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COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Draft 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 lighters

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

SUMMARY OF THE IMPACT ASSESSMENT

**{C(2009) 4020 final}
{SEC(2009) 708}**

Lead DG: Enterprise and Industry

Other involved services: ENV, SANCO, TRADE, SG

Agenda planning or WP reference: 2009/ENTR/022

BACKGROUND

This impact assessment accompanies a Proposal for a Commission Decision restricting the supply to the general public of those lamp oils and grill lighter fluids that are labelled with the standard risk phrase R-65 (Harmful: may cause lung damage if swallowed).

Some grill lighter fluids and fuels used in lamp oils can cause severe damage to children's health if swallowed, and a significant number of such accidents have been reported. To address this concern, restrictions were introduced at EU level on coloured and scented lamp oils, labelled R65, sold to the general public, in Directive 97/64/EC adapting to technical progress for the fourth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations¹. Protective measures on grill lighters and lamp oils have also been introduced in the general EU framework on classification and labelling of dangerous substances and preparations, as well as in European Standards.

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.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

Discussions have been conducted during the last two years with Member States and other stakeholders at several meetings of the Commission Working Group responsible for the implementation of Council Directive 76/769/EEC (hereinafter referred to as the 'Limitations Working Group'). The discussions have covered possible measures on both lamp oils and grill lighter fluids.

Representatives of various industry associations attended these meetings, including the oil companies' European organization for environment, health and safety (CONCAWE), the Hydrocarbon Solvent Producers Association (HSPA), the German Grill Lighters Association (Grillverband) and a German company placing on the market both grill lighters and lamp oils (Schmalfuss). The proposed restrictions on lamp oils and grill lighter fluids have been also discussed with other Commission services, in particular with DG SANCO and DG ENV.

To avoid any legal overlap or contradictions, other related legislation was also examined, such as: the General Product Safety Directive², legislation on classification and labelling of dangerous substances and preparations³ and existing European standards on oil lamps and grill lighters⁴.

¹ OJ L 262, 27.9.1976, p. 201.

² 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).

³ 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

2. PROBLEM DEFINITION AND OBJECTIVES OF THE POLICY INITIATIVE

A significant number of accidents 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 targeted grill lighters and lamp oils should be fitted with child-resistant fastening, accidents still occur as containers are not closed properly, the substance has been transferred from large original containers to smaller containers without child-proof closures or children suck the wick of old oil lamps and garden torches.

Lamp oils and grill lighter fluids may contain paraffin-based oils and petroleum distillates with aliphatic hydrocarbons (n-paraffins)⁵. In case of accidental ingestion, the paraffin-based substances may enter the lungs due to their low viscosity 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, and even death.

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, in some cases resulting in death.

The main objective of the Proposal that accompanies this impact assessment is to limit the risks to the health of consumers, in particular small children, by reducing the number of accidental intoxication involving lamp oils or grill lighter fluids.

3. RIGHT OF THE COMMISSION TO ACT

Directive 76/769/EEC is a well-established instrument at Community level to control risks from dangerous substances and preparations. The Directive establishes harmonised rules to achieve a high level of protection of human health and the environment throughout the Community and to avoid divergent national legislation that cause barriers to intra-Community trade. Directive 76/769/EEC already contains provisions on oils used in decorative lamps. Since 1 July 2000, this Directive, as amended by Directive 97/64/EC, prohibits the sale to the general public of coloured or scented oils, which are labelled R65, for use in decorative oil lamps.

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 on a harmonised area, are limited to concerns based on environmental reasons, not on human health. On the other hand, as grill lighters are outside the harmonised area, Member States could adopt national measures on grill lighters for the protection of human health, but only if those measures were to be adopted before 1 June 2009. On 1st June 2009 Directive 76/769/EEC will

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).

⁴ EN 14059:2002 Decorative oil lamps – Safety requirements and test methods and 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.

⁵ These molecules are made up of chains of carbon atoms (length 9-16) and hydrogen.

be replaced by Regulation N° 1907/2006 (REACH Regulation). According to the new rules, Member States will have the possibility to prepare a restriction dossier intended to justify the need for Community wide measures (Title VIII of the REACH Regulation).

4. COMPARISON OF THE VARIOUS POLICY OPTIONS TO ACHIEVE THE OBJECTIVES

Different options to achieve the intended objectives have been analysed in the Impact Assessment report. The selected option takes into account the remaining uncertainties regarding availability of suitable alternatives for lamp oils for all types of lamps, a potential increase in the number of accidental burns involving grill lighters and lower availability of alternatives in the future due to the replacement of the current system for classification and labelling of dangerous substances with the forthcoming EU rules intended to implement the Globally Harmonised System (GHS) at EU level. A summary of this analysis is given in the table below:

OPTION	Effectiveness	Efficiency
<p>1: No action</p>	<p>Very low: This option will not prevent accidents (fatal or not) for consumers, in particular intoxications with children below 3 years old.</p> <p>Member States cannot adopt national measures on lamp oils and could adopt diverging rules for grill lighters which would create obstacles to the Internal Market. However this right of initiative is limited until 1 June 2009. After that date a Member State would have the possibility of preparing a dossier to request a restriction at Community level.</p>	<p>Low: No extra costs for industry but the objective will not be reached.</p>
<p>2: Voluntary action by industry</p>	<p>Very low: Likelihood that industry would agree on voluntary action is very low as they perceive that the main cause of the problem is lack of parental awareness and surveillance.</p> <p>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</p>	<p>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>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>3: Labelling and packaging on grill lighter fluids and lamp oils, labelled R65, for supply 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, both from containers and from oil lamps.</p> <p>Besides, the packaging provisions would reduce the likelihood that children confuse these products for drinks.</p>	<p>High: The costs for the additional labelling will be very low as within the same time frame industry would 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 is very low in relation to the final price. 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>4: 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 in children will be reduced, which represents the main cause of accidents reported by Member States. 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</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>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>5: Ban on the sale to consumers of grill lighter fluids, and of lamp oils, labelled R65.</p>	<p>1) Grill lighters (as above) 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) 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 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</p>

		alternatives.
6: Ban on the sale to consumers of lamp oils labelled R-65 and grill lighter fluids labelled R-65 or classified as highly flammable and extremely flammable	<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</p> <p>Low: Losses for manufacturers of all the targeted grill lighters and higher costs for consumers who currently use methylated spirits as grill lighters due to their lower cost. Gains are to be expected for manufacturers of alternatives.</p> <p>Nevertheless not enough data has been generated in the course of the current analysis to assess the overall impact of such measure to industry.</p> <p>2) Lamp oils (as above)</p>

5. CONCLUSION

Based on the information available as well as on discussions with industry and Member States during the meeting of the Limitations Working Group, the most proportionate option seems to be option 3, which means labelling and packaging requirements for both lamp oils and grill lighters. This conclusion is based on the need for action as soon as possible to reduce the number of reported accidents involving children 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.

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, Member States would 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 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, 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 ECHA. 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. 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.

6. MONITORING AND EVALUATION

Member States have long-established mechanisms and have nominated authorities to monitor compliance with the restrictions of Directive 76/769/EEC. Regulation (EC) No 1907/2006 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.

A review mechanism will be established with a view to a potential phase-out of these products in line with the provisions foreseen in the Regulation (EC) No 1907/2006.

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 from 1 June 2009 the restrictions will be included into Annex XVII of the REACH Regulation and will then become directly applicable.