derivs.

<sup>2</sup>Commission Recommendations on the results of the risk evaluation and the risk reduction strategies for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; Bis(pentabromophenyl)ether; 5-tert-butyl-2,4,6-trinitro-m-xylene<sup>2</sup>. To be published

#### 1.1.1. 2-(2-methoxyethoxy)ethanol (DEGME)

2-(2-methoxyethoxy) ethanol (DEGME) belongs to the group of glycol ethers, which are mainly used as co-solvents in a wide variety of applications. The substance is identified by the CAS number 111-77-3 and the EINECS number 203-906-6.

The main use of DEGME is as anti-icing agent in jet fuel. DEGME is further used as chemical intermediate, basic chemical (processing solvent) and solvent in paints and varnishes, paint strippers, cleaning agents, self-shining emulsions, floor sealants, windscreen washer liquids, skin-cleaning products (soap) and skin-care products<sup>3</sup>.

#### 1.1.2. 2-(2-butoxyethoxy)ethanol (DEGBE)

2-(2-butoxyethoxy)ethanol (DEGBE) belongs to the group of glycol ethers, which are mainly used as co-solvents in a wide variety of applications. The substance is identified by the CAS number 112-34-5 and the EINECS number 203-961-6.

DEGBE is used in paints, dyes, inks, detergents and cleaners. The major function of this agent is to dissolve various components of mixtures in both aqueous and non-aqueous systems<sup>4</sup>.

#### 1.1.3. methylenediphenyl diisocyanate (MDI)

Methylenediphenyl diisocyanate (MDI) refers to a number of isomeric compounds with the chemical formula  $C_{15}H_{10}N_2O_2$ . The material defined by EINECS number 247-714-0 and CAS number 26447-40-5, encompasses all isomeric mixtures and also all of the specific isomers even if those isomers have specific CAS or EINECS numbers.

MDI is mainly used in the industrial production of rigid polyurethane foams with world wide use. Many other uses are in the fields of paints and coatings, adhesives, sealants (including weather resistant sealing material), elastomers, and footwear. There is use also in the production of particle board (for the bonding of wood) and mould cores for the foundry industry<sup>5</sup>.

#### 1.1.4. cyclohexane

Cyclohexane is a cyclic alkane with the molecular formula  $C_6H_{12}$ . It is identified by the CAS number 110-82-7 and the EINECS number 203-806-2.

The main use as a solvent is in adhesives (cyclohexane combined with other solvents). These are mostly “neoprene” (polychloroprene) based adhesives used in the leather industry (shoes), the construction industry (floor coatings) and the automobile equipment industry. Cyclohexane adhesives products are mainly used by craftsmen but also by the general public in household and “do-it-yourself” products<sup>6</sup>.

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<sup>3</sup> Risk assessment report under Council Regulation (EEC) 793/93 published in 1999, available at: <http://ecb.jrc.it/esis/>

<sup>4</sup> Risk assessment report under Council Regulation (EEC) 793/93 published in 1999, available at: <http://ecb.jrc.it/esis/>

<sup>5</sup> Risk assessment report under Council Regulation (EEC) 793/93 published in 2005, available at: <http://ecb.jrc.it/esis/>

<sup>6</sup> Risk assessment report under Council Regulation (EEC) 793/93 published in 2004, available at: <http://ecb.jrc.it/esis/>

### 1.1.5. ammonium nitrate (AN)

Ammonium nitrate, molecular formula  $\text{NH}_4\text{NO}_3$  has the CAS number 6484-52-2 and the EINECS number 229-347-8. Although it is not formally classified as an oxidising substance, it can have strong oxidising properties under certain conditions.

Ammonium nitrate is widely used throughout the EU as a fertiliser, but it also constitutes the main ingredient in the commercial blasting agent ANFO (ammonium nitrate fuel-oil). Ammonium nitrate is used in fertiliser both alone, and in blends with other nutrient substances. In the terminology of the fertiliser industry, these two categories are referred to as straight and compound fertilisers, whereas the equivalent terminology in the chemicals legislation is substances and preparations. Fertilisers containing more than 28% nitrogen are known as high-nitrogen ammonium nitrate fertilisers.

## 1.2. Risk evaluation and risk management measures

### 1.2.1. 2-(2-methoxyethoxy)ethanol (DEGME)

The risk assessment carried out in accordance with Council Regulation (EEC) No 793/93 by Netherlands concluded that there was a need for limiting the risks for human health (workers and consumers). Health risks for consumers were expected during the use of DEGME in paints or paint strippers.

The risk assessment report was submitted to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) which adopted its opinion during the 6th plenary meeting of 27 November 1998. Apart from general comment on the derived Health Based Occupational Reference Values which were not fully supported by CSTEE, the risk assessment report was considered of good quality.

The Commission Recommendation 1999/721/EC<sup>8</sup>, contained a strategy to limit the risks for consumers in order to prevent dermal exposure to DEGME in paints and paint strippers. For workers the legislation already in force under Council Directive 98/24/EC<sup>9</sup> was considered to give adequate protection against the risks of DEGME.

According to a survey carried out by the European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE) in 2000, there was only a negligible use of DEGME in paints sold to the general public. CEPE had recommended its member companies to replace DEGME by alternatives in all consumer paints and they do not longer intentionally use DEGME in paints for the consumer market.

In December 2006, the Commission contacted European paint strippers manufacturers who confirmed that they no longer sell DEGME for consumer uses.

### 1.2.2. 2-(2-butoxyethoxy)ethanol (DEGBE)

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<sup>7</sup> Opinion available at: [http://ec.europa.eu/health/ph\\_risk/committees/sct/sct\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm)

<sup>8</sup> OJ, L292, 13.11.1999 p 42.

<sup>9</sup> Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L 131, 5.5.1998, p. 11

The risk assessment carried out in accordance with Council Regulation (EEC) No 793/93 by Netherlands concluded that there was a need for limiting the risks for human health (workers and consumers). The conclusions of a need to limit the risk for consumers were based on the risks from the use of DEGBE in paint spraying applications.

The risk assessment report was submitted to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), which adopted its opinion during the 6th plenary meeting of 27 November 1998<sup>10</sup>. Apart from general comments on the derived Health Based Occupational Reference Values, which were not fully supported by CSTEE, the risk assessment report was considered of good quality.

Commission Recommendation 1999/721/EC defined a risk reduction strategy for DEGBE<sup>11</sup>. The strategy recommended not making available to consumers paints containing DEGBE that are intended to be sprayed. Furthermore, paints containing DEGBE placed on the market for supply to the general public should clearly indicate that they should not be sprayed. For workers the legislation already in force under Council Directive 98/24/EC of 7 April 1998 was considered to give adequate protection against the risk of DEGBE.

In October 2001, the Commission conducted a study on “the advantages and drawbacks of introducing Community-wide restrictions on the marketing and use of DEGBE”. The study examined the advantages associated with the possible restrictions and their drawbacks (economic or otherwise), the suitability of substitute chemicals and the implications for small and medium enterprises. Consideration was given during the study to a number of possible risk reduction measures that could be adopted such as a ban of preparations containing DEGBE in spray painting or additional labelling requirements. A threshold for the maximum allowable concentration of DEGBE in paints was considered an appropriate measure to eliminate the risks for consumers in spray painting applications.

In February 2007, after the discussion of the Working Group of the Competent Authorities responsible for the implementation of Directive 76/769/EEC (Limitations Working Group), the Oxygenated Solvents Producers Association (OSPA) provided new information on the toxicity and exposure to DEGBE<sup>12</sup> which was evaluated by the Rapporteur of the EU risk assessment, the Netherlands. Using this information from a drinking water study, the lung effects found in an inhalation study were assessed as of local acute character rather than systemic, and based on conservative assumptions with regard to the respirable fraction and the particle size distribution of aerosols it was concluded that the safe concentration limit of DEGBE in spray paints is 3%. A similar evaluation was also conducted for other paints containing DEGBE and the exposure to DEGBE vapour from surfaces painted with a brush or a roller was not of toxicological concern. Consequently, no risks were identified from brushing and rolling applications.

### 1.2.3. methylenediphenyl diisocyanate (MDI)

The risk assessment, carried out in accordance with Council Regulation (EEC) No 793/93 by Belgium, concluded that there is a need for limiting the risks for human health (workers and consumers).

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<sup>10</sup> Opinion available at: [http://ec.europa.eu/health/ph\\_risk/committees/sct/sct\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm)

<sup>11</sup> OJ, L 292, 13.11.1999 p 42.

<sup>12</sup> Statement from the “Oxygenated Solvents Producers Association, OSPA”, May 2007 provided to the Commission and the Members of the Limitations Working Group.

The risk assessment report was submitted to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), which adopted its opinion during the 41st plenary meeting of 8 January 2004<sup>13</sup>. The CSTEE confirmed the conclusions of the risk assessment.

A human health risk reduction strategy for MDI was prepared by ECOLAS on behalf of the Belgian Rapporteur in November 2004. The conclusions of this study recommended personal protection equipment and sufficient instructions for preparations containing MDI sold to the general public.

A study was conducted by BIPRO on behalf of the Belgian Rapporteur in June 2006, on the advantages and drawbacks of various possible measures restricting the marketing and use of MDI. The conclusions of this study recommended restricting marketing and use of preparations containing MDI which are sold to the general public to those being sold with adequate personal protection equipment, as well as additional handling and use instructions.

Commission Recommendation 2007/xxx/EC defined a strategy for limiting the risks for MDI<sup>14</sup>. The strategy considers that it is necessary to adopt marketing and use restrictions for the use of MDI in consumer products. For workers the strategy recommended to establish at Community level occupational exposure limit values for MDI in accordance with Council Directive 98/24/EC.

#### 1.2.4. cyclohexane

The risk assessment was carried out in accordance with Council Regulation (EEC) No 793/93 by France which concluded that there was a need for limiting the risks for human health (workers and consumers) due to the exposure arising from use of adhesives containing cyclohexane. Adhesives containing cyclohexane are considered the main consumer use and the risk assessment was focused specifically on carpet laying applications for which the highest exposure was expected.

The risk assessment report was submitted to the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), which adopted its opinion during the 29th plenary meeting of 9 January 2002<sup>15</sup>. The CSTEE confirmed the conclusions of the risk assessment.

Commission Recommendation 2007/xxx/EC<sup>16</sup> defined a strategy for limiting the risk for consumers and it recommended marketing and use restrictions for the use of cyclohexane in neoprene based adhesives intended for consumer use. For workers the legislation already in force under Council Directive 98/24/EC of 7 April 1998 was considered to give adequate protection against the risks of cyclohexane during industrial uses.

#### 1.2.5. ammonium nitrate (AN)

The possibility of accidental explosion for AN fertilisers exists only if the ammonium nitrate content, or more precisely the total nitrogen content, exceeds a critical value. Such high-

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<sup>13</sup> Opinion available at:  
[http://ec.europa.eu/health/ph\\_risk/committees/sct/sct\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm)

<sup>14</sup> OJ, C [...], [...], p. [...]

<sup>15</sup> Opinion available at:  
[http://ec.europa.eu/health/ph\\_risk/committees/sct/sct\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/sct/sct_opinions_en.htm)

<sup>16</sup> OJ, C [...], [...], P.[...]

nitrogen AN fertilisers are defined in Regulation (EC) No 2003/2003 on fertilisers as those containing more than 28% by mass of nitrogen in relation to ammonium nitrate. Ammonium nitrate based fertilisers containing less than 28% nitrogen are not considered to pose a risk of explosion under normal conditions of handling and use.

To circulate freely on the internal market, fertilisers with a high ammonium nitrate content must comply with a test for resistance to detonation as specified in Regulation (EC) No 2003/2003. They must also meet a number of technical requirements concerning their porosity, particle size, pH and impurity content.

However, Regulation (EC) No 2003/2003 is only applicable to fertilisers falling within its scope, and that are marketed as “EC fertiliser”, so that it cannot be used to impose measures on non-EC fertilisers. Manufacturers of non-EC fertilisers can comply with the Regulation on a voluntary basis.

For fertilisers intended for sale only within a single Member State, manufacturers may choose to conform only to requirements existing at national level. Therefore these fertilisers may not conform with the safety requirements set at the European level. To ensure a uniform level of safety within the EU, all ammonium nitrate fertilisers should conform to the same safety requirements.

In addition to the risk of detonation under conditions of normal handling and use in agriculture, AN fertilisers have also been used by terrorists to manufacture explosives. To make acquisition of high nitrogen AN fertilisers for deliberate misuse more difficult, the nitrogen content of fertilisers sold to the general public should be limited to the lower limit of 20%.

### 1.3. Intended effects of EU legislation

Due to the fact that there is a need for limiting the risks for consumers and in particular for ensuring adequate protection during the “Do-It-Yourself” uses, certain restrictions should be applied for preparations containing DEGME, DEGBE, MDI or cyclohexane which are placed on the market for supply to the general public.

The present Decision would amend Annex I to Directive 76/769/EEC by adding the following chemical substances: DEGME, DEGBE, MDI and cyclohexane. The placing on the market for supply to the general public of preparations containing these substances will be restricted for certain applications.

Relevant measures, such as maximum concentration of the substance (e.g. DEGME and DEGBE), package size reduction (e.g. cyclohexane), mandatory sale of gloves with the product (e.g. MDI) and additional instructions on the product (e.g. DEGBE, MDI, cyclohexane) should be applied under the provisions of the present Decision in order to reduce the possible risks to consumers when using preparations containing these substances.

In order to ensure a uniform high level of safety for farmers and distributors within the EU for all ammonium nitrate fertilisers, and to limit access to high nitrogen fertilisers to agricultural professionals the Annex I to Directive 76/769/EEC should also be amended to impose the same safety requirements on all ammonium nitrate fertilisers marketed in the EU, and to limit the nitrogen content of the ammonium nitrate fertilisers that are sold to the general public.



## 2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

### 2.1. Consultations

For DEGBE, DEGME, MDI and cyclohexane, in addition to the various studies mentioned in the previous chapter, advice on the preparation of the proposal was sought through a number of meetings of the Working Group of the Competent Authorities responsible for the implementation of Directive 76/769/EEC. Experts from industry, the European Chemical Industry Council (Cefic) and other industry organisations were consulted, as was the European Consumers Organisation (BEUC).

For ammonium nitrate, advice on the preparation of the proposal was sought at a meeting on 24 March 2006 of the Commission's Working Group on Fertilisers involving experts from the Competent Authorities and Industry, represented by EFMA<sup>17</sup>, which concluded that: "... a number of actions that should be considered to improve the safety of ammonium nitrate fertilisers in normal use. ... use of 76/769/EEC should be considered to bring all ammonium nitrate fertilisers within the scope of the Fertiliser Regulation, which currently addresses only "EC fertilisers".

### 2.2. Impact Assessment

A detailed impact assessment has been prepared and was sent to the Impact Assessment (IA) Board on 29 May 2007 which expressed its opinion on 15 June 2007 after the Board meeting on 13 June 2007.

All the comments of the Board (IA quality checklist and final opinion) have been included in the final impact assessment version<sup>18</sup>.

The main findings of the impact assessment are as follows.

#### 2.2.1. Conclusions of the Impact assessment

For DEGME:

A total ban of the placing on the market paints and paint strippers containing DEGME for consumer use is an effective and efficient measure to eliminate the risks for consumers. From the analysis conducted there are no additional costs for industry, therefore this measure will be proportionate.

For DEGBE:

Setting a limit value of 3% for DEGBE in spray paints to be sold to the general public is an effective and efficient measure to eliminate the risks to consumers. This measure will not cause high costs to industry as the content of DEGBE in most spray paints is already around or below 3%. The additional instruction "Do not use in paint spraying equipment" on all other paints containing DEGBE above the limit of 3% will avoid misuse by consumers. The costs for industry for a change in labelling are limited and can be reduced through a longer

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<sup>17</sup> European Fertilizer Manufacturers Association

<sup>18</sup> Commission Staff working document: "Impact assessment report" available at: [http://ec.europa.eu/enterprise/chemicals/studies\\_en.htm](http://ec.europa.eu/enterprise/chemicals/studies_en.htm)

transition period before the measure will have to be implemented. Therefore this measure will be proportionate.

For MDI:

A requirement to add polyethylene gloves and specific warnings and use instructions to all products containing MDI sold to the general public are effective and efficient measure to reduce the health risks to consumers. Consumers can reduce dermal exposure and will be well informed to avoid misuse during the application of MDI products. The costs of polyethylene gloves are low compared to the product price and the costs for change in labelling can be reduced if a longer transition period is foreseen before the measure will have to be implemented. Therefore the additional requirement of gloves and more specific instructions on the products will be proportionate measures.

During the Limitations Working Group meetings, the Member States Competent Authorities, the Stakeholder and the Commission agreed that a study to collect more data on possible cases of respiratory allergy due to products containing MDI. The study will involve specialised centres and will be agreed by the Commission. Based on the results of this study and further analysis of cost-benefits if the risks for consumers will be confirmed, further protective measures will have to be considered.

For Cyclohexane:

Additional labelling "Do not use for carpet laying" and "Do not use under conditions of poor ventilation" as well as a reduced package size to 650g for neoprene-based adhesives containing cyclohexane and sold to the general public are effective and efficient measures to reduce the risks for consumers. The costs for industry for changing the labelling are not very high and can be reduced if a longer transition period is foreseen before the measure will have to be implemented. Therefore these measures will be also proportionate.

For Ammonium Nitrate (AN):

Restricting the marketing of AN fertilisers in such a way that placing on the market of fertilisers with a nitrogen content  $> 28\%$  is only possible when they meet the safety requirements of Regulation (EC) No 2003/2003, is the most effective and cost efficient option to ensure that all AN fertilisers would meet harmonised and recognised safety standards: currently Member States apply different measures for national fertilisers. This measure is needed to cover the gap in the current legislation which allows the sale of national fertilisers in parallel with the sale of "EC fertilisers" under Regulation (EC) No 2003/2003. Sale to the general public will be restricted to fertilisers containing  $<20\%$  nitrogen. The loss of sales to the general public of fertiliser containing more than 20% nitrogen is negligible and will be compensated through sales of other fertiliser types of equivalent performance at similar cost.

### 3. LEGAL ELEMENTS OF THE PROPOSAL

#### 3.1. Legal basis

The legal basis of the proposal is Article 95 of the Treaty.

The present Decision would provide harmonised rules for the placing on the market and use of DEGME, DEGBE, MDI and cyclohexane preparations for supply to the general public. It

would also provide harmonised rules for the placing on the market of AN as a substance and in preparations for use as a fertiliser.

The present Decision would establish uniform rules for the circulation of the products and it would avoid obstacles to trade because of differences in legislation between the Member States. This proposed amendment to the Directive 76/769/EEC would improve the conditions for the functioning of the Internal Market and it would guarantee a high level of protection of human health.

### 3.2. Subsidiarity and proportionality principles

Council Directive 76/769/EEC relating to restrictions on the placing on the market and use of certain dangerous substances and preparations, seeks to establish harmonised rules throughout the EU and to avoid divergent national legislation, which is liable to cause barriers to intra-community trade. This cannot be achieved by leaving the responsibility to act solely to the Member States.

The measures proposed in the present Decision are proportionate insofar as they do not go beyond what it required to achieve the aim of improving the protection of human health whilst the economic costs to industry and society at large for all the specific applications are limited.

### 3.3. Choice of instruments

The Commission has chosen Council Directive 76/769/EEC as the best instrument to preserve the Internal Market and at the same time ensure a high level of protection of human health and the environment. It is therefore in conformity with Article 95(3) of the Treaty.

Directive 76/769/EEC will be repealed on 1 June 2009 by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. The amendments to be made to Annex I of Directive 76/769/EEC by this Decision will be applied after 1 June 2009 and will be introduced in Annex XVII of Regulation (EC) No 1907/2006.

It is more appropriate to amend the Annex I of Directive 76/769/EEC using a Decision rather than a Directive as transposition of the proposed restrictions into national law would be accomplished only a few months before the Directive 76/769/EEC is repealed. Transposition will therefore not serve any useful purpose. In this situation a Decision is a more appropriate legal act than a Directive.

## 4. BUDGETARY IMPLICATION

There are no budgetary implications arising from the present Decision.

Proposal for a

**DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of certain dangerous substances and preparations 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate**

**(amendment of Council Directive 76/769/EEC)**

**(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<sup>1</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>2</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>3</sup>,

Whereas:

- (1) The risks posed to human health by 2-(2-methoxyethoxy)ethanol (DEGME), 2-(2-butoxyethoxy)ethanol (DEGBE), methylenediphenyl diisocyanate (MDI) and cyclohexane 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 substances<sup>4</sup>. The risk assessment for all these chemical substances identified the need to reduce the risks posed to human health. Those conclusions were confirmed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE).
- (2) Commission Recommendations 1999/721/EC of 12 October 1999 on the results of the risk evaluation and on the risk reduction strategies for the substances: 2-(2-butoxyethoxy)ethanol; 2-(2-methoxyethoxy)ethanol; Alkanes, C10-13, chloro; Benzene, C10-13-alkyl derivs.<sup>5</sup> and 2007/xxx/EC on the results of the risk evaluation and the risk reduction strategies for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2-yne-1,4-diol; Methyloxirane; Aniline; 2-

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<sup>1</sup> OJ C , , p. .

<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

<sup>4</sup> OJ L 84, 5.4.1993,p. 1. Regulation as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

<sup>5</sup> OJ L 292, 13.11.1999, p. 42

Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; Bis(pentabromophenyl)ether; 5-tert-butyl-2,4,6-trinitro-m-xylene<sup>6</sup>, adopted within the framework of Regulation (EEC) No 793/93, proposed a strategy for limiting the risks for DEGME, DEGBE, MDI and cyclohexane respectively, recommending that restriction measures under 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 preparations<sup>7</sup> must be applied for preparations containing these substances placed on the market for supply to the general public.

- (3) In order to protect the consumers, it therefore appears necessary to restrict the placing on the market and the use of preparations containing DEGME, DEGBE, MDI and cyclohexane during specific applications.
- (4) DEGME is no longer used as a constituent of consumer paints and paint strippers. The aforementioned risk assessment has shown that there is a risk to the health of consumers through dermal exposure to paints and paint-strippers containing DEGME. Preparations containing DEGME used in paints and paint strippers should therefore not be placed on the market for supply to the general public. A limit value of 0.1% of DEGME in preparations should be adopted for market surveillance purposes.
- (5) DEGBE is used as a constituent of paints. The aforementioned risk assessment for DEGBE has shown that there is a risk to the health of consumers through inhalation exposure during spray painting application. A derived safe concentration limit of 3% for DEGBE in spray paints should be introduced to prevent the risk of inhalation exposure for consumers.
- (6) For other paints than spray paints, a warning against using such paints in spraying equipment should be required where those paints contain a DEGBE concentration limit which is equal to or more than 3%.
- (7) In order to ensure an appropriate phase out of paints not meeting the concentration limits for DEGBE, different dates should be fixed for the applicability of the restriction in respect of the first placing on the market and the final sale for DEGBE in spray paints.
- (8) The risk assessment for MDI has shown that there is a need to limit the risks during consumer applications of preparations containing MDI due to concerns from inhalation and dermal exposure. To prevent and eliminate these risks, the placing on the market for supply to the general public of preparations containing MDI should be permitted only under certain conditions such as the mandatory supply of polyethylene gloves to the packaging and additional instructions to the packaging. As the provision of the protective equipment and the printing of relevant instructions will require specific efforts by producers, a longer period of transition should be provided.

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<sup>6</sup> OJ C , , p. .

<sup>7</sup> OJ L 262, 27.9.1976 p. 201. Directive as last amended by Commission Decision 2006/139/EC (OJ L 384, 29.12.2006, p. 94)

- (9) MDI is widely used in consumer products such as One Component Foam (OCF). The incidence of cases of respiratory allergy among consumers is still unquantified. There is a need to collect more data on possible cases of persons suffering from respiratory allergy as a consequence of exposure to preparations containing MDI. The data should be collected in accordance with a study protocol agreed by the Commission that should involve specialised centres of respiratory allergy. Where new data has been collected and it is demonstrated that there is a further need for restriction measures, the procedure laid down under Article 69 (1) and (3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>8</sup> should apply and be based on those data.
- (10) The risk assessment for cyclohexane focused on the exposure of consumers during the use of preparations containing cyclohexane for carpet laying, and concluded that restriction measures were necessary to reduce the risk for consumers during such applications. Neoprene-based adhesives containing cyclohexane should therefore only be placed on the market for supply to the general public with a reduced package size. Harmonised instructions provided to the product should prevent consumers from the use under inappropriate conditions, i.e. poor ventilation or inappropriate application such as carpet laying.
- (11) Ammonium nitrate, which is widely used throughout the Community as a fertiliser, can act as an oxidising agent. In particular, it has the ability to explode when mixed with certain other substances. Ammonium nitrate fertilisers should therefore meet certain requirements when placed on the market to ensure that they are safe against accidental detonation.
- (12) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers<sup>9</sup> provides for harmonised requirements, including the safety requirements, for ammonium nitrate fertilisers. Fertilisers complying with those requirements may be labelled “EC fertiliser” and may circulate freely on the internal market.
- (13) For fertilisers intended for sale only within a single Member State, manufacturers may choose to conform only to requirements existing at national level. Therefore those fertilisers may not comply with the safety requirements set at Community level. To ensure a uniform level of safety within the Community, all ammonium nitrate fertilisers should therefore conform to the same safety requirements.
- (14) Regulation (EC) No 2003/2003, in its Annex III, specifies a test of resistance to detonation for ammonium nitrate fertilisers containing more than 28% nitrogen. It also specifies a number of physical characteristics and limits on the chemical impurity content for such fertilisers in order to minimise the risk of detonation. Ammonium

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<sup>8</sup> OJ L 396, 30.12.2006, p. 1.

<sup>9</sup> OJ L 304, 21.11.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 162/2007 (OJ L 51, 20.2.2007, p. 7).

nitrate fertilisers that comply with those requirements, or that contain less than 28% nitrogen, are accepted by all Member States as being safe for use in agriculture.

- (15) All ammonium nitrate fertilisers sold within the Community should therefore conform to the safety requirements as set out in Regulation (EC) No 2003/2003.
- (16) Ammonium nitrate fertilisers have been misused for the illicit manufacture of explosives. Fertiliser types that can be used for this purpose have a nitrogen content as low as 20%. Access to those fertiliser types should be limited to professional agricultural use by imposing a limit of less than 20% of the nitrogen content in ammonium nitrate preparations sold to the general public.
- (17) Directive 76/769/EEC should be amended accordingly,
- (18) This Decision is without prejudice to 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<sup>10</sup> and individual Directives based thereon, in particular Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version)<sup>11</sup> and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)<sup>12</sup>,

HAVE ADOPTED THIS DECISION:

#### *Article 1*

Annex I to Directive 76/769/EEC is amended in accordance with the Annex to this Decision.

#### *Article 2*

This Decision shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.

#### *Article 3*

This Decision is addressed to the Member States.

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<sup>10</sup> OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>11</sup> OJ L 158, 30.4.2004, p. 50.

<sup>12</sup> OJ L 131, 5.5.1998, p. 11.

Done at Brussels,

*For the European Parliament*

*For the Council*

*For the European Parliament*  
*The President*

*For the Council*  
*The President*



## ANNEX

In Annex I to Directive 76/769/EEC, the following points 53 to 57 are added:

<p>(53)</p> <p>2-(2-methoxyethoxy)ethanol (DEGME)</p> <p>CAS N°: 111-77-3</p> <p>EINECS N°: 203-906-6</p>	<p>Shall not be placed on the market after [18 months after the entry into force of the Decision], for supply to the general public, as a constituent in paints and in paint strippers in concentrations equal to or higher than 0.1% by mass.</p>
<p>(54)</p> <p>2-(2-butoxyethoxy)ethanol (DEGBE)</p> <p>CAS N°: 112-34-5</p> <p>EINECS N°: 203-961-6</p>	<p>(1) Shall not be placed on the market for the first time after [18 months after the entry into force of the Decision], for supply to the general public, as a constituent of spray paints in concentrations equal to or higher than 3% by mass.</p> <p>(2) Paints not conforming to the concentration limit in point (1) shall not be placed on the market for supply to the general public after [24 months after the entry into force of the Decision].</p> <p>(3) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, paints other than spray paints containing more than 3% by mass of DEGBE that are placed on the market for supply to the general public shall be legibly and indelibly marked by [24 months after the entry into force of the Decision] as follows: "Do not use in paint spraying equipment".</p>
<p>(55)</p> <p>methylenediphenyl diisocyanate (MDI)</p> <p>CAS N°: 26447-40-5</p> <p>EINECS N°: 247-714-0</p>	<p>(4) Shall not be placed on the market after [24 months after the entry into force of the Decision], as a constituent of preparations in concentrations equal to or higher than 0.1% by mass for supply to the general public, unless the packaging:</p>

	<p>(a) contains polyethylene gloves.</p> <p>(b) is marked legibly and indelibly as follows, and without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations:</p> <ul style="list-style-type: none"> <li>– “May cause allergic reactions to individuals already sensitised to diisocyanates other than MDI.</li> <li>– May elicit asthma-like reactions in individuals with asthma.</li> <li>– May cause dermal reactions to individuals suffering from skin problems.</li> <li>– Use a mask with an antigas filter (i.e. type EN 14387:2004 mask with type of filter A1) under conditions of poor ventilation.”</li> </ul> <p>(5) By way of derogation, point (1) (a) does not apply to hot melt adhesives.</p> <p>(6) Natural or legal persons placing on the market for the first time preparations containing MDI shall, within 3 years from the date of implementation of the restrictions set forth in paragraph (1), collect data on possible cases of persons suffering from respiratory allergy during the use of preparations containing MDI and make those data available to the Commission. Data shall be collected in accordance with a study protocol that shall involve specialised centres</p>
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	<p>and shall be agreed by the Commission.</p> <p>(7) Article 69(1) and (3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council*, all apply, unless the data collected demonstrates that there is no need for further restriction measures other than those already applied.</p>
<p>(56)</p> <p>cyclohexane</p> <p>CAS N°: 110-82-7</p> <p>EINECS N°: 203-806-2</p>	<p>(8) Shall not be placed on the market for the first time after [18 months after the entry into force of the Decision], for supply to the general public, as a constituent of neoprene based adhesives in concentrations equal to or higher than 0.1% by mass in package sizes greater than 650 g.</p> <p>(9) Neoprene based adhesives containing cyclohexane and not conforming to (1) shall not be placed on the market for supply to the general public after [24 months after the entry into force of the Decision].</p> <p>(10) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, neoprene based adhesives containing cyclohexane in concentrations equal to or higher than 0.1% by mass that are placed on the market for supply to the general public after [24 months after the entry into force of the Decision] shall be legibly and indelibly marked as follows:</p> <ul style="list-style-type: none"> <li>– “Do not use under conditions of poor ventilation.</li> <li>– Do not use for carpet laying.”</li> </ul>
<p>(57) ammonium nitrate (AN)</p> <p>CAS No 6484-52-2</p> <p>EINECS No229-347-8</p>	<p>(1) Shall not be placed on the market for the first time after [<i>18 months after the entry into force of the Decision</i>] as a substance, or in preparations that contain more than 28% by mass of</p>

	<p>nitrogen in relation to ammonium nitrate, for use as a solid fertiliser, straight or compound, unless the fertiliser complies with the technical provisions for ammonium nitrate fertilisers of high nitrogen content set out in Annex III to Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers**.</p> <p>(2) Shall not be placed on the market for supply to the general public after [18 months after the entry into force of the Decision] as a substance, or in preparations that contain 20% or more by mass of nitrogen in relation to ammonium nitrate.</p>
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\* OJ L 396, 30.12.2006, p.1.

\*\*OJ L 304, 21.11.2003.