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Accompanying document to 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
(amendment of Council Directive 76/769/EEC)**

IMPACT ASSESSMENT REPORT

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Lead DG: Enterprise and Industry

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Disclaimer:

This report commits only the Commission's services involved in its preparation and does not preclude the final form of any decision to be taken by the Commission.

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Note: This impact assessment has been sent to the Impact Assessment (IA) Board on 29 May 2007 which expressed its opinion on 15 June 2007 after the Board meeting of 13 June 2007.

This impact assessment has been revised – in particular in the Background section and Section 2 – in order to take into account the comments in the opinion of the IA Board and the comments of the IA quality checklist received by DG Enterprise and Industry before the Board meeting.

The comments received from the Commission services during the interservice consultation are also included in this report.

The Bibliography included in Section 9 lists all documents that have been used in the preparation of this impact assessment. They are accessible either by internet or upon request from DG Enterprise and Industry.

BACKGROUND

This impact assessment presents the possible policy options and their comparative advantages and drawbacks that could be adopted to control the risks for consumers during the use of the chemical substances for specific applications that are concerned by the Proposal accompanied by the assessment.

Four of the chemical substances for which policy options are analysed in this impact assessment, [2-(2-methoxyethoxy)ethanol (DEGME), 2-(2-butoxyethoxy)ethanol (DEGBE), methylenediphenyl diisocyanate (MDI) and cyclohexane] have been identified as priority substances for evaluation in Commission Regulations (EC) No 1179/94, (EC) No 2268/95 and (EC) No 143/97 as foreseen under Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances¹.

The Member States Competent Authorities designated to conduct the risk assessments have identified risks for consumer health during the use of products containing these chemicals for certain specific applications and have suggested a strategy for limiting the risks in accordance with Regulation (EEC) No793/93.

This strategy took into consideration all the possible risk reduction measures such as handling and use instructions, regulatory concentration limits, industry voluntary actions and marketing and use restrictions. The various measures were evaluated in terms of their effectiveness, practicality, economic impact and monitoring. After discussions with all Member States, other stakeholders and the Commission, marketing and use restrictions at Community level under Council Directive 76/769/EEC have been agreed as the most efficient risk reduction measures. This has been formalised through the adoption of relevant Commission Recommendations.

The purpose of this impact assessment is to refine these recommendations and to provide support for a legislative Proposal to implement the recommended measures.

Ammonium nitrate is not included in the priority lists under Regulation (EEC) No 793/93 – however risks of inadvertent explosion have been identified when it is used in high concentrations in fertilisers. These risks need to be addressed throughout the EU.

¹ OJ L 84, 5.4.1993, p. 1

Section 1: Procedural issues and consultation of interested parties

A first outline for possible restrictions for the substances concerned by the Proposal accompanied by this impact assessment (hereinafter referred to as 'the Proposal') was discussed at the meeting of the Working Group of the Competent Authorities responsible for the implementation of Directive 76/769/EEC concerning restrictions on the marketing and use of dangerous substances and preparations (hereinafter referred to as the 'Limitations Working Group') on 27 November 2006. The Working Group comprises also representatives of industry and other stakeholders. During that meeting there was general support for the Proposal and the Commission services therefore continued their preparatory work. During another Limitations Working Group meeting on 15 February 2007, the Commission introduced a draft proposal of a Decision to amend Directive 76/769/EEC which was broadly welcomed by the members of the Working Group.

Ammonium nitrate was on the agenda of the Working Group of the Competent Authorities responsible for the implementation of the legislation on fertilisers on 24 March 2006 during which it was discussed how to ensure at Community level the control of the placing on the market of those ammonium nitrate fertilisers which are not covered by Regulation (EC) No 2003/2003 on fertilisers. During that meeting it was unanimously agreed by Member States and industry that all high nitrogen ammonium nitrate fertilisers should conform to the harmonised EU safety requirements and that Directive 76/769/EEC is the best legal framework to be used as it would cover both EC and national fertilisers.

Experts from industry, representatives from the European Chemical Industry Council (CEFIC) and from the European Consumers Organization (BEUC) attended the Limitations Working Group meetings and were consulted repeatedly in the process of drawing up the Proposal. The European Fertiliser Manufacturers Association (EFMA) participated in the meetings of the Fertiliser Working Group.

The consultation with industry helped the Commission to avail of the most up-to-date overview of the current market situation for substances such as DEGME and DEGBE for which the risk assessments under Regulation (EEC) No 793/93 had already been finalised in 1999. Some clarifications were made regarding the different distribution chains for the products containing the substances and comparisons were made with the realities in different Member States. Technical discussions with industry and the Rapporteur Member States of the risk assessments were carried out before, during and after the Limitations Working Group meetings and during the preparatory work of this impact assessment, to agree on specific requirements such as the material of gloves, the harmonisation of the use instructions to be included on the labels on the product, and the limit values of concentrations in preparations for each substance. For those products which actually have a large distribution to the consumer market and where restrictions could have a significant economic impact, the investigation was more detailed. For those products which have already been withdrawn and/or replaced a minor economic impact can be expected and only a minimum investigation has been carried out. In all cases the most appropriate measure in terms of cost-effectiveness has been selected.

Other legislation such as the General Product Safety Directive, the Regulation on Fertilisers, the Directives on the classification, packaging and labelling of dangerous substances and preparations, the Directive with regards to the transport of dangerous goods by road, were also examined to avoid any legal overlap or contradictions.

All these measures have been discussed involving also other Commission services such as DG Environment and DG Health and Consumer Protection to arrive at a general agreement for the measures for each substance included in the Proposal.

Section 2: Problem definition

In the conclusions of the comprehensive EU risk assessments for DEGME, DEGBE, MDI, and cyclohexane risks were identified only for human health. No risks were identified for the environment.

For human health concerns were identified for workers and consumers mainly due to dermal and inhalation exposure from certain applications and uses. During finalisation of the risk reduction strategy, for workers 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 work² and individual Directives based thereon, in particular 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 work³, 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 work⁴ was considered an appropriate and sufficient legislative instrument to eliminate and reduce the risks. For consumers, the Commission recommended to consider at Community level marketing and use restrictions under Directive 76/769/EEC. Therefore, this impact assessment will analyse only the problems identified for consumers. For ammonium nitrate the only risk identified is of explosion when it is used in high concentrations in fertilisers.

For the environment the risk assessment considered all environmental compartments (aquatic, terrestrial and atmosphere) and potential risks from all the identified uses of DEGME, DEGBE, MDI and cyclohexane. No environmental risk was identified for any of these substances and the conclusions of the assessment did not identify the need for further information and/or testing, nor for risk reduction measures beyond those which are being applied already.

The particular problems to be solved are:

2-(2-methoxyethoxy) ethanol (DEGME)

The risk assessment under Regulation (EEC) No 793/93⁵ concluded that there were risks for human health for consumers during the use of DEGME in paints or paint strippers.

2-(2-butoxyethoxy) ethanol (DEGBE)

²OJ 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).

³ OJ L 131, 5.5.1998, p. 11.

⁴ OJ L 158, 30.4.2004, p. 50.

⁵EU Risk Assessment Report on 2-(2-methoxyethoxy) ethanol (DEGME). Published in 1999; <http://ecb.jrc.it/existing-chemicals/>

The risk assessment under Regulation (EEC) No 793/93⁶ initially concluded that there were risks of respiratory irritation to human health for consumers from the use of DEGBE in paints during spraying applications. After the last Limitations Working Group meeting, the Oxygenated Solvents Producers Association (OSPA) provided new information on the toxicity and exposure to DEGBE⁷ which was evaluated by the Rapporteur of the EU risk assessment, the Netherlands. Using the 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.

Methylenediphenyl diisocyanate (MDI)

The risk assessment under Regulation (EEC) No 793/93⁸ concluded that there were risks to human health for consumers (dermal and respiratory irritation and sensitisation) from MDI contained in certain products sold to the general public.

Cyclohexane

The risk assessment under Regulation (EEC) No 793/93⁹ concluded that there were risks to human health for consumers from the use of cyclohexane in neoprene-based adhesives for carpet laying on large floors area.

As data for scenarios other than carpet laying are missing, a new study is currently conducted by the Rapporteur of the EU risk assessment, France, together with the Netherlands and the industry, to evaluate exposures from other possible scenarios of applications of neoprene based adhesives containing cyclohexane, which could present further concerns.

Ammonium nitrate (AN)

Ammonium nitrate is widely used throughout the EU as a fertiliser to supply crops with nitrogen as a nutrient, but it also constitutes the main ingredient in the commercial blasting agent ANFO (ammonium nitrate fuel-oil). The ease of detonation of ammonium nitrate has led to a number of major accidents. Although the safety of AN fertiliser during transport by road is largely ensured through specialised legislation¹⁰, a risk of explosion nevertheless remains in the event of a fire following a vehicle collision. The most recent cases in Europe were in Romania and Spain, both in 2004, resulting in 13 and 2 fatalities respectively. Those two cases are exceptions as most such fires have not resulted in explosion. Furthermore, it is known that the possibility of accidental explosion exists only if the ammonium nitrate

⁶ EU Risk Assessment Report on 2-(2-butoxyethoxy) ethanol (DEGBE). Published in 1999; <http://ecb.jrc.it/existing-chemicals/>

⁷ Statement from the "Oxygenated Solvents Producers Association, OSPA", May 2007 provided to the Commission and the Members of the Limitations Working Group.

⁸ EU Risk Assessment Report on methylenediphenyl diisocyanate (MDI). Published on 2005; <http://ecb.jrc.it/existing-chemicals/>

⁹ EU Risk Assessment Report on cyclohexane. Published on 2004. <http://ecb.jrc.it/existing-chemicals/>

¹⁰ Directive 94/55/EC with regard to the transport of dangerous goods by road

content, or more precisely the total nitrogen content, exceeds a critical value, i.e. in “high nitrogen” fertilisers. Under Regulation (EC) No 2003/2003 relating to fertilisers¹¹, high-nitrogen AN fertilisers are defined as those which contain more than 28% by mass of nitrogen in relation to ammonium nitrate. As the risk associated with AN is well known, and unlike the other four substances, no risk assessment was carried out on AN under Regulation (EEC) No 793/93.

EU farmers use high-nitrogen fertilisers widely and regard them as essential for commercial crop production. In contrast, their use by the general public is both very limited and non-essential.

In addition to the risk of detonation under conditions of normal handling and use in agriculture, AN fertilisers have also been misused for the illicit manufacture of explosives. Fertiliser types that can be misused for the illicit manufacture of explosives, e.g. calcium ammonium nitrate, can have nitrogen contents as low as 20%, for example fertiliser type A.1.5. in the list of types of EC fertilisers in Annex I to Regulation (EC) No 2003/2003 relating to fertilisers. 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 less than 20%.

The risk of explosion under conditions of normal handling and use can be significantly reduced if certain safety standards, such as those defined in Regulation (EC) No 2003/2003 are respected. First, there is a maximum limit for porosity to ensure that the fertiliser is not able to absorb sufficient fuel-oil (4%), or other combustible liquid, to make ANFO and particles should not be smaller than 0.5 mm. Second, threshold levels of copper, heavy metals, chlorine and organic impurities, all of which can promote detonation, must not be exceeded. Finally, a sample of the fertiliser must not detonate when tested using a standardised method in which a charge of 500 g of plastic explosive is exploded next to 8-9 kg of the fertiliser in a sealed steel tube. These criteria date from the 1970s and more than thirty years of practical experience have demonstrated that the safety provisions of Regulation (EC) No 2003/2003 for high-nitrogen AN fertilisers provide the required high degree of safety.

The purpose of Regulation (EC) No 2003/2003 is, on the one hand, to guarantee the minimum nutrient content and safety of the fertiliser to the farmer and, on the other, to provide access to the internal market to the manufacturer. Fertilisers that comply with the Regulation may be labelled “EC fertiliser” and may circulate freely on the internal market. Such fertilisers are recognised as safe by all Member States. However, the scope of the Regulation is limited to “EC fertilisers”, i.e. when manufacturers chose to market their fertilisers in this way. For fertilisers intended for sale only within a single Member State, there is no requirement to label them as “EC fertilisers” and to conform to the safety standards of Regulation (EC) No 2003/2003. Manufacturers of national fertilisers may comply with the Regulation on a voluntary basis. However, as the Regulation offers no advantages to manufacturers who supply only one national market, many AN fertilisers do not comply with its provisions. Manufacturers may choose to conform instead to requirements existing at national level. However, it is not possible to make a meaningful comparison between national and EU safety standards because they are based on different sets of criteria. Therefore these “national” fertilisers meet different safety requirements than those set at EU level. Whether these

¹¹ Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers. OJ L 304, 21.11.2003, p. 1

different requirements offer an equivalent degree of safety is not known. Due to the special facilities needed for carrying out detonation tests (only 4 laboratories in the EU), intercomparisons have not been carried out. The only significant work on the safety testing of AN fertiliser made since current tests were introduced in the 1970s was carried out in 2006 by TNO in the Netherlands which demonstrated that fertilisers that pass the EU tests (amounts of 8-9kg) are also safe when tested in amounts up to 20 tonnes. The Commission is not aware that such large-scale testing has been carried out on national fertiliser types. The uncertainty about the equivalence of safety standards excludes the possibility of mutual recognition, and means that Member States need to devote additional resources to control of the cross-border trade in national AN fertilisers.

In summary, there is clear evidence that AN fertilisers with high nitrogen content pose a risk of explosion unless they meet a set of well known safety criteria as laid down in Regulation (EC) No 2003/2003. Measures to address those fertilisers that do not meet these criteria have, therefore, a sound knowledge base and there are no knowledge gaps that would require application of the precautionary principle. The users of AN affected by the measures will be mainly farmers and distributors.

Section 3: Right of the Commission to act

Directive 76/769/EEC relates to restrictions on the marketing and use of certain dangerous substances and preparations and it is a well established instrument to control risks from dangerous substances and preparations. The Proposal to amend this Directive to include the various substances listed above intends to eliminate and reduce the identified risks at Community level.

Council Directive 76/769/EEC seeks to establish harmonised rules to achieve a high level of protection of human health and the environment throughout the Community 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. As the problems identified for each of the substances occurs in all Member States, action at Community level is the most efficient and proportionate way to eliminate or reduce the identified risks. Article 95 of the Treaty is the appropriate legal base for the Proposal.

Section 4: Objectives

The objective of the Proposal is to reduce the identified risks in order to achieve a high level of protection of consumer health and to establish harmonised rules throughout the EU to avoid barriers to intra-Community trade in products containing the substances.

The objectives are in particular:

- to control the risks when consumers use 2-(2-methoxyethoxy) ethanol (DEGME) in paints and paint strippers during 'Do-It-Yourself' applications;
- to control the risks when consumers use spray paints containing 2-(2-butoxyethoxy) ethanol (DEGBE) at concentration higher than 3% during 'Do-It-Yourself' applications;

- to control the risks for consumers from the use of products containing methylenediphenyl diisocyanate (MDI) in order to reduce exposure by skin contact and inhalation during ‘Do-It-Yourself’ applications;
- to control the risks for consumers during the application of neoprene-based adhesives containing cyclohexane to avoid acute effects from inhalation exposure during ‘Do-It-Yourself’ applications;
- 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 professional agricultural uses.

Section 5: Policy options

Different options to achieve the intended objectives are analysed below for each substance. The selected options take into account the existing market situations for the various chemicals, their actual uses, and the latest information from industry and from the Member States competent authorities as available to the Commission at the time of writing this impact assessment. These options consider in particular also the conclusions of the EU risk assessments and the related risk reduction strategies published in the Official Journal of the EU.

The various policy options for each substance are detailed in the following:

1) 2-(2-methoxyethoxy) ethanol (DEGME)

No action

This would mean that the status quo (i.e. no restrictions concerning the placing of the market and use of paints and paint strippers containing DEGME for consumers) would continue.

Voluntary action by industry

A voluntary commitment would be made by producers, distributors and importers of paints and paint strippers containing DEGME. The commitment could be recognised by the public authorities. The producers, distributors and importers of the substance and the formulators would subsequently implement the measures and monitor compliance with the commitment periodically. The results achieved would have to be assessed at regular intervals.

Additional use instructions on the products containing DEGME

It would be foreseen that paints and paint strippers containing DEGME would have to bear additional use instructions which would specify that the product was intended only for professional uses. This would potentially increase the protection of consumer when distribution chains for professional and consumer use are not clearly separated and the general public may also have access to products intended for professional use.

Total ban for consumer uses

A total ban of the placing on the market of paints and paint strippers containing DEGME which are supplied to the general public would be established.

2) 2-(2-butoxyethoxy) ethanol (DEGBE)

No action

This would mean that the status quo (i.e. no restrictions concerning the placing of the market and use of DEGBE for consumer spray paint application) would continue.

Voluntary action by industry

A voluntary commitment would be made by producers, distributors and importers of paints containing DEGBE. The commitment could be recognised by the public authorities. The producers, distributors and importers of the substance and the formulators would subsequently implement the measures and monitor compliance with the commitment periodically. The results achieved would have to be assessed at regular intervals.

Additional use instructions on the products containing DEGBE

It would be foreseen that each spray paint containing DEGBE at concentrations higher than 3% would have to bear additional use instructions which would specify that the product was intended only for professional uses. This would potentially increase the protection of consumer when distribution chains for professional and consumer use are not clearly separated and the general public may also have access to products intended for professional use. Other paints containing DEGBE would have to be labelled with the instruction that the paint is not intended to be used for spray applications. This measure would reduce the probability that consumers misuse paint containing DEGBE for those applications which present a risk for their health.

Reduction of the concentration limit of DEGBE in spray paints

An upper limit of 3% for the concentration of DEGBE in preparations sold to the general public for spraying application would be established.

Total ban for DEGBE consumer spray paints

A total ban for placing on the market of spray paints containing DEGBE for supply to the general public would be established.

3) Methylenediphenyl diisocyanate (MDI)

No action

This would mean that the status quo (i.e. no restrictions concerning the placing of the market and use of MDI consumer products) would continue.

Voluntary action by industry

A voluntary commitment would be made by producers, distributors and importers of products containing MDI. The commitment could be recognised by the public authorities. The producers, distributors and importers of the substance and the formulators would subsequently implement the measures and monitor compliance to the commitment periodically. The results achieved would have to be assessed at regular intervals.

Appropriate personal protective equipment (PPE) sold with the product

It would be foreseen that each product containing MDI would have to be sold together with proper personal protective equipment (PPE) such as gloves or a mask against dermal and inhalation exposure.

Additional use instructions on the products containing MDI

It would be foreseen that each product containing MDI would have to bear additional use instructions that would appropriately protect consumers during their use. The instructions would represent a positive incentive for consumers to adapt their behaviour and reduce the possibility of misuse when they use these products for “Do It Yourself” applications.

Total ban for consumer uses

A total ban of the placing on the market of products containing MDI for supply to the general public would be established.

4) Cyclohexane

No action

This would mean that the status quo (i.e. no restrictions concerning the placing of the market and use for consumers of cyclohexane in neoprene-based adhesives) would continue.

Voluntary action by industry

A voluntary commitment would be made by producers, distributors and importers of neoprene-based adhesives containing cyclohexane. The commitment could be recognised by the public authorities. The producers, distributors and importers of the substance and the formulators would subsequently implement the measures and monitor compliance to the commitment periodically. The results achieved would have to be assessed at regular intervals.

Regulatory reduction of package size

It would be foreseen that neoprene-based adhesives containing cyclohexane could only be sold to the general public in package sizes not exceeding an upper limit. As a consequence this would limit the surface area to which these products can be applied reducing also the exposure of users.

Appropriate handling and use instructions added on the package

It would be foreseen that each neoprene-based adhesive containing cyclohexane would have to bear additional instructions to inform consumers not to use such products for carpet laying (scenario for which unacceptable risks were identified in the EU risk assessment). Specific instructions could represent a positive incentive for consumers to adapt their behaviour and reduce the possibility of misuse when using these products for “Do It Yourself” applications.

Total ban for consumer uses

A total ban of neoprene-based adhesives containing cyclohexane for supply to the general public would be established.

5) Ammonium nitrate

No action

This would mean that the status quo (i.e. existing conditions concerning the safety of ammonium nitrate fertilisers apply only for EC fertilisers and not for national fertilisers) would continue.

Voluntary action by industry

Producers and importers of ammonium nitrate fertilisers would ensure that the technical provisions with regards to the content of nitrogen in ammonium nitrate fertilisers would be in compliance with the EC fertilisers Regulation. The commitment could be recognised by the public authorities. The quality control would be conducted by the manufacturers and importers which would have to ensure that fertilisers remain within certain specifications. The results achieved would have to be assessed at regular intervals.

Decrease of nitrogen content in all ammonium nitrate (AN) fertilisers

The nitrogen content of AN fertilisers would be reduced below the recognised safe limit of 28% by admixture of at least 10% by mass of substances such as calcium or magnesium carbonate.

Placing on the market of fertilisers with a nitrogen content >28% only if they comply with the safety requirements of regulation (EC) No 2003/2003, and restriction on sales to consumers of fertilisers with a nitrogen content of 20% or more

The placing on the market of all high nitrogen (>28%N) ammonium nitrate fertilisers that do not comply with the technical provisions set out in Regulation (EC) No 2003/2003 would be prohibited. The effect would be to bring all high-nitrogen AN fertilisers within the safety provisions set out in the Fertiliser Regulation. The use of high-nitrogen fertilisers by the general public is both very limited and non essential.

Section 6: Analysis of impacts

The analysis of the impacts of the various policy options has been conducted taken into consideration the efficiency and proportionality of the options to reduce the identified risks. Advantages and disadvantages have been examined for each option for all the substances to support the legislator in making the most appropriate and science-based decisions.

The marketing data and estimated costs refer to the latest information available to the Commission at the time of writing this impact assessment from discussions with all stakeholders at Working Group meetings and through further bilateral contacts.

1) 2-(2-methoxyethoxy) ethanol (DEGME)

No action

Currently, EU companies do not sell paints or paint strippers containing DEGME to the general public. However, without any regulatory action, it would be possible for companies from outside the EU to import such products which would have a negative impact on consumer health. There is no information available as to the quantities of such imports.

Furthermore, without action at Community level, there is the possibility that Member States would start legislating nationally and apply different restriction measures which would create obstacles to the internal market.

Voluntary action by industry

According to the last survey, the EU industry already moved to alternatives to DEGME in paints and paint strippers without any formal voluntary commitment and consequently there is no incentive to set one up. Setting up a voluntary commitment, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all EU companies including small and medium-sized enterprises, and in particular also importers, would create a significant administrative burden to companies and the relevant industry associations. In addition, the associations would monitor only their member companies and consequently there would be a lack of information and control with regard to those companies which are not associated - in particular the small and medium-sized enterprises. As a consequence, also Member States Competent Authorities would have difficulties to monitor the products sold to the general public and to verify which companies complied with a voluntary agreement. This evaluation suggests that this initiative would not be expected to be sufficiently effective.

Additional use instructions on the products containing DEGME

During the last Limitations Working Group, a Member State Competent Authority proposed to require mandatory affixation of additional instructions to specify the category of users of paints and paint strippers containing DEGME. In general terms an extra-labelling '*For professional users only*' on products that can be accessible also to consumers seems an efficient risk reduction measure; however in terms of practicality and proportionality this measure would create some unnecessary burden due to the different realities of the distribution chains in the Member States. Industry has confirmed that products available to professional users (such as in the automotive industry) are in general not accessible to consumers as both product categories have different distribution channels. A requirement for a general change in labelling of these products would economically impact companies in a disproportionate way as there are no additional benefits (as consumers cannot buy products for professional users anyway). Requiring selective labelling only for those cases, where there is a possibility that products could be bought by consumers (for example in stores that would not have a separate area for professionals), can be very complicated from a logistics point of view. Companies would face high administrative burdens.

Total ban for consumer use

A total ban of the sale of paints and paint strippers containing DEGME to the general public would not cause any costs to companies as they have already moved to alternatives and do not sell these products on the EU market anymore. This option would ensure that no imported products containing DEGME could be placed on the market and would therefore lead to an equal treatment of companies inside and outside the EU and ensure the full benefits in terms of protection of human health. For regulatory purpose a limit value of 0.1% of DEGME would be established - below this limit, substances are usually considered as impurities or trace contaminants that have not been deliberately added. This option would ensure fully the harmonised management of this substance within the EU market. It also constitutes a lower administrative burden than the option considered before, as it would not entail any additional labelling costs for companies. Industry has confirmed that products containing DEGME available to professional users are in general not accessible to consumers as both product categories have different distribution channels. When this cannot be ensured through direct

delivery from suppliers to professional users, distributors will have to ensure that consumers have no access to products containing DEGME, for example through establishing separate sales areas reserved for professional buyers as is often already the case due to other reasons (such as taxation).

2) 2-(2-butoxyethoxy) ethanol (DEGBE)

No action

Currently, various types of paints containing DEGBE are sold to the general public. These may include both solvent-borne paints and water-borne paints, although the latter are more common.

From a survey in 2000¹² it resulted that the total quantity of DEGBE (in all applications such as cleaning agent, chemical intermediate, paints) is around 58 000 tonnes. Data from the Oxygenated Solvents producers association (OSPA) in 1995 confirm that there is no import of DEGBE into EU. The use of DEGBE in paints is around 33 000 tonnes which represents 57% of the total use. The specific use of DEGBE in retail paints (those available to consumers) represents only a relatively small percentage of the total use in the EU and of the total amount of solvents used in paints. The direct value of DEGBE that would be affected by marketing and use restrictions is estimated at around €3 million, with the related value of the consumer paints in which DEGBE is used being around €230 million. Paints containing DEGBE that are intended to be sprayed by consumers have an estimated value of €2.3 million, with the value of DEGBE affected being around €0.003 million. Other consumer paints containing DEGBE, which might feasibly be sprayed by consumers (if they have specific equipment), represent around ten times these values.

Without any action, the risks identified for consumers as described in section 2 would remain. Furthermore, without action at Community level, there is the possibility that Member States would start legislating nationally and apply different restriction measures which would create obstacles to the internal market.

Voluntary action by industry

Setting up a voluntary commitment, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all companies including small and medium enterprises, and in particular also importers, would create a significant administrative burden to companies and the relevant industry associations. In addition, the associations would monitor only their member companies and there would consequently be a lack of information and control regarding those companies which are not associated, in particular the small and medium-sized enterprises. As a consequence, also Member States Competent Authorities would have difficulties to monitor the products sold to the general public and to verify which companies complied with a voluntary agreement. It seems that so far, even in the absence of a voluntary commitment, EU companies have already reduced the content of DEGBE in spray paints, but other paints available on the market do still contain DEGBE and might be used by consumers in spraying equipment, even if this was not intended by the companies placing the paints on the market. In addition, there might be imports into the EU from companies that are not members of any association and therefore no information about contents of DEGBE is

¹² Study on “The advantages and drawbacks of introducing Community-wide restrictions on the marketing and use of 2-(2-butoxyethoxy) ethanol (DEGBE) prepared for EU Commission-DG ENTR by RPA on October 2001.

available. It is doubtful that under these circumstances a voluntary commitment by industry could be set up and function. This evaluation suggests that this initiative would not be expected to be sufficiently effective.

Additional use instructions on certain paints containing DEGBE

Under a worst case scenario evaluated recently by the EU risk assessment Rapporteur, the Netherlands, and industry, it was shown that only paints with DEGBE at concentrations higher than 3%, pose unacceptable risks to consumers when they are sprayed in ‘Do-It-Yourself’ applications. Therefore, no particular measures are necessary for spray paints containing DEGBE at concentrations lower than 3 %.

With regard to spray paints containing DEGBE at concentrations higher than 3%, a Member State competent authority proposed during the last meeting of the Limitations Working Group to require mandatory affixation of additional instructions to specify the category of users of such products. In general terms an extra-labelling '*For professional users only*' on spray paints that can be accessible also to consumers seems an efficient measure; however in terms of practicality and proportionality this measure would create unnecessary burdens due to the different realities of the distribution chains in the Member States. Industry has confirmed that spray paints containing DEGBE, available to professional users are in general not accessible to consumers as both categories have different distribution channels. A requirement for a general change in labelling of these products would economically impact companies in a disproportionate way as there are no additional benefits (as consumers cannot buy products for professional users anyway). Requiring selective labelling only for those cases, where there is a possibility that products could be bought by consumers (for example in stores that would not have a separate area for professionals), can be very complicated from a logistics point of view. Companies would face high administrative burdens.

As explained above DEGBE is used in spray paints but also in other paints which could in fact be used by consumers also in spraying equipment. Therefore paints which are not intended to be sprayed and contain DEGBE in concentrations of more than 3% should be labelled with a warning "*Do not use in paint spraying equipment*". Companies placing such paints on the market would face some additional re-labelling costs for their products which would, however, be offset by the health benefits for consumers. The costs could be further reduced by foreseeing a longer transition period before the measure would have to be implemented. During that time all paints already in the distribution chain would be sold and no re-labelling would be necessary.

Reduction of the concentration limit of DEGBE in spray paints

Establishing a concentration limit of 3% for DEGBE in spray paints placed on the market for consumer use would effectively ensure that there is no concern for consumer health. Based on the currently available information of the EU market the concentration of DEGBE used in most consumer paints is around 3%, although some paints appear to contain DEGBE in concentration up to 7%. Taking into consideration that paints containing DEGBE intended to be sprayed make up only 1% of all consumer paints and only few of them contain DEGBE at concentrations higher than 3%, the impacts on industry would be overall negligible. On the other hand, without establishing such a limit, there is the possibility that such paints would be placed on the market in the future (in particular from imports) and this would lead to unacceptable risks for human health.

So far, no risks have been identified from paints other than spray paints, therefore no concentration limit is needed.

Total ban for DEGBE consumer spray paints

The costs of substituting DEGBE in all paints (i.e. also those with concentrations < 3%) that are specifically intended to be sprayed would be around €16 000 per product over ten years in terms of the increased costs of substitute chemicals, with one-off costs of reformulation of around €25 000. Total present value costs for substitution of DEGBE in these paints are therefore €41 000 for a ten year period. These are estimated minimum costs; the actual costs could be somewhat higher depending upon the complexity of reformulation required of companies⁶.

A number of companies have indicated that they would be likely to suffer employment losses in the case of a total ban of spray paints containing DEGBE, as they would not be able to replace DEGBE completely in their formulations. Based on the last survey from industry, there does not appear to be any major difference between the effects upon smaller companies as compared to larger ones. However, the Research & Development costs required to substitute DEGBE will represent a relatively greater proportion of turnover for small companies than for larger companies, potentially exacerbating the impacts on small companies.

As imported paints represent only a small proportion of all paints sold in the EU, a ban for the placing on the market of products containing DEGBE would not have a negative effect on the import trade.

3) Methylenediphenyl diisocyanate (MDI)

No action

Currently, methylenediphenyl diisocyanate (MDI) is placed on the market in one component foams (OCF), hot melt adhesives and other products for gluing, putty/filler systems in cartridges and brush painting. In Western Europe approximately 540 000 tonnes of MDI were manufactured in 1993. Sales volumes for 1996 were 790,000 tonnes. Export out of the EU reaches 105 000 tonnes. There are currently six manufacturing companies (spread over 11 manufacturing sites in total). There is virtually no import of the substance - import into the EU lies in the range of 2 500-3 500. The amount produced in the EU is expected to continue to rise. About 12 110 t/y of MDI are contained in products which are used by consumers in 'Do-It-Yourself' applications. The most important product type is OCF with a share of 9 500 t/y, followed by gluing and the use of putty/filler in cartridges, brush painting (1 650 t/y), sealants (950 t/y) and a very small amount of hot melt adhesives. For OCF the differentiation into quantities used by consumers and professional users is difficult. It is assumed that about 36 million cans reach consumers while 134 million cans remain in the professional area. It is estimated that about 20 million private users buy OCF in the EU per year. For all the other products the differentiation between private and professional users is clearer, the importance of the professional sector is in all cases much higher than that of the private sector¹³.

With respect to markets and economic values the following data are relevant:

Turn over with OCF consumer products	about 200 million €/year
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¹³ Study on "Advantage and Drawback M&U restrictions and impact. Consumer Part" conducted by the consultant BIPRO on behalf of the Belgian Competent Authority. Published in June 2006

Turn over with sealants consumer products	about 5 million €/year
Turn over with hot melt adhesives	less than 1 million €/year
Turn over with all remaining MDI consumer products (glues, putty filler systems)	less than 30 million €/year

MDI products placed on the market for the general public already contain some information on their labels due to the requirements of Directive 1999/45/EC on the classification and labelling of dangerous preparations. According to Annex V to Directive 1999/45/EC, preparations containing isocyanates (as monomers, oligomers, prepolymers, etc. or as mixtures thereof), and irrespective of their classification as dangerous within the meaning of Article 6 of Directive 1999/45/EC, must bear the following inscription: ‘Contains isocyanates. See information supplied by the manufacturer.’

Without any action, the risks identified for consumers as described in section 2 would remain. Furthermore, without action at Community level, there is the possibility that Member States would start legislating nationally and apply different restriction measures which would create obstacles to the internal market.

Voluntary action by industry

Voluntary action by industry was considered by the Rapporteur of the EU risk assessment (Belgium) for different uses of products containing MDI¹⁴ and was considered not relevant for many use scenarios such as spray painting, one-component foams (OCF), glueing and the use of putty/filler in cartridge and brush painting. Some reasons identified are:

- there are a lot of players in the market of spray paints, OCF, and glues, which makes it difficult to assure full coverage of the market
- for OCF, there are no substitutes available that combine the technical properties of OCF in one single product.

Therefore voluntary agreements were not further assessed by the Belgian Rapporteur as potential risk reduction measures for these three scenarios (spray painting, one component foam, glueing and etc).

During the Limitations Working Groups meetings, industry proposed some voluntary actions with regards to additional warning instructions on the products which were, however, considered as not sufficient by the Member States and other stakeholders to protect consumer health during use.

Appropriate personal protective equipment (PPE) sold with the product

The risks identified in Section 2 could be reduced through the use of appropriate dermal and respiratory personal protective equipment (PPE)⁷.

¹⁴ “Human health risk reduction strategy on methylenediphenyl diisocyanate” conducted in January 2005 by consultant ECOLAS on behalf of the Belgian Competent Authority.

Systematic use of suitable gloves can be considered an effective risk reduction measure for dermal exposure of consumers to MDI. The addition of a pair of gloves to the packaging of the products would be much more effective than the sole indication on the label to use gloves. The material of the gloves has to be chosen according to the chemical nature of MDI and the length of exposure. In terms of practicality and economic impact the addition of gloves would be relatively easy for companies and estimations of the extra costs are presented below for OCF products as these represent the most important share of MDI containing products placed on the market.

The mandatory sale of polyethylene (PE) gloves with each can of product would cause additional costs of up to 0.15 € per can (for comparison, a can currently costs ca. 7-8 €), which means additional costs for OCF producers of at least 4 million €/year (around 2% of extra costs compared to the overall turnover). The use of one can will last three to four minutes and PE gloves will give protection for, typically, ten times this time. In addition, hands will be protected from a reacting mixture of MDI and other chemicals, not MDI itself, and the viscosity of the mixture will be increasing rapidly and any deposits on the gloves will be a foaming solid. This significantly increases the protection time. PE-gloves are small in volume, comfortable for consumers to use and can easily be supplied in the cap of every MDI product can.

PE gloves have been compared to nitrile and neoprene gloves which are mostly used during industrial processes to apply insulation to roofs, walls, tanks, etc. The applicators are likely to spray the foam several hours per day and should use full PPE including heavily protective gloves such as those made from neoprene or nitrile and designed for continuous operation and the handling of quite heavy machinery. This industrial process is completely different in scale, technology and purpose from consumer use of OCF products containing MDI. Nitrile or neoprene gloves would cost 3.5 € and 10 € per pair, would be too big to be placed in the cap of products and due to their size and stiffness, would be uncomfortable to be used by consumers. It is, therefore, unlikely that they would be used. The costs would also be prohibitive.

In order to reduce inhalation exposure to MDI, the additional requirement of a mandatory sale of a mask (either a normal dust mask or complete gas mask) with the product has been considered in terms of efficiency and appropriateness during consumer application. The integration of a dust mask in the packaging of OCF (one component foams) products will cause additional costs of up to 10 € per can; that means additional costs for OCF producers of up to 360 million €/year. However, a normal dust mask would actually not eliminate MDI and therefore not offer any protection. A gas mask offering full protection would have to conform to EN 14387:2004 which is equipped with a specific type of filter. These filters are designed for a use of less than 1 hour, they have a protection factor 10 (considered to protect against levels up to 10 times the Occupational Exposure Level (OEL)) and they are expected to be disposed of after use and not to be used after one day of use. The estimated cost for an EN 14387:2004 mask is 70 € which would be disproportionate if compared to the cost of a MDI containing OCF can, which is around 7-8 €. De facto the requirement to include such a mask with all MDI products would therefore constitute a ban of these products. On the other hand it is unlikely that conditions during the occasional use of OCF products by consumers would actually correspond to such severe exposure conditions. In addition, it can be expected that consumers would not be willing to use inhalation PPE to the same extent as dermal PPE (which is easy to handle).

The EU risk assessment also highlighted some risks for respiratory allergy for workers which could potentially also be relevant for consumers. However, in the case of respiratory allergy the extrapolation from workers to consumers is difficult, since the exposure scenarios are very different and there is very limited understanding of dose response relationships in respiratory allergy. Information currently available from poison centres seems to indicate that there are no or only very few cases of respiratory allergy of consumers caused by MDI containing products. On the other hand, collecting data from clinics or poison centres is fraught with complexity and allergy cases are not normally recorded at poison centres in many Member States. For this reason it will be necessary to collect more data through a specific study before this question can be answered definitively. In case of “evidence of absence” of respiratory allergy, no additional measure would seem necessary and risks of respiratory allergy as evaluated at EU level will be relevant only for workers. Otherwise further protective measures would have to be considered to protect consumers.

Appropriate use instructions on the products containing MDI

Additional instructions such as: *“May cause allergic reaction to individuals already sensitised to diisocyanates other than MDI”, “May elicit asthma-like reactions in individuals with asthma”, “May cause dermal reactions to individuals suffering from skin problems”, “Use a mask with an antigas filter (I.e. type EN 14387:2004 mask with filter type A1) under conditions of poor ventilation”,* would be a means to provide better information on the potential dangers and correct use conditions of MDI containing products and it would reduce the probability of misuse by consumers.

Direct economic consequences will be incurred by companies for changing the labelling of OCF products which in terms of costs will be in the order of 75 000 € for all OCF producers (150 € is the cost of new improved and harmonised instructions on product labels which would be required for about 500 different products). However, compared to the overall market value of MDI products, this is minor and could be further reduced by foreseeing a longer transition period before the measure would have to be implemented. During that time all products already in the distribution chain would be sold and no re-labelling would be necessary. In addition, indirect (positive) consequences will result mainly for printing companies.

Total ban of consumer use

A total ban of consumer use of OCF products containing MDI would cause a direct loss of about 180 million € in turnover for the whole production chain. There will be a loss for producers in turnover up to 50 million € and about 100 jobs lost. There will also be jobs lost in Do-It-Yourself stores due to reduced turnover; however it is more difficult to estimate the numbers in a reliable way as such stores sell a wide range of products and the quantification of the consequences from an elimination of MDI containing products is uncertain¹⁵. For consumers, there would be a significant problem as no equally performing alternatives are available for Do-it-yourself applications. Even though in many cases there are alternatives, these are often of a lower quality compared to MDI-products, more difficult to handle and are more expensive.

¹⁵ According to the study on “Advantage and Drawback M&U restrictions and impact. Consumer Part” conducted by the consultant BIPRO on behalf of the Belgian Competent Authority, published in June 2006, up to 1500 jobs (corresponding to one third of a job in each DIY store in the EU) would be lost which actually seems a very high estimation.

Most of these alternatives present advantages and drawbacks depending to the different application requirements than MDI. In the case of OCF products used to install windows, the advantages and drawbacks can be summarised as follows⁷:

Advantages	Drawbacks
Human health risks might be lower, but depends on alternative insulation material used.	Application specifications are not fulfilled
	Worse insulation results directly in significant energy loss (CO ₂ emissions)
	Worse and more inefficient handling (huge drawbacks in working time/window)
	Contribution of production waste, emissions and energy during the production process and transportation is higher than for OCF

On the other hand, the non-availability of OCF for consumers could lead to an increased use of professionals to carry out tasks that consumers would otherwise have done in DIY – however it is not possible to quantify this in terms of increased turnover or jobs.

4) Cyclohexane

No action

In 1995, the total production volume of cyclohexane in the EU was 835 000-925 000 t/y, while the import volume was at ca. 18 000-63 000 t/y. Hence, the overall volume used was estimated at 900 000 t/y in the EU. In 2003, the volume of cyclohexane used in the EU had increased to an estimated 1 118 000 tonnes and around 97% are used as feedstock for the chemical industry, mainly as synthesis intermediate in the production of nylon. About 7 764 tonnes of cyclohexane are used in adhesives which represents only 0.6% of the total EU market for all uses or destinations of cyclohexane¹⁶.

Without any action, the risks identified for consumers as described in section 2 would remain. Furthermore, without action at Community level, there is the possibility that the Member States would start legislating nationally and apply different restriction measures which would create obstacles to the internal market.

Voluntary action by industry

Setting up a voluntary commitment, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all companies producing neoprene-based adhesives containing cyclohexane including small and medium sized enterprises, and in particular also

¹⁶ “Strategy for limiting risks for consumers” conducted by the French agency for environmental safety (AFSSE) on behalf of the French Ministry of health. Draft of December 2004

importers, would create a significant administrative burden to companies and the relevant industry associations. In addition, the associations would monitor only their member companies and there would consequently be a lack of information and monitoring related to those companies which are not associated, in particular the small and medium-sized enterprises. As a consequence, also Member States Competent Authorities would have difficulties to monitor the products sold to the general public and to verify which companies complied with a voluntary agreement. This evaluation suggests that this initiative would not be expected to be sufficiently effective.

Regulatory reduction of the package size

A reduction of the package size would ensure a limited application of adhesives on smaller surface areas only, which would reduce the exposure to consumers during application.

In a use scenario of contact application such as shoe repairing, the cyclohexane concentration in the air has been calculated based on the application of 4.5 g neoprene-based adhesives containing cyclohexane. In a typically sized room with an overall air volume of around 30 m³, the concentration of cyclohexane measured under non-ventilated conditions corresponds to 45 mg/m³. Permitted values (Threshold Limit Value (TLV), Time Weighted Average (TWA) for eight hours working time are between 172 (DK) and 1000 mg/m³ in Europe, with a short term multiplication factor (15 min) between 3 and 4 i.e. up to 4 g/m³.

Based on these figures, the use of the entire contents of a typical package of 650 g of adhesive in a non-ventilated medium sized room (60 m³) would result in an exposure equivalent to the maximum permitted short time exposure. A package size restriction to 650 g would therefore offer some but not completely sufficient protection to human health. Reducing the overall amount of adhesives used at one time and ensuring good ventilation during the use of adhesives that contain cyclohexane should be seen as the primary way of reducing risk, which can best be achieved through appropriate use instructions (see also next policy option).

Further calculations that are currently ongoing should allow a better assessment of the level of risk for various use scenarios and the possible need to reduce the packaging size to lower volumes.

Appropriate handling and use instructions added on the package

Although use of neoprene-based adhesives can be considered safe for small scale applications such as shoe repair, carpet laying usually involve larger surfaces and therefore there is a possibility that consumers would use several packages of 650 g at one time. This would then again lead to unacceptable risks.

Therefore, additional instructions such as "*Do not use for carpet laying*" would be a means to dissuade consumers from using neoprene-based adhesive for carpet laying. In addition, consumers should be informed to ensure good ventilation during use of neoprene-based adhesives containing cyclohexane for any other application. This would reduce the amount of this volatile substance actually inhaled. Such an instruction could read "*Do not use under conditions of poor ventilation*".

The changes of the labelling will have associated additional manufacturing costs for formulators and distributors. It can be assumed that such costs would be limited given the fact that some manufacturers already give such information on their products. The costs could be further reduced by foreseeing a longer transition period before the measure would have to be

implemented. During that time all paints already in the distribution chain would be sold and no re-labelling would be necessary.

Total ban for consumer use

A total ban of neoprene-based adhesives containing cyclohexane for consumer uses will come up against the absence of alternatives and the economic effects would be severe for manufacturers and distributors of adhesives. These costs would not be proportionate to the magnitude of the risks which can be reduced through other means. A total ban for other applications than carpet laying would in any case not be justified as a risk evaluation is still missing.

5) Ammonium nitrate

No EU action

AN fertilisers are used in large amounts in EU agriculture, but they are not the only source of nutrient nitrogen. Due to the varying nutrient content of different types of fertiliser, the consumption of fertilisers is best described not as tons of fertiliser, but as tons of the nutrient element, in this case nitrogen, contained in them. The total nitrogen nutrient content of fertilisers in the EU amounts to about 10 million tons annually, of which high nitrogen AN fertilisers (i.e. those containing more than 28 % nitrogen by mass in relation to ammonium nitrate) account for about 18% of the overall quantity. The other main nitrogen fertilisers are urea (14%) and calcium ammonium nitrate (26%). Calcium ammonium nitrate (CAN) consists of a mixture of AN with up to 10% calcium / magnesium carbonate. Nitrogen in AN and CAN has the agronomic benefit of providing a quick acting supply of nitrogen (nitrate nitrogen) combined with a slower, longer lasting supply of nitrogen (ammoniacal nitrogen). In addition, for CAN, the calcium/magnesium carbonate helps to counteract acidity of the soil. In contrast, urea is a slower acting supply of nitrogen, and is suitable mainly for heavy soils. Urea can therefore be considered as an alternative source of nitrogen only for some agricultural circumstances. In addition, when used as a fertiliser, urea tends to release ammonia to the atmosphere where it forms acidic salts and contributes to acid rain. To combat acid rain, Member States have committed to certain emission targets, including targets for ammonia, under the Gothenburg Protocol, and some Member States would strongly oppose a large-scale move from AN to urea because their emission targets for 2010 for ammonia could no longer be met.

Nitrogen fertilisers are derived from natural gas, and fertiliser prices have risen rapidly in the recent past in response to large changes in the gas price. A number of major EU producers have shut down plants (in some cases temporarily) due to unsustainable costs and fertiliser prices continue to fluctuate rapidly as supply and demand struggle to find a new equilibrium. Nevertheless, as a general rule nitrogen in AN and CAN is about one third more expensive than urea (about €740/tonne nitrogen against €550/tonne nitrogen in March 2007).

As explained in Section 2, only those AN fertilisers designated “EC fertilisers” in accordance with Regulation (EC) 2003/2003 will comply with well-proven harmonised safety standards. However, a large quantity of fertilisers is marketed as so-called 'national fertilisers', which comply with divergent national safety standards and will continue to be available to farmers in the 'no action' policy option. Farmers located near national borders who find it cheaper to purchase AN fertiliser in neighbouring Member States create additional work for Competent

Authorities to ensure compliance by farmers with national rules. This situation would continue indefinitely at about the same level if no EU action is taken.

Some Member States require high nitrogen fertilisers to be treated in the same way as explosives, for example, secure storage requirements are imposed. This effectively prevents sale to the general public in those Member States and greatly reduces the potential for illicit diversion. In other Member States, high nitrogen fertilisers are sold in garden centres and the possibility for diversion remains open.

Voluntary action by industry

Setting up a voluntary commitment for all AN fertilisers to comply with the requirements of Regulation (EC) No 2003/2003, ensuring participation by all actors concerned and guaranteeing monitoring of compliance by all companies including small and medium-sized enterprises, and in particular also importers, would create a significant administrative burden to companies and the relevant industry associations. The control of imports of AN fertilisers would be particularly difficult to be implemented by EU companies through a voluntary action as the imports are not normally from a regular supplier in a single country, but often occur through different distribution channels. In addition, the associations would monitor only their member companies and there would consequently be a lack of information and control with regards to those companies which are not associated, in particular the small and medium-sized enterprises. As a consequence, also Member States Competent Authorities would have difficulties to monitor the products sold to the general public and to verify which companies complied with a voluntary agreement.

In addition, the option to market all fertilisers as EC fertilisers is already open to manufacturers and importers under the Fertiliser Regulation, but it is not used by certain companies, despite the advantage of access to the whole internal market. It is therefore unlikely that a voluntary agreement would be effective. For the same reason, restrictions on sales of high nitrogen fertilisers to consumers through retail outlets also appears unlikely to be effective through voluntary actions from the industry side. Voluntary action from the retail sector appears equally unlikely given the large number of outlets and the lack of coordination in the retail sector.

This evaluation suggests that voluntary action would not be expected to be sufficiently effective.

Decrease of nitrogen content in all ammonium nitrate (AN) fertilisers

This option is not supported by a number of stakeholders who consider the availability of AN fertilisers with high nitrogen content essential for certain agricultural conditions. Furthermore, in cases where the additive used to bring down the overall content of nitrogen has no agronomic benefit, the addition of inert substances increases transport and storage cost by about the same amount (10%).

Placing on the market of fertilisers with a nitrogen content >28% only if they comply with the safety requirements of regulation (EC) No 2003/2003, and restriction on sales to consumers of fertilisers with a nitrogen content of 20% or more

As described in Section 2, Regulation (EC) No 2003/2003, the Fertiliser Regulation, requires that EC fertilisers with a high AN content meet a number of chemical and physical property requirements that should ensure that they are not capable of detonation.

In order to assure that all ammonium nitrate fertilisers sold in the Member States reach the same standards of safety and because Regulation (EC) No 2003/2003 applies to only those fertilisers that the manufacturers choose to designate as “EC fertiliser”, standard harmonised measures for EC and national fertilisers under Directive 76/769/EEC would impose the same safety requirements on all ammonium nitrate fertilisers marketed in the EU. The same effect could in principle be achieved by changing the scope of the Fertiliser Regulation, but that Regulation is intended to provide access to the internal market to those manufacturers who wish to participate by labelling their fertiliser “EC fertiliser”. The Fertiliser Regulation does not aim at full harmonisation for all fertilisers. Mixing provisions that are mandatory for all AN fertilisers with provisions for other fertiliser types that are non-mandatory (in the sense that the manufacturer chooses to apply them only if he wishes to label the fertiliser as “EC fertiliser”) would require extensive rewriting of the Fertiliser Regulation. This would also complicate the text of the Regulation, which would make it more difficult to apply it correctly. Moreover, as the provisions of the Regulation apply to only a limited number of fertiliser types, which are listed in its Annex I, national fertiliser types could potentially be excluded from national markets. The structure of the Fertiliser Regulation therefore seems ill-suited to ban non-compliant fertilisers. Directive 76/769/EEC is therefore considered to be the best option for achieving harmonised safety standards for AN fertilisers at the EU level.

The cost in the EU for testing compliance with the requirements of the Fertiliser Regulation are broadly comparable (cost of the test of resistance to detonation is about €3 000 - 3 500) which would prove the safety and would permit the manufactures to have advantages for selling ammonium nitrate fertilisers throughout the internal market. The costs for complying with the chemical purity requirements are negligible. Ammonium nitrate is made by reacting ammonia obtained from natural gas with nitric acid. The standard merchant-grade quality of both these widely-available bulk chemicals is sufficiently pure for both precursor chemicals. The physical properties of the fertiliser, i.e. porosity and particle size, are controlled by the way the plant is operated. Most plants are capable of producing a range of densities to meet the specifications of both the fertiliser market (low porosity) and the explosives market (higher porosity, also known as technical-grade). Some older plants may require improvements to process control to minimise the amount of reject material which would need to be recycled.

By permitting supply to the general public only of fertilisers containing less than 20% nitrogen, the acquisition of fertilisers types that can be misused for the illicit manufacture of explosives through this route will be effectively prevented. The loss of sale to the general public is negligible and will be compensated through sale of other fertiliser types.

Section 7: Comparing the options

2-(2-METHOXYETHOXY) ETHANOL (DEGME)	Effectiveness	Efficiency
<u>No action</u>	Very low: Paints and paint strippers containing DEGME	Low: No extra costs for industry but the objectives will

	<p>could still be sold to the general public (in particular through imports).</p> <p>The potential risks for consumer health would not be reduced.</p> <p>Member States could adopt diverging rules, which could impact adversely the Internal Market.</p>	not be reached.
<u>Voluntary action by industry</u>	<p>Very low: Difficulties to set up a voluntary agreement with all actors and to monitor small and medium sized enterprises and also imports. Difficulties for the Member States Competent Authorities to verify the compliance of the industry with voluntary action.</p> <p>Consumer health will not be guaranteed.</p>	Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.
<p><u>Additional use instructions on the products containing DEGME</u></p> <p><i>“For professional users only”</i></p>	<p>Average: It would dissuade consumers from using such products in cases where they might have access to those products which are intended only for professional users.</p>	Low: Additional costs for companies to label all products without benefits to consumer health as products are already sold in different channels for consumers and professionals. Selective labelling will have a high administrative burden.
<u>Total ban for consumer use</u>	<p>High: It would avoid that paints and paint strippers containing DEGME reappear on the EU market and it would guarantee the protection of consumer health.</p>	High: No additional cost for companies as paints and paint strippers containing DEGME are currently not placed on the EU market for consumer uses.

2-(2-BUTOXYETHOXY) ETHANOL (DEGBE)	Effectiveness	Efficiency
<u>No action</u>	<p>Very low: Paints containing DEGBE could still be sold to the general public. The potential risks for consumer health would not be reduced.</p> <p>Member States could adopt</p>	Low: No extra costs for industry but the objectives will not be reached.

	diverging rules, which could impact adversely the Internal Market.	
<u>Voluntary action by industry</u>	<p>Very low: Difficulties to devise an agreement with the involvement of large and small and medium sized enterprises. Member States Competent Authorities would not be able to adequately monitor the compliance of a voluntary action by industry.</p> <p>Consumer health will not be guaranteed.</p>	Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.
<p><u>Additional use instructions on certain paints containing DEGBE</u></p> <p><i>“Do not use in paint spraying equipment”</i> on paints other than spraying with more than 3% of DEGBE</p> <p><i>“Only for professional users”</i> for spray paints containing DEGBE at 3%</p>	<p>High: The additional instruction will alert consumers not to use paints containing DEGBE in concentration more than 3% for spraying application.</p> <p>Average: It would dissuade consumers from using such products in cases where they might have access to those products which are intended only for professional users.</p>	<p>Average: Companies will have some additional costs for the change of labelling of the products which can be reduced by foreseeing a longer transitional period before the obligation has to be implemented.</p> <p>Low: Additional costs for companies to label all products without benefits to consumer health as products are already sold in different channels for consumers and professionals. Selective labelling will have a high administrative burden.</p>
<u>Concentration limit of 3% DEGBE in spray paints</u>	High: The establishment of a limit of 3% for DEGBE in spray paints ensures that all risks to consumers are reliably eliminated.	High: Only very limited costs from the withdrawal or reformulation of those few remaining spray paints containing more than 3% of DEGBE.
<u>Total ban for DEGBE consumer spray paints</u>	High: No more spray paints with DEGBE will be available on market and consumer health will be completely guaranteed.	Very Low: Need to withdraw or reformulate all spray paints containing DEGBE which will be costly. In addition there would be a loss of turnover and reduction in employment for those companies which would be unable to replace DEGBE in

	for effective masks.	to the frequency (time period) of the use of such products and to the overall exposure resulting for such application. The most appropriate masks for MDI products are those complying with EN 14387:2004 which cost around 70 € (i.e. up to 10 times more expensive than a can of OCF).
<p><u>Appropriate use instructions on products containing MDI</u></p> <p><i>“May cause allergic reaction to individuals already sensitised to diisocyanates other than MDI”</i></p> <p><i>“May elicit asthma-like reactions in individuals with asthma”</i></p> <p><i>“May cause dermal reactions to individuals suffering from skin problems”</i></p> <p><i>“Use a mask with an antigas filter (I.e. type EN 14387:2004 mask with filter type A1) under conditions of poor ventilation”</i></p>	<p>Average: Specific instructions and warnings would inform and protect consumer during the use of MDI products in particular for those consumers already sensitised to other diisocyanates substances. The warning to use a mask under poor ventilation conditions will encourage consumers to improve ventilation and ensure that professionals use a mask where necessary.</p>	<p>High: Companies will face some additional costs due to the change in labelling of their products placed on the market. The impact of these costs could be reduced by allowing companies additional time to comply.</p>
<p><u>Total ban for consumer use</u></p>	<p>High: MDI products would not longer be available hence there would not be any risk to consumers.</p>	<p>Very low: A ban of MDI containing products would not be proportionate to the risks evaluated for consumers. The direct loss from a ban for consumers of all MDI containing products will be about 200 million € turnover for the whole production chain. About 100 jobs lost in manufacturing companies and further job losses in DIY-stores. Some alternatives to MDI are available but they do not cover all the uses and they do not have the same performance as MDI.</p>

CYCLOHEXANE	Effectiveness	Efficiency
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<p><u>No action</u></p>	<p>Very low: The risks for consumers during carpet laying with neoprene-based adhesives containing cyclohexane will not be reduced.</p> <p>Member States could adopt diverging rules, which could impact adversely the Internal Market.</p>	<p>Low: No extra costs for industry but the objectives will not be reached.</p>
<p><u>Voluntary action by industry</u></p>	<p>Very Low: Difficulties to set up an agreement on voluntary action with all companies concerned and to monitor small and medium sized enterprises and also imports. Difficulties for the Member States Competent Authorities to verify the compliance of the industry voluntary action.</p> <p>Consumer health will not be guaranteed.</p>	<p>Average: Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.</p>
<p><u>Regulatory reduction of the package size</u></p>	<p>Average: Reduction of the packaging size to 650 g will reduce the surface area during application and hence exposure. Still, consumers could use several packages during one application.</p>	<p>Average to high: A limit value of 650 g for carpet laying application would not cause significant economic costs to industry. There would still be a need to complement the measure by appropriate labelling instructions.</p>
<p><u>Appropriate handling and use instructions added on the package</u></p> <p><i>“Do not use for carpet laying”</i></p> <p><i>“Do not use under conditions of poor ventilation”</i></p>	<p>Average: specific warnings will dissuade consumers to use neoprene-based adhesives containing cyclohexane under poor ventilation condition and for carpet laying. This would reduce the risks to consumer health.</p>	<p>High: Some additional costs to industry due to the change in labelling of the cyclohexane products. The impact of these costs could be reduced by allowing companies additional time to comply.</p>
<p><u>Total ban for consumer use</u></p>	<p>High: Consumer health would be fully protected as neoprene-based adhesives containing cyclohexane would no longer be available.</p>	<p>Low: A total ban of neoprene-based adhesives containing cyclohexane would create high costs as there are currently no alternatives to replace cyclohexane especially for small-scale applications such as shoe repairing, which would have to be developed.</p>

AMMONIUM NITRATE	Effectiveness	Efficiency
<u>No action</u>	Very low: continued lack of harmonised rules within EU for all ammonium nitrate fertilisers which are outside the scope of the Fertilisers Regulation. The risks identified would not be reduced.	Low: No additional cost for companies but no benefits either.
<u>Voluntary action by industry</u>	Very Low: The possibility to comply with the safety standards of Regulation (EC) 2003/2003 is already available, but it is not used despite advantage of access to EU internal market. Difficulties to monitor small and medium sized enterprises and also imports. Difficulties for the Member States Competent Authorities to verify the compliance of the industry voluntary action.	Low: A voluntary commitment would be difficult to apply due to fragmented nature of industry supply. Administrative costs for industry for setting up, enforcing and monitoring a voluntary commitment can be significant.
<u>Decrease of nitrogen content in all ammonium nitrate (AN) fertilisers</u>	High: the addition of calcium or magnesium carbonate will reduce the AN content below the recognised safe limit of 28% to avoid detonation.	Low: Additional costs of 10% for transport and storage by the addition of calcium or magnesium carbonate. Most soils do not require additional carbonate, so no benefits.
<u>Placing on the market of fertilisers with a nitrogen content >28% only if they comply with the safety requirements of Regulation (EC) No 2003/2003, and restriction on sales to consumers of fertilisers containing 20% or more of nitrogen</u>	High: It will guarantee that all fertilisers comply with the harmonised safety specification of Regulation No 2003/2003 and that the risks of inadvertent explosion are effectively reduced. Only professional users will have access to fertilisers that can be misused.	High: Some minor additional costs for modifying the composition and properties of fertilisers and proving the compliance with the test of detonation. Loss of sale to the general public is negligible and will be compensated through sale of other fertiliser types.

In conclusion, the following options or combination of options emerge as the most balanced and proportionate. During the discussion of the Limitations working group and the Fertilisers

Working Group, these options have also received general support from the Member States Competent Authorities and the stakeholder representatives:

- **For DEGME:**

A total ban of the placing on the market of 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.

An additional labelling requirement '*For Professional Use Only*' would not be justified, because products containing DEGME available to professional users are in general not accessible to consumers as both product categories have different distribution channels and consumers have normally no access to products intended for professional use.

- **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 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 Groups meetings, the Member States Competent Authorities, the Stakeholders and the Commission agreed that a study is needed 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, further protective measures will have to be considered if the risks for consumers will be confirmed.

- **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 fertilisers containing <20% nitrogen is negligible and will be compensated through sale of other fertiliser types of equivalent performance at similar cost.

Section 8: Monitoring and evaluation

Directive 76/769/EEC 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 to control and limit the risk of certain dangerous substances as such or contained in preparations during specific uses and applications. This legal instrument permits to have harmonised rules throughout the European Union and to control the market in terms of production, import, distribution and use.

Member States have put into place long-standing mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. These same structures can be used under Regulation (EC) 1907/2006 to monitor compliance with the new restrictions of this Proposal which will therefore not create a significant administrative burden. Although the Directive does not contain any mechanism or indicators for progress achieved, a satisfactory level of feedback is obtained through cases registered by the poison centres, recommendations/complaints by the Member States and by industry.

The collection and evaluation of new data concerning respiratory allergy from products containing MDI or from the evaluation of further exposure scenarios for neoprene-based adhesives containing cyclohexane will be monitored by the Commission who could request further evaluation by the European Chemicals Agency (ECHA) in accordance with Regulation (EC) No 1907/2006 which will repeal Directive 76/769/EEC on 1 June 2009.

Section 9: References

- EU Risk Assessment Report on 2-(2-methoxyethoxy) ethanol (DEGME). Published on 1999; <http://ecb.jrc.it/existing-chemicals/>
- EU Risk Assessment Report on 2-(2-butoxyethoxy) ethanol (DEGBE). Published on 1999; <http://ecb.jrc.it/existing-chemicals/>
- Commission recommendation of 12 October 1999 (L192/42) on the risk reduction strategies on 2-(2-methoxyethoxy) ethanol and 2-(2-butoxyethoxy) ethanol.
- Study on “The advantages and drawbacks of introducing Community-wide restrictions on the marketing and use of 2-(2-butoxyethoxy) ethanol (DEGBE) prepared for EU Commission-DG ENTR by RPA on October 2001; http://ec.europa.eu/enterprise/chemicals/studies_en.htm

- EU risk assessment report on methylenediphenyl diisocyanate (MDI). Published on 2005; <http://ecb.jrc.it/existing-chemicals/>
- “Human health risk reduction strategy on methylenediphenyl diisocyanate” conducted on January 2005 by consultant ECOLAS on behalf of the Belgian Competent Authority.
- Study on “Advantage and Drawback M&U restrictions and impact. Consumer Part conducted by the consultant BIPRO on behalf of the Belgian Competent Authority. Published on June 2006
- EU Risk assessment report on Cyclohexane. Published on 2004. <http://ecb.jrc.it/existing-chemicals/>
- “Strategy for limiting risks for consumers” conducted by the French agency for environmental safety (AFSSE) on behalf of the French Ministry of health. Draft of December 2004
- Commission recommendations on the risk reduction strategies for methylenediphenyl diisocyanate and cyclohexane. To be published in the OJ
- Data sources on fertilisers prices to farmers available in Internet.
- Data from the “Oxygenated Solvents Producers Association, OSPA”, May 2007 provided to the Commission and the Members of the Limitations Working Group.