Basic information

2007/0200(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Decision	Procedure completed
Dangerous substances and preparations: restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate **Subject** 3.70.13 Dangerous substances, toxic and radioactive wastes (storage, transport) 3.70.20 Sustainable development 4.60.04 Consumer health	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	OUZKÝ Miroslav (PPE-DE)	09/10/2007

Committee for opinion	Rapporteur for opinion	Appointed
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	
IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2904	2008-11-18

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter

Key events

Date	Event	Reference	Summary
02/10/2007	Legislative proposal published	COM(2007)0559	Summary
11/10/2007	Committee referral announced in Parliament, 1st reading		

26/03/2008	Vote in committee, 1st reading		Summary
09/04/2008	Committee report tabled for plenary, 1st reading	A6-0135/2008	
09/07/2008	Decision by Parliament, 1st reading	T6-0345/2008	Summary
09/07/2008	Results of vote in Parliament		
18/11/2008	Act adopted by Council after Parliament's 1st reading		
16/12/2008	Final act signed		
16/12/2008	End of procedure in Parliament		
24/12/2008	Final act published in Official Journal		

Technical information

Procedure reference	2007/0200(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/54277

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE400.667	06/02/2008	
Amendments tabled in committee		PE402.840	05/03/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0135/2008	09/04/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0345/2008	09/07/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03665/2008/LEX	16/12/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2007)0559	02/10/2007	Summary
Document attached to the procedure	SEC(2007)1237	02/10/2007	

Document attached to the procedure	SEC(2007)1238	02/10/2007	
Commission response to text adopted in plenary	SP(2008)4891	27/08/2008	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0483/2008	12/03/2008	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Decision 2008/1348
OJ L 348 24.12.2008, p. 0108 Summary

Dangerous substances and preparations: restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate

2007/0200(COD) - 09/07/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted, by 678 votes to 9 with 7 abstentions, a legislative resolution amending 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. The report had been tabled for consideration in plenary by Miroslav **OUZKY** (EPP-ED, CZ), on behalf of the Committee on the Environment, Public Health and Food Safety. The amendments were the result of a compromise between Parliament and Council.

The main amendments – adopted under 1st reading of the codecsion procedure – were as follows:

- DEGME restrictions should also apply to cleaning agents, self-shining emulsions and floor sealants;

- **DEGBE** restrictions should also apply for the spray form of cleaning products, as the possibility of inhalation is also likely;

- MDI: gloves for MDI should be protective gloves which comply with the requirements of Council Directive 89/686/EEC. MDI packaging must be visibly marked as follows: “persons already sensitized to diisocyanates may develop allergic reactions when using this product;

- persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product.

- this product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used."

- Cyclohexane should have a reduced package size of 350g rather than 650g as the Commission had proposed;

Ammonium Nitrate: Parliament restricted the marketing of Ammonium Nitrate in preparations that contain 16 % or more by mass of nitrogen in relation to ammonium nitrate except for supply to: downstream users and distributors, farmers for use in agricultural activities, and persons engaged in professional activities such as horticulture, plant growing in greenhouses, maintenance of parks, gardens or sport pitches, forestry or other similar activities.

However, Member States may until 1 July 2014, for socio-economic reasons, apply a limit of up to 20% by mass of nitrogen in relation to ammonium nitrate for substances and preparations placed on the market within their territories.

Parliament defined the terms “farmer” and “agricultural activity”.

Dangerous substances and preparations: restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate

2007/0200(COD) - 02/10/2007 - Legislative proposal

PURPOSE: to provide harmonised rules for the placing on the market and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate**,** and cyclohexane preparations for supply to the general public, and to provide harmonised rules for the placing on the market of ammonium nitrateas a substance and in preparations for use as a fertiliser.

PROPOSED ACT: Decision of the European Parliament and of the Council.

CONTENT: Council Directive 76/769/EEC establishes a framework for harmonised rules throughout the EU concerning the placing on the market and use of dangerous substances and preparations. It 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).** 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.
- **2-(2-butoxyethoxy) ethanol (DEGBE).** This 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.
- **methylenediphenyl diisocyanate (MDI).** This 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.** The main use as a solvent is in adhesives (cyclohexane combined with other solvents). These are mostly “neoprene” 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 (AN).** Ammonium nitrate is widely used throughout the EU as a fertiliser, but it is 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.

Restrictions: 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.

This proposal 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 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 will 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.

Dangerous substances and preparations: restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate

2007/0200(COD) - 16/12/2008 - Final act

PURPOSE: to restrict the marketing of five chemicals that are potentially harmful to health.

LEGISLATIVE ACT: Decision No 1348/2008/EC of the European Parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate.

CONTENT: following an agreement reached with the Parliament at first reading, this Decision will impose restrictions on the conditions for use and sale to the public in specific applications for:

- 2**-(2-methoxyethoxy)ethanol, also known as "DEGME"**, which is a constituent part of certain paints, paint strippers, cleaning agents, sealants etc.: this substance shall not be placed on the market after 27 June 2010, for supply to the general public, as a constituent of paints, paint strippers, cleaning agents, self-shining emulsions or floor sealants in concentrations equal to or greater than 0.1% by mass;
- 2-(2-butoxyethoxy)ethanol, also known as "DEGBE", used mainly as a cosolvent in a wide range of applications: this substance shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of spray paints or spray cleaners in aerosol dispensers in concentrations equal to or greater than 3% by mass. Spray paints and spray cleaners in aerosol dispensers containing DEGBE and not conforming to the aforementioned point shall not be placed on the market for supply to the general public after 27 December 2010;
- **methylenediphenyl diisocyanate, also known as "MDI"**, used widely in the production of polyurethane foam: this substance shall not be placed on the market after 27 December 2010, as a constituent of preparations in concentrations equal to or greater than 0.1% by mass for supply to the general public, unless the packaging: (a)contains protective gloves; (b)is marked visibly, legibly and indelibly as follows: (i) persons already sensitised to diisocyanates may develop allergic reactions when using this product; (ii) persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product; (iii) this product should not be used under conditions of poor ventilation unless a protective mask with an appropriate gas filter (i.e. type A1 according to standard EN 14387) is used;
- **cyclohexane, used inter alia as a solvent in glues and adhesives**: this substance shall not be placed on the market for the first time after 27 June 2010, for supply to the general public, as a constituent of neoprene-based contact adhesives in concentrations equal to or greater than 0.1% by mass in package sizes greater than 350 g;
- **ammonium nitrate**, which is used mainly as a fertiliser: this substance shall not be placed on the market for the first time after 27 June 2010 as a substance, or in preparations that contain more than 28% by mass of 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. Moreover, it shall not be placed on the market as a substance, or in preparations that contain 16% or more by mass of nitrogen in relation to ammonium nitrate except for supply to farmers and natural or legal persons engaged in professional activities. However, Member States may until 1 July 2014, for socioeconomic reasons, apply a limit of up to 20% by mass of nitrogen in relation to ammonium nitrate for substances and preparations placed on the market within their territories. They shall inform the Commission and other Member States thereof.

The risk assessment for these substances identified the need to limit the risks posed to the health of workers and consumers. Those conclusions were confirmed by the Scientific Committee on Toxicity, Ecotoxicity and the Environment.

The provisions of the Decision will be incorporated in the European REACH system for the registration, evaluation and authorisation of chemicals.

The Decision also amends Directive 76/769/EEC on restrictions on the marketing and use of certain dangerous substances and preparations, which lays down a framework of harmonised rules applicable throughout the EU.

ENTRY INTO FORCE: 27/12/2008.