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Accompanying document to the

COMMISSION DECISION

Amending, for the purpose of adaptation to technical progress, Annex I to Council Directive 76/769/EEC as regards restrictions on the marketing and use of lamp oils and grill lighter fluids

(Adaptation to technical progress of Council Directive 76/769/EEC)

IMPACT ASSESSMENT REPORT

**{C(2009) 4020 final}
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Lead DG: Enterprise and Industry

Other involved services: ENV, SANCO, TRADE

Agenda planning or WP reference: 2009/ENTR/022

Disclaimer:

This report commits only the Commission's services involved in its preparation and does not prejudge 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 21 November 2007 which expressed its opinion on 18 December 2008 in written procedure.

This IA has been revised in order to take into account the comments in the final opinion of the IA Board and the comments of the IA quality checklist received by DG Enterprise and Industry before the Board issued its opinion.

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.

EXECUTIVE SUMMARY

This impact assessment accompanies the Proposal for a Commission Decision adapting to technical progress the restriction on the marketing and use of lamp oils and grill lighter fluids, labelled with the standard risk phrase R65 (Harmful: may cause lung damage if swallowed), for supply to the general public.

Grill lighter fluids and fuels used in lamp oils classified for aspiration hazard, labelled with R65, can cause severe damage in children's health if accidentally swallowed. To address this concern, restrictions have already been introduced at EU level on coloured and scented lamp oils, labelled R65, sold to the general public. This has been done in the context of Directive 97/64/EC amending Directive 76/769/EEC on restrictions of the marketing and use of dangerous substances and preparations. Protective measures have also been introduced in the general EU framework on classification and labelling of dangerous substances and preparations, as well as in European Standards on both products.

Despite these measures, data provided by Member States indicate that a significant number of accidents still occur with the non-scented and non-coloured lamp oils, labelled R65, and that there is a growing trend of accidents involving children due to accidental ingestion of grill lighter fluids.

To address the identified concerns, six options were analysed in terms of their effectiveness, practicality and socio-economic impacts:

1. No action (baseline scenario), where the status quo would continue;
2. Voluntary action by industry;
3. Labelling and packaging requirements for grill lighter fluids and lamp oils, labelled R65, sold to the general public;
4. Prohibition of the sale to consumers of grill lighter fluids, labelled R65, and additional labelling and packaging requirements for lamp oils labelled R65;
5. Prohibition of the sale to consumers both grill lighter and lamp oils labelled R65;
6. Prohibition of the sale to consumers of lamp oils labelled R65 and grill lighter fluids labelled R65 or classified as highly flammable or extremely flammable.

In the light of the analysis conducted, option 3 emerged as the most favourable measure. It takes into account remaining uncertainties on the availability of alternatives for lamp oils and concerns that a ban on grill lighters may have, as unintended consequence, the effect of inducing consumers to use alternative products that are more flammable and therefore more likely to increase the number of accidental burns.

This option is expected to be effective in raising consumer awareness, limiting the likelihood that children mistake these products for drinks, and therefore, significantly reducing accidental ingestion by small children. It would also be efficient as there are only limited additional costs for industry and the administrative burden for companies and authorities is low.

In order to encourage development of safer alternatives by industry and assess the effect of the proposed labelling and packaging measures, the Commission will request the European Chemical Agency to prepare a restriction dossier in the near future, where particular attention will be given to the availability of alternatives.

BACKGROUND AND CONTEXT

This impact assessment presents the possible policy options with their comparative advantages and drawbacks that could be adopted to control the risks to consumers – in particular small children – from lamp oils and grill lighter fluids, labelled with the standard risk phrase R65 (Harmful: may cause lung damage if swallowed). The analysis and results of this impact assessment accompany the legislative Proposal related to a modification of the already existing restrictions on the marketing and use of certain lamp oils.

Lamp oils and grill lighter fluids may contain low-viscosity hydrocarbons such as paraffins and petroleum distillates. Due to their physicochemical properties, these hydrocarbons can enter the lungs and can cause severe chemical pneumonia if they are sipped or swallowed.

Member States have indicated that every year there are a number of serious accidents where small children ingest lamp oils and grill lighter fluids, resulting in severe lung damage and sometimes even death.

Lamp oils are used in decorative lamps and garden torches in households, in restaurants, in recreational facilities and in similar areas. They are also used in agrarian country lamps, classical paraffin lamps and high luminosity lamps (also called Argand lamps or 'quinquets' in France).

Grill lighter fluids are liquid substances or preparations, which are readily ignitable by the application of a naked flame and which can be used to ignite solid barbecue fuel, such as charcoal, used in barbecue and grill appliances.

The use of preparations labelled with R65 in coloured and scented lamp oils sold to consumers has already been restricted since January 1999 under Commission Directive 97/64/EC adapting to technical progress for the fourth time Annex I to Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations¹. The Community measure prohibits the use of colouring agents or perfume in liquid substances or preparations, labelled with R65, which can be used as fuel in decorative lamps and are placed on the market in packaging of a capacity up to 15 litres. A European standard for the design of safe decorative oil lamps² was also adopted in September 2002 in order to minimise the possibility of small children having access to the oils used in decorative oil lamps. Despite these measures several Member States continue to report a significant number of accidents with lamp oils involving children.

Discussions have been conducted during the last year with Member States and other stakeholders at several meetings of the Commission Working Group responsible for the implementation of Council Directive 76/769/EEC concerning the restriction of marketing and use of dangerous substances and preparations³ (hereinafter referred to as the 'Limitations Working Group'). The discussions have covered possible measures on both lamp oils and grill lighter fluids. This impact assessment includes a detailed analysis of the possible measures as discussed during the meetings in terms of their effectiveness, practicality, economic impact and monitoring, in order to reduce the number of accidents related to the use of lamp oils and grill lighter fluids by consumers.

¹ OJ L 315, 19.11.1997, p.13.

² EN 14059:2002 Decorative oil lamps – Safety requirements and test methods.

³ OJ L 262, 27.9.1976, p. 201.

All these potential measures have been discussed with other relevant Commission services such as DG Environment, DG Health and Consumer Protection and DG Trade to arrive at a general agreement for the measures to be adopted to manage and reduce the risks from lamp oils and grill lighter fluids.

Section 1: Procedural issues and consultation of interested parties

Already in 2004 Germany informed the Commission that despite the existing restrictions, it was concerned by the remaining number of accidents with lamp oils and grill lighters involving small children and requested a review of the current restrictions under Directive 76/769/EEC as they were deemed to be insufficient. Germany advocated that the ban on the selling to consumers of coloured and scented lamp oils containing low-viscosity hydrocarbons and labelled with R65 should be extended to colourless and unscented lamp oils as well as to grill lighter fluids.

The Commission has repeatedly discussed the issue with Member States and other stakeholders at different meetings of the Limitations Working Group. At the meeting of December 2007, the German Federal Institute for Risk Assessment (BfR) made a presentation on a study conducted in Germany regarding incidents with children (sometimes fatal) involving lamp oils and grill lighters labelled with R65. The study highlighted that there is still a considerable number of registered accidents with children due to lamp oils and a growing number of accidents involving grill lighters, the main reasons being direct drinking from bottles containing these preparations that, despite fitted with children-resistant fastening, have not been adequately closed and from old lamps that do not correspond to the standard EN 14059 but are still in use in households.

The Commission asked all Member States to react to the German study and to report on the number of accidents related to those applications in their territories in order to assess the relevance of amending the existing restrictions at Community level.

At the meeting of the 'Limitations Working Group' in March 2008, the Commission presented different options on how the current entry on lamp oils in Directive 76/769/EEC could be adapted to further restrict the marketing and use of lamp oils and grill lighter fluids marked with R65 for consumers use. It also drew Member States attention to the possibility of using the current standard on lamp oils to withdraw non-compliant decorative lamps from the market based on non compliance with the General Product Safety Directive.

The Commission took note of Member States reactions and presented revised options at a subsequent meeting of the 'Limitations Working Group' in July 2008. During the discussion, opinions of the Member States and stakeholders were much divided. Several Member States supported a ban for both lamp oils and grill lighter fluids, labelled R65, for consumers use. Others supported such a ban for grill lighter fluids but not for lamp oils due to concerns about the availability of alternatives. Two Member States insisted that they would need in any case an exemption from a possible ban for religious and cultural reasons. Furthermore, some Member States as well as industry expressed concerns about the lack of information with regard to the availability of suitable alternatives which do not have to be labelled with R65. The replacement of the current system for classification and labelling of dangerous substances with the Globally Harmonised System (GHS) in the near future could also lead to a situation where more substances would have to be labelled with R65, thus eliminating the use of alternatives that still seemed possible today. Finally, there were worries about unintended consequences that could result from a ban on grill lighters labelled R65 as currently in some

Member States many accidents are not linked to ingestion by children but to burns by both children and adults. Such a ban could lead to the use of alternatives that are more flammable – such as alcohols – and, therefore, to an increased number of accidental burns.

At a subsequent meeting of the Limitations Working Group in October 2008, the Commission presented revised proposals together with an early draft of this impact assessment to support the debate. Member States and industry indicated that support could be given to a compromise proposal which would impose labelling requirements for a transitional period and a ban in a few years time, if alternatives became available. This compromise was supposed to take into account remaining uncertainties on the availability of alternatives.

The data used for this impact assessment has been mainly provided by the national authorities and industry in the context of discussions within the Limitations Working Group.

Industry has been involved in these discussions all along the process. The following industry associations have been consulted and have participated in discussions with the Member States:

- CONCAWE (the oil companies' European organization for environment, health and safety);
- HSPA (the Hydrocarbon Solvent Producers Association);
- Grillverband (the German Grill Lighters Association) and
- Schmalfuss (a German company selling both grill lighters and lamp oils).

The European Consumers Association (BEUC) as well as NGOs have been invited to join discussions at the Limitations Working Group. They have not attended any meetings nor sent any written position.

Other legislation such as the General Product Safety Directive⁴ legislation on classification and labelling of dangerous substances and preparations⁵ and existing European standards on oil lamps and grill lighters were also examined to avoid any legal overlap or contradictions.

All potential measures have been discussed with other relevant Commission services such as DG ENV and DG SANCO, who have been present during discussions at the Limitations Working Group. to arrive at a general agreement for the measures to be adopted to manage and reduce the risks from lamp oils and grill lighter fluids. An inter-service meeting to discuss the draft impact assessment was organised in October 2008 involving relevant Commission services. DG ENV, DG SANCO, DG TRADE, DG RESEARCH, JRC and SG were invited. Only DG SANCO attended the meeting.

Changes made to the report in accordance with the Impact Assessment Board Opinion.

⁴ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (OJ L 11, 15.01.2002, p. 4).

⁵ Directive 67/548/EEC of the European Parliament and the Council on the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p. 1); Directive 1999/45/EC of the European Parliament and the Council on the classification, packaging and labelling of dangerous preparations (OJ L 200, 30.7.1999, p. 1 and Regulation XX/XX* of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (*Add reference once it is published).

The Board made the following recommendations for improvement:

- Justify the need to act under Directive 76/769/EEC rather than acting through the procedure foreseen under the REACH Regulation;
- Demonstrate more clearly the risk-reducing effect of the proposed additional labelling and packaging requirements for lamp oils under option 3;
- Further explain why labelling and packaging requirements for lamp oils are expected to reduce the risks to an acceptable level and why overall they are preferred over a ban.
- Explore more fully the trade-off between, on the one hand, the reduction of ingestions due to ban on grill lighters instead of better labelling and, on the other, the potential increase of accidental burns due to the use of more dangerous alternatives.

The following changes have been made in the revised report to address those comments:

- Section 3 has been redrafted to provide information about the reasons for acting under Directive 76/699/EEC and the consequences of waiting to act under the REACH Regulation.
- Option 3 in section 5 has been modified to further explain the differences between the current labelling and the expected benefits of the more extensive labelling and packaging measures.
- Option 5 in section 5 clearly indicates concerns on the availability of alternatives if a ban had to be introduced on lamp oils. This concern is further emphasized in section 7 where the effectiveness and efficiency of the different options are compared.
- The analysis of option 4 in section 6 includes a comparison between accidents due to ingestions of grill lighters and lamp oils and accidents due to burns by methylated spirits and other inappropriate substances being misused by consumers. The situation is quite serious already and it could well be that there would be even more burns if grill lighters labelled R65 are banned. Despite the fact that an effective ban on grill lighters would eliminate ingestion accidents altogether, whereas a new label will do so only incompletely, it is not possible for the Commission, based on current data, to make a proposal which has the potential to worsen overall consumers protection. The final aim of protecting human health would not be achieved.

Section 2: Problem definition

A significant number of accidents (see below) are reported every year involving small children, mainly those below 3 years old, drinking from bottles containing liquid grill lighters and lamp oils, or even just sucking the wick of garden torches and decorative oil lamps. Although containers of the grill lighters and lamp oils concerned should be fitted with child-resistant fastening, accidents still occur as containers are not closed properly, are simply left open, or the fluid has been removed from large original containers and poured into smaller packages.

Lamp oils and grill lighter fluids may contain paraffin-based oils and petroleum distillates with aliphatic hydrocarbons (n-paraffins)⁶. Some of these contain low quantities (up to 10%) of lower alcohols (e.g. isopropanol or isobutanol). Due to their low viscosity, in case of accidental ingestion, the paraffin-based substances may enter the lungs and can cause severe inflammation, commonly referred to as chemical pneumonia. Even small amounts can creep into the lungs after being swallowed and trigger severe chemical inflammation. For this reason, and according to the legislation on classification and labelling of dangerous substances and preparations, lamp oils and grill lighters which contain these substances have to be classified and labelled with the standard phrase R65 (i.e. Harmful: may cause lung damage if swallowed) and containers must be fitted with child-resistant fastenings.

Member States have repeatedly reported accidents with these substances leading, in particular, to severe damage to the health of small children. Reported cases have involved hospitalisation with massive breathing disturbances, and subsequent severe disorders of the respiratory tract, or even death.

In order to address this problem several measures have been introduced at Community level since 1997 with the aim of reducing the number of accidents involving lamp oils and grill lighter fluids:

- Since 1 January 1999, Commission Directive 97/64/EC⁷, amending Directive 76/769/EEC, bans coloured and scented lamp oils marked with R65 for consumer use in decorative lamps. It also requires containers to be marked with the sentence “Keep lamps filled with this liquid out of the reach of children”.⁸
- Since September 2002, a European standard for the design of childproof oil lamps⁹ intends to minimise the risk of accidental poisoning of small children by limiting the accessibility of the liquid in the lamp and by imposing the following marking requirements on the oil lamp:
“(a) WARNING: In the case of small children, just a sip of lamp oil – or even sucking the wick – may lead to life-threatening lung damage.
“(b) WARNING: If lamp oil is swallowed, do not induce vomiting. Seek medical advice immediately or contact a poison information centre and show these warnings”.

This standard is included in the list of standards that provide a presumption of conformity to the General Product Safety Directive. This means that, even though the standard in itself is not legally binding, products complying with the standard are presumed to conform to the safety requirements of the General Product Safety Directive and can freely circulate in the EU. Therefore, since the publication of this standard in the Official Journal of the EU in March 2004¹⁰, national authorities could control and withdraw those oil lamps placed on the market on the basis that they are not compliant with the General Product Safety Directive.

⁶ These molecules are made up of chains of carbon atoms (length 8-16) and hydrogen.

⁷ OJ L 315, 19.11.97, p.13.

⁸ Coloured and scented lamp oils were considered more likely to attract or arouse the curiosity of children, who mistake these products with drinks.

⁹ EN 14059: Decorative oil lamps – Safety requirements and test methods.

¹⁰ OJ C 100, 24.4.2004, p. 20.

- There are no marketing and use restrictions for grill lighter fluids. However, since June 2003, there is also a European Standard containing safety measures for fire lighters¹¹. It specifies the safety, performance, labelling and packaging requirements including the test methods for firelighters used to light solid fuels in barbecue and grill appliances. The standard covers firelighters supplied as either solid, liquid, thickened liquid or gel formulations. Amongst others, it contains measures regarding the composition of the fluids, - such as the prohibition to contain substances or preparation classified as very toxic, toxic, corrosive, explosive, oxidising, sensitising or class 1 or 2 carcinogens -, an obligation to use child-resistant closures and the warning sentence “Keep out of the reach of children”. Nevertheless, this standard has not been published under the list of standards presumed to conform to the General Product Safety Directive and therefore manufactures are not obliged to use it. It remains of voluntary nature.
- Since 1998 the obligation to use the risk phrase R65 apply to dangerous substances and preparations presenting an aspiration hazard and meeting the criteria introduced by Commission Directives 1996/54/EC¹², regarding dangerous substances, and Directive 1996/65/EC¹³, regarding dangerous preparations. Furthermore, since July 2002 additional protective measures have been introduced by Directive 1999/45/EC regarding the classification and labelling of dangerous preparations, requiring that preparations labelled with R65 have to be sold to the public in containers fitted with child-resistant fastening¹⁴. Similar measures exist for the packaging of substances labelled with R65¹⁵.

Figure 1: Measures applicable to lamp oils and grill lighters at European level

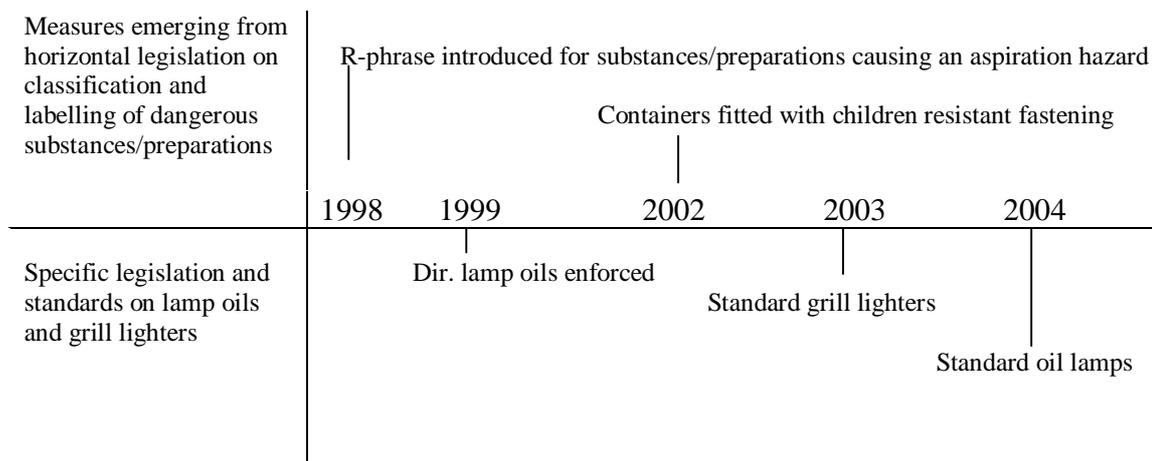
¹¹ EN 1860-3: Appliances, solid fuels and firelighters for barbecuing – Part 3: Firelighters for igniting solid fuels for use in barbecue appliances – Requirements and test methods.

¹² Commission Directive 96/54/EC of 30 July 1996 adapting to technical progress for the twenty-second time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 248, 30.9.1996, p. 1)

¹³ Commission Directive 96/65/EC of 11 October 1996 adapting to technical progress for the fourth time Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations and modifying Directive 91/442/EEC on dangerous preparations the packaging of which must be fitted with child-resistant fastenings (OJ L 265, 18.10.1996, p. 15)

¹⁴ See Annex IV, Part A of Directive 1999/45/EC.

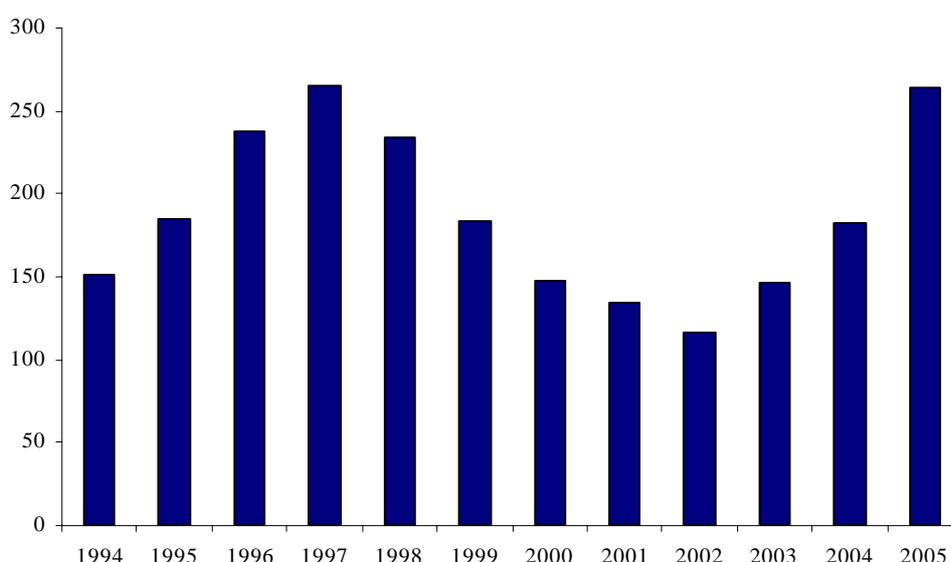
¹⁵ See Article 9.1.3 and Annex IX, Part A of Directive 67/548/EEC.



Despite being requested from all Member States, there is no sufficient data to assess the impact of all these measures in reducing the number of accidents in all the EU countries. As an orientation, information can be provided from the Netherlands and Germany.

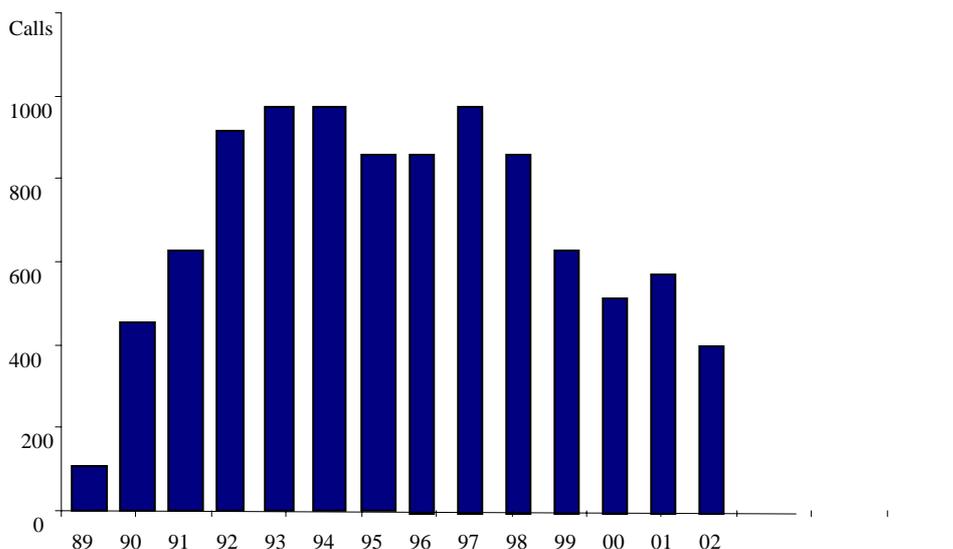
In the Netherlands, the Dutch Poison Information Centre (NVIC) has provided information on lamp oil intoxications over the past 12 years. It has observed a clear pattern in the frequency of lamp oil intoxications (see figure 2). Once Directive 97/64/EC came into force in 1999, a decrease was observed, with the smallest number of information requests on lamp oils ingestions reported in 2002. Ever since, the number of cases has been increasing again. This could be due to the fact that sales of the clear unscented variety of these fuels – which are not banned – are steadily increasing, but this is not sure.

Figure 2: Number of requests for information about lamp oil intoxications – NVIC – The Netherlands



In Germany, a decrease in requests for information was observed when the Directive entered into force.

Figure 3: Number of requests for information about lamp oil intoxications – BfR – Germany



Despite the existing provisions, it seems that additional measures may be needed to come to terms with the remaining number of incidents with lamp oils involving ingestion by small children and to tackle an increasing trend involving grill lighter fluids which are the cause of similar accidents.

- In the Netherlands, in the period between 2005 and 2007 around 250 incidents with small children involving lamp oils were reported per year. The Dutch Poison Information Centre (NVIC) performed a study in 2005 intended to assess the circumstances, frequency, nature and seriousness of the poisonings with different kinds of lamp oils¹⁶. From April till December 2005, 152 cases of lamp oil intoxication were reported. In 64% of the cases patients drank from oil lamps, 14% drank directly from the bottle and 14% of the patients sucked the wick. Almost all patients were younger than 5 years. In total 79 of the patients (72%) had complaints including prickling cough, vomiting, feeling of sickness, drowsiness. In about 20% of the cases, indicators of a chemical pneumonitis were found. It was shown that almost all of the reported cases involved paraffin containing lamp oils
- In Germany, a study by the German Federal Institute for Risk Assessment (BfR) and the German Surveillance Unit for Rare Diseases in Childhood (ESPED)¹⁷ recorded 765 accidents with lamp oils in German children's hospitals in the period between 2000 and 2006. Almost 300 cases (40%) lead to severe health impairment (pneumonia) and two infants died. The two fatal cases involved a girl aged 13 months who drank lamp oil contained in a garden torch and a boy aged 20 months who drank from a lamp or perhaps just sucked from the wick. Both had developed severe pneumonia and destruction of lung tissue after ingestion of lamp oils. Both children died from the consequences of lamp oil aspiration, in spite of intensive medical treatment. In both cases the substances involved were colourless and odourless lamp oils on a paraffin basis, which were compliant with existing Community restrictions.

¹⁶ De Vries I & van Gorcum TF (2006). Rapportage Onderzoek naar vergiftiging met lampolie 2005. Briefrapport NVIC.

¹⁷ Erhebungssystem Seltener Pädiatrischer Erkrankungen in Deutschland

- The Norwegian national Poison Centre has informed that, during the years 2004-2007, 112 cases were reported for lamp oils and 455 for grill lighter fluids involving small children below 4 years of age. Approximately 30% of those cases were estimated to lead to hospitalisation
- In Sweden, 400-500 incidents with lamp oils and grill lighters involving infants are reported every year to the Swedish Poison Information Centre. The following table provides the cases reported between 2000 and 2007 with children aged 0-4 years:

Year	Lamp oil	Grill lighter fluids
2000	134	326
2001	116	356
2002	119	399
2003	122	464
2004	181	437
2005	147	276
2006	125	288
2007	142	246

- In Ireland, the National Poisons Information Centre has also provided information on the number of enquiries received during the period of January 2004 to July 2008. It received 11 enquiries on lamp oils and 11 enquiries on grill lighters. The cases concerned suspected ingestion by young children, with the exception of 2 enquiries on grill lighters which concerned accidental ingestion by adults. None of the cases were followed up and therefore no data is available on the poisoning severity.
- In France, 177 cases of accidental ingestion of grill lighters and lamp oils were registered in 2007, out of which 13 cases lead to a chemical pneumonia. All the patients recovered favourably. According to the French authorities the number of accidents linked to ingestion of grill lighters and lamp oils is considered very low compared to other household chemicals. In fact these accidents represent only 0.09% of all the intoxication cases registered by the National Poison Centre, in 2007.
- In the Slovak Republic, based on data supplied by the National Toxicological Information Centre (NTIC), the number of intoxications has followed an increasing trend between during 2002-2007. Data on intoxications by grill lighters is only available since 2006. The large majority of the cases have only led to mild symptoms, 4 cases have raised serious and persisting symptoms and 1 case, involving lamp oils, has lead to life threatening symptoms. No fatal cases have been reported.

Year	Lamp oil	Grill lighter fluids
2002	12	
2003	16	
2004	14	
2005	18	
2006	24	5
2007	117	9

Due to the different ways Poison Information Centres operate in the Member States, it is not possible to give an estimated figure of accidents for the EU as a whole.

The following precisions should be made about the above reported data. All the figures refer to accidents of ingestion and not to burns. It cannot be confirmed, however, whether the number of accidents or enquiries refer exclusively to grill lighter fluids and lamp oils labelled R65. Some of the inquiries may have involved substances and preparations that may not cause lung damage if swallowed and therefore do not need to be labelled with R65.

The fact that all the data reported by Member States on grill lighters refers to accidents of ingestion and not to burns is particularly important. In some Member States burns remain the main cause of accidents involving both children and adults. While it would be useful to present these data to assess the impact of these measures within a wider perspective, the scope of the current assessment is limited to assess whether the current restriction on lamp oils under Directive 76/769/EEC could and should be amended in a way that reported accidental intoxications by children are minimised. Accidental burns will only be taken into account so far as to ensure that potential restrictions of grill lighters do not lead to the use of alternative products that have not been conceived to be used as such, for example white spirit or methylated alcohol, and that due to their alcohol content are more flammable, and thus, more likely to increase the number of accidental burns. Even though consumers are already misusing these products, if grill lighters fluids labelled R65 are restricted further and alternatives are very expensive, the situation could become more severe.

How would the problem evolve if new measures are not taken

Despite the existing ban of the sale to consumers of coloured and scented lamp oils being labelled with R65, accidents with infants are still happening. According to the German Federal Institute for risk assessment (BfR) this is because sales of the clear, unscented variety of these fuels – which are not banned – are steadily increasing.

Only a few Member States have been able to provide data on the volumes of lamp oils and grill lighters sold in their territories. These figures provide only a rough orientation as they refer to all grill lighters and lamp oils, not just to those labelled with R65, which anyway remain the vast majority.

Member State (year)	Lamp oils	Grill lighters
Germany (2007)	6 million bottles	5 million bottles
Finland (2007)	500 tons	223 tons
Sweden (2006)	650 tons	4000 tons

According to Annex VI, Part A, of Directive 1999/45/EC regarding the classification, labelling and packaging of dangerous preparations, containers of preparations presenting an aspiration hazard (Xn, R65), and classified and labelled accordingly, have to be fitted with child-resistant fastenings. Despite this protective measure, a significant number of intoxications by lamp oils and grill lighter fluids labelled R65 involving infants still remain. These intoxications are due to either non compliant child-proof fastening (or where fluids had

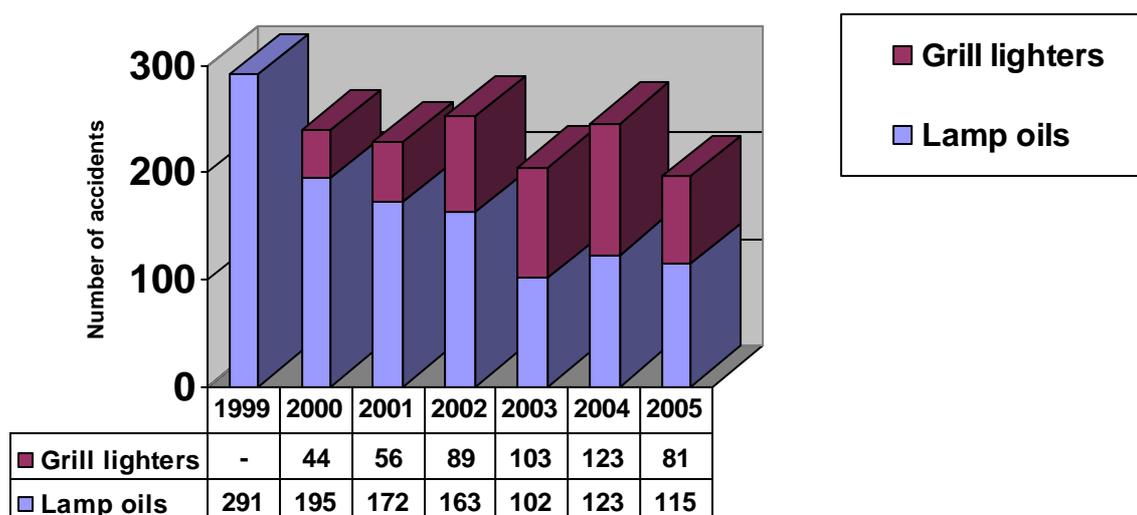
been refilled in containers without child proof fastening) or children drinking from bottles that remained opened.

In an attempt to reduce the number of cases, some Member States have implemented information campaigns intended to raise consumer awareness and inform parents about safety measures to take towards small children. In Sweden between 2000 and 2003 the number of intoxications with grill lighter fluids involving infants increased from 326 to 464 cases. The government launched consumer campaigns on TV. A decrease observed after 2004 was probably due to this strategy together with the introduction of alternative grill lighters on the market, not labelled R65. However 246 cases of intoxication with grill lighter fluids were still reported in 2007.

In Germany, the authorities have been trying to raise consumer awareness through press releases. However, there is a worrying increasing trend of intoxications with grill lighter fluids. The number of reported cases has increased from 100 in 2000 to more than 350 cases in 2006.

A similar concern has been reported by the Poison Information Centre from Berlin (one of the 9 Poison Centres in Germany), which has signalled a significant increase in the number of accidents with grill lighter fluids in recent years:

Trend Grill Lighters: Figures from Poison Center Berlin



In Norway, 340 cases of intoxication with grill lighter fluids were reported during the years 2004-2007. There are more accidents with grill lighters than with lamp oils, even if the grill season in Norway is very short and the period with dark days, when lamp oils are more likely to be used, is much longer. In the period 2004-2007, 112 cases related to lamp oils were reported. One possible explanation provided by the Norwegian Pollution Control Authority (SfT) is that Norway, for several years, has had a national ban on the manufacture and sale of oil lamps with an open flame designed to burn petroleum fuel, where the lamps have a loose wick holder. Sales of lamps with a wick that is not permanently attached or with a separate filling hole that does not have a fixed lid is prohibited.

Those oil lamps are also forbidden at EU level. In fact, the European Standard on decorative oil lamps (EN 14059) is primarily intended to restrict the access of small children to the lamp

oil contained in decorative oil lamps. As explained in section 2, due to the link between this standard and the General Product Safety Directive, national authorities can control and withdraw those oil lamps placed on the market that are not compliant with the standard. Such withdrawals are in principle documented in the EU rapid alert system for all dangerous consumer products (RAPEX), which is intended to exchange information between national authorities and Member States on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. The system covers both, measures ordered by national authorities and measures taken voluntarily by producers and distributors. Between 2005 and September 2008, 20 oil lamps have been withdrawn from the market due to non compliance with the standard on decorative oil lamps. 4 withdrawals took place in Germany, 9 in the UK and 6 in Slovenia.

While increased market surveillance by Member States would certainly reduce the number of intoxications, it has to be noted that the standard only applies to oil lamps placed on the EU market after March 2004. It cannot be used to withdraw old lamps which are already in use in households.

National information campaigns could certainly be launched to further inform consumers of risks linked to those old lamps and increase parents awareness in order to keep lamp oils and grill lighters labelled R65 out of the reach of children. Information provided by Germany and Sweden have shown that those campaigns may lower the number of accidents but to a limited extent.

It is, therefore, to be expected that if no further action is taken at Community level, these trends may continue. The number of accidents may decrease following improved national monitoring and information campaigns, but this has not lead to a major impact in those Member States where such actions had already been undertaken in the past. Furthermore, as it will be explained in section 3 of this report, whilst for lamp oils Member States are already barred from taking further national legislative measures, they could well do so for grill lighters but only if the national measures are adopted before 1 June 2009, which does not seem a probable scenario.

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 is a well-established instrument at Community level to control risks from dangerous substances and preparations. The Directive 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 would cause barriers to intra-Community trade. It is based on Article 95 of the EC Treaty.

Directive 76/769/EEC already contains provisions on oils used in decorative lamps. Since 1 July 2000, this Directive prohibits the sale to the general public of coloured or scented oils, which are labelled R65, for use in decorative oil lamps. In fact, this Directive contains measures for liquid substances or preparations which are regarded as dangerous according to the definitions in Council Directives 67/548/EEC¹⁸ and 1999/45/EC¹⁹ regarding the classification, packaging and labelling of dangerous substances and preparations. This legal

¹⁸ OJ L 196, 16.8.1967, p.1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

¹⁹ OJ L 200, 30.7.1999, p. 1. Directive as last amended by Regulation (EC) No 1907/2006 of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 1).

instrument can therefore be used to introduce further rules on the marketing and use of both lamp oils and grill lighter fluids that are labelled R65 for consumers use.

The control of such risks cannot be achieved by leaving the responsibility to act solely to the Member States. In fact, as there are already harmonised rules on lamp oils, Member States cannot introduce additional national restrictions. The provisions foreseen under Article 95.5 of the Treaty, allowing Member States to request new national derogations in a harmonised area, are limited to concerns based on environmental reasons, not human health. On the other hand, regarding grill lighters, Member States could adopt national measures on grill lighters but only if those measures are adopted before 1 June 2009. On 1st June 2009, Directive 76/769/EEC will be replaced by Title VIII and Annex XVII of Regulation (EC) N° 1907/2006 (REACH Regulation). According to the new rules, for restrictions that address a Community wide concern, Member States will have the possibility, under REACH, to prepare a restriction dossier (Annex XV of REACH) intended to justify the need for Community measures and submit it to the European Chemicals Agency for triggering the process to establish a restriction.

Transition to REACH:

Due to the entry into force of the new rules on 1st June 2009, the provisions of the proposal accompanied by this impact assessment will be included into Annex XVII of REACH, which contains restriction measures. If the proposal is not adopted by the Commission before end of May, the current procedure to adopt a restriction proposal could no longer be used. The Commission may still ask the European Chemicals Agency to prepare a restriction dossier in accordance with the procedure foreseen in Title VIII of the REACH Regulation. As explained above, a Member State could also prepare such a dossier. This procedure can be used as from June 2009 and it could lead to the adoption of a Commission Decision after approximately 2 years.

Nevertheless, consultations with the Member States in the elaboration of the current report have provided strong indications that availability of alternatives at the present stage remain questionable and thus Member States would have difficulties to prepare a dossier in June 2009, which could be the basis for a ban. For the same reasons, it would not be useful if the Commission requested the European Chemical Agency (ECHA) to start preparing a dossier immediately after June 2009. Further information concerning alternatives would probably become available only after 2010 (end of the registration period for substances placed on the market in quantities above 1000 tonnes) and only then would the ECHA have information available that could allow it to produce an Annex XV Dossier. Legislative measures based on this could then be adopted only in 2012.

Under these circumstances, it is deemed more appropriate to already adopt proportionate Community measures under the current legislative system. As these measures would be enforced once Directive 76/769/EEC is taken over by REACH, the provisions would be taken in the form of a Commission Decision, rather than a Directive. No transposition measures would be required in the Member States, and the provisions would be enforced by December 2010 through the automatic incorporation into Annex XVII of the REACH Regulation. This would allow taking already action to tackle reported accidents with lamp oils and the worryingly increasing trend involving grill lighter fluids.

Section 4: Objectives

The objective of the Proposal is to achieve a high level of health protection for consumers, in particular small children, with regard to risks emanating from lamp oils and grill lighters labelled R65. The specific objective is to reduce or eliminate the number of children's intoxications from accidental ingestion of these substances while at the same time other risks to human health should not be increased and a fragmentation of the internal market should be avoided. The operational objective of this initiative is to strengthen – where necessary and in a proportionate manner – the available instruments at EU level to achieve the specific objective by adopting measures in the near future that could be already implemented by December 2010.

These objectives are not inconsistent with horizontal EU strategies such as the Sustainable Development Strategy or the Strategy for Growth and Jobs.

Section 5: Policy options

Different options could be used to achieve the intended objectives of reducing the number of accidents from the use by consumers of grill lighter fluids and lamp oils labelled R65. The options take into account the available information from the national poison centres, the existing standards and legislation at EU level and the views of stakeholders as available to the Commission at the time of writing this impact assessment. The options were developed on the basis of the information submitted by Member States and industry.

No separate option has been developed regarding action taken under REACH rather than under the current legislative framework of Directive 76/769/EEC. Nevertheless as Directive 76/769/EEC will be taken over by REACH on 1st June 2009, the scenario to take no immediate action but rather act through REACH at a later stage is taken into account in the conclusions based on the analysis of the various options.

Option 1: No additional action (baseline scenario)

In this option no additional restrictions would be adopted at Community level concerning the placing of the market and use of grill lighters within the framework of Directive 76/769/EEC. Only scented and coloured lamp oils, labelled R65, would be prohibited for sale to the general public. Member States could foresee taking national actions on grill lighter fluids but only if those measures are adopted before June 2009. Once the rules of REACH will apply to restrictions on marketing and use of chemicals (as explained in section 3), Member States can only prepare a restriction dossier for action at Community level.

Option 2: Voluntary action by industry

A voluntary commitment would be made by manufacturers of lamp oils and grill lighter fluids. The actions taken could involve a commitment to no longer use substances and preparations labelled R65 in lamp oils and grill lighter fluids sold to the general public, or other measures such as additional labelling, information campaigns or others. These measures would be monitored by industry and national authorities responsible for market surveillance.

Option 3: Additional labelling and packaging requirements for grill lighter fluids and lamp oils, labelled R65, sold to the general public

For lamp oils, the additional labelling requirements would complement the already existing restrictions on the marketing and use by including an additional warning phrase intended to further raise awareness of the risks for children in case of ingestion. The additional sentence

would read: “Just a sip of lamp oil – or even sucking the wick – may lead to life-threatening lung damage”.

For grill lighters, it would be required to mark the packaging with the sentence “Just a sip of grill lighter may lead to life-threatening lung damage”.

In addition, grill lighter fluids and lamp oils may be mistaken for drinks by small children. The packaging provisions would impose that these products shall be packaged in such a way as to minimise the likelihood of such a mistake. This could be achieved by an opaque dark packaging.

Option 4: Prohibition of the sale to the general public of grill lighter fluids labelled R65 and additional labelling and packaging requirements for lamp oils labelled R65

This option would prohibit the marketing of grill lighter fluids labelled R65 for consumer use and would complement the already existing restrictions on the marketing and use of certain lamp oils by including the additional warning phrase and the packaging requirements described in option 3.

Option 5: Prohibition of the sale to the general public of both grill lighter fluids and lamp oils labelled R65

In this option the marketing to consumers of both grill lighter fluids and lamp oils, labelled R65, would no longer be allowed.

Option 6: Prohibition of the sale to the general public of lamp oils labelled R65 and grill lighter fluids labelled R65 or classified as highly flammable or extremely flammable

Some Member States have indicated that the number of accidents linked to the ingestion of grill lighters by small children is minor compared to accidents due to burns. This option would extend the restriction on grill lighters to also cover highly flammable and extremely flammable grill lighter fluids sold to the general public. Regarding lamp oils, the measure would be identical to the one described in the previous option.

Section 6: Analysis of impacts

The analysis of the impacts of the various policy options has been conducted taking into consideration the following criteria: effectiveness and proportionality to reduce the identified risks, practicality, economic impact and monitorability. Advantages and disadvantages have been examined for each option.

The marketing data and estimated costs refer to the latest information available to the Commission at the time of writing this impact assessment. This information has been supplied mainly by the Competent Authorities from the Member States attending the Limitations Working Group. However, despite repeated efforts the information available remains scarce, in particular regarding alternatives.

Option 1: No additional EU action

Despite the existing ban of the sale to consumers of coloured and scented lamp oils being labelled with R65, accidents with infants are still happening and the trend regarding grill lighters is increasing.

As detailed in section 2, if no further action is taken at Community level, these trends may continue and even though the number of accidents may decrease if Member States would improve national monitoring and information campaigns, this will have a limited impact.

Furthermore, whilst for lamp oils, Member States are barred from taking further national legislative measures they could well do so for grill lighters but only before June 2009, which seems unlikely.

Option 2: Voluntary action by industry

According to the information received during discussions in the Limitations Working Group, industry is not inclined to take voluntary action. Quite on the contrary, representatives from industry considered that the accidents observed were due to negligence or misuse and expected that useful information, in particular on alternatives, will be developed under the REACH Regulation. Therefore, according to industry, if a ban on lamp oils and grill lighter fluids labelled with R65 was to be proposed, it would be more efficient to wait for the outcome of the registration process under REACH before taking further action. Furthermore, lamp oil and grill lighter producers are concerned that the restriction on lamp oils would lead to the use of so-called alternatives which, according to their experience, do not work properly. Regarding grill lighters, producers have indicated that such a restriction may induce consumers to use alternative products which are not intended to be used as grill lighters, such as white spirits or methylated alcohol. Such behaviour could increase the number of accidental burns due to their higher flammability. On that basis it is unlikely that industry would be interested in setting up a voluntary commitment aiming at phasing out certain substances and preparations for use in grill lighter fluids and lamp oils or take other voluntary measures such as additional labelling or information campaigns.

Besides, with the exception of Germany, companies placing on the market lamp oils and grill lighter are not organised in industry associations. 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, could therefore create a significant administrative burden for companies and – if existing - the relevant industry associations.

It is not possible to quantify with any certainty the administrative burden to companies for this option. There is no reliable information on how many companies would actually participate, how big the coverage of the market would be and how they would organise and monitor compliance.

Option 3: Additional labelling and packaging requirements for grill lighter fluids and lamp oils, labelled R65, sold to the general public

Current legislation on lamp oils already imposes the obligation to label lamp oils with the following sentence “Keep lamps filled with this liquid out of the reach of children”. A requirement to add the statement “Just a sip of lamp oil – or even sucking the wick – may lead to life-threatening lung damage” to the already existing labels of lamp oils, would entail some additional costs to industry. However, this cost would be quite limited, if any at all, as it could be done at the same time industry is required to re-label these products in order to comply with the obligations derived from the new EU rules on Classification, Labelling and

Packaging (CLP) of dangerous substances and mixtures²⁰. The same assessment would apply to grill lighter fluids, for which there is currently no requirement to add any warning phrase in addition to those derived from the legislation on classification and labelling of dangerous substances and preparations.

The new EU rules on classification and labelling, which have just been adopted in December 2008 and are likely to be published before the end of 2008, are intended to align EU legislation on classification, labelling and packaging of substances and mixtures to the United Nations Globally Harmonised System (GHS). After a transitional period, the new Regulation will replace the current Community rules on classification, labelling and packaging of dangerous substances (Directive 67/548) and dangerous mixtures (Directive 1999/45/EC). The deadline for substances classification and labelling according to the new rules will be 1 December 2010 and for mixtures 1 June 2015.

All the lamp oils and grill lighter fluids covered by the Commission proposal will be affected by these new rules, since they contain dangerous substances (i.e. they have to be labelled with R65). As an example, the R65 terminology (“Harmful: may cause lung damage if swallowed”) which currently appears on the labels of the products intended to be covered by the Commission proposal, will be replaced by the hazard statement “H304: May be fatal if swallowed and enters airways”. This means that as a consequence of this horizontal legislation, lamp oils and grill lighters will have to be re-labelled in any case. Since according to the definitions in the chemicals legislation (REACH), most, if not all, lamp oils and grill lighter fluids are substances, the re-labelling due to the requirements imposed by the CLP rules and by the Commission proposal on lamp oils and grill lighters, could be done at the same time, in particular by 1 December 2010. No additional administrative burden could therefore be expected from this option.

As regards the benefits of the additional labelling requirements for lamp oils, the new provisions are expected to increase parent’s awareness about the seriousness of the risks linked to the misuse of these products. Current labelling requirements are correctly implemented by manufacturers but they draw parents awareness mainly to the lamps filled with this liquid, not to the container itself. Besides, parents may not have been sufficiently informed about the drastic consequences of leaving these products within the reach of children. The new warning phrase will clearly specify that life-threatening damage can be caused by just a sip of lamp oil or sucking the wick of the oil lamp. For grill lighter fluids the benefits will be even larger, as no specific provisions were required so far, only the general rules emerging from the provisions on classification and labelling of dangerous substances.

If, despite the information provided in the label, parental supervision fails and children are still able to have access to these products, it is considered that a change in the packaging of the container, of both lamp oils and grill lighters, could make these substances less attractive to children. At present, it seems that many children mistake these liquids with drinks since they are mainly sold in transparent bottles which are very similar to water bottles. To minimise the likelihood of such a mistake, it is proposed to change the packaging of containers in order to make them less attractive for small children. A black container is deemed to meet that purpose. There is no specific figure to assess the cost of such a measure. Industry has nevertheless confirmed that the impact would be minimal as already now these

²⁰ Regulation XX/XX* of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006 (*Add reference once it is published).

products are packaged in plastic bottles. Using a different plastic material with the addition of a pigment will only marginally increase costs. This impact could be further reduced by foreseeing an appropriate transition period of 15 months. The date of December 2010 could be the most appropriate. Industry could minimise the cost by introducing the labelling and packaging measures at the same time.

This option will not have significant impacts on the environment or on employment, and companies will continue to sell their products with improved information on the label and with a similar package that most likely would come from the same supplier or a very similar one.

As regards grill lighters, it could be that the new information on the label will reduce the risk of ingestion by deterring the purchase rather than by inciting consumers to take more precautions to keep the product out of the reach of children. This could lead to a situation where consumers would buy existing alternatives which are safe. However, it could also lead to the use of products that have not been conceived to be used as grill lighters and that are more flammable, leading to an increase in the number of accidental burns, as further described in Option 4. It seems reasonable to assume however, that a consumer who does not buy a grill lighter based on information contained on the label, is likely to also read labels of alternative products and buy appropriate safe alternatives. Also in this case, the additional labelling requirements would have an overall net positive impact in consumers protection.

Option 4: Prohibition of the sale to the general public of grill lighter fluids labelled R65 and additional labelling and packaging requirements for lamp oils labelled R65.

Lamp oils labelled R65

For lamp oils this option and hence the impacts are identical to Option 3.

Grill lighter fluids labelled R65

Industry has considered a ban on grill lighter fluids labelled R65 quite disproportionate. As with many other domestic accidents with household chemicals, appropriate parental supervision should ensure that containers are safely stored and are out of the reach of children.

Reactions from the Member States in the Limitations Working Group were in principle not opposed to a ban on grill lighter fluids labelled R65 as alternatives are currently available, such as the following:

(a) Grill lighter fluids not labelled R65:

- Methyl esters of long chain fatty acids (i.e. rapeseed oil)
- Isopropyl alcohol
- Propyl alcohol
- Butyl alcohol
- Ethanol

- Paraffinic and naftenic base oils, complex combination of hydrocarbons (C10-C50)
- Some distillates of high petroleum

(b) Grill lighters that are not fluid

- Grill lighter gel
- Solid paraffin cubes
- Impregnated briquettes
- Electric grill lighters

Due to the lack of detailed data it is not possible to undertake a full economic analysis of this measure but, it seems that – with exception of the electric grill lighters - producers of grill lighter fluids labelled R65 are in most cases also producing the alternatives. Regarding the cost to consumers of alternative formulations, 1 litre of liquid grill lighter costs 3-4 euros, which is just a bit cheaper than the cost of 1 litre of grill lighter gel or a box of solid paraffin cubes or impregnated briquettes. Although the chemical composition of solid cubes or bar-shaped grill lighters is similar to the fluids, these alternative products are less dangerous because the liquid constituents are bound to sawdust or cork powder. Therefore, there is almost no risk that the harmful oils in these products can creep into the lungs if ingested. The same conclusion is applicable to gels.

Regarding the risks to human health of alternatives, preparations not labelled R65 do not pose an aspiration hazard and therefore accidents leading to chemical pneumonia are not likely to occur. Alternatives might lead to other effects after ingestion such as dizziness, drowsiness, vomiting or others, but such effects are less severe and are fully reversible. Besides, those accidents are less likely to occur as it would be necessary to drink larger amounts, which is not likely to happen as kids would normally stop drinking after a few sips.

Despite the fact that an effective ban on grill lighters would eliminate ingestion accidents altogether, whereas a new label will do so only incompletely, it is not possible to ignore an important concern raised by industry and some Member States regarding the potential increase of accidental burns if a ban was proposed. In fact there is a possibility that, as a consequence of the ban, consumers may increase the use of products that have not been conceived to be used as grill lighters. Those products contain alternatives that are more flammable – such as alcohols - which would lead to an increased number of accidents, not linked to ingestion but to burns. A report on methylated spirits prepared in June 2008 by the French national poison centre (CCTV) concludes that methylated spirits, which contain ethanol or methanol (up to 7%), are currently being (mis)used by consumers as grill lighters and are the main cause of accidental burns linked to grill lighters. In fact, despite the availability of alternative safe grill lighters, in France, accidental burns involving alcohol based products also used as grill lighters are 4 times more frequent than accidental intoxications with paraffin based grill lighters. To avoid that the ban on grill lighter fluids labelled R65 would worsen the current situation and indirectly lead to a higher number of accidental burns, the French national poison centre recommends to only allow the use of solidified forms of methylated spirits. It also recommends to eliminate methanol from methylated spirits or to limit the concentration up to 5%. An opinion of the French Committee

for Consumers Protection (CSC²¹) on methylated spirits and grill lighter fluids and gels concludes that similar measures are necessary to avoid the estimated 580 cases of accidental burns each year. In 2007, France reported 177 cases of accidental ingestions linked to lamp oils and grill lighters. This figure is much lower than the reported 580 cases linked to accidental burns with methylated spirits. It is therefore likely that a ban on grill lighter fluids labelled with R65 may induce consumers to increase the (mis)use of methylated alcohol for grill lighting, which would increase the risks of burns and lead to the opposite result as intended, namely that consumer safety, in general terms, will not be improved.

It would be appropriate to compare whether the potential increase in the costs due to the additional accidental burns would off-set the total elimination of the costs related to ingestion accidents if a ban on grill lighter fluids was to be proposed. Rough estimates (based on the difference in average ingestion and burn accident costs due to the share of children involved and the probable risk of a fatal outcome) show that under the plausible assumptions that accidental burns with methylated spirits are to a significant extent the result of their (ab)use as grill lighters and the majority of consumers would switch to this (cheaper) alternative, a ban might possibly lead to an overall *increase* in accidental costs. However, in the discussions with national authorities and industry, not enough data have become available to provide a detailed quantitative analysis.

Finally, some Member States have indicated a basic problem in supporting option 4. In some national markets, many of the grill lighter fluids and lamp oils contain the same constituents classified R65. Therefore, if grill lighter fluids labelled R65 were to be removed from the EU market, lamp oils labelled R65 should be removed also, and not just labelled with additional warning phrases. A restriction on only grill lighter fluids labelled R65 would reduce, but not remove the risk to children, as lamp oils labelled R65 with the same constituents could still be accessible in households.

Option 5: Prohibition of the sale to the general public of both grill lighter fluids and lamp oils labelled R65.

For grill lighter fluids this option and hence the impacts are identical to Option 4.

Regarding the impact of a ban on lamp oils labelled R65, the main concern expressed by Member States during discussions in the Limitations Working Group was about the availability of suitable and economically feasible alternatives. On the basis of a note prepared by the German authorities (BfR / BAM), the following information on substitutes can be provided:

- (1) Rapeseed oil-based products

Chemical description: Rapeseed methyl ester (C18-C22; RME, biodiesel)

Reports on accidental ingestion: The BfR-ESPED Study 2000-2006 (total survey of all lamp oil accidents in all German paediatric hospitals) recorded 6 cases of ingestion with no symptoms. There have been no health impairments signalled from German Poison Control Centres

²¹ Commission de la Sécurité des Consommateurs.

However, according to the results of technical performance testing (see below), rapeseed methyl esters are no suitable alternatives in most types of lamps and torches.

Suitability	Rapeseed methyl ester	R65 product
Decorative oil lamps	No	Yes
Classical paraffin lamps	No	Yes
Pressure lamps	No	Yes
Garden torches	No	Yes
Grill lighting	Yes, with restrictions	Yes

Purchase price : About 1.5 times that of R65-labelled products.

(2) Edenor LPL (Palm oil-based)

Chemical description: Mostly coconut or palm oil / palm kernel oil fractions with esters of saturated fatty acids (branched chains C14-C18), 2-ethylhexyl ester of octanoic acid.

Reports on accidental ingestions: the BfR-ESPED study 2000-2006 did not record any cases of ingestion and there have been no health impairments signalled from German Poison Control Centres.

According to the results of technical performance testing (see below), the preparations are suitable alternatives for decorative lamps, albeit with some limits, whereas they are not suitable for other types of lamps.

Suitability	« Palm oil »	R65 product
Decorative oil lamps	Yes, but lower creep capability in the wick	Yes, very high creep capability in the wick
Classical paraffin lamps	No	Yes
Pressure lamps	Yes, but 50% lower brightness	Yes
Garden torches	Yes, but lower creep capability in the wick	Yes, very high creep capability in the wick
Grill lighting	Yes	Yes

Purchase price: About 5 to 7 times that of R65-labelled products.

(3) Low-viscosity n-paraffins (carbon chain length C15-C30)

Chemical description: Alkanes from different hydrocarbon cuts C15-C30.

Report from accidental ingestions: Reports on accidental ingestions: the BfR-ESPED study 2000-2006 did not record any cases of ingestion and there have been no health impairments signalled from German Poison Control Centres.

According to the results of technical performance testing (see below), the preparations are suitable alternatives for decorative lamps and some other types of lamps and torches, albeit with some limits, whereas they are not suitable for classical paraffin lamps.

Suitability	n-Paraffins (C15-C30)	R65 product
Decorative oil lamps	Yes, but low creep capability in the wick	Yes, very high creep capability in the wick
Classical paraffin lamps	No	Yes
Pressure lamps	Yes, but restricted in cold surroundings	Yes
Garden torches	Yes, but low creep capability in the wick	Yes, very high creep capability in the wick
Grill lighting	Yes	Yes

Purchase price: about 1.5 times that of R65-labelled products.

In summary, based on the data submitted by the German authorities to the “Limitations Working Group”, fairly suitable substitutes for decorative lamp oils would be the palm oil-based product “Edenor LDL” and the low viscosity n-paraffins (carbon chain length C15-C30), provided that the distance between the liquid and the upper end of the wick is less than 50 mm.

The cost to the consumer of the alternatives is 1.5 times higher in the case of n-paraffins (C15-C30) and around 5 to 7 times higher in the case of palm oil.

The possibility of using these substances as alternatives is however contested by the German Federal Institute for Materials Research and Testing (BAM) as well as by industry. BAM investigated the combustion and performance characteristics of these three so-called child-safe lamp oils and concluded that the performance of these alternative fuels is insufficient. All three alternative oils exhibited a much poorer performance in terms of combustion behaviour at the wick than the traditional lamp oils. The product from palm kernel oil was identified as the best alternative. The RME lamp oil showed the poorest combustion performance. This oil contains unsaturated compounds and is inclined to slowly resinify under light and air impact, which causes the wick to clog and become useless.

Palm seed oil could be considered as a potential suitable substitute. Nevertheless palm kernel is currently scarce because of a worldwide demand for renewable raw materials (biodiesel) which is likely to lead to an increase in price beyond the 5 to 7 times higher prices initially estimated.

A second concern is that lamp oils labelled R65 used in decorative oil lamps are the same as those used in agrarian country lamps, classical paraffin lamps and high luminosity lamps (also

called Argand lamps). According to the information of the performance test mentioned above, none of the alternatives are suitable for these lamps. If a ban of lamp oils labelled R65 was to be adopted, it seems that classical paraffin lamps could not be used. The possibility of granting a derogation for this application is not foreseeable as it would make the restriction on lamp oils labelled R65 useless. The same substances would be available on the market and present in households.

Information provided by the Irish authorities and a surveillance exercise in Belgium have identified lamp oils that are not labelled R65 and that are currently been sold in those markets. These are:

- Paraffins (petroleum), normal C5-20 (CAS 64771-72-8),
- 100% liquid paraffins (CAS 8042-47-5)
- Lubricating oils, petroleum based C1530, neutral oil, hydrotreated

However, it can not be excluded that the first alternative on the list has been wrongly labelled since a product with the same CAS number is labelled with R65 in other Member States. Furthermore, the forthcoming implementation of the new system for classification and labelling of dangerous substances and preparations (CLP) would lead to more substances being classified as R65 and therefore substances that are currently considered as alternatives may no longer be available in the future. This is due to the fact that the criteria for labelling substances as H304 (the new terminology to replace R65) are stricter, cover a wider range of substances and are more protective of human health. In fact, according to HSPA, the majority of the potential alternatives, if not all, would be classified as H304 (i.e. May be fatal if swallowed and enters airways) when the new system would enter into force.

Cyprus and Greece have indicated that according to the orthodox tradition, in many households people place oil lamps in front of icons. So far none of the mentioned alternatives seem to be available in those countries. To be respectful of such a tradition, the proposal for a prohibition of the sale to consumers of lamp oils and grill lighters could envisage a derogation based on cultural and religious traditions. Nevertheless it would be necessary to assess whether the alternatives that seem to be available in other countries could not be also used in the lamps used by orthodox, or whether the use of olive oil could not be envisaged. Otherwise, the restriction on grill lighters labelled R65 in these two countries would be difficult to enforce as consumers would still have access to lamp oils labelled R65.

Regarding the economic impact of a ban on grill lighter fluids and lamp oils, labelled R65, for consumers use, the German Federal Ministry for Science and Technology made an estimate in 2007 based on a measure that would impact 5 million bottles of grill lighter fluids and 6 million bottles of lamp oils. It calculated that the ban, in Germany alone, would lead to a situation were 200 jobs will be lost (producers and importers) and cause losses of 22.000.000 € in sales and profits. These losses may nevertheless be compensated by the benefits generated by alternative products.

Also in Germany, the Federal Institute for Risk Assessment has calculated the economic impact of the intoxications. In the time between January 1999 and December 2006, almost 1.900 cases of health impairment were reported. This led to 780 pneumonias and 2 fatal casualties. For that period of time, a cost assessment of the financial burden caused through physician consultations, hospital admittance, diagnostic and therapeutic costs resulted in 20

million € without taking into account the cost that could be attributed to fatal casualties, parents out of work and follow-up costs.

The data provided by Germany might indicate that, without valuing the negative health impacts beyond treatment costs or valuing the loss of lives, a total ban would have a very low economic impact as losses in sales and profits will be very close to the expected benefits. However, simply transposing these figures does not reflect the problem linked to the lack of available alternatives for certain oil lamps. In any case, due to the lack of data it is not possible to extrapolate this figure to the whole EU

In summary, it seems that, although alternatives not labelled R65 could be currently available in some countries, the adverse impact of a ban for possible use of classical oil lamps remains high and the availability of alternatives is questionable once the new classification and labelling rules would enter into force. The measure would be effective in decreasing children intoxications as lamp oils and grill lighters labelled R65 would no longer be available to consumers, at least when all existing stock in households is used up. On the other hand, the risk of accidents from burns would most likely increase.

Option 6: Prohibition of the sale to the general public of lamp oils labelled R65 and grill lighter fluids labelled R65 or labelled as highly flammable and extremely flammable.

For lamp oils, this option and hence the impacts are identical to Option 5.

This option would mean that, in addition to the restriction on grill lighter fluids sold to the general public labelled R65, grill lighters fluids sold to the general public carrying the indication of being highly flammable and extremely flammable should only be placed on the market in gel or solid form, not liquid.

A ban on grill lighter fluids labelled R65 would most likely lead to an increase in price of liquid grill lighters. As a consequence, manufacturers may switch to place on the market grill lighters containing alternatives that are more flammable. This option is therefore intended to avoid that a ban on grill lighter fluids labelled R65 may encourage producers to use cheaper alternative products, in particular methylated spirits, which, due to their alcohol content, are flammable and therefore likely to lead to an increasing number of accidental burns.

As liquid methylated spirits are used not only in grill lighters but also in other applications, such as fondues, solvents, insecticides, disinfectants or cleaning products, it would be necessary to launch an appropriate debate with industry and authorities to fully understand the products that would be affected, the availability of alternatives in the Community and the enforceability of the measure. Adopting measures only applicable to grill lighter fluids would not avoid the problem of misuse. More importantly it should be assessed whether the number of accidents due to methylated spirits is higher than those linked to other flammable products such as petrol or white spirit and, therefore, whether taking measures only on methylated spirits would be justified. Currently the Commission does not possess appropriate data to assess the impact of this option.

An option that could be deemed more appropriate is a revision of the European Standard containing safety measures for fire lighters. As explained in section 2, this standard specifies, amongst others, the composition of firelighters. The use of highly flammable liquids is, however, specifically excluded from the scope of the standard as their use as barbecue firelighters is regarded as highly dangerous. Additional work could be envisaged in this area to ensure that an appropriate assessment is done of all substances that due to their

flammability should not be used as firefighters or of any other measure that would make them safer, such as the placing on the market in a solidified form.

Section 7: Comparing the options

OPTION	Effectiveness	Efficiency
<p>Voluntary action by industry</p>	<p>Very low: Likelihood that industry would agree on voluntary action is very low as, in their view, the main cause of the problem is lack of parental awareness and surveillance.</p> <p>Besides, with the exception of Germany, companies placing on the market lamp oils and grill lighter are not organised in industry associations. 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, could therefore create a significant administrative burden for companies.</p> <p>Difficulties for the Member States Competent Authorities to verify the compliance of the industry with voluntary action.</p>	<p>Very low: Administrative costs for industry and market surveillance authorities for setting up, enforcing and monitoring a voluntary commitment can be a significant burden.</p>
<p>Labelling and packaging on grill lighter fluids and lamp oils, labelled R65, sold to the general public</p>	<p>Average: The labelling provisions will lead to higher awareness of risks and necessary measures to protect children from accidental ingestion. Additional and more accurate information will be provided on the container regarding safe use of lamp oils as well as precautions required when using the product in oils lamps</p> <p>Besides, the packaging provisions imposing black containers would reduce the likelihood that children confuse these products for drinks.</p>	<p>High: The costs for the additional labelling and packaging will be very low as industry will, in any case, have to re-label these products to meet the obligations imposed by the new EU rules on classification, labelling and packaging of dangerous substances.</p> <p>The cost of re-packaging in order to use a container that is less appealing to children is very low as the cost of the container in the final price is just marginal. The impact could be further reduced by foreseeing the same implementing date after an adequate transition period. Consequently, no additional administrative burden is expected.</p>

<p>Ban of the sale to consumers of grill lighter fluids and labelling/packaging on lamp oils, labelled R65, for consumer use.</p>	<p>Average to high for grill lighters: risks of chemical pneumonia linked to grill lighters will be eliminated. However, in some national markets, many of the grill lighter fluids and the lamp oils contain the same constituent classified R 65. Therefore if only grill lighter fluids labelled R65 were to be removed from the EU market, children would have access to the same substances via lamp oils which could still be accessible in households.</p> <p>Secondly, the ban on grill lighter fluids may lead to an increase in the number of accidental burns. A ban on grill lighter fluids labelled R65 would most likely lead to an increase in price of liquid grill lighters. As a consequence, manufacturers may switch to place on the market grill lighters fluids containing alternatives that are more flammable which may lead to an increase in the number of accidental burns.</p> <p>Average for lamp oils: This will lead to higher awareness of risks and necessary measures to protect children from accidental ingestion, both from containers and from oil lamps. It will also minimise the likelihood of mistaking lamp oils for drinks.</p>	<p>Average for grill lighters: No significant costs are expected for consumers, due to existence of alternatives of comparative cost (in gel or solid form) and technical feasibility for this application. Relatively neutral for certain manufacturers many of whom already produce alternative formulations. The implementation of the new rules on classification and labelling of dangerous substances will, most likely, lead to more substances being classified as R-65 (or H304 under the new rules) and therefore less alternatives available.</p> <p>High for lamp oils (as above)</p>
<p>Ban of the sale to consumers of grill lighter fluids and lamp oils, labelled R65.</p>	<p>1) Grill lighters (as above)</p> <p>2) Lamp oils</p> <p>High: This measure would ensure elimination of cases of chemical pneumonia.</p> <p>In order to respect the orthodox tradition, it might be necessary to foresee a derogation for cultural and religious reasons in some Member States as uncertainties remain on the availability of alternatives</p>	<p>1) Grill lighters (as above)</p> <p>2) Lamp oils</p> <p>Low to average: Significant costs are expected for consumers due to the higher price of potential alternatives (from 5 to 7 times higher). Concerns remain on the technical feasibility of the alternatives for these applications.</p> <p>Furthermore, there will be no supply for the classical paraffin lamps, agrarian country lamps and high luminosity lamps, for</p>

		<p>which currently there are no suitable alternatives.</p> <p>The implementation of the new rules on classification and labelling of dangerous substances would lead to more substances being classified as R-65 (or H304 under the new rules) and therefore less alternatives available</p> <p>Some SMEs would have to adapt their formulation to stay in the market. Some losses would be compensated by gains for manufacturers of alternatives</p>
<p>Ban of the sale to consumers of lamp oils labelled R65 and grill lighter fluids labelled R65 or classified as highly flammable and extremely flammable</p>	<p>1) Grill lighters</p> <p>High: this measure would ensure elimination of reported cases of accidents due not only to ingestion but also to burns.</p> <p>Not enough data is available to assess the overall impact.</p> <p>2) Lamp oils (as above)</p>	<p>1) Grill lighters (as above)</p> <p>Low: Losses for manufacturers of all the targeted grill lighters and higher costs for consumers which currently use methylated spirits as grill lighters due to their lower cost. Gains are to be expected for manufacturers of alternatives.</p> <p>2) Lamp oils (as above)</p>

In conclusion, based on the information available as well as discussions with industry and Member States during the meeting of the Limitations Working Group option 3 is for the time being the most proportionate. This conclusion is based on the need for action to reduce the number of reported accidents involving children as soon as possible without disregarding remaining uncertainties, in particular:

- the availability of safer alternatives for all types of lamps;
- lower availability of alternatives due to the replacement of the current system for classification and labelling of dangerous substances with the Globally Harmonised System (GHS), which may lead to a situation where more substances would have to be labelled and thus, eliminating the use of alternatives that still seem possible today;
- possible use of less suitable products that may increase the problem of accidental burns linked to grill lighters. Although it cannot be excluded that the potential increase of accidental burns could be set-off by the elimination of ingestions, if a ban on grill lighter fluids labelled R65 was to be proposed, this proposal cannot be recommended with confidence based on existing data. The labelling and packaging measures for grill lighters (option 3) are deemed to be more appropriate within the current knowledge, as they are

expected to reduce the number of accidental ingestion by children and do not have any negative effects in terms of increased number of burns compared to the present situation.

The level of protection would thus be increased as of the end of 2010. Taking no action now and proposing instead action after 1 June 2009 in the framework of REACH would delay an increase of the level of protection to at least 2012. In fact, consultations with the Member States in the elaboration of the current report have provided strong indications that availability of alternatives at the present stage remain questionable for lamp oils. Member States would therefore have difficulties to prepare an Annex XV Dossier under REACH in order to strengthen the existing restrictions in June 2009, which could be the basis for a ban. For the same reasons, it would not be useful if the Commission requested the European Chemical Agency (ECHA) to start preparing a dossier immediately after June 2009. Further information concerning alternatives would probably become available only after 2010 (end of the registration period for substances placed on the market in quantities above 1000 tonnes) and only then would the ECHA have information available that could allow it to produce an Annex XV Dossier. Legislative measures based on this could then be adopted only in 2012.

In addition, as questions about safer alternatives remains the crucial element in this dossier and the level of detail of the information contained in registrations under REACH will probably not allow to identify all possible alternatives via a search in the registration data base, a reporting mechanism should be established to gather data on development of alternatives and provide the basis for a review by the European Chemical Agency. During the consultations, Member States requested this very strongly – also as an incentive for industry to look for alternatives. The industry consulted did not object to such a reporting obligation. Whilst this would impose some administrative burden on industry and national authorities, the amount of required information could be kept limited in order to minimise the impact.

Considering the overall costs and benefits, this measure is proportionate. There would be no impact on the EU budget. The proposal will also be notified to the WTO under the TBT agreement, which will give third countries the possibility to comment.

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 apply the relevant controls on the market in terms of production, import, distribution and use. In addition, in order to encourage industry to actively seek for alternatives a review of the proposed measures and of the availability of alternatives would be included in the Commission proposal. 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 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 with respect to the number of accidents is obtained through cases registered by the poison centres, recommendations/complaints by the Member States and by industry. Nevertheless, as information on alternatives to lamp oils remain the crucial question in this dossier, a reporting mechanism should be established to gather data on

development of alternatives and provide the basis for a review by the European Chemical Agency.

As already mentioned the Regulation (EC) No 1907/2006 (REACH Regulation) will repeal Directive 76/769/EEC on 1 June 2009. The Regulation has established a European Chemical Agency for the purposes of managing and carrying out technical, scientific and administrative aspects of the Regulation and to ensure consistency at Community level in relation to these aspects. In particular, a Forum for Exchange of Information on Enforcement will be managed by the Agency and will coordinate a network of Member States authorities responsible for enforcement of this Regulation. The National Authorities competent to monitor compliance with the REACH Regulation will be also responsible to ensure enforcement of the restrictions in Annex XVII.

There will be no transposition costs for the Member States, as the proposed Decision will not require any transposition by the Member States. With effect of 1 June 2009, the restrictions will be included into Annex XVII of the REACH Regulation and will then become directly applicable.

Section 9: References

- (1) Lamp oils - De Vries I & van Gorcum TF (2006). Rapportage Onderzoek naar vergiftiging met lampolie 2005. Brieffrapport NVIC. (<http://rivm.openrepository.com/rivm/bitstream/10029/13393/1/660100001.pdf>)
- (2) BfR-ESPED Study: Dangerous Lamp Oils – Documentation of lamp oil poisonings 2000-2006, International Congress of the EAPCCT in Seville, 2008. (http://www.eapcct.org/publicfile.php?folder=congress&file=Abstracts_Seville.pdf)
- (3) Opinion of the French Committee for Consumers Safety regarding methylated alcohol and grill lighter fluids and gels. September 2008. (www.securiteconso.org)

Annex 1: Main Lamp oils and grill lighters classified R65 and their alternatives

LAMP OILS

(a) Main substances used as lamp oils labelled with R65 (non-exhaustive list)

Composition	Identification
Paraffins (petroleum), normal C5-20	CAS 64771-72-8
Alkanes, C10-14	CAS 93924-07-3
Distillates (petroleum) hydrogenated light	CAS 64742-47-8
Naphtha (petroleum), hydro-treated heavy	CAS 64742-48-9
Naphtha (petroleum), heavy alkylate	CAS 64741-65-7

(b) Main substances used as lamp oils not labelled with R65

Liquid paraffins	
N-paraffins (C5-20)	
Edenor LPL (Palm-oil based)	
Low-viscosity n-paraffins C15-C30	

GRILL LIGHTERS

(a) Main substances used as grill lighter fluids labelled R65

Paraffins (petroleum), normal C5-20	CAS 64771-72-8
Alkanes, C10-14	CAS 93924-07-3
Distillates (petroleum) hydrogenated light	CAS 64742-47-8
Naphtha (petroleum), hydrotreated heavy	CAS 64742-48-9
Distillates (petroleum) hydrotreated light paraffinic	CAS 64742-55-8
Paraffins (petroleum) normal C5-20, acid and clay-treated	CAS 90669-79-7
Naphtha (petroleum), light aliphatic	CAS 64742-89-8

(b) Main substances used in grill lighter fluids which are not labelled with R65

- Methyl esters of long chain fatty acids (i.e. rapeseed oil)
- Isopropyl alcohol
- Propyl alcohol
- Butyl alcohol
- Ethanol
- Paraffinic and naphthenic base oils, complex combination of hydrocarbons (C10-C50)
- Some distillates of high petroleum
- Grill lighter gel

(c) Grill lighters that are not fluid

- Solid paraffin cubes
- Impregnated briquettes
- Electric grill lighters