Danish Ministry of the Environment
Environmental Protection Agency

Survey of toluene

Part of the LOUS review

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Title:

Survey of toluene

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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 whose 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 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 ongoing activities under REACH, among others.

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

This survey concerns the aromatic organic substance toluene (CAS No. 108-88-3), which was first included in the list in 2009.

The main entry in LOUS for the substance is the group "organic solvents", which presently only comprises toluene and styrene. Toluene is included because of its classification as toxic through prolonged or repeated exposure as well as reproduction toxicity.
The main objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process

The survey has been undertaken by COWI A/S, the Danish Technological Institute (TI) and the National Food Institute at the Technical University of Denmark (DTU Food) from September 2013 to June 2014. The work has been followed by an advisory group consisting of:

- Lea Stine Tobiassen, Danish Environmental Protection Agency (Chairman)
- Nikolai Stubkjær Nilsen, Confederation of Danish Industry
- Helle Fabiansen, Danish Plastics Federation
- Mette Holm, Danish Veterinary and Food Administration
- Pia Vestergaard Lauridsen, Danish Working Environment Authority
- Jesper Kjølholt, COWI A/S (Project Manager)

Data collection

The survey and 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);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention, and the Basel Convention.
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs 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;
- Production and external trade statistics from Eurostat's databases (Prodcom and Comext);
- Export of dangerous substances from the Edexim database;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Information from Circa on risk management options (confidential, for internal use only, not searched via the Internet)
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, the European Food Safety Authority (EFSA) and the INIRIS database.
- Waste statistics from the Danish EPA;
- Chemical information from the ICIS database;
- 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, OSPAR, HELCOM, and the Basel Convention;
  - Environmental authorities in Norway (Klif), Sweden (KemI and Naturvårsverket), Germany (UBA), UK (DEFRA and Environment Agency), the Netherlands (VROM, RIVM), Austria (UBA). 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.
- PubMed and Toxnet databases for identification of relevant scientific literature.

Besides, direct enquiries were made to Danish and European trade organisations and a few key market actors in Denmark.

Summary and conclusions

This review report concerns the substance toluene, which is one of 40 chemical substances on the Danish Environmental Protections Agency's (DEPA) "List of Undesirable Substances" (LOUS). Toluene is listed in the group "organic solvents". All the LOUS-substances are undergoing similar reviews over the period 2012-2015.

Toluene is a liquid at ambient temperature and has a boiling point of 110 degrees Celsius. Water solubility is relatively low: approx. 580 mg/L. The main applications of toluene are as raw materials and auxiliaries in the chemical industry and as solvents in many applications including paints, textile coatings, printing industry, etc. In Denmark, it is use as a solvent that is the most significant.

Regulatory aspects

Under the CLP regulation toluene is classified as: H225 (Highly flammable liquid and vapour), H304 (May be fatal if swallowed and enters airways), H315 (Causes skin irritation), H336 (May cause drowsiness or dizziness), H361d (Suspected of damaging the unborn child), and H373 (May cause damage to organs through prolonged or repeated exposure).

The concentration of toluene in products is restricted to ≤ 0.1% in adhesives and spray paints under REACH and to 25% in nail polish according to the cosmetics regulation. There are no restrictions in other types of products where consumer exposure can occur, such as paints or thinners.

The Danish legislation addressing occupational handling of toluene includes general requirements regarding for instance risk assessement, preventive measures and training. A Danish occupational exposure limit of 25 ppm has been set, which is more conservative than the indicative European limit value (50 ppm). Moreover, national environmental quality standards have been established for fresh and marine surface waters (74 µg/l and 7.4 µg/l, respectively).

Ecolabelling requirements pertaining to toluene are mainly related to the substance as a VOC. However, toluene-specific criteria do exist for boat and car care products and for gravure printing.

Manufacture and uses

Toluene is produced in the 1,000,000 - 10,000,000 tons/year band in the EU but there is no production in Denmark. In 1995, the total amount of toluene produced in Europe was about 2,600,000 tons, but this had decreased to about 1,400,000 tons in 2012.

The consumption of toluene in the EU was about 2,750,000 tons in the late 1990s but had decreased to approximately 1,250,000 tons in 2012. In Denmark, the consumption of toluene was in the range 3430-3940 tons in 2012 according to the Danish Product Register. Apparently, also the consumption in Denmark has decreased significantly in recent years.

Toluene is used globally as a raw material in the production of a large number of chemicals, including amongst others benzene, benzoic acid, nitrotoluenes, tolyl diisocyanates, as well as dyes, pharmaceuticals, food additives, plastics, etc. It has excellent solvent properties; consequently, for a long time it has been the preferred solvent in many applications, including coatings, adhesives, inks, pharmaceuticals and chemical processing.

The use of toluene as a chemical intermediate accounts for 70-80 % of use in the EU, while use as solvent amounts to about 20 % of the total. In Denmark, the use as a chemical intermediate accounts for less than 13 %, and the major application is use as a solvent, especially in thinners and for cleaning in the automobile repair and maintenance sector.

Waste management

Toluene must be handled as hazardous waste and be collected and treated by approved operators. The same is the case for products containing 25 % or more of toluene.

Interviews with three adhesive and paint producing companies in Denmark revealed that only one of the companies uses toluene as a solvent and for professional use. However, the paint is not produced in Denmark; hence, the production will not result in toluene waste in this country.

Only paints and coatings in the use phase, in relation to professional use, may in some cases result in toluene-containing waste. However, no data on the amounts have been identified. Some toluene will end up in municipal sewage sludge but no monitoring data on concentrations are available.

Environmental effects and exposure

Toluene evaporates easily from water and soil surfaces and degrades quite rapidly in air, resulting in various VOC degradation products, thereby contributing to tropospheric ozone formation. The substance is easily biodegradable in water while abiotic degradation is insignificant. There are, however, observations that toluene degrades rather slowly in natural waters at low concentrations. Toluene is considered to be rather mobile in soil and it has a rather low bioaccumulation potential.

The toxicity of toluene to aquatic organisms such as fish and crustaceans is moderate and of the same magnitude of short term LC/EC_{50} values, mostly of around 3-10 mg/l, while the lowest chronic toxicity value (NOEC) is 0.74 mg/l for the daphnid *C. dubia*. The toxicity in the terrestrial compartment appears to be moderate-low to earthworms and low to plant species. However, data are few.

Toluene is assessed to be released primarily to the air compartment, partly from the many different types of production and partly during use of the products for a variety of purposes. Elevated concentrations of toluene (1.3-3.7 $\mu g/m^3$) are measured in urban areas with heavy traffic, since toluene is a constituent of fuel for vehicles.

Smaller amounts of toluene are released through the wastewater system. Monitoring data show low levels of toluene in the aquatic environment (wastewater treatment plant effluents and rainwater).

In the EU Risk Assessment Report (RAR) for toluene it is concluded that for a number of standard (generic) local production and processing site categories there is a need for limiting the risks to the environment, taking into account the risk reduction measures already applied. Formulation of paints is the only of the industry categories mentioned that appear to be relevant for Denmark. It should be noted that the EU conclusion is reached mainly because “insufficient information has been available to exclude a risk”.

Human health effects and exposure

Toluene is of low acute toxicity in experimental animals following inhalation, oral intake and dermal contact. Based on human data, toluene is classified for specific organ toxicity following single exposure. Toluene is classified as a skin irritant but is not considered an eye irritant. Toluene did not cause sensitisation in a guinea pig study; no human data are available. The central nervous system and the inner ear are the main target organs after repeated dosing and toluene is classified for specific organ toxicity following repeated exposure.

Toluene is not considered a mutagen based on results from several test systems. Regarding carcinogenicity, the evidence is not considered strong enough by EU and IARC for classification for this effect. Toluene has not shown clear effects on fertility, whereas studies in experimental animals provide strong evidence for developmental toxicity; toluene is classified for developmental toxicity.

Consumer exposure to toluene occurs primarily from the use of toluene-containing products. Exposure assessments and risk characterisations have been performed by the EU for four different use scenarios, i.e. gluing, spray painting, car maintenance (polishing, and cleaning hands in solvent based cleaning agent), and carpet laying. For most of the scenarios, no concern was identified. For two consumers scenarios (spray painting and carpet laying), it was concluded that there was a need for limiting the risks, and risk reduction measures applied already would be taken into account. Consumers can also be exposed to toluene when filling gasoline at self-service gas stations but no risk characterisation was performed by EU for this scenario. However, an Australian study with 6 different exposure scenarios for service station emissions, including consumer scenarios for filling gasoline, indicates no concern for consumers with regard to toluene. Several Danish consumer surveys have demonstrated, mostly low, releases of toluene from many different consumer products. It is assessed that, if occurring at the same time, the sum of releases from all potential sources to the indoor air in a children's room would amount to a daily intake for a child very close to the Tolerable Daily Intake (TDI) and Reference Dose for toluene of 223 µg/kg bw/d.

Occupational exposure to toluene occurs primarily in industries where toluene and gasoline are produced; where toluene is used as a chemical agent, an ingredient or an intermediate; and from use of toluene-containing products. Concern was identified for a number of uses, including production of toluene and use of toluene as an intermediate in the chemical industry, production of toluene-containing products (semi-products as well as products for sale), and use of a variety of toluene-containing products. For these uses, there was a need for limiting the risks. The estimated human oral intake when using toluene professionally has been shown to exceed the TDI established by WHO in two of the modelled production scenarios, i.e. use of toluene as a solvent and use of toluene as an extraction agent

Estimated intakes of toluene via the environment do not indicate that toluene is of major concern when compared with the TDI value.

Alternatives to toluene

In general, it is judged to be relatively easy to find alternatives to toluene used as a solvent for most products/applications in Denmark, as the solvent is not reactive and technical alternatives exist for a number of applications. The possibilities will depend on the specific technical, occupational and working environmental conditions. Use for publication and packaging gravure printing in the printing industry is an exception to this.

A number of interviewed Danish adhesive/paint/coating producing companies stated that they have already phased out toluene in their products. One company still uses toluene in products for professionals, but states that in the future, alternatives to toluene will be used.

The replacement solvents to toluene are typically blends of ketones, esters, alcohols and aliphatic hydrocarbons. For products where toluene is not regulated, the amount of toluene may be reduced by using xylene and/or cyclohexane in the formulations.

None of the solvents identified as possible alternatives to toluene are classified as acutely toxic, toxic to reproduction, carcinogenic or mutagenic.

Conclusions
Toluene is considered undesirable because of its classification as toxic through prolonged or repeated exposure and as a developmental toxicant in category 2.

Exposure to toluene appears to be a concern in relation to professional exposure scenarios(i.e. use of toluene as a solvent and use of toluene as an extraction agent) .

Concerns for consumers are identified in relation to specific scenarios involving spray painting and carpet laying. Certain risk reduction measures have been implemented in the EU legislation including restrictions on the content of the substance in certain products (adhesives, spray paints and cosmetics). With regard to indirect exposures via the environment the European Risk Assessment Report concludes that existing risk reduction measures with respect to the consumers are sufficient.

From an environmental point of view toluene is not of high general concern although it contributes as a VOC to tropospheric ozone formation. It is easily biodegradable, the toxicity of the substance to aquatic and soil organisms is moderate-low and it does not bioaccumulate.

Toluene has for many years been widely used partly in basic chemical production and partly as a solvent in a large variety of applications. It does seem, however, that the use of the substance has been decreasing in recent years, in the EU as a whole as well as in Denmark. It is not known to what extent this is due to replacement by alternatives, but it is assessed that, in general, technical alternatives are available for the different uses as a solvent.

Data gaps
The uses of toluene in Denmark have due to confidentiality restrictions not been possible to fully elucidate or to assess quantitatively. Neither has quantitative data on occurrence and levels in waste or in sewage sludge been identified.

Sammenfatning og konklusion

Denne rapport omhandler stoffet toluen, der er et af de i alt 40 stoffer på Miljøstyrelsens Liste over uønskede stoffer (LOUS). Toluen indgår (sammen med styren) på listen i gruppen "organiske opløsningsmidler. For alle LOUS-stofferne udarbejdes tilsvarende rapporter i perioden 2012-2015.

Toluen er en væske ved stuetemperatur og koger ved 110 grader Celsius. Det har en relativt lav vandopløselighed på omkring 580 mg/l. På EU niveau er de væsentligste anvendelser af toluen som udgangs- og hjælpestof i den kemiske industri samt som opløsningsmiddel til en lang række formål, f.eks. i malinger, tekstilcoatninger, trykkerier osv. I Danmark er anvendelsen som opløsningsmiddel den vigtigste.

Lovgivning og anden regulering
Toluen er under CLP-forordningen klassificeret som H225 (Meget brandfarlig væske og damp), H304 (Kan være livsfarligt, hvis det indtages og kommer i luftvejene), H315 (Forårsager hudirritation), H336 (Kan forårsage sløvhed eller svimmelhed), H361d (Mistænkt for at skade forplantningsevnen eller det ufødte barn) og H373 (Kan forårsage organskader ved længerevarende eller gentagen eksponering).

Hvad angår produkter er indholdet af toluen i klæbemidler og spraymalinger under REACH begrænset til <0,1 % og til 25 % i neglelak i henhold til Kosmetikforordningen. Der er ikke fastsat maksimalværdier for indholdet i andre typer af produkter, hvor eksponering af forbrugere eventuelt forekomme, så som maling og fortyndere.

Den danske arbejdsmiljølovgivning af relevans for toluen omfatter generelle krav vedrørende f.eks. risikovurdering, forebyggende foranstaltninger og uddannelse. Der er fastsat en dansk grænseværdi på 25 ppm for toluen i arbejdsmiljøet, hvilket er en mere restriktiv værdi end den vejledende grænseværdi i EU på 50 ppm. Desuden er der fastsat nationale danske miljøkvalitetskrav for toluen i ferskvand og saltvand på hhv. 74 µg/l og 7.4 µg/l.

Miljømærkekriterier af relevans for toluen vedrører primært stoffet som VOC, men der er dog fastsat specifikke kriterier for anvendelse i plejemidler til både og biler samt til dybtryk.

Fremstilling og anvendelser
I følge EU-registreringen af toluen under REACH produceres stoffet i en årlig mængde i EU på mellem 1 og 10 millioner tons, men der finder ingen fremstilling af stoffet sted i Danmark. I 1995 var den samlede produktion af stoffet i Europa omkring 2,6 millioner tons, men den var faldet til omkring 1,4 millioner tons i 2012.

Forbruget af toluen i Europa var ca. 2,75 millioner tons i slutningen af 1990'erne, men var faldet til ca. 1,25 millioner tons i 2012. Forbruget i Danmark var i 2012 mellem 3430 og 3940 tons ifølge data fra Produktregistret, hvilket også er noget lavere end i tidligere år.

Globalt anvendes toluen især til fremstilling af en lang række andre kemiske stoffer, heriblandt benzen, benzoesyre, nitrotoluener og tolylisocyanater samt farvestoffer, farmaceutiske produkter, fødevaretilsætningsstoffer, plasttsoffer m.fl. Det har glimrende tekniske egenskaber som opløsningsmiddel og har derfor gennem lang tid været det foretrukne stof til mange formål så som til overfladebehandling, i klæbemidler, blæk, farmaceutika og industrielle kemiske processer.

Anvendelsen af toluen som intermediær i kemisk produktion tegner sig på EU-plan for 70-80% af det samlede forbrug, mens omkring 20% af forbruget er som opløsningsmiddel. I Danmark er det mindre end 13 %, der anvendes i kemisk produktion, mens langt størstedelen af forbruget går til formål som opløsningsmiddel, særligt til fortyndere og som rensemiddel i autobranchen.

Affald

Toluen er i affaldssammenhæng at betragte som farligt affald og skal indsamles og behandles af godkendte operatører. Det samme er tilfældet for produkter, der indeholder 25 % toluen eller mere.

Interviews med tre danske virksomheder inden for klæbemiddel- og malingsbranchen i forbindelse med projektet viste, at kun en af virksomhederne anvendte toluen som opløsningsmiddel i et af deres produkter (kun til professionelt brug). Dette produkt fremstilles dog ikke i Danmark og produktionen vil således ikke medføre frembringelse af toluenholdigt affald her i landet.

I anvendelsesfasen vil malinger og andre coatningsprodukter til professionelt brug i nogle tilfælde give anledning til toluenholdigt affald. Der er dog ikke fundet konkrete tal for omfanget.

Toluen kan også blive udledt til spildevand og dermed principielt forekomme i spildevandsslam, men heller ikke her er der fundet konkrete tal om de mulige koncentrationer.

Miljømæssige effekter og opførsel samt eksponering

Toluen har et højt damptryk og fordamper let fra vand- og jordoverflader. Det nedbrydes ret hurtigt i atmosfæren ved fotooxidation til forskellige VOC'er hvorved stoffet bidrager til ozondannelse i den nederste del af atmosfæren. Stoffet betragtes som let bionedbrydeligt i vand, mens der ikke forekommer abiotisk nedbrydning af betydning. Der er dog observationer, der tyder på, at toluen nedbrydes ret langsomt i naturlige vandmiljøer når koncentrationerne er lave. Toluen anses for at være ret mobilt i jord og det vurderes ikke at være bioakkumulerende.

Giftigheden af toluen over for vandlevende organismer så som fisk og krebsdyr er moderat med typiske akutte LC_{50}/EC_{50} –værdier i området 3-10 mg/l, mens den laveste kroniske NOEC er 0,74 mg/l for dafniearten *C. dubia*. I det terrestriske miljø vurderes giftigheden også at være moderat-lavt over for regnorme og planter, dog ud fra et meget begrænset datagrundlag.

Toluen afgives til miljøet primært via udslip til luft, dels fra de mange typer af produktion, hvor stoffet anvendes, og dels ved brugen til en lang række formål. Forhøjede koncentrationer af toluen i luft (1,3-3,7 $\mu g/m^3$) er påvist i bymiljøer med stærk traffik som følge af, at toluen er en bestanddel af almindelig motorbenzin.

Mindre mængder af toluen tilgår de offentlige spildevandssystemer. Moniteringsdata viser dog, at koncentratioerne af toluen er lave i spildevand og afstrømmende regnvand fra veje o.lign.

I EU's risikovurdering af toluen fra 2003 konkluderes det, at der for et antal standard kategorier af anvendelser i kemisk og heraf afledet produktion er behov for at reducere risikoen ift. miljøet lokalt, dog under hensyntagen til de begrænsende foranstaltninger, der allerede er sat i værk. Af de nævnte anvendelsesområder er det dog kun malingsfremstilling, der synes at være relevant for Danmark. Det skal bemærkes, at EU's konklusion hovedsageligt skyldes, at utilstrækkelig information bevirker, at en risiko ikke kan udelukkes.

Sundhedseffekter og eksponering af mennesker

Den akutte giftighed af toluen hos forsøgsdyr er lav både ved inhalation, oral indtagelse og hudkontakt. På baggrund af data på mennesker er toluen klassificeret som værende giftigt over for specifikke organer ved en enkelt eksponering. Centralnervesystemet og det indre øre er fundet at

være de vigtigste målorganer ved længere tids eksponering og toluen er derfor også klassificeret som værende giftigt over for specifikke organer ved gentagne eksponeringer. Stoffet er desuden klassificeret som hudirriterende, men ikke irriterende på øjet. Toluen virkede ikke sensibiliserende i et studie med marsvin, men der er ingen data på mennesker.

Toluen anses ikke for at være et mutagent stof, denne vurdering er baseret på resultater fra et betydeligt antal testsystemer. Dokumentationen vedrørende carcinogenicitet er af EU og IARC ikke fundet tilstrækkelig til at berettige en klassificering. Toluen har ikke vist tydelige effekter på reproduktionen, mens der i eksperimentelle dyrestudier er fundet stærk evidens for udviklingstoksicitet og toluen er derfor klassificeret som havende denne virkning.

Eksponering af forbrugere for toluen sker primært i forbindelse med anvendelse af produkter, der indeholder stoffet. Eksponerings- og risikovurderinger er blevet foretaget af EU for fire anvendelsesområder: Limning, sprøjtemaling, bilpleje (rengøring af hænder med organisk opløsnings-middel) samt lægning af gulvtæpper. For de fleste scenarier blev der ikke fundet årsag til bekymring. For to forbrugerscenarier (sprøjtemaling og gulvtæppelægning) blev det konkluderet, at der var behov for at begrænse risikoen, dog under hensyntagen til allerede implementerede, begrænsende foranstaltninger. Forbrugere kan også blive eksponeret under påfyldning af benzin på deres biler, men der er ikke gennemført nogen EU-risikovurdering af dette scenarie. Til gengæld viste en australsk undersøgelse af 6 forskellige eksponeringsscenarier fra tankstationer, hvoraf nogle er forbrugsscenarier ved påfyldning af benzin, at der ikke er årsag til bekymring for forbrugere hvad angår toluen. Der foreligger tillige en række danske forbrugerproduktstudier, der også har omfattet toluen, hvor (overvejende lave) indhold i og afgivelser af stoffet fra produkter er blevet påvist. Det er vurderet, at hvis alle afgivelser fra potentielle kilder til indeluften i et børneværelse lægges sammen, vil den daglige eksponering for et barn være tæt på den tolerable daglige indtagelse (TDI) og Reference dosis for toluen på 223 µg/kg lgv/dag.

Arbejdsmiljømæssig eksponering for toluen forekommer primært i de industrier, hvor toluen og benzin fremstilles, hvor toluen benyttes som syntesestof eller ingrediens samt ved brug af produkter, der indeholder toluen. I EU-vurderingen blev der konstateret behov for at reducere risikoen ved et antal anvendelser af toluen inklusive produktion af stoffet selv, anvendelse som syntesestof i kemisk industri, produktion af produkter indeholdende toluen samt brugen af en række af disse produkter. Det estimerede humane orale indtag, i forbindelse med erhvervsmæssig anvendelse af toluen, viste en overskridelse af TDI-værdien fastlagt af WHO i to af de modellerede produktions scenarier, henholdsvis anvendelse af toluen som opløsningsmiddel og anvendelse af toluen som et ekstraktionsmiddel.

Estimerede indtag af toluen via miljøet sammenlignet med TDI fastlagt af WHO tyder ikke på, at toluen er et væsentligt problem.

Alternativer til toluen

Det er forfatternes vurdering, at det principielt vil være relativt enkelt at substituere toluen anvendt som opløsningsmiddel i langt de fleste anvendelser i Danmark, idet der ikke er tale om et reaktivt opløsningsmiddel og der eksisterer et antal tekniske alternativer. Mulighederne for substitution er afhængige af de enkelte tekniske og arbejdsmiljømæssige forhold. En undtagelse fra den generelle vurdering er anvendelse til industriel dybtryk af magasiner, reklamer mv. samt fleksible emballager, hvor toluen synes sværere at erstatte.

Et mindre antal danske virksomheder inden for malings- og klæbemiddelbrancherne, der er interviewet som del af projektet, har tilkendegivet, at de allerede har udfaset toluen i deres produkter. En enkelt virksomhed benytter stadig toluen i visse produkter til professionelle formål, men fremtidige produkter vil blive udviklet uden toluen.

De opløsningsmidler, der kan erstatte toluen, er typisk forskellige blandinger af ketoner, estre, alkoholer og alifatiske kulbrinter. I produkter, hvor der ikke er nogen reguleringsmæssige krav til indholdet af toluen, kan indholdet af toluen typisk reduceres ved i stedet at benytte xylen og/eller cyclohexan i formuleringerne.

Ingen af de opløsningsmidler, der er identificeret som mulige tekniske alternativer til toluen, er klassificeret som akut giftige eller som kræftfremkaldende, mutagene eller skadelige for reproduktionen.

Konklusioner
Toluen betragtes som uønsket på grund af sin klassificering som giftig ved længerevarende eller gentagen eksponering og på grund af udviklingstoksicitet.

Udsættelse for toluen synes overvejende at give anledning til bekymring i forhold til erhvervsmæssig eksponering, dvs. brugen af toluen som opløsnings- og ekstraktionsmiddel.

Bekymring i relation til forbrugeres udsættelse er identificeret i forhold til specifikke scenarier med sprøjtemaling og pålægning af gulvtæpper. Risikobegrænsende foranstaltninger er derfor blevet gennemført i EU-lovgivningen, herunder restriktioner af indholdet af stoffet i visse produkter (f.eks. klæbemidler, spraymaling og kosmetik)Med hensyn til indirekte eksponering via miljøet konkluderer EUs risikovurderingsrapport, at de eksisterende risikobegrænsende foranstaltninger ift. forbrugere er tilstrækkelige.

I relation til miljøet giver styren ikke anledning til væsentlig bekymring selv om stoffet i kraft af sin status af VOC bidrager til ozondannelse i troposfæren. Stoffets er let bionedbrydeligt, giftigheden over for både vandlevende og terrestriske organismer er moderat eller lav, og styren er helle rikke bioakkumulerende.

Toluen har gennme mange år været vidt udbredt som basiskemikalie i kemisk produktion og som opløsningsmiddel til en lang række formål. Det synes dog som om, at både produktion og forbrug af stoffet er blevet mindre i de senere år både i EU som helhed og i Danmark. Det vides ikke i hvilken grad dette skyldes substitution med andre stoffer eller metoder, men det vurderes, at der for de fleste anvendelser som opløsningsmiddel eksisterer teknisk anvendelige alternativer til toluen.

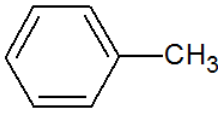
Manglende oplysninger
På grund af fortrolighedsbestemmelser har det ikke været muligt at klarlægge anvendelserne af toluen i Danmark fuldstændigt eller vurdere deres betydning og omfang kvantitativt. Endvidere er der ikke identificeret kvantitative data om forekomsten af toluen i affald eller i spildevandsslam.

1. Introduction to the substance

1.1 Definition of the substance

This name and other identifiers of toluene included in this study are listed in Table 1.

TABLE 1
NAME AND OTHER IDENTIFIERS OF TOLUENE

Substance name	Toluene
EC number	203-625-9
CAS number	108-88-3
Synonyms	-
Molecular formula	C_7H_8
Structure	
Molecular weight (g/mol)	94.12

1.2 Physical and chemical properties

The physical and chemical properties of toluene are shown in Table 2. The listed properties mainly refer to the registration dossiers available at ECHA's website. The registration dossiers may include different values for the same parameter; in this case, a range is indicated.

TABLE 2
PHYSICAL AND CHEMICAL PROPERTIES OF TOLUENE [ALL DATA PRSENTED ARE REACH REGISTRATION DATA EXTRACTED FROM ECHA'S WEBSITE IN OCTOBER 2013]

Property	Toluene
Physical state	Colourless liquid
Melting point at 1013 hPa (°C)	-95
Freezing point (°C)	-
Boiling point at 1013 hPa (°C)	110.6

Property	Toluene
Relative density at 20°C (g/cm³)	0.87
Vapour pressure at 70 °F (PSI) Vapour pressure at 80 °F (PSI)	0.448 0.599
Surface tension at 25 °C (mN/m)	27.73
Water solubility at 25 °C and pH 7 (mg/L)	573 - 580
Log P (octanol/water) at 20 °C	2.73

1.3 Function of the substance for main application areas

The main applications of toluene are as raw materials and auxiliaries in the chemical industry and as solvents in many applications including paints, textile coatings, printing industry, etc.
In Denmark, which has little heavy chemical industry, its use as a solvent is the most significant.

The consumption of toluene in Denmark has been reported to account for about 3,300 tons (SPIN database 2013). Toluene is registered under REACH in the tonnage band 1-10 million t/year.

2. Regulatory framework

This chapter gives an overview of how toluene is addressed in existing and upcoming EU and Danish legislation, international agreements and by EU and Nordic eco-label criteria. The chapter primarily focuses on legislation where toluene is addressed specifically. Legislation whereby the substance is implicitly addressed, i.e. where it is included in the overall scope of a regulation or directive (e.g. due to its classification), is not listed. Thus, instruments regulating volatile organic compounds (VOC) in general are not listed, even though toluene will be comprised by such instruments due to its VOC properties.

In Appendix 1, an overview of legal instruments in the EU and DK is presented. The appendix also gives a brief introduction to the chemicals legislation, explains the lists referred to in section 2.1.3 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and provides a short introduction to international agreements and the EU and Nordic ecolabelling schemes.

2.1 Legislation

2.1.1 Existing legislation

Table 3 provides an overview of current key legislation addressing toluene with respect to substance regulation, waste, environmental emissions, and occupational environment. For each area of legislation, the table first lists the EU legislation (if applicable) and then (as concerns Directives) existing transposition into Danish law and/or other national rules. The latter is elaborated in the case that Danish rules differ from EU rules.

TABLE 3
LEGISLATION ADDRESSING TOLUENE

Legal instrument*	DK/ EU	Substance (as identified in the instrument)	Requirements
Regulation addressing substances and products			
Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII amended by **COMMISSION REGULATION (EC) No 552/2009, 22 June 2009**	EU	Toluene, CAS No 108-88-3, EC No 203-625-9	Subject to restriction (Annex XVII): Shall not be placed on the market, or used, as a substance or in mixtures in a concentration equal to or greater than 0,1 % by weight where the substance or mixture is used in adhesives or spray paints intended for supply to the general public.

Legal instrument*	DK/ EU	Substance (as identified in the instrument)	Requirements
REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	EU		Toluene is classified according to harmonised classification and labelling of hazardous substances (Table 3.1) and according to harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC (Table 3.2)
Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Annexes II, III, V and VI amended by **COMMISSION REGULATION (EU) No 344/2013 of 4 April 2013**	EU	Toluene, 108-88-3, 203-625-9	Subject to Annex III LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN: Maximum concentration in nail products is 25%. Keep out of reach of children To be used by adults only.
Statutory order on food contact materials, No. 822 of 26/06/2013 [Bekendtgørelse om fødevarekontaktmaterialer, BEK nr. 822 af 26/06/2013] /Danish Ministry of Food		Toluene	Annex 3 - List of substances which may be used in the manufacture of regenerated cellulose, Part B - Surface treated films of regenerated cellulose: Less than or equal to 0.06 mg/dm² of the coating on the side in contact with foodstuffs.
Regulation addressing waste			
Statutory order on landfills, No. 1049 of 28/08/2013 [Bekendtgørelse om deponeringsanlæg, BEK nr 1049 af 28/08/2013] Amending Statutory order on landfills, No. 252 of 31/03/2009 [Bekendtgørelse om deponeringsanlæg, BEK nr 252 af 31/03/2009] /Danish Ministry of Environment		Toluene	The maximum content of toluene in groundwater, as the basis for the environmental impact assessment, is 5 µg/L. The limit value for solid content of BTEX (benzene, toluene, ethylbenzene, and xylenes) in inert waste is 6 mg/kg dw. The limit value for solid content of BTEX (benzene, toluene, ethylbenzene, and xylenes) in mineral waste is 15 mg/kg dw. The limit value for BTEX in hazardous waste deposited in a waste unit for mineral waste is 15 mg/kg dw.

Legal instrument*	DK/ EU	Substance (as identified in the instrument)	Requirements
Regulation addressing emissions to the environment			
Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (PRTR Regulation)	EU	CAS no. 108-88-3, Toluene	The operator of a facility that undertakes one or more of the activities specified in Annex I above the applicable capacity thresholds shall report the amounts annually to its competent authority if the releases are above the following threshold for releases: To air: - To land: 200 kg/year (as BTEX) To water: 200 kg/year (as BTEX)
Statutory order on water quality and monitoring of water supply systems, No. 1024 of 31/10/2011 [Bekendtgørelse om vandkvalitet og tilsyn med vandforsyningsanlæg, BEK nr 1024 af 31/10/2011] /Danish Ministry of Environment	DK	Toluene	This order establishes quality requirements for drinking water and water with specific quality requirements, and outlines amongst others which studies should be be carried out with the water, the methodologies for the control of abstraction volume, and inspections of the water utilities. Toluene is comprised by Annex 7: Control of organic micro-contaminations (at the water work), compounds that have to be controlled on a regular basis (for toluene , no quality requirements in drinking water are defined here).
Statutory order on assessment and management of air quality, No. 1326 of 21/12/2011 [Bekendtgørelse om vurdering og styring af luftkvaliteten, BEK nr 1326 af 21/12/2011] /Danish Ministry of Environment	DK	Toluene	Toluene is included in the list of measurement of ozone precursor substances including nitrogen oxides (NO and NO2), and applicable volatile organic compounds (VOCs). Thus toluene is recognized as an ozone precursor substance appropriate for monitoring.
Statutory Order on environmental quality standards for the aquatic environments and requirements regarding discharges of pollutants to streams, lakes and the sea [Bekendtgørelse om miljø-kvalitetskrav for vandområder og krav til udledning af forurenende stoffer til vandløb, søer eller havet, BEK nr 1022 af	DK	108-88-3 toluene	Subject to Annex 2 - Contaminants with national environmental quality requirements (µg/L). General quality requirement, freshwater: 74 General quality requirement, marine water: 7,4 Short-term quality requirement, freshwater: 380 Short-term quality requirement, marine water: 380

Legal instrument*	DK/ EU	Substance (as identified in the instrument)	Requirements
25/08/2010] /Danish Ministry of Environment			
Statutory Order on quality requirement to environmental analyses, No. 900 of 17/08/2011 [Bekendtgørelse om kvalitetskrav til miljømålinger, BEK no 900 of 17/08/2011] /Danish Ministry of Environment	DK	Toluene	Sets requirements concerning quality control of chemical analyses of toluene in environmental and product samples and requirements concerning standard deviation and detection limits on the measurements. Concerns analyses prepared as part of the authorities' enforcement of the Danish Environmental Protection Act, the Chemical Substances and Products Act and other legal instruments in the field of the environment and analyses being part of national monitoring programs
Regulation addressing occupational environment			
COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work	EU	-	The Directive sets out general rules for the working environment, imposing the duty on employers to asses any risk to the safety and health of workers arising from the presence of hazardous chemical agents at the workplace, take the necessary preventive measures and to ensure the safety and health requirements for activities involving hazardous chemical agents are met.
Statutory order on working with substances and materials, No. 292 of 26/04/ [Bekendtgørelse om arbejde med stoffer og materialer, BEK nr 292 af 26/04/2001]	DK/ EU*	-	Implementing COUNCIL DIRECTIVE 98/24/EC.
Statutory order on youth work, No. 239 of 6 April 2005 [Bekendtgørelse om unges arbejde, BEK nr 239 af 06/04/2005]	DK	-	In relation to work with organic solvents, this statutory order prohibits that workers below 18 years of age work with organic solvents listed by the Danish Working Environment Authority as well as with materials containing 1 % or more of these solvents.
COMMISSION DIRECTIVE 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending	EU	Toluene, EINECS 203-625-9, CAS no. 108-88-3	Listed in the Annex: INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES Limit values 8 hours: 192 mg/m^3, 50 ppm Short-term: 384 mg/m^3, 100 ppm skin notation

Legal instrument*	DK/ EU	Substance (as identified in the instrument)	Requirements
Directives 91/322/EEC and 2000/39/EC			
Statutory order on changing the statutory order on limit values for substances and materials, No. 986 of 11/10/2012 [Bekendtgørelse om ændring af bekendtgørelse om grænseværdier for stoffer og materialer, BEK nr 986 af 11/10/2012] Amending statutory order on limit values for substances and materials, 507 of 17/05/2011 [Bekendtgørelse om grænseværdier for stoffer og materialer, BEK nr. 507 af 17/05/2011] /Danish Ministry of Employment	DK	108-88-3 Toluene	Occupational exposure limits: Limit values of toluene are 25 ppm and 94 mg/m³. Toluene is marked as H – skin penetrating.
Statutory order on determination of code numbers, Order No. 301 of 13/05/1993 [Bekendtgørelse om fastsættelse af kodenumre, BEK nr 301 af 13/05/1993] /Danish Ministry of Employment **Statutory order on working with code-numbered products, No. 302 of 13 May 1993.** [Bekendtgørelse om arbejde med kodenummererede produkter, BEK nr. 301 af 13/05/1993] /Danish Ministry of Employment	DK	Toluene (syn: methylbenzene, phenylmethane)	The Metrological Occupational Air Requirements, called MAL [Danish: Måleteknisk Arbejdshygiejnisk Luftbehov] are defined for toluene as follows: **Toluene content > 0%** - MAL-factor (m³ air / 10g substance): 74 - Content (limit weight %) / Marker number: ≥10% / -3 Defines minimum safety measures which have to be applied when working with code-number labelled products depending on working situtions (outside, inside, large or small application areas) and processes (e.g. painting, grouting). As a minimum, work with toluene requires gloves; in many cases it also requires a full face mask with breathing apparatus, hat, and coveralls.

* Unauthorised translation of Danish legislation instrument names into English. "Bekendtgørelse" is translated as "Statutory order" in all cases, even though the Danish Working Environment Authority commonly uses the translation "Executive order".

Toluene is registered under REACH. The substance is included in Annex XVII under REACH restricting the use of the substance to ≤ 0.1% in adhesives and spray paints. Toluene is classified according to harmonised classification and labelling of hazardous substances as specified in the CLP regulation. Further information on the provisions under CLP and REACH are given in sections 2.1.2 and 2.1.3.

The maximum concentration in nail polish shall not exceed 25% according to the Commission regulation on cosmetics (no. 344/2013).

Companies or facilities are obliged to report activities that lead to environmental emissions exceeding 200 kg/year according to EU regulation.

With respect to occupational exposures, indicative occupational exposure limit values of toluene are defined in the EU Commission Directive on indicative occupational exposure limit values.
The Council Directive on the protection of the health and safety of workers from the risks related to chemical agents (98/24/EC) does apply generally, imposing obligation to employers to ensure the safety and health requirements for activities involving hazardous chemical agents and take the necessary preventive measures.

In Denmark, a number of statutory orders[1] regulate chemical substances in general in the context of occupational exposures. Furthermore, Danish legislation requires that a code number is set for products and mixtures containing toluene, which are used for the purposes listed in the statutory order. Safety measures are required according to the code number. The Danish air limit value concerning occupational exposure is considerably lower (25 ppm) than the European indicative occupational exposure limit value (50 ppm).

The maximum allowable concentrations of toluene in waste and groundwater with respect to landfills are defined in order to protect ground- and surface waters. Furthermore, national environmental quality requirements exist for fresh and marine surface waters. Waterworks shall regularly control for toluene content in drinking water; however, quality requirements for toluene in drinking water are not defined. With respect to air, toluene is recognized as an ozone precursor substance and thereby as a VOC appropriate for monitoring.

2.1.2 Classification and labelling

Harmonised classification in the EU

Table 4 lists the harmonized classification and labelling for toluene according to Annex VI of the CLP Regulation.

[1] Translation of the Danish "Bekendtgørelse". Depending on organisation and context, other translations might be used, e.g. 'executive order'. In this report, the translation 'statutory order' is used consistently.

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

Index No	International chemical identification	CAS No	Classification		
			Hazard Class and Category Code(s) [1]	Hazard statement Code(s) [2]	Pictogram
601-021-00-3	toluene	108-88-3	Flam. Liq. 2	H225	
			Asp. Tox. 1	H304	
			Skin Irrit. 2	H315	
			STOT SE 3	H336	
			Repr. 2	H361d	
			STOT RE 2	H373	

[1] Hazard Class: Flam. Liq. - Flammable liquid; Asp. Tox. - Aspiration hazard ; Skin Irrit. - Skin corrosion/irritation; STOT SE - Specific target organ toxicity — single exposure; Repr. - Reproductive toxicity; STOT RE - Specific target organ toxicity — repeated exposure

[2] Hazard statement Code(s)H225: Highly flammable liquid and vapour; H304: May be fatal if swallowed and enters airways; H315: Causes skin irritation; H336: May cause drowsiness or dizziness; H361d: Suspected of damaging the unborn child; H373: May cause damage to organs through prolonged or repeated exposure

Self-classification in the EU

Additionally to the harmonized classification, toluene has been notified as Eye irrit. 2 (H319), Aquatic Chronic 2 (H411), and Aquatic Chronic 3 (H412) (50 times or more out of a total of 3951 notifications).

2.1.3 REACH

Toluene is registered under REACH in the 1.000.000 – 10.000.000 t/y band.

For toluene, 66 registrants/suppliers are listed in Europe. The registering companies are situated in 16 countries in total: Belgium, Czech Republic, Finland, France, France, Germany, Hungary, Italy, The Netherlands, Poland, Portugal, Romania, Slovakia, Spain, Sweden, United Kingdom.

Toluene is included in the restriction annex (Annex XVII) under REACH, restricting the use of the substance to ≤ 0.1% in adhesives and spray paints.

Community rolling action plan (CoRAP)

Toluene is included in the CoRAP (ECHA, 2012) for 2012-2014. The reasons for the inclusion of tolueneare stated to be issues related to human health combined with the chemical's wide-spread use.

TABLE 5
SUBSTANCES IN THE COMMUNITY ROLLING ACTION PLAN FOR 2012-2014 (ECHA, 2012).

CAS No	EC No	Substance Name	Year	Member State	Initial grounds for concern
108-88-3	203-625-9	toluene	2012	Finland	Human health/CMR and systemic toxicity; Exposure/Wide dispersive use, consumer use, high aggregated tonnage

Registry of Intentions

Toluene is not comprised in the Registry of Intentions by ECHA and Member States' authorities for restriction proposals, proposals for harmonised classifications and labelling and proposals for Substances of Very High Concern (SVHC).

Candidate list

Toluene is not on ECHA's Candidate list of Substances of Very High Concern (SVHC) (October 2013).

Annex XIV recommendations

Toluene has not been recommended for Annex XIV (Authorisation List) inclusion (ECHA, 2013).
NB: Possible inclusion would first require uptake on the candidate list.

2.2 International agreements

Generally, toluene is not specifically addressed in international agreements concerned with chemicals in the environment, hereunder the OSPAR Convention, HELCOM, Rotterdam Convention (PIC), and Basel Convention. Under the Convention on Long-range Transboundary Air Pollution (CLRTAP), toluene is classified as a substance of least importance in episodic ozone formation.

TABLE 6
INTERNATIONAL AGREEMENTS ADDRESSING TOLUENE.

Agreement	Substances	How the substances are addressed
Convention on Long-range Transboundary Air Pollution (CLRTAP)	Toluene	Mentioned in the 1991 Geneva Protocol concerning the Control of Emissions of Volatile Organic Compounds or their Transboundary Fluxes. - As a substance of least importance in episodic ozone formation (Table 1) - Comparison between weighting schemes (expressed relative to ethylene = 100) for 85 VOC species (Table 3)

2.3 Eco-labels

Table 7 gives an overview of how toluene is addressed by the EU and Nordic eco-labelling schemes, with an indication of requirements.

Toluene is only addressed specifically in the criteria on car and boat care products, printing companies and printed matter (Nordic Swan), as well as in the EU criteria for printed paper.

Since toluene is a volatile organic compound and an aromatic solvent, its use and content is generally restricted or prohibited by a large number of Ecolabelling criteria for many different product groups, e.g. candles, toys, exterior doors and windows, and industrial cleaning and degreasing agents. In many of these, toluene is supposedly merely applied as a process substance, and possible product content is due to residue or impurity content.

Many eco-label criteria have general requirements for chemicals (e.g. due to classification) and waste management (hazardous waste). These are not specifically mentioned here.

A comprehensive overview of VOC-restricting criteria can be seen in Appendix 2.

TABLE 7
ECOLABELS TARGETING TOLUENE

Eco-label	Substances	Relevant criteria	Document title /number
Nordic Swan	VOC (toluene)	The product may contain a limited quantity only of volatile organic compounds (VOC) that may contribute to the formation of photochemical smog, measured as POCP. Products with a VOC content of < 1.2% do not need to undergo POCP calculation since the requirement will be fulfilled even in a worst case scenario. The maximum content of VOC in the product is 12 g ethylene equivalents/kilo of product. The POCP factor of toluene is 0.5 (Appendix 7).	Nordic Ecolabelling of Car and boat care products Version 5.2 • 21 March 2012 – 31 March 2016
	Toluene	Gravure printers must have a closed system or a recovery plant for toluene to inspect, measure and register VOC emissions, in which the recovery of toluene is at least 92%. Hazardous chemicals classified with hazards phrases as specified in the criteria (hereunder H373 and H304) must not be used. However, toluene-based washing agents and printing ink for gravure printing are exempted from the requirement.	Nordic Ecolabelling of Printing companies, printed matter, envelopes and other converted paper products Version 5.4 • 15 December 2011 – 31 December 2017

Eco-label	Substances	Relevant criteria	Document title /number
EU flower	Toluene	Classification as H304 (amongst other) excludes hazardous substances and mixtures from use in printing, coating, and finishing operations of the final printed paper product. However, toluene in closed or encapsulated rotogravure printing processes is exempted from this requirement. The criteria for washing agents (amount of aromatic hydrocarbons in the washing agent products used does not exceed 0,1 % (w/w); amount of aromatic hydrocarbon-based washing agent used annually does not exceed 5 % of the total amount of washing agent used in one calendar year) does not apply to toluene used as washing agent in rotogravure printing.	COMMISSION DECISION of 16 August 2012 establishing the ecological criteria for the award of the EU Ecolabel for printed paper

2.4 Summary and conclusions

Toluene is subject to harmonised classification under the CLP regulation and is classified as: H225 (Highly flammable liquid and vapour), H304 (May be fatal if swallowed and enters airways), H315 (Causes skin irritation), H336 (May cause drowsiness or dizziness), H361d (Suspected of damaging the unborn child), and H373 (May cause damage to organs through prolonged or repeated exposure).

Under REACH (Annex XVII), the concentration of toluene in adhesives and spray paints is restricted to ≤ 0.1%.

The content of toluene in nail polish is restricted to 25 % according to the cosmetics regulation. There are no specific restrictions of toluene in other types of products where consumer exposure can occur, such as paints or thinners.

The Danish legislation addressing occupational handling of toluene includes general requirements regarding for instance risk assessment, preventive measures and training and the establishment of Danish occupational exposure limits.

The Danish occupational exposure limits (25 ppm) for toluene are more conservative than the indicative European limit values (50 ppm). Moreover, maximum concentrations of toluene are established for waste and landfill leachates, as well as for fresh and marine surface waters.

Toluene is generally not addressed in international agreements and conventions.

Toluene is directly mentioned in only a single eco-labelling criteria document, but is indirectly comprised in eco-labelling criteria for a wide range of products, based on prohibition or restriction of VOC content.

3. Manufacture and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

The production of toluene is described in the European Risk Assessment Report (RAR) on toluene (ECB, 2003). Toluene is mainly produced by continuous processes in closed systems. It is both a constituent of crude oil and a component of the condensate from natural gas production. Thus, it is synthesised together with many other substances in petroleum refinery and chemical plant processes, primarily by catalytic reforming, steam cracking, and dealkylation.

Toluene is also recovered during the production of coal-derived chemicals, primarily from coke oven by-products. Part of the toluene recovered during production of coal-derived chemicals is purified for production of commercial grade toluene.

The distribution between the different manufacturing methods is described as follows in the EU RAR on toluene (ECB, 2003): "*The principal source of toluene is catalytic reforming of refinery streams. This source accounts for ca. 87% of the total toluene produced. An additional 9% is separated from pyrolysis gasoline produced in steam crackers during the manufacture of ethylene and propylene. Other sources are an additional 2% recovered as by-product from styrene manufacture and 1-2% entering the market from separation from coal-tars.*"

3.1.2 Manufacturing volumes and sites

Toluene is registered under REACH in the 1,000,000 - 10,000,000 tons/year band in the EU.

In 1995, the total amount of toluene produced by the stakeholders that provided information was 2,600,000 tons (ECB, 2003). This production volume does not include toluene as a (minor) constituent of gasoline (i.e. non-isolated toluene). In the EU RAR, information from 31 sites is available (ECB, 2003). In the beginning of the 2000s, 19 sites were producing isolated toluene, 6 sites produced and performed on-site processing of toluene and 6 sites solely processing toluene were identified.

According to the PRODCOM[2] database, the average production of toluene in the EU27[3] was 1,795,000 tons in the period 2007 – 2011, and 1,412,000 tons in 2012.

3.2 Import and export

3.2.1 Import and export of toluene in Denmark

Danish import and export of toluene is shown in Table 8 based on data from Statistics Denmark (2013). According to Eurostat, toluene is not produced in Denmark.
Two different CN8-codes[4] have been assigned to toluene; however, trade amounts appear to be registered only for one of them. The net import of toluene was 1,871 t/y on average for the period 2007-2011 and 1,722 t in 2012.

[2] The PRODCOM database is Eurostat's database on manufactured goods under the "Industry, trade and services" branch. Eurostat is a Directorate-General of the European Commission providing European statistical information and promoting the harmonisation of statistical methods.
[3] Since the joining of Croatia in July 2013, the EU now comprises 28 Member States.
[4] Code number are assigned according to the Combined nomenclature and used for identifying goods.

TABLE 8
DANISH PRODUCTION, IMPORT AND EXPORT OF TOLUENE (STATISTICS DENMARK 2013, EUROSTAT PRODCOM DATABASE 2013;).

CN8 code	Substance	Import, t/y		Export, t/y		Production	
		Average 2007-2011	2012	Average 2007-2011	2012	Average 2007-2011	2012
2902 3000	Toluene	1,980	1,867	109	145	-	-
2707 2000	Toluol (toluene)	0	0	0	0	-	-

3.2.2 Import and export of toluene in EU

Statistics on EU external trade of toluene from Eurostat are shown in Table 9. The most recent import and export figures from 2012 are lower than the average of the 4 previous years.
The net consumption of toluene using the production volume of 1,412,000 tons (2012) can thus be calculated as 1,248,825 tons in 2012.

TABLE 9
EU27 EXTERNAL IMPORT AND EXPORT OF TOLUENE (EUROSTAT, 2013)

CN8 code	Substance	Import, t/y		Export, t/y	
		Average 2007-2011	2012	Average 2007-2011	2012
2902 3000	Toluene	21,642	16,108	343,421	179,283
2707 2000	Toluol (toluene)	-	-	-	-

3.3 Use

3.3.1 General use and function of the substance

Toluene is a high-production volume substance and is extensively employed in a broad spectrum of applications. Commercial toluene is used as a raw material in the production of benzene and several other chemicals (e.g. benzoic acid, nitrotoluenes, tolyl diisocyanates, as well as dyes, pharmaceuticals, food additives, plastics, etc.).

Toluene has excellent solvent properties, making it a preferred solvent in many applications, including coatings, adhesives, inks, pharmaceuticals and chemical processing.
Toluene is also present in many consumer products, including paints, varnishes, adhesives, and glues (ECB, 2003).

In the registrations on ECHA's homepage (as of March 2014), the following use categories are listed:

- Manufacture
- Distribution
- Use as a laboratory reagent
- Formulation
- Use in coatings
- Use as a fuel
- Use in binders and release agents
- Use in functional fluids
- Use in rubber production and processing
- Use as an intermediate

- Toluene
- Use in cleaning agents
- Use in oilfield drilling and production operations.

The use of toluene as feedstock for synthesis of other substances has been estimated and is shown in Table 10. The uses of toluene in the production of benzene and as a solvent therefore appear to be the dominating uses.

The fractions correspond to newer information stating that about half of all toluene is used to make on-purpose benzene, mixed xylenes and para-xylene, while toluene diisocyanate production is the second-largest single-derivative market for toluene, accounting for 7% of world demand in 2012 (HIS, 2013).

TABLE 10
FRACTIONS OF USE OF TOLUENE AS FEEDSTOCK FOR SYNTHESIS OF OTHER CHEMICALS (ESTIMATES FROM USAGE IN WESTERN EUROPE IN 1994-1995, ECB, 2003).

End use	Fraction
Benzene	32%
Phenol	7%
Nitrotoluene / caprolactam / phthalates	2%
TDI (toluene diisocyanate)	11%
Disproportionation* (from toluene to C6, C8 or C9)	16%
Motor gasoline (as additive solvent)	3%
Miscellaneous	10%
Total as feedstock and miscellaneous	**81%**
Used as solvent	**19%**

* Special type of redox reaction, where two reaction products are simultaneously formed by oxidation and reduction, respectively, from a single reaction substrate. Disproportionation of toluene is used to produce benzene and xylenes (Bawa et al. 1973).

According to statements in the EU RAR, it is difficult to obtain accurate estimates for the use of toluene as solvent. Solvent uses comprise the rotogravure industry (printing technique for magazines, postcards, catalogues, etc.), in paints, varnishes and adhesives, and also in pesticides, wood preservatives and as a processing aid (ECB, 2003).

Volumes of toluene in Europe, according to industrial and use category, have been estimated and are given in Table 11. Use as an intermediate accounts for about 70 % across the different industrial categories, while use as solvent in the different industries amounts to about 20 % of the total use. The use of the remaining 10 % is as extraction agent, process regulator and for coating.

The total use of 2,747,600 based on the 1997/1999 data is considerably higher than the consumption estimate of appr. 1,250,000 tons based on trade and production data from 2012.

TABLE 11
VOLUMES OF TOLUENE USED IN VARIOUS PROCESSES IN THE EU ACCORDING TO DATA FROM 1997/1999 (ECB, 2003)

Industrial category	IC no.	Use category	UC no.	Use (1000 tons/year)
Chemical industry: Chemicals used in synthesis	3	On-site intermediate Off-site intermediate	33 33	**534.0** **1,411.0**

Chemical industry: Basic Chemical	2	Solvent	48	**200.0**
Chemical industry: Basic Chemical	2	Extraction agent	34	**150.0**
Mineral oil and fuel industry	9	Solvent	48	**160.9**
Polymers industry	11	Process regulator, dry	33	**113.4**
Agricultural Industry	1	Intermediate	33	**8.1**
Personal/domestic industry	5	Solvent	48	**8.1**
Electrical/electronic industry	4	Solvent	48	**0.2**
Textile processing industry	13	Coating	0	**0.1**
Other	15	Other	0	**15.2**
Paint, lacquer and varnish industry	14	Solvent	48	**90.0**
Ink making	14	Solvent	48	**1.6**
Publication gravure	12	Solvent	48	**30.0**
Packaging printing	12	Solvent	48	**5.0**
Wall covering	12	Solvent	48	**1.0**
Adhesives	12	Solvent	48	**19.0**
Total				**2,747.6**

3.3.2 Uses in Denmark

Data on toluene registered in the Danish Product Register were retrieved in October 2013. The Danish Product Register (PR) includes substances and mixtures for professional use which contain at least one substance classified as dangerous in a concentration of at least 0.1% to 1% (depending on the classification of the substance). Thus, the PR data do not necessarily provide a complete picture of the presence of the substances in mixtures placed on the Danish market, because they only comprise application in the professional sectors.

Table 12 gives an overview of the data from the Danish Product Register on the use of toluene by industrial sector, which can be reported with respect for the confidential nature of the data. As shown, the major sectors are maintenance and repair of motor vehicles, retail sale of automotive fuel, manufacture of paints, varnishes and similar coatings as well as sealants, and coating of metal. A substantial part of the consumption is confidential, as few companies or products are registered.

Table 13 on the other hand shows the toluene registrations in the Product Register by function. Of the functions which can be named, solvents, intermediates, adhesives/binding agents and paints, lacquers and varnishes represent the majority of the consumption. For many of the registrations of solvent use, the sectors involved are coating of metal, vehicle construction workshops and car-painting workshops, where the main use may likely be car-painting activities.

Note that the sums of registered toluene consumption by sector and by functions are not identical; this is because the designation of sectors (and functions, respectively) may have some overlap. The total production/import for toluene across all codes in 2012 is registered as 3,715-4,219 t/y, the total export is 283-284 t/y, i.e. the Danish consumption is in the range 3430-3940 tons. The total

number of products is 1,068 and the total number of companies registered is 174. Please note that the total import and export figures given above do not match the total figures given in the last line of Table 12 and Table 13 (likewise reported by the Product Register). These differences occur because some consumption figures are registered under more than one sector or function.

TABLE 12
OVERVIEW OF REGISTRATIONS FOR TOLUENE BY INDUSTRY SECTOR IN THE DANISH PRODUCT REGISTER (2012 DATA EXTRACTED FOR THIS STUDY).

Sector (NACE5)		No. of products	No. of companies	Production /Import range, t/y	Export range, t/y
G4520	Maintenance and repair of motor vehicles	320	51	2149 - 2150	247.0
G4730	Retail sale of automotive fuel in specialised stores	4	3	958	0.0
C2030	Manufacture of paints, varnishes and similar coatings, printing ink and mastics	33	14	385	6.0
C2561	Treatment and coating of metals	108	17	131 - 133	0 – 0.05
C2052	Manufacture of glues	4	3	26 - 27	0.0
C1800	Printing and reproduction of recorded media	10	6	26	0.0
C2500	Manufacture of fabricated metal products, except machinery and equipment	34	17	22 - 26	7.0
C2900	Manufacture of motor vehicles, trailers and semi-trailers	7	4	22 - 24	7.0
C2800	Manufacture of machinery and equipment n.e.c.	20	10	20 - 22	7.0
F4334	Painting and glazing	67	31	20	10.0
T9800	Undifferentiated goods- and services-producing activities of private households for own use	91	22	20	14.0
C2600	Manufacture of computer, electronic and optical products	7	5	17 - 19	7.0
C2700	Manufacture of electrical equipment	7	5	17 - 19	7.0
C2210	Manufacture of rubber products	7	3	12	0,0
C2220	Manufacture of plastic products	14	7	12	0.003 – 0.004
Sum of confidential major sectors (rounded)				1500 - 2010	30 - 40
Sum of other sectors				79 - 85	10 - 11
Totals (rounded)				**5420 - 5948**	**354 - 361**

TABLE 13
OVERVIEW OF REGISTRATIONS FOR TOLUENE BY FUNCTION IN THE DANISH PRODUCT REGISTER (2012 DATA EXTRACTED FOR THIS STUDY).

Function code		No. of products	No. of companies	Production /Import range, t/y	Export range, t/y
48	**Solvents**	51	33	2596 - 2598	264 - 265

33	**Intermediates**	5	5	27 - 514	0.00001
2	**Adhesives, binding agents**	79	45	75 - 76	1.8 – 2.1
59	**Paints, laquers and varnishes**	607	71	30 - 44	0.1 – 0.5
61	**Surface treatment**	23	19	17	4.3
39	**Non-agricultural pesticides and preservatives**	13	5	15	0
31	**Impregnation materials**	7	7	12	0.0002
9	**Cleaning/washing agents**	15	12	9	1.0
20	**Fillers**	54	30	6	5.0
34	**Laboratory chemicals**	3	3	3	0
43	**Process regulators**	3	3	2	2.0
14	**Corrosion inhibitors**	22	15	2	0.1
28	**Fuel additives**	9	8	0,8 - 0,9	0.001
6	**Anti-set-off and antiadhesive agents**	3	3	0,5	0.003
50	**Surface-active agents**	10	7	0,09	0.010
10	**Colouring agents**	38	3	0,08	0
35	**Lubricants and additives**	16	10	0,05	0.030
13	**Construction materials**	6	6	0,002 - 0,02	0.001
45	**Reprographic agents**	33	14	0,002 - 0,02	0
	Others	11	11	0,003	0
Sum of confidential functions (rounded)				963	4.0
Totals (rounded)		**1011**	**165**	**3757 - 4261**	**283 - 284**

According to the information from industry in Denmark, the concentration of toluene in thinners for cleaning of painting equipment (e.g. spray equipment for vehicle repair) typically ranges from 60 – 80 %.

Moreover, toluene might be present as an impurity in certain binding agents and solvents, typically in concentrations < 0.1 and 0.5%, respectively, or constitute the solvent for certain applications.

A substantial part of toluene consumption is, as mentioned, confidential. When comparing the use functions and sectors from the product register with the listed uses from the REACH registrations, it appears as if the confidential Danish consumption might be within oilfield drilling and production operations.

The use of toluene as an intermediate makes up only a minor fraction of the total use in Denmark (about 0.8 – 13% based on product register data), opposed to about 70 - 80 % of total use in Europe. The major application in Denmark is use as a solvent, predominantly in maintenance and repair of motor vehicles.

3.4 Historical trends in use

3.4.1 European trends in use patterns

The European production and use data (compare section 3.1.2 and 3.3.1) indicate that the consumption of toluene may have been decreasing during the last decades. Unfortunately, more precise historical consumption data could not be identified.

The use restriction of toluene to ≤ 0.1% in adhesives and spray paints in 2006 might have contributed to a consumption decrease, but is unlikely to have a significant impact on the larger consumption pattern, since the major European use is as chemical intermediate.

3.4.2 Use pattern in Denmark

The total use of toluene has generally been increasing during the last decade and amounted to 14,900 tons in 2009. In 2010 and 2011, toluene consumption was reported to account for only 4,330 and 3,340 tons, respectively. An explanation for this recent development was not identified in this survey.

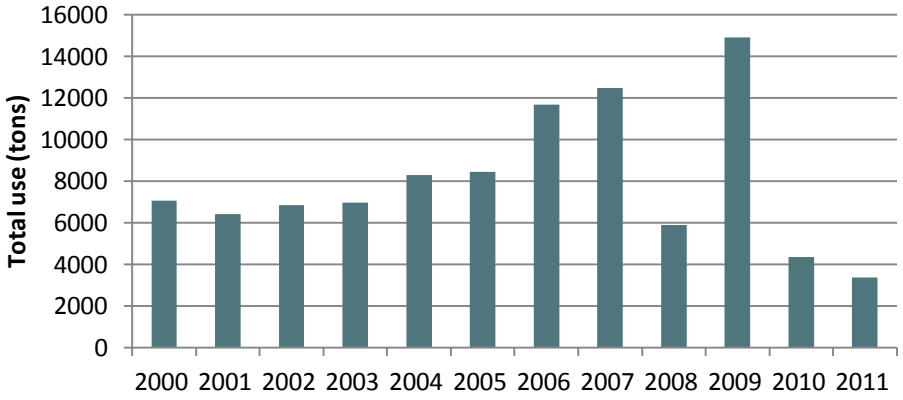


FIGURE 1
TOTAL USE OF TOLUENE IN DENMARK (DATA FROM SPIN DATABASE, 2014).

3.5 Summary and conclusions

3.5.1 Manufacture and consumption

Toluene is produced in the 1,000,000 - 10,000,000 tons/year band in the EU. In the beginning of the 2000s, there were about 25 toluene producing facilities in the EU, but there are no production facilities located in Denmark. In 1995, the total amount of toluene produced in Europe was about 2,600,000 tons, but decreased to about 1,400,000 tons in 2012.

Recent trade figures show that the European export of toluene, about 200,000 tons, exceeds import by a factor of 11. In Denmark, there is no production of toluene, and the net import was approximately 1,700 t in 2012.

The EU consumption of toluene was about 2,750,000 tons in the late 1990s, and decreased to approximately 1,250,000 tons in 2012.
Danish consumption was in the range 3430-3940 tons in 2012 according to the Danish Product Register. In 2011, total consumption was about 3340 tons.

3.5.2 Applications

Commercial toluene is used globally as a raw material in the production of a large number of chemicals, amongst which are included benzene, benzoic acid, nitrotoluenes, and tolyl diisocyanates, as well as dyes, pharmaceuticals, food additives, plastics, etc.

Toluene has excellent solvent properties; consequently, for a long time it has been the preferred solvent in many applications, including coatings, adhesives, inks, pharmaceuticals and chemical processing. Therefore, toluene is also present in many consumer products such as surface-treated wooden furniture and printed matter.

Toluene as a chemical intermediate accounts for 70-80 % of use in the EU, while use as a solvent amounts to 19 % of the total use.

In Denmark, however, the use as a chemical intermediate accounts for less than 13 % of the total, and the major application is use as solvent, especially in thinners and for cleaning in the motor vehicle repair and maintenance sector.

4. Waste management

4.1 Introduction

Toluene is a non-reactive solvent. Toluene enters the waste stream when products that are based toluene solutions end up in the waste stream, e.g. paint, adhesives or cleaning solvents.

For a number of products where toluene has been used as solvent, toluene will only be present in the final product in trace concentrations, as most of it has evaporated to the environment or has been captured by gas-filtering equipment placed in the exhaust system.

The amount of toluene annually ending up in waste in Denmark is unknown, because:

- There is not a specific EAK[5] code for toluene; it falls under the EAK codes for organic solvents;
- Toluene is often mixed with other compounds such as polyester or acetone when it is disposed of, and
- There are many EAK codes related to organic solvents because the EAK code system is built around industries and there are many industries that use toluene.

The information presented here about waste management is based on the following sources:

- Technical literature;
- Internet searches;
- Information from the Danish Coatings and Adhesives Association), and
- Interviews with two paint companies and one adhesive company situated in Denmark.

4.2 Waste from production of toluene

Toluene is not manufactured in Denmark, and therefore there are no associated waste streams from production of the chemical substances in this country.

4.3 Waste from the use of toluene

Toluene may end up as waste from cleaning processes (e.g. for cleaning of paint equipment) and must be collected and handled as hazardous waste at plants approved to treat this type of waste. Toluene may be distilled or incinerated in these plants. To our knowledge, there is no plant in Denmark that recycles toluene by distillation, but chemical plants using toluene as a solvent in their production may recycle toluene by distillation at their own plants.

The adhesive manufacturing company has stated that toluene was phased out before 2007. For this reason, the company has no toluene containing waste at all at their production site.

The same is the case for one of the paint producing companies; it has totally phased out toluene use and has no toluene-containing waste at their site.

[5] EAK = Europæisk Affalds Katalog (European Waste Catalogue)

The other paint producing company has no production in Denmark, but has production sites in Europe. The company mainly produces paints and coatings for professional use and uses toluene in products as a solvent. But as production does not take place in Denmark, there is no waste at their site in this country. The company states that they follow European laws regarding hazardous substances.

For the latter company, it must be concluded that if toluene based products ends up in the waste stream, it is as a result of use by professionals.

4.3.1 Waste water and sewage sludge

Toluene is to some extent released to municipal wastewater where it typically occurs at sub-µg/l concentrations (see Table 17, section 5.3.2). However, no data on the concentration in sewage sludge have been identified. The very low concentration is assessed not to be a problem for the environment.

4.4 Summary and conclusions

Toluene must be handled as hazardous waste and be collected and treated by approved operators. The same is the case for products containing 25% or more of toluene.

It is not possible to obtain reliable data on the amount of toluene which ends up in the waste stream because there is no specific EAK code for toluene.

In interviews with an adhesive producing company and two paint producing companies in Denmark, it became clear that only one paint producing company uses toluene as solvent and for professional use. However, the paint is not produced in Denmark, so there is no toluene waste in Denmark from their production.

Only paints and coatings in the use phase in relation to professional use may in some cases result in toluene-containing waste. However, no data on the amounts have been identified.

Likewise, no data have been identified on the amount of toluene that ends up in municipal sewage sludge.

5. Environmental effects and exposure

This section on environmental fate, effects and exposure is largely based on the EU Risk Assessment report (RAR) for toluene (ECB, 2003), which is still considered to be valid with regard to the level of current knowledge on these subjects for toluene. Searches for newer data have been made by consulting ECHA's registration database and the US EPA's ECOTOX database, but these searches have yielded very few more recent data.

5.1 Environmental fate

5.1.1 Abiotic degradation

Hydrolysis of toluene does not take place as the substance does not possess hydrolysable groups and photolysis in water is also regarded as a marginal fate process for toluene. Therefore only 8.4 % degradation was found after 17 hours of irradiation at >290 nm (ECB, 2003).

Photooxidation of toluene in the atmosphere takes place rather rapidly, primarily due to reaction with hydroxyl radicals. An experimental half-life of 1.3 days is reported while the half-life calculated with the AOPWIN model was approx. 2 days (ECB, 2003).

5.1.2 Biodegradation

Ready biodegradability of toluene in standard tests has been demonstrated but it has also been observed in experimental studies that the rate of degradation becomes significantly lower at lower, and environmentally more relevant, concentrations if other carbon sources are not available. Thus, slow degradation of toluene in water was observed at concentrations below 31 µg/l if no other carbon sources were present, while 0.9 µg/l degraded to below 0.002 µg/l in 8 days when other such sources were present (ECB, 2003). The EU RAR (ECB, 2003) uses a half-life of 30 days for the aquatic risk assessment.

Degradation in sewage treatment plants takes place rapidly; a half-life for the process has been determined at 0.0289 days (ECB, 2003).

In soil, experimental half-lives for degradation of toluene in the range 83-92 days have been found but values of a few days are also reported. The EU RAR conservatively uses a half-life in soil of 90 days in the risk assessment. No anaerobic degradation half-life has been determined for toluene in sediments, but 34-49 % anaerobic degradation in 2 weeks has been observed at high concentrations of the substance (ECB, 2003).

5.1.3 Environmental distribution

The **volatilization** of toluene from water, as well as from soil surfaces, takes place fast. From surface water the half-life is typically on the order of hours (but depends on water depth, mixing and temperature); a half-life of 4.9 hours has been reported from the surface of a sandy soil with low organic carbon content (ECB, 2003).

A calculated estimated K_{OC} in soil of 177, based on the Log Pow value, indicates that toluene has a **relatively high mobility in soil** (ECB, 2003).

An experimental BCF for fish (golden ide, *Leuciscus idus*) of 90 days has been determined experimentally together with an elimination half-life of less than 2 days, while a BCF = 36 has been calculated based on the Log Pow of 2.7 (ECB, 2003). These values, of which the former is used in the EU risk assessment, indicate **a rather low bioaccumulation potential** of toluene.

5.2 Environmental hazard

5.2.1 Classification

Toluene has a harmonised (CLP) classification but is not classified based on environmental hazards. Self-classifications by industry by a total of 3951 notifiers include 82 "Aquatic Chronic 3" classifications and 89 "Aquatic Chronic 2" classifications.

In Denmark, general national EQS values for toluene in the aquatic environment have been established at 74 µg/l for freshwater and 7.4 µg/l for marine water (see table 3, section 2.1.1).

5.2.2 Environmental effects

Toluene is a volatile substance, which in open systems will easily evaporate from the test system, especially static test systems (unless closed), thereby resulting in an uncertain, but lower exposure level than expected. Several short term aquatic ecotoxicity tests have been carried out with toluene of which a large portion, however, were considered to be invalid in the EU RAR (ECB, 2003) due to the aforementioned uncontrolled actual level of exposure.

Results of selected studies among the remaining, valid studies are included in Table 14 below for short term aquatic studies and Table 15 for chronic studies.

TABLE 14
SELECTED DATA ON SHORT TERM TOXICITY OF TOLUENE TO AQUATIC ORGANISMS IN LABORATORY STUDIES (DATA FROM ECB, 2003).

Group	Species	Study type	Endpoint	Value (mg/l)*
Fish, freshwater	*Pimephales promelas*	96 h, flow-through	LC50	26 (m)
	Lepomis macrochirus	96 h, static (closed)	LC50	13 (n)
	Carassius auratus	96 h, flow-through	LC50	22.8 (m)
Fish, saltwater	*Onchorhynchus gorbuscha*	24 h, static	LC50	5.5 (m)
	Morone saxatilis	24 h, static	LC50	6.3 (m)
Invertebrates, freshwater	*Daphnia magna*	48 h, static (closed)	EC50	11.5 (n)
	Cerodaphnia dubia	48 h, static renewal (closed)	LC50	3.8 (m)
Algae, freshwater	*Chlamydomonas angulosa*	72 h, static (closed)	EC50	134 (n)

* (m) = measured concentration; (n) = nominal concentration

Thus, among fish, the most sensitive species in acute toxicity tests was the saltwater species *Onchorhynchus gorbuscha* (pink salmon) with an LC_{50} = 5.5 mg/l while the most sensitive species overall in such tests was the freshwater daphnid *Cerodaphnia dubia* with an EC_{50} = 3.8 mg/l.

TABLE 15
SELECTED DATA ON CHRONIC TOXICITY OF TOLUENE TO AQUATIC ORGANISMS IN LABORATORY STUDIES (DATA FROM ECB, 2003).

Group	Species	Study type	Endpoint	Value (mg/l)*
Fish, freshwater	*Pimephales promelas*	32 d, flow-through	NOEC	4 (m)
	Onchorhynchus kisutch	40 d, flow-through	NOEC	1.4 (m)
	Onchorhynchus mykiss	27 d, static renewal	NOEC	1.4 (m)
Invertebrates, freshwater	*Daphnia magna*	21 d, static renewal (closed)	NOEC	1 (m)
	Cerodaphnia dubia	7 d, static renewal (closed)	NOEC	0.74 (m)
Algae, freshwater	*Selenastrum capricornutum*	96 h, static (closed)	NOEC	10 (n)
Algae, saltwater	*Skeletonema costatum*	72 h, static (closed)	NOEC	10 (n)

* (m) = measured concentration; (n) = nominal concentration

In the chronic tests as well, *Cerodaphnia dubia* turned out to be the most sensitive species with a chronic (7 days) NOEC = 0.74 mg/l. This value was used by ECB (2003) to determine the $PNEC_{water}$ for toluene at 0.074 mg/l by applying an assessment factor, AF = 10, taking into account that full data sets of EC/LC_{50}s and NOECs are available for fish, invertebrates and algae.

For microorganisms in sewage treatment plants (STPs), the lowest NOEC = 29 mg/l has been established for *Pseudomonas putida* (bacteria). However, ECB (2003) used the EC_{50} = 84 mg/l for the nitrifying bacteria *Nitrosomonas* (nitrification is usually considered the most sensitive process in STPs) and an AF = 10 to establish a $PNEC_{microorganisms} = PNEC_{STP}$ = 8.4 mg/l.

ECB (2003) does not consider it relevant to establish a PNEC for toluene in sediment.

For the terrestrial environment, ECB (2003) refers to studies showing that toluene is toxic to plants only at high concentrations in soil. The lowest reported LOEC for phytotoxic effects was 200 mg/kg soil for maize. Likewise, toluene is only directly toxic to plants exposed via air at very high concentrations, but the chemical may contribute indirectly to effects; as a VOC, it contributes to ozone formation in the lower atmosphere.

The effects of toluene on earthworms were studied in a 28-day artificial soil study with *Eisenia foetida* in which the lowest NOEC (visual inspection of condition) was found to be 15 mg/kg soil (ECB, 2003). This value was used by ECB to establish an "indicative" $PNEC_{soil}$ = 0.3 mg/kg soil using an AF = 50 due to availability of two long-term studies on plants and earthworms.

5.3 Environmental exposure

5.3.1 Sources of release

The main use of toluene in Denmark is as a solvent, whereas internationally, the dominant consumption of the substance (81%) is as a raw material or intermediate in the production of a range of other basic aromatics such as benzene, phenol, TDI (toluene diisocyanate), phthalic acid etc., while use as solvent only accounts for 19%. Furthermore, toluene is a constituent of fuel for cars; therefore, air concentrations of toluene are typically elevated in streets where traffic is dense (see Table 16).

The main uses of toluene in Denmark are for maintenance/repair of vehicles, manufacture of paints, lacquers and similar coatings, for cleaning and degreasing of surfaces in metal and electronic industry, and in the printing industry.

Emission to air is considered to be the primary pathway of release of toluene to the environment, either directly from industrial plants using this chemical as a solvent, or due to evaporation during use of professional or consumer products (e.g. paints and adhesives), including evaporation of residues present in the products manufactured e.g. surface coatings (paint, lacquer) on wooden furniture. To a lesser extent, some release to the wastewater system will also occur.

The RAR (ECB, 2003) presents Predicted Environmental Concentrations (PECs) for the main environmental compartments. At the regional level, the following PEC values are reported:
PEC_{air} = 2.79 µg/m³
$PEC_{surface\ water}$ = 6.25 µg/L
$PEC_{sediment}$ = 26 µg/kg ww
$PEC_{soil,\ natural}$ = 0.033 µg/kg ww ; $PEC_{soil,\ agricultural}$ = 0.703 µg/kg ww.

5.3.2 Monitoring data

The Danish NOVANA assessment programme

Toluene is included in the NOVANA programme with respect to air monitoring as VOC (and thereby toluene) are described as key hazardous air pollutants and substances, which contribute to the formation (precursors) of the hazardous air pollutants (Naturstyrelsen, 2011). The substance is also included in the NOVANA point sources monitoring programme for the aquatic environment (WWTP effluents).

Table 16 shows the most recent measurements from 3 locations in Copenhagen. Furthermore, point sources of toluene, mainly wastewater treatment plants (WWTPs), have been monitored for several years and concentrations from recent years are shown in Table 17.

TABLE 16
NOVANA AIR QUALITY MONITORING DATA FOR TOLUENE (COPENHAGEN, DENMARK)

Site in Copenhagen	Number of results	Weekly average (µg/m³)	90 % Percentil	Year	Source
Traffic (H.C.Andersens. Boul.)	51	3.4	-	2011	Ellermann et al. 2012
Traffic (Jagtvej)	51	3.6	-	2011	Ellermann et al. 2012
Urban Background (H.C.Ørstedsvej)	307	1.61	2.99	2011	Ellermann et al. 2012
Traffic (H.C.Andersens Boul.)	50	3.4	-	2010	Ellermann et al. 2011
Traffic (Jagtvej street)	48	3.7	-	2010	Ellermann et al. 2011
Urban Background (H.C.Ørstedsvej.)	214	1.36	2.48	2010	Ellermann et al. 2011

In 2012 (Ellermann et al., 2013), the weekly averages of toluene in ambient air at two major and heavily trafficked streets, H.C.Andersen's Boulevard and Jagtvej, were approximately the same as stated in the table for 2011, i.e. significantly below the guideline value of 260 µg/m³. In the years 2001-2004, the annual average concentrations of toluene at Jagtvej were approx. 15-17 µg/m³ but decreased rapidly in the following five years to reach approximately the current level around 2010.

TABLE 17
MOST RECENT MONITORING DATA FOR TOLUENE IN OUTLETS FROM POINT SOURCES FROM THE NATIONAL MONITORING AND ASSESSMENT PROGRAMME (NOVANA).

Point source	Number of samples	Average µg/l	Median µg/l	Year	Source
Effluents from WWTPs	32	0.19	0	2011	Naturstyrelsen, 2012
Effluents from WWTPs	22	0.10	0.067	2010	Naturstyrelsen, 2011a
Rain water	13	0.13	0.12	2010	Naturstyrelsen, 2011
Effluents from WWTPs	31	0.026	0	2009	Naturstyrelsen, 2010

No Danish monitoring data presenting concentrations of toluene in rivers, lakes, marine waters or in the terrestrial environment have been identified.

Monitoring data from outside Denmark
There is a substantial amount of data on toluene in wastewater effluents from chemical and other industries around Europe summarised by ECB (2003), which, however, are generally not considered relevant in this context as they mainly relate to industrial sectors (atypical for Denmark). Data from WWTP effluents outside Denmark, primarily from the USA, are old and show levels significantly above the recent Danish levels presented in Table 17.

Data on toluene in German rivers typically show levels in the sub-µg/l range (in many cases only 0.01-0.02 µg/l) and, in an extensive study from 1993-94 by Frauenhofer Institute (cfr. ECB, 2003), toluene was only found above the determination limit in 7 out of 146 samples. The mean concentration was 0.0329 µg/l if the samples with contents below the limit value were included, such as 0 (zero) µg/l and 0.975 µg/l, if including these samples with 0.5 x the determination limit value.

Dutch data from the 1980s on toluene in air (cfr. ECB, 2003) show levels of 2-6 µg/m^3 in the countryside in one study and 13-21 µg/m^3 in urban areas, and in another a range from 3.6-19 µg/m^3 (type of location not specified). In a UK study from 1995, the average of rural and urban values was 8.43 µg/m^3. These values are higher than the most recent levels measured in central Copenhagen streets (Table 16).

5.4 Environmental impact

The EU risk assessment report (ECB, 2003) concludes for all three main environmental compartments (water, air and soil) that "*there is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account*".

For the aquatic environment, as well as for the terrestrial compartment, the following industrial use categories are mentioned:

- Industry use as intermediate and as a basic chemical;
- Mineral oil and fuel formulation;
- Formulation of polymers;
- Formulation of paints, and
- Textile processing.

In Denmark, the most important industrial use of toluene is in the manufacture of paints while the other uses are of no or limited importance. Further, it should be noted that the conclusion is

reached mainly because “insufficient information has been available to exclude a risk” for a number of generic use scenarios.

For the air compartment, it is the issue of ozone and smog formation that is addressed. It is recommended to include toluene in the assessment of management measures under the relevant air quality directives, aiming to reduce ozone and smog formation and by extension, the resulting impairment of air quality.

5.5 Summary and conclusions

Toluene is a volatile substance, which evaporate easily from water and soil surfaces and degrades quite rapidly in the air compartment by photooxidation, resulting in various VOC degradation products, thereby contributing to tropospheric ozone formation.

The substance is considered easily biodegradable in water while abiotic degradation is insignificant. There are, however, observations that toluene degrades rather slowly in natural waters at concentrations below a certain level if no other carbon sources are available. From the sorption characteristics, toluene is considered rather mobile in soil, while the bioaccumulation potential is rather low.

The toxicity of toluene to aquatic organisms like fish and crustaceans is moderate and of the same magnitude as short term LC/EC_{50} values, mostly of around 3-10 milligrams per liter. Chronic toxicity data are only available for toluene for which the lowest NOEC is 0.74 mg/l for the daphnid *C. dubia*. Although only few data are available, the toxicity in the terrestrial compartment appears to be moderate-low to earthworms, and low to plant species.

Toluene is assessed to be released primarily to the air compartment, partly from the many different types of productions and partly from evaporation during use of the products for a variety of purposes, e.g. paints and other coatings, adhesives, polymers, maintenance and repair of vehicles etc. Smaller amounts of toluene are released through the wastewater system.

Monitoring data show low levels of toluene in the aquatic environment (wastewater treatment plant effluents and rainwater). Levels of 1.3-3.7 $\mu g/m^3$ of toluene are measured in urban areas with heavy traffic, since toluene is a constituent of fuel for vehicles. These levels correspond reasonably well to the regional PEC calculated for air (2.79 $\mu g/m^3$).

In the EU Risk Assessment of toluene, it is concluded that there is a need for limiting the risks to the environment while, however, taking into account the risk reduction measures that are already being applied. Formulation of paints is the only of the industry categories mentioned that appears to be relevant for Denmark. It should be noted that the conclusion is reached mainly because “insufficient information has been available to exclude a risk” for a number of generic use scenarios.

6. Human health effects and exposure

The toxicity of toluene has been thoroughly investigated in both humans and experimental animals and has been described in detail in the RAR for toluene, for which Denmark was the rapporteur Member State (ECB, 2003). The data on toxicokinetics, as well as on acute and chronic toxicity are summarised in the following based on the RAR. For some effects, e.g. developmental toxicity, newer studies not included in the RAR are available in the registration dossiers with a confidentiality clause. These studies have not been identified in the open literature, and are therefore not included in the present report.

6.1 Human health hazard

6.1.1 Classification

Toluene is subject to harmonised classification as a skin irritant (cat. 2), for specific target organ toxicity after single exposure (cat.3) and after repeated exposure (cat. 2), for developmental toxicity (cat. 2), and for aspiration hazard (cat. 1) (Table 18).

TABLE 18
HARMONISED HEALTH HAZARD CLASSIFICATIONS ACCORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International chemical identification	CAS No	Classification	
			Hazard Class and Category Code(s)*	Hazard statement Code(s) **
601-021-00-3	Toluene	108-88-3	Asp. Tox. 1 Skin Irrit. 2 STOT SE 3 Repr. 2 STOT RE 2	H304 H315 H336 H361d H373

* Hazard Class: Flam. Liq. - Flammable liquid; Asp. Tox. - Aspiration hazard ; Skin Irrit. - Skin corrosion/irritation; STOT SE - Specific target organ toxicity — single exposure; Repr. - Reproductive toxicity; STOT RE - Specific target organ toxicity — repeated exposure

** Hazard statement codes: H361d Suspected of damaging the unborn child, H304 May be fatal if swallowed and enters airways, H373 May cause damage to organs through prolonged or repeated exposure, H315 Causes skin irritation, H336 May cause drowsiness or dizziness.

6.1.2 Toxicokinetics

Toxicokinetic data are available in the RAR for toluene, for which Denmark was the rapporteur Member State (ECB, 2003). The data are summarised in the following.

Toluene is absorbed rapidly via inhalation with an absorbed fraction of inhaled toluene of approximately 50%, depending on pulmonary ventilation. Absorption from the gastrointestinal tract is also rapid and the absorbed fraction of ingested toluene is approximately 100% in animals. Uptake after dermal contact with liquid toluene occurs to a limited degree, whereas uptake after dermal contact with toluene vapour is not significant.

Toluene is widely distributed throughout the body with the highest concentrations in fat; the concentrations in brain tissues are higher than in blood. Toluene readily crosses the placenta with concentrations in the foetus of about 75% of that in the maternal blood. Toluene is secreted into human breast milk.

Within a few hours after termination of exposure, the blood and alveolar air contains very little toluene, whereas the elimination from human tissues takes longer, with half-lives of up to three days. Around 20% of the absorbed toluene is eliminated unchanged in the exhaled air. The remaining 80% of the absorbed toluene is oxidised in the liver by the P450 enzyme system, mainly via benzyl alcohol and benzaldehyde to benzoic acid. Benzoic acid is then conjugated with glycine and excreted in the urine as hippuric acid. Saturation of glycine conjugation occurs in the case of a high concentration of benzoic acid; then, benzoic acid is conjugated with glucuronic acid and excreted in the urine as benzoylglucuronide. A minor metabolic pathway is ring hydroxylation of toluene to form o-, m-, and p-cresol, which are excreted in the urine as sulphate or glucuronide conjugates.

There are no indications of particular species differences in the toxicokinetics, metabolism or distribution of toluene, except that the elimination of toluene from adipose tissue appears to be much faster in the rat compared to humans.

6.1.3 Acute and chronic toxicity

The toxicity of toluene has been intensively investigated in both humans and experimental animals and has been described in detail in the RAR for toluene, for which Denmark was the rapporteur Member State (ECB, 2003). The data are summarised in the following.

Acute toxicity

Toluene is of low acute toxicity in experimental animals following inhalation, oral intake and dermal contact. In rats, an inhalation LC_{50}-value of 28,100 mg/m^3/4 hours and an oral LD_{50}-value of 5580 mg/kg bw have been reported. A dermal LD_{50}-value of 12.4 g/kg bw has been determined in the rabbit. Following inhalation, acute effects observed in animals include mucous membrane irritation, unrest, increased respiration, ataxia, impaired cognitive function, disturbance of the equilibrium system, changed response frequency in operant task test, neurochemical changes, and increased levels of liver enzymes involved in the metabolism of toluene. Based on the available data, classification for acute toxicity is not warranted.

In human volunteers, headache, dizziness, feeling of intoxication, irritation and sleepiness were reported at concentrations of 281 mg/m^3 and above; a NOAEC of 150 mg/m^3 was identified for these effects. Toluene has been demonstrated to impair neuropsychological function in performance tests at concentrations of 285 mg/m^3 and above, the lowest concentrations tested. Based on the human data, toluene is classified for specific organ toxicity following single exposure (STOT SE 3) with the hazard statement H336 (may cause drowsiness or dizziness).

Toluene is also classified for aspiration toxicity (Asp. Tox. 1) with the hazard statement H304 (may be fatal if swallowed and enters airways).

Irritation and sensitization

The results of the studies performed in experimental animals show that toluene is irritating to the skin of rabbits, mice, and guinea pigs. Based on a study in rabbits performed according to an EU guideline standard method, toluene is classified as a skin irritant (Skin Irrit. 2) with the hazard statement H315 (causes skin irritation). No human data are available.

The results of three studies performed in rabbits show that liquid toluene has the potential to cause eye irritation. In humans, toluene vapours in concentrations at and above 281 mg/m^3 resulted in complaints of eye irritation; a NOAEC of 150 mg/m^3 was identified for this effect. Based on the available data classification for eye irritation is not warranted. Irritation to the respiratory tract in experimental animals has only been observed at very high concentrations.

The results of a guinea pig maximization test performed in accordance with EU guideline B6 indicate that toluene is not a skin sensitizer. No human data are available. It is unlikely that toluene is a respiratory sensitizer.

Repeated dose toxicity
General systemic effects have been observed in rats and mice following repeated exposure. A NOAEC for general systemic toxicity of 1125 mg/m^3 (the highest concentration tested) for inhalation exposure was selected in the RAR based on a 2-year inhalation study in rats, and a NOAEL of 625 mg/kg bw/day for oral administration was selected based on neuronal cell necrosis and organ weight increases observed at higher dose levels (1250 mg/kg bw/ day and above) in a 90-day study in rats. No data on repeated dermal exposure have been found.

Repeated exposure to toluene via inhalation has been shown to affect the central nervous system and the inner ear: Several effects on the central nervous system have been observed in experimental animals. A reduced number of neurons in the hippocampus and a reduced hippocampal weight were observed in rats exposed to 5625 mg/m^3 of toluene via inhalation for 6 months. In very young rats exposed to toluene via inhalation on postnatal day 1-28, reduced volume of certain hippocampal structures was found at 380 mg/m^3 and above. Changes in brain neurochemistry in rats have also been reported.

In humans, long-term high-level exposure to toluene (abuse) via inhalation has caused serious damage to the brain including severe neurological abnormalities and brain atrophy. Long-term exposure to volatile solvents at exposure levels possible in occupational settings may lead to organic brain syndrome. For toluene, two studies have shown an increased prevalence in toluene-exposed workers compared with the control group. In both studies, workers had been exposed for a long time. One study involved workers employed at two rotogravure plants who had been exposed to toluene for more than 12 years. Exposure during the years preceding the investigation was not well described, whereas the recent exposure data were well documented. In general, LOAECs and NOAECs cannot be determined for organic brain syndrome, since well-documented exposure information covering a considerable proportion of the entire period of employment would be necessary, but is not available. Consequently, this endpoint cannot be evaluated quantitatively in humans. There is no evidence suggesting that the levels of toluene found in the working environment can cause damage to the peripheral nervous system.

The ototoxicity of toluene in the rat is well documented by behavioural, electrophysiological, and morphological techniques. Impaired hearing function has been demonstrated in the rat following inhalation exposure at concentration levels of 3750 mg/m^3 for 2 weeks. A NOAEC for ototoxicity of 2625 mg/m^3 was selected in the RAR based on a 16-week inhalation study in rats. Occupational exposure to toluene at high concentrations may increase the risk of developing mild high-frequency hearing loss. The available studies were, however, not considered appropriate for determining a LOAEC or NOAEC.

Toluene is classified for specific organ toxicity following repeated exposure (STOT RE 2) with the hazard statement H373 (may cause damage to organs through prolonged or repeated exposure), since several types of serious toxic effects after inhalation have been observed.

Mutagenicity/genotoxicity
Toluene did not show a mutagenic potential in the standard *Salmonella typhimurium* test strains in the plate incorporation assay, or in a well-performed preincubation test, which is more appropriate for the test of compounds with volatility comparable to toluene. In addition, toluene did not induce DNA repair mediated toxicity to various bacteria, gene conversion in *Saccharomyces cerevisiae* or genotoxic effects in *Drosophila melanogaster*. In mammalian cell *in vitro* tests, toluene did not induce biologically significant increases in forward mutations, sister chromatid exchanges, micronuclei or DNA damage at non-cytotoxic doses. In studies where benzene contamination could be excluded, toluene did not induce biologically significant cytogenetic changes in the bone marrow of rodents or DNA damage in peripheral blood cells, bone marrow and liver of mice. Toluene was not considered to be mutagenic to the sperm of mice in a dominant lethal assay.

In human volunteers, increased frequencies of sister chromatid exchange were not observed in peripheral blood lymphocytes following prolonged exposure to 190 mg/m^3 toluene. In workers exposed to toluene in the occupational environment, equivocal results have been reported in studies with biological monitoring of various genotoxic effects in peripheral blood lymphocytes; however, confounding due to co-exposure to other solvents and various genotoxic substances in the working environment and/or due to smoking could not be excluded. Based on these studies, the RAR concluded that toluene can be considered to be non-genotoxic.

Carcinogenicity
The results of an inhalation carcinogenicity study in rats indicate that toluene is not carcinogenic to rats. In a mouse carcinogenicity study, a single adenoma of the *pars intermedia* in the pituitary gland (a very rare non-malignant tumour type) was found in each of the toluene-exposed groups of females, and in the highest dose group of males. In a skin-painting study in mice, skin irritation and tumour development were observed; however, the difference in tumour incidence was just below statistical significance (p=0.055). Only one of the epidemiological cancer studies was considered adequate; an excess of tumours in toluene-exposed workers was not reported. Based upon the available data, the RAR concluded that it cannot be evaluated whether toluene is carcinogenic. However, the evidence was not considered to be strong enough to fulfil the EU criteria for classification for carcinogenicity.

Toluene has also been evaluated for carcinogenicity by IARC, most recently in 1999. IARC concluded that there is inadequate evidence in humans for the carcinogenicity of toluene and that there is evidence suggesting lack of carcinogenicity of toluene in experimental animals. Thus, the overall evaluation was that toluene is not classified as a carcinogen to humans (Group 3).

Reproductive toxicity
Toluene does not have clear effects on fertility in rats; however, reduced sperm count was observed in a 90-day study in male rats exposed by inhalation to a concentration of 7500 mg/m^3. A NOAEC of 2250 mg/m^3 was identified for this effect. In humans, no studies of adequate quality are available. Rat inhalation studies provide strong evidence for developmental toxicity (lower birth weight, long-lasting developmental neurotoxicity). Lower birth weights have been found in offspring of rat dams exposed to concentrations of around 3750 mg/m^3; the NOAEC was 2250 mg/m^3. Long-lasting developmental neurotoxicity (impairment of learning ability) has been demonstrated in offspring of rats exposed prenatally or pre- and postnatally by inhalation to a concentration of 4560 mg/m^3; a NOAEC cannot be determined for developmental neurotoxicity based on the available studies. Human case studies on high-level toluene exposure (abuse) have provided evidence of developmental toxicity in the form of a syndrome in human foetuses

characterised by physical and neurological abnormalities, resembling foetal alcohol syndrome. Two human studies indicate an increased risk for spontaneous abortions at toluene concentrations in the working environment around 330 mg/m^3; this concentration was selected in the RAR as the overall LOAEC for developmental toxicity. Data from the registration dossiers are in line with these findings.

Toluene is classified for reproductive toxicity (Repr. 2) with the hazard statement H361d (suspected of damaging the unborn child).

6.1.4 No-effect levels

Occupational exposure limit values

Occupational exposure limit values for toluene for selected European countries are presented in Table 19. The Danish limit values are half of the European and German limit values.

TABLE 19
OCCUPATIONAL EXPOSURE LIMIT VALUES FOR TOLUENE IN EU AND SELECTED COUNTRIES

	Limit value 8-hours		Limit value short term	
	ppm	mg/m^3	ppm	mg/m^3
Denmark	25	94	50	188
European Union	50	192	100	384
Germany	50	190	100	380

Derived no-effect levels

The proposed derived no-effect levels (DNELs) for toluene are provided in the REACH Registrations on ECHA's website and presented in Table 20. It should be noted that only limited information on derivation and justification is available from the publicly available reporting from the confidential substance registrations reports. Furthermore, the proposed DNELs as provided by the registrant have not been subject to scrutiny by ECHA or any EU expert group.

As presented in Table 20, the DNEL for workers' long term local and systemic inhalation exposure corresponds to the German occupational exposure limit value. The DNEL for workers' acute/short term exposure by inhalation are derived as two times the German occupational exposure limit value and are similar to the DNEL for long term dermal exposure. For consumers, the long term DNELs are considerably lower for inhalation and oral exposure.

TABLE 20
PROPOSED DERIVED NO-EFFECT LEVELS (DNELS) FOR TOLUENE (HTTP://ECHA.EUROPA.EU/INFORMATION-ON-CHEMICALS).

Population - route	Exposure	DNEL	Most sensitive endpoint	Comment (DNEL derivation method)*
Workers - inhalation	Long term exposure - systemic effects - local effects	192 mg/m³	Systemic: Neurotoxicity Local: Resp. tract irr.	Systemic: Derived from a NOAEC with an AF of 1. Neither NOAEC nor method are specified.
	Acute/short term exposure - systemic effects - local effects	384 mg/m³	Not specified	Systemic: Derived from a NOAEC with an AF of 1. Neither NOAEC nor method are specified.
Workers - dermal	Long term exposure - systemic	384 mg/kg bw/day	Not specified	Neither dose descriptor starting point nor method are specified.
General population/ consumers - inhalation	Long term exposure - systemic effects - local effects	56.5 mg/m³	Not specified	AF of 1.7. Neither dose descriptor starting point nor method are specified.
	Acute/short term exposure - systemic effects - local effects	226 mg/m³	Systemic: Not specified' Local: Resp. tract irr.	AF of 1.7. Neither dose descriptor starting point nor method are specified.
General population/ consumers - dermal	Long term exposure - systemic effects	226 mg/kg bw/day	Not specified	AF of 1.7. Neither dose descriptor starting point nor method are specified.
General population/ consumers - oral	Long term exposure - systemic effects	8.13 mg/kg bw/day	Not specified	AF of 1.7. Neither dose descriptor starting point nor method are specified.

* AF – Overall assessment factor

Tolerable daily intake

WHO has established a tolerable daily intake (TDI) of 223 µg/kg of body weight derived from a LOAEL for marginal hepatotoxicity in mice of 312 mg/kg of body weight per day. In this study the animals were dosed 5 days per week, and the LOAEL is therefore equivalent to 223 mg/kg of body weight per day based on 7 days dosing per week. An uncertainty factor of 1000 (100 for inter- and intraspecies variation and 10 for the short duration of the study and use of a LOAEL instead of a NOAEL) is applied resulting in the TDI of 223 µg/kg of body weight (WHO, 2004).

In 1996, Health Canada established a TDI (inhalation) of 3.8 mg/m³ (1 ppm) based on a NOAEC of 150 mg/m³ for nervous system effects in humans adjusted by a factor of 6/24 for 24 h, 7 day/week exposure and using an uncertainty factor of 10 for inter-individual differences (Aylward *et al.*, 2008).

6.2 Human exposure

6.2.1 Direct exposure

Consumers

Data on consumer exposure are available in the RAR for toluene (ECB, 2003). The data are summarised in the following.

According to the Danish Product Register (data from 1998), toluene was present in various consumer products, including paints, adhesives, varnishes, and inks for pens.

Measured data on toluene in consumer products were found only for glue products. In an investigation of 26 glue products for non-occupational use (Rastogi, 1993), twenty-two contained toluene in concentrations of 0-0.042% (9 products), 0.043-0.05% (6 products) and 1.0-28.5% (7 products).

Five scenarios were considered for assessment of consumer exposure:

1. Gluing;
2. Spray painting;
3. Car maintenance, 3A car polishing, 3B cleaning hands in solvent based cleaning agent;
4. Carpet laying, and
5. Filling gasoline at self-service gas stations.

The scenarios were selected based on the amount of product used, the concentration of toluene in the product, and the frequency of exposure.

For scenarios 1-3 (gluing, spray painting, car polishing, and cleaning hands in solvent based cleaning agent), an acute time scale was considered appropriate based on the frequency of use for these scenarios (estimated to be once a week) and the half-life of toluene in the body (approximately 3 days).

For scenario 4 (carpet laying), an acute time scale was considered appropriate based on the very low frequency of use for this scenario.

For scenario 5 (filling gasoline at self-service gas stations), a chronic time scale was considered appropriate based on the frequency of use for this scenario.

The defaults used for the exposure assessment were an inhalation rate of 20 m^3/day, a consumer body weight of 70 kg and a hobby room size of 20 m^3.

The results from estimated exposures for the above-mentioned scenarios are presented in Table 21.

TABLE 21
SUMMARY OF CONSUMER EXPOSURE ESTIMATES FOR TOLUENE (ECB, 2003)

Exposure	Scenarios					
	1 (gluing) Acute	2 (spray painting) Acute	3A (car polishing) Acute	3B (cleaning hands) Acute	4 (carpet laying) Acute	5 (gasoline filling) Chronic
Air concentration (mg/m3)	7.1	1000	10	Negligible	195	63
Uptake via inhalation (mg/kg bw/event)	0.3	41.7	0.42	Negligible	18.6	0.13 2)
Potential dermal exposure (mg/kg bw/event) 1)	0.01	1.43	0.014	9.3	30	Negligible

1) Dermal exposure modelled using the EASE because of the similarity to workers exposure
2) mg/kg bw/day

In Australia, a comprehensive evaluation of the adverse health effects of human exposure to benzene, toluene and xylene from service station emissions was carried out using exposure data from the scientific literature (Edokpolo et al, 2014). The data was grouped into 6 different scenarios based on activity, location and occupation, including consumer filling of gasoline. The results suggested minimal risk for most of the exposed population for the consumer scenarios.

The Danish EPA has published results from a number of surveys on selected consumer products that might contain problematic substances, or products that consumers are highly exposed to. Some reports focus on the content of chemicals in the products; others also include releases to indoor air and migration studies.

The presence of toluene has been demonstrated in several product types. An overview of the different findings of toluene in consumer products is presented in Table 22. The overview is based on the information in the Consumer Products Database on the DEPA homepage and covers results from screening analyses, quantitative analyses, emissions and migration analyses. Products where content of toluene has been identified but not quantified are not included in the table.

TABLE 22
OVERVIEW OF TOLUENE IN CONSUMER PRODUCTS AS PRESENTED IN THE CONSUMER PRODUCTS DATABASE OF THE DANISH EPA (DEPA)

Product type	Amount	Unit	Type of measurement
Liquid latex (role play)	7	µg/m3	Emission
Ointment (treatment of injuries)	1,7-2,6	mg/kg	Conc. in product
Balm (treatment of injuries)	2,3-4,4	mg/kg	Conc. in product
Lotion (treatment of injuries)	< 1	mg/kg	Conc. in product
Gel (treatment of injuries)	2.6	ppm	Conc. in product
Stick (treatment of injuries)	< 1	mg/kg	Conc. in product
Perler beads	<10	mg/kg	Conc. in product
Perler beads	theoretical max 720	µg/m3	Indoor climate conc.

Product type	Amount	Unit	Type of measurement
Pegboard	8,8-72	mg/kg	Conc. in product
Vibrator (sex toy)	69-165332	ng/180 min	Degassing, 180 minutes
Vibrator (sex toy)	0,02-2,1	g/kg	Conc. in product
Vibrator (sex toy)	22-54	mg/dm²/time	Migration to synt. sweat
Gag (sex toy)	0,03	g/kg	Conc. in product
Transparent bra (sex toy)	147	ng/180 min	Degassing, 180 minutes
Fetich clothing, mini dress (sex toy)	1016	ng/180 min	Degassing, 180 minutes
Scented candle	7	% degassed subst.	Degassed substance
Spray for textile impregnation	0,02-0,78	mg/g	Conc. in product
Lamination material		5-84 ng/l air (15-30 min) 3-16 ng/l air (30-60 min)	Inhalation exposure
Monitor	16-38,3	µg/m³	Indoor climate Conc.
Game console	0,2	µg/m³	Indoor climate conc.
Iron	0,0-2,9	µg/m³	Indoor climate conc.
Iron	25	µg/unit/hour	Emission after 7 hours
Iron	0,64	µg/unit/hour	Emission after 9 days
Lamp	1,0-6,7	µg/m³	Indoor climate conc.
Lamp	58	µg/unit/hour	Emission after 7 hours
Lamp	8,6	µg/unit/hour	Emission after 9 days
Mobile phone	29	µg/unit/hour	Emission after 7 hours
Mobile phone	<1	µg/unit/hour	Emission after 9 days
Mobile phone with charger	17	µg/unit/hour	Emission after 7 hours
Mobile phone with charger	<0,03-2,0	µg/m³	Indoor climate conc.
Mobile phone with charger	<1	µg/unit/hour	Emission after 9 days
Television	0,7-2,2	µg/m³	Indoor climate conc.
Rechargeable batteries	<0,1	µg/m³	Indoor climate conc.
Rechargeable batteries	77	µg/unit/hour	Emission after 7 hours
Rechargeable batteries	9,4	µg/unit/hour	Emission after 9 days
Printed papers	Theoretical max 2097	µg/m³	Indoor climate conc.
Incence	Theoretical max 59	µg/m³	Indoor climate conc.
Children's tent	Theoretical max 27	µg/m³	Indoor climate conc.
Products fom exotic wood	Theoretical max 74	µg/m³	Indoor climate conc.
Chloroprene-products	Theoretical max 1,7	µg/m³	Indoor climate conc.

Product type	Amount	Unit	Type of measurement
Spray paint	Theoretical max 36000	µg/m³	Indoor climate conc.
Rubber toy (scented)	500	mg/kg	GC-MS screening
Rubber toy (scented)	140	mg/kg	Quantitative analysis
Rubber toy (scented)	6700	g/m³	Emission test
Letter paper (scented)	32	g/m³	Emission test
Cube (scented toy)	47	g/m³	Emission test
Cuddly toy (scented)	68	g/m³	Emission test
Flower with filling (scented)	45	g/m³	Emission test
Slimy toys	0-1,8	µg/g	Migration to sweat
Slimy toy	0-1,9	µg/g	Migration to synt. saliva
Slimy toy	1-66	% m/m	% of degassing (VOC)
Wooden toy	1,0-5,3	µg/g	Migration to synt. saliva
Porcelain colour	45-50	mg/kg	Conc. in product
Dining table (gum tree)	74-48-29	µg/m³	Emission after 3, 10 and 28 days

In one of the surveys, "Overall health assessment of chemicals in the indoor climate from selected consumer products" (Jensen and Knudsen, 2008), the potential indoor concentrations of eight selected volatile chemicals, including toluene, which have been included in different consumer surveys up to 2005, are estimated. Concentrations were estimated in three model rooms: a hall/utility room, a kitchen/family room and a children's room, based on pragmatic model calculations with some assumptions and simplifications. Because the available data in the DEPA reports have different character and aim, they are not equally reliable, and are not necessarily produced with the purpose of assessing indoor climate.

According to the report, the highest calculated concentrations of toluene were found in the children's room with a concentration of about 49 µg/m³ for new electronic products and about 19 µg/m3 for used products. The contribution mainly came from one particular PC monitor but also included contributions from a decorative lamp, a television, mobile phone and a game console. Potential contributions from other consumer products of up to 900 µg/m³, and about 2,980 µg/m³ with printed matters and 39,000 µg/m³ from spray paint are not included and should also be added. In the report it is concluded that if all potential sources are included a child may have a daily intake very close to the Tolerable Daily Intake (TDI) and Reference Dose for toluene of 223 µg/kg bw/d.

Occupational exposure

Data on occupational exposure are available in the RAR for toluene (ECB, 2003). The data are summarised in the following.

Workers can be exposed to toluene in industries where toluene and gasoline are produced; where toluene is used as a chemical agent, an ingredient or an intermediate; and from use of toluene-containing products. Exposure by inhalation of vapours and liquid aerosol is the main exposure route. Exposure by dermal contact with the liquid may also occur, whereas dermal exposure to vapours was considered to be insignificant.

Measured data on occupational toluene inhalation exposure were available for the relevant exposure scenarios. The air exposure was considered to be the concentration measured in the breathing zone of the workers without taking use of personal protection equipment into account. Full-shift values (8-hour time-weighted averages) were reported for exposure scenarios where the work pattern did not vary considerably from day-to-day; short-term exposures were reported whenever possible. The main result of the exposure estimations was the "reasonable worst-case" (RWC) estimate.

No measured data were available on dermal exposure. Dermal exposure was therefore estimated with the dermal model of EASE based on general assumptions on work pattern (use pattern and contact level) and the exposed area. Evaporation from the skin due to the high volatility of toluene was not taken into account in the dermal exposure assessment. For the occupational exposure, four scenarios based on the type of use of toluene were assessed:

1. Production of toluene and use of toluene as an intermediate in the chemical industry, including quality control sampling and drumming, storage and handling (i.e. transfer from one container to another) cleaning, repair and maintenance of production equipment;
2. Production of gasoline, sampling and analysis of quality control samples, cleaning, repair and maintenance of the equipment;
3. Production of toluene containing products (semi-products as well as products for sale), including transferal of toluene, adding to the process and drumming, and
4. Use of toluene containing products, such as spray application, brushing, rolling and cleaning (including manual transferral and mixing of such products).

The results from estimated exposures for the above-mentioned scenarios are presented in Table 23.

TABLE 23
SUMMARY OF OCCUPATIONAL EXPOSURE ESTIMATES FOR TOLUENE (ECB, 2003)

Scenario / sub-scenario	Exposure		Estimated inhalation exposure level (mg/m³)		Estimated dermal exposure level (mg/kg bw/day) RWC*
	Duration (hr/day)	Frequency (day/year)	Full shift [1] RWC*	Short-term [2] RWC*	
1. Production and use as an intermediate					
a) production and use as an intermediate	6-8	200	45	100	6
b) use as an intermediate	6-8	200	15	?	6
c) maintenance	6-8	200	45	?	9
2. Production of gasoline					
a) maintenance and tank cleaning	2-4	200	70	140	1.9
b) operators at production sites	6-8	200	20	30	1.2
c) transfer of gasoline	6-8	200	50	100	1.2
d) attendants at service stations	4-6	200	3	6	0.6
3. Production of products (transfer, filling and drumming)	6-8	200	98	200	6
4. Use of toluene-containing products					
a) manual cleaning	4-6	200	120	200	90
mechanical cleaning	4-6	200	44	90	0.6
b) use of adhesives	4-6	200	400	500	279

Scenario / sub-scenario	Exposure		Estimated inhalation exposure level (mg/m³)		Estimated dermal exposure level (mg/kg bw/day) RWC*
	Duration (hr/day)	Frequency (day/year)	Full shift [1] RWC*	Short-term [2] RWC*	
c) printing	4-6	200	350	700	6
d) painting: manual	4-6	200	50	100	29
spraying	4-6	200	50	100	279
mechanical coating	4-6	200	170	340	6

* RWC: Reasonable worst case 1) Based on measured data

2) Based on expert judgement, except for sub-scenario 4b which is based on measured data

As shown in Table 23, several values exceed the EU occupational exposure limit of 192 mg/m³ (50 ppm) and thereby also the Danish OEL of 94 mg/m³ (25 ppm), most notably in relation to use of toluene-containing products such as adhesives and in relation to printing.

6.2.2 Indirect exposure

Data on indirect exposure are available in the RAR for toluene (ECB, 2003). The data are summarised in the following.

An overview of estimated human intake from indirect exposure in local and regional scenarios is shown in Table 24. The estimations were performed according to the environmental distribution model EUSES. In the different local assessment scenarios, all food products come from the vicinity of one point source. In the regional assessment, all food products are taken from the regional model environment.

TABLE 24
ESTIMATED HUMAN INTAKE OF TOLUENE IN MG/KG BW/DAY, LOCAL AND REGIONAL (ECB, 2003)

Scenario	Drinking water	Fish	Leaf crops	Root crops	Meat	Milk	Air	Total intake mg/kg/d
1. Intermediates								
Processing	0.0155	0.161	$2.02*10^{-5}$	$1.68*10^{-5}$	$1.78*10^{-6}$	$2.35*10^{-6}$	0.0121	0.189
2. Basic chemicals								
Formulation	0.0065	0.0669	$1.37*10^{-4}$	0.0025	$2.89*10^{-6}$	$3.81*10^{-6}$	0.0824	0.158
Processing	0.129	1.34	$8.62*10^{-4}$	0.0497	$2.64*10^{-5}$	$3.48*10^{-5}$	0.517	2.03
3. Mineral oil and fuel								
Formulation	0.0042	0.0436	$8.91*10^{-5}$	0.00163	$1.88*10^{-6}$	$2.48*10^{-6}$	0.053	0.103
Private use	0.0001	0.0009	$4.91*10^{-6}$	$3.49*10^{-6}$	$9.04*10^{-8}$	$1.19*10^{-7}$	0.0030	0.004
4. Polymers								
Formulation	0.0015	0.0159	$1.33*10^{-5}$	$5.57*10^{-4}$	$3.65*10^{-7}$	$4.81*10^{-7}$	0.008	0.026
Processing	0.0001	0.0015	$8.60*10^{-6}$	$2.79*10^{-5}$	$1.57*10^{-7}$	$2.08*10^{-7}$	0.0052	0.007
5. Paint, etc.								
Formulation	0.0021	0.022	$1.84*10^{-5}$	$7.88*10^{-4}$	$5.06*10^{-7}$	$6.67*10^{-7}$	0.0111	0.036
Private use	0.0001	0.0009	$9.96*10^{-7}$	$6.01*10^{-7}$	$2.50*10^{-8}$	$3.30*10^{-8}$	0.0006	0.0016
6. Basic chemical								
Formulation	0.0020	0.0207	$4.18*10^{-5}$	$7.53*10^{-4}$	$8.83*10^{-7}$	$1.16*10^{-6}$	0.0251	0.0486
Processing	0.0581	0.601	$3.88*10^{-4}$	0.0223	$1.19*10^{-5}$	$1.57*10^{-5}$	0.233	0.914

Scenario	Drinking water	Fish	Leaf crops	Root crops	Meat	Milk	Air	Total intake mg/kg/d
7. Personal / domestic								
Formulation	0.00018	0.0188	$6.53*10^{-6}$	$6.6*10^{-4}$	$2.78*10^{-7}$	$3.66*10^{-7}$	0.0039	0.025
Private use	0.00016	0.0016	$1.08*10^{-6}$	$2.13*10^{-5}$	$3.25*10^{-8}$	$4.29*10^{-8}$	0.0006	0.0024
8. Pulp, paper and board								
Formulation	0.00079	0.0082	$1.59*10^{-5}$	$2.76*10^{-4}$	$3.39*10^{-7}$	$4.48*10^{-7}$	0.010	0.0188
Processing	0.00028	0.0029	$3.15*10^{-4}$	$2.80*10^{-4}$	$5.29*10^{-6}$	$6.98*10^{-6}$	0.189	0.193
9. Textile Processing	0.0017	0.0072	$1.78*10^{-6}$	$1.81*10^{-3}$	$1.86*10^{-7}$	$2.45*10^{-7}$	0.0011	0.0117
10. OtherProcessing	0.0004	0.0038	$7.22*10^{-5}$	$1.68*10^{-4}$	$1.24*10^{-6}$	$1.63*10^{-6}$	0.0433	0.0477
Regional	$8.92*10^{-5}$	0.0009	$9.96*10^{-7}$	$6.65*10^{-6}$	$2.49*10^{-8}$	$3.29*10^{-8}$	0.0006	0.0016

Only in the case of two production scenarios, 2 and 6, the estimated total oral intake excluding the contribution from air exceeds the tolerable daily intake (TDI) as estimated by WHO (0.223 mg/kg bw/d). In scenario 2 (toluene used as a solvent) the total oral daily intake was estimated at 1.51 mg/kg bw/d, and in scenario 6 (toluene as an extraction agent) the estimated oral intake was 0.68 mg/kg bw/d.

Monitored levels of toluene on the streets and urban background areas of Copenhagen are presented in section 5.3.2. The highest average values (up to 3.7 µg/m^3) are approximately three orders of magnitude lower than the inhalation TDI (3.8 mg/m^3) established by Health Canada.

6.3 Bio-monitoring data

Toluene and its metabolites can be measured in blood, urine or exhaled air. Toluene is a sensitive and specific biomarker in blood and blood concentrations of toluene have been found to be highly correlated to toluene in air at levels approximating 1 ppm (EPA, 2005). It is also a specific biomarker in urine, but it is difficult to quantify the relationship between exposure and observed levels. Toluene is also a specific biomarker in exhaled air; however, reproducible results have been difficult to obtain. Hippuric acid (metabolite) is sometimes used as a biomarker in urine, but it has limited value except in relation to acute exposures due to the short half-life.

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey combines interviews and physical examinations. A non-representative sample of adults in NHANES III (1988-1994) had geometric mean and median blood toluene levels, respectively, of 0.52 and 0.28 µg/L, which were generally higher than comparable levels in NHANES 2001-2002, 2003-2004, and 2005-2006. Similar median blood toluene levels have been reported in U.S. children and in studies of adults without occupational exposure. Population studies in Italy and Mexico have reported median blood toluene levels that were about twice as high as those in the U.S[6]. Street vending can result in blood toluene levels that are two to three times higher than background levels. No recent data from Europe have been identified.

[6] http://www.cdc.gov/biomonitoring/Toluene_BiomonitoringSummary.html

6.4 Human health impact

6.4.1 Consumers

Risk characterisations for consumers were performed for the following scenarios in the RAR (ECB, 2003):

1. Gluing;
2. Spray painting;
3. Car maintenance, 3A car polishing, 3B cleaning hands in solvent based cleaning agent, and
4. Carpet laying.

For scenarios 1 , 3A and 3B, it was concluded for all toxicological end-points that there was no need for further information and/or testing, and no need for risk reduction measures beyond those which are being applied.

For scenarios 2 and 4, it was concluded for acute inhalation toxicity and eye irritation that there was a need for limiting the risks, and risk reduction measures already being applied would be taken into account. For toxicity to reproduction in relation to the two scenarios, it was concluded that there was a need for further information and/or testing. For the remaining end-points it was concluded that there was no need for further information and/or testing, and no need for risk reduction measures beyond those already applied.

Risk characterisation was not performed for the scenario 'Filling gasoline at self-service gas stations' since toluene exposures arising from the production and handling of gasoline were not formally a part of the risk assessment (ECB, 2003).

Several of the consumer product surveys conducted by the Danish EPA also evaluated the health risk posed by either toluene or for the sum of detected substances including toluene.
Most evaluations concluded that the emissions of toluene in consumer products were too low to cause any unacceptable health risk (applies to tents and tunnels for children, incenses, printed matter including rotogravure and most electrical and electronic products). An exception among electrical and electronic products was voltage converters, where toluene was estimated to contribute to a possible health risk.

6.4.2 Workers

Risk characterisation for workers was performed for the following scenarios in the RAR (ECB, 2003):

1. Production of toluene and use of toluene as an intermediate in the chemical industry, including quality control sampling and drumming, storage and handling (i.e. transfer from one container to another) cleaning, repair and maintenance of production equipment;
2. Production of toluene containing products (semi-products as well as products for sale), including transferral of toluene, adding to the process and drumming, and
3. Use of toluene containing products, such as spray application, brushing, rolling and cleaning (including manual transferral and mixing of such products).

For scenario 1, it was concluded for acute inhalation toxicity that there was a need for limiting the risks, and risk reduction measures which are already being applied shall be taken into account. For all other toxicological end-points, it was concluded that there was no need for further information and/or testing, and no need for risk reduction measures beyond thosealready applied.

For scenario 2, it was concluded that for acute inhalation toxicity, eye irritation, repeated inhalation dose toxicity and toxicity to reproduction that there was a need for limiting the risks, and risk reduction measures which already applied would be taken into account. For the remaining end-

points it was concluded that there was no need for further information and/or testing, and no need for risk reduction measures beyond those already applied.

For scenario 3, it was concluded for a number of sub-scenarios and a number of toxicological end-points that there was a need for limiting the risks, and risk reduction measures already applied would be taken into account. For the remaining sub-scenarios and end-points it was concluded that there was no need for further information and/or testing, and no need for risk reduction measures beyond those already applied.

Risk characterisation was not performed for the scenario 'Production of gasoline, sampling and analysis of quality control samples, cleaning, repair and maintenance of the equipment' since toluene exposures arising from the production and handling of gasoline were not formally a part of the risk assessment (ECB, 2003).

6.4.3 Humans exposed via the environment

With all the indirect exposure sources combined, the RAR (ECB, 2003) concluded that at present there is no need for further information and/or testing and no need for risk reduction measures beyond those already applied. This conclusion was drawn for all toxicological end-points.

Measurements of toluene in streets and urban background areas in Copenhagen at levels of 1.36 – 3.7 µg/m^3 did not give rise to any immediate concerns when comparing the levels with the inhalation TDI established by Health Canada (3.8 mg/m^3; 1 ppm) which was three orders of magnitude higher than the highest measured average levels.

The estimated total exposure from food based on EUSES estimations exceeded the TDI value established by WHO in two scenarios (2 and 6), where the intake of toluene from fish alone (1.34 mg/kg bw/d and 0.601 mg/kg bw/d respectively) was higher than the TDI (0.223 mg/kg bw/d). The the total oral intake was 1.51 mg/kg bw/d and 0.68 mg/kg bw/d respectively.

Combined exposure

The RAR (ECB, 2003) concluded that combining local environmental exposure and occupational exposure will not influence the characterisation of the risks associated with environmental exposure alone.

6.5 Summary and conclusions

The EU Risk Assessment for toluene for which Denmark was the rapporteur Member State (ECB, 2003) is identified as the most recent comprehensive evaluation of toluene; it therefore provides the main background for the present evaluation. Few newer data are available in the registration dossiers in the ECHA database.

Toluene is of low acute toxicity in experimental animals following inhalation, oral intake and dermal contact. Effects observed in human volunteers include central nervous system effects and irritation; based on the human data, toluene is classified for specific organ toxicity following single exposure. Toluene is classified as a skin irritant but is not considered an eye irritant. Toluene did not cause sensitisation in a guinea pig study performed in accordance with EU guideline B6; no human data are available.

The central nervous system and the inner ear are the main target organs after repeated dosing; toluene is classified for specific organ toxicity following repeated exposure.

Toluene is not considered a mutagen based on results from several test systems. Based upon the available data, it cannot be evaluated whether toluene is carcinogenic, but the evidence is not

considered strong enough to fulfil the EU criteria for classification for carcinogenicity. This decision is in line with the IARC evaluation "not classifiable as to its carcinogenicity to humans."

Toluene has not shown clear effects on fertility, whereas studies in experimental animals provide strong evidence for developmental toxicity; toluene is classified for developmental toxicity.

Consumer exposure to toluene occurs primarily from use of toluene containing products. Exposure assessments and risk characterisation have been performed for four different use scenarios, i.e. gluing, spray painting, car maintenance (polishing, and cleaning hands in solvent based cleaning agent), and carpet laying. For most of the scenarios no concern was identified.

For two consumers scenarios (spray painting and carpet laying), it was concluded that there was a need for limiting the risks, and risk reduction measures already applied would be taken into account. In addition, it was concluded that there was a need for further information and/or testing in relation to reproductive toxicity. Consumers can also be exposed to toluene due to filling gasoline at self-service gas stations; however, toluene exposures arising from the handling of gasoline were not formally a part of the risk assessment and therefore, a risk characterisation was not performed for this scenario. However, an Australian study with 6 different exposure scenarios for service stations emissions, including consumer sceniarios for filling gasoline, indicated minimal risk for consumers.

Several Danish consumer surveys have demonstrated content in and release of toluene from many different consumer products, mostly indicating relatively low contributions from the the individual products. However, when calculating the sum of contributions from all potential sources likely to release toluene to the indoor air in a children's room at the same time, the total calculated daily intake for a child is very close to the Tolerable Daily Intake (TDI) and Reference Dose for toluene of 223 µg/kg bw/d.

Occupational exposure to toluene occurs primarily in industries where toluene and gasoline are produced; where toluene is used as a chemical agent, an ingredient or an intermediate; and from use of toluene-containing products. Exposure assessments and risk characterisation have been performed for these use scenarios, except for toluene exposures arising from the production and handling of gasoline which were not formally a part of the risk assessment. Concern was identified for a number of uses including production of toluene and use of toluene as an intermediate in the chemical industry, production of toluene containing products (semi-products as well as products for sale), and use of toluene containing products, such as spray application, brushing, rolling and cleaning. For these uses there was a need for limiting the risks.

Indirect exposure to toluene can occur through air, drinking water and food. Estimated (modelled) oral intakes of toluene from food and drinking water have been shown to exceed the TDI suggested by WHO (in relation to drinking water guidelines) for two production/processing scenarios; use of toluene as a solvent and use of toluene as an extraction solvent.

7. Information on alternatives

7.1 Introduction

Toluene is used as an aromatic solvent in a number of applications, e.g. for adhesives and paints. According to the EU Risk Assessment report (ECB, 2003) only 19 % of toluene is used as a solvent, while the remaining amount is used as an intermediate for the manufacture of benzene, phenols and aromatic isocyanates. However, toluene is not used as intermediate in Denmark.

According to EU occupational health and safety legislation, companies that use hazardous substances in their production are obliged to look for alternatives to these substances and substitute them with less hazardous substances where feasible.

When considering alternatives, the first step will always be to look for other chemical substances of a lower hazard which meet the legal and technical requirements, are compatible with the production process, and can be adequately controlled and disposed of under the existing control and waste disposal measures. The substitution should result in safer products with the required performance and, at the same time, the alternative must be commercially available in sufficient quantities.

In general, it is judged to be relatively easy to find alternatives to toluene as a solvent because it is possible to make mixtures of other non-reactive solvents to match the solubility parameter for toluene and to adjust the evaporation rate.

Information collection on alternatives has been based on the following:

- Technical literature;
- Internet searches, and
- Interviews with three significant adhesive/paint/coating producing companies in Denmark.

Searches on the Internet were carried out by using the words "substitution" and "alternatives" in combination with the substance name.

7.2 Identification of possible alternatives to toluene

Alternative solvents and solvent mixtures may be used instead of toluene, if:

- They have similar solvent properties for dissolving the chemical substances (polymers, additives etc.) in the formulation, and
- They evaporate with a rate adapted to the application.

The solubility parameters of different solvents and their mixtures can be used for the optimisation of the alternatives.

Eastman (Eastman, 2013a and 2013b) claims that they can replace toluene with n-propyl propionate for the following applications:

- Coatings OEM(original equipment manufacturer) and special purpose;
- Process solvent for high-solids acrylic resins;
- Industrial cleaners;

- Industrial printing inks;
- Automotive refinish, and
- Appliance coatings.

The sum of Hansen solubility parameters (nonpolar, polar and hydrogen bonding) for the n-propyl propionate totals 8.6, compared to 8.9 for toluene. The evaporation rate is 1.2 for n-propyl propionate compared to 1.9 for toluene (reference is n-BuOAc =1).

The principle behind the Hansen solubility parameters (HSP) (Hansen, 2000) is that the total energy of vaporization of a liquid/solvent consists of several individual parts. These arise from (atomic) dispersion forces, (molecular) permanent dipole-permanent dipole forces, and (molecular) hydrogen bonding. The total cohesive energy can be measured by evaporating the solvent, i.e. breaking all the cohesive bonds which attract the solvent molecules to each other. Solvents or materials having the same HSP have a high affinity for each other. The evaporation rate is an arbitrary scale where the evaporation rate for n-butylacetate is used as reference.

Eastman claims to also have a solvent mixture to replace toluene in a two-component polyurethane clearcoat system. In this solvent mixture, toluene was also replaced by n-propyl propionate. The solubility parameter of the toluene-free reformulation was 8.60, compared to the formulation with toluene 8.58 . For both formulations the evaporation rate was 0.9.

Eastman has reformulated four other solvent mixtures to substitute for toluene by optimising evaporation rates and solubility parameters for different suggested applications.

Total Fluids & Solutions has discussed the possibility of replacing toluene with alternatives in "Alternatives to Toluene & Xylene: Totals answer for industry". Methyl cyclohexane is one of the suggestions for substitution of toluene. In order to use acetone as a substitute, it is necessary to be careful as acetone has a different evaporation rate and a different solubility parameter.

When replacing toluene, it is stated (PCI, 2006) that the difference in evaporation rates between n-propyl propionate and toluene, 1.2 and 1.9 respectively, may require the addition of a faster-evaporating solvent to achieve the desired evaporation rate characteristics. According to the interviewed companies, other potential replacements for toluene include blends of ketones, esters, alcohols and aliphatic hydrocarbons. It is mentioned that a replacement blend used for wood furniture coatings may not be suitable for other coating applications, but that information on those blends can be obtained from solvent suppliers.

A survey of some of the specific solvents which have been mentioned in the literature is provided below (Table 17), but other solvents can also be used by making solvent mixtures and adjusting solubility parameter and evaporation rate.

TABLE 25
OVERVIEW OF ALTERNATIVES TO TOLUENE

Use/function	Alternative substance	Technical characteristics	Advantages /drawbacks	Experience with alternative	Reference
Solvent	Methyl cyclohexane	Aliphatic hydrocarbon solvent	Less hazardous but other evaporation rate	Good according to reference	www.eastman.com
	Cyclohexane	Aliphatic hydrocarbon solvent	Less hazardous but other evaporation rate	Good according to reference	www.eastman.com

Use/function	Alternative substance	Technical characteristics	Advantages /drawbacks	Experience with alternative	Reference
	Xylene	Aromatic hydrocarbon solvent	Less hazardous but other evaporation rate	Judged good for non-regulated products	Judged by DTI
	n-Propyl propionate	Aliphatic ester-based solvent	Less hazardous but other evaporation rate	Good according to reference	www.eastman.com

Solvent substitution tools are offered commercially e.g. by Eastman Chemical Company for calculating blends of solvents which can replace toluene. The replacement solvents are typically blends of ketones, esters, alcohols and aliphatic hydrocarbons.

It is still necessary to check the blend in the actual applications before commercial use and one must at the same time consider the health and environmental aspects of the non-HAP[7] blend. As a general rule, the formulations developed commercially are confidential and not publicly accessible.

The company using toluene in their paints and coatings stated that for newly developed products, alternatives to toluene will be used.

7.3 Human health and environmental aspects of alternatives

The harmonised classification of alternatives to toluene according to the CLP Regulation are listed in the table below (based on ECHA's CLP Inventory Database). None of the substances are classified as acutely toxic, toxic to reproduction, carcinogenic or mutagenic.

TABLE 26
HARMONISED CLASSIFICATION OF ALTERNATIVES TO TOLUENE ACCORDING TO THE CLP REGULATION

Alternative substance	EC number	CAS number	Hazard Class and Category Code(s)	Hazard Statement Code(s)[1]
Cyclohexane	203-806-2	110-82-7	Flam. Liq. 2 Asp. Tox. 1 Skin Irrit. 2 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1	H225 H304 H315 H336 H400 H410
Methyl cyclohexane	203-624-3	108-87-2	Flam. Liq. 2 Asp. Tox. 1 Skin Irrit. 2 STOT SE 3 Aquatic Chronic 2	H225 H304 H315 H336 H411

[7] HAP – Acronym for Hazardous Air Pollutants

Alternative substance	EC number	CAS number	Hazard Class and Category Code(s)	Hazard Statement Code(s)[1]
Xylene	215-535-7	1330-20-7	Flam. Liq. 2 Acute Tox. 4* Skin Irrit. 2 Acute Tox. 4*	H226 H312 H315 H332
n-propyl propionate	203-389-7	106-36-5	Flam. Liq. 2 Acute Tox. 4*	H226 H332

1 Hazard statements: H225 Highly flammable liquid and vapour, H226 Flammable liquid and vapour, H304 May be fatal if swallowed and enters airways, H312 Harmful in contact with skin, H315 Causes skin irritation, H332 Harmful if inhaled, H336 May cause drowsiness or dizziness; Environmental hazards: H400 Very toxic to aquatic life, H410 Very toxic to aquatic life with long lasting effects, H411 Toxic to aquatic life with long lasting effects.

* The classification as obtained under Annex VII shall then substitute the minimum classification indicated in this Annex if it differs from it.

7.4 Historical and future trends

The trend to replace toluene with other less hazardous solvents is foreseen to continue with the aim of reducing the exposure of workers and consumers to the substance.

Formerly, huge amounts of toluene have been used in the printing industry but for some applications new printing technology (laser print and head set print) has eliminated the need for toluene for printing. However, toluene is still widely used for publication and packinging gravure printing and appears to be hard to replace in these applications.

It is encouraging that two of the leading companies in Denmark for adhesives and for paints already have phased out toluene in their products and that the other paint and coating company will phase out toluene in their future development of products.

7.5 Summary and conclusions

In general, it is judged to be relatively easy to find alternatives to toluene used as a solvent for most products/applications in Denmark, as the solvent is not reactive and alternatives exist for a number of applications. The possibilities will depend on the specific technical, occupational and working environmental conditions. Use for publication and packaging gravure printing in the printing industry is an exception to this.

A Danish adhesive producing company has already phased out the use of toluene in their products a long time ago. The same is the case for a paint and coating producing company. A Danish-owned paint and coating producing company still uses toluene in products for professionals, but stated that in future, in newly developed products, alternatives to toluene will be used. This company has no production factories in Denmark; these are located in the European Union and follow European law regarding the use of hazardous substances.

The most important technical parameters when reformulating solvent mixtures to replace toluene are solubility and the evaporation rate.

Solvent substitution tools are offered commercially for calculating blends of solvents which can replace toluene. The replacement solvents are typically blends of ketones, esters, alcohols and aliphatic hydrocarbons.

It is still necessary to check the blend in the actual applications before commercial use and one must at the same time consider the health and environmental aspects of the non-HAP blend.

For products where toluene is not regulated, the amount of toluene may be reduced by using xylene and/or cyclohexane in the formulations.

None of the alternative solvents (listed in table 25) are classified as acutely toxic, toxic to reproduction, carcinogenic or mutagenic.

8. Abbreviations and acronyms

ADI	Acceptable daily intake
AF	Assessment Factor
AOPWIN	Atmospheric Oxidation Program for Windows (US EPA)
BCF	Bioconcentration factor
CEFIC	European Chemical Industry Council
CLP	Classification, Labelling and Packaging Regulation
CoRAP	Community Rolling Action Plan
CRLTAP	Convention on Long-Range Transboundary Air Pollution
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DEPA	Danish Environmental Protection Agency
DFL	Trade organisation for the paint and adhesives industry in Denmark
DNEL	Derived No-Effect Level
DT	Degradation time
DTU	Technical University of Denmark
EAK	Det Europæiske AffaldsKatalog (European Waste Catalogue)
EASE	Estimation and Assessment of Substances Exposure (model)
EC_n	Effect concentration where n % of the organisms tested show the effect
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
E-PRTR	European Pollutant Release and Transfer Register
EQC	Equivalent level of concern
EU	European Union
EUSES	European Union System for the Evaluation of Substances
HAP	Hazardous Air Pollutants
HELCOM	The Baltic Marine Environment Protection Commission (Helsinki Commission)
HSP	Hansen solubility parameter
Kow	Octanol/water partitioning coefficient
Koc	Organic carbon/water partitioning coefficient
Kp	Partial pressure equilibrium constant
LC	Lethal effect concentration
LOAEC	Lowest Observed Adverse Effect Concentration
LOUS	List of Undesirable Substances (of the Danish EPA)
MAL	Måleteknisk Arbejdshygiejnisk Luftbehov
MSWI	Municipal solid waste incinerators
MWWTP	Municipal waste water treatment plant
NHANES	National Health and Nutrition Examination Survey (USA)
NMC	Nation Mean Concentration
NOAEC/L	No observable adverse effect concentration/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
PBT	Persistent, Bioaccumulative and Toxic
PEC	Predicted environmental concentration
PIC	Prior Informed Consent (Convention) (the Rotterdam Convention)
PNEC	Predicted no effect concentration
Pow	Octanol-water partitioning coefficient
PR	Produktregistret (the Danish Product Register)
QSAR	Quantitative Structure and Activity Relationship
RAR	Risk Assessment Report (EU)
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 (EU Regulation)
RWC	Reasonable Worst Case
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
TGD	Technical guidance document
ThOD	Theoretical oxygen demand
TDI	Tolerable daily intake
VOC	Volatile Organic Compound
WHO	World Health Organisation
WWTP	Wastewater Treatment Plant

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Appendix 1: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 3. 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 manoeuvering as to the form and means of implementation. However, there are great differences in the space for manoeuvering 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).
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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 ecolabelling Regulation in relation to establishing ecolabel 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 Regulation[8] and the CLP Regulation[9] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP

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

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

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 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.

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.

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:

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:

- It has to be identified as a SVHC leading to inclusion in the candidate list[10]
- 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)
- 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
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 intensions 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.

[10] 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).

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 recommendationsset 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.

CLRTAP - Convention on Long-range Transboundary Air Pollution
Since 1979 the Convention on Long-range Transboundary Air Pollution (CLRTAP) has addressed some of the major environmental problems of the UNECE (United Nations Economic Commission for Europe) region through scientific collaboration and policy negotiation.

The aim of the Convention is that Parties shall endeavour to limit and, as far as possible, gradually reduce and prevent air pollution including long-range transboundary air pollution. Parties develop policies and strategies to combat the discharge of air pollutants through exchanges of information, consultation, research and monitoring.

The Convention has been extended by eight protocols that identify specific measures to be taken by Parties to cut their emissions of air pollutants. Three of the protocols specifically address the emission of hazardous substances of which some are included in LOUS:

- The 1998 Protocol on Persistent Organic Pollutants (POPs); 33 Parties. Entered into force on 23 October 2003.
- The 1998 Protocol on Heavy Metals; 33 Parties. Entered into force on 29 December 2003.

- The 1991 Protocol concerning the Control of Emissions of Volatile Organic Compounds or their Transboundary Fluxes; 24 Parties. Entered into force 29 September 1997.

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 ecolabelling 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 ecolabel; 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.

Appendix 2: Ecolabels

Eco-label	Substances	Relevant criteria	Document title /number
Nordic Swan	VOC (toluene)	The product may contain a limited quantity only of volatile organic compounds (VOC) that may contribute to the formation of photochemical smog, measured as POCP. Products with a VOC content of < 1.2% do not need to undergo POCP calculation since the requirement will be fulfilled even in a worst case scenario. The maximum content of VOC in the product is 12 g ethylene equivalents/ kilo of product. The POCP factor of toluene is 0.5 (Appendix 7).	Nordic Ecolabelling of Car and boat care products Version 5.2 • 21 March 2012 – 31 March 2016
	Organic solvents, TVOC	The content of organic solvents must not exceed 1% by weight of the candle. Alternatively, reference may be made to test results, which show the Total Volatile Organic Compounds (TVOC) in the candle to be less than 1200 µg/m3 of air measured in a test chamber for 24 hours and using gas chromatography/mass spectrometry (GC/MS).	Nordic Ecolabelling of Candles Version 1.3 • 13 December 2007 – 30 June 2015
	VOC	The following substances must not be actively added to the chemical products mentioned elsewhere in the criteria, e.g. cleaning products, paints, lacquers, adhesives, sealants used in final assembly of white goods and surface treatment): - volatile organic compounds at more than 1% by weight - volatile organic compounds (VOCs) at more than 5% by weight in surface treatment agents	Nordic Ecolabelling of White Goods Version 5.0 • 20 June 2013 - 30 June 2017
	Volatile organic compounds	The use of volatile organic compounds for textile cleaning is prohibited.	Nordic Ecolabelling of Alternative Dry Cleaning Version 1.4 • 23 March 2006 – 31 March 2014
	Volatile organic compounds	Solvents for impregnation and surface treatment: Pressure impregnation is not permitted. The emission of volatile organic compounds (VOC) resulting from impregnation shall not exceed 11 kg/m³.	Nordic Ecolabelling of Windows and Exterior Doors Version 3.4 • 4 November 2008 – 31 December 2014

Eco-label	Substances	Relevant criteria	Document title /number
	Volatile organic compounds and volatile aromatic compounds	Prohibited substances and additives - volatile aromatic compounds that exceeds 1% by weight - volatile organic compounds (VOC) that exceed the limit of 130 g/l chemicals used for surface treatment - Volatile aromatic compounds (VAH) must not be added directly to the product. Ingoing compounds containing VAH can be added if the total content of VAH in the final product does not exceed 0,1% by weight.	Nordic Ecolabelling of Toys Version 2.0 • 21 March 2012 – 31 March 2016
	TVOC	A test report shall declare that the analyse results for toner powder to be used for Nordic Ecolabelled toner cartridges must be smaller or equal to the limit values listed: Styrene: Determination limit (mg/kg): 4 Limit value (mg/kg): 40 TVOC: Determination limit (mg/kg): 100 Limit value (mg/kg): 300	Nordic Ecolabelling of Remanufactured OEM Toner Cartridges Version 5.1 • 15 June 2012 – 30 June 2016
	Volatile organic compounds	Printing pastes must not contain more than 5% volatile organic compounds (VOC).	Nordic Ecolabelling of Textiles, hides/skins and leather Includes products for apparel and furnishings Version 4.0 • 12 December 2012 – 31 December 2016
	Volatile organic compounds and aromatic solvents	The following substances must not be added to the chemical product or the material used: - aromatic solvents in the chemical product, more than 1% by weight - VOC (volatile organic compounds) more than 3% by weight. The content of Volatile Organic Solvents, VOC, in the production of surface treatments must be either: 1) below 5% by weight, or 2) not in excess of 10g/m² of the surface	Nordic Ecolabelling of Panels for the building, decoration and furniture industries Version 5.2 • 17 March 2011 – 30 June 2015

Eco-label	Substances	Relevant criteria	Document title /number
	Solvents, aromatic	The content of solvents with a vapour pressure of more than 2.5 kPa at 20 °C or an aromatic content in excess of 1% by weight in the finished products must not exceed a total maximum quantity of 1% by weight.	Nordic Ecolabelling of Industrial cleaning and degreasing agents Version 2.5 • 13 October 2005 – 31 March 2016
	Volatile organic compounds and volatile aromatic compounds	VOC content shall not exceed the following limits (g/L including water): - Interior Matt (walls/ceiling) (Gloss <25@60°) - 15; - Interior glossy (walls/ceiling) (Gloss >25@60°) - 60; - Interior trim and cladding paints for wood and metal including undercoats - 90; - Interior trim varnishes and wood-stains, including opaque woodstains - 75; - Interior minimum build woodstains - 75; - Primers – 15; - Binding Primers – 15; - Pack performance coatings - 100; - Two-pack reactive performance coatings for specific end use such as floors - 100; - Decorative effect coatings – 90 Volatile aromatic hydrocarbons shall not be directly added to the product before or during tinting (where applicable); however ingredients containing VAH may be added up to such a limit that the VAH content in the end product will not exceed 0.1% (m/m).	Nordic Ecolabelling of Indoor paints and varnishes Version 2.3 • 4 November 2008 – 31 March 2015
	Volatile organic compounds	The following substances must not be actively added to chemical products, for example, cleaning products, paints, lacquers, adhesives or sealants used in final assembly of heat pumps and surface treatment: - volatile organic compounds (VOC) at more than 1% by weight. - volatile organic compounds (VOC**) at more than 5% by weight in surface treatment agents	Nordic Ecolabelling of Heat pumps Version 3.0 • 13 March 2013 - 31 March 2017

Eco-label	Substances	Relevant criteria	Document title /number
	Volatile organic compounds	The individual product's total concentration of volatile organic compounds must not exceed the following limits: - Wash-and-wax care products and wash polish: VOC < 0.5 w/w% - Base coat polish, floor polish and floor wax: VOC < 5.0 w/w% - Polish removers and wax removers : VOC < 20.0 w/w%	Nordic Ecolabelling of Floor care products Version 4.1 • 15 June 2012 – 31 December 2015
	Volatile organic compounds	The emissions of VOCs during polymerisation of polyester, expressed as an annual average, shall not exceed 1.2 g/kg of produced polyester resin.	Nordic Ecolabelling of Fabric cleaning products containing microfibers Version 2.1 • 12 October 2010 – 31 March 2016
EU Flower	Volatile organic compounds	The final products of all-purpose cleaners and sanitary cleaners (as sold) shall not contain more than 6 % (by weight) of volatile organic compounds with a boiling point lower than 150 °C. Alternatively, for concentrated products to be diluted in water, the total concentration of volatile organic compounds with a boiling point lower than 150 °C shall not exceed 0,2 % (by weight) in the washing water. The final products of window cleaners (as sold) shall not contain more than 10 % (by weight) of volatile organic compounds with a boiling point lower than 150 °C.	COMMISSION DECISION of 28 June 2011 on establishing the ecological criteria for the award of the EU Ecolabel to all-purpose cleaners and sanitary cleaners
	Volatile organic compounds	The emissions of VOCs during polymerisation and fibre production of polyester, measured at the process steps where they occur, including fugitive emissions as well, expressed as an annual average, shall not exceed 1,2 g/kg of produced polyester resin.	Commission Decision of 9 July 2009 establishing the ecological criteria for the award of the Community Ecolabel for textile products

Eco-label	Substances	Relevant criteria	Document title /number
	Volatile organic compounds and volatile aromatic compounds	VOC content shall not exceed the following limits (g/L including water): - Interior Matt (walls/ceiling) (Gloss <25@60°) - 15; - Interior glossy (walls/ceiling) (Gloss >25@60°) - 60; - Interior trim and cladding paints for wood and metal - including undercoats - 90; - Interior trim varnishes and wood-stains, including opaque woodstains - 75; - Interior minimum build woodstains - 75; - Primers – 15; - Binding Primers – 15; - Pack performance coatings - 100; - Two-pack reactive performance coatings for specific end use such as floors - 100; - Decorative effect coatings – 90. Volatile aromatic hydrocarbons shall not be directly added to the product before or during tinting (where applicable); however ingredients containing VAH may be added up to such a limit that the VAH content in the end product will not exceed 0,1 % (m/m).	Commission Decision of 13 August 2008 establishing the ecological criteria for the award of the Community eco-label to indoor paints and varnishes

Eco-label	Substances	Relevant criteria	Document title /number
	Volatile organic compounds and volatile aromatic compounds	VOC content shall not exceed (g/l including water): - Coatings for exterior walls of mineral substrate – 40; - Exterior trim and cladding paints for wood and metal including undercoats - 90 ; - Exterior trim varnishes and wood-stains, including opaque woodstains - 90 ; - Exterior minimum build woodstains - 75 ; - Primers (for exterior use) - 15 ; - Binding Primers (for exterior use) - 15 ; - Pack performance coatings - 100 ; - Two-pack reactive performance coatings for specific end use such as floors – 100. Volatile aromatic hydrocarbons shall not be directly added to the product before or during tinting (where applicable); however ingredients containing VAH may be added up to such a limit that the VAH content in the end product will not exceed 0,1 % (m/m).	Commission Decision of 13 August 2008 establishing the ecological criteria for the award of the Community eco-label to outdoor paints and varnishes
	Volatile organic compounds	The emissions of VOCs during polymerisation and fibre production of polyester, measured at the process steps where they occur, including fugitive emissions as well, expressed as an annual average, shall not exceed 1,2 g/kg of produced polyester resin.	Commission Decision of 30 November 2009 on establishing the ecological criteria for the award of the Community Ecolabel for textile floor coverings

Eco-label	Substances	Relevant criteria	Document title /number
	Volatile organic compounds	Emissions to air: The following criterion must be met: $(P_{VOC} - R_{VOC})/P_{paper} < 5$ [kg/tonnes] Where: P_{VOC} = the annual total kilograms of VOC contained in the purchased chemical products used for the annual total production of printed products R_{VOC} = the annual total kilograms of VOC destroyed by abatement, recovered from printing processes and sold, or reused P_{paper} = the annual total tonnes of paper purchased and used for the production of printed products Volatile solvents from the drying process of heat-set offset and flexography printing shall be managed by means of recovery or combustion or any equivalent system. In all cases where no legislative measures apply, the emissions of VOC to air must not exceed 20 mg C/Nm³.	Commission Decision of 16 August 2012 establishing the ecological criteria for the award of the EU Ecolabel for printed paper.

Survey of toluene

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The survey concerns the aromatic organic substance toluene. This substance was included in the LOUS list in 2009. The report defines the substance and present information on the use and occurrence of toluene internationally and in Denmark, information on existing regulation, on environmental and health effects, on monitoring and exposure, on waste management and on alternatives to the substance.

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Kortlægningen omhandler det aromatiske organiske stof toluen. Rapporten definerer stoffet og indeholder blandt andet en beskrivelse af brugen og forekomsten af toluen internationalt og i Danmark, om eksisterende regulering, en beskrivelse af miljø- og sundhedseffekter af stoffet, af moniteringsdata, af affaldsbehandling samt alternativer til stoffet.

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