Danish Ministry of the Environment
Environmental Protection Agency

Survey of Tris(2-chloro-1-methylethyl)-phosphate

A LOUS review project

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tris(2-chloro-1-methylethyl)Tris(2-chloro-1-methylethyl)phosphate

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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 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 on going 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 tris(2-chloro-1-methylethyl)phosphate (TCPP) (CAS 13674-84-5). This substance was included on LOUS in 2009. The main reason for the inclusion in LOUS is TCPP´s potential human health effect as TCPP according to QSAR analysis is self-classified as mutagenic (mut3; R68) and toxic to reproduction (Rep3; R63). According to the CLP classification (Classification, Labelling and Packaging Regulation) this corresponds to Muta. 2; H341 and Repr. 2 ; H361.

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 DHI from March to October 2013. The project team was:

- Dorthe Nørgaard Andersen, DHI, Project Manager
- Tine Slothuus, DHI, contributor
- Henrik Rye Lam, DHI, contributor
- Poul Bo Larsen, DHI, contributor

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

- Louise Grave-Larsen, Danish EPA, Project Manager
- Lone Schou, Danish EPA
- Thilde Fruergaard Astrup, Danish EPA
- Ulla Hansen Telcs, Confederation of Danish Industry
- Bente Fabech, Danish Veterinary and Food Administration

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.

In addition to databases, websites, reports and literature the following person(s) besides the advisory group have contributed with valuable information:

Thomas Brønnum, The Danish Plastics Federation

Summary and conclusions

TCPP on LOUS
The Danish EPA has put TCPP / a flame retardant used mainly in polyurethane foam (PUR foam) on the LOUS list based on the Danish EPA self-classification (based on QSAR predictions) of the substance as Muta 2, H341 (Suspected of causing genetic effects) and Repr 2.,H 361 (Suspected of damaging fertility or the unborn child).

Identity of TCPP
TCPP is a chloroalkyl phosphate containing mainly four isomers:

tris(2-chloro-1-methylethyl)phosphate	(approx. 50-85%);
bis(1-chloro-2-propyl)-2-chloropropyl phosphate	(approx. 15-40%);
bis(2-chloropropyl)-1-chloro-2-propyl phosphate	(less than 15%)
tris(2-chloropropyl)phosphate	(less than 1%)

Regulatory measures towards TCPP
No specific regulation applies for TCPP neither on international, EU or national level.
Also, there is no EU harmonized classification for the substance. However, according to the self-classifications notified by the suppliers in EU the following classifications are used either alone or in combination:

Acute tox. 4; Skin Irrit. 2; Eye Irrit. 2; and Aquatic Chronic 3.

The most often used classifications by the notifiers are Acute tox 4 and Aquatic Chronic 3, respectively. Also, a few notifiers do not classify the substance at all.

As discussed later there seems to be toxicological data that justify a classification as Carc 2 and Repr 2 for the substance.

The Danish EPA has put TCPP on the LOUS list based on their QSAR self-classification as Muta 2 and Repr 2. As seen from the notified classifications no suppliers in Europe apply these classifications.

Recently, two European consumer organizations ANEC and BEUC has in a statement in 2012 proposed a ban of TCPP (and TDCP) in toys as they consider these substances similar to TCEP which is a substance under authorisation in REACH based on its harmonized EU classification as toxic to reproduction 1B, H360F (may damage fertility).

Ecolabelling schemes such as the EU-flower and the Nordic Swan apply criteria for several product types that eco-labelling () restrict the use of TCPP (together with other flame retardant) in e.g. mattresses, furniture, carpets, textiles, refrigerators, and building products, and in textiles in toys.

TCPP volumes and trends in EU and DK
In year 2000 the total EU production of TCPP was 36,000 tonnes. Between 1998 and 2003, production has increased significantly. This increased use of TCPP in Europe has been linked to a decreased use of tris(2-chloroethyl)phosphate (TCEP)- due to human health concerns for TCEP. According to the EU RAR (2008) there was in 2008, based on industry information, no reason to anticipate further significant tonnage increases in the near future.
The production of TCPP takes place at three plants in Germany and one in UK. In 2001 the import into EU was 8,304 tonnes and the export was 6,211 tonnes. These volumes comply with current

REACH registrations which indicate a yearly tonnage level in the range of 10,000-100,000 tonnes of the substance.

- A further quantity of 1,201 tonnes of TCPP is believed to be imported into the EU in finished goods i.e. in furniture, in one-component PUR foams, and in rebounded foam.

All use of TCPP in Denmark has to be imported as no production of TCPP takes place in Denmark.

According to the registration in the Danish Product Register (which only registers chemical mixtures/ products considered as hazardous) the annual consumption of TCPP has since 2006 been rather stable at about 200 tonnes per year. Overall, in Denmark the use of TCPP in chemical products has declined from 700 tonnes in 2001 to 200 tonnes in 2011.
However, these figures do not cover the content of TCPP in PUR foam in articles.

Uses
Over 40,000 tonnes of TCPP were used in the EU in the year 2000, and most of this (> 98%) was used as flame retardant in the production of polyurethane (PUR) for the use in construction e.g. insulation/ fillers as rigid foam) and furniture as flexible foam.

Most TCPP is used in rigid PUR foam (over 80%) mainly for construction applications. The remaining PUR applications are accounted for by flexible foam (over 17%), used in upholstery and bedding for the UK and Irish markets. TCPP tends not to be used in flexible PUR for automotive applications owing to its volatility and fogging potential. TCPP is according to industry information in Denmark only rather seldom used in flexible foam indicating that most uses of TCPP in Denmark are in relation to rigid foam.

In the PUR foam the typical levels of TCPP and other chloroalkyl phosphates are in the range of 5-15%. This has been confirmed by the Danish Plastics Federation that reports a typically content of TCPP of 5-10% as TCPP in flexible PUR is mostly used in combination with melamine which keeps the concentration at TCPP down at a lower level.

In Denmark nearly all PUR foam for furniture, mattresses, and refrigerators is without flame retardants, however, TCPP in flexible foam may be used for mattresses and furniture for the UK market or for institutions such as e.g. prisons and hospitals. These data may indicate that TCPP used in PUR foam in Denmark is primarily used in rigid foam e.g. in construction.
The dominant use in rigid foam is supported by data from the Danish Product Registry that indicate that the TCPP use in 2011 primarily was in connection with insulation materials (109 tonnes) and fillers (32.8 tonnes).

Waste
In general PUR waste containing TCPP are not to be considered as hazardous waste as the typical TCPP content is in the range of 5-10% which is below the level of classification for the classification end-points currently used for TCPP)

TCPP is in Denmark seldom used in flexible PUR foam and it must be assumed that the largest volume of flexible PUR foam waste is without TCPP.
Thus when TCPP occur in the waste stream this may typically be associated to use of TCPP in rigid PUR foam e.g. in construction materials (typically insulation and fillers).

At the production sites in Denmark industrial PUR waste is subject to recycling. And in 2005 up to approximately 60% of the PUR waste was estimated to be recycled. The part of industrial PUR waste that is not recycled and the domestic waste containing PUR (mattresses, furniture, refrigerators, construction materials etc.) will go for incineration due to the high energy content of the PUR foam.

Based on Danish figures from 2005 at least 7730 tonnes of PUR foam comes from industrial PUR waste and from domestic waste with products containing PUR. The PUR waste (including the TCPP) will typically go to incineration where PUR and TCPP undergo thermal decomposition.

Overall, there is a low potential for release and exposure to TCPP in connection to TCPP in the waste stream of PUR products. Also, it is not considered to have any significant implication for waste treatment if PUR foam with TCPP was to be considered as hazardous waste (e.g. due to lower classification limit for TCPP) as PUR foam in the waste stream is subjected to incineration due to the high energy content of the foam.

Environment
There are ecotoxicological data on TCPP available on the acute toxicity to fish; acute and chronic tests with aquatic vertebrates, and on algae. Furthermore results from toxicity tests with terrestrial organisms and microorganisms are available.
A classification of Aquatic Chronic 3; H412 seems proper since the lowest $L(E)C_{50}$ values reported for fish and algae are 51 mg/L and 82 mg/L, respectively (criteria values > 10 to ≤100 mg/L) and TCPP is *not* ready biodegradable.
At present no harmonized classification and labelling are appointed to TCPP according to Annex VI of the CLP Regulation.

With respect to PBT evaluation, TCPP can be considered to meet the screening criterion as persistent (P) or potentially very persistent (vP) based on its ultimate mineralization. The available information on bioaccumulation (measured BCF (fish) of 0.8-4.6) shows that TCPP does not meet the bioaccumulation (B) criterion. The criterion for toxicity (T) criterion is also not met.

Monitoring data on TCPP in the environment and predicted environmental concentrations do not indicate any risk for the aquatic- and terrestrial compartment (including sediment) as well as waste water treatment plants.

In Denmark in 2010 an average level of 1.4 µ TCPP/L was measured in the effluents from sewage treatment plants and an estimated total of about 700 kg of TCPP was emitted into the Danish marine waters.

Human health effects
The EU Risk Assessment Report from 2008 presents an excellent review of the available toxicological data and provides estimates of the potential human exposure levels. A database search did not reveal any new relevant data.

TCPP is extensively and rapidly absorbed (about 80% of dose) after oral exposure and is widely distributed to organs. TCPP is extensively metabolized and excreted by urine and faces.
Acute toxicity is low with most LD_{50} values below 2000 mg/kg bw complying with a classification as Acute Tox. 4, H302.
Skin and eye irritation is only slight, and no data on respiratory irritation are available. Skin sensitisation was not demonstrated.

A 28-day gavage study established a NOAEL on 100 mg/kg bw/day (liver target organ) and another repeated dose oral toxicity study for 13 weeks demonstrated a LOAEL of 52 mg/kg bw/day (liver and thyroid gland target organs).

TCPP is non-genotoxic as established in *in vitro* and *in vivo* studies. However, QSAR analyses have implied indications of mutagenicity. But, taking account to the animal experimental data and the conclusion made in the EU risk assessment *report there seems to be no reason to maintain the concern for a genotoxic potential of TCPP.*

No carcinogenicity studies are available. However, a qualitative basis read-across approach is justified to data from TCEP and TDCP as concluded in the EU risk assessment report and also by the Scientific Committee of Health and Environmental Risks who have evaluated the substances. *Thus TCPP should be classified as Carc. 2, H351*, as this corresponds to the EU-harmonized classifications for the two read-across substances TCDP and TCEP.

From a 2-generation reproductive toxicity study in rats a LOAEL of 99 mg/kg bw was derived for effects on fertility, based on effects on the uterus weight seen in all dosed females in the F0 generation. A LOAEL of 99 mg/kg bw is derived for developmental toxicity based on the increased number of runts observed in all dose groups of the F0 generation.
Maternal toxicity may play a rule in these findings, however, *a possible classification of TCPP would be a classification as Repr, 2; H361.*

The endocrine disruption potential of TCPP was investigated in an *in vitro* study with a H295R cell line where testosterone concentration was increased at 1, 10 and 100 mg/L. Furthermore, data from the 2-generation reproductive toxicity study indicate hormonal disturbance by TCPP due to the findings of decreased uterus weight and prolongation of the oestrus cycle. These results indicate that TCPP could alter sex hormone balance. This could support a classification as indicated above. However, it remains to be determined whether increased testosterone levels also occur *in vivo* and whether this could be associated to the decrease in uterus weight. Thus, further verification/studies would be needed to clarify the potential for endocrine disruption of the substance.

Read-across to TCEP in relation to the reproductive toxicity (as done for the carcinogenic effects) seems less reliable as no effects on uterus have been found for TCEP, and also TCEP strongly affect the male reproductive system which has not been found for TCPP.

Human exposure and risk
Only very minute exposure to consumers for TCPP is anticipated in relation to the use of TCPP in articles and chemical products, and in general very large margins of exposure have been found compared to the effects levels in experimental animals. Thus the current use of TCPP is considered safe for the consumers.

Overall, in relation to human health, a classification of TCPP with Carc. 2, H351 seems warranted. Further, a classification with Repr, 2; H361 may be relevant as well.
The current uses of TCPP are not –due to very low potential for exposure- considered to possess any risk forthe consumers.

Alternatives to TCPP
TCPP is itself used as an alternative to the very closely related substance TCEP which have been used to a great extent as flame retardant. However, the use of TCEP has stopped due to the classification of this substance as Repr. 1B.

No data have been found to which extent substitution to some of the proposed non-halogenated alternative flame retardants is technically feasible. This may be because there have not been any drivers or intentions to find substitutes for TCPP, as this flame retardant itself was considered as the ideal substitute for TCEP.

Sammenfatning og konklusion

TCPP på LOUS
Miljøstyrelsen har placeret TCPP, -en flammehæmmer, der hovedsageligt anvendes i polyurethanskum (PUR-skum), på LOUS-listen som følge af Miljøstyrelsens selvklassificering (baseret på QSAR forudsigelser) af stoffet som Muta 2, H341 (Mistænkt for at forårsage genetiske effekter) og Repr 2., H 361 (Mistænkt for at skade forplantningsevnen eller det ufødte barn).

Identitet af TCPP
TCPP er en chloreret alkylphosphat, som hovedsageligt indeholder fire isomerer:

tris(2-chloro-1-methylethyl)phosphat	(ca. 50-85 %);
bis(1-chloro-2-propyl)-2-chloropropylphosphat	(ca. 15-40 %);
bis(2-chloropropyl)-1-chloro-2-propylphosphat	(mindre end 15 %)
tris(2-chloropropyl)phosphat	(mindre end 1 %)

Lovgivningsmæssige tiltag overfor TCPP
Der er ikke nogen specifik lovgivning for TCPP, hverken på internationalt, EU- eller nationalt plan. Der er heller ikke nogen EU-harmoniseret klassificering af stoffet. Men ifølge de selvklassificeringer, der er anmeldt af leverandører i EU, anvendes følgende klassificeringer enten alene eller i kombination:

Acute tox. 4; Skin Irrit. 2; Eye Irrit. 2; and Aquatic Chronic 3.

Anmeldernes mest anvendte klassificeringer er henholdsvis Acute tox 4 og Aquatic Chronic 3. Der er også nogle enkelte anmeldere, som slet ikke klassificerer stoffet.

Som omtalt senere, foreligger der imidlertid toksikologiske data, der kunne begrunde en klassificering som Carc 2 og Repr 2 for stoffet.

Som tidligere nævnt har Miljøstyrelsen sat TCPP på LOUS-listen baseret på QSAR selvklassificeringerne som Muta 2 og Repr 2. Som det fremgår af de anmeldte klassificeringer, er der ingen leverandører i Europa, som anvender disse klassificeringer.

To europæiske forbrugerorganisationer ANEC og BEUC har i en erklæring i 2012 foreslået et forbud mod TCPP (og TDCP) i legetøj, da de anser disse stoffer for at ligne TCEP, der er under godkendelsesordningen i REACH, som følge af den harmoniserede EU-klassificering som reproduktionstoksisk 1B, H360F (Kan skade forplantningsevnen).

Miljømærkeordninger som EU-blomsten og den nordiske Svane anvender kriterier for flere produkttyper, så TCPP (sammen med andre flammehæmmere) ikke kan anvendes i miljømærkede produkter fx madrasser, møbler, tæpper, tekstiler, køleskabe, byggeprodukter samt i tekstiler i legetøj.

TCPP, mængder og udvikling i EU og DK
Produktionen af TCPP foregår på tre fabrikker i Tyskland og en i Storbritannien. I 2000 var den samlede EU-produktion af TCPP på 36.000 tons. Mellem 1998 og 2003 er produktionen steget markant. Den øgede anvendelse af TCPP i Europa sættes i forbindelse med mindre anvendelse af

tris (2-chlorethyl)phosphat (TCEP) – som følge af de sundhedsmæssige betænkeligheder omkring anvendelsen af TCEP. Ifølge EU's risikovurdering af TCPP i 2008, anså man på dette tidspunkt ingen yderligere stigning i tonnagen af TCPP. Die angivne mængder er i overensstemmelse med de nuværende REACH registreringer, der viser et årligt tonnageniveau i intervallet 10.000-100.000 tons af stoffet.

I 2001 var importen til EU 8.304 tons, og eksporten var 6.211 tons.
Yderligere 1.201 tons TCPP formodes at blive importeret til EU i færdigvarer, dvs. i møbler, i én-komponent PUR-skum og i genanvendt presset skum.

TCPP, der til anvendes i Danmark, importeres, da produktion af TCPP ikke finder sted i Danmark.

Ifølge registreringer i det danske Produktregister (som kun registrerer kemiske blandinger/produkter, der anses for at være farlige) har det årlige forbrug af TCPP siden 2006 været ret stabilt på omkring 200 tons om året. Den samlede anvendelse af TCPP i kemiske produkter i Danmark er faldet fra 700 tons i 2001 til 200 tons i 2011. Men disse tal dækker udelukkende kemiske produkter og ikke indholdet af TCPP i PUR-skum i artikler.

Anvendelser
Der blev anvendt over 40.000 tons TCPP i EU i 2000, og det meste (> 98 %) blev anvendt som flammehæmmer i produktionen af polyurethan (PUR) til brug i byggeriet (fx som hårdt skum i isolering eller fyldstoffer) og i møbler som fleksibelt skum.

I EU anvendes TCPP mest i hårdt PUR-skum (over 80 %), hovedsageligt til byggeopgaver. Resten af anvendelsen i PUR udgøres af fleksibelt skum (over 17 %), der anvendes til polstring og i sengetøj bl.a. til det britiske og irske marked. I autobranchen anvendes TCPP praktisk taget ikke i blødt PUR-skum på grund af dets flygtighed og dugpotentiale.

TCPP anvendes ifølge branchens oplysninger kun ret sjældent i Danmark i fleksibelt skum. Anvendelsen af TCPP i Danmark må således formodes primært at være knyttet til brug i hårdt skum inden for byggebranchen. Dette understøttes af data fra det danske Produktregister, der viser, at TCPP-anvendelse i 2011 primært var i forbindelse med isoleringsmaterialer (109 tons) og fyldstoffer (32,8 tons).

I PUR-skum ligger de typiske niveauer af TCPP og andre chlorerede alkylphosphater i intervallet 5-15 %. Dette er blevet bekræftet af den danske Plastindustri, der rapporterer et typisk indhold af TCPP på 5-10 %, hvor TCPP i fleksibelt PUR mest benyttes i kombination med melamin, hvilket holder koncentrationen af TCPP nede på et lavere niveau.

Affald
Generelt skal PUR-affald indeholdende TCPP ikke betragtes som farligt affald, da TCPP-indholdet typisk er i størrelsesordenen 5-10 %, hvilket er under det koncentrationsniveau der medfører klassificering i blandinger for de fareklasser, der i øjeblikket anvendes for TCPP.

I Danmark anvendes TCPP sjældent i fleksibelt PUR-skum, og det må antages, at den største mængde fleksibelt PUR -affald ikke indeholder TCPP. Så, når TCPP forekommer i affaldsstrømmen, vil dette typisk være forbundet med anvendelsen af TCPP i hårdt PUR-skum fx i byggematerialer (typisk i isolering og i fyldstoffer).

I Danmark genanvendes industrielt PUR-affald, og i 2005 anslås det, at op til ca. 60 % af PUR-affaldet blev genanvendt. Den del af industrielt PUR-affald, der ikke genanvendes, samt husholdningsaffald indeholdende PUR (madrasser, møbler, køleskabe, byggematerialer osv.) sendes typisk til forbrænding på grund af det høje energiindhold i PUR-skum. Dette drejer sig om mindst 7.730 t PUR-affald pr år (baseret på tal fra 2005). TCPP vil i den forbindelse blive termisk nedbrudt.

Samlet set er der lille risiko for frigivelse og eksponering for TCPP i forbindelse med TCPP i affaldsstrømmen af PUR-produkter. Det anses heller ikke for at have nogen væsentlig betydning for affaldsbehandling, hvorvidt PUR-skum med TCPP betragtes som farligt affald (fx på grund af en evt. lavere klassificeringsgrænse for TCPP), da PUR-skum i affaldsstrømmen forbrændes på grund af skummets høje energiindhold.

Miljø
Der foreligger en række økotoksikologiske data for TCPP, bl.a. vedrørende akut toksicitet i fisk samt akutte og kroniske tests med akvatiske hvirveldyr og alger). Endvidere er der toksicitetstests med jordlevende organismer og mikroorganismer. Ud fra dette vurderes en klassificering som Aquatic Chronic 3, H412 for relevant, da de laveste $L(E)C_{50}$-værdier rapporteret for fisk og alger er henholdsvis 51 mg/L og 82 mg/L (kriterieværdier> 10 til ≤ 100 mg/L). Endvidere er TCPP ikke let biologisk nedbrydeligt.
I 2010 blev der i Danmark målt et gennemsnitligt niveau på 1,4 µ TCPP/L i udledninger fra rensningsanlæg, og anslået blev en samlet mængde på omkring 700 kg TCPP udledt i de danske farvande.

Med hensyn til PBT-vurdering kan TCPP anses for at opfylde kriteriet som persistent (P) eller potentielt meget persistent (vP). De tilgængelige oplysninger om bioakkumulering (målt BCF (fisk) på 0,8-4,6) viser, at TCPP ikke opfylder kriteriet for bioakkumulering (B). Kriteriet for toksicitet (T) er heller ikke opfyldt. TCPP kan således ikke betragtes som et PBT stof.

Måledata på TCPP i miljøet og beregnede koncentrationer i miljøet peger ikke på nogen risiko for skadelige effekter i vand, jord, sediment eller i rensningsanlæg.

Sundhedsskadelige virkninger
EU's risikovurderingsrapport fra 2008 indeholder en fyldig og opdateret gennemgang af de tilgængelige toksikologiske data, samtidig med at rapporten også anfører beregninger mht. eksponeringsniveauer for befolkningen herunder forbrugere og arbejdere.
TCPP absorberes hurtigt og i stor udstrækning (ca. 80 % af dosis) efter oral indtagelse og fordeles i stor udstrækning til kroppens organer. TCPP metaboliseres i stor udstrækning i organismen og nedbrydningsprodukterne udskilles via urin og fæces.

Den akutte giftighed er lav, da de fleste orale LD_{50} værdier ligger under 2000 mg/kg legemsvægt i overensstemmelse med en klassificering som Acute Tox. 4, H302.

Der er i tests kun set lettere grader af hud- og øjenirritation, mens der ikke findes data om irritation af luftvejene. På baggrund af tests anses TCPP ikke for at være allergifremkaldende ved hudkontakt.

Ud fra et oralt 28-dages forsøg i rotter blev der fastlagt en NOAEL-værdi på 100 mg/kg legemsvægt/dag (mht. levereffekter), og i et oralt 90-dages forsøg med rotter blev der fundet en LOAEL-værdi på 52 mg/kg legemsvægt/dag, mht effekter på lever og skjoldbruskkirtel.

TCPP er ikke fundet genotoksisk/ mutagent hverken i *in vitro* eller i *in vivo* dyreforsøg. Derimod har QSAR model-analyser forudsagt at stoffet kunne være mutagent, men under hensyntagen til de dyreeksperimentelle data og til konklusionen i EU's risikovurderingsrapport, synes der ikke at være noget grundlag for, at vurdere stoffet som genotoksisk..

Der er ingen tilgængelige cancerundersøgelser for TCPP. Men i EU´s risikovurderingsrapport og i EU´s Videnskabelige Komité for Sundheds- og Miljørisici anser man det for muligt at lave analogi slutninger i forhold til cancerdata for stofferne TCEP og TDCP. På den baggrund bør TCPP klassificeres som Carc. 2, H451, da dette er den EU-harmoniserede klassificering for de to analogistoffer TCDP og TCEP.

Med hensyn til effekter på foster og forplantningsevne er der blevet udledt en LOAEL-værdi på 99 mg/kg legemsvægt fra et 2-generations reproduktions toksicitetstudie i rotter, baseret på virkninger på uterusvægt set i alle doserede hunner i F0-generationen. En LOAEL-værdi på 99 mg/kg legemsvægt er afledt for udviklingstoksicitet hos afkommet baseret på det forøgede antal af dværgvækst, observeret i alle dosisgrupper i F0-generationen.

Toksiske effekter i moderdyrene kan spille en rolle for disse resultater, men en mulig klassificering af TCPP ville være en klassificering som Repr 2; H361.

TCPP's hormonforstyrrende potentiale er endvidere blev undersøgt i et in vitro studie med en H295R cellelinie, hvor testosteron-koncentrationen blev forøget ved TCPP koncentrationer på 1, 10 og 100 mg/L. Desuden peger data fra 2-generations reproduktionsstudiet på hormonelle forstyrrelser af TCPP på grund af fund af uterusvægt og forlængelse af østrogencyclus. Disse resultater indikerer, at TCPP kan ændre kønshormon-balancen, hvilket kan understøtte en klassificering som angivet ovenfor. Dog er det endnu ikke fastslået, om et øget testosteron-niveau også vil forekomme i *in vivo* forsøg, og om dette kan være forbundet med nedgangen i uterusvægt. Således vil yderligere bevis/undersøgelser være nødvendige for at klarlægge potentialet for hormonforstyrrende virkninger af stoffet.

Analogislutning til TCEP i forhold til reproduktionstoksicitet (som for de kræftfremkaldende virkninger) må anses for mindre pålidelig, da der ikke er fundet nogen virkning på uterus for TCEP, samtidig med at TCEP også i høj grad påvirker det mandlige reproduktionssystem, hvilket ikke er fundet for TCPP.

Human eksponering og risiko
I forhold til anvendelsen af TCPP i artikler og kemiske produkter forventes der kun ganske ringe eksponering af forbrugerne. Generelt er der fundet en meget stor eksponeringsmargin i forhold til effekt niveauer i forsøgsdyr, og på baggrund heraf vurderes den nuværende anvendelse af TCPP for at være sikker for forbrugerne.

Konklusion vedr. sundhedsskadelige effekter
Alt i alt synes en klassificering af TCPP med Carc.2, H451 berettiget i forbindelse med sundhed. Derudover kan en klassificering med Repr.2, H361 være relevant.

De nuværende anvendelser af TCPP anses ikke for at udgøre nogen risiko for forbrugerne – på grund af det meget lave eksponeringspotentiale.

Alternativer til TCPP

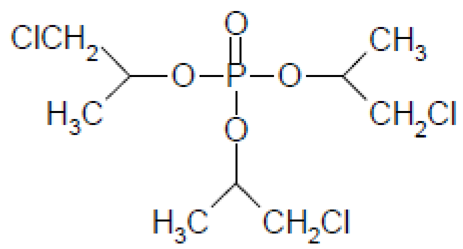
TCPP anvendes som alternativ til det meget nært beslægtede stof TCEP, som i stor udstrækning er blevet anvendt som flammehæmmer. Men anvendelsen af TCEP er ophørt på grund af stoffets klassificering som Repr. 1B.

Der er ikke fundet data for, i hvilket omfang substitution til nogle ikke-halogenerede alternative flammehæmmere er teknisk gennemførlig. Det kan skyldes, at der ikke har været noget incitament eller anden tilskyndelse til at finde erstatninger for TCPP, da denne flammehæmmer i sig selv blev betragtet som den ideelle erstatning for TCEP.

1. Introduction to the substance

1.1 Definition of the substance

TABLE 1-1
NAME AND OTHER IDENTIFIERS OF TCPP (EU RAR, 2008)

	Tris(2-chloro-1-methylethyl)phosphate
EC number	237-158-7
CAS number	13674-84-5
Synonyms	2-Propanol, 1-chloro, phosphate (3:1) Tris(monochloroisopropyl) phosphate (TMCP) Tris(2-chloroisopropyl) phosphate (TCIP) Phosphoric acid, tris(2-chloro-1-methylethyl) ester Tris(beta-chloroisopropyl) phosphate 1-Chloro-2-propanol phosphate (3:1) TCPP: this common acronym is used throughout this report
Molecular formula	C9H18Cl3O4P
Molecular weight range	327.27
Structure	

1.1.1 Isomers

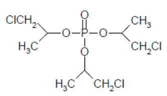
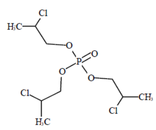
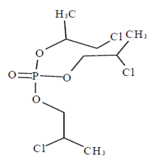
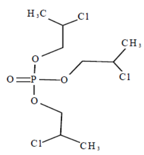
The flame retardant product supplied in the EU, marketed as TCPP (or other synonyms as given above), is actually a reaction mixture containing four isomers. The individual isomers in this reaction mixture are not separated or marketed because they are not produced individually. Consequently, all data apply for TCPP as produced by all EU manufacturers.
TCPP as shown in table1-1is the tris(1-chloro-2-propyl) form. The CAS number 13674-84-5 is used for this structure and also for the mixture of isomers as commercially produced. The 1-chloro-2-

propyl- can be replaced up to three times by 2-chloro-1-propyl (i.e. an n- hydrocarbon chain). Therefore three isomers of the main component are possible, although tris (2-chloro-1-propyl)phosphate is only present in trace levels.

The assumption is made in the European risk assessment (REF) that all isomers have identical properties in respect of risk assessment. The assumption is justified in part by the fact that they exhibit very similar chromatographic properties, even under conditions optimised to separate them and the predicted physicochemical properties differ to only a small extent. Modelling procedures required for predicted environmental concentration (PEC) values for the separate isomers would not be affected by the small differences that are expected to apply. Testing has been carried out using the commercial product, i.e. a mixture of isomers, in a composite sample. In relation to human health the toxicity studies may have been conducted using various qualities of TCPP. However, no data indicate to which extent the distribution of the various isomers affect the toxicity of the substance.

There are differences in the isomer content from each supplier, but these are not important given that the properties of the isomers are expected to be very similar.

TABLE 1-2
COMPOSITIONAL DESCRIPTION FOR TCPP ACROSS ALL COMMERCIAL PRODUCTS

Name	Structure diagram	EINECS No.	CAS No	% (w/w)
Tris(2-cloro-1-methylethyl)phosphate		237-158-7	13674-84-5	50 - 85
Bis(1-chloro-2-propyl)-2-chloropropyl phosphate		-	76025-08-6	15 - 40
Bis(2-chloropropyl)-1-chloro-2-propyl phosphate		-	76649-15-5	< 15
Tris(2-chloropropyl)phosphate		228-150-4	6145-73-9	< 1

1.1.1.1 Purity and impurities

A typical purity (total of the four isomers) is >97.9%. All testing described in this report is for the commercial product.

The impurity profile of the commercial product TCPP is specific to individual manufacturers.

1.2 Physical and chemical properties

TABLE 1-3
PHYSICAL-CHEMICAL PROPERTIES FOR TCPP (EU RAR, 2008)

Property	
Physical state	Liquid
Melting point	<-20 °C
Freezing point	-
Boiling point	Ca. 288 °C (decomp.)
Relative density	1.288 at 20 °C
Vapour pressure	1.4 x 10-3 Pa at 25 °C
Surface tension	No study available, but is not expected to exhibit surface activity
Water solubility (mg/L)	1080 mg/L at 20 °C
Log P (octanol/water)	2.68±0.36
Henry's Law Constant	3.96 x 10-4 Pa m3/mol at 25 °C

1.3 Summary

TCPP is a chloroalkyl phosphate containing mainly four isomers:

tris(2-chloro-1-methylethyl)phosphate	(approx. 50-85%);
bis(1-chloro-2-propyl)-2-chloropropyl phosphate	(approx. 15-40%);
bis(2-chloropropyl)-1-chloro-2-propyl phosphate	(less than 15%)
tris(2-chloropropyl)phosphate	(less than 1%)

TCPP is a liquid with very low vapour pressure (approx. 0.001 Pa) and a boiling point at approx. 288 °C at which temperature the substance starts to decompose. The water solubility is at about 1000 mg/L and the log Pow is 2.68.

2. Regulatory framework

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

For readers not used to dealing with legislative issues, Appendix 1 provides a brief overview of and connections between legislatives instruments in EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, explanation for lists referred to in chapter 3, as well as a brief introduction to international agreements and the aforementioned eco-label schemes.

2.1 Existing legislation

No EU or Danish regulations specifically address the use as TCPP. Also no specific requirements concerning administrative limit values for the content of TCPP have been found.

Directive 88/319/EEC of 18 June 2009 on the safety of toys specifies that toys must not contain dangerous substances or preparations within the meaning of Directive 67/548/EEC and 88/379/EEC in amounts which may harm the health of children using them. However, TCPP is not specifically covered by this legislation beyond this general aspect.

European standard EN 71-9 (Safety of Toys – part 9: Organic Chemical Compounds) states that certain specified flame retardants, including TCEP[1], which are used in textiles of toys and accessible components of toys intended for children under 3 years of age, should not be found above the limit of quantification of the test method and therefore should not be detected in toys.

2.1.1 Classification and labelling

2.1.1.1 Harmonised classification in the EU

No harmonized classification and labelling is appointed to TCPP according to Annex VI of the CLP Regulation.

2.1.1.2 Notified classification in the EU

According to the current CLP regulation companies putting chemical substances or chemical mixtures on the market in EU are obliged to notify the classification they apply for the substances to the European Chemicals Agency, ECHA.
The classifications used (and notified) by the companies can be searched at the ECHA website in the CLP inventory database. The following classifications used for TCPP are given in table 2-1 below.

[1] TCEP has a chemical structure very close to TCPP. TCEP is classified as Repr. 1B and is subject to the authorisation procedure under REACH.

TABLE 2-1
NOTIFIED CLASSIFICATIONS FOR TCPP (FROM ECHA C&L DATABASE, JUNE 11, 2013)

Chemical identification (CAS No)	Classification		No. of notifiers
	Hazard Class and Category Code(s)	Hazard statement Code(s)	
TCPP (13674-84-5)	Acute Tox. 4	H302	504 notifiers
	Acute Tox. 4 Eye Irrit. 2	H302 H319	55 notifiers
	Acute Tox. 4 Aquatic Chronic 3	H302 H412	31 notifiers
	No classification		5 notifiers
	Skin Irrit. 2 Eye Irrit. 2 Aquatic Chronic 3	H315 H319 H412	1 notifier

H302: Harmful if swallowed H315: Causes skin irritation H319: Causes serious eye irritation
H412: Harmful to aquatic life with long lasting effects

In the classification and labelling inventory of ECHA a total of 596 notifiers have notified their used classification for TCPP. 590 notifiers use a classification with Acute Tox. 4; H302, whereas 32 notifiers use Aquatic Chronic 3; H412 for environmental classification.

The Danish-EPA self-classification list recommends the following classification based on QSAR predictions: Muta2; Repr2; AcuteTox4; Skin Irr2. The inclusion of TCPP on the Danish LOUS list is based on this indication on Muta2 and Repr 2 classification.

As seen no notifiers use classifications for mutagenicity or reproductive toxicity. Further discussion on classification is given in section 6.1 where the toxicological data is described and evaluated.

2.2 REACH

2.2.1 Registration

TCPP has been registered under REACH at a tonnage band of 10,000-100,000 tonnes.

2.2.2 EU risk assessment and Annex XV transitional report

In 2008 an EU-risk assessment report was finalised under the EU ESR programme (EU-RAR 2008). The report concluded that the use of TCPP did not possess any risk for consumers and the general public, whereas risk was identified for specific occupational scenarios. After this ECHA has published an Annex XV transitional report on TCPP in which it is concluded that any restrictions for the use of TCPP would be disproportionate and that potential risks in the working environment could be handled by the current EU legislation for worker´s protection (ECHA, 2008).

2.2.3 Other legislation/initiatives

No activities for TCPP have been identified in relation to SVHC-identification, authorization or restriction under REACH.

2.3 International agreements

There has not been found any international initiatives on authority level specifically addressing the use of TCPP.

However, the two European consumer organizations ANEC and BEUC has in a statement in 2012 proposed a ban to TCPP and TDCP in toys as they consider these substances similar to TCEP (ANEC/BEUC, 2012).

2.4 Eco-labels

The general approach taken in most eco-label criteria adopted to date is to exclude eco-labelling when the products contain chemicals which have certain specific properties (classification and risk phrases). However, as there is no harmonised classification of TCPP and as the current notified classifications use less strict classifications for TCPP it is difficult to conclude on how these different classifications from the notifiers will affect the awarding of ecolabelling.

Thus another approach (compared to the classification approach) will be used to evaluate whether the criteria for some of the most PUR relevant (and TCPP relevant) product categories results in any limitations for the use of TCPP. Below eco-labelling criteria for the use of flame retardants have been validated for product categories where PUR foam may be used i.e. mattresses, furniture, refrigerators/ freezers, carpets, textiles, chemical building products, and toys.

EU-flower, mattresses:
In the criteria for mattresses it is indicted that only flame retardants chemically bound to the mattress are allowed (EU-Commission Decision, 2009a). This implies that the use of TCPP is *not allowed* for eco-labelled mattresses as TCPP is not a flame retardant that is chemically bound

EU-flower, carpets:
In the criteria for carpets it is indicted that only flame retardants chemically bound to the carpet are allowed (EU-Commission Decision, 2009b). This implies that the use of TCPP is *not allowed* for eco-labelled carpets as TCPP is not a flame retardant that is chemically bound.

Nordic Swan, textiles:
In the criteria for *textiles* and in relations to paddings/fillings in the textile, it is indicated that no halogenated organic compounds may be added. This implies that the use of TCPP is *not allowed* for eco-labelled textiles where TCPP is added to the padding/fillings (Nordic Swan, 2013a).

Nordic Swan, furniture:
In the criteria for *furniture* it is indicated that no flame retardants may be added to any material of the furniture. This implies that the use of TCPP is *not allowed* for eco-labelled furniture (Nordic Swan, 2012a).

Nordic Swan, toys:
In the criteria for it is indicated that no halogenated flame retardants may be added to any textile, skins or leather part of the toys. However, none of the criteria limits the use of TCPP in padding material of the toy. Thus the use of TCPP in PUR foam as padding material in toy is not addressed (Nordic Swan, 2013b).

Nordic Swan, building products:
In the criteria for building products e.g. filler it is indicated that sealants must not contain halogenated organic compounds, i.e. TCPP *is not allowed* to be used in these products (Nordic Swan, 2012b).

Nordic Swan, refrigerators/freezers:
No criteria that would limit the use of TCPP in PUR insolation foam (Nordic Swan, 2013c).

2.5 Other lists

TCPP is not included as a substance in the SIN-list database developed by the Chemical Secretary (ChemSec.), Sweden (data search June 11, 2013). The SIN-list includes substances which are identified by ChemSec as fulfilling the criteria for Substances of Very High Concern as defined in the REACH regulation.

TCPP is also not included on the PRIO-list developed by KEMI (the Swedish Chemical Agency) which is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals.

The Danish EPA´s guidance on self-classification (Danish EPA, 2013) has the following human health classification for TCPP: Muta 2; Repr 2; AcuteTox 4 and SkinIrr 2. The classifications on the self-classificatrion list are derived from QSAR predictions (Danish EPA, 2010). The reason for TCPP is on the Danish LOUS list pertains to this self-classification as Muta 2 and Repr2.

TCPP is not included on the EU list of 146 substances with endocrine disruption classifications (EU, 2000).

Recently, two European consumer organizations ANEC and BEUC has in a statement in 2012 proposed a ban to TCPP (and TDCP) in toys as they consider these substances similar to TCEP which is a substance under authorization in REACH based on its harmonized EU classification as toxic to reproduction 1B, H360F (may damage fertility) (ANEC/BEUC, 2012).

2.6 Summary and conclusions

No specific regulations apply for TCPP neither on international, EU or national level.
Also, there is no EU harmonized classification for the substance. However, according to the self-classifications notified by the suppliers in EU the following classifications are uses either alone or in combination:
Acute tox. 4 Skin Irrit. 2; Eye Irrit. 2; and Aquatic Chronic 3.

Here the most often used toxicological and environmental classification by the notifiers is Acute tox 4 and Aquatic Chronic 3, respectively. A few notifiers do not classify the substance at all.
(As discussed later there seems to be toxicological data for a classification as Carc 2 and Repr 2.)
The Danish EPA has put TCPP on the LOUS list based on their QSAR self-classification as Muta 2 and Repr 2. As seen from the notified classifications no suppliers in Europe apply these classifications.

Recently, two European consumer organizations ANEC and BEUC has in a statement in 2012 proposed a ban to TCPP (and TDCP) in toys as they consider these substances similar to TCEP which is a substance under authorization in REACH based on its harmonized EU the classification as toxic to reproduction 1B, H360F (may damage fertility).

Several product types awarded with eco-labelling restrict the use of TCPP (together with other flame retardant) in e.g. mattresses, furniture, carpets, textiles, refrigerators, and building products, and in textiles in toys but not in filling materials in toys.

3. Manufacturing and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

All commercial TCPP is produced by the reaction of phosphorus oxychloride with propylene oxide followed by purification. Both batch and continuous processes can be used in the manufacture of TCPP. The reaction is carried out in a closed reactor. The crude product is washed and dehydrated in a closed vessel to remove acidic impurities and residual catalyst. All transfers are done using closed lines. The product is then filtered, transferred, and packaged using sealed pumps through closed lines. Storage is in closed vessels under nitrogen to exclude moisture and oxygen (EU RAR, 2008).

3.1.2 Manufacturing sites

There are four producers of TCPP in the EU:

- Supresta, whose TCPP business earlier was owned by Akzo Nobel
- Lanxess, whose TCPP business earlier was owned by Bayer
- BASF, which sells through Elastogran
- Albemarle, whose TCPP business earlier was owned by Rhodia, and previously Albright and Wilson.

The production sites were three places in Germany and one site in UK (EU RAR, 2008).

3.1.3 Manufacturing volumes

Total EU production of TCPP in the year 2000 was 36,000 tonnes. Between 1998 and 2003, production has increased significantly but the total EU sales tonnage has remained reasonably stable within approximately 10%. The EU consumption used in the risk assessment represents the upper limit of sales in the five year period for which data are available (EU RAR, 2008).
An increased use of TCPP in Europe has been linked to a decreased use of tris(2-chloroethyl)phosphate (TCEP)- due to human health concerns for TCEP (SCHER Opinion, 2012).

Annual U.S. production/import volume was 10-50 million pounds for the reporting years 1990, 1994, 1998 and 2002.

3.2 Import and export

3.2.1 Import and export of TCPP in EU

8,304 tonnes of TCPP were imported into the EU in 2001. Data provided by CEFIC indicate that most of this was imported by companies other than the four main producers and sourced in Russia. Consultation with members of the Industry Consortium originally indicated Russia to be the only source of non-Consortium imports, though it has since been indicated that the main non-consortium TCPP imports have altered from Russia to Poland. A total of 6,211 tonnes of TCPP was exported from the EU in the year 2000. It is assumed that no handling (e.g. repackaging) takes place and that no losses of TCPP arise through import or export (EU RAR, 2008).

A further quantity of 1,201 tonnes of TCPP is believed to be imported into the EU in finished goods (EU RAR, 2008):

- Up to 680 tonnes per annum is imported into the UK in furniture sourced from outside the EU

- Around 500 tonnes of TCPP is imported in canned (one component) foams
- It is possible that finished goods containing TCPP in rebonded foam may be imported into the EU

(The remaining 21 tonnes may be from various sources).

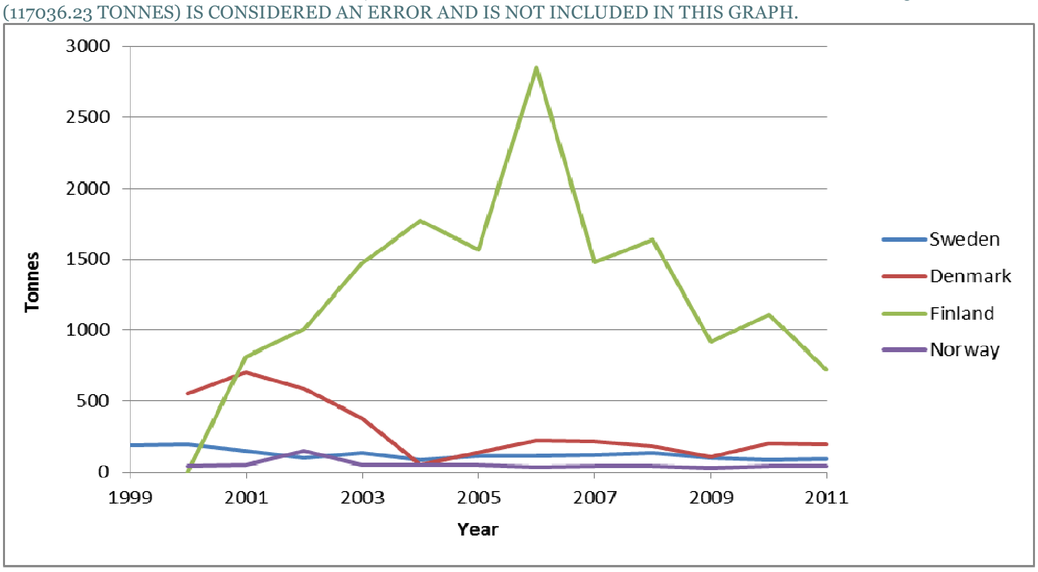
3.2.2 Import and export of TCPP in Denmark and the Nordic countries

As no production of TCPP takes place in Denmark and the Nordic countries the volumes that have been registered in the Nordic SPIN database have to be imported. Besides this import a further import of TCPP of unknown magnitude may be anticipated in imported articles e.g. TCPP as flame retardant in PUR-foam for construction or in furniture and mattresses containing PUR.

From the Nordic SPIN database ("Substances in Preparations in the Nordic Countries") information of use volumes and information on the distribution of substances in preparation in the Nordic countries has been retrieved. The SPIN database is the result of a common Nordic initiative to gather non-confidential, summarized information from the Nordic product registers on the common use of chemical substances in different types of products and industrial areas.

In figure 1 the total amount of TCPP (CAS no. 13674-84-5) registered from 1999 to 2011 in the Nordic countries is shown. The volume levels are maintained steady from 1999 to 2010 in a level ranging from 553 tonnes in 2000 to 194 tonnes in 2011 in Denmark. (The data from Denmark in 2005 shows an extremely high amount (117036.23 tonnes) compared to other years which is believed to be due to an error in the registration this year and the 2005 figure is therefore not taken into account in the figure below). Comparable levels are seen in Sweden and Norway, while significant higher volumes are seen in Finland ranging from 1000 tonnes in 2002, peaking at 1642 tonnes in 2008 and declining to 720 tonnes in 2011.

FIGURE 3-1
THE TOTAL AMOUNT OF TCPP (CAS NO. 13674-84-5) REGISTERED IN THE NORDIC SPIN DATABASE (DATA RETRIEVED FROM THE SPIN DATABASE). THE REPORTED AMOUNT IN DENMARK IN THE YEAR 2005 (117036.23 TONNES) IS CONSIDERED AN ERROR AND IS NOT INCLUDED IN THIS GRAPH.



3.3 Use

TCPP is an additive flame retardant, i.e. it is physically combined with the material being treated rather than chemically combined (ECHA, 2008).

Over 40,000 tonnes of TCPP were used in the EU in the year 2000, and most of this (> 98%) was used as flame retardant in the production of polyurethane (PUR) for the use in construction (e.g. insolation/ fillers) and furniture (ECHA, 2008).

Most TCPP is used in rigid PUR foam (over 80%) mainly for construction applications (see table 3-1). The remaining PUR applications are accounted for by flexible foam (over 17%), used in upholstery and bedding for the UK and Irish markets. TCPP tends not to be used in flexible PUR for automotive applications owing to its volatility and fogging potential (However, TCPP has been found in indoor air in cars, see section 6.2.2.1). Use of TCPP in products other than PUR tends to be associated with single users who have tried the product of their own accord and have decided to use it (ECHA, 2008). The low tonnage associated with these other uses across all producers confirms that TCPP is not widely used outside the PUR industry.

TABLE 3-1
USE PATTERN OF TCPP. DATA ARE BASED ON USE VOLUMES FROM 2000 (ECHA, 2008)

Description	Percentage of total use	Tonnage
PUR systems (formulation)	51.1%*	20,450
PUR foam for use in furniture	17.0%	6,800
Rigid PUR foam for use in construction	66.5%	26,650
Spray foams	9.6%	3,850
One component foams	4.7%	1,900
Confidential (use category 22: flame retardants and fire preventing agents or use category 47: softeners)	< 2.5%	-

* Since systems go on to be used in certain other life cycle stages, the tonnage is not included in the summation

There is only very spares information regarding the TCPP content in the products and articles. The European Flame Retardant Association and CEFIC indicate, in a fact sheet regarding the halogenated phosphate esters including TCPP, that a typical addition level of these flame retardants to PUR is in the range of 5-15% (EFRA/CEFIC, 20--). This has been confirmed by the Danish Plastics Federation that reports a typically content of TCPP of 5-10%. TCPP is used in flexible PUR mostly in combination with melamine witch keeps the concentration at TCPP down at a lower level (Danish Plastics Federation, 2013).

The Nordic countries

From the Nordic SPIN database information on the numbers of preparations have been retrieved (Figure 3- 2). Figure 3-3 show the volumes used in Denmark in the various product categories. The 2005 values for insulating materials and fillers are not included in the figure as they are believed to be based on error values reported for 2005 as mentioned previously.

FIGURE 3-2
THE TOTAL NUMBER OF PREPARATIONS CONTAINING TCPP (CAS. NO. 13674-84-5) IN THE NORDIC COUNTRIES FROM 1999 TO 2010 (DATA RETRIEVED FROM THE SPIN DATABASE)

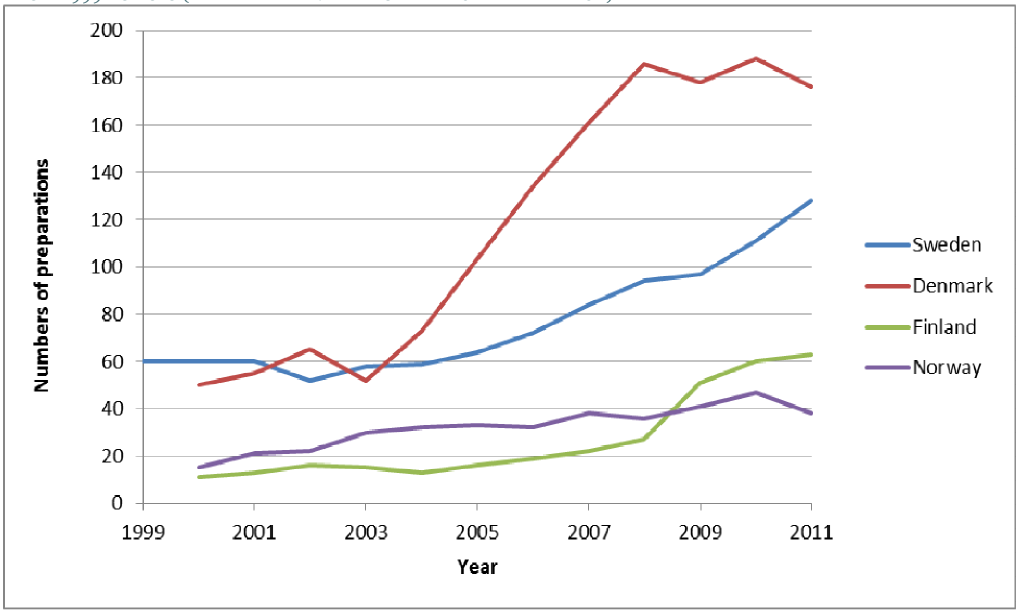
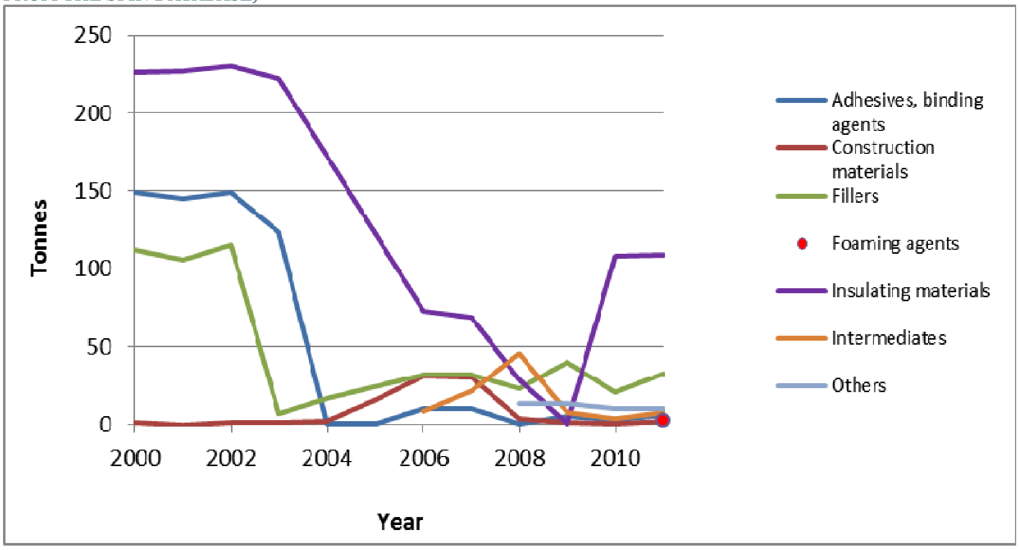


FIGURE 3-3
TOTAL TONNES OF TCPP INCLUDED IN PREPARATIONS ON THE DANISH MARKET FROM 2000 TO 2010. 2005 DATA FOR INSULATING MATERIALS AND FILLERS ARE NOT INCLUDED (DATA RETRIEVED FROM THE SPIN DATABASE)



In 2011 the most prominent uses in Denmark were:

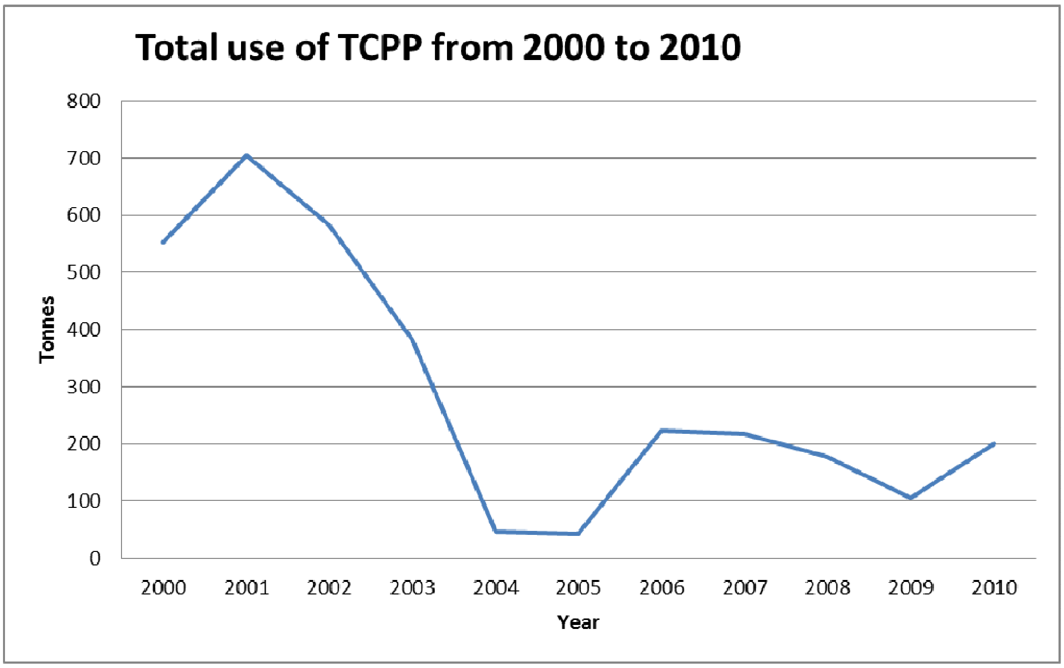
- Insulation materials	109 tonnes (34 preparations)
- Fillers	32.8 tonnes (24 preparations)
- Others	10.0 tonnes (7 preparations)
- Intermediates	7.8 tonnes (72 preparations)
- Adhesives, binding materials	6.4 tonnes (12 preparations)
- Foaming agents	2.4 tonnes (4 preparations)
- Construction materials	2.1 tonnes (13 preparations)

In Denmark nearly all PUR foam for furniture, mattresses, and refrigerators is without flame retardants, however, TCPP in flexible foam may be used for mattresses and furniture to be delivered to institutions such as e.g. prisons and hospitals (Danish Plastics Federation, 2013).

3.4 Historical trends in use

According to the EU RAR (2008) there is no reason to anticipate significant tonnage increases in the near future, based on industry information and general research. Likewise data from the SPIN database from 2000 until 2010 also do not indicate an increase in tonnage in Denmark (figure 3-4).

FIGURE 3-4
TOTAL USE PATTERN OF TCPP IN DENMARK FROM 2000 TO 2010. THE 2005 VALUES FOR INSULATING MATERIALS AND FILLERS ARE NOT INCLUDED IN THE FIGURE AS THEY ARE BELIEVED TO BE BASED ON ERROR VALUES REPORTED FOR 2005 (DATA RETRIEVED FROM THE SPIN DATABASE, 2013) (A MORE DETAILED USE PATTERN OF TCPP IS SHOWN IN APPENDIX 1)



It can be seen from this figure that the annual consumption of TCPP since 2006 has been rather stable at about 200 tonnes per year. In the years 2000-2003 the average annual consumption was at about 500 tonnes, so a decline of TCPP can be noted.

3.5 Summary and conclusions

TCPP volumes and trends in EU and DK

The total EU production of TCPP in the year 2000 was 36,000 tonnes. Between 1998 and 2003, production has increased significantly. This increased use of TCPP in Europe has been linked to a decreased use of tris(2-chloroethyl)phosphate (TCEP)- due to human health concerns for TCEP. According to the EU RAR (2008) there was in 2008 no reason to anticipate significant tonnage increases in the near future, based on industry information and general research

The production of TCPP takes place at three plants in Germany and one in UK. In 2001 the import into EU was 8,304 tonnes and the export was 6,211 tonnes. These volumes complies with current REACH registrations which indicate a yearly tonnage level in the range of 10,000-100,000 tonnes of the substance.
A further quantity of 1,201 tonnes of TCPP is believed to be imported into the EU in finished goods i.e. in furniture, in one component PUR foams, and in rebounded foam.

All use of TCPP in Denmark has to be imported as no production of TCPP takes place in Denmark.

According to the registration in the Danish Product Registry (which only registers the chemical content in dangerous chemical mixtures) the annual consumption of TCPP has since 2006 been rather stable at about 200 tonnes per year. In the years 2000-2003 the average annual consumption was at about 500 tonnes, so a decline of TCPP can be noted. Thus, these figures do not cover the content of TCPP in PUR foam in articles.

Uses

Over 40,000 tonnes of TCPP were used in the EU in the year 2000, and most of this (> 98%) was used as flame retardant in the production of polyurethane (PUR) for the use in construction e.g. insolation/ fillers as rigid foam) and furniture as flexible foam.

Most TCPP is used in rigid PUR foam (over 80%) mainly for construction applications. The remaining PUR applications are accounted for by flexible foam (over 17%), used in upholstery and bedding for the UK and Irish markets. TCPP tends not to be used in flexible PUR for automotive applications owing to its volatility and fogging potential. TCPP is according to industry information in Denmark only rather seldom used in flexible foam indicating the most uses of TCPP in Denmark are in relation to rigid foam.

In the PUR foam the typical levels of TCPP and other chloroalkyl phosphates are in the range of 5-15%. This has been confirmed by the Danish Plastics Federation that reports a typically content of TCPP of 5-10% as TCPP in flexible PUR is mostly used in combination with melamine which keeps the concentration at TCPP down at a lower level.

In Denmark nearly all PUR foam for furniture, mattresses, and refrigerators is without flame retardants, however, TCPP in flexible foam may be used for mattresses and furniture for the UK market or for institutions such as e.g. prisons and hospitals. These data may indicate that TCPP used in PUR foam in Denmark is primarily used in rigid foam e.g. in construction.
The use in rigid foam is supported by data from the Danish Product Registry that indicate that the TCPP use in 2011 primarily was in connection with insulation materials (109 tonnes) and fillers (32.8 tonnes).

In Denmark the use of TCPP in chemical products has declined from 700 tonnes in 2001 to 200 tonnes in 2011.

4. Waste management

4.1 Waste from manufacture and use of TCPP

As indicated in chapter 3 the main use of TCPP is as added flame retardant to rigid and soft PUR foam. Thus in the waste stream TCPP may occur in articles where PUR foam is used i.e. construction insulation material, fillers, furniture, mattresses, interior/panels from cars boats, insulation in refrigerators and freezers etc.

Danish EPA (2005) estimated a yearly amount of industrial PUR waste of 5100 tonnes of flexible PUR and 1150 tonnes of rigid PUR from the production sites of PUR. As 60% is recovered the remaining fraction of 40% i.e. 2500 tonnes may be considered the actual waste fraction.
From end of life products the waste amounts given in table 4-1 were given:

TABLE 4-1
VOLUMES OF SELECTED PUR WASTE STREAMS

PUR-waste from end life of products		
	Year	t/year
Automotive	2004	3500
Pre-insulated pipes	2004	950
Domestic appliances	2003	782

Thus, an annual PUR waste fraction of at least 7730 tonnes may be anticipated from these figures.

There is no information to which extent the PUR in the waste stream in Denmark actually contains TCPP (or other chlorinated phosphate esters). However, data from section 3 indicate that TCPP is mainly to be found in rigid foam for construction e.g. in insolation and fillers and to a lesser extent in flexible foam e.g. furniture and matrasses.

If present in the PUR, information from industry indicate that the concentration levels of TCPP or other chlorinated phosphate esters typically are in the range of 5-15% (EFRA/CEFIC, 20--).

4.2 Waste treatment of PUR with and without TCPP

4.2.1 Classification of waste

Waste containing TCPP has according to the Danish statutory order on waste to be treated as hazardous waste if the waste contains substances in an amount that according to classification rules for chemical substances and mixtures preparations would result in classification for either physico-chemical, toxicological or environmental properties (Danish Ministry of Environment, 2012). Thus, waste containing TCPP in an amount that would result in classification as hazardous should be treated as hazardous waste and be disposed/treated according to the instructions from local communities. Below is indicated the various concentration limit for the various classifications that have been applied for TCPP (see table 2-1):

Acut tox 4 ≥ 25%

Eye Irr 2 ≥ 10%

Aquatic chronic 3 ≥ 25%

Skin Irr 2 ≥ 10%

Danish Plastics Federation has reported a typically content of TCPP of 5-10% in PUR (Danish Plastics Federation, 2013). This indicates that at present PUR containing TCPP with the current classifications of TCPP shall not be considered as hazardous waste.

However, if classification as Carc 2, H351 (as discussed in section 6.1.7) in future has to be used for TCPP, the limit for classification as hazardous waste would be a content of 1% in the waste, whereas the limit would be 5% in connection with a classification as Repr. 2, H361 as the classification limit from the old classification system and the Repr cat3; R63 classification still applies in relation to waste (discussed in section 6.1.9.). These low classification limit would result in classification of PUR waste containing TCPP as hazardous. However it is anticipated, the consequences of this would be rather limited as waste fractions with PUR foam already today is incinerated.

Due to the lack of knowledge and specific awareness to the content of flame retardants in PUR foam or because it is assumed that PUR generally does not contain flame retardants at levels that would trigger classification as hazardous waste, it may be anticipated that PUR foam in general is not considered as hazardous waste.

For chemical product waste containing TCPP the classification as hazardous waste will also depend on whether the products contain other hazardous substances to an extent that result in a hazard classification of the product.

Only one specific waste EAK code can be identified for industrial waste streams where PUR foam may occur and this is in connection with construction waste covering "insolation materials" EAK code 17 06 04" (Danish Ministry of Environment, 2012). For domestic waste PUR foam (mattresses, furniture, refrigerators etc.) may typically be collected in connection with the municipal collection of large waste items.

4.2.2 Treatment of waste

According to the flame retardant industry materials containing flame retardants can be safely disposed of in municipal waste incinerators for energy recovery. Flame retardants delay and inhibit the burning process, but do not make materials incombustible, and thus waste incineration is not considered a problem. When domestic waste is sent to landfill sites, the flame retardants will mostly remain within the discarded treated materials, because they are physically bound, therefore the loss of significant levels into the environment is unlikely (EFRA/CEFIC, 2013). By incineration TCPP will undergo decomposition as the substance decomposes at 288°C, see table 1.3. Vitkausskinené et al. (2001) state a decomposition temperature for TCPP at 244°C. Degradation products of C-3 chloroalkanes, acrolein and hydrochloric acid are expected to occur (WHO/IPCS, 1998).

In Denmark *approximately 60%* of the industrial PUR waste from production is *recycled*, mainly by rebonding flexible foam production waste to new products. A minor part of the rigid foam production waste is converted to new raw materials, whilst *approximately 40%* of the production waste is *incinerated* with energy recovery (Danish EPA, 2005).

Used flexible PUR foam is not subject for recycling in Denmark due to hygienic reasons and in general all PUR waste which is not recycled by industry at the production site will go to incineration due to the high energy content of the PUR foam (Danish EPA, 2005; Danish Plastics Federation, 2013).

Thus based on the figures from table 4-2 it can be estimated that in total approximately 5232 tons of PUR goes into the waste stream.

Furthermore, PUR foam is not suitable for landfilling due to the low weight of the material (its low density) and the high volume. Also in this regard the Landfill Directive (1999/31/EC) calls for decreasing amounts of waste to be sent to landfill in all EU countries.

4.3 Recycling of PUR waste containing TCPP

Danish EPA (2005) made a survey on the PUR waste streams. From this survey the volumes of PUR raw materials and the PUR waste from industrial production are given as shown in table 4-2:

TABLE 4-2
VOLUMES FOR CONSUMPTION OF PUR RAW MATERIALS AND PUR PRODUCTION WASTE

	Consumption of raw materials	Production waste
Flexible foam	22.200 t/year	5.100 t/year
Rigid foam	20.800 t/year	1.150 t/year
Total	**43.000 t/year**	**6.250 t/year**

About 60% of the industrial production waste is recycled into the production.

Polyurethane may be recycled in two primary ways: mechanical recycling, in which the material is reused in its polymer form, and chemical recycling that takes the material back to its various chemical constituents (ACC, 2013):

Mechanical Recycling

- **Rebonded Flexible Foam**—Rebonded flexible foam or "rebond" is made with pieces of chopped flexible polyurethane foam and a binder to create carpet underlay, sports mats, cushioning and similar products. Rebond has been used for decades and represents nearly 90 percent of the carpet underlay market in the United States.
- **Regrind or Powdering**—Sometimes called powdering, regrind recycling takes polyurethane industrial trim or post-consumer parts and grinds them in various ways to produce a fine powder. The resultant powder is mixed with virgin materials to create new polyurethane foam or reaction injection molded (RIM) parts.
- **Adhesive Pressing/Particle Bonding**—These two recycling processes use polyurethane from various applications, such as automobile parts, refrigerators and industrial trim, to create boards and moldings, often with very high recycled content. Used polyurethane parts are granulated and blended either with a powerful binder or polyurethane systems, then formed into boards or moldings under heat and pressure. The resulting products, analogous to particleboard made from wood waste, are used in sound proofing applications, furniture that is virtually impervious to water and flooring where elasticity is needed.
- **Compression Molding**—This recycling process grinds reaction injection molded (RIM) and reinforced RIM parts into fine particles and then applies high pressure and heat in a mold, creating products with up to 100 percent recycled content and material properties that can be superior to virgin materials.

Chemical Recycling

- **Glycolysis**—This process combines mixed industrial and post-consumer polyurethanes with diols at high heat, causing a chemical reaction that creates new polyols, a raw material used to make polyurethanes. These polyols can retain the properties and functionality of the original polyols and can be used in myriad applications.
- **Hydrolysis**—This process creates a reaction between used polyurethanes and water, resulting in polyols and various intermediate chemicals. The polyols can be used as fuel and the intermediates as raw materials for polyurethane.
- **Pyrolysis**—This process breaks down polyurethanes under an oxygen free environment to create gas and oils.
- **Hydrogenation**—Similar to pyrolysis, hydrogenation creates gas and oil from used polyurethanes through a combination of heat and pressure and hydrogen.

4.4 Summary and conclusions

In general PUR waste containing TCPP are not to be considered as hazardous waste as the typical TCPP content is in the range of 5-10% which is below the level of classification for the classification end-points currently used for TCPP)
In Danish production flexible PUR *with flame retardants* are only used for mattresses and furniture for customers that supply the UK market or institutions which have specific demands for flame protection e.g. prisons and hospitals.

So the far largest volume of PUR flexible foam waste is anticipated to be without TCPP.
However, for specific construction purposes (typically insulation) TCPP may be used in rigid PUR foam.

Based on Danish figures from 2005 about 7730 tonnes of PUR foam comes from industrial PUR waste and from domestic waste with products containing PUR. The PUR waste (including the TCPP) will typically go to incineration where PUR and TCPP undergo thermal decomposition.

At the production sites in Denmark industrial PUR waste is subject to recycling. In 2005 up to approximately 60% of the industrial PUR waste was estimated to be recycled. The part of industrial PUR waste that is not recycled and the domestic waste containing PUR (mattresses, furniture, refrigerators, construction materials etc.) will go for incineration due to the high energy content of the PUR.

Based on Danish figures from 2005 at least 7730 tonnes of PUR foam from industrial waste and from domestic waste is estimated to go into the waste stream. Thus, TCPP will go to incineration together with the PUR where TCPP will undergo termal decomposition.

Overall, there is a low potential for release and exposure to TCPP in connection to TCPP in the waste stream of PUR products. Also, it is not considered to have any significant implication for waste treatment if PUR foam with TCPP was to be considered as hazardous waste (e.g. due to lower classification limit for TCPP) as PUR foam in the waste stream is subjected to incineration due to the high energy content of the foam.

5. Environmental effects and exposure

5.1 Environmental hazard

5.1.1 Toxicity to aquatic organisms
Data exist on the acute toxicity to fish and acute and chronic tests with aquatic invertebrates and algae. The table below displays the results from the test showing the highest toxicity to aquatic organisms.

TABLE 5-1
AQUATIC TOXICITY OF TCPP (EU RAR, 2008)

Test	Effect	Concentration [mg/L]
Acute toxicity to fish	LC_{50} (96h)	51
Acute toxicity invertebrates	EC_{50} (48h)	131
Acute toxicity algae	EC_{50} (72h)	82
Chronic toxicity invertebrate	NOEC (21d)	32
Chronic toxicity to algae	NOEC/EC_{10} (72h)	13/42

A predicted No Effect Concentration (PNEC) for the aquatic environment ($PNEC_{aquatic, freshwater}$) of 0.64 mg/L has been derived from the Daphnia test data by dividing the NOEC of 32 mg/l for effects on *Daphnia magna* reproduction by an assessment factor of 50. The corresponding $PNEC_{aquatic, marine}$ = 0.064mg/L (EU RAR, 2008).

5.1.2 Toxicity to microorganisms
One study report on the toxicity to microorganisms was available for the RAR. This study resulted in an IC_{50} of 784 mg/L (EU RAR, 2008).

A predicted No Effect Concentration (PNEC) for microorganisms of 0,784mg/L was determined based on the test result from the study with microorganisms and applying an assessment factor of 100 (EU RAR, 2008).

5.1.3 Toxicity to sediment living organisms
No information on the toxicity to sediment living organism is identified. The predicted No Effect Concentration (PNEC) for sediment living organisms was calculated by the equilibrium partitioning applying the PNEC for the aquatic compartment (freshwater). PNEC = 2.92 mg/kg for sediment living organisms (EU RAR, 2008).

5.1.4 Toxicity to terrestrial organisms

The results from toxicity tests with terrestrial organisms are presented in the table below.

TABLE 5-2
TERRESTRIAL TOXICITY OF TCPP (ADAPTED FROM EU RAR, 2008)

Test	Effect	Concentration [mg/L]
Toxicity to earthworms	LC_{50} (14d)	33 mg/kg dwt
Chronic toxicity to earthworms	NOEC (56d)	18 mg/kg dwt
Toxicity to higher plants	NOEC	17 mg/kg dwt
Toxicity to soil nitrifying microorganisms (read across TDCP)	NOEC (28d)	128 mg/kg wwt

The predicted No Effect Concentration ($PNEC_{soil}$) for terrestrial organisms is 17/10 = 1.7 mg/kg soil dry weight, equivalent to 1.5 mg/kg soil wet weight when applying an assessment factor of 10 to the lowest chronic NOEC (EU RAR, 2008).

5.1.5 PBT

For the PBT assessment, TCPP can be considered to meet the screening criteria as persistent (P) or potentially very persistent (vP) based on its ultimate mineralization. The available information on bioaccumulation (measured BCF (fish) of 0.8-4.6) shows that TCPP does not meet the B or vB criterion. The T criterion is not met, though this should be reviewed once the human health data set is completed (EU RAR, 2008).

5.1.6 Classification

No harmonized classification and labelling are appointed to TCPP according to Annex VI of the CLP Regulation.
In the notified classifications to ECHA 32 out of 596 notifiers have classified the substance as Aquatic Chronic 3; H412.
This seems to be a proper classification of the substance since the lowest $L(E)C_{50}$ values reported for fish and algae are 51 mg/L and 82 mg/L, respectively (i.e. > 10 to ≤100 mg/L) and TCPP is *not* ready biodegradable and can therefore be classified as Aquatic Chronic 3 classification (Council Directive 67/548/EEC of 27 June 1967).

5.2 Environmental fate

5.2.1 Environmental degradation

TCPP is not ready biodegradable according to OECD Guideline no 301.

TCPP is expected to have a half-life of at least one year under environmental conditions, based on a standard preliminary hydrolysis test.

Distribution of TCPP in waste water treatment plants is expected to be:

- Fraction to air: 0%
- Fraction to surface water: 97.9%
- Fraction to sludge: 2.1%
- Fraction degraded: 0%

(EU RAR, 2008)

5.3 Environmental exposure

5.3.1 Sources of release

In the EU RAR (2008) the following releases are described: Release from production, from formulation, from flexible foams, from rigid foams, from spray foams, from one component foams and from disposal. Emission data are presented in the table below.

TABLE 5-3
TOTAL RELEASES TO THE REGIONAL AND CONTINENTAL ENVIRONMENTAL COMPARTMENTS (EU RAR, 2008)

Endpoint	Emission in kg/d
Total regional emission to air	134.85
Total regional emission to wastewater	18.70
Total regional emission to surface water	4.68
Total regional emission to industrial soil	0.86
Total continental emission to air	89.56
Total continental emission to wastewater	24.09
Total continental emission to surface water	6.02
Total continental emission to industrial soil	7.78

5.3.2 Monitoring data

Several results from measurements of TCPP concentrations in environmental compartments are reported in the EU RAR, 2008. Monitoring data which have been evaluated as reliable in the EU RAR are summarized in the table below.

TABLE 5-4
MEASURED CONCENTRATIONS OF TCPP IN ENVIRONMENTAL COMPARTMENTS (EU RAR, 2008)

Sample type	Location	Sample period	Analytical method	Result	Scale represented
River water	EU: River Po at Ferrara	1988-89	GC	0-68 ng/L	Local
Fresh surface water	EU: UK Midlands region	1995-99, 2004-2005		Largely 5 – 10 µg/L. Highest value 304 µg/L	Not known
Fresh surface water	EU: UK Midlands region	1995-99		0.56 g/l	Regional

Sample type	Location	Sample period	Analytical method	Result	Scale represented
Freshwater Sediments	EU: England and Wales	2002 or earlier	LC-MS	Not detected (<10 µg/kg wwt)	Unclear
Sewage final Effluent	EU: UK Midlands region	1995-99		Largely <20 µg/l. Highest value 3.32 mg/L	Local (though the sources of TCPP are not made clear, and cannot be linked to specific life cycle stages)
Trade effluent	EU: UK Midlands region	1995-99		<2 g/L	Unknown
Landfill Leachate	EU: UK (Environment Agency Thames, Anglian and Wales Regions)	2005	Not stated	21 sites with analysis for TCPP: range of results 0.4 - 66.6 µg/l; mean 24.6 µg/L	Local
River water	Asia: Various rivers, Japan	1976-90	GC/MS and GC/FPD	<13.1 g/L	Maximum concentration is probably downstream from a facility but this is not explicitly stated.

In Denmark TCPP has been measured in the outlet of sewage treatment plants. In the period during 1998-2009 a 75% percentile level of 1.9 µg TCPP/L was measured and in 2010 a median level and a 95% percentile level of 1.4 and 3.2 µg TCPP/L were measured. TCPP was found in 100% of the samples and was the phosphorous triester found at the highest level.
From these data it was estimated that about 700 kg of TCPP was emitted on a yearly basis into the Danish marine waters (DCE, 2012)

5.4 Environmental impact

Water and sediment

Calculated PEC/PNEC ratios for the aquatic compartments are all well below 1 indicating no risk.

Based on the equilibrium partitioning method no risk towards sediment is anticipated (EU RAR, 2008).

Terrestrial compartment
Calculated PEC/PNEC ratios for the terrestrial compartments are all well below 1 indicating no risk (EU RAR, 2008).

Waste water treatment plant
Calculated PEC/PNEC ratios for waste water treatment plants are all well below 1 indicating no risk (EU RAR, 2008).

Secondary poisoning
The available effects data mean that PNEC is based on a limit value. This means that all PEC/PNEC ratios are presented as 'greater than' values, which could be interpreted as potential concerns. However, no values are close to 1 (they are all at least one order of magnitude below 1) and due to the lack of any significant bioaccumulation potential of TCPP, it is reasonable to conclude that there are no risks (EU RAR, 2008)

5.5 Summary and conclusions

Ecotoxicological data on TCPP were available on the acute toxicity to fish; acute and chronic tests with aquatic vertebrates, and on algae. Furthermore results from toxicity tests with terrestrial organisms and microorganisms are available.

No harmonized classification and labelling are appointed to TCPP according to Annex VI of the CLP Regulation. A classification of Aquatic Chronic 3; H412 seems proper since the lowest $L(E)C_{50}$ values reported for fish and algae are 51 mg/L and 82 mg/L, respectively (criteria values > 10 to ≤ 100 mg/L) and TCPP is *not* ready biodegradable.

With respect to PBT evaluation, TCPP can be considered to meet the screening criterion as persistent (P) or potentially very persistent (vP) based on its ultimate mineralization. The available information on bioaccumulation (measured BCF (fish) of 0.8-4.6) shows that TCPP does not meet the bioaccumulation (B) criterion. The criterion for toxicity (T) criterion is also not met.

Monitoring data on TCPP in the environment and predicted environmental concentrations do not indicate any risk for the aquatic- and terrestrial compartment (including sediment) as well as waste water treatment plants. In Denmark in 2010 an average level of 1.4 µTCPP/L has been measured in the effluent from sewage treatment plants and an estimated total of about 700 kg of TCPP was emitted into the marine water.

6. Human health effects and exposure

6.1 Human health hazard

The EU RAR (2008) presents an excellent review of the available toxicological data covering all important endpoints but carcinogenicity. According to a database search, since then, no important new data have been published. Therefore, data are compiled from EU RAR (2008).

6.1.1 Toxicokinetics

Data show an absorption of 75-100% after oral exposure and absorption of 80% was taken for the risk characterization. Bioaccumulation is considered minimal and TCPP is extensively metabolized.

No toxicokinetic data are available on inhalation (EU RAR, 2008).

6.1.2 Acute toxicity

TCPP is of low acute toxicity following inhalation exposure. The oral toxicity is moderate with LD50 values in rats and rabbits in the range of 632-4200 mg/kg bw, with the majority <2000 mg/kg bw. A NOAEL of 200 mg/kg bw can be identified for acute oral toxicity (EU RAR, 2008). There is no concern for acute delayed neurotoxicity (EU RAR, 2008).

These data are in accordance with an Acute Tox 4 classification.

6.1.3 Skin and eye irritation

No human data are available. There is an extensive database from studies in animals, indicating that TCPP is non-irritant in the rabbit eye and to skin. TCPP is not corrosive. No information is available on the respiratory sensitization potential (EU RAR, 2008).

These data do not indicate a need for classification for these end-points.

6.1.4 Skin sensitization

No evidence of skin sensitization was found in a guinea pig maximization test or in a local lymph node assay in mice. TCPP is considered to be a non-sensitizer (EU RAR, 2008).

6.1.5 Repeated dose toxicity

In a 28-day oral gavage study in rats, broadly compliant with OECD Guideline 407, the liver was identified as the target organ. A NOAEL of 100 mg/kg bw/day (mid dose) was derived (EU RAR, 2008).

A 13-weeks oral toxicity study indicated that the liver and thyroid gland might be the main target organs. A LOAEL of 52 mg/kg/day was derived based on increased liver weight and mild thyroid follicular cell hyperplasia. No data are available on inhalation or dermal repeated dose toxicity (EU RAR, 2008).

6.1.6 Mutagenicity

The mutagenic potential of TCPP has been well investigated *in vitro* in bacteria, fungi and in unscheduled DNA synthesis studies indicating no mutagenicity. *In vivo*, TCPP was not clastogenic in a mouse bone marrow micronucleus test. TCPP did not induce chromosomal aberrations in a rat bone marrow cytogenetics assay. In an *in vivo* Comet assay in the rat liver TCPP did not induce DNA damage. In conclusion TCPP is not genotoxic *in vivo (*EU RAR, 2008).

These data are in contradiction to the QSAR analysis made by the Danish EPA indicating concern for mutagenicity which made the Danish EPA to recommend a self-classification as mutagenic Muta, 2; H341.

Thus, taking account of the concrete data there seems to be no reason to maintain the concern for a genotoxic potential of TCPP.

6.1.7 Multigeneration/Reproduction/Developmental toxicity

In a 2-generation reproduction toxicity conducted according to OECD Guideline 416 rats were fed diet containing 0, 1500, 5000, or 15000 mg TCPP/kg mg/kg diet. The overall intake of TCPP was 0, 85, 293 and 925 mg TCPP/kg bw/day for males and 0, 99, 330 and 988 mg TCPP/kg bw/day for females, for the control, low, mid and high dose groups, respectively (EU RAR, 2008).

There was no treatment related differences in pre-coital time, mating index, female fecundity index, male and female fertility index, duration of gestation and post-implantation loss. In females, the length of the longest oestrus cycle and the mean number of cycles per animal were statistically significantly increased in high dose animals of both generations. A decrease in uterus weight was observed in all dosed females in F0 generation and in high dose females of F1 generation. There was no effect on sperm parameters at necropsy. No treatment related microscopic effects were observed at necropsy. A LOAEL of 99 mg/kg bw is derived for effects on fertility, based on effects on the uterus weight seen in all dosed females in F0 and high dose females in F1 (EU RAR, 2008).
In the same study, an increase in the number of runts was observed in all dose groups of F0 generation on post natal day 1 and persisted to post natal day 21 in the mid and high dose groups. In the F1 generation, the number of runts was increased in the high dose group on post natal day 14 and all dose groups on post natal day 21. A decrease in mean pup weight was noted in high dose group of F0 from post natal day 14 and onwards and of F1 from post natal day 7. Mean pup weights were decreased in the mid dose group of both generations on post natal day 21. A decrease in the mean number of pups delivered was observed in the mid and high dose groups and could be due either to decreased fertility of parental animals or a developmental effect on the pups. No treatment related macroscopic alterations were observed at necropsy of the pups. There were no treatment related differences on anogenital distance, vaginal opening and preputial separation between the TCPP fed groups and the controls. Based on the increased number of runts observed in all dose groups of F0 generation, a LOAEL of 99 mg/kg bw is derived for developmental toxicity (EU RAR, 2008). It was not possible to interpret these data in terms of irreversibility.

As maternal toxicity may play a role in these findings data are considered borderline for a classification as Repr, 2; H361.

The reproductive toxicity data on TCPP may be seen in comparison with the data on the close analogue substance TCEP that has a harmonised classification as Repr. 1B based on effects on fertility. From the risk assessment report on TCEP it is concluded (EU-RAR, 2009):
"Tris(2-chloroethyl)phosphate treatment revealed significant impairment of fertility for both sexes during continuous breeding and for two successive generations in mice. Reproductive failure was observed at daily doses of 700 mg/kg bw with at best and no more than 3 litters produced and with no pups surviving from the last litter produced. The findings were essentially confirmed from the results of a separate cross over mating trial in mice at the same dose level. The reproductive system

of male mice appeared to be more sensitive to tris(2-chloroethyl)phosphate treatment as evidenced by less successive reproduction of treated males in comparison to treated females and further by significant male reproductive organ weight reduction and sperm parameter impairment in mice of two different strains" and
"An oral NOAEL/fertility of 175 mg/kg bw/d was derived from the studies with mice. With respect to developmental toxicity, it appears on the basis of the available data, that tris(2-chloroethyl) phosphate has no embryo-/fetotoxic or specific teratogenic properties even at maternally toxic doses. An oral NOAEL/developmental toxicity of 200 mg/kg bw/d (NOAEL/maternal toxicity = 100 mg/kg bw/d) was derived from studies with rats."

Thus the available data indicate that the most critical target organ for TCEP is the male reproductive system (testes), whereas TCPP seems more to affect the female system (uterus).

6.1.8 Endocrine disruption

The endocrine disruption potential of flame retardants, including TCPP, was investigated in the H295R cell line. TCPP increased the 17-beta-estradiol concentration at 100 mg/L. The testosterone concentration was increased at 1, 10 and 100 mg/L. The results indicate that TCPP could alter sex hormone balance (Liu et al., 2012).

Furthermore, data from the 2-generation reproductive toxicity study (described above) indicate hormonal disturbance by TCPP due to the findings concerning decreased uterus weight and prolongation of the oestrus cycle (EU RAR, 2008).

Also, it is not known whether the consistent findings in the 13-weeks repeated dose toxicity study where thyroid follicular cell hyperplasia was noted in male rats down to the lowest dose level of 52 mg/kg bw/d is associated with hormonal disturbances.

6.1.9 Carcinogenicity

Carcinogenicity data are not available. However, TCPP is structurally similar to two other chlorinated alkyl phosphate esters, TDCP and TCEP, both of which are considered as non-genotoxic carcinogens. It is concluded that there is sufficient information from the structures, physical-chemical properties, toxicokinetics and mutagenic profiles of TCEP, TDCP and TCPP to support a qualitative read-across, which indicates a concern for carcinogenicity for TCPP by a non-genotoxic mechanism.

Further it is proposed that the effects observed in the 13-weeks study for TCPP are taken as a starting point for risk characterization. If these effects were to progress to cancer, they would do so by a non-genotoxic mechanism. Therefore, it is proposed that the LOAEL, of 52 mg/kg/day, identified from the 13-weeks study with TCPP should be used as a basis for risk characterization of the carcinogenicity endpoint (EU RAR 2008; ECHA 2008)

This view has afterwards been supported by Scientific Committee on Health and Environmental Risks that in an opinion on TCEP in toys agrees in relation to the concern for a carcinogenic potential of TCPP (SHER, 2012).

As both TCEP and TDCP are subjected to an EU-harmonized classification as Carc 2; H351 this classification should as well be used for TCPP.

6.2 Human exposure

6.2.1 Direct exposure

6.2.1.1 Consumers

The RAR states that most of the TCPP that is produced in the EU is used for production of polyurethane foam in Europe which is used and enclosed in upholstery and bedding. Consumers do not come into direct contact with these foams. Therefore, it is expected that exposure from these foams is very low.

Three exposure scenarios from which exposure to TCPP could occur include release from TCPP-containing flexible PUR foam in furniture; exposure during the use of one-component foams ; and use of rigid insulation foams and levels in indoor air (EU RAR, 2008).

Release from TCPP-containing flexible PUR foam:

The RAR report states, that the reasonable worst-case inhalation exposure is 3.8 µg/m3. Using default values of a 70 kg person inhaling 20 m3 of air per 24 -hour day and assuming a 100% absorption, the inhalation body burden is 1 µg/kg bw. Dermal exposure is set to the same overall exposure as for inhalation which was assumed a conservative assumption.

Oral exposure was estimated based on a child's oral ingestion of dust with realistic worst case concentration of TCPP of 11.9 µg/g dust.

Exposure during the use of one-component foams:

For consumers as a worst case the same exposure as occupational exposure was used, although a consumer does not use spray foams every day.

For inhalation a realistic worst case value of 0.005 µg/m3, 8-hour time-weighted average was used

For dermal exposure, a realistic worst case exposure value of 1.9 x 10-3 mg/cm2/day was used. It is estimated that 420 cm2 would be the area exposed particularly for inexperienced workers. In reality the use of suitable gloves would reduce exposure if changed regularly.

Indoor insulation:

Considered to be negligible as measurements of vaporisation of TCPP to indoor air were below the detection limit (no detectable level measured i.e < 1 µg TCPP/m3).

TABLE 6-1
CONSUMER EXPOSURE ESTIMATIONS ACCORDING TO EU RAR 2008

Realistic worst case exposure scenarios from - PUR in furniture - Use of one-compartment foam - Indoor insulation	Internal exposure* (µg/kg bw/d) Realistic worst case
PUR foam in furniture: Inhalation exposure at 3.8 µg TCPP/m3 *PUR foam in furniture*: Dermal exposure (assumed not exceeding inhalation exposure) *PUR foam in furniture*: Oral exposure of dust containing 11.9 µg TCPP/g (hand to mouth contact, child)	1 1 0.2
DIY one-component PUR foam: Inhalation exposure (0.005 µg TCPP/m3 (8-h average) + dermal exposure 1.9 µg TCPP/cm2/d	2.6

Realistic worst case exposure scenarios from - PUR in furniture - Use of one-compartment foam - Indoor insulation	Internal exposure* (µg/kg bw/d) Realistic worst case
Indoor insulation: vaporisation of TCPP to indoor air (no detectable level measured i.e < 1 µg TCPP/m³)	Negligible

*for calculating the internal human dose absorption rates of 100% were used for oral and inhalational exposure, whereas a dermal absorption rate of 23% was used.

6.2.1.2 Occupational exposure

Occupational exposure of workers to TCPP may occur during:

1. Manufacture of TCPP
2. Manufacture of flexible PUR foam
3. Cutting of flexible PUR foam
4. Production of foam granules and rebonded PUR foam
5. Formulation of systems and manufacture of spray foam
6. Use of spray foams
7. Manufacture of rigid PUR foam
8. Use of rigid PUR foam
9. Manufacture of one-component foams
10. Use of one-component foams

The total number of workers occupationally exposed to TCPP in the EU through various work tasks is not known. Exposure primarily occurs via dermal and inhalation routes whereas ingestion is not considered relevant for workers. The EU risk assessment report (2008) refers to exposure levels related to 10 different work scenarios (Table 6-2). No adequate newer values were identified by the database search.

TABLE 6-2
REASONABLE WORST-CASE AND TYPICAL INHALATION AND DERMAL EXPOSURE LEVELS (MODIFIED FROM EU RAR, 2008)

Exposure scenarios	Inhalation worst case (µg/m³)	Dermal worst case (mg/cm²/day)	Inhalation typical (µg/m³)	Dermal typical (mg/cm²/day)
1	25	1	12.5	0.1
2	5.1	0.07	0.62	0.002
3	4.1	$7.1\ 10^{-3}$	1.9	$2.7\ 10^{-4}$
4	4.6	$1.7\ 10^{-3}$	0.59	$5.5\ 10^{-4}$
5	5	0.11	2.5	0.05
6	187.5	0,23	25	0.12
7	150	$6.5\ 10^{-2}$	20	$3.2\ 10^{-2}$
8	4.1	$1.3\ 10^{-2}$	1.9	$6\ 10^{-3}$
9	12.5	$5.2\ 10^{-3}$	6.7	$1\ 10^{-3}$
10	$5\ 10^{-3}$	$1.7\ 10^{-3}$	$2.5\ 10^{-3}$	$9.3\ 10^{-4}$

By use of default values for a 70 kg worker inhaling 10 m³ of air per 8-hour working day and assuming a 100% absorption by inhalation and an exposed skin area of 420/210 cm² assuming 23%

skin absorption the respective body burdens were calculated in the EU RAR (2008) and given in table 6-3.

TABLE 6-3
SUMMARY OF DERMAL AND INHALATION BODY BURDEN VALUES FOR TCPP EXPOSURE SCENARIOS FOR WORK TASKS (MODIFIED FROM EU RAR, 2008)

Expo-sure scenarios	Inhalation body burden worst case (mg/kg)	Dermal body burden worst case (mg/kg)	Combi-ned worst case body burden (mg/kg)	Inhalation body burden typical case (mg/kg)	Dermal body burden typical case (mg/kg)	Combined typical case body burden (mg/kg)
1	$3.5\ 10^{-3}$	0.69	**0.69**	$1.8\ 10^{-3}$	$6.9\ 10^{-2}$	**$7.1\ 10^{-2}$**
2	$7.3\ 10^{-4}$	$9.7\ 10^{-2}$	**$9.8\ 10^{-2}$**	$8.9\ 10^{-5}$	$2.8\ 10^{-3}$	**$2.9\ 10^{-3}$**
3	$5.9\ 10^{-4}$	$1.7\ 10^{-2}$	**$1.8\ 10^{-2}$**	$2.7\ 10^{-4}$	$2.4\ 10^{-3}$	**$2.7\ 10^{-3}$**
4	$6.6\ 10^{-4}$	$4.1\ 10^{-3}$	**$4.7\ 10^{-3}$**	$8.4\ 10^{-5}$	$1.3\ 10^{-3}$	**$1.4\ 10^{-3}$**
5	$7.1\ 10^{-4}$	0.15	**0.15**	$3.6\ 10^{-4}$	$6.9\ 10^{-2}$	**$6.9\ 10^{-2}$**
6	$2.7\ 10^{-2}$	0.32	**0.35**	$3.6\ 10^{-3}$	0.17	**0.17**
7	$2.1\ 10^{-2}$	$4.5\ 10^{-2}$	**$6.6\ 10^{-2}$**	$2.9\ 10^{-3}$	$2.2\ 10^{-2}$	**$2.5\ 10^{-2}$**
8	$5.9\ 10^{-4}$	$1.6\ 10^{-2}$	**$1.6\ 10^{-2}$**	$2.7\ 10^{-4}$	$7.2\ 10^{-3}$	**$7.5\ 10^{-3}$**
9	$1.8\ 10^{-3}$	$3.6\ 10^{-3}$	**$5.4\ 10^{-3}$**	$9.6\ 10^{-4}$	$6.9\ 10^{-4}$	**$1.7\ 10^{-3}$**
10	$7\ 10^{-7}$	$2.6\ 10^{-3}$	**$2.6\ 10^{-3}$**	$3\ 10^{-7}$	$1.3\ 10^{-3}$	**$1.3\ 10^{-3}$**

As can be seen from the tables above the highest worker exposure is associated to scenario 1 worst case exposure of 0.69 mg/kg in relation to manufacture of TCPP.

6.2.2 Indirect exposure

6.2.2.1 Air

Despite being bound to different materials low levels of TCPP has been detected in indoor air (EU RAR, 2008). In Sweden concentrations of 91-850 ng/m^3 have been detected (Björklund, 2004). In a kindergarten and a lecture room the concentration was 77 and 100g ng/m^3, respectively (Tollbäck et al., 2006). In a 9-year old car a concentration of 260 ng/m^3 was found while only 23 ng/m^3 was found in a new car (Van der Veen & De Boer, 2012). These exposures can whether they are related to vapours or particulates be regarded as negligible.

6.2.2.2 Soil

No data found.

6.2.2.3 Drinking water

The TCPP concentration in samples of drinking water from Italy and Norway were in the range of <0.01-0.09 µg/L (EU RAR, 2008). Another study did not specify the concentration of TCPP that was measured in a group of other chemicals. However, it was reported to be below the detection limits (0.3-3 ng/L) (EU RAR, 2008).
The intake via drinking water can be regarded as negligible (EU RAR, 2008).

6.2.2.4 Food

As reflected in table 6-4, the concentration of TCPP has been measured in different food items.

TABLE 6-4
CONCENTRATIONS OF TCPP REPORTED IN VARIOUS FOOD ITEMS (EU RAR, 2008)

Item	Concentration
Mussel and liver from cod	Below limit of detection that was 30 µg/kg
Liver from fish from Norway	1.4-2.9 µg/kg
Muscle from fish from Norway	5.5-8.9 µg/kg
Burbot liver	17 µg/kg
Herring, perch, mussels, eelpout and salmon from Sweden	23-1300 µg/kg

Based on the data found the intake via fish, leaf crops, meat, milk and root crops can be neglected (EU RAR, 2008).

6.2.2.5 Indoor climate

There have been reported concentrations of TCPP in dusts in the range up to 14 mg/kg (van der Veen, 2012). Another study found that concentrations in dust from Boston, USA were <140 to 5490 ng/g (Stapleton et al., 2009)., whereas concentrations in samples from Belgium were 0.19-73.7 µg/g (van der Veen, 2012).
The data in this section indicate that exposure from indirect exposure to the population is far lower than direct exposure to consumers and thus it seems not relevant to perform detailed risk characterisation for indirect exposure if the higher consumer exposure is considered of no concern.

6.3 Bio-monitoring data

No data found.

6.4 Human health impact

The database search did not reveal any adequate data in the period from the EU risk assessment report (2008) was published until March 2013. Consequently, the conclusions of the EU risk assessment as given below are still relevant.

6.4.1 Workers

The EU RAR concludes that:

1. There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account. This conclusion applies to reasonable worst case dermal exposure during the manufacture of TCPP, corresponding to 1 $mg/cm^2/day$ (Table 6-2), in relation to effects on fertility and developmental toxicity.
2. There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

These conclusions apply to:
-All worker exposure scenarios for the endpoints acute toxicity, irritation, sensitisation, repeated dose toxicity, mutagenicity and carcinogenicity.
-Typical dermal exposure and inhalation exposures, both reasonable worst case and typical, during the manufacture of TCPP in relation to effects on fertility and developmental toxicity.
-All other worker exposure scenarios for both reasonable worst case and typical exposures in relation to effects on fertility and developmental toxicity.

6.4.2 Consumers

The EU RAR concludes for all consumer exposure scenarios (See table 6-1) in relation to all toxicological endpoints that there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

TABLE 6-5
RISK ASSESSMENT TO TCPP FOR CONSUMERS IN RELATION TO REALSTIC WORST CASE SCEANRIOS ACCORDING TO EU RAR 2008 (ADAPTED FROM ARCADIS, EBRC, 2011)

Exposure scenario	Internal exposure (µg/kg bw/d) Realistic worst case exposure	MOS (acute) compared to a NOAEL of 200 mg/kg bw	MOS (repeat) Compared to a LOAEL* of 42 mg/kg bw/d	MOS (carc.) Compared to a LOAEL* of 42 mg/kg bw/d	MOS (repro.) Compared to a LOAEL* of 79 mg/kg bw/d	Conclusion
PUR foam in furniture: Inhalation exposure	1	-	42,000	42,000	79,000	No concern
PUR foam in furniture: Dermal exposure	1	-	38,182	38,182	71,818	No concern
PUR foam in furniture: Oral exposure (hand to mouth contact, child)	0.2	-	210,000	210,000	395,000	No concern
DIY one-component PUR foam: Inhalation exposure	1.4	114,286	-			No concern
DIY one-component PUR foam: Dermal exposure	240	667	-			No concern

*the internal LOAEL values where calculated from the external LOAEL values of 52 mg/kg bw/d (for repeated dose toxicity and carcinogenicity) and 99 mg/kg bw/d (for reproductive toxicity) as identified in section 6.1 and adjusted with an oral absorption rate of 80% in the experimental animals

6.5 Summary and conclusions

The EU RAR (2008) on TCPP presents an excellent review of the available toxicological data and provides estimates of the potential exposure levels. A database search did not reveal any new relevant data.

TCPP is extensively and rapidly absorbed (about 80% of dose) after oral exposure and is widely distributed to organs. TCPP is extensively metabolized and excreted by urine and faces.
Acute toxicity is low with most LD_{50} values below 2000 mg/kg bw complying with a classification as Acute Tox. 4, H302.
Skin and eye irritation is only slight, and no data on respiratory irritation are available. Skin sensitisation was not demonstrated.

A 28-day gavage study established a NOAEL on 100 mg/kg bw/day (liver target organ) and another repeated dose oral toxicity study for 13 weeks demonstrated a LOAEL of 52 mg/kg bw/day (liver and thyroid gland target organs).

TCPP is non-genotoxic as established in *in vitro* and *in vivo* studies. However, QSAR analyses have implied indications of mutagenicity. But, taking account to the animal experimental data and the conclusion made in the EU risk assessment report there seems to be no reason to maintain the concern for a genotoxic/ mutagenic potential of TCPP.

No carcinogenicity studies are available.
However, a qualitative basis read-across approach is justified to data from TCEP and TDCP as concluded in the EU risk assessment and also by the Scientific Committee of Health and Environmental Risks. Thus TCPP should be classified as Carc. 2, H351, which is the EU-harmonized classification for the two read-across substances TCDP and TCEP, and may therefore be considered as a suspected non-genotoxic carcinogen

From a 2-generation reproductive toxicity study in rats a LOAEL of 99 mg/kg bw is derived for effects on fertility, based on effects on the uterus weight seen in all dosed females in the F0 generation. A LOAEL of 99 mg/kg bw is derived for developmental toxicity based on the increased number of runts observed in all dose groups of F0 generation.
Maternal toxicity may play a rule in these findings, however, a possible classification of TCPP would be a classification as Repr, 2; H361.

The endocrine disruption potential of TCPP was investigated in an *in vitro* study with the H295R cell line where testosterone concentration was increased at 1, 10 and 100 mg/L. Furthermore, data from the 2-generation reproductive toxicity study (described above) indicate hormonal disturbance by TCPP due to the findings concerning decreased uterus weight and also prolongation of the oestrus cycle. The results indicate that TCPP could alter sex hormone balance. Ths could support a classification as indicated above. However, itt remains to be determined whether increased testosterone level also occur *in vivo* and whether this could be associated to the decrease in uterus weight. Thus, further verification/studies would be needed to clarify the potential for endocrine disruption of the substance.

Read-across to TCEP in relation to reproductive toxicity seems less reliable as no effects on uterus have been found for TCEP, and also TCEP strongly affect the male reproductive system which has not been found for TCPP.

Only very minute exposure to consumers for TCPP is anticipated and in general very large margins of exposure have been found towards the effects levels in experimental animals. Thus the current use of TCPP is considered safe for the consumers.

In relation to worker exposure only one scenario was considered of concern in the EU risk assessment report. This was a worst case exposure scenario for the manufacture of TCPP where the dermal exposure had to be lowered in order to limit the risk.

7. Information on alternatives

As indicated above TCPP is a drop-in replacement for TCEP as there is a move away from use of TCEP by industry. In Western Europe, by far the largest field of application of TCEP (80-90% of the quantity produced) is as flame-resistant finishing of polyurethane in the production of celled, rigid or semi-rigid foam. One of the main industrial branches to use TCEP is (roof) insulation for the building industry.

7.1 Identification of possible alternatives

TCPP is used as a flame retardant and almost exclusively in PUR foam. It is very often used together with melamine which then keeps the content of TCPP down in the range of 5-10% in the PUR foam. The far highest volume of flexible PUR used in Denmark is without flame retardants and TCPP is only used for specific purposes where fire protection is required e.g. in connection with mattresses and furniture for use in different kind of institutions.

The search of alternatives should be seen in the light of the substitution of TCEP, which was used before, but today due to the hazardous properties of this substance is substituted by TCPP. So TCPP is a substituting substance.

In Denmark there are no on-going activities for substituting TCPP as no suitable alternatives have been identified for the specific purpose in PUR foam (The Danish Plastics Federation, 2013).

7.2 Alternatives

Efforts have been made to find alternative flame retardants to e.g. the brominated flame retardants which also have been used in PUR foam.

A Norwegian overview report regarding alternative flame retardants (compared to pentabromodiphenylether) indicates for PUR the following possible non-halogented alternatives:

- ammonium polyphosphate
- red phosphorous
- melamine
- dimethylpropylphosphonate (DMPP)
- Reofos (non-halogen flame retardant).

However, no further information as to the technical potential for substitution is given (SFT, 2009).

In 1999 The Danish EPA published a project examining alternative flame retardants for brominated flame retardants. The potential for substituting flame retardants in PUR foam is given bellow (Danish EPA, 1999):

> *Flexible PUR foam*
> During the latest decade, brominated flame retardants have been totally phased out of flexible foams produced in Denmark. The used alternatives are chlorinated phosphate esters, in some cases combined with melamine. Halogen-free additives, containing ammonium polyphosphates, and reactive phosphorus polyols are used or will be used in the near future for automotive seats and foam-lamination of textiles.
> Also an increase of the density of the foams may be sufficient to meet mild requirements. Such foams are supplied in Denmark for exclusive furniture. The

product is expensive compared to other fire retardant solutions based on halogens and phosphorous substances.

Rigid PUR foam Flame retardants for rigid PUR foams may be based on ammonium polyphosphates or red phosphorus. These types of flame retardants are commercially produced for rigid polyurethane foams, and permit the fulfillment of strong requirements of railway and aircraft standards (e.g. DIN 5510, ABD 031). Ammonium polyphosphate and red phosphorus enable applications up to the level of the strict DIN 4102 Class B1.

These alternative halogen-free flame retardants are to the knowledge of the authors not used commercially in Scandinavia. On a European scale, production of insulation panels with halogen-free flame retardants does exist, but only on a small scale.

If a flammability level corresponding e.g. to the strict German DIN 4102 B1 is needed, however, no halogen-free alternative is apparently commercially available today; but a combination of chlorinated phosphate esters and red phosphorus are commercially available. The B1 level is, however only needed in very few cases such as mining and prisons, and only a few manufacturers in Europe are supplying products of this grade. According to industry information, developments of halogen-free B1 rigid foams are in progress.

However, according to the Danish Plastics Federation there seems – for the time being - to be no clear and universal alternative to TCPP as a flame retardant in PUR foam (Danish Plastics Federation, 2013).

Summary and conclusions

TCPP is itself used as an alternative to the very closely related substance TCEP which have been used to a great extent as flame retardant. However, the use of TCEP has stopped due to the classification of the substance as Repr. 1B.

No data have been found to which extent substitution to some of the proposed non-halogenated alternative flame retardants is technically feasible. This may be because there has not been any drivers or intentions to find substitutes for TCPP as this flame retardant itself was considered as the ideal substitute for TCEP.

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Appendix 1:

Use pattern of TCPP in Denmark from 2000 to 2010 (Data retrived from the SPIN database, 2013)

Country	Tonnage	No. of products	Description	
Denmark 2000 (SPIN)	553.1	50	287.7 t (14 preparations)	Manufacture of rubber and plastic products
			42.4 t (7 preparations)	Manufacture of machinery and equipment
			59.7 t (23 preparations)	Construction
			10.2 t (4 preparations)	Private household with employed persons
Denmark 2001 (SPIN)	704.2	55	287.7 t (16 preparations)	Manufacture of rubber and plastic products
			42.4 t (7 preparations)	Manufacture of machinery and equipment
			53.1 t (25 preparations)	Construction
			6.6 t (4 preparations)	Private household with employed persons
Denmark 2002 (SPIN)	584.1	65	314.4 t (16 preparations)	Manufacture of rubber and plastic products
			42.4 t (7 preparations)	Manufacture of machinery and equipment
			56.8 t (35 preparations)	Construction
Denmark 2003 (SPIN)	381.4	52	149.5 t (25 preparations)	Manufacture of rubber and plastic products
			8.1 t (25 preparations)	Construction
Denmark 2004 (SPIN)	47.7	73	26.9 t (17 preparations)	Manufacture of rubber and plastic products
			0 t (10 preparations)	Manufacture of machinery and equipment

Country	Tonnage	No. of products	Description	
			14.4 t (23 preparations)	Construction
Denmark 2005 (SPIN)	117,036.2*	101	40.7 t (32 preparations)	Manufacture of rubber and plastic products
			1.9 t (18 preparations)	Manufacture of machinery and equipment
			20,027.1 t (39 preparations)	Construction
			0.2 t (11 preparations)	Manufacture of fabricated metal products, except machinery
			96,960.1 t (10 preparations)	Manufacture of chemicals and chemical products
Denmark 2006 (SPIN)	222.4	134	121.3 t (13 preparations)	Manufacture of chemicals and chemical products
			78.6 t (54 preparations)	Construction
			15.4 t (45 preparations)	Manufacture of rubber and plastic products
			0.3 t (13 preparations)	Manufacture of fabricated metal products, except machinery
			1.5 t (19 preparations)	Manufacture of machinery and equipment
			0 t (10 preparations)	Manufacture of wood and products of wood and cork
Denmark 2007 (SPIN)	217.4	161	122.2 t (8 preparations)	Manufacture of chemicals and chemical products
			62.2 t (53 preparations)	Construction
			1.8 t (19 preparations)	Manufacture of machinery and equipment
			0.3 t (10 preparations)	Manufacture of fabricated metal products, except machinery
			23.9 t (78 preparations)	Manufacture of rubber and plastic products

Country	Tonnage	No. of products	Description	
Denmark 2008 (SPIN)	177.4	186	0.2 t (13 preparations)	Manufacture of fabricated metal products, except machinery
			0.6 t (6 preparations)	Construction of buildings
			0.7 t (10 preparations)	Manufacture of electrical equipment
			72.9 t (8 preparations)	Manufacture of chemicals and chemical products
			67.5 t (95 preparations)	Manufacture of rubber and plastic products
			3.7 t (6 preparations)	Civil engineering
			1.3 t (13 preparations)	Manufacture of machinery and equipment
			22.1 t (39 preparations)	Specialised construction activities
Denmark 2009 (SPIN)	105.8	178	6.2 t (5 preparations)	Undifferentiated goods- and services producing activities
			0.5 t (7 preparations)	Construction of buildings
			0.4 t (9 preparations)	Manufacture of machinery and equipment
			1.3 t (6 preparations)	Civil engineering
			0.2 t (13 preparations)	Manufacture of fabricated metal products, except machinery
			33.6 t (32 preparations)	Specialised construction activities
			29.3 t (7 preparations)	Manufacture of chemicals and chemical products
			28.6 t (90 preparations)	Manufacture of rubber and plastic products
Denmark	199.5	188	0 t (15 preparations)	Manufacture of fabricated metal products, except machinery

Country	Tonnage	No. of products	Description	
2010 (SPIN)			0 t (6 preparations)	Construction of buildings
			20.0 t (98 preparations)	Manufacture of rubber and plastic products
			0 t (9 preparations)	Manufacture of machinery and equipment
			136.0 t (7 preparations)	Manufacture of chemicals and chemical products
			14.0 t (32 preparations)	Specialised construction activities
			1.0 t (6 preparations)	Civil engineering
			6.0 t (5 preparations)	Undifferentiated goods- and services producing activities

Appendix 2:

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[2] and the CLP Regulation[3] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

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

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

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

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

Restriction
If the authorities assess that 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.

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

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

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

Ongoing activities - pipeline

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

Community Rolling Action Plan (CoRAP)

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

Authorisation process; candidate list, Authorisation list, Annex XIV

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

1. It has to be identified as a SVHC leading to inclusion in the candidate list[4]
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

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

Registry of intentions

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.
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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.

[4] 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).

International agreements

OSPAR Convention

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

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

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

HELCOM - Helsinki Convention

The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

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

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)

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

Rotterdam Convention

The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;

- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

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

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

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

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

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

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the 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.

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