ANNEX XV REPORT

ASSESSMENT OF WHETHER THE USE OF GRILL LIGHTER FLUIDS AND FUELS FOR DECORATIVE LAMPS, LABELLED R65 OR H304, INTENDED TO BE SUPPLIED FOR THE GENERAL PUBLIC, SHOULD BE RESTRICTED

SUBSTANCE NAME(S): Lamp oils and grill lighter fluids labelled R65 or H304

IUPAC NAME(S): Non-applicable

EC NUMBER(S): Non-applicable

CAS NUMBER(S): Non-applicable

CONTACT DETAILS OF THE DOSSIER SUBMITTER:
EUROPEAN CHEMICALS AGENCY

DATE: 8 July 2015

About this report

This report concerns lamp oils and grill lighter fluids that "may cause lung damage, if swallowed" (Risk Phrase R65), and "may be fatal if swallowed and enters airways" (Hazard Statement H304). Based on the reports of national poison centres (NPC) from a number of EU Member States (MS) it is estimated that in 2009 there were about 1150 poisonings mainly due to sucking the wicks of garden torches and decorative lamps, containing lamp (LO) oils labelled R65 or H304, and about 1200 poisonings due to accidental ingestion of grill lighter fluids (GLF) in the EU. These accidents mainly involved small children.

In 2010, Commission Decision 2009/424/EC entered into force with the aim of reducing these poisonings. This decision was published as paragraphs 4 to 7 of entry 3 of Annex XVII to the REACH Regulation. In line with paragraph 6 of entry 3, the European Commission asked ECHA (May 2014) to prepare an Annex XV restriction dossier, with a view to ban, if appropriate, grill lighters fluids (GLF) and fuels for decorative lamps (LO), labelled R65 or H304, intended to be supplied for the general public.

This report gives an analysis of poisoning incidents based on information of two surveys carried out in 2014, as well as additional data received from the NPC of eight MS and Norway. It also contains up-to-date description of the alternatives of lamp oils and grill lighter fluids labelled R65 or H304.

Since the entry into force of the new labelling and packaging provisions in 2010, the trend in poisonings due to both LO and GLF labelled R65 or H394 in the EU has been clearly decreasing. On the average, poisonings have reduced by about 9% per annum related to lamp oils; and by about 15% related to grill lighter fluids labelled R65 or H304 in the EU.

This report concludes that due to the clearly decreasing trends and as there are no evidently safer (non R65 or H304) alternatives that would be at least at this stage technically or economically feasible, ECHA sees no need to propose an amendment of the current restriction.

It would seem prudent for Member States to monitor that the decreasing trend in poisonings due to grill lighters fluids and fuels for decorative lamps, labelled R65 or H304, will continue by using the incident data they collect from their national poison centres.

ECHA sent a draft of this Annex XV report to the Commission and to Member State Competent Authorities (MSCAs) as information point at the 18th Meeting of Competent Authorities for REACH and CLP (CARACAL) in 23-24 June 2015. The MSCAs were invited to provide comments on the draft report and especially its conclusions (document CACS/17/2015, "Commission's request to ECHA to prepare an Annex XV report on a potential restriction on the placing on the market of lamp oils and grill lighter fluids labelled R65 or H304, for supply to the general public"). ECHA received written comments from two MSCAs that supported the analysis and conclusions of the report and no request was made to discuss the draft report during the CARACAL meeting.

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Abbreviations

BfR:	Bundesinstitut für risikobewertung (Federal Institute for Risk Assessment of Germany)
BIAG:	Barbecue Industry Association Grill
CAs:	Competent Authorities
CEN:	European Committee for Standardisation
CLP:	Classification, Labelling and Packaging
CAS:	Chemical Abstracts Service
CSRs:	Chemical Safety Reports
DSD:	Dangerous Substances Directive
DPD:	Dangerous Preparations Directive
ECHA:	European Chemicals Agency
EEA:	European Economic Area
EINECS:	European Inventory of Existing Chemical Substances
EU:	European Union
GPDS:	General Product Safety Directive
GLF:	Grill Lighter Fluids
H304:	Hazard (statement) 304
HSPA:	Hydrocarbon Solvents Producers Association
IUPAC:	International Union of Pure and Applied Chemistry
LO:	Lamp Oils
LD_{50}:	Lethal Dosage
MS:	Member States
NPC:	National Poison Centres
NPIC:	Norwegian Poisons Information Centre
OECD:	Organisation for Economic Co-operation and Development
REACH:	Registration, Evaluation, Authorisation and Restriction of Chemicals
R65:	Risk (statement) 65
R&D:	Research & Development
SDS:	Safety Data Sheets
SMEs:	Small and medium-sized enterprises

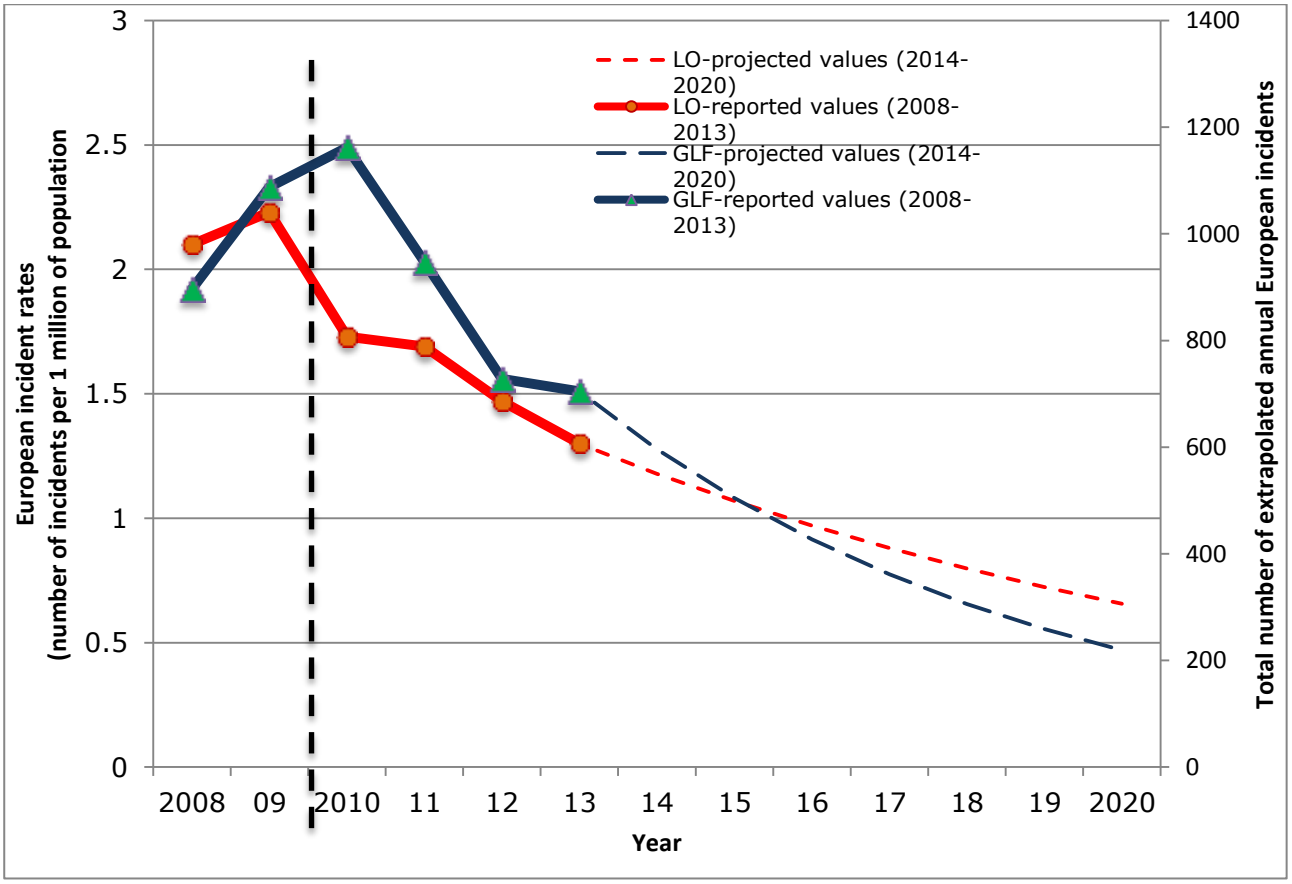
A. Conclusions

A.1 Conclusions based on the assessment

Since 2010, there are clear downward trends of poisoning incidents attributed to lamp oils (LO) and grill lighter fluids (GLF) labelled R65 or H304. These trends are estimated from the total annual number of poisoning incidents registered in eight Member States (MS) and Norway who submitted data to ECHA (representing ~43% of the population in the EU-EEA area). Around 25% and 40% total annual reductions respectively of registered incidents due to LO or GLF labelled R65 or H304 for the period 2010-2013 were reported in those MS (+Norway) that monitor the current situation through their National Poison Centres (NPC).

More detailed information on the data analysis and estimations are presented in section B.10 of this report. Figure 1 shows an overall picture of the findings at EU level.

Figure 1. ***Estimated European incident rates in 2008-13 and projections up to 2020 in the EU-EEA (number of incidents per 1 million of population)***
Sources: ECHA's 2014 consultations (data from eight MS and Norway)



The entry into force in 2010 of the Commission Decision 2009/424/EC[1] coincides with an annual average reduction[2] of 9.3% of incidents related to LO and 15% related to GLF (labelled R65 or H304). ECHA has not received any information that would indicate that this downward trend would not continue. Assuming the percentage reduction between 2010 and 2013 is continued, the poisonings in 2020 can also be estimated, obviously recognising that past trends do not necessarily apply in the future (see Figure 1). If these trends continue the number of poisonings in 2020 due to both LO or GLF labelled R65 or H304 would be in total about 1 incident per 1 million of population (i.e. about 550 incidents in total due to the consumer use of R65/H304 substances for both applications in the EU).

Over 80% of the reported incidents due to LO or GLF labelled R65 or H304 concern children and are due to accidental oral ingestion of the related products leading to minor or mild symptoms. Luckily, no fatal incidents have been reported after 2004 in the EU and EEA.

According to the information provided by MS and stakeholders during the 2014 ECHA consultations, the following conclusions were drawn:

- The main alternatives for LO (non R65 or H304 labelled vegetable oils and derivatives) do not present any aspiration hazard toxicity but they have been reported to possess less good technical performance, as well as to exert corrosive action and disturbing smell in comparison to the LO labelled R65 or H304.
- The main alternatives for GLF (non R65 or H304 denatured alcohols) have a good technical performance but due to their higher flammability, they often cause burning accidents and thereby have a more hazardous profile (more information in section C.2.1). Therefore, an increasing number of burning accidents would be expected should GLF labelled R65 or H304 be banned and the alternatives highly flammable liquids would be used.
- In addition, the non R65 or H304 labelled alternative substances seem to be about 50-100% more expensive than for LO and GLF labelled R65 or H304. In particular, this would seem to be the case for the LO labelled R65 or H304.

Based on the information gathered from EU Competent Authorities (CAs) and industry stakeholders, the existing legislative measures (Entry 3 of Annex XVII to REACH[3]), including the compliance with the European standard EN 14059 on for the design of childproof decorative oil lamps, seem to be sufficient to reduce the risks of these mixtures for the general public since 2010. This reducing trend of incidents may also associate to a raising consumer awareness given that some MS have carried out information campaigns for the proper use of LO and GLF labelled R65 or H304 (three MS have communicated to ECHA their related activities).

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[1] Decision 2009/424/EC amending, for the purpose of adapting to technical progress, Annex 1 to Directive 76/769/EEC as regards restrictions on the marketing and use of lamp oils and grill lighter fluids, OJ L 138, 04.06.2009.

[2] The average growth value for the period 2010-2013 was estimated by the: $((X_{2013}-X_{2010})/(X_{2010})+1)^{1/3} -1)$, where X was the incident rate in 2013 and 2010, respectively.

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 396, 30.12.2006, p.1.

Furthermore, the data received from some CAs indicated that the consumption of LO and GLF labelled R65 or H304 has been stable or even increased after 2010. This observation, in combination with the results showing clear downward trend of poisoning incident rates for both LO and GLF labelled R65 or H304, would further support the conclusion that the current regulatory provisions in the EU are effective.

Due to the clearly decreasing trend of poisonings attributed to LO and GLF labelled R65 or H304 (after 2010) and as there are no evidently safer technically or economically feasible alternatives, ECHA sees no need to propose an amendment to the current provisions in the entry 3 of Annex XVII to REACH. This conclusion is corroborated by the views of the stakeholders and the EU Competent Authorities who took part in the consultation during the preparation of this report.

It would seem prudent for MS to monitor that the decreasing trend in poisonings due to grill lighters fluids and fuels for decorative lamps, labelled R65 or H304, will continue by using the incident data they collect from their national poison centres (NPC).

During the 2014 consultations, ECHA gathered from a few stakeholders some general suggestions of measures that may lead to further risk reduction (as reflected in section G.4 of this report). These could be further investigated by industry (i.e. for developing ways to prevent the small numbers of accidents still occurring) and, if found useful, could be introduced on a voluntary basis.

A.2 Targeting

This report is targeted to assess whether the current provisions in entry 3 of Annex XVII to REACH for LO and GLF labelled R65 or H304 should be amended because the specific requirements are not sufficient to adequately control the risk from the substances.

This targeting is based on the request of the Commission to ECHA. The report concentrates on describing the following aspects:

- the risks to human health due to the placing on the market and use of LO and GLF, labelled R65 or H304;
- the number of accidents caused by LO and GLF labelled R65 or H304 as registered in the National Poison Centres or possibly in the National Health Services since 2008;
- the availability of alternatives to LO and GLF, labelled R65 or H304;
- any socio-economic impacts of banning LO and GLF, labelled R65 or H304, intended for supply to the general public.

A.3 Summary of the justification

A.3.1 Identification of hazard and risk

Information on uses

The following paragraphs set out the main identified consumer uses of LO and GLF labelled

R65 or H304 (more info in section B.2)

Lamp oils (LO) labelled R65 or H304: The most common consumer uses are:

a. for religious purposes as fuels for little storage tanks (mainly in «orthodox» cemeteries),

b. fuels for indoor and outdoor decorative lamps (such as candles sealed and not refillable supplied),

c. lighting uses, as torches/outdoor and ignition of kerosene lamps, and

d. in "illuminated" lamp oil mixtures, used as anti-repellents (mainly for mosquitos).

Grill lighter fuels (GLF) labelled R65 or H304: The most important identified consumer uses are mainly as fuels for light charcoal grills/barbeques, campfires (outdoor) and fireplaces (indoor).

According to the information provided by industry in the frame of ECHA 2014 consultations, LO and GLF labelled R65 or H304 compared to their commercially existing alternatives have the following advantages:

- they are relatively cheap,
- they do not produce smoke, smell, and do not leave carbon residuals,
- they are not classified as flammable,
- they have a very low concentration of aromatics,
- they do not exert any adverse effects to human health if not misused.

During the 2014 ECHA consultations, three CAs (from Finland, Norway and Cyprus) have submitted data on the reported volumes of LO and GLF labelled R65 or H304 in their national markets for the period 2008-2013. Although these data may not be considered as representative for the whole EU area, they provide with an indication that the consumer trends after 2010 are either stable or even increasing for these specific national markets (more information in section B.2.4.1).

Information on hazards to human health

Overall, for both LO and GLF labelled R65 or H304, the main relevant hazard is "aspiration hazard toxicity" (Asp.Tox. 1, according to the CLP Regulation[4]). Ingestion of LO and GLF labelled R65 or H304 can lead in extreme cases to severe lung damage; small children aged 1-3 years are at particular risk if they drink oil directly from the lamps or the container. Very small amounts of the LO/GLF substances (probably less than 80-150 mg/kg body weight) are sufficient to cause serious pulmonary complications that may require hospitalisation in the most severe cases. It should be noted, though, that no lethal cases due to these poisonings have been reported in the EU during the last decade.

[4] Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures. OJ L 353, 31.12.2008, p. 1.

Information on exposure

For the incidents of poisoning due to both LO or GLF labelled R65 or H304, (reported by CAs/NPC in the frame of ECHA 2014 consultations) the main exposure pathway is oral ingestion (in >90% of the reported cases, only approximately 6-8% of cases account for dermal exposure or inhalation).

Exposure to LO labelled R65 or H304 mainly occurs due to their use in refillable decorative lamps. The consumer, after buying the lamp fuel, may often transfer it to another container (such as a water pitcher with squeeze dispenser, battery filler) to make the lamp easier to fill. As a consequence, people (in particular children) can then accidentally drink the fuel. Therefore, it has to be noted that the poisonings due to LO/GLF labelled R65 or H304 are mainly linked to the reasonably foreseeable use of these substances and not to their function in the specific consumer applications.

Exposure to GLF labelled R65 or H304 usually occurs due to accidental drinking directly from the bottle (no burning incidents have been reported by the CAs that communicated information on incidents in the frame of ECHA 2014 consultations).

Characterisation of risk

Although there are still some risks of non-lethal poisoning incidents due to aspiration hazard from accidental oral ingestion of LO and GLF labelled R65 or H304 (given that poisoning cases are still reported in the EU area), clear downwards trends of annual incident rates have been observed after 2010, according to the data submitted by eight EU MS and Norway during the ECHA 2014 consultations.

A.3.2 Justification that action is not required on a Union wide-basis

Considering the downward trends of reported poisoning incidents due to LO and GLF labelled R65 or H304, it can be concluded that:

- The already implemented EU measures have reduced, and are likely to continue to reduce, the risk for the general public due to use of LO and GLF labelled R65 or H304. In particular it is expected that the number of poisoning incidents due to the consumer uses of these substances will continue to decline.
- Given the decreasing trends in poisonings due to LO and GLF labelled R65 or H304 and that alternative fuels for grill lighters have unwanted characteristics (highly flammable/risk of burn accidents), the health impact of an additional EU-wide restriction of the LO and GLF labelled R65 or H304 would seem to be small.

In sum, at this stage, ECHA sees no need for an amendment of the current labelling/packaging provisions (Entry 3 of Annex XVII to REACH) or for proposing stricter EU regulatory measures such as further restrictions or ban of LO and GLF labelled R65 or H304 intended to be supplied for the general public.

B. Information on hazard and risk

The documentation of information on hazard and risks of this report follows the methodology described in Annex I of the REACH Regulation. Eighteen registration dossiers were submitted to ECHA under REACH Regulation for hydrocarbon substances classified as R65 or H304, that are mainly aliphatic hydrocarbon solvents with predominant carbon numbers in the range of C9 to C14.

These dossiers have been screened to review and extract any relevant information (e.g. on health hazards or physicochemical properties).

The rest of information/data presented in this section was extracted mainly from the 2014 ECHA consultations. The available literature and SDS of a few commercial products were also screened for the purpose of this analysis.

B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)/Composition of the substance(s)

Lamp oils (LO) and grill lighter fluids (GLF) labelled R65 or H304 that are currently placed on the EU market mainly contain low-viscosity hydrocarbons. These hydrocarbons can be obtained from different processes, including petroleum refining or chemical transformations. Their composition may be complex.

According to the information received during the ECHA 2014 consultations with the MS and stakeholders, the most common substances present in the commercially available LO and GLF labelled R65 or H304 are members of a group of substances which companies have registered as part of a category entitled "C9-C14 Aliphatics. The constituents of these solvents essentially belong to one or any combination of the linear, branched or cyclic aliphatic hydrocarbon classes. Aromatic constituents, if present, represent less than 2% of the total volume [<2% Aromatics]".

Some of the LO and GLF labelled R65 or H304 also contain up to 10% of short chain alcohols such as isopropanol or isobutanol.

According to the Industry (ECHA's Call for evidence, 2014), some LO and GLF labelled R65 or H304 may also contain aliphatic hydrocarbons with wider ranges of predominant carbon atoms as indicated in table 1. Please note that table 1 provides only an indicative list of the identified LO/GLF labelled R65 or H304 relevant substances in the market (along with their CAS numbers). Several of these substances have been identified by Industry using the naming conventions developed by the Hydrocarbon Solvents Producers Association (HSPA)[5] for the purpose of REACH.

[5] http://www.reachcentrum.eu/consortium/hydrocarbon-solvents-reach-consortium-122.html

Table 1 ***List of main identified hydrocarbon substances in LO and GLF labelled R65 or H304***

(Source: ECHA's consultations, 2014)

Identified substances (HSPA naming conventions)	CAS Number
Paraffines (petroleum), normal C5-C20	64771-72-8
Hydrocarbons, C10-C13, n-alkanes, <2% aromatics	-
Hydrocarbons, C10-C13, isoalkanes, cyclics, <2% aromatics	-
Hydrocarbons, C11-C14, n-alkanes, <2% aromatics,	-
Hydrocarbons, C11-C14, n-alkanes, <2% aromatics	-
Naphtha (petroleum), hydro treated heavy	64742-48-9
Hydrocarbons, C12-C13, isoalkanes, cyclics, <2% aromatics	-
Alkanes, C12-26-branched and linear	90622-53-0
Hydrocarbons, C13-C16, isoalkanes, cyclics, <2% aromatics	-
Alkanes, C14-16	90622-46-1
Hydrocarbons, C14-C17, n-alkanes, <2% aromatics	-
Hydrocarbons, C14-C15, n-alkanes, <2% aromatics	-

B.1.2 Physicochemical properties

The aliphatic hydrocarbon substances of main interest for LO and GLF labelled R65 or H304 present a high risk of aspiration due to their physicochemical properties such as low viscosity, low surface tension and low vapour pressure.

As concluded by the 2014 ECHA consultations, the following four substances are the most commonly available on the EU market as LO and GLF labelled R65 or H304 fuels:

- Hydrocarbons, C10-C13, n-alkanes, <2% aromatics
- Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics
- Hydrocarbons, C11-C14, n-alkanes, <2% aromatics,
- Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics

Therefore, these substances have been selected as representative of the whole category of the related hydrocarbon fractions (see table 1) in order to describe the relevant physicochemical properties. The relevant REACH registration dossiers (some of the information contained is available on ECHAs dissemination website) refer to the 4 following petroleum products (HSPA naming conventions). Concerning their physical state, these are all clear, colourless liquids at 20°C and 1 atm with a characteristic mild odour of aliphatic hydrocarbon. Table 2 lists the values for the physicochemical properties of the above indicated registered substances as described in the REACH registration dossiers.

The kinematic viscosity is the physicochemical parameter that dictates the classification of these type of substances as R65 or H304 (aspiration hazard). Due to their low viscosity, in case of accidental ingestion, these paraffin-based substances may enter the lungs and can cause severe inflammation, commonly referred to as chemical pneumonia. More information on the link between kinematic viscosity and the chemical classification of substances is provided in the section B.3. Of particular interest for this category of substances are also: their vapour pressure, (kPa at 20°C) their measured surface tension (mN/m at 25°C) their flammability (V%) and flash point (°C).

According to REACH guidance R7a, the flammability of liquids is determined on basis of their flashpoint (in combination with their boiling point, as well as their combustibility), their ability to emit flammable gases upon contact with water and their pyrophoricity (spontaneous ignition in air). Given that, as noted in table 2, their flash points are clearly higher than 60°C, these specific substances are considered as non-flammable (according to the CLP Regulation). This is of particular importance for the comparison with existing alternatives for grill lighter fuels that have significantly lower flash points (thereby often characterised as flammable or highly flammable substances, depending on their flash point).

Other reported physicochemical properties are: density (g/cm3 at 15°C), the self-ignition temperature (°C), as well as the boiling and melting points (at 1 atm).

Overall, there is a clear similarity of physical chemical properties for the C9-C14 aliphatic substances (as demonstrated in the table 2, for this subgroup of substances). This observation in combination with the almost identical reported toxicology and environmental fate and effects for all the hydrocarbon substances labelled H304 (even those in wider carbon ranges) can support the grouping of these substances.

Table 2 *Physicochemical properties of a few of the most common aliphatics in LO and GLF labelled R65 or H304*

(Source: REACH registration dossiers/ECHA's website)

	Substance (IUPAC name)			
Property	Hydrocarbons C10-C13, n-alkanes, <2% aromatics	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics	Hydrocarbons, C11-C14, n-alkanes, <2% aromatics	Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics
Boiling point (at 1 atm)	202 - 220°C (ASTM E 537-07 method)	186-214 °C (ASTM D 86 method)	185 to 255 °C (ASTM D 86 method)	203 to 238 °C (ASTM D 86 method)
Density (g/cm^3 at 15°C)	0.74 (ASTM D 4052 method)	0.79 (ISO 12185 method)	0.78 (ASTM D4052 method)	0.81 (ISO 12185 method)
Flammability (V%)	0.6-7.0	0.6-7.0	0.6-7.0	0.6-7.0
Flash point (at 1 atm)-ASTM D 93 method)	79°C	65°C	67°C	77°C
Melting point (at 1 atm)	-21°C ASTM D 97-08	-54°C ASTM D 5950	-60°C ASTM D97-08	-45°C ASTM D 5950
Self-ignition temperature (at 1 atm)	200°C	>200°C	232°C	>200°C
Surface tension (mN/m at 25°C)	No data	25.3 (Wilhelmy plate method)	26.6 (Nouy tensiometer method)	26.4 (Wilhelmy plate method)
Vapour pressure (kPa at 20°C)	0.13 (ESIG tool)	0.05 (ESIG tool)	0.13 (ESIG tool)	0.035 (Internal PetroSA method)
Viscosity (mm^2/s 20°C)	1.76 (ASTMD 445 method)	1.80 (ASTM D 7042 method)	1.50-2.20 (ASTM D 445 method)	2.4 (ASTM D 7042 method)

B.2 Manufacture and uses

B.2.1 Reported uses of Lamp oils (LO) labelled R65 or H304

B.2.1.1. LO labelled R65 or H304 for decorative lamps.

A main use of lamp oils labelled R65 or H304 is as fuel in decorative lamps for various indoor and outdoor applications (e.g. in restaurants, in recreational facilities and in similar areas). The European Standard EN 14059[6] provides the following definitions:

- **Oil lamps** *(section 3.6.):* vessels in which oil is burnt at a wick to provide illumination.
- **Oil lamp for decorative purposes** *(section 3.7)*: oil lamp for interior or exterior use appealing by its design and or the light atmosphere it creates.

The European safety standard EN 14059 for oil lamps aims primarily to restrict the access of small children to the lamp oil contained in decorative oil lamps, but also covers some other safety aspects. It specifies requirements and test methods for oil lamps used for decorative purposes in households, in restaurants, in recreational facilities and in similar public or private areas. The definition of decorative oil lamps-within the context of EN 14059 (and therefore of Entry 3 of Annex XVII to REACH) does not apply to oil lamps for industrial purposes (e.g. securing of road building sites). It must be noted that this standard has been incorporated in EU legislation (according to paragraph-4 of Entry 3 of Annex XVII) as it is used to prove compliance of decorative oil lamps so as to mitigate the associated health risks for small children.

A number of EU companies informed (ECHA's call for evidence, 2014) that they provide disposable liquid decorative candles containing lamp oils labelled R65 or H304 which are sealed (not refillable), thereby much safer than the conventional ones. In certain cases, the decorative items concern lamp holders (from pink glass for example) where a clear fuel cell is placed, therefore making it look bright. Industry also claimed that since such decorative products are sold only for professional use by restaurants and hotels, they cannot be considered as items intended for retail consumer use.

B.2.1.2. LO consumer uses for religious applications.

In the frame of the 2014 ECHA's Call for evidence, the vast majority of the reported - by Industry - consumer uses for lamp oils labelled R65 or H304 were identified in Greece and Cyprus. In both countries LO labelled R65 or H304 are mainly used as fuels for special oil lamps for religious purposes (100-1000 ml) made of plastic or glass little storage tanks. More specifically, small glass pots with wick and metallic burners are commonly sold nearby Greek (and Cypriot) Orthodox cemeteries/accessories shops. In principle, these are sold empty and be filled by the consumers with lamp oil to burn for 3-10 days in cemeteries. It is a religious

[6] European Standard on "Decorative oil lamps – Safety requirements and test methods" (EN 14059) adopted by the European Committee for Standardisation (CEN)

custom in these countries to continuously burn a light for the dead and this can be technically achieved only by use of lamp oils labelled R65 or H304. According to information provided by the Cyprus Authorities, following examination of the properties and function of these specific paraffin oils, they have proven to retain their flame for much longer compared to their non R65 or H304 alternative fuels, such as vegetable oils.

B.2.1.3. LO consumer uses for other lighting purposes

Further to the above-mentioned regular applications in lamps for decorative/religious purposes, the ECHA's 2014 consultations confirmed that paraffin mixtures labelled R65 or H304 are, indeed, used for a range of indoor and outdoor applications, intended for general public such as for:

- Lighting uses, in garden torches/outdoor, ignition of classical paraffin lamps.
- Agrarian country lamps and high luminosity lamps (also called "Argand lamps" or 'quinquets' in France).
- Primus (stoves) and other heating appliances.
- Special "illuminated" lamp oil mixtures, named «citronella», used in oil lamps for mosquito repellent purposes.

B.2.1.4. LO labelled R65 or H304 professional uses

The ECHA's 2014 consultations with MS revealed that lamp oils labelled R65 or H304 are also used for other religion purposes in Italy, which are not intended to be "supplied to the general public" (therefore typically being out of the scope of this investigation). This has been communicated by Italian companies to their competent authorities that use hydrocarbons labelled R65 or H304 to produce (and distribute) lamps for liturgical use. These companies pointed out that the main reason for which candles were substituted with the paraffin oils was the need to remove the black smoke of candles that lay down on art objects of the churches. They also highlighted that these specific lamp oils are considered optimal and highly recommended for safe/daily use since they have never caused injuries or damages to people in the last 25 years.

Furthermore an Italian company informed that their LO product labelled R65 or H304 has been used for years for artistic purposes. It has been widely recognised by restoration institutes (such as the Institute of Fine Arts) as an optimal product to help preserve restorations performed on paintings or frescoes in Italian churches and Cathedrals because any available alternatives leave solid deposits, heavy smoke residues and slag.

B.2.2 Reported uses of Grill lighter fuels (GLF) labelled R65 or H304

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

The main identified uses for GLF labelled R65 or H304, in the frame of ECHA 2014 consultations, include:

- Fuel to light charcoal grills/barbeques,

- Fuel to light campfires (outdoor) and
- Fuel to light fireplaces (indoor).

B.2.3 Other general consumer uses of hydrocarbons labelled R65 or H304

Some information on general consumer uses of the main identified hydrocarbons labelled R65 or H304 (such as C10-C13 and C11-C14, *n-alkanes, <2% aromatics*) have been extracted from the relevant Chemical Safety Reports (CSRs). Broadly speaking, they concern the following applications:

- *Cleaning Agents* (anti-freeze and de-icing products, greases, washing and cleaning/soldering products),
- *Lubricants* (e.g. adhesives, sealants, polishes and wax blends),
- *Cosmetics* (perfumes, fragrances, personal care products) and
- *Fuels and functional fluids* (heat transfer, hydraulic fluids etc.). A more analytical picture is provided in the Annex 6.

An EU importer of paraffins and solvents labelled R65 or H304 informed, via the ECHA 2014 call for evidence, that further to raw material for the mixture of lamp oils, they also supply their products to formulators of detergents/cosmetics products. It must be noted though that these indicated as "general consumer applications" (other than intended for use in decorative lamps or as grill lighter fuels) for hydrocarbon substances labelled R65 or H304 are out of the scope of this report and will not be considered in the further analysis.

In addition, a few companies claimed that on top of the consumer uses, they also sell their products for professional/industrial uses (e.g. for process oils and industrial applications as solvent and lubricant oils).

B.2.4 Reported quantities of LO/GLF labelled R65 or H304

The ECHA's 2014 consultations with MS and Industry yielded some data on the quantities of LO and GLF labelled R65 or H304 (manufactured/distributed) in the European market. Although it is not possible from the submitted information to draw a picture of the whole EU area, some interesting information and observations have been extracted.

B.2.4.1 Data submitted from Member States

B.2.4.1.1 ECHA Survey (January-April 2014)

The data received from the Authorities of six MS and Norway during the ECHA survey in early 2014, are summarised in the following table 3. Rough estimations of the quantities (total number of tonnes or litres (L)/year) for both LO and GLF labelled R65 or H304 placed on the national markets were submitted by Cyprus, Estonia, Finland, Greece, Italy, Poland and Norway. This table also lists the data which had been submitted by 2 additional MS (Sweden and Germany) to the Commission in the frame of the 2009 Impact Assessment report.

Table 3 ***Total annual quantities of LO and GLF labelled R65 or H304 for consumer uses in a few European markets (reported in tonnes or litres[7])***

Source: ECHA's 2014 consultations

Country	Lamp oils (LO) labelled R65 or H304	Grill lighter fuels (GLF) labelled R65 or H304
Cyprus	approximately 8,130,000 L (=approximately 5,690 tonnes)	approximately 495,000 L (=approximately 346 tonnes)
Estonia	approximately 198,000 L (=approximately 139 tonnes)	approximately 196,000 L (=approximately 137 tonnes)
Finland 2013 2008	approximately 300 tonnes approximately 390 tonnes	approximately 470 tonnes approximately 450 tonnes
Germany 2007	6,000,000 L (=approximately 4,200 tonnes)	5,000,000 L (=approximately 3,500 tonnes)
Greece [8]	approximately 15,000 tonnes	approximately 100 tonnes
Italy	approximately 400 tonnes	approximately 400 tonnes
Norway 2013 2008	approximately 770 tonnes approximately 593 tonnes	approximately 1230 approximately 1230
Poland	> 240 tonnes	approximately 2,500,000 L (=1,750 tonnes)
Sweden 2006	650 tonnes	4,000 tonnes

Overall, according to the reported figures approximately **27,500 tonnes/year of LO** labelled R65 or H304 are placed on the markets of these eight MS and Norway for consumer uses. It is expected, though, that these figures also concern volumes of products intended for hotels/restaurants (thereby not for direct supply to the general public) as well as for professional uses (e.g. in churches/artistic work) as indicated in section B.2.1.3.

[7] Where figures in litres (L) are provided, a conversion to tonnes was made (assuming an average density of ~0.70 g/cm^3 for R65 or H304 hydrocarbons (see Table 2 of section B.1). Unless stated otherwise, we assume that the quantities reported by the Member States during the 2014 consultation concern the year 2013.

[8] For Greece, information on quantities of LO were first received by the Greek CA (ECHA Survey) that claimed >8000 tonnes are placed on the Greek market every year. Then during the ECHA Call for evidence data has been received by 14 Greek distributors. It is estimated that in total they place ~15,000 tonnes of LO labelled H304 on the market. The latest figure has been used for these estimations.

Therefore, the resulted 27,500 tonnes/year may be an overestimation. This value is also subject to "inherent" uncertainty, given that it is derived from the sum of quantities reported in different years (at the lack of more precise data). It must be noted, as well, that the vast majority out of the reported quantities (approximately 75%) is placed on the markets of Cyprus and Greece where mainly used by consumers for religious purposes. Therefore, it is not considered as appropriate to extrapolate from these submitted data a picture for the whole EU area (these may not be considered as "highly representative" given that Greece/Cyprus contribute such high number).

In addition, according to the reported data approximately **12,000 tonnes/year of GLF** labelled R65 or H304 are placed on the markets of these eight MS and Norway for consumer uses. In case of GLF we may have a more "homogenous" distribution between MS (than for LO) given that these fuels are mainly used for barbecue related applications that can be considered to be roughly similar throughout the EU. Therefore, in a quite simplistic analysis, considering that these nine reporting countries represent approximately 180 million people therefore approximately 35% of the total EU population (Eurostat 2014[9]), we could estimate an approximate figure of approximately 34,500 tonnes/year for GLF labelled R65 or H304 to be placed on the EU market. This is, though, a rough estimation and subject to various uncertainties.

B.2.4.1.2 ECHA's follow up consultation (November-December 2014)

ECHA has carried out a complementary consultation in November-December 2014 with those Competent Authorities (CAs) that have provided data on quantities of LO and GLF labelled R65 or H304 (in the frame of the Commission-ECHA survey in early 2014). ECHA has requested for any available data on consumption trends of these products in their national market, in particular during the last decade, if available. Such information would be valuable to better understand the reported trends of poisonings due to LO and GLF labelled R65 or H304. Furthermore, ECHA has asked for confirmation that the submitted data concerns LO and GLF which are labelled R65 or H304 and do not include any alternative substances which are also used as LO or GLF on the identified consumer applications.

All the responded CAs confirmed that their submitted data strictly concern LO and GLF which are labelled R65 or H304 and are placed on their national market.

In addition, Norway and Finland competent authorities have responded with some additional data on the quantities of LO and GLF labelled R65 or H304 that have been placed on their national markets (manufactured + imported) during the last 8 years (2006-2013).

A statistical analysis on this data was performed by estimating average annual values for 2006-2009 and 2010-2013 sub-periods.

Concerning the Finnish data, for the sub-periods 2006-2009 and 2010-2013, the average annual consumer uses for LO labelled R65 or H304 were estimated at 291 and 284 tonnes respectively and for GLF labelled R65/H304 at 315 and 355 tonnes respectively. Therefore, *the*

[9] Eurostat-2014: relevant data available on http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&language=en&pcode=tps00001&plugin=1

% changes of annual average consumer uses (from 2006-2009 to 2010-2013 sub periods) in Finland were estimated at -2% for LO and 13% for GLF labelled R65 or H304.

Concerning the Norwegian data, for the sub-periods 2006-2009 and 2010-2013, the average annual consumer uses for LO labelled R65 or H304 were estimated at 468 and 644 tonnes respectively and for GLF labelled R65 or H304 at 1234 and 1340 tonnes respectively. Therefore, *the % changes of annual average consumer uses (from 2006-2009 to 2010-2013 sub periods) in Norway were estimated at +37% for LO and +9% for GLF labelled R65 or H304 compared to the period 2006-2009.*

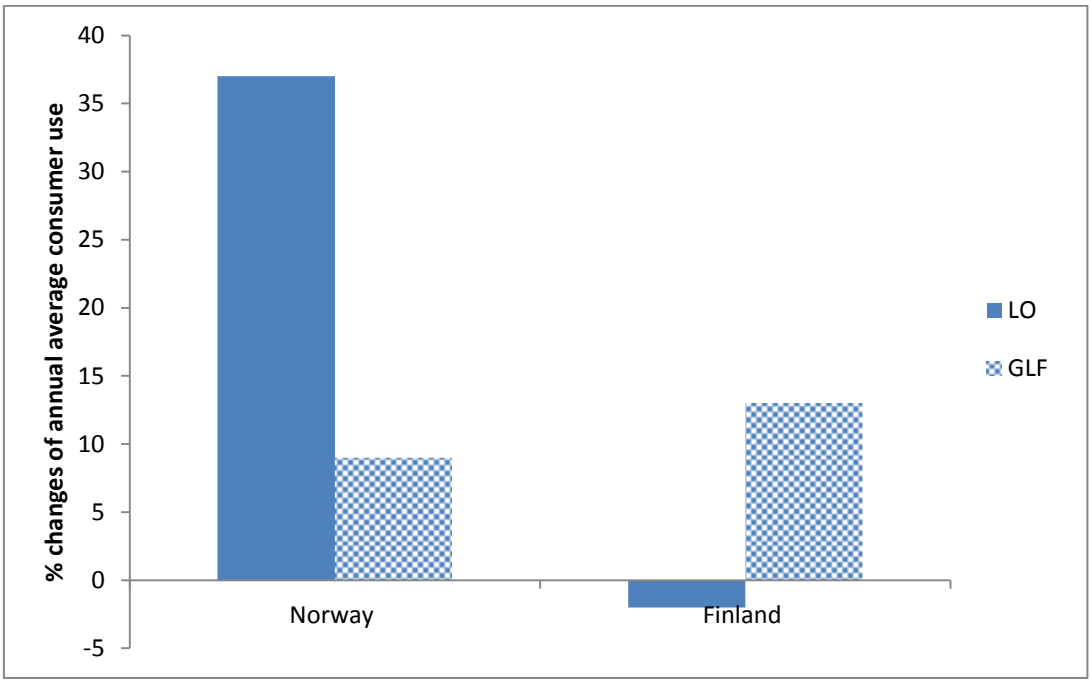
The analytical values and estimations for both Finnish and Norwegian data are presented in the Annex table 4 while the percentage changes of the average annual consumer uses are also pictured below in figure 2.

In addition, the Cyprus CAs communicated some indicative figures of volumes of LO labelled R65 or H304, which were placed on their national market by four companies that reported annual imported volumes during the last five years. A slight decrease of ~10% has been estimated for the total values reported by these 4 companies in 2013 when compared to 2008.

The data of the three reported countries (Cyprus, Finland, Norway) leads to the overall conclusion that the total annual quantities of LO and GLF labelled R65 or H304 have not significantly decreased during the last few years, in particular after 2010 when the latest legislative amendments of Annex XVII to REACH came in to force. On the contrary, mostly increasing trends for the use of LO and GLF products have been reported which may not be surprising considering that the new provisions of entry-3 of Annex XVII imposed only labelling/packaging requirements and not marketing and use restriction for LO and GLF labelled R65 or H304 products. It is unknown if this trend is relevant EU wide but it seems likely.

Please note that in sections B.10-B.11, a link between consumption trends and trends of poisonings due to LO and GLF labelled R65 or H304 is made and be discussed for the purpose of this analysis.

Figure 2. ***The % changes of annual average consumer uses from the period 2006-2009 to the period 2010-2013 for LO and GLF labelled R65 or H304 in Finland and Norway***
Source: ECHA's 2014 consultations



B.2.4.2 Data submitted from Industry

The ECHA's 2014 call for evidence yielded 29 responses from European companies associated to LO and GLF labelled R65 or H304 (manufacturers/distributors/importers etc.). More information about the responding stakeholders is given in section G.

According to the industry, the majority of the LO and GLF labelled R65 or H304 which are placed on the EU market (>70%) is produced in Europe. The EU manufacturers that responded to the 2014 ECHA's Call for evidence are located in 6 EU countries (Netherlands, UK, Spain, Italy, Germany and Greece). One of them alone, a Dutch company, informed that they manufacture on annual basis: approximately 4000 tonnes of LO labelled R65 or H304 for indoor decorative and religious applications, approximately 5000 tonnes LO labelled R65 or H304 or garden torches and other outdoor lighting applications and approximately 1500-2000 tonnes of GLF labelled R65 or H304 to be used for charcoal grills/fireplaces (indoor) and campfires (outdoor).

The overall picture resulted from the data submitted from MS, as previously discussed (Table 3), is roughly in agreement with the figures provided by the companies that responded to the ECHA's call for evidence (2014), in particular concerning the wide uses in Southern Europe for religious/outdoor applications. It has to be noted that almost half of the participants to the 2014 ECHA's call for evidence, that provided rough estimations of their marketed quantities, were Greek distributors mainly of LO labelled R65 and H304.

B.3 Classification and labelling

B.3.1 EU Classification and labelling legislative provisions linked to aspiration toxicity (R65 or H304)

This Annex XV report focuses on lamp oils (LO) and grill lighter fluids (GLF) labelled R65 or H304, which as discussed in Section B.1, concerns a wide category of substances, mainly comprised of aliphatic hydrocarbon solvents with predominant carbon numbers in the range of C9 to C14. Due to their low viscosity, in case of accidental ingestion, such paraffin-based substances may enter the lungs and can cause severe inflammation, commonly referred to as chemical pneumonia (EC Impact Assessment, 2009[10]). Even small amounts can creep into the lungs after being swallowed and trigger severe chemical inflammation. For this reason, and according to the Union legislation on classification and labelling of dangerous substances and mixtures (Directive 67/548/EEC[11], known as DSD) which has been replaced by the CLP Regulation, these specific LO and GLF hydrocarbons have to be classified and labelled with the appropriate risk (R-) and hazard (H-) phrases indicating the aspiration hazard.

Under DSD, the classification criteria for aspiration toxicity referred to substances/mixtures '*containing aliphatic, alicyclic and aromatic hydrocarbons in a total concentration equal to or greater than 10% and having*' a kinematic viscosity of less than 7 x 10^{-6} m^2/sec (eq. to 7 mm^2/s) at 40°C measured by different methods (see Section 3.2.3 in Annex VI of DSD). An exemption of classification could however be granted to substances/mixtures with a mean surface tension greater than 33 MN/m at 25°C. However, a substance/mixture could also be classified for aspiration toxicity based on '*practical experience in humans*'. Under DSD, substances were assigned the symbol 'Xn', the indication of danger 'harmful' and the risk phrase R65. Classified substances were exempted from labelling when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment. The safety phrase 'S62' (*if swallowed, do not induce vomiting: seek medical advice immediately and show this container or label*) was obligatory for classified substances and mixtures if sold to, or likely to be used by the general public.

Substances already classified for aspiration hazard under DSD were directly translated to CLP Regulation using the hazard class and category 'Asp. Tox. 1' and assigned the hazard statement code "H304: May be fatal if swallowed and enters airways". Under CLP, only one hazard category exists to cover known and suspected/presumed substances with aspiration hazard.

The classification criteria for aspiration toxicity (see Section 3.10 and Table 3.10.2 of CLP Regulation) refer to a substance being 'a hydrocarbon with a kinematic viscosity of 20.5 mm^2/s or less at 40 °C'. Although the term hydrocarbon is not defined, it has to be mentioned that substances classified in category 1 'include but are not limited to certain hydrocarbons, turpentine and pine oils'. In addition, specific considerations are given to 'some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans'. Therefore, a substance/mixture can also be classified in

[10] accessible on http://ec.europa.eu/smart_regulation/impact/ia_carried_out/docs/ia_2009/sec_2009_0708_en.pdf

[11] Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances *OJ 196, 16.8.1967, p. 1–98.*

Category 1 based on reliable and good quality human evidence.

The hazard class and category code 'Asp. Tox. 1' shall be accompanied by the pictogram GHS08 (exploding human) and several precautionary statement codes related to response, storage and disposal of such substances/mixtures. The CLP Regulation also imposes packaging to be fitted with child-resistant fastenings and with a tactile warning of danger for such hazardous substance or mixtures supplied to the general public.

Setting specific concentration limits for substances with aspiration toxicity is not appropriate[12]. Section 3.10.3 of CLP sets the rules to classify mixtures for aspiration toxicity based on the presence of 10% or more by weight of a substance or substances already classified as Asp. Tox. 1 and/or a kinematic viscosity of 20.5 mm^2/s or less at 40 °C.

Overall, it has to be noted that main target of CLP Regulation is to align EU legislation on classification, labelling and packaging of substances and mixtures to the United Nations Globally Harmonised System (GHS). In doing so, CLP replaced the previous Union rules on classification, labelling and packaging of dangerous substances (Directive 67/548/EEC) and dangerous mixtures (Directive 1999/45/EC[13]). The deadline for substances classification and labelling according to the new rules was 1 December 2010 and for mixtures 1 June 2015.

Since labelled with R65 phrases, lamp oils and grill lighter fuels have been affected accordingly by the new rules. ***Therefore, R65 terminology ("Harmful: may cause lung damage if swallowed") which currently appears on the labels of the products will have been completely replaced by the hazard statement "H304: May be fatal if swallowed and enters airways" by 1st June 2015.***

For the time being, during this transition period, labelling of LO and GLF commonly indicates both R65 and H304 phrases. For the purpose of this Annex XV report, a few Safety Data Sheets (SDS) of commercially available fuels have been checked. The following Table 4 is therefore listing the classification and labelling elements (under both DSD and CLP) to which the commercially available LO and GLF, labelled R65 or H3O4, have to comply in the EU market.

B.3.2 Classification and labelling inventory/Industry's self-classification(s) and labelling

The C&L inventory currently includes 1272 entries of 'Asp. Tox. 1'. However, only 229 substances have a harmonised classification for 'Asp. Tox. 1' (search made for the hazard statement code H304). This means that a lot of substances with potential aspiration toxicity hazard need to be harmonised. This may also be due to identification of additional substances with some relevant constituents (i.e. hydrocarbons) above 10% w/w. The higher cut-off value for kinematic viscosity under CLP may also include more substances that were exempted under DSD (20,5 mm^2/s instead of 7 mm^2/s).

[12] Guidance on the Application of the CLP Criteria. Version 4.0 – November 2013. Table 1.5.1—a: Possibilities for setting SCL for health hazards as addressed in relevant sections of the guidance.

[13] Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
OJ L 200, 30.7.1999, p. 1–68.

Table 4 List of the classification and labelling requirements *(DSD vs. CLP) for Aspiration Toxicity*

	DSD	CLP
Hazard	Aspiration toxicity	Aspiration toxicity
Classification	R65 Harmful: may cause lung damage if swallowed	Asp. Tox. 1 H304: May be fatal if swallowed and enters airways
Labelling elements	Xn  S62: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label	GHS08  Dangerous
Precautionary statements		P301 + P310 and P331 P405 (storage) P501 (disposal)
Criteria for substances and mixtures	Hydrocarbons ≥10% w/w and kinematic viscosity of less than 7 mm^2/s at 40°C Based on practical experience	Hydrocarbons and kinematic viscosity of less than 20.5 mm^2/s at 40°C Based on reliable and good quality human evidence

As already discussed under the section B.1, several of the substances identified by industry (during 2014 ECHA's call for evidence) to be used as LO and GLF labelled R65 or H304, have the name conventions developed by the Hydrocarbon Solvents Producers Association (HSPA) for the purpose of REACH.

Furthermore, a search has been performed concerning the CLP inventory for the reported by Industry (via 2014 ECHA Call for evidence) hydrocarbon substances in LO/GLF labelled as R65 or H304. The outcome is listed in the following Table 5. The name of notifiers is also recorded, while for the substance C12-26- alkanes, branched and linear (EC No 292-454-3) an additional hazard class (*Acute Tox. 4*, *Skin Irrit. 2)* and Hazard Codes *(*H332, H315) were identified.

Table 5 *Harmonised classification of LO/GLF labelled R65 or H304*

Source: CLP Inventory, 2014

Compound (HSPA)	EC Number	CLP Hazard Class	CLP Hazard Code	Number of Notifiers (Lead)
C5-C20 dearomatized fluids	924-803-9, 926-141-6, 918-481-9	Asp. Tox. 1	H304	4
C10-C13, n-alkanes, <2% aromatics	929-018-5	Asp. Tox. 1	H304	0
C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics	918-481-9	Asp. Tox. 1	H304	1
C11-C14, n-alkanes, <2% aromatics	924-803-9	Asp. Tox. 1	H304	0
C11-C14, isoalkanes, cyclics <2% aromatics	924-803-9	Asp. Tox. 1	H304	0
C12-C13, isoalkanes, cyclics, <2% aromatics	918-271-7	Asp. Tox. 1	H304	0
C12-26, alkanes, branched and Linear	292-454-3	Asp. Tox. 1 Acute Tox. 4 Skin Irrit. 2	H304 H332 H315	4
C13-C16, Isoalkanes, cyclics, <2% aromatics	918-973-3	Asp. Tox. 1	H304	0
C14-C17, n-alkanes, <2% aromatics	917-828-1	Asp. Tox. 1	H304	1
C14-C15, n-alkanes, <2% aromatics	928-868-4	Asp. Tox. 1	H304	0

B.4 Environmental fate properties

Not relevant for this report which focuses on health effects of these substances following their use by general public.

B.5 Human health hazard assessment

B.5.1 Relevant health hazard (aspiration toxicity hazard)

In general, liquid substances and mixtures may present an aspiration hazard due to their low viscosity. **Aspiration** means the entry of a liquid (or a solid) directly through the oral or nasal cavity, or indirectly from vomiting after ingestion, into the trachea and lower respiratory system. **Aspiration toxicity** as defined by the CLP Regulation is intended to apply to liquid substances and mixtures only. The entry of liquid into the respiratory tract may cause severe acute lung damage, such as chemical pneumonia, varying degrees of pulmonary injury or death. This has consequences for labelling, particularly where, due to acute toxicity, a recommendation to induce vomiting after ingestion may be considered. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendations to induce vomiting shall be modified. More information on the specific labelling provisions laid down by Directive 67/548/EC (DSD) which has been replaced by Regulation (EC) No 1272/2008 (CLP Regulation) has been provided under the section B.3 of this report (with focus on the hazard statements of relevance R65/H304).

As discussed in section B.1, the hydrocarbons contained in LO and GLF labelled R65 or H304 have more commonly chain lengths between C9 and C15 and involve a high risk of aspiration because of their physicochemical properties such as low viscosity, low surface tension and low vapour pressure. They readily pass the epiglottis by creeping and thus may cause severe chemical pneumonitis. *Aspiration of amounts as low as <1 mL may induce pneumonia in humans (BfR report, 2004).* The cardinal sign is an initial and often persistent cough. In addition, vomiting may occur. This may be followed by dyspnoea and/or tachypnea, cyanosis and less frequently, by somnolence. Such symptoms have been confirmed by reporting from Member States/EU Poison Centres during the 2014 ECHA consultations (more info in the next section B.5.2).

In cases of pulmonary manifestations, pneumonitis may develop in ca. 25-50 % of cases. However, also in the event of an initial absence of manifestations, pneumonitis may develop in 10-20 % of cases. Less often, pneumatoceles have been observed. *According to BfR, in cases of ingestion of >1mL/kg b.w. or suspected aspiration it is always recommended to seek medical advice in a hospital.* In Germany, severe health impairment with lethal outcome in two infants after ingestion of colourless and unscented lamp oils containing paraffin was reported in mid 90s and other two during 2004. Since then no other lethal cases have been reported throughout Europe.

B.5.2. Information on symptoms/adverse effects (including severity/exposure routes) of poisonings due to LO/GLF labelled R65 or H304

In the frame of Commission/ECHA Survey with Member State (2014), the *Dutch Authorities* submitted some information about the main symptoms observed in the reported incidents following the ingestion of the LO and GLF labelled R65 or H304 (presented in the tables 5.1

and 5.2 of Annex 5).

As indicated in Table 5. 1 of Annex 5, tickling cough was the main symptom upon ingestion of LO labelled R65 or H304, following by vomiting and agitation restlessness. In almost half of the cases, though, no symptoms were observed or mentioned. Dyspnoea and fever were reported as symptoms in case of ingestion of GLF (Table 5. 2 of Annex 5).

Lithuania (Environmental Protection Agency) informed that the main effects of the registered cases due to LO labelled R65 or H304 were mild gastrointestinal irritation and somnolence and all were accidental (unintentional).

In addition, *Poland (Bureau for Chemical Substances)* informed that abdominal pain and aspiration pneumonia were the main adverse effects of incidents due to LO and GLF labelled R65 or H304 while no fatal case was ever reported. The causes are usually accidental. One suicide attempt and one accident during spitting fire were identified due to the use of relevant products.

France (ANSES) has communicated some information concerning the products responsible for LO incidents, the majority of which (approximately 43%) were oils for lightening purposes/combustible uses (e.g. torches) while a significant number (approximately 13%) were anti-mosquito repellents (e.g. citronella oils). Furthermore, significant percentages of the adverse effects (approximately 35% for LO, 48% for GLF labelled R65 or H304) were reported to be of respiratory nature, followed by symptoms of hepatotoxic-digestion (25% for LO and 29% for GLF labelled R65 or H304) and incidents leading to neurological symptoms (approximately 10% for LO, approximately 6% for GLF labelled R65 or H304).

Norway reported that the majority of incidents approximately 60% (following ingestion of both LO and GLF products labelled R65 or H304) has resulted in health danger of established poisoning (of which approximately 60% concerned mild, 15% moderate and approximately 25% severe symptoms). Concerning the exposure pathway, approximately 90% of the poisonings were caused by oral exposure (ingestion), and the rest mainly through eye (4%) skin (3%) and inhalation (3%).

Germany has submitted data (December 2014) (compilation of 6/10 Regional Poison Centres, covering approximately 52 million people) concerning the poisonings due to LO/GLF labelled R65 or H304 for the period 2002-2014. Some statistics were provided about the exposure routes. Therefore, for LO related incidents (71% of which concerned small children), 90% were caused via oral ingestion, 4% dermal, 2% inhalation, 4% other or unknown. Concerning GLF labelled R65 or H304 related incidents (73% of which concerned small children), 93% were caused via oral ingestion, 1% dermal, 3% inhalation, 2% other or unknown. In addition, Germany provided some interesting figures concerning the severity of the symptoms in the registered incidents. For the LO labelled R65 or H304, the highest proportion of related incidents developed no symptoms (44%) or minor symptoms (33%), whereas much lower numbers led to moderate (6%) or severe symptoms (1%). The rest concerned incidents where the severity was not reported (16% unknown). The picture for the reported incidents due to GLF labelled R65 or H304 was somehow similar with only slight deviations. The higher percentage of incidents led to minor symptoms (36%) followed by 29% that developed no symptoms. 6% concerned moderate symptom, 4% severe symptom whereas a significant proportion of the cases (25%) remained "unknown" concerning the severity.

B.5.3. Review of studies on acute toxicity of registered hydrocarbons labelled R65 or H304

B.5.3.1 Introduction

There is a large body of literature investigating on various health effects of hydrocarbon substances such as dermal (Kim et al., 2006; Nessel et al., 1999; Riviere et al. 1999; etc.) or inhalation studies (Nielsen et al., 1988; Perleberg et al., 2004; Schreiner et al.1998; etc.). For the purpose of this analysis, the following summary in Table 6 (extracted from relevant REACH registration dossiers[14]) provides an overview of the various health end points for the hydrocarbons with chain lengths between C9 and C15 which have been indicated (as previously discussed in section B.1) as the most common substances for LO and GLF labelled R65 or H304.

As analysed in B.5.2, a few MS, in the consultations carried out, communicated their available data on the exposure pathways to LO and GLF labelled R65 and H304. On average, **90-95% of incidents related to oral exposure** (ingestion), 2-3% to dermal exposure and 2-3% to exposure via inhalation. Therefore, this section of the report will only focus on the studies based on ingestion of hydrocarbons labelled R65 and H304. For the additional health point of relevance which is **acute toxicity** (given the "aspiration hazard"), the Registration dossiers for the REACH-registered hydrocarbon substances labelled R65 and H304 (as listed in Table 2 of section B.1) have been carefully reviewed. More information is provided in the next section.

Table 6 *Summary of Toxicological Properties of C9-C14 Aliphatics (<2% Aromatics) Category Members*

Source: REACH registration dossiers/ECHA's website

Health end point	n-Paraffines, Isoparaffins, Cycloparaffins (C9-C15)
Acute Toxicity (oral)	>10,000 mg/kg
Acute Toxicity (dermal)	>3,160 mg/kg
Acute Toxicity (inhalation)	>11 mg/l
Skin Irritation	Not Irritating
Eye Irritation	Not Irritating
Skin Sensitization	Not Sensitizing
Repeated Dose Toxicity (oral)	> 5,000 mg/kg
Repeated Dose Toxicity	No data

[14] Accessible on: http://apps.echa.europa.eu/registered/data/dossiers/DISS-97daab5d-58dc-3ef0-e044-00144f67d031/DISS-97daab5d-58dc-3ef0-e044-00144f67d031_DISS-97daab5d-58dc-3ef0-e044-00144f67d031.html

(dermal)	
Repeated Dose Toxicity (inhalation)	>10,400 mg/m^3
Developmental Toxicity	>900 ppm
Reproductive Toxicity (fertility)	No evidence of reproductive effects in screening studies conducted at limit doses.
Mutagenicity (*in vitro*)	Not mutagenic
Mutagenicity (*in vivo*)	Not mutagenic
Carcinogenicity	Increased incidence of pheochromocytomas in male rats, hepatocellular adenomas in female mice. No effects in female rats, male mice.

B.5.3.2 Acute toxicity

For the hydrocarbons C10-C13, C11-C14 n-alkanes, (or isoalkanes, cyclics) < 2% aromatics, a review of the available studies on **acute toxicity** (extracted from the REACH Registration dossiers) is given in the Table 7 below.

Table 7 *Overview of experimental studies on acute toxicity after oral administration*
Sources: REACH registration dossiers/ECHA's website

METHOD	RESULTS	REMARKS	REFERENCE
(1) rat (Wistar) male/female oral: gavage OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 5000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result Test material (HSPA name): Hydrocarbons, C9- C11, cyclics, < 2% aromatics	ExxonMobil (1988a)
Executive summary C9 -C11 cyclic aliphatics were administered via oral gavage to 5 male and 5 female rats at a dose of 5000 mg/kg to assess acute oral toxicity. Animals were observed daily for 15 days post dosing. At a dose of 5000 mg/kg, signs of toxicity were sedation, dyspnoea, hunched posture and ruffled fur. All animals had recovered until day 5 of observation and survived to study termination. All animals were free of abnormalities at post-mortem examination. All surviving animals displayed increases in body weight over their day 0 values. The acute oral LD50 for C9 -C11 cyclic aliphatics is >5000 mg/kg. Classification as an oral toxicant is not warranted under the new Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) or under Directive 67/548/EEC for dangerous substances and Directive 1999/45/EC for mixtures.			

(2) rat (Sprague-Dawley) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 5000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result Test material (HSPA name): Hydrocarbons, C10-C12, isoalkanes, <2% aromatics	ExxonMobil (1995a)
Executive summary: MRD-83-205 was administered via oral intubation to 5 male and 5 female rats at a dose of 5000 mg/kg to assess acute oral toxicity. Animals were observed daily for 14 days post dosing. No overt signs of toxicity were apparent. All animals survived to study termination. All animals were free of abnormalities at post-mortem examination. All surviving animals displayed increases in body weight over their day 0 values. The acute oral LD50 for MRD-83-205 is >5000 mg/kg. Classification as an oral toxicant is not warranted under the new Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) or under Directive 67/548/EEC for dangerous substances and Directive 1999/45/EC for mixtures.			
(3) rat (Wistar) male/female oral: gavage equivalent or similar to OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)	LD_{50}: > 15000 mg/kg bw (male/female)	2 (reliable with restrictions) key study experimental result Test material (HSPA name): Hydrocarbons, C10-C12, isoalkanes, <2% aromatics	ExxonMobil (1977a)
Executive summary: The acute toxicity of MRD-77-10 was evaluated in rats via oral gavage at a dose of 15 g/kg bw. Observations were made as to the nature, onset, severity, and duration of toxicological signs once per day for a total of 14 days. All animals survived the entire observational period and displayed a low incidence of clinical symptoms. The LD50 for MRD-77-10 following oral gavage was >15 g/kg. Classification as an oral toxicant is not warranted under the new Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) or under Directive 67/548/EEC for dangerous substances and Directive 1999/45/EC for mixtures.			
(4) rat (Crj: CD(SD)) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 5000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result Test material (HSPA name): Hydrocarbons, C11-C14, isoalkanes, cyclics, < 2% aromatics	ExxonMobil (1989a)
Executive summary: The acute toxicity of P-D 20/26 was evaluated in rats via oral gavage at a dose of 5 g/kg bw. Observations were made as to the nature, onset, severity, and duration of toxicological signs once per day for a total of 14 days. All animals survived the entire observational period and displayed a low incidence of clinical symptoms. The animals displayed little or no abnormalities. The LD50 for P-D 20/26			

following oral gavage was >5 g/kg. Classification as an oral toxicant is not warranted under the new Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) or under Directive 67/548/EEC for dangerous substances and Directive 1999/45/EC for mixtures.			
(5) rat (Wistar) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 15000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result Test material (HSPA name): Hydrocarbons, C10-C13 and C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics	ExxonMobil (1977b,c)-2 studies
Executive summary: MRD 77 -11 was administered via oral gavage to ten albino Wistar rats (5 males and 5 females) at a dose of 15.0 g/kg to assess the acute oral toxicity. Animals were observed for mortality and toxic effects immediately and 1, 2, 3, 4, and 6 hours after dosing and daily for 14 days. Necropsies were performed on all rats. No deaths were observed. Hair loss in 9/10 animals and darkened kidneys in 5/10 animals were observed at necropsy. The oral LD50 for MRD 77-11 was greater than 15.0 g/kg. Classification as an oral toxicant is not warranted under the new Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) or under Directive 67/548/EEC for dangerous substances and Directive 1999/45/EC for mixtures.			
(6) rat (Wistar) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 15000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result Test material (HSPA name): Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, < 2% aromatics	ExxonMobil (1977c)
rat (Sprague-Dawley) male/female oral: gavage equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)	LD_{50}: > 15800 mg/kg bw (male/female)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) Test material (Common name): tetramethylcyclohe xanes (See endpoint summary for justification of read-across)	Johannsen, F.R., Levisnkas, G.J. (1987). Teratogenic response of dimethylacetamide in rats.
Executive summary: Pregnant CD rats (25/group) were used to determine the teratogenic potential of dimethylacetamide (DMAC). DMAC was administered in deionized water once a day by gavage on Days 6 through 19 of gestation at dosages of 0, 65, 160, and 400 mg/kg/day. Cesarean sections were performed on all females on Gestation Day 20. No treatment-related effects were observed in survival, appearance, or			

behaviour at necropsy. Mean maternal body weight gain was reduced significantly only at the 400 mg/kg/day level. Fototoxicity manifested by increased post implantation loss was seen at the 400 mg/kg/day level while reduction in mean foetal body weights was noted at the 160 and 400 mg/kg/day test levels. Developmental variations (reduced ossification and unossified skeletal variations) were increased at the 400 mg/kg/day test level and corresponded to the reduced foetal body weights which were observed. Treatment-related malformations of the heart, major vessels and oral cavity, and anasarca were seen at the 400 mg/kg/day DMAC level. No teratogenic effect of DMAC treatment was observed at or below dosage levels of 160 mg/kg/day.

Conclusion of the studies on the acute toxicity

Following a screening of the above indicated studies for the hydrocarbons *substances.* C10-C13, C11-C14 n-alkanes, (or isoalkanes, cyclics) < 2% aromatics, the following overall conclusion can be derived:

The hydrocarbons substances C10-C13, C11-C14 n-alkanes, (or isoalkanes, cyclics) < 2% aromatics, do not meet *the criteria for classification for acute toxicity with an LD_{50} of >5000 mg/kg. Therefore it is unlikely that any effect would be seen from the small amounts ingested and so the aspiration hazard remains the main danger to human health from these substances.*

B.6 Human health hazard assessment of physicochemical properties

Not relevant as these substances do not present any physicochemical hazardous properties (e.g. as indicted in B.1.2, given their flash point of >60°C, they are not characterised as "flammable"). However, the aspiration hazard is related to the kinematic viscosity, which is one of the physicochemical properties of the relevant substances (this is covered in Section B.3 (classification and labelling).

B.7 Environmental hazard assessment

Not relevant for this report which focuses on health effects of these substances following their use by general public.

B.8 PBT and vPvB assessment

Not relevant for this report.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of the existing legal requirements

EU legislation for LO and GLF labelled R65 or H304*:* The following legislative measures have been introduced, throughout the years, at Union level to reduce the health risks for consumers due to accidental ingestion of lamp oils and grill lighter fluids, labelled R65 or H304:

Commission Directive 97/64/EC[15], amending Directive 76/769/EEC[16] adapting to technical progress Annex I to Council Directive 76/769/EEC, has banned the coloured and scented lamp oils marked with R65 for consumer use in decorative lamps, while packaging requirements were also introduced (maximum capacity of 15 L or less). Coloured and scented lamp oils were considered more likely to attract or arouse the curiosity of children, who mistake these products with drinks. It also requires containers to be marked with the sentence "*Keep lamps filled with this liquid out of the reach of children*".

Commission Decision 2009/424/EC and Commission Regulation (EU) No 276/2010[17] amended REACH Regulation as regards Annex XVII (namely, lamp oils and grill lighter fluids). Paragraph 5 of the new Entry 3 of Annex XVII to REACH, imposed, since 1 December 2010, the following labelling and packaging requirements for LO/GLF labelled R65 or H304:

- *lamp oils , labelled R65 or H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children" and, by 1 December 2010, "Just a sip of lamp oil —or even sucking the wick of lamps —may lead to life threatening lung damage";*
- *grill lighter fluids, labelled with R65 or H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "just a sip of grill lighter may lead to life threatening lung damage";*
- *lamp oils and grill lighters, labelled with R65 or H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.*

It should be noted that Regulation (EU) No 276/2010 also inserted a few more provisions in the Entry 3 indicating that:

- decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN) (paragraph-4)

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[15] Commission Directive 97/64/EC, OJ L 315, 19.11.97, p.13.

[16] 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 preparations**,** OJ L 262, 27.9.1976, p. 201–203**.**

[17] Commission Regulation (EU) No 276/2010 amending Regulation (EC) No 1907/2006 (REACH) as regards Annex XVII (dichloromethane, lamp oils and grill lighter fluids and organostannic compounds. OJ L 86, 1.4.2010, p. 7–12.

- information on alternatives available for LO/GLF labelled R65 or H304 will be provided by 1 December 2011 to MS CAs (and then be passed to the Commission) by natural or legal persons placing them on the market (paragraph 7); the Commission -by 1 June 2014- to ask ECHA to review the situation (and propose a ban, if appropriate) in view of any new evidence (paragraph 6).

EU Classification and labelling provisions: the historical developments for the legislative requirements to use the risk phrase R65 and H304 in the frame of the CLP Regulation (Annex VI of Regulation (EC) No 1272/2008) were already discussed under section the section B.3 of this report.

EU standards relevant to LO/GLF labelled R65 or H304:

EN 14059-European standard for the design of childproof decorative oil lamps (Decorative oil lamps – Safety requirements and test methods), since September 2002, intends to minimise the risk of accidental poisoning of small children by limiting the accessibility to the lamp oil contained in the decorative oil lamp and by imposing the following marking requirements on the oil lamp:

- "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.
- 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-GPDS (Directive 2001/95/EC)[18]. In addition, with the Commission Regulation (EU) No 276/2010 (Entry 3 paragraph-4) it also became part of legislation as previously discussed. It must be noted that the ECHA call for evidence has yielded also some information about this standard and certain limitations of its applicability for oil lamps, which are summarised in Annex 7.

EN 1860-3-European standard concerns safety measures for firelighters[19] and is therefore of relevance to grill lighter fluids. It specifies, since June 2003 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 mixtures 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 GPDS remains of voluntary nature and therefore manufactures are not obliged to use it. Given that grill lighter fluids labelled R65 or H304 mainly concern substances with low at around 20°C flash points, as already discussed in previous sections, flammability has

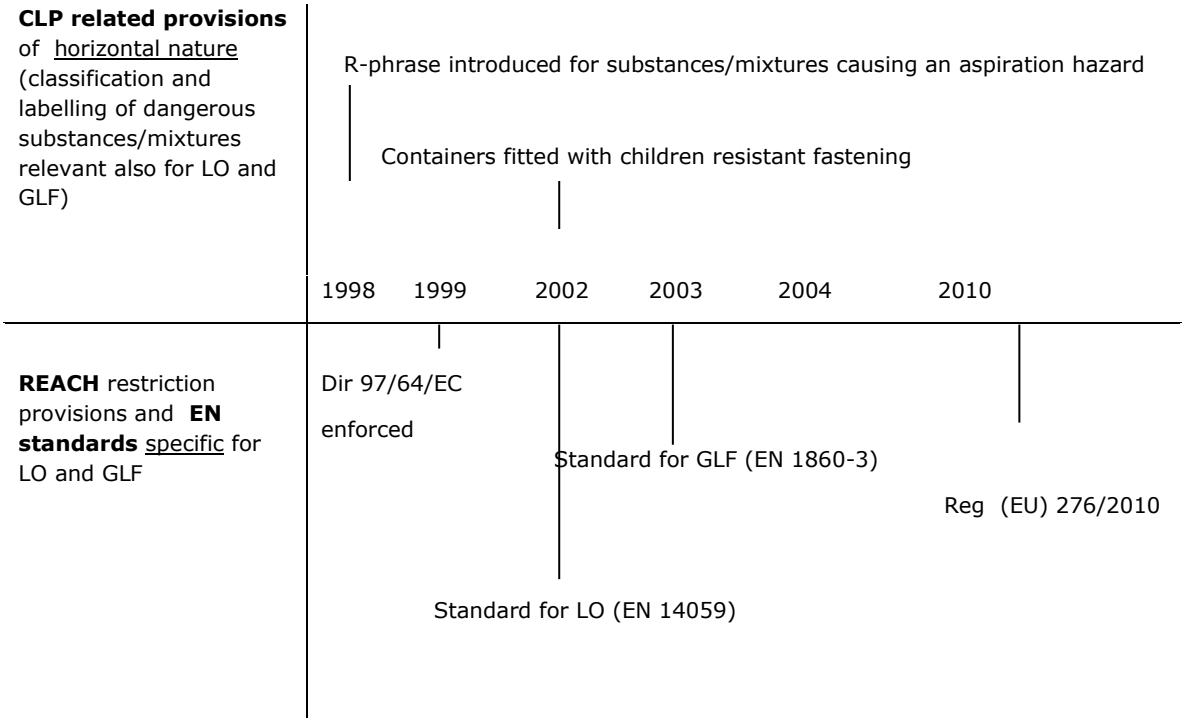
[18] Directive 2001/95/EC of the European Parliament and of the Council on general product safety. OJ L 11, 15.1.2002, p. 4–17

[19] 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.

not been identified as major issue in this assessment. It has to be noted that neither related accidents nor any need for inserting this EN standard as a new requirement in the entry 3 have been reported to ECHA by MS (in the frame of 2014 consultations). Therefore, the EN standard 1860-3 has not been further considered in the analysis of this report.

The following figure 3 gives an overview of the legislative developments during the last 15 years at EU level:

Figure 3. ***EU legislative measures (+standards) for LO and GLF labelled R65 or H304***



B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

(i) Controls of MS-CAs for compliance to legislative requirements

In the frame of the 2014 ECHA Survey, a few MS stated that during the last 4 years (since the entry into force of latest Annex XVII provisions, 1 December 2010) they have performed regular controls on commercially available LO and GLF labelled R65 or H304 to check for compliance with REACH (Annex XVII entry 3) and CLP provisions. The competent Authorities informed ECHA that if the products are non-conforming due to their packaging (either due to the colour of the container or due to the lack of child-resistant fastening) they are directly withdrawn from the market and Rapex notifications (according the article 11 of GPDS-Directive 2001/95/EC) are prepared. In most reported cases, though, non-compliances concerned insufficient labelling (e.g. missing pictogram, missing R65 phrases etc.), and following guidance and recommendations of the enforcement Authorities (e.g. warning letters), the labelling requirements were fulfilled by the companies and the products were placed again on the market. The section G.2 presents more analytical information (including figures of non-

compliant products) that have been communicated to ECHA by Member States concerning their inspection activities for LO and GLF labelled R65 or H304 (during the period 2010-2014). In addition, Poland provided some information on their inspection activities concerning oil lamps labelled R65 or H304 during the last five years.

(ii) Effectiveness of regulatory measures

The ECHA 2014 consultations yielded some relevant information on this issue from CAs and companies that manufacture/import and distribute the products in the EU market. Overall, according to the consulted parties (Member States and stakeholders), *the current specific legislative provisions in entry 3 of Annex VII to REACH (in combination with the horizontal CLP provisions) are sufficient risk management measures to ensure a safe use for the general public and should therefore remain unchanged.* It must be noted, though, that a few companies, have recommended several additional labelling/packaging requirements that could potentially contribute to a further risk reduction (discussed and elaborated under section G.4).

A few MS also informed that during the last years they have undertaken campaigns at national level to raise awareness of the public concerning the hazards and risk due to the use of LO and GLF labelled R65 or H304. More specifically:

Cyprus: Two press announcements were issued, in 2006 and in 2007, warning for the potential dangers for young children due to any accidental swallowing of lamp oils labelled R65 or H304 and explaining the legal requirements that these products have to fulfil in order to be placed on the European market. Additionally, a specific informative leaflet has been issued in 2010 titled «Packaging and Labelling of Paraffin Oils»[20]. This was distributed widely among re-fillers, suppliers, supermarkets and other retailers. Finally, inspection campaigns for the control of packaging and labelling of lamp oils are undertaken on annual basis during the usual packaging and labelling campaigns. Specific campaigns for lamp oils were undertaken in March of 2011 and in November of 2013.

Estonia: Several articles were published in the newspapers and the small cartoon for children on safe use of chemicals was elaborated (now available at the address www.lastekas.ee, 2015).

Germany: In some parts of Germany campaigns were carried out (e.g. information campaigns on trade fairs and addressing the risks in CLP flyer).

B.9.2 Relevant exposure information

The submitted CSRs and the REACH Registration dossiers of the registered hydrocarbon substances labelled with R65 or H304 did not contain any concrete exposure scenarios for their use in decorative lamps or as grill lighter fluids. The CSRs only contained some general information on the wide consumer uses of these substances (discussed under the section B.2.3 /see Annex 6). Given this limitation, the exposure analysis in this report is qualitative and based on some limited information (e.g. on exposure pathways, approximate volumes placed on the market etc.) that was submitted mainly from the reported MS CAs in the frame of 2014 ECHA consultations.

[20] http://www.mlsi.gov.cy/mlsi/dli/dli.nsf/All/E8648A614E48D101C22577D20043DBB4/$file/Parafinelaia.pdf

B.9.2.1 Lamp oils (LO) labelled R65 or H304

Exposure pathways/quantities

Some "realistic" examples of how the consumer uses of LO labelled R65 or H304 can lead to health hazards have been provided by two companies in the frame of ECHA 2014 call for evidence. According to their similar inputs, the relevant exposure due to LO labelled R65 or H304 is linked to their use in refillable decorative lamps. The consumers after buying the lamp fuel often transfer it to another container (such as a water pitcher with squeeze dispenser) to make the lamp easier to fill. As a consequence, people (in particular children) may accidentally drink the fuel from the new container or from a spillage.

The 2004 report of the German Federal Institute for Risk Assessment (BfR) on chemical poisonings[21] has described two specific cases that indicate *oral ingestion* as the most common exposure pathway for the consumer. Therefore, the following incidents could be considered as examples of the way that small children could be exposed to LO labelled R65 or H304. It must be noted, though, that the incidents refer to two very severe cases that cannot be considered as characteristic of an "average incident" concerning the reported symptoms (as already discussed under section B.5.2, overall a very small of the reported poisoning incidents due to LO labelled R65 or H304 present severe symptoms and require hospitalisation).

Case No 1: Garden torch (Figure 4-a)

When playing in the garden, a girl aged 13 months drank an unidentified quantity of clear and odourless lamp oil contained in a garden torch (date of accident, 16/05/2004). According to the analysis performed, the product involved consisted of paraffins (long-chain alkanes, fractions C9-C14) and was labelled with R65. The child was reported to have coughed, retched and vomited several times immediately after ingestion. The patient's condition deteriorated dramatically, as seen by signs of respiratory insufficiency, increase of heart rate and cyanosis. The child died after twelve hours from the consequences of lamp oil aspiration, having developed a severe pneumonia and destruction of lung tissue (confirmed histologically).

Case No 2 Oil lamp (Figure 4-b)

A boy aged 20 months drank an unknown amount of colourless and unscented paraffin-containing oil from a lamp (a heavy glass bottle equipped with a metal ring that reportedly had held a wick). However, it has also been considered as possible that the boy had only sucked from the wick because the latter was found lying beside the bottle. The lamp had been placed on the terrace. The child was reported to have coughed immediately and vomited later on. After admission to the nearest hospital, the boy was intubated and respirated while developing an increasing clouding of consciousness. The patient died after three days from the consequences of lamp oil aspiration which included development of multiple organ failure and brain damage.

As also discussed under the section B.2.4, according to the data received during the ECHA Survey (2014), approximately 27,500 tonnes of LO labelled R65 or H304 are placed on the markets of the reported eight MS and Norway for consumer uses. However, given that a high

[21] Available on http://www.bfr.bund.de/cm/364/2004_Poisoning%20reported%20by%20physicians.pdf

proportion of the marketed LO (approximately 75%) is placed on the markets of Cyprus and Greece (mainly for religious purposes) it may not be that easy to extrapolate a picture for LO labelled R65 or H304 consumption in the whole EU market.

B.9.2.2 Grill lighter fluids (GLF) labelled R65 or H304

The following incident has been described by BfR (2004) and can be considered as characteristic of the way that children are exposed to GLF (*oral exposure pathway).* A two-year old boy drank and aspirated an unknown quantity of a liquid product for grill lighting. After ingestion, the child showed signs of respiratory insufficiency. Since primary oxygen supply was insufficient as a therapy, the boy had to be intubated and respirated. As a consequence, artificial respiration had to be performed. In the further course, the patient developed subglottic granulomas, in addition to pneumonia. He was referred to inpatient treatment, which lasted for almost three weeks and resulted in complete recovery.

According to the data submitted via the ECHA 2014 consultations (as discussed under the section B.2) it is estimated that approximately 12,000 tonnes of GLF labelled R65 or H304 are placed on the markets of these eight MS and Norway for consumer uses. Furthermore, according to a simplistic (and subject to high uncertainty estimation) an approximate annual quantity of approximately 34,500 tonnes for GLF labelled R65 or H304 placed on the EU market has been derived.

Figure 4. ***Standard images[22] of: (a) garden torch (b) oil lamp***

(a)

(b)

[22] Images were provided to ECHA by Fotolia (2015)

B.10 Risk characterisation

B.10.1 Background "historical" information

During the last decades, the Member States have repeatedly reported accidents caused mainly due to the accidental ingestion of LO and GLF labelled R65 or H304, leading in certain cases to health damage of small children.

The large majority of these accidents (as also discussed under the section B.5.2) result in calls to NPC asking for medical advice following accidental oral ingestions. A rough elaboration of the info received from some MS indicates that the incidents are commonly with no or "mild symptoms" and do not require medical treatment. Very few incidents (in the range of 1-3%) develop severe symptoms and require hospitalisation (e.g. in case of significant breathing disturbances, and subsequent disorders of the respiratory tract).

Furthermore, the Impact Assessment report prepared by the European Commission (2009) summarised the available information on poisoning incidents due to ingestion of LO and GLF labelled R65 or H304 that had been reported until 2008. Some useful historical information on the development of the problem due to lamp oils labelled R65 or H304 in the last 25 years was submitted by Germany (BfR-Federal Institute for Risk Assessment of Germany/Centre for Documentation and Assessment of Poisonings) in the frame of ECHA 2014 consultations. BfR informed that based on the results of a research project and aiming at a harmonised documentation of cases of poisoning, it was possible, for the first time in 1993 to identify the attractively coloured and scented lamp oils being those posing the highest risk for children aged between 1 and 3 years, among all household chemicals. A particularly striking increase was observed after German reunification, because new gift articles had been put on the market, resulting in one death *in 1991* and approximately 250 to 300 cases of chemical pneumonia in total during 1992-1994. In spite of a number of different measures implemented in Germany, such as child-resistant closures (from 1992), special warnings (from 1996) and a newly established R phrase (R65, from 1996), a significant decrease in case *numbers was only achieved after a ban on coloured and scented lamp oils containing liquid petroleum distillates and paraffins had taken effect on 1 January 1999 in Germany, and on 1 July 2000 in the entire EU*. However, two more lethal incidents were reported to BfR in 2004 as discussed under B.9.2

In relation to GLF labelled R65 or H304, a growing market share of such substances resulted in the emergence of a new risk, which was comparable to that posed by lamp oils. It has to be noted, though, that no more deaths due to ingestion of LO and GLF labelled R65 or H304 have been reported in the last decade either in Germany or the rest of the EU.

B.10.2 Incidents of Poisoning due to lamp oils (LO) and grill lighter fluids (GLF) reported by MS/NPC.

Relevant information concerning incidents of poisonings was submitted to ECHA through the Competent Authorities in the frame of ECHA survey (January-April 2014) and direct contacts of ECHA with a few National Poison Centres (NPC) in the second half of 2014/early 2015.

An overview of all the figures (annual numbers of incidents caused by LO and GLF) labelled R65 or H304, as registered at national level in 13 reported European countries during the last decade is presented in Annex tables 1.1 (for LO) and 2.1, (for GLF). Out of these data only the figures for poisoning attributed to LO or GLF labelled R65 or H304 for the **period 2008-2013**

(provided by eight MS and Norway) have been considered for the statistical analysis on which the main conclusions of the report were drawn.

B.10.2.1 National data on poisoning incidents (2008-2013) due to LO and GLF /Estimations of national incident rates

It must be noted that the analysis of this report is based on the most recent available data that were submitted during ECHA 2014 consultations by a number of CAs/NPC for the period 2008-2013 (annual numbers of registered poisonings due to LO and GLF labelled R65 or H304). Annex tables 1.2 and 2.2 present these national data that can be summarised as follows:

France

LO: The French data for the period 2008-2013 demonstrated a steady decrease of total incidents (-46% from 2008 to 2013). The 80% of reported accidents concerned small children (1-5 years).

GLF: A small increase of total number of annual registered poisonings was observed until 2010 (+8% since 2008). However, since then a significant decrease of the incidents has been recorded (-29 % from 2010 to 2013).

France has also provided information on the exposure pathways and severity of symptoms which was previously discussed under B.5.2.

Germany

Upon request of ECHA, the German Authorities (BfR) during the 2nd half of 2014, have compiled data from six (out nine) regional Poison Centres (Berlin, Göttingen, Munich, Nuremberg, Freiburg, Erfurt) covering a population of 52 million (approximately 65% of the German- and 10.3% of the EU population). These data (November, 2014) concern total annual figures of poisonings due to either LO or GLF labelled R65 or H304 and can be summarized as follows:

LO: The figures show a small increase from 2008 to 2009 but overall a decrease for the whole period 2008-2010 (-8% from 2008 to 2010). Interestingly, after 2010, a continuous reduction of reported incidents has been observed at a higher overall rate (-20% from 2010 to 2013).

GLF: The number of poisonings was significantly higher in 2010 than 2008 (+69% from 2008 to 2010). After 2010, though, a steady significant decrease has been reported (-87% from 2010 to 2013). Furthermore, BfR informed ECHA there have been no cases related to burning and no fatal intoxications caused by GLF labelled R65 or H304.

Some indicative statistics on the exposure pathways and severity of symptoms of the reported incidents due LO and GLF labelled R65 or H304 were also provided as indicated under the section B.5.2.

Ireland

Ireland provided some figures for incidents due to LO and GLF labelled R65 or H304 after 2010 but also for the period 2004-2009.

LO**:** 10 incidents had been reported in the period 2004-2009 but only 1 after 2010 (all of which concern accidental oral ingestion by children).

GLF: While 17 incidents were reported between 2004 and 2010 (out of which 14 related to children), only 4 were registered between 2011-2013.

Italy

The Italian CAs communicated their most recent national data on poisonings due to LO or GLF labelled R65 or H304 (2008-2013), as reported by the seven Italian Poison Centers (Niguarda, Bergamo, Roma, Gemelli, Firenze, Napoli, Pavia). These data show a small number of registered incidents which overall did not significantly change over the relevant periods (e.g. for LO from 9 incidents in 2008 to 10 incidents in 2013). Therefore no conclusion could be drawn solely by these submitted Italian data on any trends or efficiency of the current regulatory measures.

Lithuania

Low figures for reported incidents due to LO (1-5 per year) and GLF (2-10 per year) labelled R65 or H304 were communicated by the Lithuanian Authorities for the period 2008-2013. No clear trend was observed for LO related incidents, whilst a steady reduction has been reported for those accidents caused by GLF after 2010.

The Netherlands

LO: The data submitted by the Dutch CAs show clear and steady decreasing trends of incidents due to LO that were evident even before 2010 (16% from 2008 to 2010) but they became even more evident after the entry into force of the new legislative amendments of Annex XVII (-47% from 2010 to 2013). It should be noted that out of the reported incidents, the vast majority (>86%), concern small children. Very interesting information was also communicated concerning the symptoms of the reported cases (see Annex 5).

GLF: Very low numbers of annual incidents (compared to LO) have been reported in the last years by the Dutch Poison centre that remain stable (e.g. 5-6/year). Out of 26 reported incidents since 2008, 18 concern accidental ingestion by small children.

Norway:

LO: According to information submitted from the Norwegian Poisons Information Centre (NPIC), the annual number of poisonings due to lamp oils labelled R65 or H304 has been significantly reduced in the period 2008-2013 (-40 % from 2008 to 2013).

GLF: The figures reported by NPIC show an increase of the annual number of incidents due to GLF labelled R65 or H304 during 2008-2010 (+25% from 2008 to 2010) was followed by a clear decrease during the last 4 years (-40% from 2010 to 2013).

It is interesting that, in Norway, the number of incidents due to GLF was 2-3 times higher than that of incidents caused by LO labelled R65 or H304 during 2008-2013. According to an earlier statement of Norwegian CAs (2008), an explanation for the lower number of accidents with LO might be that Norway for several years have had a national ban on the manufacture and sale of oil lamps with open flame designed to burn petroleum fuel (where the lamps have a loose wick holder). A wick that is not permanently attached or with a separate filling hole that does not have a fixed lid, was prohibited already before 2008.

Poland

The data submitted by Polish CAs concern a compilation of total number of incidents registered in four (out ten) NPC (thereby covering a region of approximately 9 millions).

LO: Very low number of incidents (<10) have been reported during the last decade without clear tendencies.

GLF: The number of annual incidents due to GLF is steadily reduced during the last 3 years (-60% from 2011 to 2013).

Slovak Republic

The submitted data revealed relatively low numbers of incidents per year (LO: 15-20 GLF: 10-15), which to their vast majority (approximately 85%) concern small children. During the last decade the number of incidents in both cases remained stable or even slightly increased in the last few years, on the contrary to the observed trends in most of other reported MS.

Estimation of national incident rates

An alternative presentation of the above indicated submitted national data is given in the Annex tables 1.3 and 2.3, in which the reported annual number of poisonings due to LO and GLF labelled R 65 or H304 were converted to national incident rates by considering the populations of the reported countries (Eurostat, 2014).

More specifically:

National incident rates (No of incidents/million of population) = *(total annual number of poisonings)/(population of the country).*

The estimation of national incident rates provides with some interesting comparative conclusions for the reported countries under the general assumption that *the higher the incident rate (therefore the number of incidents per million of population), the clearer the demonstration of the risk.* More specifically:

- Norway, Netherlands and Germany are the countries with the higher national incident rates due to LO labelled R65 or H304 (Annex Table 1. 3). In all 3 cases, the incident rates were decreasing much more rapidly after the 2010 (year of entry into force of the latest labelling and packaging provisions via entry 3 of Annex XVII.
- Norway, Lithuania, Germany and France are the countries with the higher national incident rates due to GLF labelled R65 or H304 (Annex Table 2.3). Overall, initial increases of the incident rates from 2008 to 2009, were followed by steady decrease in the next years, in particular after 2010.
- In France, Germany and Norway the estimated incidents rates due to GLF (labelled R65 or H304) are much higher (approximately 3-4 times) than those for LO related incidents. However, in Netherlands and Slovakia the reversed trend was reported.

Figures 5 and 6 reflect the estimated **national incident rates** (No of incidents/1 million of population) for 2008-2013 due to **LO or GLF** labelled R65 or H304, for some countries that presented the higher national incident rates.

Figure 5. ***Estimated national incident rates (No of incidents/1 million of population) for 2008-2013 due to LO labelled R65 or H304 (Norway-NO, Netherlands-NL and Germany-DE)***
Source: ECHA's 2014 consultations, data from eight MS and Norway

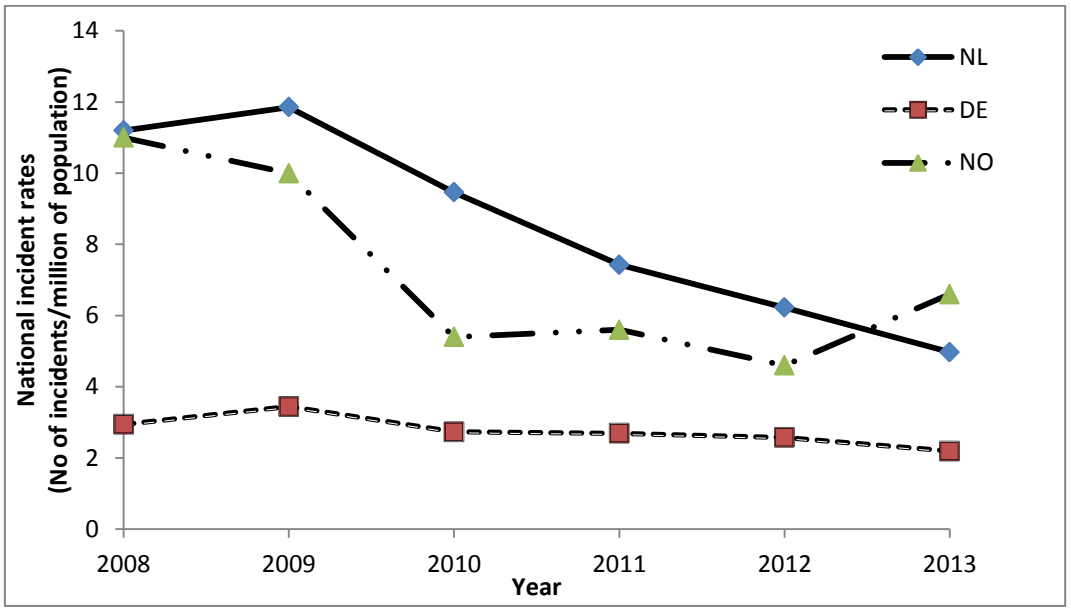
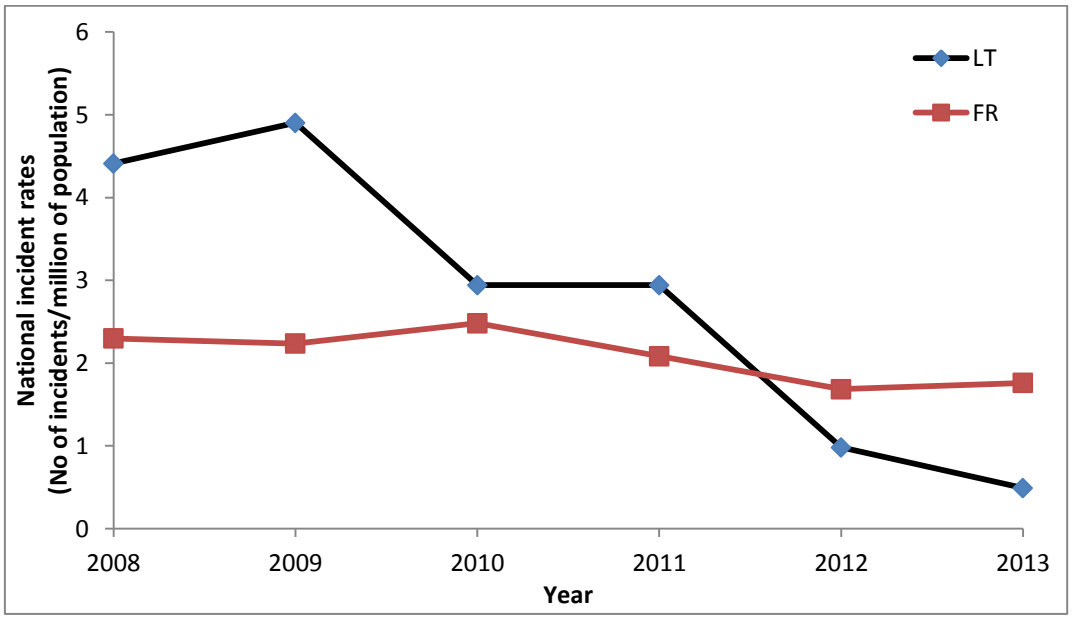


Figure 6. ***Estimated national incident rates (No of incidents/1 million of population) for 2008-2013 due to GLF labelled R65 or H304 (France-FR, Lithuania-LT)***
Source: ECHA's 2014 consultations, data from eight MS and Norway



In the frame of ECHA 2014 consultations (or earlier consultations of the European Commission, e.g. in the period 2007-2012) some MS submitted some data that for various reasons has not been considered for statistical analysis that will be discussed in the next section. For example, the Finnish CAs have submitted compiled figures for incidents due to LO and GLF substances in the period 2008-2013, which although show clear downward trends, these could not be integrated with the rest of data submitted by other Member State CAs (that separately listed poisonings due to LO or GLF labelled R65 or H304). The combined data, however, are listed in the Annex tables 1.1 and 2.1 and are also presented in more details in Annex 8.

B.10.2.2 Estimation of European incident rates due to LO and GLF, labelled R65 or H304

As indicated in the previous section, consistent data (for the period 2008-2013) concerning the total annual number of poisoning incidents caused by LO and GLF labelled R65 or H304, were submitted in the frame of the 2014 ECHA investigations by the following eight MS (and Norway): *France, the Netherlands, Germany, Poland, Ireland, Italy, Lithuania, Slovakia*.

It should be noted that the population of the 9 reported European countries (for Germany/Poland specific regions) is in total approximately **220.5 million**, thereby representing approximately **43% of the total population** for EU(+EEA), which is approximately 512.3 million (*source*: Eurostat 2014). Therefore, this population sample is assumed to be statistically significant and allows us to draw safe conclusions on the poisoning trends for the purpose of this analysis.

Some basic statistical elaboration of these data was performed and be reflected in Annex tables 1.2 and 2.2 for LO and GLF labelled R65 or H304 respectively**,** including:

- Calculation of the *total* number of registered poisoning incidents for LO and GLF per year (2008-2013) for all the reported countries (eight MS + Norway);
- Extrapolation to annual European number of poisonings due to LO and GLF
- Estimation of ***European incident rates*** expressed as number of poisonings per 1 million of population.

Results are indicated in the Annex tables 1.2 and 2.2 where also the % changes of the annual European incident rates were calculated for the two sub periods before (*from 2008 to 2010)* and after 2010 *(from 2010-to 2013),* given that 2010 is the year for reference*.*

The following main conclusions were drawn concerning the analysed data from the reported countries:

- **For lamp oils (LO) labelled R65 or H304:** The total number of annual poisoning incidents due to the consumer uses of LO labelled R65 or H304 first slightly increased from 2008 to 2009. Subsequently, a steady decrease of the number of poisonings has been observed in the last 5 years as reflected in the Annexes (Table 1. 2 and Figure 3.1). The net % changes within the critical sub-periods (before and after 2010, as year of entry into force) are expressed in terms of the estimated annual European incident rates. A decrease of the annual European incident rates is already observed in 2010 (-17 % from 2008 to 2010), and is getting higher after 2010 (-25% from 2010 to 2013). These changes are also reflected below in Table 1. 2 and pictured in figures 5 and 6. It looks as the implementation of the latest packaging and labelling provisions in Annex XVII (entry 3)

to REACH (entry into force on 1 December 2010) has most likely helped further to maintain the downward trends of poisonings. However, it is difficult to say what would have taken place without the measures imposed by the latest amendment of REACH Regulation.

- **For grill lighter fluids (GLF) labelled R65 or H304:** As indicated in Figures 7 and 8, the annual European incident rates due to GLF labelled R65 or H304 were steadily increased until 2010 *(+30% from 2008 to 2010).* However, after 2010 the trend is completely reversing as evident by a significant decrease of these incident rate values *(-40% from 2010 to 2013).* The total annual numbers of GLF poisonings and their identical trends are given in the Annexes (Table 2. 2 and Figure 3.2). Therefore, it seems that the labelling and packaging provisions imposed via the latest amendment of Entry 3 of Annex XVII to REACH have a clear risk reduction effect, as demonstrated by the completely reversed trend after 2010 (year of "entry into force").

For data on both LO/GLF labelled R65 or H304 for the period 2010-2013, **annual average reduction values for the European incident rates** have been estimated by using the formula:

$((X_{2013}-X_{2010})/(X_{2010})+1)^{1/3}-1)$,

where X was the European incident rate values in 2013 and 2010, respectively.

The annual average reduction values were estimated as: **9% for LO** and **15% for GLF** labelled R65 or H304. Based on these values, a projection of the reported figures (for the period 2008-2013) was performed until the year 2020 (2014-2020) as pictured in Figure 1 (section A.1) and be reflected in Annex 9. Assuming that the downward trends will continue, the results show that the projected European incident rate values (number of incidents per 1 million of population) **in 2020** for either LO or GLF will be less than **1 incident per 1 million of population.** More specifically, projected estimations foresee for the year 2020, a significant **decrease of ~60% for the LO** induced incidents (from about 880 incidents in 2010 to 335 in 2020) and **~80% decrease for GLF** induced incidents (from 1280 incidents in 2010 to 240 in 2020). The Annex 9 contains the analytical results of these estimations.

Figure 7. Estimation of annual European incident rates during 2008-2013 (*No of incidents per 1 million of population*) for both LO and GLF labelled R65 or H304
Source: ECHA's 2014 consultations, data from eight MS and Norway

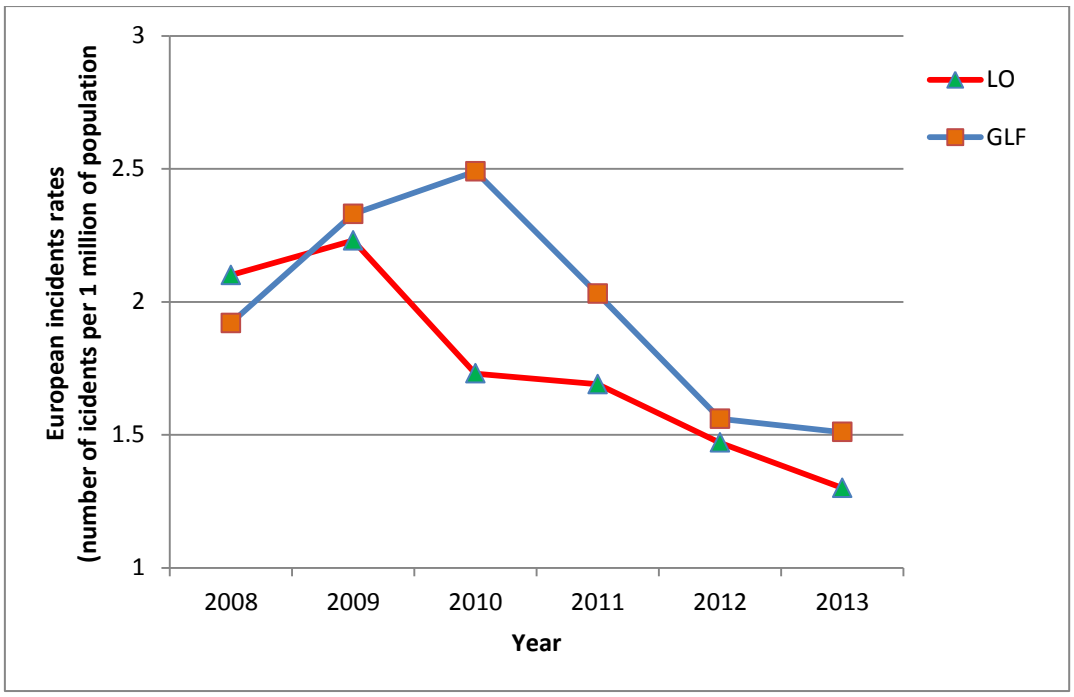
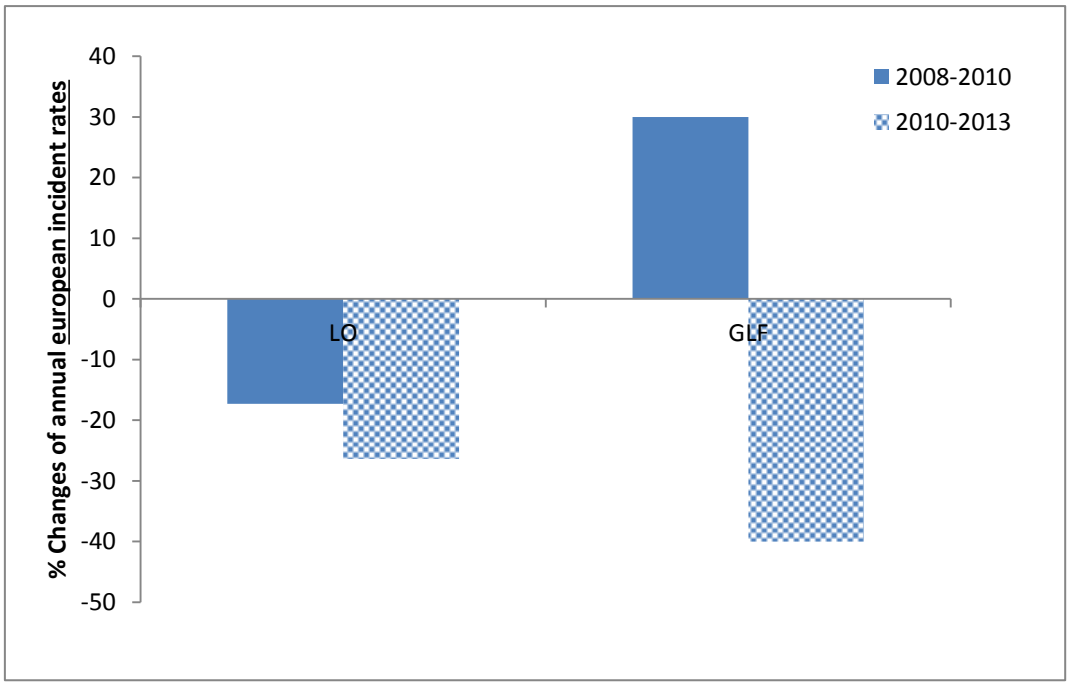


Figure 8. Percentage (%) changes of annual European incident rates for both LO and GLF labelled R65 or H304 during the sub periods *(from 2008-2010 to 2010-2013)*
Source: ECHA's 2014 consultations, data from eight MS and Norway



B.11 Summary on hazard and risk

Hazard

Overall, for both Lamp oils (LO) and grill lighter fluids (GLF) labelled R65 or H304, the main relevant hazard is "aspiration hazard toxicity" (*Asp. Tox. 1,* according to CLP Regulation). Assessment of the data communicated by Member States CAs during the 2014 Commission/ECHA consultations showed that:

(i) For the reported incidents of poisoning, the main exposure pathway is oral ingestion (>90% of cases).

(ii) Only a minor number of the reported incidents (approximately 1-5%) indicate the victim develops severe symptoms (vomiting, dyspnoea abdominal pain), which may be associated with aspiration pneumonia and require hospitalisation.

Exposure

For LO labelled R65 or H304, incidents mainly occur because children ingest the fuel during the filling of the lamps (causing spillages) or in the transfer from the purchased container to another one that is not properly labelled or fitted with a CRC. The GLF labelled R65 or H304 related incidents seem to be mainly caused by accidental drinking directly from the bottle (no burning incidents have been reported by CAs/NPC during the 2014 ECHA consultations). It seems that the incidents are more related to a reasonably foreseeable use[23] of LO and GLF labelled R65 or H304 (e.g. via accidental ingestion of small children at the lack of parental supervision) rather than to the actual function of these products. For instance, no burning accidents have been reported due to the use of GLF labelled R65 or H304 for barbecue/campfire relevant application and related consumer applications (linked to their high flash point >60°C, thereby possessing no "flammability" properties).

Risk

Although there is still some small risk from LO and GLF labelled R65 or H304 (given that poisoning cases are still reported in the EU-EEA area), clear downwards trends have been observed during the last few years, as evidenced by the analysis of the reported national data on poisoning. Based on absolute values of poisonings, extrapolated **annual European incident rates** were estimated (as discussed under section B.10) that showed:

(i) A percentage decrease of poisoning incidents due to **LO** labelled R65 or H304 *which is getting higher after 2010* (from 2008 to 2010: **-17%,** from 2010 to 2013: **-25%)**

(ii) An increase of poisoning incidents due to **GLF** labelled R65 or H304 until 2010, *which is followed by a significant decrease after 2010* (from 2008 to 2010: **+30%** from 2010 to 2013: **-40%**)

(iii) Through elaboration of the poisoning data (2010-2013), **average annual reduction values** were estimated as approximately **9% for LO** and **16% for GLF** induced accidents. Based on these values, projections were made showing that in 2020 about 550 incidents in total due to poisoning from LO and GLF will occur, thereby a total

[23] "reasonably foreseeable use" are conditions of use that can be anticipated as likely to occur. A relevant definition can be found on ECHA Guidance on Substances in Articles (2011) (http://echa.europa.eu/documents/10162/13632/articles_en.pdf)

decrease of ~75% from the total estimated number of poisonings for 2010 (~about 2,270 for the EU-EEA area).

Conclusion

Overall, the observation of decreasing poisoning incident rates after 2010 due to LO and GLF labelled R65 or H304 (as presented under B.10) leads to the conclusion that the current regulatory provisions at EU level, imposed via the Entry 3 of Annex XVII to REACH, serve as effective risk reduction measures. This conclusion is underlined by the evidence for overall stable or even increasing consumer trends in purchasing LO and GLF labelled R65 or H304 after 2010 (as discussed under the section B.2).

As additional restrictions may well have a low impact when the baseline is anyway decreasing, ECHA therefore concludes that the health impact of such an EU wide measure would be small.

It would seem prudent, though, for Member States to monitor that the decreasing trend in poisonings due to grill lighters fluids and fuels for decorative lamps, labelled R65 or H304, will continue by using the incident data they collect from their NPC.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

The ECHA 2014 consultations ("ECHA Survey during January-April 2014" and "ECHA's call for evidence" during June-August 2014), along with literature searching, yielded some information on the available alternatives for lamp oils (LO) and grill lighter fluids (GLF) labelled R65 or H304, which are currently available on the EU market. The most important information is summarised below:

C.1.1 Alternatives for lamp oils labelled R65 or H304

The main commercially available non-R65 or H304 lamp oils belong to the following two categories:

(1) Vegetable oils and derivatives

The most common vegetable oils currently used as lamp oils for consumer use (decorative or religious applications), are:

- *Olive Oil*: Pure olive oil is available at most supermarkets and grocery stores and has been used by Mediterranean people for centuries to light their lamps. Given that it is not poisonous when ingested, olive oil is a child-safe fuel to be used for household oil lamps. Olive oil is a renewable, non-petroleum fuel that will burn in the lamp without fumes or odours.
- *Palm Kernel Oil*: According to some stakeholders, palm kernel oil is considered to be the best organic, child-safe lamp alternative to low-viscosity paraffin oils. It has been claimed though, that its availability maybe limited due to an increasing worldwide demand for renewable raw materials.
- *Canola based Oil:* Canola oil is derived from crushing the grape seed and can be used as

an organic lamp fuel, but with poor combustion performance. Canola oil contains unsaturated compounds and tends to form a resin under light and air impact, causing the wick to clog.

- *Sesame Oil/Castor oils:* They both give a bright, white light, widely used outside EU (India, Egypt) mainly during religious ceremonies.

(2) *Paraffin-like (non R65 or H304) oil fractions.* More commonly, these are white mineral oils and alkanes from different hydrocarbon fractions (C15-C30). They are indicated as "hydrocarbons with a kinematic viscosity of greater than 20.5 mm^2/s measured at 40°C, (therefore not classified as H304 under the CLP Regulation, as discussed under the B.3 section). An overview of the main (non R65 or H304) LO alternatives fluids is provided in the following Table 8, along with their main technical/hazard/price related aspects.

Table 8 *List of main identified substances as alternatives to LO labelled R65 or H304*
Source: ECHA's 2014 consultations/literature searching

Alternative substance (or group of)	Hazard considerations	Technical aspect/performance	Cost aspects /price
Vegetable oils - Olive oil (EC: 232-277-0) - Peanut oil (EC: 232-296-4) - Castor oil: - Rape oil esters, palm oil esters etc.	Some vegetable oils (e.g. peanut oil) have been claimed to be irritants for skin and eyes *Adel-Patient et al, 2009);* *Binkley et al. (2011)*	They produce unpleasant smells, they are aggressive for plastic materials, low shelf life and fear sunlight and warm because they become rancid. Not very good technical performance.	The availability is small and the price is high. Olive oil/Rape oil esters: approximately 2.5-4 euros/lt.
White mineral oils (CAS number 8042-47-5) & paraffin based lamp oils (CAS number 8012-95-1)	They are less dangerous substitute for the traditional lamp oils.	They do not burn very long without fouling the wick and burner device, and then go out or burn very poorly. They are not at all suitable for most refillable lamps.	Higher costs at approximately (30-50% higher) than the LO labelled R65 or H304

C.1.2 Alternative substances for grill lighter fluids (GLF) labelled R65 or H304

In the EU market, there are commercially available non R65 or H304 alternatives fluids which are used for grill lighting purposes and have a similarly good performance. These are mainly denatured alcohols, (e.g. bio-ethanol, butyl alcohol, propyl_alcohol) but can also be methyl esters of long chain fatty acids (e.g. rapeseed oil) or paraffinic and naphthenic base oils (C10-C50).

Table 9 *List of main identified substances as alternatives for GLF labelled R65 or H304*
Source: ECHA's 2014 consultations/literature searching

Alternative substance (or group of)	Hazard considerations	Technical aspect/performance	Cost aspects /price
Denatured ethanol Bio-ethanol, (95-96%) Bio Bren ethanol (96 % Ethanol) Harris - PleinFeu (Alcool éthylique d'origine végétale dénaturé)- Alcohol à brûler (60-85 % ethanol)	- Less damaging to health upon ingestion as they do not present aspiration hazard - Risk of accidental drinking (or even intentional in case of alcoholic) - More flammable than H304 fuels. Ethanol solutions (>80%) have flash point <20℃	Bad smell has been reported in certain cases	Grill lighter fluids based on ethanol, are more expensive. Average Price 2.5-3.5 euros/lt for *Bio-ethanol,* 4.5 euros/lt (Bio Brennethanol) 6 euros/lt (Harris – PleinFeu)
Other alcohol or paraffin mixtures - Mixture containing Water 38.20%, Isopropyl alcohol 60%, Triethanolamine 1.2% and Polymer 0.6% (product in Greek market) - Methyl Ester Bio Butanol	*(Bunch and Hellemans 2004; Wolke, 2006).* Increased risk of burning accidents due to larger flames	Not good lighting performance	Higher price (approximately 30%) than the average GLF labelled R65 or H304 products.

In addition, the following items can serve as non-fluid (solid) alternatives to GLF labelled R65 or H304:

- Grill lighter gels (main components are light alcohols-such as ethanol);
- Solid paraffin cubes;
- Impregnated briquettes and papers;
- Electric grill lighters.

An overview of the main GLF alternatives (non R65 orH304) fluids are summarised in the following Table 9 (along with their main technical/hazard/price related aspects).

Furthermore, some additional information on potential alternatives to GLF labelled R65 or 304 have been submitted by a few MS.

Norway informed that according to most of the Norwegian distributors there are no sufficient alternatives for GLF labelled with R65 or H304 and only two companies reported that an ethanol-based gel can be used as a sufficient substitute for barbecue related applications.

The Netherlands noted of two received letters from companies stating that: (i) the substance dipropyleneglycolmonomethylether (CAS: 34590-94-8, EINECS: 252-104-2) can be regarded as alternative to GLF labelled R65 or H304.

Lithuania also informed that two companies place on their national market 60 - 80% ethanol solutions (CAS No. 64-17-5) as alternatives to GLF labelled R65 or H304.

C.2 Assessment of alternatives

C.2.1 Human health risks related to alternatives

Non R65 or H304 lamp Oils (LO): Overall, the alternative substances to lamp oils (mainly vegetable oils as discussed above or non R65 or H304 hydrocarbons) have a less hazardous health profile given that they do not pose an aspiration hazard and therefore accidents leading to chemical pneumonia are not likely to occur. Paraffin-based non R65 or H304 oils might lead to other effects after ingestion such as dizziness, drowsiness, vomiting or others, as indicated in the SDS of various related products but such effects are less severe and are fully reversible (Chilcott, 2006). 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.

Some vegetable oils, such as peanut oil, have been reported in literature to cause skin irritation (Adel-Patient et al. 2009; Binkley et al. 2011; Kränke et al. 1997). According to a German BfR-ESPED survey (2000-2006) lamp oil substitutes have not shown any risk potential so far. Over the entire six year study period, not a single case of health impairment due to lamp oil substitutes could be confirmed in the Federal Republic of Germany. Six incidents of ingestion of rapeseed methyl esters (C18-C22) were reported but did not lead to severe symptoms or any need for hospitalization.

Non R65 or H304 grill lighter fluids (GLF): Although they do not present aspiration hazard the most common alcohol based GLF alternative substances have the following hazard related disadvantages:

- Lower flash points (higher flammability) than those of substances labelled R65 or H304 leading to production of larger flames and thereby posing an increasing risk for burning accidents.
- Reported cases of intentional drinking (due to the high alcohol content).

Italy has recently (July 2014, REACH Committee meeting) communicated to the Commission some information on *burn accidents due to the use of denatured alcohol* (as solvent and fuel for spirit burners and camping stoves). It was noted that only in 2011, 310 accidents (caused via flame burning by misuse of denatured ethyl alcohol) were registered by 17 Health Centres. Overall, 14% paediatric burns and 18% mortality in paediatric age are caused by misuse of denatured ethyl alcohol.

Further to Italy, three more MS (Austria, Germany, and France) have communicated information on accidents due to denatured alcohol. An overall picture is presented below in Table 10. France, in the frame of 2008 Commission's consultation for the 2009 Impact Assessment report, had provided very interesting information from their French national poison centres). In France, overall, the number of intoxications by grill lighter fluids and lamp oils labelled R65 or H304 is low compared to the number of accidental burns due to the use of highly flammable alternative substances. France had reported 177 cases of accidental ingestions linked to LO and GLF labelled R65 or H304, which is much lower than the reported 580 cases caused by accidental burns with methylated spirits (French Committee for Consumers Safety, 2008). A report on methylated spirits prepared in June 2008 by the French NPC (CCTV) concluded that methylated spirits, which contain ethanol or methanol (up to 7%), were being (mis-)used by consumers causing accidental burns.

In addition, the alternative solid type grill lighters (e.g. solid cubes, bar-shaped) have been proven to be much less dangerous than the grill lighter fluids labelled R65 or H304, although their chemical composition is rather similar. This happens because in the alternative solid products (or even the gels type) the liquid constituents are bound to sawdust or cork powder and therefore their harmful ingredients are not easily accessible to creep into the lungs upon ingestions.

According to a rough estimation, based on the data reported by these 4 MS, over 3000 registered burning incidents are expected on annual basis by the use of the non R65 or H304 alcohol based GLF as a consequence of their rather lower flash point (highly flammability). This seems to be a rather significant figure.

In the frame of the 2014 ECHA consultations, Germany, France and Italy communicated their number of poisonings for 2013 due to ingestion GLF labelled R65 or H304 (listed in Annex 2, Table 2. 2), that give a total number of 208. At the same time, according to Table 10, the total number of burning related accidents in these three countries is estimated at approximately 2000 per year, thereby approximately 10 times higher. Although it is not a valid approach to compare two different types of health hazards (poisoning vs. burns) these results indicate that the alternative (non R65 or H304) alcohol based substances may present even a more hazardous profile than the GLF labelled R65 or H304.

Table 10 ***Information on burning accidents in EU countries due to denatured ethanol used as GLF***

Source: Communication with MS-CAs in the ECHA's 2014 consultations

Country	Number of accidents/year	Source of information
Austria	approximately 1000 accidents /year connected with barbecue activities of which 52% were injured by using denatured alcohol fuels	http://www.laenderversicherer.at/sicherheit/sicherheitsaktion-2013/
Germany	3000 accidents /year, most linked with flammable, volatile substances (e.g. gasoline or alcohol)	http://www.spiegel.de/gesundheit/diagnose/grillen-wie-man-den-grill-anzuendet-und-was-bei-verbrennungen-hilft-a-970563.html
France	approximately 450 /year admissions in health centres due to misuse of denatured alcohol	http://www.securiteconso.org/avis-relatif-a-la-securite-des-lalcool-a-bruler-et-des-produits-allume-feu-liquides-et-gelifies/
Italy	approximately 300/year due to denatured ethyl alcohol	Presentation of Italian Health Ministry, REACH Committee (July 2014)

C.2.2 Technical and economic feasibility of alternatives

C.2.2.1 Technical feasibility

According to information provided by Industry in the frame of the ECHA's 2014consultations, most of non R65 or H304 alternative lamp oils are technically inferior to the ones labelled R65 or H304. More specifically vegetable oils and derivatives:

(a) have a penetrating, disturbing smell (due to high volatility), and that could be problematic according to the stakeholders for their use in decorative lamps in public places (e.g. hotels, restaurants) or even for liturgical purposes (as reported by Italian CAs in 2014);

(b) have worse burning capacities, therefore being remarkably insufficient for use in outdoor applications, e.g. orthodox cemeteries (flame does not last as long as with R65 or H304 lamp oils);

(c) due to less capillary action and too high resolving power, they may cause damage to surfaces (e.g. lacquer of tables) leaving solid deposits, heavy smog residues and slag (such type of effects have been recorded by artistic organisations/Institute of Fine Art, Italy).

It has to be noted, though, that points (a) and (c) mainly concern professional types of applications and not LO or GLF intended for supply to the general public, as already discussed under the section B.2.1.

According to the information received from industrial stakeholders during the ECHA's 2014 Call for evidence, palm seed oil could be considered as the most suitable substitute (among the used vegetable oils) in terms of technical feasibility. Nevertheless it is currently scarce because of a worldwide demand for renewable raw materials (biodiesel). Furthermore, Germany (2008) had reported that according to their technical performance testing, palm oil-based products and low-viscosity n-paraffins (carbon chain length C15-C30) exerted the best performance provided that the distance between the liquid oil and the upper end of the lamp wick is less than 50 mm. However, these alternatives to LO labelled R65 or H304 are unsuitable for classical paraffin (Argand) lamps, requiring a creep height in the wick of up to 200 mm. If they are used in pressure lamps, the brightness is reduced by 50 % (palm oil") or the suitability is restricted in cold surroundings (n-paraffins). In line to the findings reported by the German Authorities, BIAG (Barbecue Industry Association), also noted that palm seed oil is not suitable for agrarian country lamps and high luminosity lamps. The technical drawbacks of the main (non R65 or H304) LO are summarized in table 9.

Concerning the (non R65 or H304) GLF alternative substances, they overall seem to have a similar lighting performance to the one of the conventional H304 paraffins. However, bad smell or not good lighting performances were also reported in certain cases.

C.2.2.2 Economic feasibility:

According the ECHA 2014 consultations with the MS and the industrial Stakeholders, the non R65 or H304 alternative substances for both LO and GLF cost on average higher than the H304 products available in the EU market. The overall picture is presented in tables 8 and 9 for the (non R65 or H304) alternative substances used for these specific applications. Similar information was submitted by a few MS during their earlier reporting for LO and GLF labelled R65/H304 (e.g. reports submitted to European Commission in 2012 according to the entry 3 requirements). More specifically:

Lamp Oils (LO): The higher-on average-prices of various vegetable oils, further to their limited availability, was noted by the stakeholders. In the EU market, 1 litre of lamp oil labelled R65 or H304 costs 2.5-3 euros on average, while olive oil and rape oil esters are most commonly sold at 3-4 euros/litre, thereby at approximately 30-50% higher prices. Germany had informed (2008) that palm oil based products are sold at even 5 to 7 times higher prices than the R65 or H304 labelled n-paraffins (depending on the basic product, i.e. coconut/palm/ palm kernel oil, sales volume and purchase price).

In addition, according to the provided information, the paraffin based-non R65 or H304 LO (other category of alternatives) cost approximately 50-100% higher compared to the LO labelled R65 or H304.

Grill lighter fluids (GLF): According to the ECHA's 2014 consultations, the retail price of the GLF labelled R65 or H304 is approximately 3.5 euros per lt. Furthermore, the stakeholders informed that GLF products based on ethanol, available on the EU market, are sold at prices which are either similar or most commonly higher than that of H304 labelled paraffins. Prices in the range of rice 3-6 euros for bioethanol commercially available products are recorded in Table 9.

Overall, it may be that a potential ban of LO and GLF labelled R65 or H304 could lead to significant substitution costs, in particular for consumer uses of lamp oils due to their replacement by the more expensive non R65 or H304 alternative substances. That would cause a particular financial burden for the SMEs in the sector of lamp oils which are the majority of EU companies in this sector, as highlighted by the consulted industrial stakeholders. It could also be claimed that the substitution costs may be partly transferrable to the consumer leading to higher priced of the commercial products, thereby to consumer losses.

C.2.3 Summary-Main conclusions

The analysis of the information provided by the MS and Industry during the 2014 ECHA consultations leads to the following conclusions:

- The main alternatives for LO (mainly non R65 or H304 vegetable oils and derivatives) do not present any aspiration hazard toxicity but they have been reported to possess less good technical performance, as well as to exert corrosive action and disturbing smell in comparison to the LO labelled R65 or H304. In addition, the non R65 or H304 alternative substances seem to be more expensive (30-50 % higher prices than for lamp oils labelled R65 or H304). As a consequence, significant substitution costs have been reported by a few companies in case of a ban of LO labelled R65 or H304.
- The main alternatives for GLF (mainly non R65 or H304 denatured alcohols) have a good technical performance but due to their higher flammability, they often cause burn accidents and thereby have a more hazardous profile. Comparing 2014 data from three MS (Italy, France, Germany) it has been demonstrated that the total number of burn accidents due to the non R65 or H304 alcohol based alternatives can be significantly (approximately 10 times) higher than the number of poisoning incidents due to GLF labelled R65 or H304. Therefore, an increasing amount of burn accidents is expected in case of a ban of GLF labelled R65 or H304 due to the fact that consumers will search for alternatives which are highly flammable liquids (petrol, spirits or bio ethanol) with dangerous consequences (domestic fires as well as bad burns).

D. Justification for action on a Union-wide basis

The placing on the market of lamp oils and grill lighter fluids labelled R65 or H304 is an EU wide issue which cannot be isolated to any specific country. Therefore the relevant paraffin based LO products can be found everywhere on the EU market. However, as demonstrated by the analysis of chapter B, during the last few years there are significant downward trends of the reported EU poisoning incidents due to the specific uses of both LO and GLF labelled R65 or H304 by the general public. Around 25% and 40% total annual reductions respectively of registered incidents due to LO or GLF labelled R65 or H304 for the period 2010-2013 were reported in those MS (+Norway) that monitor the current situation through their National Poison Centres.

Further to the proper implementation of the existing legislative labelling and packaging requirements since 2010 (Entry 3 of Annex XVII to REACH), these reducing trends of incidents may also associate to a raising consumer awareness given that certain MS perform information campaigns for the proper use of the related products. A certain risk for human health (aspiration hazard toxicity following oral exposure) is still there as evidenced by the reporting of poisoning incidents in some MS.

However, the risk links more to the misuse of the products by the consumer (accidental ingestion of small children) and is expected to be gradually diminished assuming that the downward trends of the last few years (as discussed in section B.10) will sustain in the next decade. Thus the health impact of a restriction of GLF labelled R65 or H304 at Union level would seem to be even possibly counterproductive, due to unwanted characteristics of the alternatives.

Overall, no need for an amendment of the current labelling/packaging provisions or even stricter EU regulatory measures (e.g. further restrictions or ban of LO and GLF labelled R65 or H304) has been deemed necessary at this stage following the ECHA analysis of the data submitted via the 2014 consultations.

E. Justification why the proposed restriction is the most appropriate Union-wide measure

Not applicable for this report.

F. Socio-economic Assessment of Proposed Restriction

Not applicable for this report.

G. Stakeholder consultation

G.1 Overview of the consultations

During 2014, ECHA has collected information by carrying out 2 specific web-based questionnaires:

- ECHA Survey (January-April 2014) that yielded responses from 31 MS Competent Authorities;
- a Call for evidence with Stakeholders (June-August 2014) where 30 companies/associations (EU manufacturers/distributors/importers) and a 3rd country exporter) submitted their input.

Further to these two consultations, and in order to enhance data on poisoning incidents due to LO and GLF labelled with H304, ECHA has separately contacted (September-October 2014) a number of National Poison Centres (NPC) that submitted their reported number of poisonings at either regional or national level.

More specifically, the ECHA's call for evidence yielded 31 responses from Industry including: 10 EU manufacturers (9 both of LO and GLF labelled R65 or H304, 1 of alternatives), 14 EU distributors (LO), 2 importers (LO and GLF), 2 bottling companies, 1 non EU company (USA) exporting to EU and 1 trade association (GR). Furthermore, in the frame of the Commission/ECHA survey (early 2014), Cyprus CAs informed that 25 companies (22 EU distributors and 3 importers from third countries) for LO and 2 companies for GLF are active in their market.

Concerning their geographic distribution, 14 companies of the responders are located in Greece and are mainly distributors of lamp oils. 14 more companies were identified in the rest of EU out of which: 4 in UK, 3 in Germany, 2 in Italy, 2 in Spain, 2 in Netherlands, 1 in Sweden.

Overall, a large number of small and medium enterprises placing on the market lamp oils labelled R65 or H304 have been identified in Greece (15) and Cyprus (25), mainly distributors which are active in both markets. It was indicated that only in Greece, approximately 500 micro companies place in the market lamp oils labelled LO and GLF (with their main suppliers located in Italy, the Netherlands, Belgium, etc.).

The input received from the stakeholders has been analysed and discussed in various sections

of this report such as B.2 (data on quantities of LO and GLF labelled R65 or H304), B.10 (data on poisoning), section C (alternative substances).

ECHA sent a draft of this Annex XV report (dated 17 April 2015) to the Commission and to Member State Competent Authorities as information point at the 18th Meeting of Competent Authorities for REACH and CLP (CARACAL) in 23-24 June 2015. The MSCAs were invited to provide comments on the draft report and especially its conclusions (document CACS/17/2015, "Commission's request to ECHA to prepare an Annex XV report on a potential restriction on the placing on the market of lamp oils and grill lighter fluids labelled R65 or H304, for supply to the general public"). ECHA received written comments from two MSCAs (Germany and Estonia).
ECHA received written comments from two MSCAs that supported the analysis and conclusions of the report and no request was made to discuss the draft report during the CARACAL meeting. One of the MSCAs that provided written comments emphasised the downward trend of poisoning incidents in the last years and the other that the current regulatory provisions (entry 3 of Annex XVII to REACH in combination with the horizontal CLP) seem to serve as sufficient risk management measures to ensure a safe use of LO and GLF labelled R65 or H304 for the general public.

G.2 Information received by MC-CAs concerning inspection for compliance and monitoring activities for LO and GLF labelled R65 or H304

This section provides an overview of the relevant information that was communicated by the MS (in the frame of Commission/ECHA 2014 Survey), in particular from those CAs responsible for the enforcement of Entry 3 of the Annex XVII to REACH restriction provisions.

G.2.1 Lamp Oils (LO) labelled R65 or H304

A few CAs have undertaken the following inspection and monitoring activities for the detection of non-compliant LO labelled R65 or H304:

Cyprus: Due to the wide use of LO labelled R65 or H304 by consumers, the Cyprus CAs is closely monitoring the labelling and packaging of the related products on the Cyprus market. A special informative leaflet on this issue has also been issued in 2010. A few non-conforming products were identified over the last decade and warning letters, indicating the violations and the hazards for the exposed consumers, were sent to the companies placing these products on the market. In the cases of non-conforming (to the labelling requirements) products, a new label had to be presented for control to the authorities before the product was placed again on the market. If the products were non-conforming due to their packaging (either due to the colour of the container or due to the luck of child-resistant fastening) they were withdrawn from the market. The Cyprus CAs highlighted that the taken measures were efficient since in the last two years all the LO labelled R65 or H304 currently placed on the Cyprus market are in conformity.

Finland: The enforcement CAs (Tukes) detected altogether 4 cases of non-compliant LO labelled R65 or H304 (manufactured in the EU and 2 two imported) in the early 2013, which were withdrawn from the market or recalled from the consumers. As a reaction to the

introduction of the legal requirement concerning packaging size, some actors continued marketing the same product under a different trade name/ product description, which made it challenging from an enforcement point of view.

Greece: Out of 37 LO samples labelled R65 or H304 tested since 2008, 17 were detected as non-compliant. Non-compliances had mainly to do with labelling in Greek language, content of odouring and/ or colouring agents, missing pictogram, missing R66 or R10 phrases etc. The non-compliant LO products labelled R65 or H304 were withdrawn from the market, the labelling changed and was authorised by the CA competent authority and the products were then released to the market again as being compliant.

Germany: Non-compliances of LO labelled R65 or H304 (3-4 cases/year) were detected by the national authorities, mainly due to the fact that the appropriate packaging requirements have not been fulfilled. Rapex notification (according the article 11 of Directive 2001/95/EC) was the taken measure.

Estonia: Incidents of insufficient labelling were detected for a number of LO labelled R65 or H304. Following recommendations, the labelling requirements were fulfilled (in line with entry 3 of Annex XVII to REACH) and new labels were provided.

Poland: Non-compliant products of LO labelled R65 or H304 were detected by the Polish Authorities on their market, such as:

(i) LO in transparent packaging (pet bottle), without proper pictograms and not visibly and not legibly marked according to Annex XVII to REACH provisions. The product was withdrawn from the market.

(ii) LO/naphtha lamps and torches without required information on packaging (currently under investigation).

(iii) 4 cases of different LO labelled R65 or H304 containing colouring agents and perfume the placing of which on the market was stopped.

G.2.2 Grill lighter fluids (GLF) labelled R65 or H304

The following information was received from the CAs of Member States responsible for the enforcement of Annex XVII to REACH provisions concerning the detection of non-compliant GLF products labelled R65 or H304 as well as the taken measures:

Finland: A few incidents of insufficient labelling in GLF labelled R65 or H304 have been detected and the actors in question have been urged to correct the labelling within a given timeframe.

Hungary: During the inspection, GLF products labelled R65 or H304 from 9 different distributors were on the market and 23% of the checked products did not meet the legislative provisions. Among the typical deficiencies the lack of the required pictogram, R and S phrases as well as of the tactile warning sign were mentioned.

Poland: Non-compliant GLF products labelled R65 or H304 were detected by the Polish CAs on their market, such as:

- Errors in SDS and differences with the product labelling (control activities undertaken; product withdrawn from the market);
- Product with improper labelling and not packaged in black opaque container and not marked. After inspection activities, the supplier properly amended labelling and replaced questioned product by a correct one.

G.3 Economic impacts from a potential restriction of LO and GLF labelled R65 or H304 communicated by stakeholders

The ECHA's call for evidence (January-April 2014) yielded a number of responses from various industrial stakeholders which are active in the sectors of lamp oils and grill lighter fluids (and related products). This section gives a broad picture of the main economic impacts, mainly in terms of qualitative information that were communicated to ECHA by EU manufacturers/distributors and importers of LO and GLF labelled R65 or H304.

G.3.1 EU Manufacturers of LO and GLF labelled R65 or H304

A manufacturer informed that LO and GLF labelled R65 or H304 cover about 70 to 80% of their business and therefore the potential impact of a future ban would be enormous. Another EU company producing LO and GLF labelled R65 or H304 confirmed that a potential ban would directly affect their company leading to loss of customers and their turnover. A manufacturer of alternatives however, mentioned that they would appreciate an EU ban of LO and GLF labelled R65 or H304 given that there are available alternative products on the EU market. The company also informed that the German government is planning to add energy tax on firelighters based on CAS 64742-48-9 (a common H304 hydrocarbon substance) which would eventually make existing GLF labelled R65 or H304 the same expensive with the alternative substances.

G.3.2 EU distributors of LO and GLF labelled R65 or H304

In the frame of ECHA 2014 consultations, more than 50 SMEs were identified in Greece and Cyprus to distribute lamp oils labelled R65 or H304 mainly for religious uses at their national markets. The responded EU distributors strongly opposed to a potential ban of LO and GLF labelled R65 or H304 claiming that such measures would destroy their business, pushing them to cease their activities and lose the majority of their earnings (e.g. big loss of their turnover, 20-50% for lamp oils).

In addition, the following types of expected costs have been qualitatively described by the EU distributors, in case of future EU ban on LO labelled R65 or H304:

R&D costs due to the need to formulate new products. Changes will need to be made to existing burners/candles to accommodate new wick and fuel types.

Substitution costs: as discussed in section C, the currently non R65 or H304 alternatives are one average more expensive (~30% the grill lighter ethanol preparations,~50-100% the vegetable lamp oil substances). Therefore, additional costs would be expected in case of a need for substitution in particular for LO labelled R65 or H304. The companies claim that they may not be able to pass any such cost increase on to the end user therefore a reduction of current profit margins should be expected.

Marketing costs to switch the perception of customers for alternatives substances with lower technical performances have been also reported by companies.

Labelling stock disposal and cost of renewing SDS and end-user instructions would be also resulted in case of any new legislative requirements.

In addition, a few European distributors expressed their concerns that if the LO labelled R65 of H304 will be banned for general public then this measure would be subsequently extended for the professional use in restaurants and hotels. They clarified that sealed, disposable liquid candles (based on hydrocarbons classified R65 or H304) that are not refillable have proven to be much safer for restaurants and hotels than the conventional solid wax candles. Those companies also highlighted that the relevant standard (EN 14059) needs to have some modifications (as explained in more details in Annex 7).

Furthermore, the Barbecue Industry Association (BIAG, Germany), in a recent 2014 contact, expressed their view that there is no more concern for health risks given that since 2010 no more serious accidents have been caused by GLF labelled R65 or H304. For BIAG, a general ban is therefore not proportionate whereas consumers might readily tend to use more flammable and thereby hazardous liquids, e.g. denatured alcohol. In the frame of the 2008 consultation with the Commission, BIAG had estimated that the industry turnover losses due to potential ban of GLF labelled R65 or H304 would be of the magnitude of approximately 22 million euros while the majority of companies are medium size plants (total turnover for GLF industry was estimated, in 2008, at approximately 300 million euros). In addition, the Federal Ministry of Economics and Technology in Germany (BMWi) had anticipated a gross profit loss of 2.3 million euros for the associated companies in case of a ban of lamp oils in oil lamps and torches.

G.3.3 Other companies associated to LO and GLF fuels labelled R65 or H304 (or associated articles)

Although according to the received info, the majority of LO and GLF labelled R65 or H304 products are manufactured in the EU, a few importers were identified in Germany and the Netherlands. They claim that a potential ban will destroy the business as they mainly supply restaurant/hotels for decorative uses.

A USA manufacturer that exports to the EU participated in the survey claimed that Europe is a very important market for them given that their products are imported to EU and supply a large number of SME distributors. They expressed their fears that if the LO labelled R65 of H304 are banned for general public, the ban would cross over their professional uses (supply to hotels and restaurants).

A bottler company highlighted that in case of a ban of LO and GLF labelled R65 or H304, new products will have to be developed such as gels that need special machinery and a complex process. Given that they now only have to fill bottles with a liquid such a development will cause a very high increase in the production costs.

A strong reaction was expressed by an Italian company specialized in production and worldwide distribution of religious articles (e.g. lamps, lucernes, pyrex of polycarbonate holders etc.). This company uses for their applications a special type of LO labelled R65 or H304 supplied by an Italian manufacturer. They claim that the restriction provisions imposed at EU level in 2003 (for colouring and flavouring substances in these products) as well as the

latest packaging/labelling requirements since 2010, have resulted in adverse impacts (decrease in volume of business, increased costs) for their company. In case of a future ban they expect further loss of income and reduction of their revenues.

G.3.4 Social impacts

The EU manufacturers of lamp oils labelled R65 or H304 noted that in case of a ban, their customers will have to shift to vegetable oils, and therefore throw away millions of plastic lamps resistant and unbreakable (to be replaced with glass lamps). Such a development will bring additional costs to end-user and will eventually lead to an increase of unemployment numbers for plastic SME suppliers.

The EU distributors of LO and GLF labelled R65 or H304, further to the various types of costs, they also highlighted a subsequent adverse effect of unemployment (two companies reported that 6 and 9 people may lose their jobs in case of future restrictions). In addition, the importers overall claimed that a lot unemployment is expected in their sector, in case of a ban, due to the loss of many customers and given that the alternative products are too expensive. A rough estimation had been made by the BMWi in 2008, claiming that a ban of LO and GFL labelled R65 or H304 would result in a loss of approximately 200 jobs only in Germany (producers and importers).

The Hellenic Association of Chemical Industries (Greece) informed that more than 500 micro enterprises occupying 1-4 persons are active in the sector of lamp oils labelled R65 or H304 which are exclusively for religious purposes in Greece. They also claim that in case of a ban, more than 50% out of these companies will disappear, including also bottling companies and those supplying carton packs bottles etc.

G.4 Recommendations for voluntary risk reduction measures to Stakeholders and Member States

During the 2014 consultations, ECHA gathered some suggestions as measures that would contribute to a further risk reduction concerning the reported incidents due to LO and GLF labelled R65 or H304. These mainly include the following statements:

1. Add on the label the phrase *"for adults use only".*
2. Add on the label the phrase "for *outdoor use only".*
3. Add on the label the phrase *"Use in cemeteries only"*
4. Use a more industrial-look label (which may flag potential danger due to the use of the products).

Statements 1-3 were the most popular industry recommendations mainly from Greek SMEs distributors of lamp oils labelled R65 or H304 which are intended for specific religious uses.

ECHA has considered these suggestions as well as some additional information provided mainly by stakeholders on the potential exposure and the way accidents of poisonings normally occur as described elsewhere in this report (e.g. section B.9.2.1). Furthermore, ECHA received some input from a Finnish expert on grill lighter fluids on certain issues related to these substances (e.g. flammability/flash points and safety aspects of their use such as safe handling of grill lighter fluids in relation to ignition of charcoal).

ECHA has therefore concluded that the following suggestions could be further investigated by industry (in developing methods to prevent the small number of poisoning incidents still occurring) and, if found useful, be introduced on a voluntary basis:

- For both LO and GLF, labelled as R65 or H304, the use of a supplementary pictogram to emphasise the containers of these substances should be kept out of the reach of children.
- For LO, labelled as R65 or H304, to explore/develop methods to discourage consumers from transferring the substances from the original bottle to other containers to make filling lamps easier (e.g. appropriate packaging).
- For GLF, labelled as R65 or H304, to explore and develop methods to limit the amount of fluid delivered to the substance to be lit, e.g. a spray attachment, and to warn users to wait a short time (~10-15 min according to the expert advice) before igniting the grill.

Furthermore, by considering the findings of the analysis presented in this report, ECHA recommends that:

- MS could monitor that the current decreasing trend in poisonings, due to LO and GLF labelled R65 or H304, will continue by using the incident data they collect from their NPC;
- As some MS have carried (since 2010) successful information campaigns to reduce accidents relating to LO or GLF labelled R65 or H304, it would seem good that these activities were continued and also carried out by other MS.

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Annexes

Annex 1 Data on poisoning incidents due to Lamp Oils (LO) labelled R65 or H304

Table 1. 1 Overall picture on the total annual number of LO-related poisoning incidents reported by a number of EU MS for the period 2003-2013 *(number of children in parenthesis, where available)*

Source: ECHA' 2014 consultations

CAs-NPCs /Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Netherlands (NVIC)	155	180	270	Average 250		187 (167	198 (171)	158 (138)	124 (106)	104 (88)	83 (69)
Sweden (0-4 ys)	122	181	147	125	142						
Slovak Republic (NTIC)	16	14	18	24	-----	13 (11)	14 (11)	18 (11)	15 (13)	18 (14)	19 (14)
Germany (6/9 Poison Centres)	148	170	177	142	139	153	179	142	140	134	114
France						41	35	30	46	31	22
Ireland (NPIC)		1(1)	2(2)	0	3(3)	2(2)	1(1)	0	1(1)	0	0
Italy						9	12	7	10	8	10
Lithuania						2	1	0	5	1	2
Norway						55	50	27	28	23	33
Poland (4/10 Poison Centres)						1	1	0	4	6	3
Finland (total compiled numbers for LO+GLF)						111	143	131	107	69	96
Estonia						Total: 3 (period 2008-2013)					
Greece	Total: 68 (period 1976-2011)										

Table 1. 2 Estimation of European incident rates of poisoning incidents due to LO labelled R65 or H304 for the period 2008-2013 *(Number of incidents per 1 million of population)*
Source: ECHA's 2014 consultations

Country	Population[24] (millions)	2008	2009	2010	2011	2012	2013
France	65.3	41	35	30	46	31	22
Germany (6/9 Poison Centres)	52.0 (for this these region)	153	179	142	140	134	114
Ireland	4.6	0	1	0	1	0	0
Italy	60.4	9	12	7	10	8	10
Lithuania	2.1	2	1	0	5	1	2
The Netherlands	16.7	187	198	158	124	104	83
Norway	5.0	55	50	27	28	23	33
Poland (4/10 Poison centres)	9.0 (for this these region)	1	1	0	4	6	3
Slovak Republic	5.4	13	14	18	15	18	19
Total annual number of "regional" incidents (8 MS +NO)	220.5	463	491	382	373	325	286
Extrapolated annual European numbers of incidents (EU-EEA)	512.3	1076	1141	888	867	755	664

[24] Source: Eurostat 2014

European Incident rates[25] (EU-EEA)		2.10	2.23	1.73	1.69	1.47	1.30
% changes of incident rates (EU+EEA)		**2008-2010**: **-17%**			**2010-2013**: **-25%**		

Table 1. 3 National Incident rates[26] for poisonings due to LO labelled R65 or H304 for the period 2008-2013 *(Number of incidents per 1 million of population)*
Source: ECHA's 2014 consultations

Country	Population (millions)	2008	2009	2010	2011	2012	2013
France	65.3	0.63	0.54	0.46	0.70	0.47	0.34
Germany (6/9 Poison Centres)	52.0 (total for this region)	2.94	3.44	2.73	2.69	2.58	2.19
Ireland	4.6	0.43	0.22	0.00	0.22	0.00	0.00
Italy	60.4	0.05	0.02	0.03	0.03	0.00	0.07
Lithuania	2.1	0.98	0.49	0.00	2.45	0.49	0.95
The Netherlands	16.7	11.20	11.86	9.46	7.43	6.23	4.97
Norway	5.0	11.00	10.00	5.40	5.60	4.60	6.6
Poland (4/10 Poison centres)	9.0 (total for this region)	0.11	0.11	0.00	0.44	0.67	0.33
Slovak Republic	5.4	2.41	2.59	3.33	2.78	3.33	3.52

[25] **European** incident rate **for year X** = total number of (extrapolated) poisoning incidents for the year X in the EU-EEA/ 512.3 million (EU-EEA population)

[26] **National incident rate of poisonings** for year X = total number of reported poisoning incidents for the year X/ population of MS (or covered region of MS)

Annex 2 Data on poisoning incidents due to Grill Lighter Fluids (GLF) labelled R65 or H304

Table 2. 1 Overall picture on the total annual number of GLF-related poisoning incidents reported by a number of EU MS between 2003-2013 *(number of children in parenthesis, where available)*

Source: ECHA's 2014 consultations

CAs-NPCs /Year	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Netherlands (NVIC)						1 (1)	5 (4)	5 (3)	6 (3)	4 (3)	5 (4)
Sweden (0-4 ys)	464	437	276	288	246						
Slovak Republic (NTIC)				5	9	8 (7)	10(9)	12(10)	6(5)	9(9)	12(12)
Germany (6/9 Poison Centres)	96	100	105	82	101	98	171	166	109	96	89
France (NPIC)						150	146	162	136	110	115
Ireland (NPIC)	---	1 (1)	3 (3)	2 (2)	3(2)	0	3(2)	5(4)	1(1)	1(1)	2 (2)
Italy						3	1	2	2	0	4
Lithuania						9	10	6	6	2	1
Poland (4/10 Poison Centres)						4	4	4	10	7	4
Finland (total number for LO+GLF)						111	143	131	107	69	96
Norway- (NPC)		Total: 455 (period 2004-2008) (small children <5)				150	170	188	171	114	102
Estonia						Total: 22 (period 2008-2013)					

Table 2. 2 Estimation of European incident rates of poisoning incidents due to GLF labelled R65 or H304 for the period 2008-2013 *(Number of incidents per 1 million of population)*
Source: ECHA's 2014 consultations

Country	Population[27] (millions)	2008	2009	2010	2011	2012	2013
France	65.3	150	146	162	136	110	115
Germany (6/9 Poison Centres)	52.0 (for this these region)	98	171	166	109	96	89
Ireland	4.6	1	3	5	1	1	2
Italy	60.4	3	1	2	2	0	4
Lithuania	2.1	9	10	6	6	2	1
The Netherlands	16.7	1	5	5	6	4	5
Norway	5.0	150	170	188	171	114	102
Poland (4/10 Poison centres)	9.0 (for this these region)	4	4	4	10	7	4
Slovak Republic	5.4	8	10	12	6	9	12
Total annual number of "regional" incidents (8MS +NO)	220.5	424	514	550	447	343	334
Extrapolated annual European numbers of incidents (EU-EEA)	512.3	985	1194	1278	1039	797	776

[27] Source: Eurostat 2014

European incident rates[28] (EU+EEA)		1.92	2.33	2.49	2.03	1.56	1.51
% changes of incident rates (EU+EEA)		**2008-2010**: **+30%**					
				2010-2013: **-40 %**			

Table 2.3 National Incident rates[29] for poisonings due to GLF labelled R65 or H304 for the period 2008-2013 *(Number of incidents per million of population)*
Source: ECHA 2014 consultations

Country	Population (millions)	2008	2009	2010	2011	2012	2013
France	65.3	2.30	2.24	2.48	2.08	1.68	1.76
Germany (6/9 Poison Centres)	52.0 (regional population)	1.88	3.29	3.19	2.10	1.85	1.71
Ireland	4.6	0.22	0.65	1.09	0.22	0.22	0.43
Italy	60.4	0.02	0.02	0.00	0.07	0.10	0.05
Lithuania	2.1	4.41	4.90	2.94	2.94	0.98	0.49
The Netherlands	16.7	0.06	0.30	0.30	0.36	0.24	0.30
Norway	5.0	30.0	34.0	37.6	34.2	22.8	20.4
Poland (4/10 Poison centres)	9.0(regional population)	0.44	0.44	0.44	1.11	0.78	0.44
Slovak Republic	5.4	1.48	1.85	2.22	1.11	1.67	2.22

[28] **European** incident rate **for year X** = total number of (extrapolated) poisoning incidents for the year X in the EU-EEA/ 512.3 million (EU-EEA population)

[29] **National incident rate of poisonings** for year X = total number of reported poisoning incidents for the year X/ population of MS (or covered region of MS)

Annex 3 Plots of total annual number of poisoning incidents for LO and GLF labelled R65 or H304 in the period 2008-2013 as reported by eight MS and Norway

Figure 3.1 ***Total reported annual number of poisoning incidents due to LO labelled R65 or H304 in the period 2008-2013.***
Source: ECHA's 2014 consultations, data from eight MS and Norway

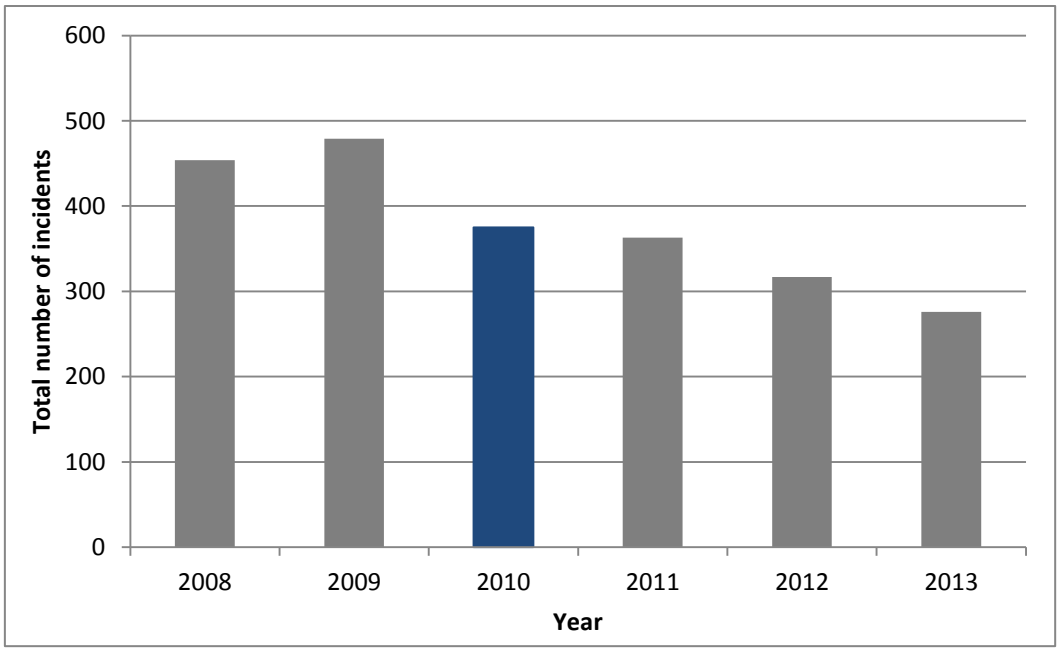
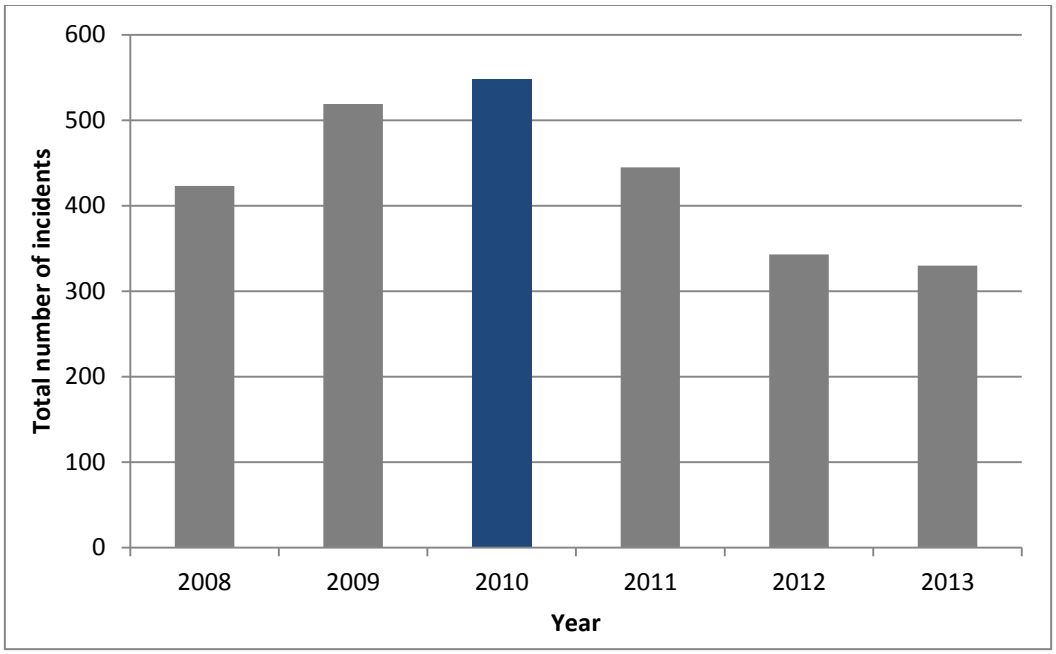


Figure 3.2 ***Total reported annual number of poisoning incidents due to GLF labelled R65 or H304 in the period 2008-2013.***
Source: ECHA's 2014 consultations, data from eight MS and Norway



Annex 4 Annual quantities of LO and GLF labelled R65 or H304 for the period 2008-2013 reported by Norway-Finland

Table 4. 1 Total annual quantities (tonnes) for lamp oils/grill lighter fluids labelled R65 or H304 during 2006-2013 reported by Norway/Finland

Source: ECHA's 2014 consultations

	Norway		Finland	
Year	**Lamp oils**	**Grill lighter fluids**	**Lamp oils**	**Grill lighter fluids**
2006	342	1233	317	422
2007	499	1276	273	324
2008	535	1125	249	241
2009	468	1303	326	276
Average (2006-2009)	**468**	**1234**	**291**	**315**
2010	635	1478	369	234
2011	251	1364	133	367
2012	921	1230	328	348
2013	770	1289	306	473
Average (2010-2013)	**644**	**1340**	**284**	**355**
% change from (2006-2009) to (2010-2013)	**+37 %**	**+9 %**	**-2%**	**+13%**

Annex 5 Data from Dutch CAs on symptoms/adverse effects due to poisoning incidents from LO and GLF labelled R65 or H304

Table 5. 1 Incidents due to LO labelled R65 or H304 in the Netherlands (2008-2013)

Source: ECHA 2014 consultations

Adverse effect	0-4 years	5-12 years	13-17 years	18-65 years	>65 years
Fever	1	1	-	-	-
Hypertension	-	-	-	-	1
Transpiration	-	1	-	-	-
Vomiting	7	-	-	1	-
Dry throat	-	1	-	-	-
Tachycardie	-	-	-	1	-
Hyperventilation	-	-	-	1	-
Abdominal pain	-	-	-	1	-
Mucosal irritation	-	-	-	1	-
Redness of mouth mucous membrane	1	-	-	-	-
Pain in mouth/throat	1	1	-	1	-
Somnolence	1	-	-	-	-
Unconsciousness	-	-	-	1	-
Tickling cough	14	2	-	-	1
Skin irritation	1	-	-	-	-
Productive cough	1	-	-	-	-
Eye irritation	-	-	-	1	-
Eye pain	-	-	-	1	-
(Chemical) pneumonitis	1	-	-	-	-

Agitation/Restlessness	2	-	-	-	-
No symptoms observed	22	1	1	2	2
Adverse effects unknown	6	1	2	1	-
Adverse effects not mentioned	11	1	-	-	-

Table 5. 2 Incidents due to GLF labelled R65 or H304 in the Netherlands (2008-2013)

Source: ECHA 2014 consultations

Symptom	0-4 years	18-65 years
Fever	1	-
Dyspnoe	1	-
No symptoms observed	2	1
Adverse effects unknown	1	-

Annex 6 Consumer uses for hydrocarbon substances labelled R65 or H304

Table 6. 1 Uses by consumers for the registered substances Hydrocarbons, C10-C13, n-alkanes, <2% aromatics <2% aromatics

Source: REACH registration dossier/CSRs

IDENTIFIED USE	USE DESCRIPTORS
Use in Cleaning Agents	Chemical product category (PC): PC 3: Air care products PC 4: Anti-freeze and de-icing products PC 9a: Coatings and paints, thinners, paint removes PC 9b: Fillers, putties, plasters, modelling clay PC 9c: Finger paints PC 24: Lubricants, greases, release products PC 35: Washing and cleaning products (including solvent based products) PC 38: Welding and soldering products (with flux coatings or flux cores.), flux products PC 0: Other: PC8 (excipient only) Environmental release category (ERC): ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems Subsequent service life relevant for that use?: no
Lubricants	Chemical product category (PC): PC 1: Adhesives, sealants PC 24: Lubricants, greases, release products PC 31: Polishes and wax blends Environmental release category (ERC): ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems ERC 9a: Wide dispersive indoor use of substances in closed systems

	ERC 9b: Wide dispersive outdoor use of substances in closed systems Subsequent service life relevant for that use?: no
Use as a fuel	Chemical product category (PC): PC 13: Fuels Environmental release category (ERC): ERC 9a: Wide dispersive indoor use of substances in closed systems ERC 9b: Wide dispersive outdoor use of substances in closed systems Subsequent service life relevant for that use?: no
Other Consumer Uses	Chemical product category (PC): PC 28: Perfumes, fragrances PC 39: Cosmetics, personal care products Environmental release category (ERC): ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems Subsequent service life relevant for that use?: no
Use in coatings	Chemical product category (PC): PC 1: Adhesives, sealants PC 4: Anti-freeze and de-icing products PC 9a: Coatings and paints, thinners, paint removes PC 9b: Fillers, putties, plasters, modelling clay PC 9c: Finger paints PC 15: Non-metal-surface treatment products PC 18: Ink and toners PC 23: Leather tanning, dye, finishing, impregnation and care products PC 24: Lubricants, greases, release products PC 31: Polishes and wax blends

	PC 34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids PC 0: Other: PC8 (excipient only) Environmental release category (ERC): ERC 8a: Wide dispersive indoor use of processing aids in open systems ERC 8d: Wide dispersive outdoor use of processing aids in open systems Subsequent service life relevant for that use?: no
Functional fluids	Chemical product category (PC): PC 16: Heat transfer fluids PC 17: Hydraulic fluids Environmental release category (ERC): ERC 9a: Wide dispersive indoor use of substances in closed systems ERC 9b: Wide dispersive outdoor use of substances in closed systems Subsequent service life relevant for that use?: no

Annex 7

Compilation of stakeholders' comments (ECHA's call for evidence 2014) regarding the standard EN 14059 to which decorative oil lamps for supply to the general public must conform, according with paragraph 4 of Entry 3 of Annex XVII to REACH

During the ECHA call for evidence (2014), a few companies have communicated some concerns related to the EN 14059 standard to which decorative oil lamps must conform in order to be placed on the market for supply to the general public, according to paragraph 4 of entry 3 of Annex XVII to REACH. More specifically:

1. A company claims that the enforcement authorities do not check sufficiently. If an oil lamp is constructed according this standard, EN 14059, it is very hard for a child to drink from the lamp or to suck the wick.

The following sentence is written in this standard: *"It is unrealistic to expect that children will not sometimes be able to gain access to the oil in the lamp. Nevertheless, it can be anticipated that the risk of accidental poisonings will be significantly reduced by oil lamps conforming to this standard"*.

2. A USA exporter to EU, claimed that the EN 14059 is not a workable except if its intention is to ban all fuel burning lamps. In summary, they recommended:

- "Leakage", sections 4.7 and 5.7 say that "no oil shall leak out of the oil lamp". This should be changed to allow some very small amount, perhaps 2 ml in a one minute period. A liquid fuel lamp will not continue burning if the fuel reservoir is not vented to atmosphere and a vacuum forms from the fuel consumed.
- The required "Wick Guard" per sections 3.8, 4.5, and 5.5 should be deleted.
- "Hydrocarbons with a kinematic viscosity of greater than 20.5 mm^2/s measured at 40°C", and which are not otherwise hazardous, are a less dangerous substitute for the traditional lamp oils and should not be subject EN 14059 standard.

3. Another company also identified the following problem concerning EN 14059:

From their reading of EN 14059, their disposable liquid candle fuel cells by themselves could not meet the requirements laid out; the entire lamp has to be considered. If however they were to try to meet the requirements of EN 14059 regardless of the above, their current liquid candle fuel cells could not meet the requirements for the following two issues:

- Their liquid candle fuel cells do not have a "Wick Guard" per sections 3.8, 4.5, and 5.5. They are not aware of a liquid candle fuel cell being sold that has such a thing.

- "Leakage", sections 4.7 and 5.7, say that "no oil shall leak out of the oil lamp". A literal reading would be that one drop would cause the lamp to fail the standard. You cannot put our liquid candle fuel cells in the positions called for in Figure A.3 for 10 seconds in each position without a drop or two coming out sometimes. This should be changed to allow some very small amount, perhaps 2 ml in a one minute period. A liquid fuel lamp will not continue burning if the fuel reservoir is not vented to atmosphere and a vacuum forms from the fuel

consumed.

They claim they do not know of a single lamp or fuel cell on the market that would comply with a literal reading of EN 14059.

4. Another company claimed that they do have three liquid candles fuel cells that should not have to meet the requirements of EN 14059. Under the introduction and paragraph 1, EN 14059 says, respectively:

"Ingestion of lamp oils can lead to severe lung damage and even death" and
"The purpose of the standard is to minimize the risk of accidental poisoning of small children up to 3 years of age by limiting the accessibility of the lamp oil".

The fuel used in their three smallest disposable liquid candle fuel cells is a heavy viscosity mineral oil. It is not considered an aspiration hazard and does not have to be labelled R65 or H304. (Technically, the mineral oil they contain is categorized as "hydrocarbons with a kinematic viscosity of greater than 20.5 mm^2/s measured at 40^oC", and are not otherwise hazardous.) It is a less dangerous substitute for the traditional lamp oils that are the subject of EN 14059.

So, they claim that if their mineral oil liquid candle fuel is not an aspiration and poisoning hazard, then EN 14059 should not apply. It is not an "Aspiration hazard" as defined by the Official Journal of the European Union, and is not a poisoning hazard.

Annex 8 Data on national poisoning incidents (due to LO and GLF labelled R65 or H304) that have not been considered in the statistical analysis

This section is listing data on poisoning incidents that for various reasons have not been considered for the statistical analysis presented in this Annex XV report. These data are listed, though, in the overall Annex tables 1.1 and 2.1.

Finland: Although the Finnish CAs communicated their most recent national data (2008-2012), these have not been considered in the statistical analysis (Annex tables 1.2/2.2), as they concern only compiled data for registered incidents caused by both LO and GLF labelled R65 or H304**.**

It is interesting, though, that the Finnish figures are in a general accordance with the trends previously discussed for the other countries. The figures reveal an increase of the total number of incidents between until 2010 (+18% from 2008 to 2010), followed by a downward trend during the next years (-36% from 2010 to 2013).

Most of the reported incidents (approximately 60%) concern children (<16 years old) and the vast majority (>90%) were caused via accidental ingestion of the fuels. The reported incidents mainly concern registered calls to the Finnish NPC.

Cyprus: In the frame of 2014 Commission/ECHA Survey, the Cypriot CAs informed that six poisoning incidents of small children due to LO had been registered during 2006-2007. Following an intensive campaign on the labelling and packaging of these products in combination with a proper implementation of the latest Annex XVII provisions since 2010, no further accidents have been reported since then. No accidents due to GLF ever reported in Cyprus.

UK: The UK CAs informed in 2014 that since 2008, 3 accidents due to LO and 22 due to GLF (labelled R65 or H304 in both cases) have been registered at national level.

Greece: Data from the Greek NPC reported 68 poisoning incidents due to LO labelled R65 or H304 from a total of 6388 poisoning cases from household chemicals registered 1976-2011. One incident (over a period of 10 years) was reported by a downstream user regarding ingestion of a sip of lamp oil form an old man, thinking that it was tsipouro (traditional colourless Greek drink) which did not lead to severe health problem or hospitalisation. In addition, the Hellenic Association of Chemical Industries highlighted that lamp oils bottles are stored in closets in the cemeteries or in high shelves and thank to the extra precaution measures implemented in Greece no serious accidents were registered to hospitals during the last 3 decades.

Sweden: Figures had been provided for the period 2003-2007, in the frame of the Commission consultation for the mixture of the 2009 Impact Assessment report

LO: All incidents concerned small children (<4 years) but annual numbers indicated no clear trends.

GLF: Interestingly, the number of GLF related incidents were 2-3 times higher than that of LO, presenting significant tendency of decrease (- 50% from 2003 to 2006). However, Sweden has not provided more recent data in the frame of the 2014 ECHA consultations.

Annex 9 Estimation of European rates of poisoning incidents due to LO and GLF for the period 2008-2020 (reported and projected values)

Table 9. 1 Estimations of European incident rates of poisonings due to LO and GLF (labelled R65 or H304) based on reported values in 2008-2013[30] and projected values for 2014-2020[31]
Source: ECHA's 2014 consultations, data from 8 MS and Norway

	LO labelled R65 or H304 Extrapolated annual European numbers of incidents	**LO labelled R65 or H304** European incident rates *(number of incidents/ 1 million of population)*	**GLF labelled R65 or H304** Extrapolated annual European numbers of incidents	**GLF labelled R65 or H304** European incident rates *(number of incidents/ 1 million of population)*
Reported figures (2008-2013) *by CAs/Poison Centres (ECHA, 2014)*				
2008	1076	2.10	985	1.92
2009	1141	2.23	1194	2.33
2010	888	1.73	1278	2.49
2011	867	1.69	1039	2.03
2012	755	1.47	797	1.56
2013	664	1.30	776	1.51
Projected figures (2014-2020)				
2014	602	1.18	657	1.28
2015	546	1.07	556	1.08
2016	495	0.97	470	0.92
2017	449	0.88	398	0.77
2018	408	0.80	337	0.66
2019	370	0.72	285	0.55
2020	335	0.66	241	0.47

[30] Estimations are indicated in tables 1.2 and 2.2 for LO and GLF respectively.

[31] The average growth values for the period 2010-2013 was estimated by the: $((X_{2013}-X_{2010})/(X_{2010})+1)^{1/3}-1)$, where X was the incident rate in 2013 and 2010, respectively. These values were then used to estimate the projected figures.