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REPORT

on the 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
(COM(2007)0559 – C6-0327/2007 – 2007/0200(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Miroslav Ouzký

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend the common position
- *** Assent procedure
majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend the common position
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the 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

(COM(2007)0559 – C6-0327/2007 – 2007/0200(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0559),
 - having regard to Articles 251(2) and 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0327/2007),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0135/2008),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1

Proposal for a decision – amending act Recital 4

Text proposed by the Commission

(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

Amendment

(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.

containing DEGME. Preparations containing DEGME used in paints, paint strippers, ***cleaning agents, self-shining emulsions and floor sealants*** 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.

Justification

As the Commission's explanatory memorandum states, DEGME poses a risk to human health through dermal exposure. According to the risk assessment report 793/93, and to the explanatory memorandum, DEGME is used in paints, paint strippers, cleaning agents, self-shining emulsions, floor sealants, windscreen washer liquids and skin-cleaning products (soap); therefore the restrictions should apply also to cleaning agents, self-shining emulsions and floor sealants.

Amendment 2

Proposal for a decision – amending act Recital 5

Text proposed by the Commission

(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.

Amendment

(5) DEGBE is used as a constituent of paints, ***dyes, inks, detergents and cleaners***. 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 ***or spray cleaners*** should be introduced to prevent the risk of inhalation exposure for consumers.

Justification

According to the risk assessment, DEGBE poses a risk to the health of consumers through inhalation exposure during spray painting application. The explanatory memorandum states that DEGBE is also used as a constituent of dyes, inks, detergents and cleaners; therefore the restrictions should also apply for the spray form of cleaning products, as the possibility of inhalation is also likely.

Amendment 3

Proposal for a decision – amending act Recital 6

Text proposed by the Commission

(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%.

Amendment

(6) For other than spray paints ***or spray cleaners***, a warning against using such paints ***or cleaners*** in spraying equipment should be required where those paints ***or cleaners*** contain DEGBE *in a* concentration which is equal to or more than 3%.

Justification

According to the explanatory memorandum, DEGBE is also used as a constituent of cleaners; therefore the restrictions should apply also for these products.

Amendment 4

Proposal for a decision – amending act Recital 8

Text proposed by the Commission

(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.

Amendment

(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 ***appropriate*** gloves *in* the packaging and additional instructions *on* 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.

Justification

According to information from institutions in the field of workers' health, there are various types of gloves that are appropriate when using MDI - but none of them are made of

polyethylene. It is therefore preferable to refer to "appropriate gloves", instead of specifying gloves that are not fit for the purpose. The actual type of appropriate gloves can then be set in comitology.

Amendment 5

Proposal for a decision – amending act Recital 16

Text proposed by the Commission

(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.

Amendment

(16) Ammonium nitrate fertilisers have been misused for the illicit manufacture of explosives. Access to those fertiliser types should be limited to professional agricultural use by imposing a limit of less than **28%** of the nitrogen content in ammonium nitrate preparations sold to the general public.

Justification

Many fertilisers produced in Europe contain around 27% ammonium nitrate. The possibility of extracting ammonium nitrate from a fertiliser depends on its quality and not only on the concentration of ammonium nitrate. The explanatory memorandum states that "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", therefore the limit of the nitrogen content should be below 28%.

Amendment 6

Proposal for a decision – amending act Recital 17 a (new)

Text proposed by the Commission

Amendment

(17a) The provisions of this Decision are adopted with a view to being incorporated in Annex XVII of Regulation (EC) No 1907/2006 (REACH), as set out in Article 137(3) of that Regulation.

Justification

This amendment clarifies the relationship between this Decision, Directive 76/769/EEC and the REACH Regulation.

Amendment 7

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 53 – column 2

Text proposed by the Commission

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.

Amendment

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, paint strippers, **cleaning agents, self-shining emulsions and floor sealants** in concentrations equal to or higher than 0.1% by mass.

Justification

As the Commission's explanatory memorandum states, DEGME poses a risk to human health through dermal exposure. According to the risk assessment report 793/93, and to the explanatory memorandum, DEGME is used in paints, paint strippers, cleaning agents, self-shining emulsions, floor sealants, windscreen washer liquids and skin-cleaning products (soap); therefore the restrictions should apply also to cleaning agents, self-shining emulsions and floor sealants.

Amendment 8

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 54 – column 2 – point 1

Text proposed by the Commission

(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.

Amendment

(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 **or spray cleaners** in concentrations equal to or higher than 3%

by mass.

Justification

According to the risk assessment, DEGBE poses a risk to the health of consumers through inhalation exposure during spray painting application. The explanatory memorandum states that DEGBE is also used as a constituent of detergents and cleaners; therefore the restrictions should also apply for the spray form of these products.

Amendment 9

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 54 – column 2 – point 3

Text proposed by the Commission

(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”.

Amendment

(3) Without prejudice to other Community legislation concerning the classification, packaging and labelling of dangerous substances and preparations, paints, **detergents and cleaners** other than **sprays** 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 spraying equipment”.

Justification

According to the risk assessment, DEGBE poses a risk to the health of consumers through inhalation exposure during spray painting application. The explanatory memorandum states that DEGBE is also used as a constituent of detergents and cleaners; therefore the restrictions should also apply for the spray form of these products.

Amendment 10

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 55 – column 2 – point 4 – point (a)

Text proposed by the Commission

Amendment

(a) contains **polyethylene** gloves.

(a) contains **appropriate** gloves.

For the sake of harmonisation, the nature of the appropriate gloves shall be adopted in accordance with the procedure referred to in Article 2a of this Directive.

Justification

According to information from institutions in the field of workers' health, there are various types of gloves that are appropriate when using MDI - but none of them are made of polyethylene. It is therefore preferable to refer to "appropriate gloves", instead of specifying gloves that are not fit for the purpose. The actual type of appropriate gloves can then be set in comitology.

Amendment 11

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 55 – column 2 – point 6

Text proposed by the Commission

Amendment

(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 and shall be agreed by the Commission.

deleted

Justification

Since the conclusion of the Risk Assessment on MDI in 2005 conducted under Existing Substances Regulation 793/93, new exposure data from the Danish Environment Protection Agency, Poison Centres in Germany, UK and Belgium and industry suggest that a risk to consumers does not exist in real life. Before wide ranging new studies are commissioned, it

should be considered, with advice from an appropriate scientific committee, if it is really needed. As the provisions of this decision will be incorporated in the REACH Regulation, relevant Articles of that Regulation will cover any possible need for further studies and restrictions and point 6 should therefore be deleted.

Amendment 12

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 55 – column 2 – point 7

Text proposed by the Commission

Amendment

(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. ***deleted***

Justification

Article 69(1) and (3) of the REACH Regulation (1907/2006) apply irrespective of this provision. They provide both the Commission and the Member States with the ability to further restrict MDI under the REACH restrictions process should it meet the clear criteria agreed by Parliament and Council. The proposed provision creates a lack of coherence between the provisions of this Decision and the REACH Regulation by establishing an unnecessary set of additional criteria for further restrictions on this substance.

Amendment 13

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 56 – column 2 – point 8

Text proposed by the Commission

Amendment

(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.**

(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 **350 g.**

Justification

As this adhesive is not meant to be applied to large surfaces, it seems appropriate to limit the package size. In the risk assessment, the size of 350 g was recommended.

Amendment 14

Proposal for a decision – amending act

Annex

Directive 76/769/EEC

Annex I – point 57 – column 2 – point 2

Text proposed by the Commission

(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.

Amendment

(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 **28%** or more by mass of nitrogen in relation to ammonium nitrate.

Justification

Many fertilisers produced in Europe contain around 27% ammonium nitrate. The possibility of extracting ammonium nitrate from a fertiliser depends on its quality and not only on the concentration of ammonium nitrate. The explanatory memorandum states that "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", therefore the limit of the nitrogen content should be below 28%.

EXPLANATORY STATEMENT

Background and Objective of the Decision

Risk assessments in the framework of Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances, have been carried out for DEGME, DEGBE, MDI and cyclohexane. 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).

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.

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 Ammonium nitrate as a substance and in preparations for use as a fertiliser. The present Decision, which proposes amendments to the Directive 76/769/EEC, would therefore improve the conditions for the functioning of the Internal Market and it would guarantee a high level of protection of human health.

Areas of Use of the Chemicals in Question

DEGME belongs to the group of glycol ethers. 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.

DEGBE belongs to the group of glycol ethers. 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.

MDI refers to a number of isomeric compounds. 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.

Cyclohexane is a cyclic alkane. 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.

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. Fertilisers containing more than 28% nitrogen are known as high-nitrogen ammonium nitrate fertilisers.

Rapporteur's Recommendation

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. It is also appropriate 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.

Considering what has been said above and that the proposed Decision would pose few problems for the industry or trade, the Rapporteur approves the Commission text with a few amendments. The proposed amendments would clarify the relation with REACH, limit unnecessary costs and improve the security for consumers.

PROCEDURE

Title	Restrictions on the marketing and use of certain dangerous substances and preparations	
References	COM(2007)0559 – C6-0327/2007 – 2007/0200(COD)	
Date submitted to Parliament	2.10.2007	
Committee responsible Date announced in plenary	ENVI 11.10.2007	
Committee(s) asked for opinion(s) Date announced in plenary	ITRE 11.10.2007	IMCO 11.10.2007
Not delivering opinions Date of decision	ITRE 22.11.2007	IMCO 21.11.2007
Rapporteur(s) Date appointed	Miroslav Ouzký 9.10.2007	
Discussed in committee	25.2.2008	
Date adopted	26.3.2008	
Result of final vote	+: 46 -: 0 0: 4	
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Pilar Ayuso, Irena Belohorská, Johannes Blokland, John Bowis, Frieda Brepoels, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Anne Ferreira, Matthias Groote, Françoise Grossetête, Satu Hassi, Gyula Hegyi, Caroline Jackson, Christa Klač, Eija-Riitta Korhola, Holger Krahmer, Urszula Krupa, Aldis Kušķis, Peter Liese, Marios Matsakis, Roberto Musacchio, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Dagmar Roth-Behrendt, Karin Scheele, Richard Seeber, Kathy Sinnott, María Sornosa Martínez, Antonios Trakatellis, Evangelia Tzampazi, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Anders Wijkmā, Glenis Willmott	
Substitute(s) present for the final vote	Iles Braghetto, Bairbre de Brún, Jutta Haug, Erna Hennicot-Schoepges	
Substitute(s) under Rule 178(2) present for the final vote	Miguel Angel Martínez Martínez	