



Danish Ministry of the Environment
Environmental Protection Agency

Survey of phenol

Part of the LOUS review

Environmental Project No. 1535, 2014



Title: Survey of XX

Survey of phenol

Editing:

Lise M. Møller, Poul Bo Larsen, Frank Leck Fotel,
Tina Slothuus, Helle Buchardt Boyd
DHI

Published by:

The Danish Environmental Protection Agency
Strandgade 29
1401 Copenhagen K
Denmark
www.mst.dk/english

Year:

2014

ISBN no.

978-87-93026-89-6

Disclaimer:

When the occasion arises, the Danish Environmental Protection Agency will publish reports and papers concerning research and development projects within the environmental sector, financed by study grants provided by the Danish Environmental Protection Agency. It should be noted that such publications do not necessarily reflect the position or opinion of the Danish Environmental Protection Agency.

However, publication does indicate that, in the opinion of the Danish Environmental Protection Agency, the content represents an important contribution to the debate surrounding Danish environmental policy.

While the information provided in this report is believed to be accurate, the Danish Environmental Protection Agency disclaims any responsibility for possible inaccuracies or omissions and consequences that may flow from them. Neither the Danish Environmental Protection Agency nor DHI or any individual involved in the preparation of this publication shall be liable for any injury, loss, damage or prejudice of any kind that may be caused by persons who have acted according to their understanding of the information contained in this publication.

Sources must be acknowledged.

Contents

Preface	5
Summary and conclusions	7
Sammenfatning og konklusion	14
1. Introduction to phenol	21
1.1 Definition of phenol	21
1.2 Physical and chemical properties	22
2. Regulatory framework	23
2.1 Legislation	23
2.1.1 Existing legislation	23
2.1.2 Classification and labelling	29
2.1.3 REACH	31
2.1.4 Working environment legislation	31
2.1.5 Food legislation	31
2.2 Eco-labels	31
2.3 Summary and conclusions	32
3. Manufacture and uses	34
3.1 Manufacturing	34
3.1.1 Manufacturing processes	34
3.1.2 Manufacturing sites	34
3.1.3 Manufacturing volumes	35
3.2 Import and export	35
3.2.1 Import and export of phenol in Denmark	35
3.2.2 Import and export of phenol in EU	35
3.3 Use	35
3.4 Historical trends in use	37
3.5 Summary and conclusions	38
4. Waste management	40
4.1 Waste from manufacture and use of phenol	40
4.2 Waste products from the use of phenol in mixtures and articles	40
4.3 Release of phenol from waste disposal	40
4.4 Summary and conclusions	41
5. Environmental effects and exposure	43
5.1 Environmental hazard	43
5.1.1 Classification	44
5.2 Environmental fate	44
5.3 Environmental exposure	46
5.3.1 Sources of release	46
5.3.2 Monitoring data	47
5.4 Environmental impact	47
5.5 Summary and conclusions	49
6. Human health effects and exposure	51
6.1 Human health hazard	51

6.1.1	Classification	51
6.1.2	Toxicokinetics, absorption, distribution, metabolism and excretion	51
6.1.3	Toxicity	51
6.1.4	Dose response modelling (TDI and DNELs).....	55
6.2	Human exposure.....	55
6.2.1	Direct exposure	55
6.2.2	Indirect exposure	60
6.3	Bio-monitoring data	62
6.4	Human health impact.....	63
6.4.1	General population	63
6.4.2	Workers	64
6.4.3	Indirect exposure	65
6.4.4	Combined exposure	65
6.5	Summary and conclusions.....	66
7.	Information on alternatives.....	69
8.	References	71
	Annex 1: Abbreviations and acronyms	78
	Annex 2: Background information to chapter 2 on legal framework.....	80

Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern for which the use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic based on quantitative structure analogy relationship evaluation using computer models. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and/or long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding on-going activities under REACH, among others.

On the basis of the surveys, the Danish EPA will assess the need for any further risk management measures, e.g. information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns phenol, with the CAS number 108-95-2.

Phenol was listed on LOUS because of its harmonised classification as:

- Muta. 2;H341 (suspected of causing genetic defects) former Mut3;R68 and
- STOT RE 2;H373 (may cause damage to organs through prolonged or repeated exposure) former Xn;R48 (with R20, 21 or 22).
- The substance is also classified as toxic Acute Tox. 3;H301 (R25), H311 (R24) and H331 (R23) as well as corrosive Skin Corr. 1B;H214 (R34).

The process

The survey has been undertaken by DHI from March to September 2013.

The project participants were:

- Lise M. Møller, DHI, Project manager
- Poul Bo Larsen, DHI, contributor
- Frank Leck Fotel, DHI, contributor
- Tina Slothuus, DHI, contributor
- Helle Buchardt Boyd, contributor
- Ole Hjelmar, DHI, contributor
- Henrik Rye Lam, DHI, Quality supervisor

The work has been followed by an advisory group consisting of:

Lea Stine Tobiassen	Danish EPA, Chemicals Unit (Chair of advisory group)
Anna-Louise Jørgensen Rønlev	Danish EPA, Companys Unit (Aarhus)

Kathrine Smidt	Danish EPA, Soils and Waste Unit
Sidsel Dyekjær	Danish EPA, Chemicals Unit
Anette Harbo Dahl	The Danish Paint and Adhesives Federation (Danmarks Farve- og Limindustri)
Birgitte Marcussen, DN	The Danish Society for Nature Conservation (Danmarks Naturfredningsforening)

Data collection

This survey/review is based on the available literature on the substances, information from databases and direct inquiries to trade organisations and key market actors.

The data search included (but was not limited to) the following:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- On-going regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHA's website;
- Data on ecolabels from the Danish ecolabel secretariat (Nordic Swan and EU Flower) and the German Angel.
- Pre-registered and registered substances from ECHA's website;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Data on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Monitoring data from the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration and the European Food Safety Authority (EFSA).
- Waste statistics from the Danish EPA;
- Reports, memorandums, etc. from the Danish EPA and other authorities in Denmark;
- Reports published at the websites of:
 - The Nordic Council of Ministers, ECHA, the EU Commission, OECD, IARC, IPCS, WHO and OSPAR;
 - Environmental authorities in Sweden (KemI) and UK (Environment Agency). Information from other EU Member States was retrieved if quoted in identified literature.
 - US EPA, Agency for Toxic Substances and Disease Registry (USA) and Environment Canada.

In addition to the written literature the following persons besides the advisory group members have contributed with valuable information/ advice:

Bente Fabech, Food Administration (Fødevarestyrelsen)
 Per Sindahl, Danish Health and Medicines Authority (Sundhedsstyrelsen).
 Jakob Lamm Zeuthen, The Danish Chamber of Commerce (Dansk Erhverv)
 Søren Jensen, Danish EPA,
 Henning Christiansen, Danish EPA,
 Marianne Ripka, Danish EPA,
 Pharmaceutical and mineral wool industries as well as industries using glue, adhesives, binders (names confidential).

Summary and conclusions

This survey concerns phenol with the CAS number 108-95-2. The substance was included in the first LOUS list in 1998 with its classification, at that time in 1998, toxic (R24/25) and corrosive (R34). Phenol was removed from the list in 2004. Since then phenol was further classified as:

- Muta. 2;H341 (suspected of causing genetic defects) former Mut3;R68 and
- STOT RE 2;H373 (May cause damage to organs through prolonged or repeated exposure) former Xn;R48 (with R20, 21 or 22),

which caused the adding to the LOUS list again in 2009.

The survey includes collection of available information on the use and occurrence of the substance, internationally and in Denmark, information on environmental and health effects, on alternatives to phenol, on existing regulation, on monitoring and exposure, and information regarding on-going activities under REACH, among others.

Identification and properties of phenol

Phenol is colourless to white or light pink crystalline solid when pure. The commercial product is a liquid. It has a distinct odour that is sickeningly sweet and tarry. Phenol can be tasted and smelled at levels lower than those which are associated with harmful effects. The threshold for odour perception is in air about 184 µg/m³; for taste and odour in water about 150 µg/l. It belongs to the chemical group of VOCs (Volatile Organic Compounds), due to its vapour pressure, but with its Henry constant of 0.022 Pa m³/mol at 20°C, phenol is only slightly volatile from an aqueous solution. It evaporates more slowly than water, and a moderate amount can form a solution with water. Pure phenol absorbs easily water from air and liquefies. Phenol is also known as monohydroxybenzene, phenylalcohol or carbolic acid.

Natural occurrence, manufacture and use

Phenol is included in the construction of lignin, which gives trees their compressive strength. Phenol is therefore a natural constituent in plant material. Phenol is released as a product from the human metabolism and from livestock, from the processing of coal, from paper production and from landfills.

Phenol is registered within the highest EU tonnage span of the REACH regulation of 1,000,000 - 10,000,000 tonnes per annum. This use tonnage is also reflected by the figures from 2006 (ECB, 2006), where 1,819,100 tonnes/annum is produced by 12 EU companies.

In the EU risk assessment report on phenol it is stated that phenol as an industrial chemical is almost exclusively (about 100%) used as a chemical parent compound/intermediate in synthesis. Approximately 65% of the produced phenol is processed further to organic chemicals (e.g. bisphenol A, caprolactam, salicylic acid, diphenyl ether, alkyl phenols, nitrophenols) and 30% is used to manufacture phenol resins. Phenol is also a solvent, which is found in a number of products such as adhesives, paints, lacquers, preservatives and metal coatings. Phenol may also occur in drinking water installations and pharmaceuticals as preservation. Further, phenol is also included in the curing process by smoking of foods (ECB, 2006).

Within the Nordic Countries (Sweden, Denmark, Finland and Norway) Finland uses the largest amount (about 200,000 tonnes/year in 2007 to 2010) followed by Sweden (about 17,000 tonnes/year). Finland and Sweden use large quantities of phenol for production of phenol-

formaldehyde resins for binders, which seems intended above all for use in the wood conversion industry (chipboard). In Denmark and Norway the consumption has decreased about 25% from 2005 to 2010.

Denmark does not produce phenol, but a total of 4,814 tonnes phenol is used in commodities (e.g. in the binder bakelite, a thermosetting phenol formaldehyde resin), 1,653 tonnes in impregnating, 750 tonnes in solvents and thinners, 21 tonnes in binding agents and 2 ton in glue (Danish Product Register, April 2013). The tar products (coal tar) cover the main part of the 1,653 tonnes used for impregnating (Danish Product Register, April 2013).

In Denmark phenol is predominantly used in the production of mineral wool as a commodity in the binder bakelite. Phenol is also used in impregnating products (mainly coal tar) and in solvents/thinners, in binding agents and in glue. It is used in e.g. certain types of paint and phenol containing binders (where binders are produced with phenol as one of the parent compounds and were residual amounts of phenol are present). According to the Danish Paint and Adhesives Federation, phenol adhesives are not used in wood-based panels (chipboard, MDF, laminated, etc.) in the Wood and Furniture Industry in Denmark any more. However, phenol is used in virtually all plywood and is expected to occur in imported wood-based panels (personal communication, Anette Harbo Dahl, The Danish Paint and Adhesives Federation, June – September, 2013).

Legislation

At EU-level, phenol is registered under REACH in the 1,000,000 to 10,000,000 tonnes per annum span. No procedure of restrictions, SVHC identification, authorisation or prioritisation for substance evaluation is in place or under discussion at present. No Risk Management Option (RMO) document has been elaborated.

The harmonised classification of phenol under the CLP regulation is:

- Acute Tox.3;H301/311/331 (toxic if swallowed, in contact with skin and by inhalation),
- Skin Corr. 1B;H314 (causes severe skin burns and eye damage),
- Muta. 2;H341 (suspected of causing genetic defects) and
- STOT RE 2;H373 (may cause damage to organs through prolonged or repeated exposure).

In addition to the harmonized classification end-points additional classifications are used by the suppliers to the market in EU. Among these 93 notifiers out of 2,870 notifiers registered in the ECHA CLP inventory use the classification “Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)”. For the environment the available biodegradation and bioaccumulation data categorise phenol as non-persistent.

Phenol has been risk assessed under regulation 793/93 in 2006. The risk assessment report gives recommendation as to the risk from phenol. The REACH registration dossier proposes DNELs. EU and national regulations include phenol on Occupational limit values for phenol application at EU level as well as on national member states level. In Denmark, regulations directed towards the content of organic solvents in paint and lacquers cover phenol, as these products should be attached with a code number (MAL-kode) according to their content of an organic solvent. The use of these products is then further restricted for indoor use depending on the value of the code number. National environmental guidance on imission level (B-værdi) has been established in order to limit the emissions. Furthermore levels in polluted soil and groundwater have also been established.

Phenol is prohibited in cosmetics in the EU and no longer permitted as a biocidal active substance. The Tolerable Daily Intake (TDI) has recently been reduced from 1.5 to 0.5 mg/kg bw/day by the European Food Safety Authority, EFSA.

Concerning eco-labelling the granting of the Nordic Swan EU Flower or the German Blue Angel label for a variety of product types is dependent on the classification of the chemical constituents and on the content of VOCs. This limits the content of phenol in product types such as; paints and glues; paints and lacquers; and furniture and fitments.

Waste management

Regulations on waste control waste generated from the use of phenol as well as the content in products to be treated as hazardous waste. Also landfill waste has limits for leaching. Based on the regulation already in place and on the response from industries (mineral wool and pharmaceutical industry) it is assumed that both liquid and solid waste containing phenol will enter into the waste stream through the municipal collection as hazardous waste and will be disposed/treated according to the instructions from local communities. This covers both industrial and consumer uses and includes domestic waste e.g. through adhesive/glue, impregnating agent (such as tar and creosote for wood with a phenol content from lignin), paints, lacquers, varnishes and solvents.

In Denmark the majority of phenol is used in mineral wool as a content of the 2-5% bakelite binder used in stone wool and glass wool, respectively.

Alternatives

Eco-labelled products (e.g. paints and glues) can be used as alternatives to phenol containing products and further, Danish produced furniture and wood-based panels (chipboard, MDF, laminated, etc.) can be used as alternatives to the imported goods. Thus, consumer behaviour may further reduce exposure to phenol.

Phenol cannot be substituted from the diffuse emissions from natural sources. Its use in chemical synthesis, where its structure and chemical properties are crucial for the particular use, cannot be changed without changes in the syntheses. Furthermore, as pharmaceuticals phenol is part of the drug approval, which is a long-lasting and very expensive process, it is not easy to substitute phenol.

Environmental effects and exposure

Phenol emitted into the atmosphere is predominantly degraded by rapid photochemical reactions. A minor part will be removed by rain. Phenol in water and soil is degraded by abiotic reactions and microbial activity.

Phenol is not regarded as acutely toxic to the aquatic environment. Phenol fulfils the criteria for classification as “Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)”, due to its chronic NOEC values in the range of > 0.01 to ≤ 0.1 mg/l. Phenol is readily biodegradable (has rapid degradability) and has no potential for bioaccumulation.

Phenol is released from a number of man-made sources. The primary sources of phenol to the environment are automobile exhaust and different combustion processes of coal and wood. Also, human and animal metabolisms result in release of phenol.

From industrial sources, phenol enters into the environment from production and processing operations. Releases also occur due to the waste water from coal and cooking plants (coal manufacturing places), from refineries, from paper pulp manufacture and landfill leachate. The contribution from human and animal metabolism (2,096 tonnes/year to the hydrosphere and approximately 6 tonnes/year into the soil via the spreading of sewage sludge in the EU) is higher than the industrial releases (124 tonnes/year to the hydrosphere in the EU). As no substantial

transport from the atmosphere into other environmental compartments is expected due to fast photochemical degradation of phenol (half-life = 42 minutes), these release quantities do not include the atmosphere (ECB, 2006).

In the EU risk assessment report no unacceptable risk for the environment was identified from the local emission to the environment as a result of production and industrial use of phenol in the chemical industry. Release into environment and thereby risk is controlled through the Water Framework Directive (WFD) together with the legislation for soil protection (EC regulation 166/2006 and Council Decision 2006/61/EC) and Council Directive 1999/31/EC regarding the potential risks from landfills without landfill leachate collecting systems (EC, 2007; EC, 2008).

The EU-RAR concludes that there is no need for risk reduction measures beyond those which are being applied already for protecting the aquatic compartment, atmosphere and terrestrial compartment. These applied risk reduction measures cover emission limit values/technical measures (according to the use of Best Available Techniques (BAT) and Directive 96/61/EC (Integrated Pollution Prevention and Control). Further risk reduction measures apply to the Member States especially with regard to potential risks from phenol production/processing sites through the approval of listed companies (2008/1/EC) and the control of major-accident hazards involving dangerous substances (96/82/EC). The risk reduction measures include also phenol in the on-going work of developing guidance on BAT and of facilitating permission and monitoring under Council Directive 96/61/EC. This is part of the risk reduction strategies in EC (EC, 2007 and EC, 2008).

Based on the findings in this survey it is likely that only very low levels occur in wastewater, wastewater treatment plants, groundwater and soil as phenol degrades in the environment.

Human health effects and exposure

Consumer's exposure to phenol occurs through contact with consumer products, medicines and food containing the substance. Exposure can occur through ingestion (food, medicine) and skin contact and inhalation of vapours/aerosols arising from the use of consumer products.

In the occupational environment (for instance when using phenol in binders or pharmaceuticals) persons who handle phenol or phenol-containing products may be exposed to phenol (EC, 2008).

Previously, phenol was used in slimicides (chemicals that kill bacteria and fungi in slimes). However, as phenol has not been supported by a dossier under the Biocidal Products Directive 98/8 or the Biocidal Products Regulation 528/2012, the substance is not allowed in any biocidal products within the EU.

Phenol is also used in impregnating paints (e.g. tar) and as preservative in medicinal preparations such as insulin, tuberculosis vaccines, allergy serums, parenteral administration and in veterinary medicine. Phenol was used in cosmetics in bath, hair and skin care products, e.g. in soaps called "carbolic soap", due to its content of phenol (carbolic acid) and its characteristic smell. Phenol has been prohibited in cosmetics in EU since 2006.

Human health effects:

Phenol is absorbed rapidly after oral, dermal or inhalational exposure. In the body phenol is rapidly distributed throughout the body and rapidly excreted in the urine. The half-life in the organism is reported to be approx. 3.5 hours. Phenol does not accumulate in the body.

Phenol is, due to its corrosive properties, acutely toxic if inhaled, if in contact with skin and if swallowed. Phenol is corrosive to skin, mucous membranes and the respiratory tract and causes severe skin burns and eye damage. Phenol is a suspected mutagen and it may cause damage to

several organs e.g. muscles and the nervous system through prolonged or repeated exposure. There is no evidence of carcinogenic effects of phenol (ECB, 2006; EFSA, 2013). The EU RAR included the following NOAEL(C)s and LOAELs: LOAEL oral subacute: 1.8 mg/kg bw/day; NOAEC inhalation local: 0.0963 mg/l; LOAEC inhalation systemic (worker): 0.021 mg/l and NOAEL dermal: 1.18%.

DNELs:

The registrations under REACH include hazard evaluation, and DNELs proposed in the dossier: Long term oral and dermal DNELs for the general population is set at 0.4 mg/kg bw/day, while a chronic inhalation DNEL of 7.8 mg/m³ long-term effects for the worker and 1.32 mg/m³ for the consumer are proposed.

New TDI:

A TDI of 1.5 mg/kg bw/day was set by the Scientific Committee for Food (SCF) in 1984 on the basis of data available at the time, e.g. “90-day oral studies in mice and rats, multigenerational studies oral in rats and 2-year studies oral in mice and rats” (EC, 1984). The European Food Safety Authority (EFSA) has re-evaluated this TDI and published its opinion on the revision of the TDI for phenol on 30 April 2013. A revised TDI for phenol of 0.5 mg/kg bw/day was concluded based on reduced maternal body weight gain in rats in a reproduction toxicity study. The TDI value of 0.5 mg/kg bw/day will only cover phenol and not its metabolic products.

Exposure:

The sources to phenol are many, both as a manufactured chemical and as a substance as part of lignin in plants. Consumers may be exposed through food contact materials, food and phenol-containing consumer products (e.g. disinfectants, pharmaceuticals, paints, floor waxes and polishers) as well as through the air/smoke (e.g. from automobile exhaust, human and animal metabolism, different combustion processes and cigarette smoke).

The highest measured exposure concentrations are:

- Prolonged (chronic) indoor inhalation (converted): 0.48 mg/kg bw/day for female adults and 0.7 mg/kg bw/day for 10-year-old children, respectively from use of floor waxes (ECB, 2006). Exposure from measured concentrations in a model children’s room: 0.09 mg/kg bw/day (Danish EPA, 2006d).
- Dermal contact (disinfectant): 0.9 mg/kg bw/event (ECB, 2006).
- Medical treatment (application to the lips): 0.02 mg/kg bw/day (ECB, 2006).
- Oral (food contact materials): 0.3 to 0.6 mg/person/day, corresponding to 0.005 to 0.01 mg/kg bw/day (EFSA, 2013).
- Oral (food total): 0.00015 mg/kg bw/day (0.046 but for local scenario only) (ECB, 2006).
- Oral (smoke flavouring): 0.16 mg/kg bw/day (EFSA, 2013).

Identified risks for **consumers** according to the EU risk assessment report:

- Skin irritation: During dermal exposure to phenol containing products (up to 2.5% reported for two-component adhesives) despite the short application times (10 minutes) (ECB, 2006).
- Systemic effects. For inhalation: A LOAEC for systemic effects of 21 mg/m³ compared to estimated exposure of 1.1 mg/m³ (the average concentration after use of floor waxes), resulted in a margin of safety (MoS) of 19 and hence was considered as a possible risk, due to uncertainties inherent in the exposure estimation which were worst case (ECB, 2006).
- Systemic effects. For dermal: A dermal internal exposure from disinfectants of 0.72 mg/kg bw/event was seen. It was compared to a converted internal human LOAEL (dermal) of ~ 3.5 mg/kg bw/day, which gave MoS of 5. Taking into account the frequent exposure and that the MoS consideration was based on a LOAEL it was considered as a possible risk (ECB, 2006).

Data on the phenol exposure concentrations are from 2006 and might have changed. The confidential parts of the numerous registrations that may include exposure scenarios for the consumer have not been reviewed for this report.

The use in cosmetics and as biocide is now prohibited, but the risks from contact with other consumer products may still pose a risk.

Risks for **workers**:

Due to dermal and inhalative exposure at the workplace systemic effects from acute toxicity and repeated dose toxicity is by ECB considered to cause concern (ECB, 2006). The findings show risk through inhalation (3.3 to 20 mg phenol/m³ measured during formulation or use of phenolic resins and further processing) compared to a critical exposure level of 4 mg/m³ (comparable to the Danish OEL value). According to the EU Commission risk reduction strategies for several substances (EC, 2008) implies that all unnecessary exposure should be avoided through the use of local ventilation and through the use of protective equipment (gloves or respiratory protection). Furthermore, substitution to less dangerous substances or products must always be considered. The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks from phenol. EU working environment legislation covers working where there is a risk of exposure to phenol. In Denmark, rules from the Working Environment Service including working with substances and materials and working with code-labelled products address risk from work with phenol.

Risks from **indirect exposure**:

The indirect exposure via food (e.g. pork, organ meats, canned wieners, fats/oils and tea/coffee) and the environment was by considered in the EU-RAR (ECB, 2006) not to cause concerns regarding repeated dose toxicity for oral intake for the regional exposure scenario. The estimated total internal dose was 0.00015 mg/kg bw/day and compared with the oral LOAEL of 1.8 mg/kg bw/day, the MoS of 12000 was in the EU-RAR judged to be sufficient. When compared with the new TDI of 0.5 mg phenol/kg bw/day and the proposed DNEL of 0.4 mg/kg bw/day the margin of safety is 2667-3334, thus still much more than 100. Thus, indirect exposure is regarded as safe.

Risks from **combined exposure**:

Individuals may be exposed to phenol at work, from consumer products and indirectly via food and the environment, which may add to the risks measured. In addition to this other sources of exposures are considered. These are for instance:

- a) Oral exposure from food contact material and smoke flavourings.
- b) Dermal exposure from contact with laminating films and bags.
- c) Computers, monitors, playing consoles, pressing irons, household ovens, TV. Apparatus, chargers and transformers, tents and chloroprene products contribution to the inhalative exposure.
- d) Exposure through medical treatment using phenol e.g. as a preservative.

As phenol is well absorbed and distributed in the body, and quickly excreted again with a half-life of approx. 3.5 hours and as it does not accumulate in the body, single exposure situation to negligible concentrations will not entail an unacceptable risk. However, repeated exposure during the same day to several of these sources that may pose a risk. For some individuals this might not be unrealistic and does therefore add further to the conclusion from ECB (2006) that the exposure from combined exposure may exceed the TDI, especially taking the lowered TDI of 0.5 mg/kg bw/day and the proposed DNEL of 0.4 mg/kg bw/day into consideration.

Overall conclusions

Inhalation exposure to phenol of the worker must be controlled by risk reduction measures according to EU and national workplace legislation. In Denmark, phenol is primarily used for the

production of various types of mineral wool and is further a constituent in wood tar. These uses, however, are not expected to cause a significant exposure to the general consumer. Phenol is used in virtually all plywood and is also expected to occur in imported wood-based panels. Exposure from this source is not known. Phenol may evaporate from a wide variety of consumer products, e.g. from computers, monitors, game consoles, pressing irons, household ovens, TV apparatus, chargers and transformers, tents and chloroprene products, but as the measured contribution of the products are from 2006 and previously, concentrations may have changed. Furthermore,; dermal exposure from contact with the laminating film and bags, as well as exposure through pharmaceuticals might contribute to the overall exposure.

Some specific exposure scenarios may lead to exposure exceeding the TDI value of 0.5 mg/kg bw/day or oral and dermal DNEL of 0.4 mg/kg bw/day or the inhalation DNELs of 7.8 mg/m³ for the worker and 1.32 mg/m³ for the consumer, respectively. This pertains to scenarios with use of floor waxes containing phenol, use of dermal disinfectants containing phenol. The contributions from drinking water and food are as part of the total regional oral internal dose exposure calculated by ECB (2006) on 0.00015 mg/kg bw/day considerably lower than the TDI.

Phenol can cause damage to organs through prolonged or repeated exposure. But as phenol does not accumulate in the body and is rapidly excreted again, it is the generally repeated excess of the TDI and DNELs which may pose a risk.

Sammenfatning og konklusion

Nærværende undersøgelse omhandler stoffet phenol med CAS nummer 108-95-2. Phenol var opført på den første LOUS liste fra 1998 med dets klassificering, som dengang var, "Giftig ved hudkontakt og ved indtagelse" (R24/25) og med "Ætsningsfare" (R34). Phenol blev fjernet fra listen i 2004.

Siden da blev phenol yderligere klassificeret som:

- Muta. 2; H341 (Mistænkt for at forårsage genetiske defekter) tidligere Mut3; R68 og
- STOT RE 2, H373 (Kan forårsage organskader ved længerevarende eller gentagen eksponering) tidligere Xn; R48 (med R20, 21 eller 22), som var årsag til at phenol blev tilføjet på LOUS listen igen i 2009.

Undersøgelsen omfatter indsamling af tilgængelige oplysninger om anvendelse og forekomst af phenol, internationalt og i Danmark, foruden oplysninger om miljø- og sundhedsmæssige virkninger, om alternativer til phenol, om den eksisterende regulering, om overvågning og eksponering samt om information om igangværende aktiviteter i henhold til blandt andet REACH.

Identifikation af phenol og dets egenskaber

Phenol er et farveløst til hvidt eller lys pink krystallinsk fast stof i ren tilstand. Det kommercielle produkt er en væske. Phenol har en karakteristisk lugt, der er kvalmende sød og tjæreagtig. Phenol kan smages og lugtes i koncentrationer, som er lavere end de koncentrationer, som forårsager skadelige virkninger. Tærsklen for hvornår phenol kan lugtes i luft er omkring 184 µg/m³, mens den for smag og lugt i vand er omkring 150 µg / l. Phenol tilhører gruppen af VOC-stoffer (flygtige organiske forbindelser), som følge af dets damptryk, men med sin Henrys lov konstant på 0,022 Pa m³/mol ved 20° C, er phenol kun lidt flygtigt fra vandig opløsning. Det fordamper langsommere end vand, og en moderat mængde kan opløses i vand. Ren phenol absorberer let vand fra luft og bliver flydende. Phenol er også kendt som monohydroxybenzen, fenyl alkohol eller karbol syre.

Naturlig forekomst, fremstilling og anvendelse

Phenol indgår i konstruktionen af lignin, der giver træer deres trykstyrke. Phenol er derfor en naturlig bestanddel i plantemateriale. Phenol udskilles fra mennesker og husdyr, som et produkt fra vores stofskifte. Phenol frigives desuden ved forarbejdning af kul, fra papirproduktion og fra lossepladser.

Phenol er registreret under den højeste EU-tonnageramme i REACH-forordningen på 1.000.000 - 10.000.000 tons om året. Denne tonnage afspejles også af tallene fra 2006 (ECB, 2006), hvor 1.819.100 tons / år produceres samlet i de 12 EU-lande, som har produktion.

I EU's risikovurdering af phenol anføres det, at phenol som industrikemikalie hovedsageligt anvendes som et kemisk udgangsstof/mellemprodukt i syntesen (ca. 100%). Ca. 65% af produktionen videreforarbejdes til andre organiske kemiske stoffer (fx bisphenol A, caprolactam, salicylsyre, difenylæter, alkylphenoler og nitrophenoler) og 30% anvendes til fremstilling af phenolharpikser (ECB, 2006).

Phenol er også et opløsningsmiddel, som findes i en række produkter såsom klæbemidler, maling, lak, konserveringsmidler og metalbelægninger. Phenol kan også forekomme i drikkevandsinstallationer og lægemidler som konservering. Derudover forekommer phenol også i hærtningsprocessen ved rygning af fødevarer.

Inden for de nordiske lande (Sverige, Danmark, Finland og Norge) bruger Finland den største mængde (ca. 200.000 tons / år i 2007 til 2010), efterfulgt af Sverige (omkring 17.000 tons/år). Finland og Sverige bruger store mængder phenol til fremstilling af phenol-formaldehyd-harpiks til bindemidler, som først og fremmest synes anvendt i den træbearbejdende industri (spånplade). I Danmark og Norge er forbruget faldet omkring 25% fra 2005 til 2010.

Danmark producerer ikke phenol, men 4.814 tons phenol anvendes i råvarer (fx i bakelit), 1.653 tons i imprægnering, 750 tons i opløsningsmidler og fortyndere, 21 tons i bindemidler og 2 ton i lim (Produktregisteret: Danish Product Register, april 2013). Tjære produkter (stenkultjære) dækker hovedparten af de 1.653 tons, der anvendes til imprægnering (Produktregisteret, april 2013).

I Danmark anvendes phenol hovedsageligt i fremstillingen af mineraluld, som en råvare i bindemidlet bakelit. Phenol anvendes også i imprægneringsmidler (hovedsageligt kul tjære), og i opløsningsmidler/fortyndere, i bindemidler og lim. Det anvendes i fx visse typer af maling og phenolholdige bindemidler (hvor bindemidler er produceret med phenol som et af udgangstofferne og hvor restmængder af phenol forekommer). Ifølge Danmarks Farve og Limindustri anvendes phenolbaserede lime ikke i træbaserede plader (spånplader, MDF, lamineret osv.) i træ- og møbelindustrien i Danmark længere. Imidlertid anvendes phenol i stort set alle krydsfinerplader og forventes at forekomme i importerede træbaserede plader (personlig kommunikation, Anette Harbo Dahl, Danmarks Farve og Limindustri, jun.-sept., 2013).

Lovgivning

På EU-plan er phenol registreret i henhold til REACH i rammen 1.000.000 til 10.000.000 tons per år. Der er ingen specifikke initiativer vedrørende phenol i henhold til REACH (fx restriktioner, SVHC identifikation, tilladelse eller prioriteret til vurdering), eller med hensyn til udarbejdelsen af et dokument med risikostyringsmuligheder (RMO).

Phenols harmoniserede klassificering i henhold til CLP reguleringen er:

- Acute Tox.3;H301/311/331 (Giftig ved indtagelse, hudkontakt eller indånding),
- Skin Corr. 1B;H314 (Forårsager svære forbrændinger af huden og øjenskader),
- Muta. 2;H341 (Mistænkt for at forårsage genetiske defekter) and
- STOT RE 2;H373 (Kan forårsage organskader ved længerevarende eller gentagen eksponering).

I tillæg til den harmoniserede klassificering anvendes yderligere klassificeringer af leverandører EU. Således har 93 ud af 2.870 anmeldere i ECHA's CLP opgørelse anvendt klassificeringen "Aquatic Chronic 2, H411 (Giftig for vandlevende organismer, med langvarige virkninger)." Med hensyn til miljøet kategoriseres phenol som ikke persistent på baggrund af data for biologisk nedbrydelighed og bioakkumulering.

Phenol er blevet risikovurderet under forordning 793/93 in 2006. EU risikovurderings rapporten giver anbefalinger i forhold til risici fra phenol.

Registreringsdossieret af stoffet under REACH indeholder forslag til DNELs (derived no effect levels).

I såvel EU som nationale regler er phenol omfattet af erhvervsmæssige grænseværdier både på EU-plan og på nationalt medlemsstatsniveau. I Danmark er phenol dækket af regler vedrørende indholdet af organiske opløsningsmidler i maling og lak, da disse produkter bør vedhæftes kodenummer for flygtighed (MAL-Koder) i henhold til deres indhold af organisk opløsningsmiddel. Anvendelsen af disse produkter er derefter yderligere begrænset til indendørs brug afhængig af graden af kodenummerets flygtighed.

National vejledning om imissions niveau (B-værdi) er blevet etableret for at begrænse bidraget til de miljømæssige emissioner. Desuden er grænser i forurennet jord og grundvand også blevet etableret.

Phenol er forbudt i kosmetik i EU og ikke længere et tilladt aktivt biocidstof.

I fødevarer er det tolerable daglige indtag (TDI) for nylig blevet reduceret fra 1,5 til 0,5 mg / kg legemsvægt / dag af den Europæiske Fødevarsikkerhedsautoritet, EFSA.

Vedrørende miljømærkning er tildelingen af den nordiske Svane mærkning, EU's blomst eller det tyske Blue Angel label for en række produkttyper afhængig af klassificeringen af de kemiske indholdsstoffer og af indholdet af VOC. Dette begrænser indholdet af phenol i produkttyper såsom; maling og lim, maling og lak, samt møbler og inventar.

Affaldshåndtering

Bestemmelser om affald sikrer at phenolholdigt affald behandles som farligt affald. Endvidere er der grænser for udvaskning fra deponeret affald.

Baseret på den gældende forordning og på svar fra industrier (mineraluld og farmaceutisk industri), antages det, at både flydende og fast phenolholdigt affald vil blive håndteret i affaldsstrømmen gennem den kommunale indsamlingsordning som farligt affald og bortskaffes / behandles i henhold til anvisningerne fra lokalsamfundene. Dette dækker både industri- og forbrugeres anvendelser og omfatter husholdningsaffald fx indsamling af klæbemidler / lim, imprægneringsmidler (såsom tjære og creosot til træ) samt maling, lak, fernis og opløsningsmidler.

I Danmark anvendes hovedparten af phenol i mineraluld med et indhold på 2-5% bakelit bindemiddel for henholdsvis stenuld og glasuld.

Alternativer

Miljømærkede produkter (fx maling og lim) kan anvendes som alternativer til phenolholdige produkter og yderligere kan dansk producerede møbler og træbaserede plader (spånplader, MDF, lamineret osv.) anvendes som alternativer til de importerede varer. Så forbrugernes adfærd kan reducere phenol-eksponeringen.

Phenol kan ikke fjernes fra de diffuse emissioner fra kilderne med naturlig forekomst af phenol. I kemisk syntese, hvor phenols struktur og kemiske egenskaber er afgørende for anvendelsen, kan phenol ikke erstattes uden at selve syntesen også ændres. For lægemidler er phenol en del af godkendelsen af lægemidlet, hvilket er en langvarig og meget kostbar proces, så derfor er det ikke let at erstatte phenol i lægemidler.

Miljømæssige effekter og eksponering

Phenol, som udledes til atmosfæren nedbrydes overvejende via hurtige fotokemiske reaktioner. En mindre del vil blive fjernet med regn. Phenol i vand og jord nedbrydes af abiotiske reaktioner og mikrobiel aktivitet.

Phenol er ikke akut giftig for vandmiljøet. Phenol opfylder kriterierne for klassifikation som "Aquatic Chronic 2, H411 (Giftig for vandlevende organismer, med langvarige virkninger)", på baggrund af sine kroniske NOEC-værdier, der ligger i intervallet $> 0,01$ til $\leq 0,1$ mg / l. Phenol er let bionedbrydeligt (har hurtig nedbrydelighed) og har ikke potentiale for bioakkumulering.

Phenol frigives fra en række menneskeskabte kilder. De primære kilder til phenol til miljøet er udstødningsgasser fra biler og forskellige forbrændingsprocesser, hvor kul og træ afbrændes. Også menneskers og dyrs stofskifte resulterer i frigivelse af phenol.

Fra industrielle kilder, frigives phenol til miljøet fra produktion og forarbejdning. Phenol udledes også med spildevand fra kul og raffinaderier, fra fremstilling af papirmasse og via perkolat fra deponering.

Bidraget fra menneskers og dyrs stofskifte (2.096 tons / år til hydrosfæren og ca. 6 tons / år til jorden via spredning af spildevandsslam i EU) er større end de industrielle udledninger (124 tons / år til hydrosfæren i EU). Bidraget fra atmosfæren er ikke medtaget i tallene ovenover da phenol hurtigt nedbrydes fotokemisk (halveringstid = 42 minutter) i atmosfæren (ECB, 2006).

EU risikovurderingsrapporten har ikke identificeret uacceptabel risiko for miljøet fra produktion og industriel anvendelse af phenol og som følge heraf udledning til det lokale miljø. Udledning til miljøet og dermed risiko styres via vandrammedirektivet (VRD) sammen med lovgivning vedrørende beskyttelse af jorden (EF-forordning 166/2006 og Rådets afgørelse 2006/61/EF) og Rådets direktiv 1999/31/EF med hensyn til de potentielle risici fra lossepladser uden opsamlingsystem for perkolat (EF, 2007 EF, 2008).

EU-RAR konkluderer, at der ikke er behov for andre risikobegrænsende foranstaltninger end dem, som allerede anvendes til at beskytte vandmiljøet, atmosfæren og det terrestriske miljø. Disse risikobegrænsende foranstaltninger omfatter emissionsgrænseværdier / tekniske foranstaltninger i henhold til brugen af de bedste tilgængelige teknikker (BAT) og direktiv 96/61/EF (integreret forebyggelse og bekæmpelse). Derudover er der risikobegrænsende foranstaltninger for medlemsstaterne især med henblik på potentielle risici fra phenol produktion / forarbejdningssteder (godkendelse af børsnoterede selskaber (2008/1/EF) og kontrol af større uheld med farlige stoffer (96/82/EF)), og omfatter også phenol i det igangværende arbejde med at udvikle retningslinjer for BAT samt lette tilladelse og overvågning i henhold til Rådets direktiv 96/61/EF. Dette er en del af resultaterne af risikovurderingen og strategier for risikobegrænsning, som er beskrevet i EC (2007 og 2008).

Baseret på denne undersøgelse er sandsynligt, at kun meget lave niveauer vil forekomme i spildevand, rensningsanlæg, grundvand og jord da phenol nedbrydes i miljøet.

Sundhedsskadelige effekter og eksponering

Forbrugere eksponeres via kontakt med forbrugerprodukter, medicin og fødevarer, som indeholder phenol. Eksponeringen kan ske via indtagelse (fødevarer, medicin) og hudkontakt samt via indånding af dampe / aerosoler i forbindelse med anvendelse af forbrugerprodukter.

I arbejdsmiljøet (for eksempel ved anvendelse af phenol i bindemidler eller lægemidler) kan personer, der håndterer phenol eller phenolholdige produkter blive udsat for phenol (EF, 2008).

Tidligere blev phenol anvendt i slimhæmningsmidler (kemikalier, som dræber bakterier og svampe i slim). Men, da phenol ikke blev understøttet af dossier i henhold til biociddirektivet 98/8 eller biocidlov 528/2012, er stoffet i dag ikke tilladt i biocidholdige produkter i EU.

Phenol anvendes også i imprægneringsmidler, maling (fx tjære) og som konserveringsmiddel i medicinske præparater såsom insulin, tuberkulosevacciner, allergi sera, farmaceutiske præparater til parenteral indgivelse (injektioner) og i veterinærmedicin. Phenol blev brugt i kosmetik i bad, hår- og hudpleje produkter, fx i sæbe kaldet "Karbolsæbe", på grund af dets indhold af phenol (carbolsyre) og dens karakteristiske lugt. Phenol har været forbudt i kosmetik i EU siden 2006.

Sundhedsskadelige effekter:

Phenol absorberes via oral og dermal eksponering samt ved inhalation. Phenol fordeles hurtigt i hele kroppen og udskilles hurtigt via urinen. Halveringstiden i organismen er rapporteret til at være ca. 3,5 timer. Phenol akkumuleres ikke i kroppen.

Phenol er som følge af dets ætsende egenskaber, akut giftig ved indånding, ved kontakt med huden og ved indtagelse. Phenol ætser huden, slimhinder og luftvejene og forårsager svære forbrændinger på huden og giver øjenskader. Phenol er mistænkt for at være mutagent, og det kan forårsage organskader (fx på muskler og nervesystem) ved længerevarende eller gentagen eksponering. Der er ingen beviser på at phenol har kræftfremkaldende egenskaber (ECB, 2006; EFSA, 2013). EU risikovurderingsrapporten omfatter følgende NOAEL(C)s and LOAELs: For giftighed ved oral eksponering: LOAEL 1,8 mg/kg bw/day; for giftighed ved inhalation (arbejdstager): LOAEC 0,021 mg/l og ved hudoptag: NOEL dermal : 1,18%.

DNELs:

Der er i REACH registreringsdossieret foreslået en række DNELs:

Oral og dermal DNEL for gentagen eksponering er sat til 0,4 mg/kg lgv/dag, mens kronisk inhalations DNELs på 7,8 og 1,32 mg/m³ for arbejderen hhv. forbrugeren er foreslået.

Ny TDI:

Den Videnskabelige Komité for Levnedsmidler (SCF) satte i 1984 en TDI-værdi på 1,5 mg / kg legemsvægt / dag på grundlag af de data, som var tilgængelige på daværende tidspunkt, fx "90-dages orale studier på mus og rotter, orale multigenerationsstudier på rotter og 2-årige studier på mus og rotter" (EC, 1984). Denne TDI-værdi blev revurderet af EFSA (Den Europæiske Fødevarer sikkerhedsautoritet), som offentliggjorde den revurderede TDI-værdi for phenol den 30. april 2013. Den nye TDI for phenol på 0,5 mg / kg legemsvægt / dag og blev baseret på nedsat vægtøgning hos hunrotter i en undersøgelse af reproduktionstoksicitet. TDI-værdien på 0,5 mg / kg legemsvægt / dag dækker kun phenol og ikke dens stofskifteprodukter.

Eksponering:

Der er mange kilder til phenol, både kemisk fremstillet og fra dets bestanddel i lignin i planter. Forbrugere kan eksponeres via fødevarer, fødevarer og phenolholdige forbrugerprodukter (fx desinfektionsmidler, lægemidler, maling, gulvvoks og poleringsmidler) samt gennem luften / røg (fx fra biludstødning, forskellige forbrændingsprocesser og fra cigaretrøg samt fra menneskers og dyrs stofskifte).

De højeste målte eksponeringskoncentrationer er:

- Langvarig (kronisk) indendørs indånding (omregnet): 0,48 mg / kg legemsvægt / dag for kvinder og 0,7 mg / kg legemsvægt / dag for 10-årige børn ved brug af gulvvoks (ECB, 2006). Eksponering fra de målte koncentrationer i et model børneværelse: 0,09 mg / kg legemsvægt / dag (Miljøstyrelsen: Danish EPA, 2006d).
- Hudkontakt (desinfektionsmiddel): 0,9 mg / kg legemsvægt / hændelse (ECB, 2006).
- Medicinsk behandling (smøring af læberne): 0,02 mg / kg legemsvægt / dag (ECB, 2006).
- Oral (kontakt med fødevarer, fødevarer og phenolholdige forbrugerprodukter): 0,3-0,6 mg / person / dag svarende til 0,005 til 0,01 mg/kg legemsvægt/dag (EFSA, 2013).
- Oral (fra fødevarer total): 0,00015 mg/kg legemsvægt / dag (0,046 men kun for lokalt scenario) (ECB, 2006).
- Oral (røg, aromaer): 0,016 mg / kg legemsvægt / dag (EFSA, 2013).

Identificerede risici for **forbrugere** i henhold til EU risikovurderingsrapport:

- Hudirritation: Via dermal eksponering for phenolholdige produkter (op til 2,5% rapporteret for to-komponent lim) trods af den korte anvendelsestid (10 minutter) (ECB, 2006).
- Systemisk effekt, indånding: LOAEC for systemisk virkning på 21 mg / m³ sammenholdt med estimeret eksponering på 1,1 mg / m³ (den gennemsnitlige koncentration efter brug af

gulvvoks), resulterede i en sikkerhedsmargin (MoS) på 19 og blev dermed anset for at udgøre en mulig risiko, som følge af usikkerheden i eksponeringsberegningen som var en worst case beregning (ECB, 2006).

- **Systemisk effekt, dermal:** Der blev set en dermal intern eksponering på 0,72 mg / kg legemsvægt / hændelse ved brug af desinfektionsmidler. Den blev sammenholdt med den konverterede interne humane LOAEL (dermal) på ~ 3,5 mg / kg legemsvægt / dag og gav en MoS værdi på 5. Det blev anset for at udgøre en mulig risiko den hyppige eksponering taget i betragtning samt at MoS var baseret på en LOAEL-værdi (ECB, 2006).

Data er fra 2006 og tidligere, og kan måske have ændret sig siden da. De fortrolige dele af registreringsrapporterne under REACH indeholder muligvis eksponeringsscenarier for forbrugeranvendelser af stoffet. Disse har ikke været tilgængelige for denne rapport. Anvendelse i kosmetik og som biocid er nu forbudt. Ifølge EC (2007) bør risici fra bidrag fra forbrugerprodukter være tilstrækkeligt kontrolleret via medlemsstaternes markedsovervågning.

Risici for **arbejdstagere:**

Toksicitet fra akut og gentagen indånding eller dermal eksponering på arbejdspladsen gav systemiske effekter, som af ECB anses for at give anledning til bekymring (ECB, 2006).

Resultaterne for indånding viser risiko (3,3 til 20 mg phenol/m³ målt under bearbejdning eller brug af phenolplast og videre forarbejdning) i forhold til et kritisk eksponeringsniveau på 4 mg/m³ (svarende til det danske OEL værdi). EU Kommissionens rapport vedrørende risikobegrænsende strategier for forskellige stoffer (EF, 2008) indebærer, at al unødvendig eksponering bør undgås ved brug af lokal ventilation og brug af værnemidler (handsker eller åndedrætsværn). Rapporten konkluderer, at lovgivningen om beskyttelse af arbejdstagerne på EU-plan giver tilstrækkelig beskyttelse og begrænsning af risici fra phenol. I Danmark er arbejdstageren beskyttet af regler fra Arbejdstilsynet, der bl.a. indebærer krav om substitution til mindre farlige stoffer eller produkter ud fra produkternes kodemærkning (flygtighed) og farlige virkninger til efterretning.

Risici fra **indirekte eksponering:**

Den indirekte eksponering via fødevarer (fx svinekød, indmad, dåse pølser, fedtstoffer / olier og te / kaffe) og miljø anses i EU-RAR (ECB, 2006) ikke for at give bekymring med hensyn til toksicitet efter gentagen dosis ved oral indtagelse for det regionale eksponeringsscenarie. Den anslåede samlede interne dosis var 0,00015 mg / kg legemsvægt / dag og sammenlignet med den orale LOAEL på 1,8 mg / kg legemsvægt / dag var MoS på 12000, hvilket i EU-RAR vurderes til at være tilstrækkelig. Sammenlignet med den nye TDI på 0,5 mg phenol / kg legemsvægt / dag bliver MoS 3334, det vil sige stadig meget mere end 100, hvorved den indirekte eksponering må betragtes som sikker.

Risici fra **kombineret eksponering:**

Personer kan udsættes for phenol dels på arbejdspladsen, dels fra forbrugerprodukter og dels indirekte gennem fødevarer og miljø, hvilket kan øge de målte risici yderligere. I tillæg hertil er der andre, som bør overvejes. Disse er for eksempel:

- a) Oral eksponering fra kontakt med fødevarekontaktmaterialer og røgromaer.
- b) Dermal eksponering fra kontakt med laminerings film og poser.
- c) Computere, skærme, spille konsoller, strygejern, husholdnings ovne, TV apparater, opladere og transformere, telte og kloropren produkter bidrager til eksponeringen som inhaleres.
- d) Eksponering via lægemidler, hvor phenol er anvendt fx som konserveringsmiddel.

Da phenol absorberes og fordeles i kroppen, samt hurtigt udskilles igen med en halveringstid på ca. 3,5 time, og da stoffet ikke ophobes i kroppen, vil enkelte eksponeringer i ubetydelige koncentrationer ikke medføre en uacceptabel risiko. Imidlertid vil gentagen eksponering fra flere af disse kilder i løbet af samme dag, kunne udgøre en risiko. For nogle personer er dette måske ikke urealistisk og føjer derfor yderligere til ECB's konklusion (2006) om, at eksponeringen fra

kombineret eksponering kan overstige TDI-værdien, især hvis den efterfølgende reducerede TDI på 0,5 mg / kg legemsvægt / dag og den foreslåede DNEL på 0,4 mg/kg lgv/day tages i betragtning.

Overordnede konklusioner

For arbejdstageren er risikoen fra inhalations eksponering for phenol nedbragt gennem af risikoreduktionstiltag i medfør af arbejdsmarkeds lovgivningen. I Danmark anvendes phenol primært til produktion af mineraluld og forekommer i træbjæle, hvorfra der ikke forventes at være en væsentlig eksponering for den almindelige forbruger. Phenol anvendes i stort set alle krydsfinérplader og forventes også at forekomme i importerede træbaserede pladematerialer. En eventuel eksponering herfra er ikke kendt. Phenol damper af fra en lang række forskellige forbrugerprodukter, fx fra computere, skærme, spille konsoller, strygejern, husholdnings ovne, TV apparater, opladere og transformere, telte og kloropren produkter, men de målte bidrag fra produkterne er fra 2006 og før, så koncentrationerne kan have ændret sig. Desuden bidrager oral eksponering fra røgromaer, dermal eksponering fra kontakt med lamineringsfilm og poser, samt eksponering via lægemidler til den samlede eksponering.

Nogle af de nævnte eksponeringsscenarier viser, at eksponeringen overstiger TDI-værdien på 0,5 mg / kg legemsvægt / dag og de orale og dermale DNEL på 0,4 mg / kg lgv /dag samt DNEL ved inhalation på respektivt 7,8 mg/m³ for professionelle og 1,32 mg/m³ for forbrugeren. Dette gælder indånding ved brug af gulvvoks samt dermal eksponering ved brug af desinfektionsmidler.. Derimod er bidragene fra drikkevand og fødevarer, som en del af den samlede regionale orale interne eksponeringsdosis beregnet af ECB (2006) til 0,00015 mg / kg legemsvægt/dag betydeligt lavere end TDI'en.

Phenol kan forårsage skader på organer ved længerevarende eller gentagen eksponering. Men da phenol ikke ophobes i kroppen og hurtigt udskilles igen, er det generelt gentagen eksponering over TDI-værdien eller DNELs i løbet af samme dag, der kan udgøre en risiko.

1. Introduction to phenol

Phenol (CAS number 108-95-2) was included in the first LOUS list in 1998 with its classification, at that time, toxic (R24/25) and corrosive (R34). Phenol was removed from the list again in 2004. But since then phenol was added the classifications Muta. 2;H341 (suspected of causing genetic defects) and STOT RE 2;H373 (May cause damage to organs through prolonged or repeated exposure), which caused the adding to the LOUS list again in 2009.

Phenol is also known as monohydroxybenzene, phenylalcohol, carbolic acid (carbolic). It has been used for more than 100 years and it is also known from bakelite. Bakelite is an early plastic (a thermosetting phenol formaldehyde resin; polyoxybenzylmethylenglycolanhydride). The manufacture of bakelit powder in Denmark ceased in 1985 (the industry overview for plastic companies: Branchebeskrivelse for plastvirksomheder, 2000).

Phenol is included in the construction of lignin, which gives trees their compressive strength. Phenol is therefore a natural constituent in plant material, which also causes the release of phenol from the processing of coal and from paper production among others. Phenol is also released from the human metabolism and livestock.

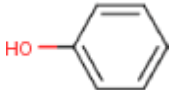
In Denmark phenol is used for the production of mineral wool, contained in impregnating products (mainly coal tar) and in solvents/thinners, in binding agents and in glue, e.g. as phenol containing binders, where the binders may contain a small amount of phenol (personal communication, Anette Harbo Dahl, The Danish Paint and Adhesives Federation, June – September, 2013).

Phenol can occur in drinking water installations and pharmaceuticals as well as in food. Content of phenol has been detected in e.g. meat, cooking fats/salad oils/margarine, tea/coffee and alcoholic drinks (Environment Canada, 1999). Phenol is also included in the curing process by smoking of foods.

1.1 Definition of phenol

TABLE 1
NAME AND OTHER IDENTIFIERS OF PHENOL

	Phenol
EC number	203-632-7
CAS number	108-95-2
Synonyms	Hydroxybenzene (IUPAC name given in KemI, 2013); Phenol (IUPAC name given in ECB, 2006 and ECHA, 2013) Carbolic acid; Monohydroxybenzene; Phenylalcohol (ECB, 2006)
Molecular formula	C ₆ H ₅ OH
Molecular weight range	94.11

Molecular structure	
---------------------	---

1.2 Physical and chemical properties

Phenol is colourless-to-white-light-pink crystalline solid when pure. The commercial product (99.8% pure) is a liquid. Phenol has a distinct odour that is sickeningly sweet and tarry. Phenol can be tasted and smelled at levels lower than those that are associated with harmful effects. A threshold for odour perception in air of 184 µg/m³ has been reported. Furthermore a threshold for taste and odour in water of 150 µg/l and threshold for taste of phenol in water at 150 to 300 µg/kg has also been reported. Phenol is a weak acid. It belongs to the chemical group of VOCs, due to its vapour pressure, but with its Henry constant of 0.022 Pa m³/mol at 20°C, phenol is only slightly volatile from an aqueous solution. It evaporates more slowly than water, and a moderate amount can form a solution with water. Pure phenol absorbs easily water from air and liquefies. Phenol can catch fire (ECB, 2006; ATSDR, 2013; EFSA, 2013).

TABLE 2
PROPERTIES OF PHENOL

Property		Reference
Physical state	Solid crystalline	ECHA (2013); ECB (2006)
Melting/ freezing point	40.9 - 41 °C	ECB (2006); ECHA (2013)
Boiling point	181.8 °C – 191.8 °C at 1,013 hPa	ECB (2006); ECHA (2013)
Ignition temp.	595 °C	ECB (2006)
Relative density	1.07 g/cm ³ at 20 °C; 1.05 g/cm ³ at 50 °C	ECB (2006); ECHA (2013)
Vapour pressure	0.2 - 0.48 hPa at 20°C; 3.5 - 307 hPa at 50 °C	ECB (2006); ECHA (2013)
Surface tension	40.9 - 71.3 mN/m at 20 °C	ECB (2006); ECHA (2013)
Water solubility (mg/L)	84 g/l at 20 °C; 70 - 87.5 g/l at 25°C	ECB (2006); ECHA (2013)
Log P (octanol/water)	logPow 1.47 – 1.5	ECB (2006); ECHA (2013)

2. Regulatory framework

An overall description of the legal framework in relation to chemicals on a regional and international level, in EU and in Denmark is given in annex 1.

2.1 Legislation

This chapter gives an overview of how phenol is addressed in existing EU and Danish legislation, international agreements and eco-label criteria. The overview reflects the findings from the data search.

2.1.1 Existing legislation

In the following sections 'legislative documents' comprise the following types:

- Statutory Orders (which implements the EU Directives within Danish law).
- National Statutory Orders (which are purely Danish laws).
- Regulations (which are EU 'regulative documents' which apply directly in the different Member States).

TABLE 3
DANISH AND EU LEGISLATION SPECIFICALLY ADDRESSING PHENOL

Legal instrument	EU/national	Requirements as concerns phenol
		Regulation addressing products
Regulation No 1907/2006 (EC) on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).	EU	REACH Annex XVII (consolidated version of 18.09.2012) Phenol itself or its CAS no 108-95-2 is not mentioned.
Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006.	EU	A harmonised classification is available for phenol. See section 2.1.2.1 for the details. In general packaging's which are sold to the public and which contains mixtures must be labelled with the indication of danger very toxic, toxic or corrosive, must be fitted with child-resistant closure.
Danish Statutory Order No. 1075 of 24/11/2011 on "classification, packaging, labelling, sale and storage of substances and mixtures". (Klassificeringsbekendtgørelsen)	DK	Toxic substances and mixtures such as phenol may not be sold to persons under the age of 18. Sale of toxic substances and mixtures require presentation of police annotated requisition. Very toxic and toxic substances and mixtures are allowed to be sold to hospitals, laboratories, doctors, dentists, etc.
Regulation (EC) No 1223/2009 on cosmetic products Entered into force on 11 July, 2013.	EU	Phenol is included in list of substances prohibited in cosmetic products (substance no. 1175, Annex 2). The substance was also included on the list of prohibited cosmetic ingredients in the former cosmetics directive in 2005 (substance no. 1175, Annex II, 2005/80/EC).

Legal instrument	EU/national	Requirements as concerns phenol
<p>Danish Statutory Order on cosmetic products, implementing the cosmetics directive:</p> <p><i>Miljøministeriets bekendtgørelse nr. 422 of 04/05/2006 om kosmetiske produkter (Kosmetikbekendtgørelsen).</i></p>	DK	<p>Phenol is included in list of substances prohibited in cosmetic products (substance no. 1202, Annex 2).</p> <p>From 11/07/2013 this statutory order was replaced by the EU regulation 1223/2009, above as stated in BEK no 803 of 21/06/2013.</p>
<p>DIRECTIVE 2009/48/EC of 18 June 2009 on “the safety of toys”.</p>	EU	<p>As phenol is classified with Muta. 2 it is not allowed in toys. The use of substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A, 1B or 2 is prohibited.</p>
<p>DIRECTIVE 2004/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC.</p>	EU	<p>The “VOC” directive that aim to avoid/ reduce ozone formation potential of the VOCs in connection with photo-chemical reactions in the ambient air defines 12 subcategories for coating products applied to buildings and 5 subcategories for vehicle refinishing products for which limits are set with regard to the content of volatile organic compounds, VOC. The maximum VOC content has been set in the range of 30 - 840 g/l depending of the product.</p>
<p>Danish Statutory order on marketing of VOCs in paints and lacquers:</p> <p><i>Miljøministeriets bekendtgørelse nr. 1049 af 27/10/2005 om markedsføring og mærkning af flygtige organiske forbindelser i visse malinger og lakker samt produkter til autoreparations-lakering.</i></p>	DK	<p>This is the implementation of directive 2004/42/EC above.</p>
<p>Danish Executive Order on derivation of code numbers:</p> <p><i>Beskæftigelsesministeriets bekendtgørelse nr. 301 af 13/05/1993 om fastsættelse af kodenumre.</i></p>	DK	<p>In this executive order the code number for phenol is:</p> <p><u>The number before the hyphen:</u></p> <p>It depends on the content of phenol and the other substances in the product. An example is the product phenol with the phenol content of >60-<100%, which has a MAL-code of 5-6 (AppliChem, 2012). This means 5 before the hyphen, which is the highest on the scale. The increasing numbers before the hyphen indicates the growing need for ventilation and the use of respirators. The scale is: 00-, 0-, 1-, 2-, 3-, 4- and 5-.</p> <p><u>The number after the hyphen:</u></p> <ul style="list-style-type: none"> • with max. content of 5%: -6* • with max. content of 0.2 to 5%: -5 • with less than 0.2%: -3. <p>Number 6 is the highest number on the scale. When the product is classified as very toxic or toxic, the product should be placed in the group -6. Increasing number after the hyphen</p>

Legal instrument	EU/national	Requirements as concerns phenol
		indicates the growing need for the use of security measures. For comparison water is given -0; the phenol content of 0.1% in pine tar results in -3 and the phenol content of 1.1% in pine tar results in -5 (Danish EPA, 2012). The numbers after the hyphen, is set to address the health risk when the products come in direct contact with skin, eyes and respiratory tract (also from a spray), or health hazard if swallowed.
Danish Statutory order on surface treatment products: <i>Miljøministeriets bekendtgørelse nr. 830 af 30/10/1999 om mærkning og begrænsning af import, salg og anvendelse af overfladebehandlings-produkter.</i>	DK	Paint must not be marketed for indoor use by the general public for painting ceilings and walls if the volatility code number for the product is above 2.
		Regulation addressing waste
COUNCIL DECISION 2003/33/EC of 19 December 2002 on establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC.	EU	Limits leaching from landfill waste in non-coastal landfills for inert waste in Class IAO. The limits for phenol is 0.5 mg/kg TS (L/S = 2 l/kg); 1 mg/kg TS (L/S= 10 l/kg) and 0.3 mg/l (C ₀). L/S is the Liquid/Solid relation, C ₀ is the start concentration. The waste class “inert waste” is characterized by being non-hazardous waste with a low content of organic matter and waste that does not undergo significant changes in landfills.
Danish Statutory Order on landfills: <i>Bekendtgørelse nr. 719 af 24/06/2011 om deponeringsanlæg</i> As implementation of COUNCIL DECISION 2003/33/EC of 19 December 2002 above.	DK	Implementation of the above 2003/33/EC.
Danish Statutory order on waste: <i>Miljøministeriets bekendtgørelse nr. 1309 af 18/12/2012 om affald.</i>		Waste generated from manufacture or from industrial use of phenol has according to the Danish statutory order on waste to be treated as hazardous waste if the waste contain phenol in an amount that according to classification rules for chemical substances and preparations would result in classification for either physical-chemical, toxicological or environmental properties. Thus, waste containing phenol in an amount that would result in classification as hazardous is treated as hazardous waste and disposed/treated according to the instructions from local communities. This includes collection of liquid and solid waste from both industries and private households, e.g. residues of paint and pine tar products must be brought to a recycling site for collection (Danish Ministry of Environment, 2012).
		Regulation addressing emissions to the environment

Legal instrument	EU/national	Requirements as concerns phenol
Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (Text with EEA relevance).	EU	Phenol is listed in Annex II as pollutant, with a threshold for release to water and land of 20 kg/year.
2006/61/EC: Council Decision of 2 December 2005 on the conclusion, on behalf of the European Community, of the UN-ECE Protocol on Pollutant Release and Transfer Registers.	EU	Phenol is listed in Annex II as pollutant, with a Threshold for release to water and land of 20 kg/year, and Threshold for off-site transfers of pollutants (column 2) of 200 kg/year, and Manufacture, process or use threshold (column 3) of 10,000 kg/year.
Danish Statutory Order on environmental information from certain companies: <i>Bekendtgørelse nr. 210 af 03/03/2010 om visse virksomheders afgivelse af miljøoplysninger.</i>	DK	Phenol is listed in Annex II as pollutant, with a threshold for release to water and land of 20 kg/year. This supplements the provisions of Regulation 166/2006 and amending Council Directive 2006/61/EC, Official Journal 2006 L 33, page 1 above.
List of quality criteria in contaminated soil and quality of drinking water (an aid to municipalities, regions, medical officers, advisers and others dealing with soil contamination) (Danish EPA, 2010): <i>Liste over kvalitetskriterier i relation til forurennet jord og kvalitetskriterier for drikkevand.</i>	DK	Soil: 70 mg/kg (for total phenols) Groundwater: 0.5 µg/l (for total phenols) Air: 0.02 mg/m ³ . This evaporation criterion expresses the maximum contribution of evaporation from the ground to the indoor or outdoor air. It is a contribution value and not a total value. The evaporation criterion is basically the same as the air quality criterion (Danish EPA, 2010).
B-værdvejledningen. Environmental guideline No. 2, 2002 (Danish EPA, 2002a). Guidelines for Air Emission. Limits the individual company's contribution to air pollution in the environment. No. 1, 2002 (Danish EPA, 2002b).	DK	Release of phenol (imission level (B-værdi) has been established in order to limit the emissions): - to ambient air from industrial plants is regulated with an imission value of 0.02 mg/m ³ (each company's contribution to air pollution in the environment; B-værdi) (Danish EPA, 2002a). - an imission limit value of 5 mg/m ³ (Danish EPA, 2002b) and - a mass-flow limit of 100 g/hour (Danish EPA, 2002b).
Directive 2000/60/EC of 23 October 2000 on establishing a framework for Community action in the field of water policy.	EU	Phenol is not on the amended list of priority substances, but as a consequence of phenols classification with Muta. 2 it is covered by the ANNEX VIII Indicative list of the main pollutants.
Danish Statutory Order on environmental quality standards for water bodies and requirements for the discharge of pollutants into rivers, lakes or the sea:	DK	General quality criteria for fresh and marine waters; 7.7 and 0.77 µg/l. Short-term quality criteria for fresh and marine waters; 310 µg/l.

Legal instrument	EU/national	Requirements as concerns phenol
<p><i>BEK nr. 1022 af 25/08/2010</i></p> <p><i>Bekendtgørelse om miljøkvalitetskrav for vandområder og krav til udledning af forurenende stoffer til vandløb, søer eller havet.</i></p> <p>Implementing directive 2006/11/EC of 15 February 2006 on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community and part of directive 2000/60/EC of 23 October 2000 on establishing a framework for Community action in the field of water policy and part of directive 2008/105/EC of 16 December 2008 on environmental quality standards in the field of water policy.</p>		
<p>Danish Statutory Order on approval of listed companies:</p> <p><i>Bekendtgørelse nr. 1454 af 20/12/2012 om godkendelse af listevirksomhed.</i></p> <p>This contains provisions implementing parts of 2008/1/EC of 15 January 2008 concerning integrated pollution prevention and control (codified version); parts of 96/82/EC of 9 December 1996 on the control of major- accident hazards involving dangerous substances and many more parts of EU legislation on environmental pollutants.</p>	DK	Phenol is not specifically mentioned in the Statutory Order, but it includes requirements/conditions on the storage and handling of hazardous substances generally through the environmental approval of the company. As phenol is on LOUS, it must be accompanied by an assessment the possibility of using cleaner technology and / or substitution.
<p>Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 (Seveso III Directive) on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC.</p> <p>Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (Seveso II Directive).</p>	EU	Phenol is not specifically mentioned in the Directive, but as the directive control the major-accident hazards involving dangerous substances, phenol is covered.
<p><i>BEK nr. 1666 af 14/12/2006</i></p> <p><i>Bekendtgørelse om kontrol med risikoen for større uheld med farlige stoffer</i></p>	DK	<p>Special measures are required for the handling and storage of phenol to minimize the risk of release.</p> <p>This is the implementation of the above 96/82/EC (Seveso II</p>

Legal instrument	EU/national	Requirements as concerns phenol
<p>(Risikobekendtgørelsen).</p> <p>This contains provisions implementing Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances; Commission Decision 98/433/EC on harmonized criteria for dispensations under Article 9 of Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances and European Parliament and Council Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances.</p>		Directive).
		Regulation addressing, feed and food
<p>Commission Implementing Regulation, No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council and</p> <p>Commission Implementing Regulation, No 793/2012 of 5 September 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council.</p>	EU	Phenol is listed in the register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996.
COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.	EU	Phenol is not authorised to be used as additive or polymer production aid. Phenol is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation. (Risk assessment is on-going for phenol).
<p>Danish Statutory Order on water quality and monitoring of water supply systems:</p> <p><i>Bekendtgørelse nr. 1024 af 31/10/2011 om vandkvalitet og tilsyn med vandforsyningsanlæg.</i></p>	DK	A limit value for total phenols in drinking water (at water works and at the consumer's tap) has been set at 0.5 µg/l water.
<p>Danish Statutory Order from the Ministry of Climate, Energy and Building regarding approvals of drinking water installations:</p> <p><i>Bekendtgørelse nr. 31 af 21/01/2013 om udstedelse af godkendelser for byggevarer i kontakt med drikkevand.</i></p>	DK	A limit for migration of phenols for installations in contact with drinking water. This includes drinking water pipes from water works and household installations connected to the cold drinking water supply in the house. No evidence of the sum of phenols in the 1 st and 3 rd extraction with a detection limit of 1 µg/l.

Legal instrument	EU/national	Requirements as concerns phenol
		Regulation addressing biocidal products
Biocidal Products Directive 98/8/EC and the Biocidal Products Regulation 528/2012 and related regulations.	EU	Phenol has not been supported in the notification phase of the review programme. Therefore phenol is not allowed in any biocidal products within the EU.
		Regulation addressing the working environment
Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Commission Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values	EU	Indicative Occupational Exposure Limit (IOEL) for phenol: - 8 mg/m ³ (2 ppm) as 8 hour time-weighted average (TWA). - 16 mg/m ³ (4 ppm) as short-term exposure limit (STEL) i.e. a 15-minute period. A “skin notation” is assigned to the occupational exposure limit value of phenol, indicating the risk of significant uptake through the skin.
Danish Executive Order from the Ministry of Employment to protect workers during work from gases, vapors and particulate pollution: <i>Bekendtgørelse nr. 507 af 2011 om grænseværdier for stoffer og materialer med senere ændringer.</i>	DK	Limit value for phenol: 1 ppm; 4 mg/m ³ ; H (absorbed through the skin).
Danish Executive Order from the Ministry of Employment to protect workers during work regarding any work with substances and materials: <i>Bekendtgørelse nr. 292 af 26/04/2001 om arbejde med stoffer og materialer med senere ændringer.</i>	DK	This Executive Order applies to any work with substances and materials, including their manufacture, use and handling. The Order demands the employer to ensure that dangerous substances and materials at the workplace are eliminated, replaced or reduced to a minimum.

2.1.2 Classification and labelling

2.1.2.1 Harmonised classification in the EU

Table 4 lists the harmonized classification for phenol according to Annex VI of the CLP Regulation.

TABLE 4
HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International chemical identification	CAS No	Classification		Specific Concentration Limits, M-Factors
			Hazard Class and Category	Hazard statement (Risk phrase from DSD*)	
604-001-00-2	Phenol; Monohydroxy	108-95-2	Acute Tox. 3 Acute Tox. 3 Acute Tox. 3	H301; Toxic if swallowed (R25) H311; Toxic in contact with skin (R24) H331; Toxic if inhaled (R23)	Skin Corr. 1B; H314: C ≥ 3% Skin Irrit. 2; H315:

benzene; Phenylalcohol; carbolic acid.		Skin Corr. 1B Muta. 2 STOT RE 2	H314; Causes severe skin burns and eye damage (R34) H341; Suspected of causing genetic defects (R68) H373; May cause damage to organs through prolonged or repeated exposure (R48/20/21/22)	1% ≤ C < 3% Eye Irrit. 2; H319: 1% ≤ C < 3%
--	--	---	---	---

*) DSD in brackets = Risk phrase from DSD (Dangerous Substances Directive, 67/548/EC).

R23: toxic if inhaled

R24: toxic in contact with skin

R25: toxic if swallowed

R34: causes burns

R68: possible risk of irreversible effects

R48/20/21/22: harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

Due to its classification “Muta. 2” phenol belongs to the substances classified in the lower CMR categories. These do not normally lead to general restrictions (see Annex 1).

2.1.2.2 Self-classification in the EU

Out of 2870 notifiers, 2819 notifiers have notified classifications according to the harmonised classification above. Some have notified additional classifications. Among those is “Eye Dam. 1, H318”, “Aquatic Chronic 2, H411” and “Aquatic Chronic 3, H412”. Table 5 lists the overview of the self-classifications for phenol according to Annex VI of the CLP Regulation. Notifiers including the harmonised classification are above and the additional classifications are below the bold line. Around 1/7 notifiers apply a classification for aquatic toxicity in addition to the harmonised classification.

TABLE 5
NOTIFIED CLASSIFICATIONS FOR PHENOL IN THE EU

Classification		Remarks
Hazard Class and Category Code(s)	Hazard statement Code(s)	
Acute Tox. 3 Acute Tox. 3 Acute Tox. 3 Skin Corr. 1B Muta. 2 STOT RE 2	H301; Toxic if swallowed H311; Toxic in contact with skin H331; Toxic if inhaled H314; Causes severe skin burns and eye damage H341; Suspected of causing genetic defects H373; May cause damage to organs through prolonged or repeated exposure	2819 notifiers
Eye Dam. 1	H318; Causes serious eye damage	472 notifiers
Acute Tox. 1 Aquatic Acute 1	H330; Fatal if inhaled H400; Very toxic to aquatic life	4 notifiers
Aquatic Chronic 2	H411; Toxic to aquatic life with long lasting effects	93 notifiers
Aquatic Chronic 3	H412; Harmful to aquatic life with long lasting effects	301 notifiers

2.1.3 REACH

Phenol has been registered under REACH in the production tonnage span of 1,000,000 - 10,000,000 tonnes per annum (joint submission) covering 44 registrants and in the tonnage span of 1,000 - 10,000 tonnes per annum (individual submission).

No further REACH activities for phenol have been identified e.g. in relation to SVHC identification, authorisation, restriction, or prioritisation for substance evaluation.

Phenol as such is not restricted but mentioned in connection with the restriction of other products with a content of phenol, such as oil products. Some oil products are restricted by the REACH annex XVII restrictions. And as phenol is a content in e.g. tar and other oil products, phenol is mentioned along with the other constituents under the restriction of these oil products (although the restriction is not based on the properties of phenol but on the content of the carcinogen benzo(a)pyrene). As an example wood treated with distillates (coal tar) shall for instance not be used inside buildings, in toys, in playgrounds, in parks, gardens, and outdoor recreational and leisure facilities where there is a risk of frequent skin contact. These restrictions although not targeted towards phenol would however, also decrease the exposure potential towards phenol.

The joint registration under REACH includes proposals for DNELs for phenol. The exposure scenarios from the confidential part of the numerous dossiers have not been accessed for this project.

2.1.4 Working environment legislation

Danish working environment legislation implements the EU directive on chemical agents on the protection of workers safety and health from risks from chemical agents (98/24/EU) in the Danish Executive order 292 of 26. April 2001 with amendments, including the substitution principle and requirements on workplace instruction for use of chemicals. A Danish executive order on the execution of work stipulates that the influence from substances and materials be reduced as much as reasonably possible under consideration of technical development.

2.1.5 Food legislation

Phenol is authorised as monomer or other starting substance or macromolecule obtained from microbial fermentation in production of food contact material made of plastic, based on Commission Regulation (EU) No 10/2011 on food contact materials.

Food flavouring regulation EU Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods lists phenol as a flavouring substance used in or on foodstuffs. A recently adopted regulation including a list of authorized smoke flavourings includes phenol.

The European Food Safety Authority has recently published an opinion on phenol, including a revised TDI for the substance.

2.2 Eco-labels

EU Flower and Nordic Swan Criteria:

The Nordic Swan and the EU Flower can largely be regarded as having the same criteria, and the EU flower is therefore considered as covered by the description of the Nordic Swan.

Phenol is covered by several criteria documents under the Nordic Swan, (e.g. criteria covering products with paints and glues) primarily due to the classification. As an example: In 'Chemical construction products' (such as paint and lacquers) phenol is not allowed, since 'No chemical

substances must be assigned one of the following risk phrases or combinations thereof: R23, R24, R25, R26, R27, R28, R33, R39, R48, R49, R68". For the EU Flower more risk phrases is covered: For instance for the indoor paints and varnishes no ingredient shall be used that fulfil the classification criteria of any of the following risk phrases (or combinations thereof): R23, R24, R25, R26, R27, R28, R33, R39, R40, R42, R45, R46, R48, R49, R60, R61, R62, R63 and R68 (Ecolabel, 2013a).

The criteria for 'Furniture and fitments' under the Nordic ecolabel also restricts the use of phenol, due to its classification with the risk phrases R23, R24 and R25. (Ecolabel, 2013b). However, chemical mixtures which contain phenol in small amounts below the limits for classification are not covered by the restriction.

German Blue Angel Criteria:

Also the German Blue Angel restricts phenol. For instance composite wood panels including phenol-containing binding agents must not exceed a phenol concentration of 14 µg/m³ in the test room". Like the Nordic Swan criteria the German Blue Angel includes phenol among other VOC substances due to their toxic effects (EC DG Environment, 2009; UBA-FB, 2009; Blue Angel, 2013).

2.3 Summary and conclusions

Phenol is subject to EU harmonised classification, classified with:

- Acute Tox. 3; H301 (Toxic if swallowed)
- Acute Tox. 3; H311 (Toxic in contact with skin)
- Skin Corr. 1B; H314 (Causes severe skin burns and eye damage)
- Acute Tox. 3; H331 (Toxic if inhaled)
- Muta. 2; H341 (Suspected of causing genetic defects)
- STOT RE 2; H373 (May cause damage to organs through prolonged or repeated exposure)

In addition to the harmonised classification end-points further classifications are used by around 1 out of 7 suppliers to the market in EU. The most widely used classifications are:

- Eye Dam. 1; H318 (Causes serious eye damage)
- Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)
- Aquatic Chronic 3; H412 (Harmful to aquatic life with long lasting effects)

Classification as eye damaging it is already included in the harmonised classification as H314. The available biodegradation and bioaccumulation data categorise phenol as non-persistent in the environment. But as phenol has its chronic NOEC > 0.01 to ≤ 0.1 mg/l, according to the CLP classification phenol fulfils the criteria for classification as "Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)" as suggested by 93 notifiers out of 2,870 notifiers.

Phenol is registered under REACH based on a production tonnage between 1,000,000 - 10,000,000 tonnes per annum. The registration includes proposed DNELs.

No specific new initiatives on phenol have been identified under REACH (e.g. restrictions, SVHC identification, authorisation or prioritisation for substance evaluation).

Recently, a revised Tolerable Daily Intake (TDI) from food was set.

There are both EU and Danish regulations on the occupational limit value on phenol and national environmental guidance's on imission values (B-værdi) and levels in polluted soil and groundwater. Regulations on waste controls waste generated from manufacture or from industrial use of phenol as well as from private households. Waste containing phenol must be treated as hazardous waste. Also landfill waste has limits for leaching.

The use of phenol was prohibited in cosmetics in the EU in 2006.

With respect to eco-labelling the granting of the Nordic swan or the German Blue angel label is for a variety of product type's dependent of the classification of the chemical constituents and the content of VOCs. This puts limits to the content of phenol in product types such as: Paints and glues; paints and lacquers; and furniture and fitments.

3. Manufacture and uses

The quantity of phenol used in the EU amounts to approximately 1,642,500 tonnes/annum. 1,819,100 tonnes/annum is produced by 12 EU companies. In addition, a quantity of 113,400 tonnes/annum is annually imported. 290,000 tonnes/annum phenol are exported to non-EU member states (ECB, 2006).

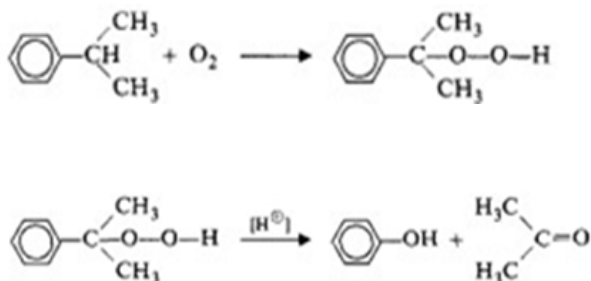
In EU phenol is mainly (about 100%) used as a chemical parent compound/intermediate in synthesis. Approximately 65% of the produced phenol is processed further to organic chemicals, for example, to bisphenol A, caprolactam, salicylic acid, diphenyl ether, alkyl phenols, nitrophenols and other chemicals. 30% is used to manufacture phenol resins and a non-quantifiable part serves as a component in medical preparations, e.g. as preservation (ECB, 2006).

3.1 Manufacturing

Phenol is mainly produced synthetically on the basis of cumene or using toluene as the starting point (ECB, 2006).

3.1.1 Manufacturing processes

The Hock method on the basis of cumene is the most common method used to produce phenol. Cumene is prepared in an industrial process from benzene and propylene. Then O₂ is added and subsequent cleavage in acidic media with H₂SO₄ to form phenol and acetone:



In 1989 the cumene method accounted for about 93% of the production capacity for phenol in Western Europe. The method for the production of phenol, which takes toluene as the starting point, is also of industrial significance and accounted for about 7%.

Phenol can also be obtained by processing coal-tar fractions, but within the EU only approximately 15,000 tonnes/annum ($\approx 1\%$) of phenol are obtained by processing coal-tar fractions.

3.1.2 Manufacturing sites

According to ECB (2006) there are 32 production and/or processing sites of phenol within the EU. They cover 12 EU companies, located in 10 countries (United Kingdom, Germany, France, Netherlands, Italy, Belgium, Finland, Sweden, Spain and Austria). The sources of the data are essentially the IUCLID data sets provided by the individual companies and further announcements (ECB, 2006; IUCLID, 2000).

In Denmark, the Danish Gas Works Tar Company (Danske Gasværker Tjære Kompagni), had during the Second World War production of Crude phenols which could be used directly for the

production of the phenol-formaldehyde plastic named Bakelite (Gyldendals, 2013). The manufacture of bakelite powder in Denmark ceased in 1985 (the industry overview for plastic companies: Branchebeskrivelse for plastvirksomheder, 2000). According to ECB (2006) Denmark does not produce phenol any longer.

3.1.3 Manufacturing volumes

The total industrial world production of phenol in 1981 was estimated at 3,375,000 tonnes (IPCS, 1994). In EU 1,819,100 tonnes/annum is produced by 12 EU companies (ECB, 2006) and phenol is registered under REACH within the tonnage of 1,000,000 - 10,000,000 tonnes per annum by joint submission (ECHA, 2013).

3.2 Import and export

3.2.1 Import and export of phenol in Denmark

According to the Danish Product Register the amount of phenol used in Denmark are 5,665 tonnes. The exported amount is 1,552 tonnes, which gives an amount of 4,112 tonnes remaining in Denmark (Danish Product Register, April 2013). The used amount of phenol in Denmark was 2,992 tonnes in 2010 according to the Nordic Product Register, SPIN, see section 3.4 (SPIN, 2013). The manufacture of bakelite powder in Denmark ceased in 1985 according to the industry overview for plastic companies (Branchebeskrivelse for plastvirksomheder, 2000). However, fluid phenol is still used in Denmark for the production of bakelite in the mineral wool production (personal communication, Marianne Ripka, Danish EPA, July 2013).

As phenol is not produced in Denmark anymore this amount equals the imported amount. The 1,552 tonnes exported amount are commodities, which is assumed to be mainly bakelite.

3.2.2 Import and export of phenol in EU

A quantity of 113,400 tonnes/annum is annually imported into the EU and 290,000 tonnes/annum phenol are exported to non-EU member states (ECB, 2006).

3.3 Use

In EU phenol is used primarily in the production of phenolic resins and in the manufacture of nylon and other synthetic fibres. It is/was also used in slimicides (chemicals that kill bacteria and fungi in slimes), as a disinfectant, preservative, antiseptic (e.g. carbolic water) and in impregnating paints (e.g. tar and creosote), and in medicinal preparations such as mouthwash and sore throat lozenges (ATSDR, 2013; Danish EPA 2002c; Danish EPA, 2012). Phenol is now prohibited in cosmetics as well as the use as biocide in the EU.

In EU, nearly 100% of the amount of phenol is used as a chemical intermediate in synthesis. Approximately 65% of the produced phenol is processed further to organic chemicals, such as bisphenol A, caprolactam, salicylic acid, diphenyl ether, alkyl phenols, nitrophenols, halogen phenols and other chemicals. 30% is used to manufacture phenol resins (ECB, 2006; EC, 2008).

According to the registration under REACH phenol is used e.g. as process regulators for polymerisation processes in production of resins, rubbers and polymers, as a laboratory reagent besides as a treatment of articles by dipping and pouring. Furthermore it is used as binders and release agents, mould forming and casting, and handling of waste besides used in coatings (paints, inks, adhesives and production of textiles, etc.). Phenol is also used for rubber production and processing such as the manufacturing of tyres and general rubber articles, vulcanising, cooling and finishing (ECHA (2013).

Small amounts of phenol have been reported to be used in cosmetics in US (Cosmetics INFO, 2013). This included bath, hair and skin care products, e.g. in soaps called “carbolic soap”, due to its content of phenol (carbolic acid) and its characteristic smell (Cosmetics INFO, 2013). The carbolic bath soap was also used to help repel mosquitos and other biting insects (Manta, 2013). But in EU phenol is now banned in cosmetics as well as the use as biocide. Furthermore, the use of small amounts of phenol include among others phenol used as a preservative in pharmaceutical products such as insulin, tuberculosis vaccines, allergy serums, parenteral administration and in veterinary medicine e.g. for injection for prevention of anemia caused by iron deficiency in piglets (ECB, 2006; the Danish Medicines Agency: Lægemiddelstyrelsen, 2011).

According to SPIN the following product types are described in Denmark: Intermediate, adhesive, binder, impregnating agent, paints, lacquers and varnishes and solvents. In Sweden phenol is listed in the product types: Intermediates, binders, in paints and lacquers, flooring, hardeners, insulating materials, adhesives and other products (SPIN, 2013). These uses are described further in section 3.4 as historical trends in use.

In Denmark the main amount (4,814 tonnes) is in commodities (as for bakelite) apart from phenol contained in impregnating (1,653 tonnes), solvents and thinners (750 tonnes), binding agents (21 tonnes) and glue (2 ton) (Danish Product Register, April 2013). In total this gives 7,240 tonnes, which is above the given total used amount of 5,665 tonnes. The reason is that the use can be registered under more than one category. It is not clear from the product registers which quantity of the phenol is used as an intermediate in the manufacture of products such as phenol resins and binders and how much remain unchanged in the final product. However, in Denmark the production of mineral wool (glass wool and stone wool) uses phenol as part of the binding agent, bakelite. Bakelite is a thermosetting phenol formaldehyde resin, formed from an elimination reaction of phenol with formaldehyde. Bakelite is used as the binding agent in the mineral wools. Glass wool produced in Denmark contains typically 5% binder. Stone wool produced in Denmark contains typically 2% binder. For insulation purposes, stone wool covered 50% and glass wool covered 36% of the use in Denmark in 1995 (Vejdirektoratet, 2013; Isover, 2013, Danish EPA, 2003a).

About 2,000 tonnes of phenol is used nowadays as an intermediate in the production of mineral wool. The fibers are embedded in the bakelite. Phenol is fluid when used in the bakelite (personal communication, Marianne Ripka, Danish EPA, July 2013).

According to the most recent figures the use of phenol as commodities (4,814 tonnes) covers the main part of the total amount of 5,665 tonnes phenol used in Denmark yearly (Danish Product Register, April 2013). This can be confirmed by the figures from SPIN, where 2,889 tonnes of phenol were used in the manufacture of other non-metallic mineral products in 2010 given by the Nace (Nomenclature des Activités Économiques dans la Communauté Européenne) code C23 and furthermore with the given 2,139 tonnes of phenol used in intermediates in 2010 given by SPIN in the use category UC62 No. 33 (See Figure 1).

For impregnating, the tar products (coal tar) cover the main part of the 1653 tonnes (Danish Product Register, April 2013).

As mentioned the used amount in binding agents and glue is 21 tonnes and 2 ton, respectively. Phenol seems not to be used in the wood conversion industry (chipboard, MDF, laminated, etc.) in Denmark. According to the Wood and Furniture Industry, they do not use adhesives with phenol (phenolic, phenol-resorcinol glue, melamine-urea-phenol-formaldehyde, etc.). But plywood (which is not for the furniture industry), is produced with phenol glue. Furthermore phenol may also be used in chipboard, MDF, laminated, etc. imported to Denmark (personal communication, Anette Harbo Dahl, The Danish Paint and Adhesives Federation, June 2013). Based on this and compared

to the information provided by the Danish Product Register it is assumed that the main part of the phenol is covered by phenol containing resins binding agents for tubes of paper and cotton fabric based laminates as well as for plastics besides adhesives for e.g. rubber-metal purposes. In binding agents and in glue, it is phenol containing binders, where the binders may contain a small amount of phenol (personal communication, Anette Harbo Dahl, The Danish Paint and Adhesives Federation, June – September, 2013).

Country	Year	Use category	Number	Amount
DK	2010	Paint, lacquers and varnishes	316	0.0
DK	2009	Paint, lacquers and varnishes	301	0.2
DK	2008	Paint, lacquers and varnishes	348	0.4
DK	2007	Paint, lacquers and varnishes	352	5.4*
DK	2006	Paint, lacquers and varnishes	355	1.0
DK	2005	Paint, lacquers and varnishes	334	0.6
DK	2010	Manufacture of other non-metallic mineral products (Nace, C23)	10	2889
DK	2010	Manufacture of rubber and plastic products (Nace, C22)	29	85
DK	2010	Manufacture of chemicals and chemical products (Nace, C20)	32	3
DK	2010	Manufacture of fabricated metal products, except machinery and equipment (Nace, C23)	188	0
DK	2010	Intermediates (UC62, 33)	7	2139

FIGURE 1 SELECTED FIGURES OF THE USE OF PHENOL IN TONNES AND THE NUMBER OF PREPARATIONS (SPIN, 2013).

*) This high figure might be due to an error in the registration of a single product (personal communication, Poul Andersen, The Product Register in Denmark).

In Denmark pharmaceuticals for injections, tablets and many skin prick tests contain phenol (Personal communication, Per Sindahl, Sundhedsstyrelsen (the Danish Health and Medicines Authority), August 2013).

Phenol is used as a preservative in pharmaceuticals in an amount above 2 tonnes per year (Personal communication, confidential Danish pharmaceutical company, July-August 2013).

3.4 Historical trends in use

The amount of phenol used in Sweden, Denmark, Finland and Norway is presented in the figures below. According to data from SPIN (2013), both the total used amount of phenol and the number of preparations with phenol in each country have been at about the same level over the past 5 year-period from 2005 to 2010 in Sweden and Finland. In Denmark and in Norway the consumption has decreased about 25% from 2005 to 2010.

Finland uses the largest amount (about 200,000 tonnes/year in 2007 to 2010) followed by Sweden (about 17,000 tonnes/year as the largest, which was in year 2009). Despite the small amount (about 3,000 tonnes / year) Denmark uses the largest number of preparations with phenol (ranging from about 700-900) followed by Sweden (ranging from about 300-400 preparations). The group of "paint, lacquers and varnishes" covers the largest number of preparations – in Denmark, but this might be due to different reporting strategies for preparations between the Nordic countries.

The group of "Paint, lacquers and varnishes" covers a large number of the preparations and that group is mostly present in Denmark. It covers about half of the number of preparations. However, the amount of phenol used in this use category in Denmark is less than 1 tonne over the past 5 years. The second largest group of preparations is binding agents. Binding agents are mostly used in Sweden and Finland. According to KemI (2013), Sweden imports large quantities of phenol for production of phenol-formaldehyde resins for binders, intended above all for use in the wood

conversion industry (chipboard). The same picture seems to cover the use in Finland, but not in Denmark. The used amount of phenol in Finland is about 10 times larger than in the other countries, but covers only about 200 preparations/year, which is in the lower end among the countries. In 2010 Finland used a total of 233 preparations, where 129 preparations was in the group of “Adhesives, binding agents” and 57 preparations was in the group of “Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials”.

Country	Year	Number	Amount (tonnes)
SE	2005	329	11636
SE	2006	332	13636
SE	2007	342	10623
SE	2008	277	13005
SE	2009	390	17020
SE	2010	431	15847
DK	2005	825	3918
DK	2006	857	3913
DK	2007	809	2173
DK	2008	747	3295
DK	2009	673	2766
DK	2010	680	2992
FI	2005	169	143789
FI	2006	215	173800
FI	2007	226	182538
FI	2008	220	206777
FI	2009	234	203459
FI	2010	233	193413
NO	2005	120	2985
NO	2006	131	2453
NO	2007	129	1778
NO	2008	120	2592
NO	2009	119	1862
NO	2010	119	1930

FIGURE 2 THE TOTAL USE OF PHENOL IN TONNES AND THE NUMBER OF PRODUCTS. THE DATA COVER A PERIODE FROM 1999 TO 2010 FOR SWEDEN, DENMARK, FINLAND AND NORWAY SEPERATELY (SPIN, 2013).

3.5 Summary and conclusions

From the REACH registration it can be seen that phenol is within the highest tonnage of 1,000,000 - 10,000,000 tonnes per annum. This pattern is also reflected by the figures from ECB (2006), where 1,819,100 tonnes/annum is produced by 12 EU companies, excluding Denmark.

In EU phenol is mainly (about 100%) used as a chemical parent compound/intermediate in synthesis. This covers use as process regulators for polymerisation processes in production of

resins, rubbers and polymers, as laboratory reagent, as binder and release agent, besides component in coatings (paints, inks, adhesives and production of textiles, etc.) and component in the rubber production and processing (manufacturing of tyres and general rubber articles, vulcanising, cooling and finishing) (ECHA (2013)). Approximately 65% of the produced phenol is processed further to organic chemicals, for example, to bisphenol A, caprolactam, salicylic acid, diphenyl ether, alkyl phenols, nitrophenols and other chemicals. 30% is used to manufacture phenol resins and a very small amount serves as component in pharmaceutical products such as insulin, tuberculosis vaccines, allergy serums, parenteral administration and in veterinary medicine e.g. as preservation.

Within the Nordic Countries (Sweden, Denmark, Finland and Norway) Finland uses the largest amount (about 200,000 tonnes/year in 2007 to 2010) followed by Sweden (about 17,000 tonnes/year). Finland and Sweden use large quantities of phenol for production of phenol-formaldehyde resins for binders, which seems intended above all for use in the wood conversion industry (chipboard).

For Denmark 4,814 tonnes are used in commodities (e.g. for bakelite). Another 1,653 tonnes are used in impregnating, 750 tonnes in solvents and thinners, 21 tonnes in binding agents and 2 ton in glue. The production of mineral wool uses the main part of phenol in Denmark, where phenol is used as part of bakelite. The tar products (coal tar) cover the main part of the 1,653 tonnes used for impregnating (Danish Product Register, April 2013).

4. Waste management

4.1 Waste from manufacture and use of phenol

Waste generated from manufacture or from industrial use of phenol has according to the Danish statutory order on waste to be treated as hazardous waste if the waste contain substances in an amount that according to classification rules for chemical substances and preparations would result in classification for either physical-chemical, toxicological or environmental properties (Danish Ministry of Environment, 2012).

Thus, waste containing phenol in an amount that would result in classification as hazardous should be treated as hazardous waste and be disposed/treated according to the instructions from local communities. This includes collection of liquid and solid waste from both industries and private households. For instance consumers must bring residues of paint and pine tar products to a recycling site for collection.

For solid waste it is assumed that waste containing phenol from consumer uses will enter into the waste stream through the municipal collection of domestic waste i.e. through adhesive/glue and varnishes.

For liquid waste it is assumed that waste containing phenol from consumer uses will enter into the waste stream through the municipal collection of domestic waste i.e. through impregnating agent (such as tar and creosote for wood), paints, lacquers and solvents.

These waste types will often be classified as hazardous waste and treated as such.

In Denmark the largest amount of phenol is used in the industrial production of the phenolic resin bakelite as binder in the production of mineral wool (glass wool and stone wool). The manufacture of bakelite powder in Denmark ceased in 1985 and the potential for contamination of soil and groundwater from the processing of bakelite based on purchased moulding powder is considered to be low (Branchebeskrivelse for plastvirksomheder, 2000). However, fluid phenol is still used in Denmark in the bakelite production (personal communication, Marianne Ripka, Danish EPA, July 2013), but it is also assumed that the residue content of phenol from bakelite is very little. The leaching of phenol for Rockwool has been measured to be less than 5 µg/l (Rockwool, 2012). Bakelite cannot be reused, but is degraded by complete combustion to CO₂, nitrogen-containing compounds (catalyst residues) and water vapour (Plastnet, 2013). Based on this the phenol content in mineral wool are not considered to pose a problem in waste.

4.2 Waste products from the use of phenol in mixtures and articles

Due to the use of phenol in mixtures and articles a small amount of waste containing phenol may derive from consumer use. Thus a small amount may go into the municipal collection and treatment of domestic waste under a waste flow for coal tar, etc. The various types of products with a possible content of phenol can be seen in section 3.

4.3 Release of phenol from waste disposal

In EU phenol may be released from many sources. The sources cover:

- Release via the waste water from cooking plants and low-temperature carbonisation plants (from the cooking, gasification and liquefaction of coal),
- release via refinery waste water (mixture of phenol and alkyl phenols are typical components of refinery waste water, occurring from thermal and catalytic conversion processes and contained in petroleum itself),
- release via the waste water from pulp manufacture,
- release via landfill leachate,
- release via municipal waste water, but in rare cases only as the phenol containing products will most likely not be poured into drainage.

Disposal to soil:

Production and processing: No information was provided by ECB (2006) for the direct emission of phenol to soil during production and processing and was considered to be of minor relevance. But with regard to the occurrence of phenol in soils, an investigation from 1987 into contaminated soils at a gasworks near Copenhagen exists which reveals concentrations between 0.05 and 29 mg/kg, which is below the quality criteria for soil (70 mg/kg for total phenols). Other monitoring data of phenol in soils or ground water are not available (ECB, 2006).

Manure: Phenol from the spread of liquid manure from livestock farming over agricultural areas has been measured between 0.5 and 45 mg/l phenol was detected in fresh liquid manure produced by pigs, 1983. The liquid manure derived from livestock farming is typically collected in large open tanks over a long time period before spreading over agricultural areas for the purpose of fertilisation (ECB, 2006). In Denmark the phenol content was measured to 31 mg ww per day in cattle manure and 26 mg ww per day in pig manure (GEUS, 2003). The phenol would be rapidly eliminated in the collecting tanks and the concentration of phenol in the manure at the time of the spreading is much lower than in fresh manure (ECB, 2006). These concentrations are not considered to be high compared to the quality criteria for soil of 70 mg/kg.

Sludge: According to ECB (2006) the sewage sludge arising from the production and processing of phenol in the chemical industry are for the most part disposed of by incineration or landfilling. However, release into the soil as a result of the spreading of sewage sludge from municipal WWTPs is possible. These plants receive waste water from private households, containing phenol as a product of human metabolism. The application of sewage sludge was calculated to 1.69 mg/kg (dry weight) for the fertilisation of the soil used for agricultural purposes (ECB, 2006). In a measurement of phenol in sewage sludge showed 3.8-105 mg/kg dry weight (Avedøre, Marselisborg and Skævinge in 1992) (DMU, 1997). Only the highest concentration is above the quality criteria for soil of 70 mg/kg.

In Denmark the main part of phenol is used in mineral wool as a content of the 2-5% bakelite binder used in stone wool and glass wool, respectively. But chemically bonded sand used in iron and steel foundries may also contain phenol from the binder. According to the description for iron and steel foundries this may pose a risk to soil and groundwater contamination reported in the industry overview for the iron and steel foundries (the industry overview for iron- and metal foundries: Branchebeskrivelse for jern- og metalstøberier, 1997). However, it is expected that waste containing phenol is treated as hazardous waste and disposed/treated according to the instructions from local communities.

4.4 Summary and conclusions

Based on this and combined with the regulation already in place it seems that both liquid and solid waste containing phenol from both industrial and consumer uses will enter into the waste stream through the municipal collection of domestic waste i.e. through impregnating agent (such as tar and creosote for wood), varnishes and solvents.

For Denmark the main part of phenol is used for bakelite in stone wool and glass wool. According to information from industries the phenol content in mineral wool is not considered to pose a problem in waste. And in general it is expected that waste containing phenol is treated as hazardous waste and be disposed/treated according to the instructions from local communities.

The measured environmental concentrations are below (or close to) the quality criteria. And since phenol under optimal conditions degrades rapidly in the environment by aerobic conditions and also degrades anaerobically, it will likely be very limited quantities which remain in wastewater, wastewater treatment plants and groundwater. As soil microorganisms are capable of utilizing phenol as a growth substrate and volatilization of phenol is expected to be rapid from dry near-surface soils it will likely be very limited phenol quantities which remain in soil.

5. Environmental effects and exposure

Phenol is released from a number of man-made sources, but the diffuse emissions by automobile exhaust, human and animal metabolism and different combustion processes turn out to be higher than the industrial emissions (ECB, 2006). Phenol is non-persistent in the environment and the major part of phenol in the atmosphere is degraded by photochemical reactions. A minor part will be removed by rain. Phenol in water and soil is degraded by abiotic reactions and microbial activity.

The data in the following section are mostly based on information from the EU-Risk Assessment Report (EU-RAR) (ECB, 2006) and from Environment Canada (1999).

5.1 Environmental hazard

There have been many studies on the toxicity of phenol to organisms in the environment, covering short-term and long-term toxicity to fish/vertebrates, invertebrates, short term toxicity to algae and toxicity to microorganisms. For some of these data there were large discrepancies and it was decided by the EU member states not to use some of these data.

The selected values for the risk characterization by ECB (2006) are mentioned in the following.

Aquatic: The short-term acute toxicity data for fish, daphnia and algae (L(E)C₅₀) are all above 1 mg/l, but the lowest in the range from 1-10 mg/l. Long-term tests with species from three trophic levels are available for phenol. The most sensitive group was fish. The lowest long-term NOEC was found for the fish *Cirrhina mrigala* (2 day old larvae exposed to phenol for 60 days) with a Maximum Acceptable Toxic Concentration (MATC) of 77-94 µg/l reported. With the assumption that the MATC is given as the range between the NOEC and the LOEC, a NOEC of 77 µg/l was derived from this long-term test for fish. This chronic NOEC was supported by a MATC of 110-130 µg/l found for *Cyprinus carpio* and by a NOEC of 100 µg/l for *Oncorhynchus mykiss*. For the derivation of the PNEC_{aqua} an assessment factor of 10 was applied to the NOEC of 77 µg/l, resulting in a PNEC_{aqua} of 7.7 µg/l.

Microorganisms: From the various test results the lowest three were chosen to show the derivation of this PNEC. According to the different endpoints and sensitivities of the test systems, the following assessment factors (AF) were applied:

- *Pseudomonas putida* NOEC (6 h) of 15.1 mg/l AF = 1 ⇒ PNEC = 15.1 mg/l
- *Entosiphon sulcatum* NOEC (72 h) of 33 mg/l AF = 1 ⇒ PNEC = 33 mg/l
- *Nitrosomonas spec.* IC₅₀ (24 h) of 21 mg/l AF = 10 ⇒ PNEC = 2.1 mg/l
- Activated sludge, industrial IC₅₀ (0.5 h) of 300 mg/l AF = 100 ⇒ PNEC = 3 mg/l

As a worst case assumption a PNEC_{microorganism} of 2.1 mg/l was used in the risk characterisation for waste water treatment plants (ECB, 2006).

Sediment: Not enough data were available, but according to the physico-chemical properties currently known (logK_{ow} = 1.5), there is nothing indicating that phenol accumulates in sediment. Therefore ECB (2006) decided that a quantitative risk assessment were not necessary for sediment.

Atmosphere: Data on biotic or abiotic effects in the atmosphere were not available, but because of the short half-life adverse effects are not to be expected (ECB, 2006).

Terrestrial compartment: Data on earthworms and plants were used using the assessment factor (AF) of 1,000 as only results from acute tests were available. Therefore from a result for worm *Eisenia foetida*, 14-day, a LC₅₀ of 136 mg/kg (dry weight soil contained 10% peat) the PNEC_{soil} of 136 µg/kg dry weight was calculated (ECB, 2006).

Secondary poisoning: As phenol has only a low bioaccumulation potential (logK_{ow} = 1.5) no risk characterisation for secondary poisoning was carried out (ECB, 2006).

5.1.1 Classification

Phenol does not have a harmonized classification with respect to environmental effects.

Nevertheless, some notifiers have suggested such classifications. Out of 2870 notifiers it is:

- Aquatic Acute 1; H400 (Very toxic to aquatic life); 4 notifiers.
- Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects); 93 notifiers.
- Aquatic Chronic 3; H412 (Harmful to aquatic life with long lasting effects); 301 notifiers.

According to the CLP classification (No 286/2011 of CLP 1272/2008 table 4.1.0; EUR LEX, 2011) substances with chronic NOEC > 0.01 to ≤ 0.1 mg/l, should be classified with “Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)” if the substance is rapidly degradable. The aquatic chronic NOEC of 0.077 mg/l in the 60 day fish test on *Cirrhina mrigala* described in ECB (2006) leads to the evaluation that phenol fulfils the criteria for classification as “Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)”, which was also suggested in the REACH registration.

5.2 Environmental fate

Several reviews of the scientific literature on degradation rates of phenol in various environmental compartments have been prepared. Photooxidation in air and biodegradation in water and soil are expected to be the major removal processes (Environment Canada, 1999). The major part of phenol in the atmosphere is degraded by photochemical reactions to dihydroxybenzenes, nitrophenols, and ring cleavage products. A minor part will be removed by rain. Phenol in water and soil is degraded by abiotic reactions and microbial activity to a number of compounds, the most important of which are carbon dioxide and methane (IPCS, 1994). The fate of phenol in each environmental compartment is summarized briefly below.

Air: In the atmosphere, phenol exists predominantly in the vapour phase. The estimated half-life in air generally varies depending upon specific atmospheric conditions (e.g., temperature, time of year), and values ranging from 2.28 to 22.8 hours for reaction with hydroxyl radicals have been reported in the literature. A half-life of 17 hours for phenol in air for photooxidation is suggested (Environment Canada, 1999) covering one of the three main different schemes for photochemical degradation reactions (UV photolysis, UV photooxidation and UV photocatalytic oxidation). However, ECB (2006) reports a photochemical degradation of phenol with a half-life of 42 minutes. Because of its short half-life, phenol is not expected to be transported over great distances in the atmosphere. Phenol has the potential to be removed from the atmosphere via photooxidation by reaction with hydroxyl and nitrate radicals, photolysis, and wet and dry deposition (Environment Canada, 1999).

Water: The biodegradability of phenol in water has been shown in a number of investigations under the most varied conditions. Only two standardised tests for ready biodegradability are available. In these MITI-I-tests, levels of degradation amounting to between 60 and 70% (after 4 days) and to

85% (after 14 days) were determined. These results show that phenol is readily biodegradable. The results from the other available tests also points toward ready biodegradability (ECB, 2006). With the change for environmental classification according to CLP the term “readily biodegradable” has been changed to “rapid degradability” and is also mentioned as “rapid degradation”. The limit for readily biodegradable/rapid degradability is still > 70% biodegradation after 28 days (No 286/2011 of CLP 1272/2008 EUR LEX, 2011). In this survey “readily biodegradable” and “rapid degradability” will therefore both be used reflecting the source of the data being cited. Phenol reacts as a weak acid in water but, based upon its high pKa (9.99), is not expected to dissociate in the pH range typical in the natural environment. Phenol may undergo numerous removal processes, including biodegradation, photooxidation, photolysis and volatilization. Biodegradation is a major process for the removal of phenol from surface waters, provided the concentration is not high enough to cause significant inhibition. Phenol is non-persistent in water and will completely biodegrade over a period of approximately 70 hours. The suggested half-life of phenol in water is 55 hours. Phenol generally reacts with hydroxyl and peroxy radicals and singlet oxygen in sunlit surface waters. Half-lives were reported to be 100 hours for the hydroxyl radical reaction and 19.2 hours for the peroxy radical reaction. In estuarine waters, photolysis is a minor transformation process, particularly in summer when biodegradation predominates. The half-life of phenol due to volatilization from surface water is 3.2 months. The estimated half-life of phenol in groundwater ranges from 12 to 168 hours. Many factors influence the potential for groundwater contamination, including soil depth and type and microbial abundance (Environment Canada, 1999).

Sediment: Phenol has a low organic carbon/water partition coefficient ($\log K_{oc} = 1.15-3.49$) and a low octanol/water partition coefficient ($\log K_{ow} = 1.46$) and is therefore not expected to significantly adsorb to suspended or bottom sediment in water. A biodegradation half-life of 550 hours for phenol in sediment was suggested (Environment Canada, 1999).

Soil: The physical and chemical properties of soil that influence the fate and behaviour of phenol are pH, exchange capacity, organic matter, clay content and texture. Phenol may undergo numerous removal processes, including biodegradation, adsorption/desorption, volatilization and oxidation. These processes determine the mobility (e.g., leaching), distribution and persistence of phenol in soil.

Phenol is an abundant naturally occurring chemical that tends to biodegrade rapidly in the environment. Both aerobic and anaerobic soil microorganisms are capable of utilizing phenol as a growth substrate, although decomposition is more rapid under aerobic conditions than under anaerobic conditions. The reported biodegradation half-life of phenol in various soil types ranges from 2.7 to 552 hours. The suggested half-life of phenol in soil is 170 hours. Degradation of phenol decreases with increasing concentration, indicating inhibition of biodegradation by phenol itself.

Because phenol has a low $\log K_{oc}$ and a low $\log K_{ow}$, sorption to organic matter is expected to be low. In acidic soil, low adsorption and high mobility have been reported for phenol.

Because of a moderate vapour pressure (47 Pa) and a Henry's law constant of $0.059 \text{ Pa} \cdot \text{m}^3/\text{mol}$, volatilization of phenol is expected to be rapid from dry near-surface soils. Phenol is sensitive to oxidizing agents (including metal ions, such as manganese and iron) and may auto-oxidize to form coloured complexes such as quinones (Environment Canada, 1999).

Biota: Bioconcentration factors (BCFs) are reported. ECB used the BCF of 17.5 from fish for its further assessment (ECB, 2006).

In conclusion phenol is regarded as readily biodegradable and not bioaccumulating, thus non-persistent. With a $\log K_{ow} = 1.46$ and a $\text{BCF} = 17.5$ phenol is not bioaccumulating according to the

limits for classification ($\log K_{ow} < 4$; $BCF < 500$). With the data mentioned above phenol also fulfils the limit for being readily biodegradable of $> 70\%$ biodegradation after 28 days.

5.3 Environmental exposure

Phenol is released from a number of man-made sources. The primary sources of environmental phenol are automobile exhaust (direct emission and photochemical degradation of benzene), human and animal metabolism and different combustion processes. From industrial sources, it enters the environment from production and processing operations. Releases also occur due to the waste water from cooking plants and low-temperature carbonisation plants using hard coal and brown coal, from refineries, from pulp manufacture and landfill leachate.

The diffuse emissions by automobile exhaust, human and animal metabolism and different combustion processes turn out to be higher than the industrial emissions (ECB, 2006).

5.3.1 Sources of release

Phenol is released into the environment from natural sources and during production and processing. The following releases are estimated for Europe.

Diffuse sources for phenol release: The sources cover (ECB, 2006):

- Release through photochemical degradation of benzene to the atmosphere: Benzene in the presence of NO and NO₂ with OH radicals is converted to phenol with a yield of about 20%. A release of phenol due to the photochemical degradation of benzene in the atmosphere amounting to approximately 84,600 tonnes/annum for the EU. Release as a result of vehicle exhaust fumes: Phenol is formed during the incomplete combustion of motor fuels amounting approximately 8,814 tonnes/annum for the EU (see table 6).
- Release as a result of further combustion processes. Phenol is formed during the combustion of organic substances:
 - a) from smoke gases from using brown-coal briquettes as fuel in family house (approximately 355 tonnes phenol/annum).
 - b) from smoke gas during the combustion of wood (approximately 218 tonnes/annum).
 - c) from decomposition products of lignin, above all in the case of bush and forest fires. Larger quantities of phenol may be released into the atmosphere, but no amount was estimated.
 - d) from cigarette smoke where a phenol emission of approximately 50 tonnes/annum was estimated for Germany.
 - e) from combustion processes, such as those involving hard coal, fuel oil or fuel gas, but release quantities are not available.

Industrial production and processing sources: As mentioned in section 3.3 there are different kinds of production and processing with possible phenol releases. In EU these sources are mainly the production of bisphenol A, caprolactam, salicylic acid, diphenyl ether, alkyl phenols, nitrophenols, halogen phenols and phenolic resins. Other sources for release are the manufacture of nylon and other synthetic fibers, the use in slimicides, the use as a disinfectant and antiseptic, and the use in cosmetics and medicinal preparations.

Phenol is released into the environment during production and processing in estimated amounts for Europe of:

- Approximately 124 tonnes/annum into the hydrosphere and
- approximately 535 tonnes/annum into the atmosphere.

In relation to the releases of phenol as a result of industrial production and processing, the diffuse releases of phenol into the environment are considerably higher and represent the main source of phenol in the environment. The figures for EU are:

- From human metabolism, approximately 2,096 tonnes/annum phenol is released into the hydrosphere and approximately 6 tonnes/annum into the soil via the spreading of sewage sludge.
- Releases into the atmosphere due to the photochemical degradation of benzene, vehicle exhaust fumes and a very wide range of combustion processes were calculated to be approximately 96,830 tonnes/annum. Despite the high release quantities, no substantial transport from the atmosphere into other environmental compartments is expected due to fast photochemical degradation of phenol (half-life = 42 minutes).

TABLE 6
EMISSION OF PHENOL FROM DIFFERENT SOURCES IN EU (ECB, 2006).

Source of phenol	Release into the hydrosphere in t/a	Release to soil	Release into the atmosphere in t/a
Production and processing	124	-	535.5
Human metabolism	2,096	Approx. 6	-
Photochemical degradation of benzene	-	-	84,600
Vehicle exhaust fumes	-	-	8,814
Further combustion processes	-	-	2,880
Total	-	-	96,829.5

Based on these figures and consideration of all point sources and diffuse emissions, a regional background concentration of phenol in the hydrosphere of 2.41 µg/l was calculated by ECB (2006). Furthermore for the atmosphere, a regional PEC of 0.026 µg/m³ and in natural soil a regional background concentration of 0.59 µg/kg was estimated. **In conclusion** the local exposure in EU of the environment as a result of production and industrial use of phenol in the chemical industry has been estimated to be significantly below the concentrations resulting from unintentional releases. No unacceptable risks for the environment have been identified for the production and industrial use of phenol in EU (ECB, 2006).

5.3.2 Monitoring data

There are some data on phenol in air, water or soil in EU. Examples are mentioned:

- Air: Mean phenol emission in cigarette smoke is 0.4 mg/cigarette (ECB, 2006).
- Water environment: From refinery waste water, the average concentrations of phenol in final effluents of seven refineries in Ontario (Canada) were monitored for a 12 month period in 1989-90. The concentrations ranged from 0.24 to 9.56 µg/l (ECB, 2006).
- Soil: Phenol in contaminated soils at a gasworks near Copenhagen in 1987 reveals concentrations between 0.05 and 29 mg/kg (ECB, 2006).
- Sludge: Average concentration of phenol in sludge in Denmark 1998-2003 was 29 mg/kg (KU, 2010).

As phenol in the atmosphere is degraded by photochemical reactions and phenol in water and soil is degraded by abiotic reactions and microbial activity and phenol is not bio-accumulating exposures will not persist for a long period.

5.4 Environmental impact

ECB (2006) concludes that there is at present in EU no need for further information and/or testing and for risk reduction measures beyond those which are being applied already for the aquatic compartment, atmosphere, the terrestrial compartment and secondary poisoning.

The risk reduction measures applied by EU covers:

- Special regard to potential risks from phenol production and/or processing sites, in respect of industrial wastewater treatment plants situated at such sites. This include also in respect of humans exposed via the environment (plant shoots contaminated by air emissions from such sites), e.g. to prevent secondary poisoning.
- Emission limit values or equivalent parameters or technical measures regarding phenol in order to operate according to the Best Available Techniques (BAT). This includes the technical characteristic of the installations concerned, their geographical location and the local environmental conditions in the permits issued under Directive 96/61/EC (Integrated Pollution Prevention and Control).
- Monitoring the implementation of BAT regarding phenol and report any important developments to the Commission in the framework of the exchange of information on BAT.
- Include phenol in the on-going work to develop guidance on BAT, to facilitate permitting and monitoring under Council Directive 96/61/EC (EC, 2007; EC, 2008).

For about 25% of the biological waste-water treatment plants (WWTPs) ECB (2006) state that there was a need for limiting the risks to the microorganism population. However the risk reduction measures has been applied (EC, 2007; EC, 2008). These included controlling of local emissions to the environment and to industrial wastewater treatment plants by national rules to ensure that no risk for the microorganisms in the industrial wastewater treatment plants and to humans exposed via the environment is expected (EC, 2007; EC, 2008). These national rules cover in Denmark the Danish Statutory Order no. 1022 of 25/08/2010 on environmental quality standards for water bodies and requirements for the discharge of pollutants into rivers, lakes or the sea, the Danish Statutory Order on approval of listed companies no. 1454 of 20/12/2012 on requirements and conditions on the storage and handling of hazardous substances generally through the environmental approval of the company and the Danish Statutory Order no. 1666 of 14/12/2006 on minimizing the risk of release through control of the major-accident hazards involving dangerous substances.

But for the unintentional releases part ECB (2006) concludes that the there is need for further information and/or testing. This covers:

- Release of phenol as a product of human metabolism with 30% of the EU population releasing their waste water directly into a receiving stream. ECB concludes that the risk could not be calculated and that further investigations are needed. However, Denmark discharges more than 90% of the total volume of wastewater through wastewater treatment plants (Danish Nature Agency: Naturstyrelsen, 2011).
- Exposure for the aquatic environment with regard to the areas relating to the cooking, gasification and liquefaction of coal, refineries and pulp manufacture. It has not been possible to provide estimation.
- Exposure from spreading of liquid manure from livestock farming. For the spread of liquid manure derived from livestock farming over agricultural areas it has not been possible to estimate a total release to soil (see section 4).
- Exposure to the aquatic and terrestrial environment from landfills without landfill leachate collecting system. It has not been possible to estimate the exposure for those without landfill leachate collecting system (ECB, 2006).

To this EC addresses management via the directives and actions including needed additional risk management via Directive 2000/60/EC (Water Framework Directive) (see table 3) and legislation

with regard to soil protection (covering EC/166/2006 and Council Decision 2006/61/EC on Pollutant Release and Transfer Register for soil) together with Council Directive 1999/31/EC, which are considered sufficient to address potential risks from landfills without landfill leachate collecting systems (EC, 2008).

Following these EC recommendations with phenol falling under Annex VIII of the Water Framework Directive, Member States have derived Environmental Quality Standards (EQSs) for phenol. These EQS are in line with the 7.7 µg/l valid in Denmark (see table 3) (UK Environment Agency, 2007; UK Technical Advisory Group, 2008; NIEA, 2009).

Apart from the unintentional releases where the main part is caused by the natural content of phenol in humans, manure and organic materials from wood as coal and paper the risk is either not present or controlled.

Overall the major part of phenol in the atmosphere is degraded by photochemical reactions and phenol in water and soil is degraded by abiotic reactions and microbial activity. Phenol is not regarded as toxic with its L(E)C₅₀ above 1 mg/l and it is readily biodegradable (has rapid degradability) and has no potential for bioaccumulation.

5.5 Summary and conclusions

The major part of phenol in the atmosphere is degraded by photochemical reactions. A minor part will be removed by rain. Phenol in water and soil is degraded by abiotic reactions and microbial activity.

Phenol is not regarded as toxic with its L(E)C₅₀ above 1 mg/l and it is readily biodegradable (has rapid degradability) and has no potential for bioaccumulation. But as phenol has its chronic NOEC > 0.01 to ≤ 0.1 mg/l, phenol fulfils the criteria for classification as “Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects)” according to CLP, as suggested by 93 notifiers, including the REACH registrant.

Phenol is released from a number of man-made sources. The primary sources of environmental phenol are automobile exhaust (direct emission and photochemical degradation of benzene), human and animal metabolism and different combustion processes. From industrial sources, it enters into the environment from production and processing operations. Releases also occur due to the waste water from cooking plants and low-temperature carbonisation plants using hard coal and brown coal, from refineries, from pulp manufacture and landfill leachate.

The diffuse emissions by automobile exhaust, human and animal metabolism and different combustion processes are higher than the industrial emissions.

With regard to the local exposure of the environment, as a result of production and industrial use of phenol in the chemical industry, then no unacceptable risks for the environment have been identified for the production and for industrial use of phenol in EU. Apart from the unintentional releases (where the main part is caused by the natural content of phenol in humans, manure and organic materials from wood as coal and paper) the risk is either not present (calculations from ECB (2006) resulted in a predicted environmental concentration below the predicted no effect concentration) or controlled. It is controlled through the WFD, legislation with regard to soil protection and Council Directive 1999/31/EC regarding the potential risks from landfills without landfill leachate collecting systems.

Based on the evaluation by ECB there is no need for risk reduction measures beyond those which are being applied already for the aquatic compartment, atmosphere, terrestrial compartment, and secondary poisoning. These risk reduction measures already applied cover emission limit values/technical measures (operate according to the BAT and Directive 96/61/EC as well as

monitoring the implementation of BAT) apart from the potential risks from Member States concerning phenol production/processing sites and apart from phenol in the on-going work of developing guidance on BAT and of facilitating permission and monitoring under Council Directive 96/61/EC concerning integrated pollution prevention and control (EC, 2007; EC, 2008).

Overall, as phenol degrades in the environment, it will likely be very limited quantities which remain in wastewater, wastewater treatment plants and groundwater. And as soil microorganisms are capable of utilizing phenol as a growth substrate and volatilization of phenol is expected to be rapid from dry near-surface soils, it will likely be very limited phenol quantities which remain in soil.

6. Human health effects and exposure

The newer safety evaluation by WHO and FAO/JECFA on phenol (WHO, 2011) did not add newer information on phenol to that included in ECB from 2006. But in 2009 EFSA was asked by the German Federal Institute for Risk Assessment (BfR) to re-evaluate the TDI for phenol. The CEF Panel (the Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids) by EFSA went through the available data for phenol, including new studies (EFSA, 2013). In the following “the Panel” refers to the CEF Panel.

6.1 Human health hazard

6.1.1 Classification

Phenols harmonised classification according to CLP is:

- Acute Tox. 3; H301; Toxic if swallowed (former R25)
- Acute Tox. 3; H311; Toxic in contact with skin (former R24)
- Skin Corr. 1B; H314; Causes severe skin burns and eye damage (former R34)
- Acute Tox. 3; H331; Toxic if inhaled (former R23)
- Muta. 2; H341 Suspected of causing genetic defects (former Mut3;R68) and
- STOT RE 2; H373 May cause damage to organs through prolonged or repeated exposure (former Xn; R48/R20/21/22).

6.1.2 Toxicokinetics, absorption, distribution, metabolism and excretion

Exposure to phenol may occur through inhalation, ingestion or dermal contact. Phenol is well absorbed via gastrointestinal, respiratory tract and the dermal route even when applied to intact skin and it is rapidly distributed throughout the body. In its risk assessment ECB uses 100% uptake rates of oral and inhalation absorption, whereas for dermal exposure the rate was set to 80%. The liver and kidneys achieve the highest concentrations of phenol-derived products. After oral exposure, phenol undergoes large first-pass metabolism, with high absorption rates (e.g. 90% (rats), 85 % (sheep), and 84% (pigs). Via inhalation 60 to 88% phenol is absorbed (humans).

The metabolism of phenol is saturable and it predominantly occurs in liver, gut and kidneys. Data in humans and laboratory animals support that phenol is rapidly excreted in urine, which is the main elimination pathway (mostly as phenyl sulfate and phenyl glucuronide), and that it does not accumulate in the body (ECB, 2006; EFSA, 2013). After dermal application of phenol to rats the excretion by urine was essentially complete (with 75%) by 24 hours (ECB, 2006). A halftime of about 3.5 hours for urinary excretion was reported in Danish EPA (1995).

6.1.3 Toxicity

The toxicity data on phenol were reviewed by ECB (2006) and by EFSA (2013) as compiled below. As phenol has been used for more than 100 years, a large part of the human health effects known today is due to poisoning cases etc. in historical times.

6.1.3.1 Acute toxicity

The lethal oral dose for humans is reported to be 140-290 mg/kg body weight. For animals, oral LD₅₀ values of 340 mg/kg bw are reported for rats, of approximately 300 mg/kg bw for mice, and of less than 620 mg/kg bw for rabbits. A dermal LD₅₀ value of 660-707 mg/kg bw was determined for female rats (ECB, 2006).

However, an inhalation exposure may be of concern. LC₅₀ values are not available but rats are reported to tolerate phenol concentrations as high as 900 mg/m³ for 8 hours, resulting in ocular and nasal irritation, loss of co-ordination, tremors, and prostration (ECB, 2006).

6.1.3.2 Irritation/corrosivity

Corrosivity is the main effect at the site of contact. Skin and eyes can be severely affected when coming into contact depending on substance concentration (even a 1% phenolic solution is reported to have caused severe chemical burns and skin necrosis) (ECB, 2006). Phenol has the harmonised classification “C, corrosive” and “R34, causes burns” which is now transferred to “Skin Corr. 1B; H314; Causes severe skin burns and eye damage”.

6.1.3.3 Sensitisation

There is no evidence of skin sensitising properties of phenol in animal tests as well as through human experience (ECB, 2006).

Diabetics using insulin preserved with phenol report allergic reactions after insulin injection, which they believe is caused by the phenol content (single observations seen on the internet). They report affects like “suffering with severe, asthma like, chest pain and the inability to catch my breath” (see exposure from medical treatment below).

Based on this the Danish Health and Medicines Authority was contacted. Adverse reaction reports from the database at Danish Health and Medicines Authority show that there are few cases of anaphylactic reactions and some cases of injection-related allergic reactions, but there were no cases of difficulty breathing, chest pain, etc. None of the reports indicated that the allergic relationships were related to phenol. The insulin product information for Levemir, Humulin NPH and Pethidine has no information about that phenol can cause allergic reactions, and phenol are also not mentioned in the Excipient guideline (EC, 2003). Furthermore, based on the number of allergic reactions such as chest pain and breathing difficulty, there is no immediate evidence to suggest a tendency for products containing phenol (Personal communication, Per Sindahl, Danish Health and Medicines Authority, August 2013).

6.1.3.4 Repeated dose toxicity

A range of studies with oral, inhalative, dermal, subcutaneous, intra-peritoneal application modus, and with short repeated periods (only few days) up to sub-chronic exposure (90 days) on several species (rat, mouse, rabbit, guinea pig) showed effects on central nervous system, bone marrow (hemopoietic system and stromal cell function), immune system, liver, lung, kidneys, heart, and skin (ECB, 2006). Repeated exposures induced muscle tremors and loss of coordination. Exposure to high concentrations of phenol in the air for several weeks caused paralysis and severe injury to the heart, liver, kidneys, and lungs, and in some cases, death (ATSDR, 2008; Danish EPA, 2002c). The studies, which serve as the background for classification with STOT RE 2, H373; May cause damage to organs through prolonged or repeated exposure (former R48 with R20, 21 or 22) are summarised in table 7.

TABLE 7
SUMMARY OF THE RELEVANT TOXIC EFFECTS GIVING RISE TO THE R48 CLASSIFICATION (TABLE 4.12 IN ECB, 2006).

Application route	Oral	Inhalation
Study	Subacute	subacute/subchronic

duration		
Critical dose for classification	≤150 mg/kg bw/day	≤ 0.75mg/l/< 0.25 mg/l
Species		
Mouse	28 days/drinking water: RBC↓ ≥1.8 mg/kg bw/day hematocrit↓ ≥33.6 mg/kg bw/day brain neuro-transmitters↓ ≥1.8 mg/kg bw/day (Hsieh et al., 1992)	
Rat	14 days, gavage: premature deaths at 120 mg/kg delayed pupil response at 120 mg/kg bw/day liver and kidney degeneration at 40 mg/kg bw/day spleen/thymus atrophy and necrosis ≥ 12 mg/kg bw/day (Berman et al., 1995; Moser et al., 1995, MacPhail et al., 1995)	14 days motor disorders and impaired function of balance regulation at 0.1 mg/l (Dalin and Kristoffersson, 1974)
Rabbit		63 exposures during 88 days: degeneration of the myocard, liver and kidneys at 0.1-0.2 mg/l (Deichmann et al., 1944)
Guinea pig		20 exposures during 28 days: unscheduled deaths, decreased activity, paralysis, degeneration of the myocard, liver and kidneys at 0.1-0.2 mg/l (Deichmann et al., 1944)

6.1.3.5 Chronic toxicity and carcinogenicity

Long-term exposure to phenol has shown effects on the nervous system and liver (in humans and animals), and on hematopoietic and immune system, kidneys, and skin (animals) (ECB, 2006). When prior treatment with a known carcinogen has been performed, phenol has demonstrated promotion of skin cancer in mice. This is associated with a stronger effect of phenol due to the corrosive properties of phenol (Danish EPA, 2002c).

Results from a chronic/carcinogenicity study on rats and mice (1000 ppm and 5000 ppm in the drinking water) in 1980 showed no other non-neoplastic effects than reduced body weight for rats at the high dose and for mice at both doses, with the only possible exception of chronic inflammation of the kidney of female rats. Increases in tumour incidence were only seen in male rats and mainly in the low dose group, in the absence of a dose-response relationship. Based on the overall evidence the Panel considered that the results did not provide evidence of carcinogenic effects of phenol for rats and mice under the test conditions applied (EFSA, 2013).

6.1.3.6 Reproductive and developmental toxicity

Phenol has caused minor birth defects and low birth weight in animals generally at exposure levels that also were toxic to the pregnant mothers. A two-generation study on impairment of reproductive performance and fertility in rats was by the Panel seen as the key study. At the highest tested drinking water concentrations of 5,000 ppm, which led to reduced water intake and consequently decreased body weight and body weight gain in the parents (Po) and offsprings (F1 generation), no impairment of reproductive capability and fertility was revealed for both sexes. However, this two-generation toxicity study on impairment of reproductive performance and fertility (by Ryan et al. (1999, 2001) cited in EFSA, 2013) reports a reduction in pup survival across both generations, with the effect being more pronounced in the F2 generation. No NOAEL for the F2 generation or further information on effects in the developing F2 generation were provided. The systemic NOAEL for Po and F1 was considered by the Panel to be 70 mg /kg bw/day for males and 93 mg phenol/kg bw/day for females based on reduced water intake, body weight and organ weight changes in the Po and F1 animals and the reduction in pup survival across both generations. In another key study on the developmental toxicity study on phenol in rats (York, 1997 cited in EFSA, 2013), foetal body weights were significantly reduced for males and females in the highest dosage groups (360 mg/kg bw/day) and were associated with reduced maternal body weights in this group. This high dose did not affect any other Caesarean-sectioning or litter observations. All foetal gross external, soft tissue and skeletal malformations were considered unrelated to the test article. Maternal body weight and body weight gain were always reduced until the end of the study at the highest dose. Also a slight but significant reduction in the maternal rat body weight gains was seen at the mid dose of 120 mg/kg bw/day, supporting a maternal NOAEL of 60 mg/kg bw/day. This NOAEL is only slightly lower than the systemic NOAEL from the first study of 70 mg /kg bw for males and 93 mg phenol/kg bw for females.

ECB (2006) concludes from the assessment of the available animal studies that phenol was not identified to possess any specific properties adverse to reproduction.

6.1.3.7 Immunotoxicity

In ECB (2006) a 28 day immunotoxicity study in mice by Hsieh et al. (1992) cited in EFSA (2013) was selected as the critical study for repeat dose toxicity of phenol. But in the view of the Panel, two other studies on rats do not substantiate the immunotoxic potential suggested by the Hsieh study (EFSA, 2013).

6.1.3.8 Neurotoxicity

The study reported by Hsieh et al. (1992) also included neurochemical investigations on CD-1 mice administered doses equivalent to 1.8, 6.2, and 33.6 mg/kg bw/day in the drinking water for 28 consecutive days. Because of limitations in the study performance and reporting, no conclusions could be drawn, and no NOAEL could be established for this toxicological endpoint.

In the neurotoxicity study by Beyrouthy (1998) cited in EFSA (2013) the Panel noted that changes in female motor activity were reported at a low phenol dose (107 mg/kg bw/day), and therefore initially considered these data for dose-response modelling. However, the Panel decided not to further analyse these data in consideration of the shortcomings in the study reporting and statistics and of the variability of changes in motor activity counts. The Panel noted however that in 2002 the U.S. EPA had performed BMD analyses of these data obtaining a BMDL value of 219 mg/kg bw/day, which is higher than the BMDL10 values estimated from the York and Ryan studies.

6.1.3.9 Genotoxicity

Phenol showed DNA-damaging activity in *in vitro* tests in yeast and mammalian cells. In *in vivo* studies with orally administered phenol, negative results were obtained in tests in rodents for chromosomal aberrations, DNA strand breaks and DNA adducts, while negative or borderline positive results were obtained in bone marrow micronucleus tests in mice. Based on the current weight of the evidence, the Panel concluded that orally administered phenol is devoid of biologically

relevant genotoxicity *in vivo*. This conclusion is in line with the results of long term oral studies in rodents, which the Panel concluded did not provide evidence that phenol was carcinogenic for rats and mice under the test conditions applied (EFSA, 2013).

Phenol is classified as category 3 mutagen and labelled “R 68, possible risks of irreversible effects” (ECB, 2006), which is now transferred to “Muta. 2;H341 (suspected of causing genetic defects)” (ECB, 2006).

6.1.4 Dose response modelling (TDI and DNELs)

EFSA was asked to re-evaluate the former TDI for phenol of 1.5 mg/kg bw/day, since this value is within the same dose range which was reported to be associated with some haematotoxic and immunotoxic effects in an oral study on phenol. The old TDI of 1.5 mg/kg bw/day was set by the Scientific Committee for Food (SCF) in 1984 on the basis of data available at the time. This refers to “90-day oral studies in mice and rats, multigenerational studies oral in rats and 2-year studies oral in mice and rats”, with no further specification given on the studies (EC, 1984). The Panel comprehensively reviewed the available toxicological studies, mainly those using an oral route of exposure. The Panel did not consider immunotoxicity as a suitable endpoint on which to base a new TDI for phenol, given the study limitations and the lack of confirmation of phenol-induced immunotoxic effects in other studies. The Panel considered a gavage developmental toxicity study by York, 1997 and an oral two-generation reproduction toxicity study by Ryan, 1999 as the two most robust toxicity studies, and performed a dose-response analysis of these data using the benchmark dose (BMD) approach. The lower 95 % confidence bound (one-sided) of the BMD, denoted BMDL, was then taken as the reference point.

The Panel noted that the lowest point of departure was provided by the York study for reduced maternal body weight gain in rats exposed to phenol by gavage from GD6 to GD16. Therefore, the Panel used the BMDL₁₀ of 52 mg/kg bw/day from this study to derive a TDI for phenol. The Panel considered it appropriate to apply to this value a standard uncertainty factor (UF) of 100 to account for inter- and intra-species variability, and derived a TDI of 0.5 mg/kg bw/day. Further adjustment factors to account for the short duration of the treatment in the York study were not considered necessary, as data from other studies of longer duration such as the Ryan study and the 90-day and chronic oral toxicity studies from NTP in 1980 support the effect levels seen in the York study (EFSA, 2013). The new TDI for phenol is now 0.5 mg/kg bw/day.

In the joint registration of phenol under REACH a long term oral DNEL for the general population is proposed at 0.4 mg/kg bw/day, thus slightly lower than the new TDI value. The registrant evaluated that an oral DNEL for oral toxicity is not relevant for the worker. The registration includes a chronic inhalation DNEL of 7.8 mg/m³ for systemic long-term effects for the worker, while the value for the consumer is proposed to be 1.32 mg/m³. Further, a dermal long-term systemic DNEL for the worker, of 1.23 mg/kg bw/day, based on route-to-route extrapolation from the OEL is proposed. For the general population the chronic systemic dermal systemic DNEL is proposed at 0.4 mg/kg bw/day.

6.2 Human exposure

6.2.1 Direct exposure

Consumers:

Chronic exposure by use of phenol-containing consumer products may occur via the inhalation and dermal route. According to ECB (2006) the use of phenol-containing disinfectants, antiseptics, medicinal products, cosmetics, paints, floor waxes, polishes etc., and other consumer products or application of phenol-formaldehyde resins may result in dermal and/or inhalatory exposure of consumers to unbound phenol. Some phenol-containing products used by consumers are mentioned: primers (content < 1.0%) and two-component adhesives (content < 2.5%), (ECB, 2006).

Inhalation: Exposure from using polishes/floor waxes, disinfectants, printing inks and 2-component-adhesives besides inhalation of cigarette smoke was calculated by ECB. In addition phenol has been measured in different surveys by the Danish EPA (See table 8).

TABLE 8
INHALATION EXPOSURES FOR CONSUMERS.

Product/parameter	Description and calculations	Reference
Polishes/floor waxes*	30 g of product containing 2.5% phenol used every day for a period of 0.144 hours: The average room concentration was estimated to ≈ 4.0 mg/m ³ during use (0.144 hours) and an average of 1.1 mg/m³ after use (20 hours). From this estimation, the active user will be exposed to a maximum of 0.063 mg/kg/bw/day, and to 0.48 mg/kg/bw/day after use. The daily use of products was mentioned as the most important source of exposure. Bystanders, e.g. children may also be exposed to considerable amounts after use of about 0.7mg/kg/bw/day .	ECB (2006)
Disinfectants*	For a weekly use, the average phenol concentration in room air of 0.08 mg/m ³ after use, resulting in 0.018 mg/kg/bw/day (for a female person staying in the room for 20 hours) and 0.048 mg/kg/bw/day (for a child staying 15 hours). No further details were given in this scenario.	ECB (2006)
Printing inks and 2-component-adhesives (< 2.5%)*	0.02 mg phenol/kg per event. No further details were given in these scenarios.	ECB (2006)
Inhalation of cigarette smoke	In a non-ventilated room having a volume of 50 m ³ , the smoke from 10 cigarettes will result in a phenol concentration of 0.06-0.08 mg/m ³ , resulting in 0.02 mg/kg bw/day (respiratory volume 19 m ³ within 20 hours).	ECB (2006)
Computer**	0.0161 mg/m ³	Danish EPA (2006d)
Monitor**	minimum 0.0181 - 0.0226 mg/m ³	Danish EPA (2006d)
Playing console**	0.0005 - 0.0015 mg/m ³	Danish EPA (2006d)
Pressing iron**	0.0001 - 0.0014 mg/m ³	Danish EPA (2006d)
Household oven**	0.0003 mg/m ³	Danish EPA (2006d)
TV apparatus**	0.001 - 0.0034 mg/m ³	Danish EPA (2006d)
Chargers and transformers**	minimum 0.0001 - 0.0014 mg/m ³	Danish EPA (2006d)
Tents**	0.018 (3 h in climate chamber), 0.015 (after 3 days) and 0.007 mg/m ³ (after 10 days), respectively	Danish EPA (2006d)
Chloroprene products (gloves, waders)**	approximately 0.00063 mg/m ³	Danish EPA (2006d)

Product/parameter	Description and calculations	Reference
Concentration in model room**	0.0014 - 0.0436 mg/m ³	Danish EPA (2006d)
Pine tar	5 products with phenol content between 1.000 – 11.000 mg/kg (0.1 to 1.1%). Concentration in inhaled air from the tare with the highest content was 73 µg/m ³ , which is only about 2% of the limit value of 4000 µg/m ³ for phenol during work (1,7 dm ² wood were added 1,2 g tare at 20 °C, inhaled air content measured on day 0).	Danish EPA (2012). The products were bought in 2005.

*) The phenol content was based on concentrations reported in the products available from the Swedish product register (1995); Berufsgenossenschaft der Bauwirtschaft (1995), the product data base of the BfR and content reported between 1988 and 1990 available from Spiller et al. (1993), cited in ECB (2006). This means that the calculations from ECB are based on knowledge of the phenol content in products, which is at least almost 8 years old and the use as biocide and content in cosmetics is no longer permitted.

**) The scenarios cover indoor air concentrations in a room of 17.4 m² and an air flow of 0.5 h⁻¹.

During the application of floor waxes/polishes, and disinfectants consumers may be exposed via inhalation. The average concentration after use of floor waxes was calculated to be 1.1 mg/m³, which by ECB was used for the risk characterisation of chronic exposure. Exposure of consumers due to prolonged (chronic) inhalation was estimated not to exceed 0.48 mg/kg bw/day for female adults and 0.7 mg/kg bw/day for 10-year-old children, respectively. A very rare acute exposure by using high amounts of paints containing phenol as a conservation agent may lead to higher values. However, the frequency of occurrence of acute exposure was not assessed due to lack of sufficient information on the number of phenol-containing products available on the market (ECB, 2006).

Based on different collections of maximal worst-case phenol exposure, which is in a children's room, a concentration of 0.062 mg/m³ is calculated. For a child weighing 10 kg inhaling the worst-case concentration of 0.062 mg/m³ the whole day with an inhalation rate of 0.6 m³/h, it receives a total dose of about 0.9 mg/day or 0.09 mg/kg bw/day; or a little below the USEPA Reference Dose (RfD) for phenol of 0.1 mg/kg bw/day developed with a built-in safety factor. This shows that in a children's room, where a single pollution source may not be important, the total burden to phenol from all sources in the worst case may approach the highest tolerable for children (Danish EPA, 2006d).

Dermal: Phenol vapours are absorbed by the dermal route, thus contributing to the total dermal exposure in addition to the dermal contact with phenol-containing products. Exposure from dermal contact with polishes/floor waxes, disinfectants and cosmetics was calculated by ECB and other investigations were available from surveys by the Danish EPA (see table 9).

TABLE 9
DERMAL EXPOSURES FOR CONSUMERS.

Product/parameter	Description and calculations	Reference
Polishes/floor waxes	The dermal exposure was estimated to 0.44 mg/kg bw per event. Hand contact with the wiping cloth (210 cm ² x 25 mg/cm ³ (maximum concentration of phenol on wiping cloth) x 0.01 cm (thickness of layer on skin) x 0.5 (dilution factor) revealing an exposure of 26.25 mg/event corresponding to 0.44 mg/kg bw per event.	ECB (2006)
Disinfectants (no longer permitted)	The dermal exposure was estimated to 0.9 mg/kg bw per event (corresponding to an internal exposure of 0.72 mg/kg bw/day assuming 80 %	ECB (2006)

Product/parameter	Description and calculations	Reference
	dermal absorption). Hands in disinfectant solutions using 52.5 mg phenol/event (420 cm ² surface x 25 mg phenol/cm ³ product x 0.5 (dilution factor) x 0.01 cm thickness of product layer on the skin).	
Cosmetics (no longer permitted)	<p>In EU member states the use of phenol and its alkali salts in soaps and shampoos was permitted in concentrations up to 1% (calculated as phenol), but put on the list of prohibited cosmetic ingredients in 2005 (substance no. 1175, Annex, 2005/80/EC). Dermal exposure of the consumer via soaps and shampoos was assumed to be 0.0213 mg/kg bw/day (8 µg/kg bw/day from soap used 6 times per day and 13.3 µg/kg bw/day from shampoo used once a day), (ECB, 2006).</p> <p>Phenol was found in 5 pleasure gel bought in DK in 2005 in concentrations between 1.0 and 20 mg phenol/kg gel (Danish EPA, 2006a).</p> <p>Phenol was also found in 7 cosmetics products for treatment of sports injuries and pains bought in DK in 2005. The phenol content was 2.4 and 16 mg/kg in 2 gels, 5.6 mg/kg in a stick, 2 and 11 mg/kg in two conditioners and 4.4 and 6.5 mg/kg in two ointments (Danish EPA, 2006b). Thus in total the concentrations are between 1.0 and 20 mg phenol/kg product investigated by Danish EPA, corresponding to 0.0001 to 0.002% and thereby far below the 1% used in the calculations by ECB (2006).</p>	ECB (2006); Danish EPA (2006a); Proshave (2013)
Laminating film	The dermal exposure was estimated to 0.0053 mg/kg bw day based on 269 mg/kg film as the measured phenol migration.	Danish EPA (2008a)
3 School bags & a toy bag	1-3 mg/kg, migration in artificial sweat corresponding to 0.00018 – 0.00074 mg/kg bw/day with dermal contact.	Danish EPA (2007).
Pine tar	5 products with phenol content between 1,000 – 11,000 mg/kg. Migration in sweat corresponding to 730 – 2,867 µg/dm ² .	Danish EPA (2012). The products were bought in 2005.

The dermal exposure from use of phenol containing waxes and disinfectants was accounted to 0.44 mg/kg bw/event and 0.9 mg/kg bw/event, respectively (ECB, 2006).

The dermal exposure of the consumer via cosmetics (soaps and shampoos) was assumed to be about 0.021 mg/kg bw/day (ECB, 2006). However, as phenol is now prohibited in cosmetics, this source of exposure is expected to be negligible. The dermal exposure of consumers via disinfectants lead to the conclusion in the RAR report in ECB (2006) that there was a need for limiting the risks because of systemic repeated dose toxicity and possible skin irritation. Phenol is not permitted as a biocide in disinfectants.

Oral: BfR (2009) report phenol concentrations in utensils and toys with mucous membrane contact in concentration ranged from 400 to 500 mg/kg. A migration test in water revealed that phenol migrates at amounts of 15 mg/kg to 110 mg/kg into the aqueous preparation. Furthermore, there are indications that suggest that packaging film can be highly contaminated with residual solvents that contain phenol. The packaging of a swim tube was found to have 129 mg/kg phenol migration into an aqueous preparation (1 h, 40°C), (BfR, 2009).

EFSA (2013) roughly estimates that exposure to phenol from food contact materials is likely to be in the range of 0.3 mg to 0.6 mg/person/day, which results in daily intakes below the new TDI of 0.5 mg/kg bw/day for all age groups. Phenol (and salts of phenol) is authorised to be used as additive in plastic food contact materials (Regulation no 10/2011 of 14 January 2011). Phenol can be part of dyes, solvents, polymerization aids and coatings in food contact materials, but the use shall comply with the general requirements, e.g. should not be released in quantities that are harmful to health (Regulation no 1935/2004 of 27 October 2004). According to the Danish Food Administration the general control projects have not focused specifically on phenol in food contact materials (Personal communication, Bente Fabech, Food Administration, August, 2013).

Migration from sex toys investigated by Danish EPA (2006c) consisting of dildos and gags were considered similar to oral uptake due to the mucous membrane contact in mouth and vagina. The concentrations from 8 Sex toys were 20-3500 mg/kg corresponding to 0.004 - 0.21 mg/kg bw per event (Danish EPA, 2006c).

Exposure via pharmaceuticals: Phenol is used as a preservative in pharmaceutical preparations and therefore some exposures via medical treatments has been mentioned (see table 10).

TABLE 10
EXPOSURE VIA MEDICAL TREATMENT

Product/parameter	Description and calculations	Reference
Application to the lips	The medicinal product, Labiosan Med ® with a phenol content of 0.5%, results in a human exposure of 0.02 mg/kg bw/day (assuming a 100% absorption), when application to the lips of 300 mg ointment per day.	ECB (2006)
Preservative for parenteral administration	Phenol as a preservative in pharmaceutical preparations for parenteral administration is used in a concentration up to 0.5% according to information from the Danish Medicines Agency in 2003.	ECB (2006)
Insulin preparations	Phenol is used as a preservative in concentrations of 0.65 mg/ml. Insulin is dosed at an average daily dose for an adult of about 40 IE of insulin/day, thus a diabetic will inject about 0.26 mg phenol (0.004 mg/kg bw) subcutaneously each day. (Lægemiddelkataloget; www.lmk.dk (ECB, 2006). A search May and July 2013 on "lmk.dk", "pro.medicin.dk" and "min.medicin.dk" with substances and ingredients in medicine did not give any hit on "phenol" or "fenol" it selves). Further search on "pro.medicin.dk" revealed that e.g. phenol is used as the preservative in insulin products and in Petidin (a strong painkiller).	ECB (2006); Pro Medicin (2013)

As exposures from pharmaceuticals are regulated under another EU legislation, these exposures were not brought forward to the risk characterisation by ECB (2006), but are mentioned here as they are a source for exposure and thus an adding to the total combined exposure. In Denmark pharmaceuticals for injections, tablets and many skin prick tests contain phenol (Personal communication, Per Sindahl, Danish Health and Medicines Authority, August 2013).

Concentrations in products:

The content of phenol has also been measured in different surveys by the Danish EPA, where solely the measured concentration in the product was mentioned:

- **Foam in a nursing pillow:** 30 mg phenol/kg foam (Danish EPA, 2008b).
- **Glue for children:** 54 mg/kg, one glitter from 2006 (Danish EPA, 2008c).
- **Wrapping paper:** 4.1 – 5.1 mg/kg (Danish EPA, 2003b).

- **Christmas decoration (Silver tinsel):** 32 – 37 mg/kg (Danish EPA, 2003b).

They are included here as examples of products with a content of phenol from where possible further exposure can occur in addition to the exposures mentioned above.

Occupational exposure

Exposure to phenol occurs during the handling of pure phenol and phenolic resins containing up to 15% phenol. In the case of phenolic resins phenol is released especially during the hardening process at elevated temperatures ($\leq 180^{\circ}\text{C}$). The following uses are regarded by ECB (2006) to be relevant for occupational exposure:

1. Production of phenol and further processing as a chemical intermediate in the large-scale chemical industry.
2. Production of phenolic resins.
3. Use of phenolic resins.

The exposure as a result of phenol vapours from cosmetic products and medical preparations at room temperature is assessed as low due to the relatively low vapour pressure of pure phenol of 20 Pa, the low concentration of phenol of < 2% phenol and the circumstance, that works with aerosols formed and processes at elevated temperatures are not probable (ECB, 2006).

In the assessment by ECB (2006) of dermal exposure, it was considered that phenol and its preparations containing $\geq 3\%$ phenol are classified as corrosive. The experience of skin damage due to the corrosive properties of a substance leads to reduced dermal exposure. But for phenol, the situation is more complex: beside the corrosive effect, phenol has local anaesthetic properties; therefore afflicted persons described reduced experience of pain after dermal contact with phenol. Dermal exposure was assessed on a non-daily basis for the handling of phenol and its preparations classified as corrosive ($\geq 3\%$ phenol). Thus more important might be dermal exposure to non-corrosive preparations (< 3% phenol), because in this case exposure was assessed to occur daily (ECB, 2006). According to personal communication with the Danish Working Environment Authority skin contact should basically not occur as the worker should use appropriate personal protective equipment (in this case gloves).

For the large scale chemical industry, it is assumed that the production and further processing of phenol is mainly performed in closed systems. Exposure occurs if the systems are breached for certain activities, e.g. filling. Due to the high melting temperature of phenol (40.9°C), transfer and drumming of the liquid substance are performed at temperatures of $> 60^{\circ}\text{C}$ and dermal contacts are avoided. Non-daily exposure is assessed for handling corrosive solid phenol (ECB, 2006).

For the production of phenolic resins the highest exposure occurs at open handling of phenol containing materials, at processes at elevated temperature (processing of phenolic resins in foundries, hardening in furnaces) and during spray-techniques. The industries involved are the manufacture of abrasive disks and abrasive coverings, ceramic compounds, coating agents, fillers and adhesives. Surface coating (spraying) is performed in different industries (metalworking/mechanical engineering, woodworking and plastics processing industries) (ECB, 2006).

6.2.2 Indirect exposure

Humans are exposed to phenol via the environment, such as e.g. via food, drinking water and the air, but most importantly through ingested food.

Measurements of phenol concentrations in food collected in a market basket survey in Ontario 1992 gave: cured pork (0.13 $\mu\text{g/g}$), organ meats (0.81 $\mu\text{g/g}$), cold cuts (0.08 $\mu\text{g/g}$), canned wieners (0.32 $\mu\text{g/g}$), cooking fats/salad oils/margarine (0.073 $\mu\text{g/g}$), tea/coffee (0.014 $\mu\text{g/g}$) and alcoholic drinks (0.13 $\mu\text{g/g}$). Phenol was for instance not detected in selected milk products (milk, cream, yogurt, cheese, butter) or in egg or selected meat products (beef, pork, lamb, chicken, turkey, fish, shellfish,

soups) or in bread, flour, cake, cookies, pizza, pies, pasta, vegetables, fruit, juice fruit, peanuts, sugar, jam or soft drinks (Environment Canada, 1999).

The calculated predicted environmental concentrations and intake quantities from environmental sources are given below (ECB, 2006).

TABLE 11
DATA BEHIND THE CALCULATION OF THE INDIRECT EXPOSURES (ECB, 2006)

Predicted Environmental Concentration (PEC)	Local scenario (point source)	Regional background concentrations
Annual average PEC in surface water in mg/l	0.0023	0.00241
Annual average PEC in air in mg/m ³	0.018	0.000026
PEC in grassland in mg/kg	0.0021	-
PEC in agriculture soil in mg/kg	-	0.000172
PEC in porewater of grassland in mg/l	0.0013	-
PEC in groundwater under agriculture soil in mg/l	0.00094	0.00011

Based on this the resultant daily doses for phenol is:

- DOSE_{tot} = 46.4 µg/kg bw/day in the local scenario (90th percentile of the local concentration in water and air), and
- DOSE_{tot} = 0.15 µg/kg bw/day with regional background concentrations.

TABLE 12
CALCULATED INTAKE QUANTITIES (ECB, 2006).

Intake route	Local scenario (point source) % of total intake	Regional background concentrations % of total intake
Drinking water	0.14	45.6
Air	8.32	3.69
Plant shoot	91.47	40.88
Root	0.01	0.51
Meat	<0.01	<0.01
Milk	0.02	0.01
Fish	0.03	9.29

According to ECB (2006) the plant shoot are the most significant intake route for point sources of phenol, while the indirect exposure from drinking water are for the regional approach followed by the plant shoot again (ECB, 2006). The plant shoot concentration was calculated using the default values in the Technical Guidance Document (TGD) for plants in general, thus it does not refer to a specific plant. For humans exposed indirectly from environmental sources (orally, via food, air and drinking water) the highest levels were estimated to be 0.046 mg/kg bw/day, which represents the

local scenario and which according to EFSA (2013) are comparatively low compared with exposures from other sources and the exposures from food contact materials were not considered.

The plant concentrations were estimated by ECB, solely using theoretical estimations of each part of the plant and resulting in the concentration in the plant shoot given above. In its assessment EFSA mentions that the contribution of phenol from food is hampered by the fact that most of the data available in the literature refer to total phenolic compounds and EFSA did not comment on the plant shoot and root estimations used in the calculations by ECB (2006). For the regional oral exposure the total calculated internal dose by ECB (2006) was 0.00015 mg/kg bw/day, with the most important contributions from drinking water and food (see table 12).

According to EFSA (2013) phenol can be present in traditionally smoked foods but the estimation of dietary exposure to phenol from this source is hampered by the fact that most of the data available in the literature refer to total phenolic compounds. Phenol can also be a constituent of smoke flavourings. Smoke flavourings may be added to foods as an alternative to the traditional smoking revealed that these may constitute sources of dietary exposure to phenol. Smoke flavourings are condensates of heated wood. Their chemical composition is complex and they contain many phenolic substances including phenol itself. Consequently, EFSA (2013) estimates that phenol as a constituent of smoke flavouring may result in a dietary exposure of 0.62-0.96mg phenol/person/day, corresponding to up to 0.016 mg/kg bw/ (EFSA, 2013).

EFSA (2013) mentions that a literature search failed to find any migration data for phenol into foods or food simulants (EFSA, 2013).

Phenolic acid compounds (polyphenols)

The food content of phenol is not to be confused with the content of phenolic acid compounds. As mentioned above the estimations of phenol exposure from food is hampered by the fact that most of the data available in the literature refer to total phenolic compounds. Such phenolic acid compounds include polyphenols, which seem to be universally distributed in plants e.g. in tea, coffee, berries and fruits. They are said to make up the active substances in many plants and are responsible for controlling the activity of a range of enzymes and cell receptors, thus protecting the plant from bacterial and fungal infections and UV radiation damage and to play a role in e.g. the prevention of degenerative diseases such as cancer and cardiovascular diseases (Arrantz et al., 2012).

Plants with such phenolic acid compounds are for instance fruits (the darker the fruit, the greater the content, e.g. plums, grapes and cherries), vegetables, grains, legumes and spices.

The content of total phenolic acids ranges from 0 (pear cider) to 103 mg/100 g fresh weight (rowanberry). Among fruits, the highest contents (28 mg/100 g) are in dark plum, cherry, and the apple variety Valkea Kuulas. While coffee (97 mg/100 g) as well as green and black teas (30-36 mg/100 g) is the best sources among beverages (Sahelian, 2013; Reed, 2013; Manach C et al, 2004).

Thus, compared to the negative impact from phenol the impact from polyphenols is considered as positive and it is therefore important not to include polyphenols in the assessment of phenol.

6.3 Bio-monitoring data

As phenol is rapidly excreted in urine and does not accumulate in the body bio-monitoring, data in humans would only express the exposure a short time before the measurement. Furthermore the natural presence of phenols in food and drug metabolites makes biological monitoring impossible (IPCS, 1999).

The data search revealed only literature expressing difficulties with measuring the bio-monitoring data for phenol. For instance “Impact of human variability on the biological monitoring of exposure to toluene, phenol, lead, and mercury: II. Compartmental based toxicokinetic modelling” (Pierrehumbert et al, 2002).

6.4 Human health impact

6.4.1 General population

Population at special risk

Persons affected with hepatic or kidney diseases should not be exposed to phenol for any length of time, because even intermittent exposure to vapours may become dangerous, particularly when handled at elevated temperatures (Clayton & Clayton, 1982 cited in ECB, 2006).

Consumers

Following the exposure assessment, consumers are not expected to be exposed to phenol in the range of hazardous doses which can be derived from acute oral or dermal toxicity figures. Regarding chronic toxicity and carcinogenicity ECB concludes that there are no data revealing an association of phenol exposure to increased tumour rates in humans. As well as for genotoxicity ECB concludes that a risk for consumers is not expected (ECB, 2006).

These findings regarding potential risks for consumers were found:

- **Skin irritation:** During exposure, consumers are expected to be dermally exposed to phenol containing products. Given the levels of phenol contained in consumer products (up to 2.5% reported for two-component adhesives) it cannot be excluded that skin irritation will occur despite the short application times (10 minutes) (ECB, 2006).
- **Systemic effects. For dermal:** The dermal exposure from consumer's use of phenol containing waxes and disinfectants can account 0.44 mg/kg bw/event and 0.9 mg/kg bw/event, respectively. Assuming a dermal absorption of 80% the internal exposure from disinfectants may be 0.72 mg/kg bw/event. A converted human internal LOAEL (dermal) of ~ 3.5 mg/kg bw/day was calculated. It was based on LOAEC for workers on 21 mg/m³ (systemic effects by inhalation) assuming a breathing volume of 10 m³ and 100% absorption. The phenol concentration of 21 mg/m³ was converted into an internal dose of 210 mg/person corresponding to 3.5 mg/kg bw/day for the dermal risk assessment. The margin of safety between the exposure level of 0.72 mg/kg bw and the converted human LOAEL (dermal) of ~ 3.5 mg/kg bw/day was 5. This was judged by ECB (2006) not to be sufficient taking into account a frequent exposure, the MoS consideration based on a LOAEL and the limitations of the human LOAEC used for the route-to-route extrapolation (ECB, 2006).
- **Systemic repeated dose toxicity by inhalation:** Furthermore a LOAEC for systemic effects of 21 mg/m³ (from observations on phenol-exposed workers, but used in the consumer scenario) is available and the estimated exposure is 1.1 mg/m³ (the average concentration after use of floor waxes). This resulted in a MoS of 19 being below 100 and hence this was considered as a possible risk although it may be considered as a border-line case due to the uncertainties inherent in the exposure estimation which were worst case conditions (ECB, 2006).

As conclusion for consumer exposures ECB (2006) states that there is a need for limiting the risks for consumers. The dermal exposure of consumers via disinfectants poses a risk because of systemic repeated dose toxicity and possible skin irritation. In addition, application of floor waxes leads to concern with respect to systemic repeated dose toxicity by inhalation (ECB, 2006). But these

calculations are based on knowledge of the phenol content in products, which is at least almost 8 years old.

According to SPIN the content of phenol in paint, lacquers and varnishes has as least in Denmark been decreasing from 1 ton in 2006, to 0.2 tonnes in 2009 and even lower in 2010 (see figure 1). But in addition to ECB's calculations there are contributions to the inhaled concentration from many other sources, e.g. electronics (monitors, etc.), tents and chloroprene products as well as contributions to the dermal exposure from sources like laminating film and bags. Beside these there is an oral contribution from food contact materials and also contributions from medical treatment for some individuals.

Regarding contributions from the consumer products the data on the phenol exposure concentrations are from 2006 and might have changed. The use in cosmetics and as biocide is now prohibited. However, the risks from contact with other consumer products may still pose a risk.

6.4.2 Workers

The physico-chemical properties may affect e.g. workers in their handling of phenol.

Phenol is not explosive and it is not highly flammable. According to DIN 51 794 the ignition temperature is in the region of 595°C. Due to its chemical structure, phenol is not expected to possess any oxidising properties (ECB, 2006).

Ignitable mixtures may form with air. The lower explosion limit in air amounts to 1.3% by volume at 1,013 hPa. This corresponds to a concentration of 50 g phenol/m³. The measured maximum phenol concentrations at the workplace are 19 or 42 mg/m³. With the lower explosion limit of 50 g/m³ ECB concludes that a risk is negligible.

In the case of leakage from a closed system, however, phenol concentrations above the lower explosion limit cannot be excluded. The risk from explosion can be controlled if the notices relating to fire and explosion protection (keep away from ignition sources, no smoking) are observed (ECB, 2006).

In ECB (2006) the following findings regarding inhalative exposures at workplaces are highlighted:

- Formulation of phenolic resins resulting in 20 mg phenol /m³, which pose a risk for systemic repeated dose toxicity effect as the critical exposure level is 4 mg/m³. Also for systemic acute toxicity effect risk is indicated as the critical exposure level is 21 mg/m³.
- Use of phenolic resins resulting in 5 mg phenol /m³, which pose a risk for systemic repeated dose toxicity effect as the critical exposure level is 4 mg/m³.
- Production and further processing of phenol resulting in 3.3 mg phenol /m³, which pose a risk for systemic repeated dose toxicity effect as the critical exposure level is 4 mg/m³.

and these regarding dermal exposures:

- Use of phenolic resins (spraying techniques) resulting in 300 mg phenol /person/day, which pose a risk for systemic repeated dose toxicity effect as the critical exposure level is 44 mg phenol /person/day and for systemic acute toxicity effect as the critical exposure level is 263 mg phenol /person/day.
- Formulation of phenolic resins) resulting in 90 mg phenol /person/day, which pose a risk for systemic repeated dose toxicity effect as the critical exposure level is 44 mg phenol/person/day (ECB, 2006).

Due to dermal and inhalative exposure at the workplace systemic effects from acute toxicity and repeated dose toxicity is by ECB considered to cause concern (ECB, 2006). But according to personal communication with the Danish Working Environment Authority inhalation of phenol and skin contact with phenol should basically not occur as the worker should use appropriate personal protective equipment. And according to EC (2008) the legislation for workers' protection currently

in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply. As mentioned in chapter 2 the Occupational Exposure Limit (OEL) in Denmark is 1 ppm (ml/m³ air) or 4 mg/m³. In EU the corresponding Occupational Exposure Limits (OEL) is:

- 2 ppm or 8 mg/m³ as 8 hour time-weighted average (TWA).
- 4 ppm or 16 mg/m³ as short-term exposure limit (STEL) i.e. a 15-minute period.

Furthermore, the legislation in Denmark demands the employer to ensure that the work is planned in order to secure the safety and health of the worker, and that any undue exposure is avoided. Preventive measures are evaluated in specific situations..

6.4.3 Indirect exposure

The indirect exposure via food (e.g. pork, organ meats, canned wieners, fats/oils and tea/coffee) and the environment was by considered in the EU-RAR (ECB, 2006) to cause concerns regarding repeated dose toxicity for oral intake, but for the local scenario only. The internal dose for local exposure was 0.0464 mg/kg bw/day and compared with the oral LOAEL of 1.8 mg/kg bw/day for hematotoxic and immunotoxic effects from a mouse study on subacute toxicity (see Table 7), the margin of safety (MoS) was judged not to be sufficient.

For the regional exposure the total calculated internal dose was 0.00015 mg/kg bw/day and compared with the oral LOAEL of 1.8 mg/kg bw/day, the MoS was in the EU-RAR judged to be sufficient. The MoS was 12000. When using the new TDI instead of the LOAEL, MoS is 3334, thus still much more than 100 and the indirect exposure can be regarded as safe.

According to EC (2007) "Local emissions to the environment and to industrial wastewater treatment plants should, where necessary, be controlled by national rules to ensure that no risk for the microorganisms in the industrial wastewater treatment plants and to humans exposed via the environment is expected".

In Denmark it is controlled by the following limits (from chapter 2):

- Water Quality Criteria (the limit in water effluent):
 - a) General for fresh waters: 7.7 µg/l
 - b) General for marine waters: 0.77 µg/l
 - c) Short-term quality criteria for fresh and marine waters: 310 µg/l
- Groundwater limit value for total phenols: 0.5 µg/l water
- Soil Quality Criteria: 70 mg/kg soil
- B-value/Evaporation criteria (each company's contribution to air pollution in the environment): 0,02 mg/m³ air

Furthermore there are limits for migration of phenol from food contact materials, from drinking water installations (at least in Denmark) and the TDI limits the concentration in food. This is the risk reduction measures, which have been implemented to control the indirect exposure.

6.4.4 Combined exposure

In addition to the human health impact mentioned for consumers, workers and through indirect exposure above the combined exposure needs also to be taken into consideration.

Exposure of an individual to phenol can happen at work, from consumer products and indirectly via food and the environment. The EU-RAR (ECB, 2006) evaluates the margin of safety between combined exposure levels in the range of 1 to 5 mg/kg bw/day and the human LOAEL of ~ 3.5 mg/kg bw/day not to be sufficient.

Furthermore there are more sources of exposures, than considered by ECB. These are for instance oral exposure from food contact material and smoke flavourings mentioned by EFSA (2013), besides dermal exposure from contact with laminating films and bags; and from computers, monitors, playing consoles, pressing irons, household ovens, TV apparatus, chargers and transformers, tents and chloroprene products contribute to the inhalative exposure reported in surveys by Danish EPA. In addition to that some individuals may be exposed through medical treatment using phenol e.g. as a preservative.

The reported highest concentrations are:

- Prolonged (chronic) indoor inhalation: 0.48 mg/kg bw/day for female adults and 0.7 mg/kg bw/day for 10-year-old children, respectively from use of floor waxes (ECB, 2006). Concentration in a model children's room: 0.09 mg/kg bw/day (Danish EPA, 2006d).
- Dermal contact (disinfectant): 0.9 mg/kg bw/event (ECB, 2006).
- Medical treatment (lips): 0.02 mg/kg bw/day (ECB, 2006).
- Oral (food contact materials): 0.3 to 0.6 mg/person/day (EFSA, 2013).
- Oral (food total): 0.00015 mg/kg bw/day (0.046 but for local scenario only) (ECB, 2006).
- Oral (smoke flavourings): 0.016 mg/kg bw/day (EFSA, 2013).

As phenol is well absorbed and distributed in the body, exposure during the same day to more of these exposures might not be unrealistic and therefore add further to the conclusion from ECB (2006) that the risk from combined exposure is considered to cause concerns, especially with the lowered TDI of 0.5 mg/kg bw/day and proposed DNELs of 0.4 mg/kg bw/day in mind. But as phenol is also excreted with a halftime of about 3.5 hours only exposures in the same period of the day will increase the concentration in the body.

6.5 Summary and conclusions

Most of the phenol inhaled or ingested will enter the bloodstream, but phenol will also enter through contact with the skin. Exposure to phenol may occur through inhalation, ingestion or dermal contact. Phenol is well absorbed, rapidly distributed throughout the body and rapidly excreted in urine with a $T_{1/2}$ of about 3.5 hours. Phenol does not accumulate in the body (ATSDR, 2008; Danish EPA, 2002c).

Human health hazard:

Phenol is acutely toxic if inhaled, in contact with skin and if swallowed. It is corrosive and causes severe skin burns and eye damage. Furthermore phenol is suspected of causing genetic defects and it may cause damage to organs through prolonged or repeated exposure.

During dermal exposure to consumer products it cannot be excluded that skin irritation will occur despite short application times.

Diabetics using insulin preserved with phenol report allergic reactions after insulin injection, which they believe is caused by the content of phenol. They report side-effects as e.g. "suffering with severe, asthma like, chest pain and the inability to catch my breath". This despite the fact that there is no evidence for skin sensitising properties of phenol by animal tests and no immediate evidence to suggest a tendency for products containing phenol in Denmark.

New TDI:

EFSA was asked to re-evaluate the TDI for phenol as the former TDI was within the range of the doses of phenol which were reported to cause haematotoxicity and immunotoxicity. The TDI for phenol was lowered from 1.5 to 0.5 mg/kg bw/day, based on reduced maternal body weight gain in rats in a reproduction toxicity study. The TDI value of 0.5 mg/kg bw/day will only cover phenol and not its metabolic products. It has been in force since 30 April 2013.

DNEL values:

The registration of phenol under REACH includes proposal for DNELs: A long term oral DNEL for the general population is proposed at 0.4 mg/kg bw/day. Setting an oral DNEL for the worker is not deemed relevant. Based on route-to-route extrapolation from the OEL, a dermal long-term systemic DNEL for the worker, of 1.23 mg/kg bw/day, is proposed. For the general population the chronic dermal systemic DNEL is proposed at 0.4 mg/kg bw/day. A chronic inhalation DNEL of 7.8 mg/m³ is set for systemic long-term effects for the worker, while the value for the consumer is proposed to be 1.32 mg/m³.

Exposure sources of phenol:

The sources to phenol are many, both as a manufactured chemical and as a substance as part of lignin in plants. Consumers may be exposed through food contact materials, food and phenol-containing consumer products (e.g. disinfectants, pharmaceuticals, paints, floor waxes and polishes) as well as through the air/smoke (e.g. from automobile exhaust, human and animal metabolism, different combustion processes and cigarette smoke).

Risks from exposure:

Risks for **consumers** (possible concern):

- Skin irritation: During dermal exposure to phenol containing products (up to 2.5% reported for two-component adhesives) despite the short application times (10 minutes).
- Systemic effects. For inhalation: A LOAEC for systemic effects of 21 mg/m³ compared to the estimated exposure of 1.1 mg/m³ (the average concentration after use of floor waxes), may be considered as a possible risk with a MoS of 19, but a border-line case, due to uncertainties inherent in the exposure estimation which were worst case conditions (ECB, 2006).
- Systemic effects. For dermal: A dermal internal exposure from disinfectants of 0.72 mg/kg bw/event was seen. It was compared to the converted internal human LOAEL (dermal) of ~ 3.5 mg/kg bw/day. Taking into account the frequent exposure and that the MoS of 5 is based on a LOAEL it may be considered as a possible risk.

Data on the phenol concentrations are from 2006 and might have changed since then. The use in cosmetics and as biocide is now prohibited, but the risks from contact with other consumer products may still pose a risk.

Risks for **workers** (possible concern):

- Due to inhalative exposure at the workplace systemic effects from acute toxicity and repeated dose toxicity is considered to cause concerns.
- Due to dermal exposure at the workplace systemic effects from acute toxicity and repeated dose toxicity is considered to cause concerns.

The findings above show risk through inhalation (3.3 to 20 mg phenol/m³ measured during formulation or use of phenolic resins and further processing) compared to the OEL in Denmark of 4 mg/m³. According to EC (2008) the legislation for workers' protection currently in force at Community level is generally considered to provide an adequate framework of limiting the risks of the substance to the extent needed and shall apply. Overall, work with phenol shall be organised to ensure the safety of the workers. Thus all unnecessary exposure should be avoided through the use of local ventilation and use of protective equipment (gloves or respiratory protection). Furthermore, substitution to less dangerous substances or products must always be considered. In Denmark, the working environment rules stipulate that the safety and health of the worker shall be ensured through relevant risk reduction measures. Such measures are evaluated on a case by case basis, and requirement control measures can be given that personal protection measures must be applied in addition to the generic protection measures..

Risks from **indirect exposure** (possible concern):

The risks are controlled by the implemented limits (criteria for air/evaporation, water and soil) and limits for migration of phenol from food contact materials, from drinking water installations and furthermore from the TDI limits in the concentration of food.

Risks from **combined exposure** (possible concern):

It is possible for an individual to receive exposure to phenol at work, from consumer products and indirectly via food and the environment, which may cause a risk. In addition to this there are more sources of exposures, than considered above. These are for instance;

- a) oral exposure from food contact material and smoke flavourings;
- b) dermal exposure from contact with laminating films and bags;
- c) computers, monitors, playing consoles, pressing irons, household ovens, TV apparatus, chargers and transformers, tents and chloroprene products contribution to the inhalative exposure;
- d) exposure through medical treatment using phenol e.g. as a preservative.

Exposure during the same day to more of these exposures might not be unrealistic and therefore adds further to the conclusion from ECB (2006) that the risk from combined exposure are considered to cause concerns, especially with the lowered TDI of 0.5 mg/kg bw/day in mind. The contribution from indirect exposure from food contains the contribution from the natural content, which is considered difficult to reduce, but the other contributions might be possible to reduce.

In conclusion

Dermal exposure from contact with the laminating film and bags, as well as exposure through pharmaceuticals might contribute to the overall exposure and may lead to exposure exceeding the TDI value of 0.5 mg/kg bw/day. On the other side the contributions from drinking water and food are as part of the total regional oral internal dose exposure calculated by ECB (2006) on 0.00015 mg/kg bw/day considerably lower than the TDI. Inhalation exposure in industrial production as well as from various household apparatus may exceed the DNEL

7. Information on alternatives

Due to the legislative requirements phenol has been phased out from legitimate cosmetic products and food contact materials. Furthermore eco-labelled products (such as paint and lacquers or furniture and fitments) can be used as alternatives to products without the eco-labelling. Eco-labelled products have either no content of phenol or the content is below the limit for classification.

As phenol seems not to be used in the wood conversion industry (chipboard, MDF, laminated, etc.) in Denmark, also the Danish produced furniture and wood-based panels can be used as alternatives to imported goods. As alternative to the adhesives with phenol (phenolic, phenol-resorcinol glue, melamine-urea-phenol-formaldehyde, etc.) urea-formaldehyde or melamine-urea-formaldehyde-adhesives are typically used (personal communication, Anette Harbo Dahl, The Danish Paint and Adhesives Federation, June 2013). According to the legislation it is only permitted to use particle board, plywood and other wood-based panels, containing a formaldehyde releasing glue in furniture, fixtures and if the release of formaldehyde is not more than 0.15 milligrams per cubic meter of air, when tested in a climate chamber (Danish Statutory Order no 289 of 22/06/1983).

Phenol as part of lignin is released from the diffuse emissions by automobile exhaust and different combustion processes. Furthermore phenol is released through human and animal metabolism. But phenol cannot be substituted from the diffuse emissions from natural sources.

The overall main use of phenol is as a parent compound/intermediate in chemical synthesis for other substances. As the structure and chemical properties of phenol is crucial for the particular use, substitution would require changes in the syntheses. But through the legislation the industrial use of phenol and emission to the environment is very well controlled and is not considered as a problem in the applications with no emission or where the levels can be controlled (see table 3). This includes protection of the work environment at industries too. Furthermore for industrial uses phenol must be accompanied by an assessing the possibility of using cleaner technology and / or substitution according to the Danish Statutory Order on approval of listed companies, no. 1454 of 20/12/2012.

In the mineral wool industry, where the majority of the industrial use of phenol in Denmark takes place, the industry is continuously working to phase out the use of phenol, and it is likely that the work will lead to a phasing out over a number of years (Personal communication, Anne-Louise Jørgensen Rønlev, Danish EPA, September 2013). Phenol is a substance covered by the Danish risk legislation (see table 3, No. 1666 of 14/12/2006). Therefore, special measures are required for the handling and storage of phenol to minimize the risk of release. For this reason it is also desirable to substitute phenol.

No information was available on the extent to which phenol in the use as preservative and/or disinfectant in consumer products are likely to be substituted now or in the future.

But a few observations have been found:

- Cryoprobe treatment: Where destruction of tissue by application of extreme cold is used as an alternative to phenol injections for painful neuromas after amputation. Neuroma is a

tumor or mass growing from a nerve (usually consisting of nerve fibers):

<http://www.ncbi.nlm.nih.gov/pubmed/19020222>

- o-Phenylphenol (a derivative of phenol) have been used as alternative to phenol in anti-bacterial wipes: <http://www.2xlcorp.com/No-Phenol>

In some pharmaceuticals phenol as a preservative may be substituted by m-cresol. However, preservatives are part of the drug approval, which is long-lasting and very expensive, so as a result, it is not simple to change (Personal communication, confidential Danish pharmaceutical company, July-August 2013). Cresol is classified as toxic, so it may not be a good substitute anyway.

Furthermore a search in the CatSub catalogue revealed one product with phenol content. The CatSub is a web site with a catalogue of examples of substitution of hazardous chemicals, i.e. case stories describing successful substitutions with less hazardous chemicals. The case stories primarily come from companies, occupational health services and the Danish Working Environment Authority.

In the case regarding phenol, a primer with content of phenol was suggested as an alternative to an epoxy primer, thus the main focus was not to substitute the phenol content. The epoxy primer was replaced by a polyvinyl butyral primer (PVB-primer), which is used for priming of steel components. The epoxy primer was replaced to a two-component PVB primer – and it was recommended to look for a primer with the least content of phenol (CatSub, 2013).

Overall, the largest amount of phenol is in Denmark used in the industrial production of the phenolic resin bakelite mainly used in the production of mineral wool. The potential for contamination of soil and groundwater from the processing of bakelite based on moulding powder is considered to be low and it is assumed that the residue content of phenol from bakelite is very little. Therefore, based on this there seems not to be a special need to substitute phenol from the use in mineral wool.

Furthermore eco-labelled consumer products can be used as alternatives to phenol containing products in some cases and further, Danish produced furniture and wood-based panels can be used as alternatives to the imported goods. Thus, consumer behaviour may further reduce exposure to phenol.

8. References

AppliChem (2012). Material Safety Data Sheet for phenol, 04.10.2012.

http://www.applichem.com/fileadmin/datenblaetter/A1153_da_DK.pdf

Arranz S., G. Chiva-Blanch, P. Valderas-Martínez, A. Medina-Remón, R. M. Lamuela-Raventós and R. Estruch (2012). Wine, Beer, Alcohol and Polyphenols on Cardiovascular Disease and Cancer.

Nutrients 2012, 4(7), 759-781; doi:10.3390/nu4070759. <http://www.mdpi.com/2072-6643/4/7/759>

ATSDR (2013), Agency for Toxic Substances and Disease Registry:

<http://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=27> (visited March-April, 2013).

ATSDR (2008). PHENOL, CAS 108-95-2. September, 2008.

BfR (2009). Limit values for phenol in food-contact articles and toys are to be updated

BfR Opinion Nr. 038/2009, 18 August 2009.

Blue Angel (2013). The Blue Angel. [http://www.blauer-](http://www.blauer-engel.de/en/company/publications/publications.php)

[engel.de/en/company/publications/publications.php](http://www.blauer-engel.de/en/company/publications/publications.php) (visited May, 2013).

Branchebeskrivelse for jern- og metalstøberier (1997). The industry overview for iron- and metal foundries: Branchebeskrivelse for jern- og metalstøberier. Teknik og Administration Nr. 6 1997.

<http://www.jordforurening.info/filer/udgivelser/brancher/30/jernmetal.pdf>.

Branchebeskrivelse for plastvirksomheder (2000). The industry overview for plastic companies:

Branchebeskrivelse for plastvirksomheder. Teknik og Administration Nr. 4 2000.

<http://www.jordforurening.info/filer/udgivelser/brancher/36/plastrapport.pdf>

Catsub (2013). www.catsub.EU: <http://www.catsub.dk/singeloplysning.aspx?ID=193&sprog=da>

(visited May, 2013).

Clayton, G. D. and F. E. Clayton (1982). Patty's Industrial Hygiene and Toxicology: Volume 2A, 2B, 2C: Toxicology. 3rd ed. New York: John Wiley Sons, 1981-1982., p. 2578, cited in

<http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~NacsfG:1> (visited March, 2013).

Cosmetics INFO (2013). Cosmetics INFO.org:

http://www.cosmeticsinfo.org/ingredient_details.php?ingredient_id=124 (visited May, 2013).

Danish EPA (2012) by Kragh Hansen M. and L. Steen, Arbejdsmiljøhuset. Survey and health assessment Tar products in Denmark. Træbjærevare-produkter i Danmark – forskellige sundhedsfarer. Træbjærevare – Kortlægning og vurdering af sundheds- og miljøfare. Survey of chemical substances in consumer products, No. 119, 2012. Miljøstyrelsen. Remark: The products were bought in 2005.

Danish EPA (2011). Danish Environmental Protection Agency. "Listen over uønskede stoffer 2009" (List of undesirable substances 2009). Orientering fra Miljøstyrelsen nr. 3 2010. Miljøministeriet, Miljøstyrelsen.

Danish EPA (2010). Liste over kvalitetskriterier i relation til forurennet jord og kvalitetskriterier for drikkevand. Updated June and July 2010. http://www.mst.dk/NR/rdonlyres/0AB0AF23-4BD6-4901-BCD9-43F6F6FD6FC1/124958/Kvalitetskriterierjord_og_drikkevandfinaljuniogjul.pdf.

Danish EPA (2008a) by Høg Lejre A.L., K. Tønning, N. Nilsson, E. Jacobsen, E. Pedersen, Danish Technological Institute and I. Søborg and K.H Cohr, DHI. Survey and health assessment of ingredients in laminating materials used in the child care. Survey of chemical substances in consumer products, No. 97, 2008.

Danish EPA (2008b) by Tønning K., E. Pedersen, A.D. Lomholt, B. Malmgren-Hansen, P. Woin, L. Møller & N. Bernth, Danish Technological Institute. Survey, emission and health assessment of chemical substances in baby products. Survey of chemical substances in consumer products, No. 90, 2008.

Danish EPA (2008c) by Hansen P.L, K. Tønning, B. Malmgren-Hansen & E. Jacobsen, Danish Technological Institute. Survey and health assessment of chemical substances in hobby products for children. Survey of chemical substances in consumer products, No.93, 2008.

Danish EPA (2007) by Svendsen N., E. Bjarnov & P. B. Poulsen, FORCE Technology. Survey as well as health assessment of chemical substances in school bags, toy bags, pencil cases and erasers. Survey of chemical substances in consumer products, No. 84, 2007.

Danish EPA (2006a) by Tønning K., P.L.Hansen, K. Pommer and B. Malmgren-Hansen, Danish Technological Institute. Survey and health assesment of chemicals substances in pleasure gel. Survey of chemical substances in consumer products, No. 76, 2006.

Danish EPA (2006b) by Hansen P.L., K. Tønning, K. Pommer, B. Malmgren, O.C. Hansen & M. Poulsen, Danish Technological Institute. Survey and health risk assessment of products for treatment of sports injuries and pains. Survey of chemical substances in consumer products, No. 79, 2006.

Danish EPA (2006c) by Nilsson N.H., B. Malmgren-Hansen, N. Bernth, E. Pedersen & K. Pommer, Danish Technological Institute. Survey and health assesment of chemicals substances in sex toys. Survey of chemical substances in consumer products, No. 77, 2006.

Danish EPA (2006d) by Jensen A.A., FORCE Technology & H.N. Knudsen SBI-Statens Byggeforskningsinstitut. Total health assessment of chemicals in indoor climate from various consumer products. Survey of chemical substances in consumer products, No. 75, 2006.

Danish EPA (2003a). Methods for recycling of colored broken glass for the production of bricks and concrete and road construction (in Danish). Metoder til genanvendelse af farvede glasskår til produktion af tegl og beton og til vejbygning. Environmental Project (Miljøprojekt), no 819, 2003.

Danish EPA (2003b) by Eurofins Intecon Consultancy A/S. Mapping and exposure to chemical substances in Christmas decorations. Survey of chemical substances in consumer products, No. 37, 2003.

Danish EPA (2002a). B-værdivejledningen. Environmental guideline No. 2, 2002 (in Danish).

Danish EPA (2002c): Phenoler. (in Danish). <http://www.mst.dk/NR/rdonlyres/B52C2067-5D10-4BCE-8390-4DAE015A015C/o/Phenolerdec2002.pdf>

Danish EPA (2002b). Guideline for air emission regulation. Environmental guideline No.1 2002 (English version).

Danish EPA (2002c). Datablade for stoffer med jord og drikkevandskvalitetskriterier. Phenoler. April 1995 PBL/IT/4. December 2002 ENI/IFSE (In Danish): <http://www.mst.dk/NR/ronlyres/B52C2067-5D10-4BCE-8390-4DAE015A015C/o/Phenolerdec2002.pdf>.

Danish EPA (1995). Toksikologiske kvalitetskriterier for jord og drikkevand. Projekt om jord og grundvand fra Miljøstyrelsen, no 12.

Danish Ministry of Environment (2012). Statutory Order no. 1309, 18/12/2012 on Waste. Ministry of Environment of Denmark: <https://www.retsinformation.dk/Forms/R0710.aspx?id=144826>.

DMU (1997) by Vikelsøe J., B. Nielsen, E. Johansen. Analyse af miljøfremmede stoffer i kommunalt spildevand og slam. Report from DMU no. 186. http://www2.dmu.dk/1_viden/2_publicationer/3_fagrapporter/rapporter/FR186.pdf.

Dow Chemical Company (1994). Pharmacokinetics, metabolism, and distribution of ¹⁴C-phenol in Fischer 344 rats after oral gavage, drinking water and inhalation exposure. Study ID: K-002727-022, cited in ECB (2006).

EC (2008). EU Commission. INFORMATION FROM EUROPEAN UNION INSTITUTIONS AND BODIES. Commission communication on the results of the risk evaluation and the risk reduction strategies for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tertbutylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene. 7.2.2008. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:034:0001:0033:EN:PDF>

EC (2007). COMMISSION RECOMMENDATION of 6 December 2007 on risk reduction measures for the substances: Piperazine; Cyclohexane; Methylenediphenyl diisocyanate; But-2yne-1,4-diol; Methyloxirane; Aniline; 2-Ethylhexylacrylate; 1,4-Dichlorobenzene; 3,5-dinitro-2,6-dimethyl-4-tert-butylacetophenone; Di-(2-ethylhexyl)phthalate; Phenol; 5-tert-butyl-2,4,6-trinitro-m-xylene. notified under document number C(2007) 5901. 2008/98/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:033:0008:0011:EN:PDF>

EC (2003). Excipients in the label and package leaflet of medicinal products for human use. Medicinal products for human use Safety, environment and information. VOLUME 3B Guidelines, July 2003: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC50003412.pdf

EC (2006). COM 231. Thematic Strategy for Soil Protection, Brussels, 22.9.2006 COM(2006)231 final: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2006:0231:FIN:EN:PDF>

EC (1984). Reports of the Scientific Committee for Food (Seventeenth series). EUR 10778 EN: http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_17.pdf

ECB (2006). European Union Risk Assessment Report. Phenol, CAS: 108-95-2. Revised Edition. November 2006. EUR 22522 EN/1. European Commission.

EC DG Environment (2009). Technical Specifications for Green Public Procurement. Wall Panels Background Report. Report for the European Commission – DG Environment by AEA, Harwell, April 2009.

ECHA (2013). European Chemicals Agency. Dossier for registration of phenol:
http://apps.echa.europa.eu/registered/data/dossiers/DISS-9d87b5ae-c1a2-150b-e044-00144f67d249/AGGR-89f977cc-7375-4914-8452-1fe78395ea86_DISS-9d87b5ae-c1a2-150b-e044-00144f67d249.html#AGGR-89f977cc-7375-4914-8452-1fe78395ea86 (visited March-September, 2013).

ECHA (2012). CMR substances from Annex VI of the CLP Regulation registered under REACH and/or notified under CLP. A first screening - Report 2012:
http://echa.europa.eu/documents/10162/13562/cmr_report_en.pdf

Ecolabel (2013a). Nordic Ecolabelling of Chemical building products. Version 1.6 • 29 May 2008 – 31 October 2014. http://www.ecolabel.dk/kriteriedokumenter/097e_1_6.pdf

Ecolabel (2013b). Nordic Ecolabelling of furnitures and construction materials. Svanemerkning av Møbler og innredninger. Versjon 4.4 • 17. mars 2011 – 30. juni 2015 (In Norwegian).
http://www.ecolabel.dk/kriteriedokumenter/031_4_4.pdf

EFSA (2013). Scientific Opinion on the toxicological evaluation of phenol. EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF). EFSA Journal 2013;11(4):3189: <http://www.efsa.europa.eu/en/efsajournal/doc/3189.pdf>

Environment Canada (1999): Phenol. PRIORITY SUBSTANCES LIST ASSESSMENT REPORT. Canadian Environmental Protection Act. Co-published by Health Canada. http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/psl2-lsp2/phenol/phenol-eng.pdf

EUR LEX (2011). COMMISSION REGULATION (EU) No 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:083:0001:0053:en:PDF>

GEUS (2003). Grundvandområkning 2003. Organiske mikroforureninger. <http://www.geus.dk/> (visited May, 2013).

IUCLID (2000). 108-95-2, Phenol
http://esis.jrc.ec.europa.eu/doc/IUCLID/data_sheets/108952.pdf (visited April, 2013).

KemI (2013). KemI, Swedish Chemicals Agency.
http://apps.kemi.se/flodessok/floden/kemamne_eng/phenol_eng.htm
(visited March-April, 2013).

Gilman, AG, L S Goodman, and A Gilman (1980). Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan Publishing Co., Inc. 1980, p. 967, cited in <http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~NacsfG:1> (visited March, 2013).

Gyldedals (2013). Den store danske – Gyldendals åbne encyklopædi.
http://www.denstoredanske.dk/It%2c_teknik_og_naturvidenskab/Kemi/Organisk_kemi_og_stofcyper/phenol (visited April, 2013).

Hogg SJ, Curtis CG, Upshall DG and Powell GM (1981). Conjugation of phenol by rat lung. Biochem. Pharmacol. 30, 1551-1555. Cited in ECB (2006).

Hotchkiss SA, Hewitt P, Caldwell J, Chen WL and Rowe RR (1991). Prediction of Percutaneous Penetration, S. 472-482. Hrsg.: Scott, R.C., IBC Tech. Service, London, cited in ECB (2006).

Hughes MF and Hall LL (1995). Disposition of phenol in rat after oral, dermal, intravenous, and intratracheal administration. *Xenobiotica* 25, 873-883, cited in ECB (2006).

IPCS (1999). Phenol, International Programme on Chemical Safety Poisons Information Monograph 412. <http://www.inchem.org/documents/pims/chemical/pim412.htm>

IPCS (1994). Phenol, Health and Safety Guide No. 88. Published by the World Health Organization for the International Programme on Chemical Safety.
http://www.inchem.org/documents/hsg/hsg/hsg88_e.htm (visited April, 2013).

Isover (2013).
http://www.isover.dk/files/ISOVER_DK/Produkter/Sikkerhedsdatablade/sikkerhedsblad_tek_dk.pdf.
<http://ipaper.ipapercms.dk/SaintGobainConstruction/IsoverDK/IsoverDKByg/BredygtiggranulatfraISOVER/> (visited July, 2013).

Jetzer WE, Hon SY, Huq AS, Duraiswamy N, Ho NFH and Flynn GL (1988). Temperature dependency of skin permeation of waterborne organic compounds. *Pharm. Acta. Helv.* 63, 197-201, cited in ECB (2006).

Kao J, Bridges JW and Faulkner JK (1979). Metabolism of ¹⁴C phenol by sheep, pig and rat. *Xenobiotica* 9, 141- 147, cited in ECB (2006).

KU (2010) by Ingvertsen S.T., J. Magid, E.M. Thaysen & L. S. Jensen. Genanvendelse af spildevandsslam og anden affaldsbiomasse til jordbrugsformål (in Danish): Hvidbogsprojekt udført for Brancheforeningen for Genanvendelse af Organiske Restprodukter til Jordbrugsformål (BGORJ). http://www.dakofa.dk/Aktiviteter/A-N/affald_jord_grundvand/slam/Dokumenter/Hvidbog-2nd-udg-april-2010.pdf

Liao JTF and Oehme FW (1981). Tissue distribution and plasma protein binding of (¹⁴C) phenol in rats. *Toxicol. Appl. Pharmacol.* 57, 220-225, cited in ECB (2006).

Lægemiddelstyrelsen (2011) (the Danish Medicines Agency). PRODUKTRESUMÉ for Uniferon, injektionsvæske, opløsning, beregnet til pattegrise. 9. November 2011.

Manach C., Scalbert A., Morand C., Rémésy C. and Jime'nez L. (2004). Polyphenols: food sources and bioavailability. *Am J Clin Nutr* 2004;79:727-47:
<http://ajcn.nutrition.org/content/79/5/727.full.pdf+html>.

Manta (2013). www.manta.com:
<http://www.manta.com/cp/mx7zfw/m/4f738b23d1f71f7e06000003/blue-power-carbolic-soap>
(visited May, 2013).

Naturstyrelsen (2011), Danish Nature Agency. Nøgletal for miljøfarlige stoffer i spildevand fra renseanlæg – på baggrund af data fra det nationale overvågningsprogram for punktkilder 1998-2009:
http://www.naturstyrelsen.dk/pv_obj_cache/pv_obj_id_85FD85F82C981495F41BC54E71C9AEAFC3DE1600/filename/Noegletal_for_miljoefarlige_stoffer_Renseanlaeg_19.pdf

NIEA (2009). River Basin Management Plans, Rationale for Water Framework Directive Freshwater Classification. Northern Ireland Environment Agency (NIEA), December 2009.
http://www.doeni.gov.uk/niea/classification_freshwater.pdf;
http://www.legislation.gov.uk/nisr/2011/10/pdfs/nisr_20110010_en.pdf

Pierrehumbert G., Droz P.O., Tardif R., Charest-Tardif G., Truchon G. (2002). Impact of human variability on the biological monitoring of exposure to toluene, phenol, lead, and mercury: II. Compartmental based toxicokinetic modelling. Toxicology Letters, Volume 134, Number 1, 5 August 2002, pp. 165-175(11).
<http://www.ingentaconnect.com/content/els/03784274/2002/00000134/00000001/art00186>

Piotrowski JK (1971). Evaluation of exposure to phenol, absorption of phenol vapour in the lungs and through the skin and excretion of phenol in urine. Brit. J. Ind. Med. 28, 172-178, cited in ECB (2006).

PrescriptionDrug-Info (2013). www.prescriptiondrug-info.com: <http://www.prescriptiondrug-info.com/Discuss/Phenol-in-insulin-197716.htm> (visited May, 2013).

Pro Medicin (2013). www.pro.medicin.dk: <http://pro.medicin.dk/Medicin/Praeparater/1585> (visited May, 2013).

Pro shave (2013). www.proshave.dk: <http://www.proshave.dk/the-handmade-soap-co-carbolic-soap.aspx> (visited May, 2013).

Plastnet (2013).
http://www.plastnet.dk/index.php?option=com_content&view=article&id=125%3Aphenolplast-pf& (visited September, 2013).

Reed K. (2013). List of High Phenol Foods: <http://www.livestrong.com/article/165497-list-of-high-phenol-foods/> (visited May, 2013).

Rockwool (2012). UMWELT-PRODUKTDEKLARATION nach ISO 14025 und EN 15804, 18.12.2012. http://bau-umwelt.de/download/CY25b9d33X13bfb20858aX2086/EPD_DRW_2012111_D.pdf

Sahelian R. (2013). Phenolic Compounds and Acids, benefit of phenols by Ray Sahelian, M.D.: <http://www.raysahelian.com/phenolic.html> (visited May, 2013).

Schlosser PM, Kenyon EM, Seaton MJ and Medinsky MA (1995). Determinants of Benzene Metabolism and Disposition. CIIT Activities 15, 6, cited in ECB (2006).

SPIN (2013). SPIN – Substances in Preparations in the Nordic Countries. Database accessed April 2013 at: <http://90.184.2.100/DotNetNuke/default.aspx>

Tudiabetes (2013). www.tudiabetes.org: <http://www.tudiabetes.org/forum/topics/least-toxic-insulin> (visited May, 2013).

UBA-FB (2009). Testing of Emissions from Office Devices during the Printing Phase for the Advancement of the Blue Angel Environmental Award for Laser Printers and Multi-function Devices with Special Consideration of Ensuring Good Indoor Air Quality. Report No. (UBA-FB) 001159E, 16/2009. <http://www.blauer-engel.de/downloads/publikationen/3807.pdf>

UK Environment Agency (2007). Proposed EQS for Water Framework Directive Annex VIII

substances: phenol. Science Report: SCo40038/SR12; SNIFFER Report: WFD52(xii). February 2007. <http://www.wfduk.org/sites/default/files/Media/phenol.pdf>

UK Technical Advisory Group (2008). PROPOSALS FOR ENVIRONMENTAL QUALITY STANDARDS FOR ANNEX VIII SUBSTANCES. January 2008 (Revised June 2008). http://www.wfduk.org/sites/default/files/Media/Environmental%20standards/Specific%20pollutants%20proposals_Final_010608.pdf

Vejdirektoratet (2013). http://udbud.vejdirektoratet.dk/udbud/VD_standarder/Instruktioner/Miljoe/Handbog/Miljo/kapitel4/Kap47.htm (visited July, 2013).

WHO (2011). Safety evaluation of certain food additives and contaminants. WHO FOOD ADDITIVES SERIES: 64. Prepared by Joint FAO/WHO Expert Committee on Food Additives (JECFA). FAO & WHO, 2011.

Annex 1: Abbreviations and acronyms

ADI	Acceptable daily intake
AF	Assessment Factor
ATSDR	Agency for Toxic Substances and Disease Registry
BCF	Bioconcentration factor
BMD	Benchmark dose
BMDL	Benchmark dose lower limit
BMDU	Benchmark dose upper limit
BMR	Benchmark response
CEFIC	European Chemical Industry Council
CLP	Classification, Labelling and Packaging Regulation
COHIBA	Control of hazardous substances in the Baltic Sea region
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DNEL	Derived No Effect Level
DFL	Trade organisation for the paint and adhesives industry in Denmark
DT	Degradation time
DTU	Technical University of Denmark
EC	European Commission
EC _n	Effect concentration where n % of the species tested show the effect
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EQC	Equivalent level of concern
EU	European Union
HELCOM	The Baltic Marine Environment Protection Commission (Helsinki Commission)
K _{ow}	Octanol/water partitioning coefficient
K _{oc}	Organic carbon/water partitioning coefficient
K _p	Partial pressure equilibrium constant
LC	Lethal effect concentration
LOUS	List of Undesirable Substances (of the Danish EPA)
mTAMDI	Modified Theoretical Added Maximum Daily Intake
MATC	Maximum Acceptable Toxic Concentration
MSWI	Municipal solid waste incinerators
MWWTP	Municipal waste water treatment plant
NACE code	NACE (Nomenclature des Activités Économiques dans la Communauté Européenne)
NIH	U.S. National Institute of Health
NMC	Nation Mean Concentration
NOAEL	No observable adverse effect level
NOEC	No observable effect concentration
NOVANA	Danish national monitoring and assessment programme
OECD	Organisation for Economic Co-operation and Development
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PEC	Predicted environmental concentration
PFR	Phenol/formaldehyde resins
PHMB	Poly (hexamethylene biguanide) hydrochloride
PNEC	Predicted no effect concentration
QSAR	Quantitative Structure and Activity Relationship
RATG	Risk Assessment Task Group of the American Chemistry Council's Petroleum Additives Panel

RED	Reregistration Eligibility Decision
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SIDS	Screening Information Data Sets
SPT	Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries
STP	Sewage treatment plant
SVHC	Substance of Very High Concern
TDI	Tolerable daily intake
TGD	Technical guidance document
ThOD	Theoretical oxygen demand
TS	Dry weight (TørStof in Danish)
WE	Western Europe
ww	Wet weight

Annex 2: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 2. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 3.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: Gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvring as to the form and means of implementation. However, there are great differences in the space for manoeuvring between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market, the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: Bekendtgørelser).

The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive) even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU eco-labelling Regulation in relation to establishing eco-label criteria for specific product groups.
- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulate to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation¹ and the CLP Regulation² are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration

All manufacturers and importers of chemical substance > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation

A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation

Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction

If the authorities assess that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling

The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

1. Harmonised classification and labelling for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.

¹ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

² Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

2. Classification and labelling inventory. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 2 to the main report.

Ongoing activities - pipeline

In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

CMR substance

As phenol has the classification “Muta. 2” it is considered as a CMR substance.

The more severe CMR categories covers:

- Carc. 1A or Carc. 1B (May cause cancer), and/or
- Muta. 1A or Muta. 1B (May cause genetic defects), and/or
- Repr. 1A or Repr. 1B (May damage fertility or the unborn child)

while substances classified in lower CMR categories covers:

- Carc. 2 (Suspected of causing cancer),
- Muta. 2 (Suspected of causing genetic defects), and/or
- Repr.2 (Suspected of damaging fertility or the unborn child) (ECHA, 2012).

Phenol belongs to the substances classified in the lower CMR categories. These do not normally lead to general restrictions.

Community Rolling Action Plan (CoRAP)

The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV

Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list³.
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site).
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions

³ It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.

This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intentions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions

for the three types of Annex XV dossiers.

International agreements

OSPAR Convention

OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- Issues of importance.
- Agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- Guidelines or guidance setting out the way that any programme or measure should be implemented.
- Actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden.

HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- An environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;

- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention

The objectives of the Rotterdam Convention are:

- To promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:

- The reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels

Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the eco-labelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower

The EU ecolabelling Regulation lays out the general rules and conditions for the EU eco-label; the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan

The Nordic Swan is a cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Ecolabelling Board consists of members from each national Ecolabelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Ecolabelling Denmark "Miljømærkning Danmark" (<http://www.ecolabel.dk/>). New criteria are applicable in Denmark when they are published on the Ecolabelling Denmark's website (according to Statutory Order no. 447 of 23/04/2010).

Blue Angel (Blauer Engel)

The Blue Angel is a national German eco-label. More information can be found on:

<http://www.blauer-engel.de/en>.

Survey of phenol

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The report includes an introduction of the substance and presents available information on the use and occurrence of the substance internationally and in Denmark, on legislation concerning phenol. It compiles information on environmental and health effects, on waste management and on alternatives to the substance.

Kortlægning af phenol

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Ud fra tilgængelig viden indeholder rapporten en introduktion til stoffet og indeholder blandt andet en beskrivelse af brugen og forekomsten af stoffet internationalt og i Danmark og om lovgivningen der er relevant for stoffet. Rapporten sammenfatter viden om miljø- og sundhedseffekter af phenol, om affaldsbehandling af phenol og om alternativer til stoffet.



Danish Ministry of the Environment
Environmental Protection Agency

Strandgade 29
1401 Copenhagen K, Denmark
Tel.: (+45) 72 54 40 00

www.mst.dk