THIS DOCUMENT HAS BEEN PREPARED ACCORDING TO THE PROVISIONS OF ARTICLE 136(3) “TRANSITIONAL MEASURES REGARDING EXISTING SUBSTANCES” OF REACH (REGULATION (EC) 1907/2006). IT IS NOT A PROPOSAL FOR A RESTRICTION ALTHOUGH THE FORMAT IS THE SAME

Transitional Annex XV dossier

STRATEGY FOR LIMITING RISK

Substance name: Tris(2-chloro-1-methylethyl) phosphate (TCPP)
EC Number: 237-158-7
CAS Number: 13674-84-5

Submitted by: Ireland

Date: 1st December 2008

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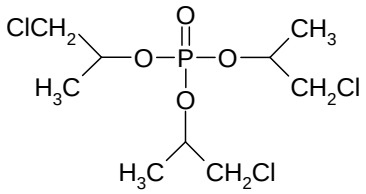
PART A: PROPOSAL

A.1 PROPOSAL FOR STRATEGY FOR LIMITING RISK

A.1.1 Identity of the substance

CAS Number: 13674-84-5
EINECS Number: 237-158-7
IUPAC Name: Tris(2-chloro-1-methylethyl) phosphate
Molecular formula: $C_9H_{18}Cl_3O_4P$
Structural formula:



Molecular weight: 327.57
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

Smiles notation O=P(OC(CCl)C)(OC(CCl)C)OC(CCl)C

It can be seen from the structural formula that TCPP has chiral centres. The producers have confirmed that TCPP is a mixture of stereoisomers.

A.2 SUMMARY OF THE JUSTIFICATION

A.2.1 Identified hazard and risk

A European Union Risk Assessment Report[1] (RAR) (HSA/EA, 2008) was carried out for tris(2-chloro-1-methylethyl) phosphate (herein referred to as 'TCPP') in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

Article 10(3) of the Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances states that:

[1] Work on the RAR began before enlargement of the EU to 27 Member States in 2006. Therefore the conclusions of the risk assessment are based on information regarding the former EU of 15 member states.

'Following a rapporteur's evaluation of the risk of that substance to man and the environment, it shall suggest a strategy for limiting these risks, including control measures and/or surveillance programmes, if appropriate'.

The RAR for TCPP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers to TCPP, during the manufacture of TCPP (worker scenario 1) in relation to fertility and developmental toxicity.

As a result of these conclusions, a strategy for limiting these risks is required.

It should be noted that in the case of the typical dermal exposure of workers during the manufacture of TCPP (worker scenario 1) the RAR concluded there was no need for risk reduction measures beyond those that are being applied already.

Regulation EC No. 793/93 on the evaluation and control of the risks of existing chemicals was repealed by the REACH Regulation (1907/2006) on 1st June 2008. Art 136(3) of the REACH Regulation lays down transitional measures regarding existing substances, stating that a Member State whose rapporteur has not forwarded by 1st June 2008 the risk evaluation and, where appropriate, the strategy for limiting the risks, in accordance with Article 10(3) of Regulation (EEC) No. 793/93 shall:

a) Document information on hazard and risk in accordance with Annex XV Part B of this Regulation
b) Apply Article 69(4) of this Regulation on the basis of the information referred to in point (a) and
c) Prepare a documentation of how it considers that any other risks identified would need to be addressed by action other than an amendment of Annex XVII of the Regulation.

As the risk evaluation and strategy for limiting risks was not forwarded by 1st June 2008, this transitional Annex XV report has been compiled in accordance with Article 136(3). In a letter dated 10th July 2008, the European Chemicals Agency (ECHA) invited all REACH Competent Authorities preparing transitional dossiers under Art 136(3) of the REACH Regulation to use a revised draft format for Annex XV restriction reports "to the extent that is possible". Hence the rapporteur has attempted to adhere to this request during the development of this transitional Annex XV report.

This transitional Annex XV report will outline the recommended strategy for limiting the risk associated with reasonable worst case dermal exposure during the manufacture of TCPP (worker scenario 1). This strategy has been developed through an interactive process with the industry consortium involved in the development of the RAR.

Throughout this transitional Annex XV report reference is made to particular sections of the RAR for TCPP; particularly in Sections B.4 (Environmental Fate Properties), B.5 (Human Health Hazard Assessment), B.6 (Human Health Hazard Assessment of Physico-chemical properties) and B.7 (Environmental Hazard Assessment). Section B.9 provides an assessment of the information relevant to dermal exposure of workers only, as this where the risk needs to be further controlled, as identified in the RAR.

A.2.2 Justification that action is required at community-wide basis

The RAR for TCPP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers to TCPP, during the manufacture of TCPP (worker scenario 1) in relation to fertility and developmental toxicity.

As a result of these conclusions, action is required at community-wide basis to ensure reduction of the exposure to a level that allows adequate control of identified risk.

A.2.3 Justification that a safe system of work is the most appropriate measure

Establishing a safe system of work is considered a proportionate measure to the risk to workers, identified for reasonable worst case dermal exposure. The RAR also concluded that there is no concern for workers working in nine downstream uses of TCPP. There is also no concern for humans via the environment or consumers. In addition, no concern for workers exposed to TCPP via the inhalation route was observed in the RAR. It is felt that a 'safe system of work' approach is a proportionate mechanism to address the identified risk to workers. This can be achieved through technical and/or organisational means, using the existing framework of occupational health and safety legislation as the basis.

Hence the rapporteur recommends that:

Existing Community legislation for workers' protection is generally considered to give an adequate framework to limit the risks of the substance to the extent needed.

PART B: INFORMATION ON HAZARD AND RISKS

B.1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

B.1.1 Name and other identifiers of the substance

Chemical Name: Tris(2-chloro-1-methylethyl) phosphate

EC Name: Tris(2-chloro-1-methylethyl) phosphate

CAS Number: 13674-84-5

IUPAC Name: Tris(2-chloro-1-methylethyl) phosphate

B.1.2 Composition of the substance

B.1.2.1 Impurities

Isomers

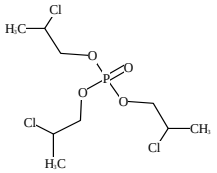
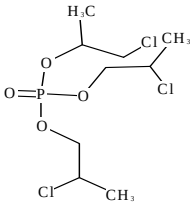
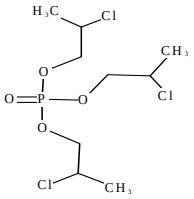
The flame retardant product supplied in the EU, marketed as TCPP (or other synonyms as given above), is actually a reaction mixture containing four isomers. The individual isomers in this reaction mixture are not separated or marketed. The individual components are never produced as such. These data are true for TCPP produced by all EU manufacturers.

TCPP as shown in the accompanying diagrams is 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 RAR 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. 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.

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 B.1 Compositional description for TCPP across all commercial products

Name	Structural diagram	EINECS number	CAS number	% (w/w)
Tris(2-chloro-1-methylethyl) phosphate	Shown above	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

Purity

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

Impurities

The impurity profile of the commercial product TCPP is specific to individual manufacturers. Details are given in the confidential annex of compositional data. It is not likely that the impurities will have had particular influence on any of the results obtained.

Additives

No additives are used.

B.1.3 Physico-chemical properties

The physico-chemical property values of TCPP that have been reported in the RAR for TCPP (HSA/EA, 2008) are summarised in **Table B.2.**

Table B.2 Summary of physico-chemical properties

REACH ref Annex, §	Property	IUCLID section	Value	Comments
VII, 7.1	Physical state	3.1	Liquid	
VII, 7.2	Melting point	3.2	-42°C pour point	Coomber, 1993. Result only
			<-30 pour point°C	Result only; of unknown source
			<-20°C**	Cuthbert and Mullee, 2002a
VII, 7.3	Boiling point	3.3	341.5°C	Coomber, 1993. Result only
VII, 7.4	Relative density	3.4 density	**Ca. 288°C** (decomp.)**	Boiled with decomposition. Cuthbert and Mullee, 2002a
			1.2932 Specific gravity 20/20	Coomber, 1993. Result only
			1.29	Result only; of unknown source; IPCS209 [x]
VII, 7.5	Vapour pressure	3.6	**1.288 at 20°C****	Cuthbert and Mullee, 2002a
			<689Pa	Result only; of unknown source.
			Ca. 3.3 Pa at 20°C	Krawetz, 2000. Result certificate only
			<100 Pa	Result only; of unknown source.
			3590 Pa	Rhodia MSDS
VII, 7.6	Surface tension	3.10	100 Pa	Akzo MSDS
			3.3 Pa	
			1.4 x 10^{-3} Pa at 25°C **	The result is consistent with the chemical structure of the main component and the other properties, in particular the boiling point. Tremain, 2002.
				No study available, but not expected to exhibit surface activity
VII, 7.7	Water solubility	3.8	1600 mg/l	Robson, 1994. Summary of methods and results only; no information on analytical method.
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	900 mg/l	Bayer MSDS
			1080 mg/l at 20°C**	Cuthbert and Mullee, 2002b.
			3.33	Robson, 1994. Summary of methods and results only; no information on analytical method or stock concentration.
			2.59	CITI, 1992. Result only; MITI experimental result
			2.68 ± 0.36**	Cuthbert and Mullee, 2002b
			2.89	Accepted calculation method (SRC KOWWIN v. 1.67)

REACH ref Annex, §	Property	IUCLID section	Value	Comments
VII, 7.9	Flash point	3.11	**No flash up to 245°C, then decomposes**	Tremain and Bartlett, 1994. Information about the composition of the sample used is not available
			199°C	Coomber, 1993. Result only
			185°C	Result only
	Autoflammability (autoignition temperature)	3.12	>400°C	Tremain and Bartlett, 1994. Information about the composition of the sample used is not available
VII, 7.10	Flammability	3.13	Non-flammable	Not expected to be flammable. Derogation accepted by TC NES
VII, 7.11	Explosive properties	3.14	Not explosive	Not expected to be explosive. Derogation accepted by TC NES
VII, 7.13	Oxidizing properties	3.15	No oxidising properties	Not expected to be oxidising. Derogation accepted by TC NES
XI, 7.17	Viscosity (kinematic viscosity)	3.22	68.5 cP at 20°C	Coomber, 1993. Result only
	Henry's law constant		3.96 x 10^{-4} $Pa.m^3/mol$ at 25°C	By calculation from VP and WS results

Studies marked ** were performed with a composite sample of purity 97.9% (total of the four isomers), derived from recent representative commercial products from the main producers.

[1] Klimisch code

B.1.4 Justification for grouping

Not relevant for this proposal.

B.2 MANUFACTURE AND USES

B.2.1 Manufacture and import of the substance

During the development of the RAR for TCPP, the four producers (see below, along with Clariant) participated as an industry consortium on the risk assessment of TCPP. This consortium assisted in the early stages of the study by sending out a questionnaire to users of TCPP. The results were collated confidentially by the rapporteur. More recently, the consortium has assisted with further consultation with the confidential downstream users. Relevant industry organisations (ISOPA, the European Di-isocyanate and Polyol Producers' Association; EUROPUR, the European Association of Flexible Polyurethane Foam Blocks Manufacturers; and BING, the Federation of European Rigid Polyurethane Foam Associations) acted as a focal point for input from downstream users of TCPP in the RAR.

Relationship between TCPP, TDCP and V6

In the RAR for TCPP, the substances TCPP, tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP) and 2,2-bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate (V6) were considered to be good candidates for a concurrent assessment in view of their similar use pattern and chemical similarity. All three substances are used predominantly in various types of polyurethane foam applications in the EU (>97.5% of TCPP; >85% of TDCP and >95% of V6). Chlorinated alkyl phosphate esters (particularly TCPP) were identified as possible substitutes for pentabromodiphenyl ether (pentaBDE) in the risk reduction strategy for that substance (EC 2001). However it has since become clear, from discussion with the industry, that in the EU these chemicals are not direct replacements for pentaBDE, and that changes in consumption are linked mostly with the decline in tris (2-chloroethyl) phosphate (TCEP) use and increase in the market for polyurethane (PUR) generally (communication, herein referred to as 'comm.', 1st March 2004). As discussed in **Section 2.1.2** of the RAR for TCPP, consumption levels appear to have stabilised in recent years; this risk assessment represents a realistic upper limit of EU production and consumption and significant increases are not anticipated in the near future.

B.2.1.1 Manufacturing process

All commercial TCPP is produced by the reaction of phosphorus oxychloride with propylene oxide followed by purification (WHO 1998). Both batch and continuous processes can be used in the manufacture of TCPP (UNEP 1999).

Data on the TCPP production process has been provided by three of the four producers, which indicate that production is carried out along the lines suggested in UNEP (1999). 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.

B.2.1.2 Manufacturing capacity

There are four producers of TCPP in the EU:

- ICL-IP/Supresta, whose TCPP business was owned earlier in the assessment process by Akzo Nobel

- Albemarle, whose TCPP business was owned earlier in the assessment process by Rhodia, and previously by Albright and Wilson
- Lanxess, whose TCPP business was owned earlier in the assessment process by Bayer
- BASF, which sells through Elastogran.

Total EU production of TCPP in the year 2000 was 36,000 tonnes, with production taking place at three sites in Germany and one in the UK. 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 RAR represents the upper limit of sales in the five year period for which data are available. The rapporteur has no reason to anticipate significant tonnage increases in the near future, based on industry information and general research.

Discussions with the Phosphate Ester Flame Retardant Consortium (PEFRC) indicate that there is unlikely to be any future increase due to substitution for TCEP, replacement having been completed for all the applications for which replacement is possible.

B.2.1.3 Imports

8,304 tonnes of TCPP were imported into the EU in 2001. Data provided by CEFIC (comm. 19th February 2002, 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 (comm. 27th February 2002, Akzo Nobel and comm. 28th February 2002, PEFRC), though it has since been indicated that the main non-consortium TCPP imports have altered from Russia to Poland (EFRA 2006a and b).

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.

Table B.3 EU production and consumption of TCPP in the year 2000

Life Cycle Stage	Tonnes
Production	36,038
Imports	8,304
Exports	6,211

A further quantity of 1,201 tonnes of TCPP is believed to be imported into the EU in finished goods and this is accounted for in the risk assessment:

- Up to 680 tonnes per annum is imported into the UK in furniture sourced from outside the EU (see **Section 2.2.2.2.6** of the RAR for TCPP)
- Around 500 tonnes of TCPP is imported in canned (one component) foams (see **Section 2.2.2.5.6** of the RAR for TCPP)
- It is possible that finished goods containing TCPP in rebonded foam may be imported into the EU. This is not accounted for in the assessment as there is too little information, although it is not likely to be significant.

B.2.2 USES

B.2.2.1 Introduction

TCPP is an additive flame retardant, i.e. it is physically combined with the material being treated rather than chemically combined. The amount of flame retardant used in any given application depends on a number of factors such as the flame retardancy required for a given product, the effectiveness of the flame retardant and synergist within a given polymer system, the physical characteristics of the end product (e.g. colour, density, stability, etc.) and the use to which the end product will be put.

Over 40,000 tonnes of TCPP were consumed in the EU in the year 2000. Most TCPP (over 98%) is used as a flame retardant in the production of polyurethane (PUR) for use in construction and furniture.

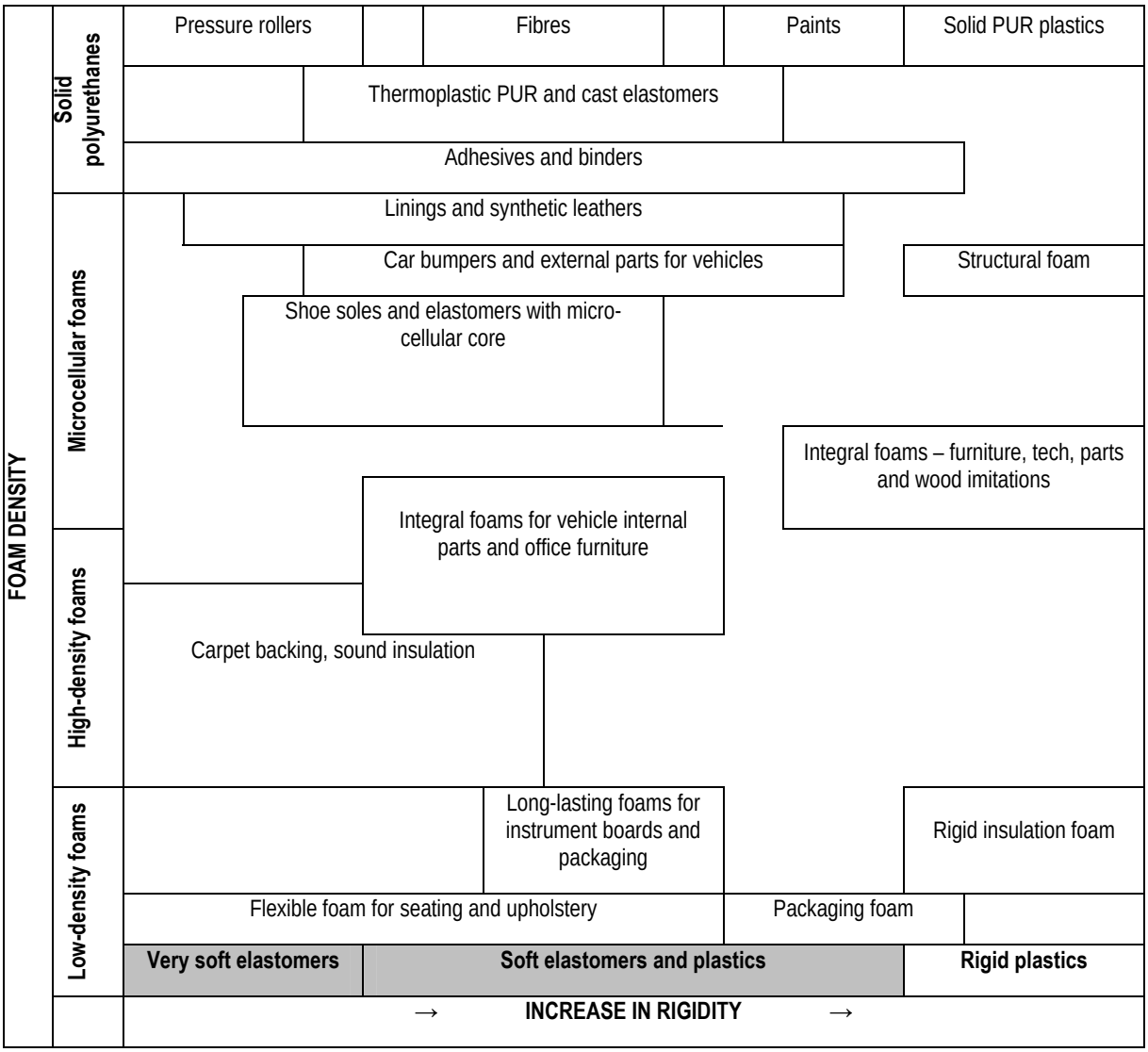
PUR is produced from the reaction of di-isocyanates with polyols. TCPP can be added to polyols in the production of PUR systems (formulations, refer to **Section 2.2.2.1** of the RAR; around 50-60% of TCPP is used in this way), or added directly at the point of foaming.

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.

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 (comm. 19th March 2002, Rhodia). The low tonnage associated with these other uses across all producers confirms that TCPP is not widely used outside the PUR industry.

Figure B.1 below, which is a simplified diagram taken from Koschade (2002), shows the variation of end uses associated with PUR over a range of density and rigidity.

Figure B.1 Examples of the application of polyurethanes by density and rigidity



The life cycle stages considered in this assessment are reported in **Table B.4** and shown in **Figure B.2**. Further information including information on the confidential life cycle stages is given in the confidential annex of the RAR for TCPP (HSA/EA 2008). The tonnages used in the RAR are principally derived from survey data relating to the consumption in the year 2000.

As all members of the industry consortium have provided a detailed breakdown of tonnage it is believed that the life cycle is well defined. However, no data was provided by CEFIC concerning the downstream uses of the TCPP imported from Russia (the main non consortium TCPP imports have since altered from Russia to Poland) (see **Section 2.1.2.2** of the RAR). In addition, some TCPP is sold by members of the industry consortium to traders and distributors. Together these account for over 10% of the TCPP tonnage. In the absence of information concerning the downstream uses of this TCPP it is assumed that this is consumed in Uses A to E in the same proportions as for the TCPP arising from uses specified by the industry consortium.

Table B.4 Use pattern for TCPP

Ref. Env[1]	Ref. HH[2]	Industry Category	Use category	Description	Percentage of total use	Tonnage
A	5	11	22	PUR systems (formulation)	[51.1%][3]	20450
B	2,3	11	22	PUR foam for use in furniture	17.0%	6800
C	7,8	11	22	Rigid PUR foam for use in construction	66.5%	26,650
D	6	11	22	Spray foams	9.6%	3850
E	9,10	11	22	One component foams	4.7%	1900
F	-	Confidential	22	Confidential	<2.5%	
G	-	Confidential	22	Confidential		
H	-	Confidential	22	Confidential		
I	-	Confidential	22	Confidential		
J	-	Confidential	22	Confidential		
K	-	Confidential	22	Confidential		
L	-	Confidential	22	Confidential		
M	-	Confidential	47	Confidential		
N	-	Confidential	22	Confidential		
P	-	Confidential	22	Confidential		
O	4	11	22	Rebonding of flexible foam	This is a form of recycling	
Q	-	11	22	Adhesive pressing of waste rigid foam	This is a form of recycling	
R	-	11	22	Recycling as loose crumb	This is a form of recycling	
Total					100%[3]	

Industry Category 11 = polymers industry Use category 22 = flame retardants and fire preventing agents Use category 47 = softeners

Notes:

1 – Reference letter used in the Environmental risk assessment

2 – Reference number used in the Human Health risk assessment

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

Product Register Data

Data from product registers have been provided by Denmark, Sweden and Switzerland. This information is summarised in **Table B.5**, together with data from the SPIN database (data about the use of substances in Norway, Sweden, Denmark and Finland).

Data for Sweden (year 2000) and Denmark account for 1,312 tonnes of TCPP (around 3.5% of EU consumption in the year 2000). Data for Sweden in 1999 are for TDCP combined with TCPP and are therefore of limited use.

It is notable that the industry's view is that not all uses here are current or recommended uses: in particular foaming agent, concrete, intermediate plastic manufacture, metal products, wood applications and cement are considered not to apply (EFRA, 2006).

Table B.5 Product register and SPIN data

Country	Tonnage	No. of Products[a]	Concen-tration[b]	Description	
Denmark	499	15	5 –10% (4) 10-20% (9) 20-100% (2)	Fillers	Building and civil engineering Manufacture of rubber and plastic products Manufacture of chemicals and chemical products Manufacture of machinery and equipment Manufacture of transport equipment Private household
	277	22	1 –10% (9) 10-20% (10) 20-100% (3)	Insulating materials	
	190	3	5-50%	Foaming agents	
	185	13	5-10% (8) 10-50% (5)	Adhesives, binding agents	
	23	7	5-20% (7)	Construction materials	
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 households with employed persons
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 households with employed persons
Finland 2001 (SPIN)	812.9	13		775.0 t (6 preparations)	Manufacture of rubber and plastic products
					Manufacture of fabricated metal products, except machinery and equipment
				17.3 t (4 preparations)	Construction
Finland 2000 (SPIN)	Not stated	11		4 preparations	Manufacture of rubber and plastic products
				1 preparation	Manufacture of electrical machinery and apparatus
				4 preparations	Construction
Sweden[c] 1999	350	45 (9)	-	Plastics, concrete, textiles and insulation materials	
Sweden 2000	-	3 (0)	-	Use: raw material (fire prevention additive in plastics). Trade code: Industry for plastic products; industry for other chemical products.	
	67	20 (0)	-	Use: intermediates (plastics manufacture). Trade code: Wholesale of chemical products; industry for plastic products; export.	

Country	Tonnage	No. of Products[a]	Concen-tration[b]	Description	
	42	10 (0)	-	Use: binders (paints, adhesives); adhesives; hardeners (for adhesives). Trade code: Industry for other non-metallic mineral products; industry for fabricated metal products (except machinery and equipment); industry for wood and products of wood, cork, cane, etc. except furniture; industry for electrical machinery and apparatus.	
	13	12 (4)	-	Use: insulating materials; jointing materials: Trade code: construction industry; export.	
	8	12 (8)	-	Use: caulking compounds; sealing compounds. Trade code: construction industry; wholesale and retail trade, repair shops for motor vehicles, motorcycles and personal and household goods; export.	
	2 to 8	2 (1)	-	Use: other. Trade code: paint stores; industry for wood and products of wood, cork, cane, etc. except furniture export.	
Sweden 2000 (SPIN)	195.0	60[e]		26.0 t	Manufacture of chemicals and chemical products
				84.0 t	Manufacture of rubber and plastic products
				7.0 t	Construction
				29.0 t	Wholesale trade and commission trade, except of motor vehicles and motorcycles
				6.0 t	Retail trade, except of motor vehicles and motorcycles; repair of personal and household goods
Sweden 1999 (SPIN)	185.0	60[e]		25.0 t (4 preparations)	Manufacture of chemicals and chemical products
				91.0 t (23 preparations)	Manufacture of rubber and plastic products
				8.0 t (18 preparations)	Construction
				29.0 t (7 preparations)	Wholesale trade and commission trade, except of motor vehicles and motorcycles
				4.0 t (4 preparations)	Retail trade, except of motor vehicles and motorcycles; repair of personal and household goods
Norway 2001 (SPIN)	50.5	21[e]		23.6 t (5 preparations)	Manufacture of chemicals and chemical products
				5.4 t (5 preparations)	Manufacture of rubber and plastic products
				14.4 t (11 preparations)	Construction
Norway 2000 (SPIN)	43.6	14		12.8 t (4 preparations)	Manufacture of chemicals and chemical products
				10.4 t (5 preparations)	Manufacture of rubber and plastic products
				15.9 t (8 preparations)	Construction
Switzerland	-	25 (10)	1-10% (4) 10-50% (21)	Use in glue, surfacer, cement, sealing mass	

Country	Tonnage	No. of Products[a]	Concen-tration[b]	Description
	-	26 (0)	1-10% (2) 10- 50% (23) 50-100% (1)	Use in polymers
	-	4 (0)	1-10% (2)	Use in paints, dyes, varnish
	-	8 (0)	1-10% (1) 10- 50% (3) 50-100% (3)	Not defined
Total[d]	1312			

a: Total number of products (number of consumer product).

b: Danish and Swiss data – number in brackets is number of products at this concentration

c: Combined data with TDCP

d: Uses data for Sweden for the year 2000

e: Confirmed in SPIN database that some preparations are for consumer use, but number not presented

The product register data indicates that most products are available for professional use only, with limited use of products by consumers, in one-component foams for example (see **Section 2.2.2.5** of the RAR).

On the basis of the general description of uses reported in the product registers and the detailed descriptions of use pattern given by producers it is believed that the product register data do not provide new information concerning uses of TCPP.

A life cycle assessment study by SP, Sweden and IVL-Swedish Environmental Research Institute, Sweden (Simonson *et al.*, undated) investigated emission of pollutants associated with different life cycle stages of sofas. Three sofas were tested, two of which were made with TCPP-containing foam. The purpose was to assess pollutant emissions at all stages of the sofas' life cycle, including in the event of fire. Emissions of the flame retardant (FR) itself were not investigated. The information and assumptions regarding the life cycle are useful for comparison with the assessment made in the current risk assessment. A schematic representation shows the life cycle stages of relevance for the flame retardant as:

- Flame retardant production
- material (i.e. foam) production
- production of primary product (i.e. item of furniture)
- use of primary product (i.e. in-service)
- recycling processes (see below)
- incineration; landfill/landfill fire
- fire of primary products.

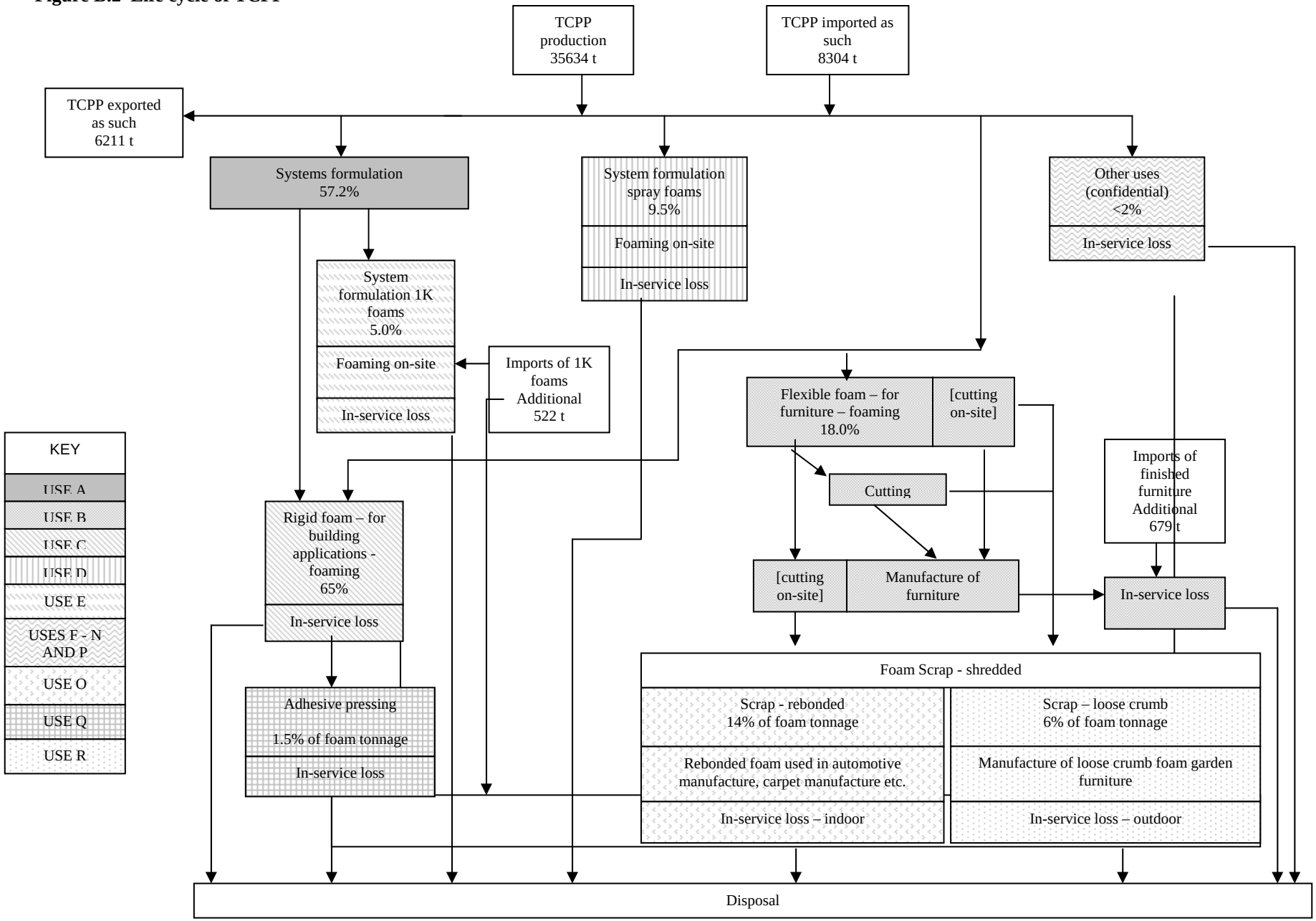
B.2.3 Uses advised against

As of the date of this transitional Annex XV report, two of the four manufacturers of TCPP indicated that they only support the use of TCPP in polyurethane foam applications. It was indicated by these manufacturers that the final decision to include uses advised against will

depend on the supply chain communication (i.e. if the manufacturers are approached by customers wanting to use it for other purposes, they may advise against other uses) (pers. comm. 28th October 2008, Albemarle; pers. comm. 11th November 2008, ICL-IP).

Another manufacturer of TCPP would only support the use of TCPP in polyurethane foam and would advise against its use in toys (pers. comm. 8th October 2008, Lanxess). The remaining manufacturer of TCPP would advise against its use in toys and consumer goods for food contact. This manufacturer indicated that it may not be the case that TCPP is unsuitable in every possible application in those fields however this manufacturer wants to make sure that downstream users consult them before using TCPP in these applications. An endorsement from this manufacturer would depend on detailed evaluation of the toxicological risk, product liability and legal situation of the region effected (pers. comm. 17th November 2008, BASF).

Figure B.2 Life cycle of TCPP



B.3 CLASSIFICATION AND LABELLING

TCPP is not listed in Annex I of Directive 67/548/EEC.

B.3.1 Proposed classification for human health

An Annex XV proposing a harmonised classification and labelling for TCPP has been prepared by the rapporteur and submitted to ECHA, to be discussed by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee in due course. In this Annex XV C&L dossier the rapporteur proposes no classification for the harmonised classification endpoints (i.e. CMRs or respiratory sensitiser).

In addition the data summarised in the RAR for TCPP is consistent with the classification R22 (harmful of swallowed), which led Industry to self-classify TCPP as Xn; R22.

B.3.2 Classification for the environment

The Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals agreed that TCPP did not meet the criteria for classification as dangerous for the environment on 28-30th September 2005.

B.3.3 Industry's self classification(s) and labelling

The manufacturers of TCPP have self-classified TCPP as Xn; R22 (pers. comm. 25th September 2008, ICL-IP; pers. comm. 8th October 2008, Lanxess; pers. comm. 28th October 2008, Albemarle; pers. comm. 17th November 2008, BASF).

B.4 ENVIRONMENTAL FATE PROPERTIES

Please refer to **Section 3.1.3** of the RAR for TCPP.

B.4.1 Degradation

Please refer to **Section 3.1.3.1** of the RAR.

B.4.2 Environmental distribution

Please refer to **Section 3.1.3.2** of the RAR.

B.4.3 Bioaccumulation

Please refer to **Section 3.1.3.3** of the RAR.

B.4.3.1 Aquatic bioaccumulation

Please refer to **Section 3.1.3.3.1** of the RAR.

B.4.3.2 Terrestrial bioaccumulation

Please refer to **Section 3.1.3.3.2** of the RAR.

B.4.4 Secondary poisoning

Please refer to **Section 3.1.7** of the RAR.

B.5 HUMAN HEALTH HAZARD ASSESSMENT

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Please refer to **Section 4.1.2.1** of the RAR.

B.5.2 Acute toxicity

Please refer to **Section 4.1.2.2** of the RAR.

B.5.3 Irritation

Please refer to **Section 4.1.2.3** of the RAR.

B.5.3.1 Skin

Please refer to **Section 4.1.2.3.1** of the RAR.

B.5.3.2 Eye

Please refer to **Section 4.1.2.3.2** of the RAR.

B.5.3.3 Respiratory tract

Please refer to **Section 4.1.2.3.3** of the RAR.

B.5.3.4 Summary and discussion of irritation

Please refer to **Section 4.1.2.3.4** of the RAR.

B.5.4 Corrosivity

Please refer to **Section 4.1.2.4** of the RAR.

B.5.5 Sensitisation

Please refer to **Section 4.1.2.5** of the RAR.

B.5.6 Repeated dose toxicity

Please refer to **Section 4.1.2.6** of the RAR.

B.5.7 Mutagenicity

Please refer to **Section 4.1.2.7** of the RAR.

B.5.8 Carcinogenicity

Please refer to **Section 4.1.2.8** of the RAR.

B.5.9 Toxicity for reproduction

A 2-generation reproductive toxicity study with TCPP found 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 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.

In the same study, an increase in the number of runts was observed in all dose groups of F0 generation on PN1 and persisted to PN21 in the mid and high dose groups. In the F1 generation, the number of runts was increased in the high dose group on PN14 and all dose groups on PN21. A decrease in mean pup weight was noted in high dose group of F0 from PN14 onwards and of F1 from PN 7. Mean pups weights were decreased in the mid dose group of both generations on PN21. 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. No missing 13^{th} rib or cervical ribs were observed in the skeletons of the F1-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 is derived for developmental toxicity.

Please refer to **Section 4.1.2.9** of the RAR for detailed information.

B.5.10 Other effects

Not relevant for this proposal.

B.5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response

B.6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

B.6.1 Explosivity

Please refer to **Section 4.2.2.1** of the RAR.

B.6.2 Flammability

Please refer to **Section 4.2.2.2** of the RAR.

B.6.3 Oxidising properties

Please refer to **Section 4.2.2.3** of the RAR.

B.7 ENVIRONMENTAL HAZARD ASSESSMENT

B.7.1 Aquatic compartment (including sediment)

Please refer to **Section 3.3.1** of the RAR.

B.7.2 Terrestrial compartment

Please refer to **Section 3.3.2** of the RAR.

B.7.3 Atmospheric compartment

Please refer to **Section 3.3.3** of the RAR.

B.7.4 Microbiological activity in sewage treatment systems

B.7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

B.8 PBT AND VPVB ASSESSMENT

B.8.1 Assessment of PBT/vPvB properties – Comparison with criteria of Annex XIII

Not relevant for this proposal.

B.2 Emission characterisation

B.9 EXPOSURE ASSESSMENT

B.9.1 General discussion on releases and exposure

In the RAR for TCPP exposure assessment was carried out by the bringing together of measured exposure data and predictions from the EASE (Estimation and Assessment of Substance Exposure) model. EASE is a general purpose predictive model for workplace exposure assessments. Occupational exposure information has been made available through the manufacturers and users of TCPP.

TCPP is a liquid at room temperature with a low vapour pressure of 1.4×10^{-3} Pa at 25^0C and a calculated saturated vapour concentration (SVC) of 0.19 mg/m^3 at 21^0C.

Occupational exposure to TCPP may occur during its manufacture and during the manufacture and cutting of flexible and rigid polyurethane (PUR) foam. Inhalation of vapours and liquid aerosols and skin contact are the predominant routes of exposure during manufacture of TCPP and manufacture of foam, while inhalation of dust and skin contact are thought to be the predominant routes of exposure during foam conversion and cutting of rigid foam. Oral exposure is not considered to be a significant route of exposure under normal working practices. The total number of people occupationally exposed to TCPP is not known but it is likely to be thousands if the foam cutting companies and construction workers using laminates are taken into account.

Descriptions of the processes and sources of occupational exposure are discussed below along with a discussion of exposure levels. All of the measured data used in this assessment has been supplied by industry, either directly or through trade organisations. The occupational exposure scenarios are:

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

Following manufacture, most TCPP (over 98%) produced in the EU is used as a flame retardant in the production of polyurethane (PUR) for use in construction and furniture. PUR is produced from the reaction of di-isocyanates with polyols. TCPP can be added to polyols in the production of PUR systems (around 50-60% - see section 4.1.1.1.5 below) or added directly at the point of foaming.

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 market.

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 decided to use it. Industry has indicated that other possible applications include paints, unsaturated polyester resins and epoxy resins. No further information is available on these uses or the number of workers potentially exposed to TCPP through these uses. The very low tonnage involved confirms that TCPP is not widely used outside the PUR industry and so the uses were not considered further for the purpose of the RAR for TCPP.

The total number of workers potentially exposed to TCPP during the production of PUR foam in the EU is difficult to estimate. Industry has informed the rapporteur that for flexible foam, EUROPUR members (representing about 85% of the market) have about 68 plants in the EU. Some plants use TCPP more frequently than others. A fair assumption may be that approximately 5 operators per plant can be around the foaming tunnel during production, bearing in mind the frequency of use of TCPP will vary somewhat from plant to plant. This gives an estimated total of 340 workers exposed to TCPP through the manufacture of flexible polyurethane foam in the EU.

For the production of rigid foam, a recent survey has shown that there are about 190 rigid foam manufacturing plants in the EU (ISOPA survey, 2003). Again, it is difficult to estimate the total number of operators potentially exposed to TCPP in these plants, as not all plants use TCPP. A reasonable estimate would be that about 10 workers or 2 per shift would work in the foam production area. This gives an estimated total of 1,900 workers exposed to TCPP through the manufacture of rigid polyurethane foam in the EU.

B.9.1.1 Summary of the existing legal requirements

B.9.1.1.1 Directive 67/548/EEC on Classification Packaging and Labelling of Dangerous Substances

An Annex XV proposing harmonised classification for human health (HSA, 2008c) has been prepared for TCPP by the rapporteur and has been submitted to ECHA, to be reviewed by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee (SEAC) in due course. In this Annex XV C&L dossier the rapporteur proposes no classification for the harmonised C&L endpoints (i.e. CMRs and respiratory sensitiser).

All manufacturers of TCPP have indicated that they have self-classified this substance as Xn; R22 (pers. comm. 25th September 2008, ICL-IP; pers. comm. 8th October 2008, Lanxess; pers. comm. 28th October 2008, Albemarle; pers. comm. 17th November 2008, BASF). The data summarised in the RAR for TCPP is consistent with the classification R22 (harmful of swallowed).

The Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals agreed that TCPP did not meet the criteria for classification as dangerous for the environment on 28-30 September 2005.

As TCPP meets certain criteria for classification as dangerous, it should be packaged and labelled in accordance with Directive 67/548/EEC.

B.9.1.1.2 Safety data sheets

Article 31 of Regulation (EC) No. 1907/2006 (herein called the REACH Regulation) states that any supplier of a substance or preparation shall provide the recipient of the substance or preparation with a safety data sheet (SDS) compiled in accordance with Annex II, where the substance or preparation meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or 1999/45/EC. Such a recipient could be a downstream user of the substance e.g. manufacturer of flexible PUR foams.

The four manufacturers of TCPP provided an up-to-date SDS for TCPP (pers. comm. 19th September 2008, Albemarle; pers. comm. 8th October 2008, Lanxess; pers. comm. 30th October 2008, ICL-IP and pers. comm. 17th November 2008, BASF) in which classification Xn; R22 is

communicated to recipients in addition to information on hazards, composition, first-aid, fire fighting and accidental release measures, handling and storage, personal protection, physical and chemical properties, stability and reactivity, toxicology, ecotoxicology, disposal and transport.

In addition, article 35 of the REACH Regulation states that workers and their representatives must be granted access by their employer to hazard and exposure information for a substances and/or preparations he/she uses or may be exposed to in their course of work.

B.9.1.1.3 Occupational safety and health legislation

Regarding the production and use of TCPP the following Directives are primarily applicable as general legislation for occupational safety and health at European level.

B.9.1.1.3.1 Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work

Directive 89/391/EEC requires that employers take all measures necessary for the safety and health protection of workers. This should include measures for the prevention of occupational risks and the provision of information and training. In addition, employers should ensure the necessary organization and means are in place to ensure the safety and health protection of workers. The employer shall be alert to the need to adjust these measures to take account of changing circumstances, where necessary and should aim to always seek improvements to existing situations.

B.9.1.1.3.2 Directive 98/24/EC on the protection of workers from the risks related to exposure to chemical agents at work

Directive 98/24/EC lays down obligations on the employer regarding the determination and assessment of risk of hazardous chemical agents. It lists the general principles for preventing risks associated with hazardous chemical agents, which includes the following mechanisms which an employer should use to eliminate the risk or reduce it to a minimum:

- The design and organisation of systems of work at the workplace
- The provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work
- Reducing to a minimum the number of workers exposed or likely to be exposed
- Reducing to a minimum the duration and intensity of exposure
- Appropriate hygiene measures
- Reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned
- Suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents

Where the nature of the activity does not permit risk to be eliminated by substitution, Directive 98/24/EC requires that the employer ensures that the risk is reduced to a minimum by application of protection and prevention measures in the following order of priority:

- Design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimise the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work

- Application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organisational measures

- Where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment

B.9.1.1.3.3 Directive 89/656/EEC on the use of Personal Protective Equipment

Directive 89/656/EEC requires that personal protective equipment shall be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation. Personal protective equipment must be appropriate for the risks involved and must correspond to the existing conditions of the workplace. The conditions of use of personal protective equipment in particular the period for which it is worn, shall be determined on the basis of the:

- Seriousness of the risk
- Frequency of exposure to the risk
- Characteristics of the workstation of each worker
- Performance of the personal protective equipment

B.9.1.1.4 Occupational Exposure Limit Values

An occupational exposure limit value (OELV) can be defined as an exposure standard for a chemical in workplace air, with reference to either an 8-hour reference period or a 15 minute reference period. OELVs provide a basis for ensuring that exposure to airborne contaminants in the workplace is controlled in such a way as to prevent adverse health effects. An OELV for a particular chemical represents the maximum exposure to the chemical in workplace air, which is considered consistent with this objective. In practice, exposure levels should be maintained well below the OELV and should always be as low as reasonably achievable (HSA, 2007).

There are currently no occupational exposure limit values for TCPP.

B.9.1.1.5 National legislation in Member States

The rapporteur consulted representatives from Member States, in order to ascertain whether any current or planned national regulations (or other measures) existed in other Member States, aimed at reducing the risks to workers from the manufacture of TCPP. Responses were received from Cyprus (pers. comm. 27th August 2008, Permanent Representative for Cyprus), United Kingdom (pers. comm. 8th September 2008, Health and Safety Executive), Denmark (pers. comm. 10th September 2008, Danish Ministry of the Environment) and Estonia (pers. comm. 12th September 2008, Ministry of Social Affairs of Estonia). All indicated that they do not have any current or planned national regulations or other measures to reduce the risks to workers from the manufacture of TCPP. The same situation applies in Ireland.

B.9.1.2 Summary of the effectiveness of the implemented risk management measures

The information presented in the RAR suggests that risk reduction measures were not being effectively implemented at the time when exposure monitoring was taken. Poor hygiene procedures observed during the monitoring of operators are thought to be the reason for the (reasonable worst case) dermal risk to workers involved in the manufacture of TCPP. It is felt that the existing legal requirements should be sufficient to ensure reduction of the exposure to a level that allows adequate control of the identified risk, if implemented correctly.

B.9.2 Manufacturing

TCPP is manufactured by four producers in the EU. In the year 2000, the total EU production 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%.

In all production facilities, TCPP is produced by reacting phosphorous oxychloride with propylene oxide followed by purification. The crude product is washed and dehydrated to remove acidic impurities and residual traces of catalyst. The product is then filtered, transferred to storage tanks for despatch in road tankers or packed into drums. There are some slight differences in procedures between the four different production plants. A brief description of production processes is given below for each facility and comments made in the summary part regarding the differences and typical procedures.

B.9.2.1 Occupational Exposure

B.9.2.1.1 Measured dermal exposure data

Dermal exposure measurements were only taken at one of the four production plants (production plant 1).

Production plant 1

In a study conducted by industry (2002) hand exposures of 2 operators in one of the TCPP manufacturing plants were evaluated under actual working conditions. At this plant, TCPP is produced in a closed system. It is produced in batches, with 3 batches being run simultaneously. All transfers are done using closed lines. Storage is in closed vessels under nitrogen to exclude moisture and air. The processes are computer-controlled. The computers monitor and control reactors, reaction conditions such as temperature and pressure, chemical additions and process alarms. This limits the possibilities of operator contact with TCPP during the production steps.

Only one operator per shift is assigned to the plant and he spends most of his time in the control room. Highest dermal exposures are likely to occur during drumming and activities such as material sampling and maintenance. Samples are taken from a sampling valve into a 250 g bottle. There is no local exhaust ventilation at the sampling point. The operator wears PVC gloves, safety spectacles, hard hat and work coveralls. Sampling takes less than 1 minute to complete. Analysis is carried out by a laboratory technician. Extraction ventilation and personal protective equipment are employed to reduce exposure. At the fluids plant, blending and drumming occurs. There are 2 filling stations and both are semi-automatic and equipped with local exhaust ventilation. The plunger is also designed in such as way as to avoid drops falling down when the lance is transferred from one drum to another. Although the operator moves the lance from drum to drum, it is carried out using a boom so that the operator does not come into contact with the lance. The operator does secure lids and fits seals to the drums.

In total it has been estimated that the total time spent on maintenance in a year for the three production lines is between 20 and 40 hours per year. The PPE worn depends on the type of maintenance being carried out, but is a minimum of gloves, hard hat, safety spectacles, safety shoes and coveralls.

In total (including operators and supervisors, lab personnel and maintenance workers), there are approximately 30 people who could be potentially exposed to TCPP in this plant.

Operators monitored were involved in production and blend drumming (one operation of blend drumming was monitored; blend contained 10% TCPP). For dermal exposure monitoring, 100% cotton absorbent gloves were used as dosimeters. If protective gloves were used, the absorbent gloves were worn beneath them. The absorbent gloves were peeled off and replaced at times when the worker normally washed his hands and were placed in a plastic bag. They were extracted with toluene before chromatography.

The method for dermal monitoring has been developed and validated by industry for TCPP. The method for determination of TCPP concentration is Akzo Nobel Method CG/6.089.3. The limit of detection was evaluated to be 0.1 μg for TCPP and 3 μg on cotton gloves.

Table B.6 below gives a summary of the results for the dermal monitoring.

Table B.6 Results of personal dermal monitoring carried out on operators involved in production of TCPP and blend drumming

Operator's Task	Length of time monitored (mins)	Dermal exposure TCPP (mg/kg bw)
Production	500	0.02
Blend drumming	177	0.20

During the monitoring period the production operator supervised the production of 3 batches, pumped TCPP into the tank and sampled TCPP three times (including from the funda filter and from the tank). During these activities, he wore protective gloves (Vygen plus PVC gloves, cotton lined). The operator carrying out the task of blend drumming filled 23 drums of 300 kg each for a period of 3 hours (this was equivalent to 690 kg of TCPP). He also attached labels to the drums. He was monitored for 177 minutes (3 hours), which is the length of time taken to carry out his work with TCPP. For the remainder of his shift he worked at the drumming station, but handled substances other than TCPP. He did not wear PPE while carrying out these tasks. Industry has indicated that theoretically, an operator could be working with TCPP for a full 8-hour shift, depending on requirements.

Production plant 2

In a second TCPP production plant, TCPP is produced in a batch-wise manner. The system is a closed one, except for loading stations. All of the processes are computer controlled, with a specific operator permanently present in the control room. The filling stations are automatic and equipped with LEV. There are approximately 30 operators potentially exposed to TCPP in this production plant.

There are 4 maintenance personnel on site, who work in conjunction with maintenance contractors, suppliers etc. It is estimated that up to 10 people may be exposed to TCPP in relation to their maintenance work activities (industry information). They may spend up to 7 hours per day carrying out work that could expose them to TCPP. They work under a permit to work regime and there are systems in place to ensure that pipework/vessels are purged prior to maintenance work. The

personal protective equipment worn depends on the type of work being carried out but would include helmets, goggles and coveralls, and may also include gloves and respiratory protective equipment as required.

No dermal exposure was measured at Production plant 2.

Production plant 3

In a third manufacturing facility, some of the equipment is in an open-air plant and some in a closed building with ventilation (8 air changes per hour). The equipment is operated from a measuring station. TCPP is produced continuously in what industry has described as a substantially closed system. The manufactured TCPP is conveyed to receivers in the basement via fixed pipelines and from there to the storage tank. This is a closed transfer system. The product is decanted into drums, polyethylene containers and road tankers, as required. Drums and polyethylene containers are filled automatically by siphoning. The operator stages empty containers and monitors filling from a control console. Filling time depends on the order, but can last an entire shift. Road tankers are filled via fixed pipeline and a loading spout. The lid on the top of the tanker is covered by a conical hood through which the filling pipeline, level indicator and the pipe for displaced air are fed (open-air).

While the tanker is being filled, the operator performs follow-up and completion work (time < 15 mins). Samples are taken using an open flask (4 samples every 2 hours) by the operator during inspections for unit monitoring (time < 1 min). During filling and sampling the worker wears coveralls, safety glasses, safety shoes and helmets. A laboratory worker takes a sample from the pure product containers twice a day. The sampling time is < 2 mins and analysis takes about 15 mins. These samples are taken using an evacuated flask which is attached to the sampling point via tubing. There is a slight chance of exposure when the flask is withdrawn from the sampling point. Laboratory staff wear coveralls, gloves, goggles and respiratory protective equipment while taking samples. The analysis takes place in a fume cupboard. While carrying out the analysis the laboratory worker wears coveralls, gloves and goggles.

No dermal exposure measurements were taken at Production Plant 3.

Production plant 4

One other production company produced a flame retardant blend containing 50% TCPP. TCPP was mixed with one mass-equivalent of another flame retardant. The plant is a closed system, where the raw materials are pumped via pipes to the mixing vessels and from there to storage tanks. The operator spends about 50% of his time in a control room from where he monitors the process. The remaining 50% of the time, he spends in the plant.

During the process of blend production, overpressure is released via a safety valve. It occurs when the storage tanks are being filled, an event which occurs once daily (max) and takes about 10-15 mins. The TCPP concentration in the release air was monitored twice (both times for 4 hours) and the personal exposure of the worker running this operation over 4 hours was monitored once (there is only one operator involved in this work at any one time). The release of air via safety valves occurs at a level about 3-4 metres above the head of the operator. Industry has indicated that during this time, the operator is located in the control room, monitoring the process. Quality control samples are taken twice per day. The operator wears gloves when taking samples, with respiratory protective equipment available if required. Following manufacture about 50% of the blend is distributed exclusively by road tankers with the other 50% being transferred by pipeline for polyol blending. The TCPP blend is transferred via an automatic pumping station to the road tankers so there is little opportunity for exposure.

There is no daily maintenance carried out on the plant. Planned maintenance is carried out about once per year. Prior to maintenance starting, the TCPP is pumped out of the pipelines and the pipelines are flushed through with water. Checks are carried out to ensure that the OELs for methyl oxirane and phosphorus oxy-chloride are met. Maintenance staff is equipped with chemical suits, goggles and nitrile rubber gloves to carry out their work.

No dermal exposure measurements were taken at Production Plant 4.

B.9.2.1.1.1 Summary of measured dermal exposure to TCPP during its manufacture

For dermal exposure, measured in plant 1, an operator involved in production was exposed to 0.2 mg/kg bw TCPP while an operator involved in blend drumming was exposed to 0.2 mg/kg bw. The production operator wore protective gloves while carrying out his tasks, while the operator involved in blend drumming did not.

B.9.2.1.2 Modelled dermal exposure data

For workers involved in the manufacture of TCPP, the appropriate EASE scenario would be a closed system (breached for sampling and maintenance) with no direct handling. For this, EASE has predicted the dermal exposure to be very low.

For sampling of TCPP during the manufacturing process, default values are taken from the TGD for the scenario quality control sampling of liquids. It is considered however, that the contact is intermittent, rather than incidental, with non-dispersive use and an exposure area of 210 cm^2. The exposure estimate for this was 0.1 to 1 mg/cm^2/day.

For drumming of TCPP and TCPP blends, using the default values of reasonable worst-case dermal exposure for the scenario of drumming of liquids given in the TGD (non-dispersive use, with intermittent contact and an exposure area of 210 cm^2), gave an estimate of 0.1 to 1 mg/cm^2/day. The exposure area of 210 cm^2 was selected as there was little opportunity for large-scale dermal exposure during normal operations as most of the production takes place in closed systems with breaches for sampling and drumming.

B.9.2.1.3 Values taken forward for risk characterisation

For dermal exposure, the reasonable worst case taken forward to risk characterisation was the EASE estimate of 1 mg/cm^2/day. This was for the processes of sampling and drumming during the production scenario. It was estimated that the area of exposure would be 210 cm^2. The RWC is therefore 210 mg/day. For typical exposure a value of 0.1 mg/cm^2/day was found, which was the lowest value predicted using EASE modelling, but still higher than the lower of the two real values obtained (assuming a 70 kg man and the area exposed is 210 cm^2). The typical dermal exposure was therefore 21 mg/day. Both of these estimates were found to be higher than the real data obtained, but as there were only two data points it was decided to err on the side of caution in the RAR calculations.

B.9.3 USES

B.9.3.1 Manufacture of flexible PUR foam (scenario 2)

The RAR for TCPP concluded there was no need for further risk reduction measures during the manufacture of flexible PUR foam. Hence the occupation exposure for this scenario will not be

discussed further here. Please refer to **Section 4.1.1.1.2** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.2 Cutting of flexible PUR foam (scenario 3)

The RAR for TCPP concluded there was no need for further risk reduction measures during the cutting of flexible PUR foam. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.3** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.3 Production of foam granules and rebounded foam (scenario 4)

The RAR for TCPP concluded there was no need for further risk reduction measures during the production of foam granules and rebounded foam. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.4** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.4 Formulation of systems and manufacture of spray foams (scenario 5)

The RAR for TCPP concluded there was no need for further risk reduction measures during the formulation of systems and manufacture of spray foams. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.5** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.5 Use of spray foams (scenario 6)

The RAR for TCPP concluded there was no need for further risk reduction measures during the use of spray foams. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.6** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.6 Manufacture of rigid PUR foams (scenario 7)

The RAR for TCPP concluded there was no need for further risk reduction measures during the manufacture of rigid PUR foams. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.7** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.7 Use of rigid PUR foams (scenario 8)

The RAR for TCPP concluded there was no need for further risk reduction measures during the use of rigid PUR foams. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.8** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.8 Manufacture of one-component (1-K) foams (scenario 9)

The RAR for TCPP concluded there was no need for further risk reduction measures during the manufacture of one-component foams. Hence the occupation exposure for this scenario will not be

discussed further here. Please refer to **Section 4.1.1.1.9** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.9 Use of one-component (1-K) foams (scenario 10)

The RAR for TCPP concluded there was no need for further risk reduction measures during the use of one-component foams. Hence the occupation exposure for this scenario will not be discussed further here. Please refer to **Section 4.1.1.1.10** of the RAR for more details on this process and the sources of occupational exposure during this exposure scenario.

B.9.3.10 Summary of occupational dermal exposure

A summary of the dermal exposure values taken forward to risk characterisation for scenario 1 is presented in **Table B.7**, below.

Table B.7 Summary table of RWC and typical dermal exposure values taken forward for risk characterisation

Scenario	Dermal exposure (mg/cm²/day)		Dermal exposure area (cm²)
	RWC	Typical	
1: Production of TCPP	1	0.1	210

B.9.4 Other sources (for example natural sources)

Not relevant for this proposal.

B.9.5 Summary of environmental exposure assessment

Not relevant for this proposal.

B.9.6 Combined human exposure assessment

Not relevant for this proposal.

B.10 RISK CHARACTERISATION

B.10.1 Human health

This section of the transitional Annex XV report will focus on the risk characterisation associated with dermal exposure of workers to TCPP during the manufacturing of TCPP, whereby the RAR concluded a strategy for limiting risks is required.

For the purposes of risk characterisation, two types of worker exposure are considered. 'Typical' exposure covers the circumstances in which most workers are exposed and is based on normal industry working practice. 'Reasonable worst case' (RWC) exposures are intended to cover exposure situations where adequate control is lacking. RWC exposures are not considered as extreme incidents, but rather higher end exposures which are reasonably foreseeable.

B.10.1.1 Workers

To make a comparison between exposure data and data from the toxicological studies for each end-point, total body burdens have been calculated for workers for the worst-case and typical and dermal exposure scenarios. This section only includes the body burden dermal calculations for the worker scenarios whereby the RAR identified a risk. Please refer to **Section 4.1.3.2** of the RAR for information on the remaining exposure scenarios.

Scenario 1: Manufacture of TCPP

The reasonable worst-case dermal exposure was 1 mg/cm^2/day. Using default values of a 70kg worker with 210 cm^2 of exposed skin and assuming 23% absorption, the dermal body burden was 0.69 mg/kg.

The typical dermal exposure in this scenario was 0.1 mg/cm^2/day, leading to a dermal body burden of 6.9 x 10^{-2} mg/kg.

Table B.8 below gives the worst case and typical dermal body burden values for TCPP exposure scenario 1 (manufacture of TCPP).

Table B.8 Summary of reasonable worst case and typical dermal body burden values for all TCPP exposure scenarios

Scenario	Dermal body burden worst case (mg/kg)	Dermal body burden typical case (mg/kg)
1	0.69	6.9 x 10^{-2}

B.10.1.1.1 Acute toxicity

In the RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.2 Irritation and corrosivity

In the RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.3 Sensitisation

B.10.1.1.3.1 Skin

In the RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.3.2 Respiratory tract

In RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.4 Repeated dose toxicity

In the RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.5 Mutagenicity

In RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.6 Carcinogenicity

In the RAR for TCPP, **conclusion (ii)** was drawn for this end-point for all exposure scenarios.

B.10.1.1.7 Toxicity for reproduction

B.10.1.1.7.1 Effects on fertility

As mentioned in **Section B.5.9** a LOAEL of 99 mg/kg is derived for effects on fertility in a two-generation oral reproductive toxicity study in rats with TCPP. This was based on a decrease in relative uterus weight seen in all dosed females in F0 and the high dose females in F1. Assuming 80% absorption by the oral route, this led to an internal body burden of 79 mg/kg.

In line with the draft TGD (2005), the minimal margin of safety (MOS) for effects on fertility was 150. This is established by taking into account an interspecies factor of 10 (4 for metabolic size differences * 2.5 for sensitivity differences) and an intraspecies factor of 5. A factor of 3 to account for the use of a LOAEL rather than a NOAEL was also employed. Although the effects seen at the low dose were slight, they did reach statistical significance and were considered to be biologically significant as they followed a dose dependent trend.

For scenario 1, manufacture of TCPP, with respect to dermal exposure, the body burden for the reasonable worst-case exposure was 0.69 mg/kg, leading to a MOS of 114. The total body burden for the reasonable worst case for this scenario was also 0.69 mg/kg, again leading to a MOS of 114. The body burden for the typical dermal exposure, the body burden was 6.9×10^{-2} mg/kg, which results in a MOS of 1,145.

When the MOSs were compared with the minimal MOS of 150, there was a concern for the reasonable worst case dermal exposure. Therefore, **conclusion (iii)** was drawn. There was no concern for the typical dermal exposure.

In RAR for TCPP **conclusion (ii)** was drawn for this end-point for the remaining exposure scenarios 2, 3, 4, 5, 6, 7, 8, 9 and 10.

Tables B.9 summarises the MOSs and conclusions for fertility for the reasonable worst case and typical exposures for scenario 1 (manufacture of TCPP).

Table B.9 MOS values and conclusions for effects on fertility for TCPP – Reasonable worst case and typical exposure values

Minimal MOS: 150						
Scenario	**RWC Dermal**			**Typical Dermal**		
	Body burden (mg/kg)	**Body burden (mg/kg)**	**Body burden (mg/kg)**	**Body burden (mg/kg)**	**MOS**	**Concl**
1.Manufacture of TCPP	0.69	6.9×10^{-2}	6.9×10^{-2}	6.9×10^{-2}	114	**(iii)**

B.10.1.1.7.2 Developmental toxicity

As mentioned in **Section B.5.9** a LOAEL of 99 mg/kg is derived for developmental toxicity in a two-generation oral reproductive toxicity study in rats with TCPP. This was based on a treatment related effect on the number of runts observed in all TCPP-treated groups of the F0 generation. Assuming 80% absorption by the oral route, this led to an internal body burden of 79 mg/kg.

In line with the draft TGD (2005), the minimal MOS for developmental toxicity was 150. This was established by taking into account an interspecies factor of 10 (4 for metabolic size differences * 2.5 for sensitivity differences) and an intraspecies factor of 5. A factor of 3 to account for the use of a LOAEL rather than a NOAEL was also used.

For scenario 1, manufacture of TCPP, with respect to dermal exposure, the body burden was 0.69 mg/kg, leading to a MOS of 114. The body burden for the typical dermal exposure was 6.9×10^{-2} mg/kg, which results in a MOS of 1,145.

When the MOSs were compared with the minimal MOS of 150, there was a concern for the reasonable worst case dermal exposure. Therefore, **conclusion (iii)** was drawn. There was no concern for the typical dermal exposure.

In RAR for TCPP **conclusion (ii)** was drawn for this end-point for other exposure scenarios.

Table B.10 summarises the MOSs and conclusions for fertility for the reasonable worst case and typical exposures for scenario 1 (manufacture of TCPP).

Table B.10 MOS values and conclusions for developmental toxicity for TCPP – Reasonable worst case and typical exposures

Scenario	**RWC Dermal**			**Typical Dermal**		
	Body burden (mg/kg)	**Body burden (mg/kg)**	**Body burden (mg/kg)**	**Body burden (mg/kg)**	**MOS**	**Concl**
1.Manufacture of TCPP	0.69	6.9×10^{-2}	6.9×10^{-2}	6.9×10^{-2}	114	**(iii)**

B.10.1.1.8 Summary of risk characterisation for workers

With respect to worker scenario 1 (manufacture of TCPP), the MOS for reasonable worst case dermal exposures for fertility and developmental toxicity were found to be below the minimal MOS and therefore **conclusion (iii)** was drawn in the RAR for TCPP. There was no concern for the typical dermal exposure for this exposure scenario.

In the RAR for TCPP, a **conclusion (ii)** is drawn for all other worker exposure scenarios. This conclusion applies to all endpoints.

B.10.1.2 Consumers

In the RAR for TCPP, a **conclusion (ii)** is drawn for consumers for all exposure scenarios. This conclusion applies to all endpoints.

B.10.1.3 Indirect exposure of humans via the environment

In the RAR for TCPP, a **conclusion (ii)** is drawn for both regional and local exposures of humans via the environment for all exposure scenarios. This conclusion applies to all endpoints.

B.10.2 Combined exposures

Section 4.1.3.5 of the RAR for TCPP contains a discussion of the combined exposure to TCPP. That is the sum of all the specific sources (occupational exposure, consumer exposure and indirect exposure via the environment). Therefore, a worst case estimate for this combined exposure would be the sum of the RWC estimates, for inhalation and dermal exposures, for the three populations; i.e. workers, consumers and man exposed via the environment.

Occupational exposures were not included in the combined exposure calculation in the RAR for TCPP. The body burdens for the reasonable worst case and typical occupational exposures were found to be significantly higher than those for consumers or for indirect exposure via the environment. Therefore, the occupational exposure value would have dominated the combined exposure estimate, resulting in conclusion (iii)'s being drawn, as per those for the worker risk characterisation. It was therefore considered more appropriate to exclude occupational exposure from the combined exposure risk characterisation of the RAR.

B.10.3 Environment

Not relevant for this proposal.

PART C: INFORMATION ON ALTERNATIVES

As the control measures recommended in this transitional Annex XV dossier do not include recommendations for restriction of TCPP, analysis of alternatives was not performed.

C.1 INFORMATION ON THE RISKS TO HUMAN HEALTH AND THE ENVIRONMENT RELATED TO THE MANUFACTURE OF USE OF THE ALTERNATIVES

C.2 AVAILABILITY OF ALTERNATIVE, INCLUDING THE TIME SCALE

C.3 HUMAN HEALTH RISKS RELATED TO ALTERNATIVES

C.4 ENVIRONMENTAL RISKS RELATED TO ALTERNATIVES

C.5 TECHNICAL AND ECONOMICAL FEASIBILITY

C.6 OTHER INFORMATION ON ALTERNATIVES

PART D: JUSTIFICATION FOR ACTION ON A COMMUNITY-WIDE BASIS

As this transitional Annex XV dossier does not include a recommendation for a Community-wide restriction of TCPP, Part D has not been completed.

D.1 CONSIDERATIONS RELATED TO HUMAN HEALTH AND ENVIRONMENTAL RISKS

D.2 CONSIDERATIONS RELATED TO INTERNAL MARKET

D.3 OTHER CONSIDERATIONS

D.4 SUMMARY

PART E: JUSTIFICATION WHY RECOMMENDING A SAFE SYSTEM OF WORK AS THE MOST APPROPRIATE RISK REDUCTION MEASURE

E.1 IDENTIFICATION AND DESCRIPTION OF RISK MANAGEMENT OPTIONS

E.1.1 Risk to be addressed – the baseline

The RAR for TCPP concluded that there is a need for limiting the risk associated with reasonable worst case dermal exposure of workers during the manufacture of TCPP (scenario 1) in relation to effects on fertility and developmental toxicity. This conclusion was based on exposure monitoring data taken from one of the four EU production plants.

As a result of this RAR conclusion, a strategy for limiting these risks is required. It should be noted that in the case of the reasonable worst case dermal exposure of workers in the remaining nine scenarios there was no need for risk reduction measures beyond those that are being applied already. This was also the case for the typical dermal exposure of workers in all ten exposure scenarios.

In order to adequately address the risks identified for reasonable worst case dermal exposure of workers during the manufacture of TCPP (scenario 1) the first step would be to establish the extent to which risk management measures were in place at the time when exposure measurements were taken.

E.1.1.1 Manufacture of TCPP (scenario 1)

The RAR for TCPP indicates that two operators were monitored for dermal exposure at production plant 1 in 2002. During the monitoring period, the production operator supervised the production of 3 batches, pumped TCPP into the tank and sampled TCPP three times (including from the funda filter and from the tank). During these activities, he wore protective gloves (Vygen plus PVC gloves, cotton lined). The monitoring data indicated that operator 1 was exposed to 0.02 mg/bw TCPP.

The second operator carrying out the task of blend drumming filled 23 drums of 300 kg each for a period of 3 hours (this was equivalent to 690 kg of TCPP). He also attached labels to the drums. He was monitored for 177 minutes (3 hours), which is the length of time taken to carry out his work with TCPP. For the remainder of his shift operator 2 worked at the drumming station, but handled substances other than TCPP. He did not wear PPE while carrying out these tasks. Industry has indicated that theoretically, an operator could be working with TCPP for a full 8-hour shift, depending on requirements. The monitoring data indicated that operator 2 was exposed to 0.2 mg/bw TCPP.

From this information given in the RAR for TCPP, it appears that adequate hygiene procedures were not being implemented at the TCPP production plants where exposure monitoring was carried out. A representative from production plant 1 informed the rapporteur that subsequent to the monitoring measurements being taken in 2002, hygiene procedures have improved as a consequence of this monitoring carried out for the RAR. Gloves are now mandatory in all operations and improved hygiene procedures are now in place. During filter plate changing operations chemically impervious suits are used.

The revised hygiene procedures applied include the following procedures:

- Contaminated gloves must be discarded and replaced at the end of a working day or shift. Contaminated gloves must not be taken into control rooms, mess rooms or changing rooms such that they could contaminate work surfaces, other clothing or PPE. Grossly contaminated gloves should not be used for an extended period of time. Also gloves should be replaced if they have tears, punctures or splits.

- Office based personnel and visitors to site should wear a minimum of disposable gloves when they visit and intend to go inside the production plants and associated areas.

- Gloves and other PPE are to be disposed and stored at a dedicated place.

(Pers. comm. 31st July 2008, PEFRC)

Subsequent to the monitoring documented in the RAR, follow up hygiene surveys were performed in 2005 and 2006. These surveys confirmed that the hygiene procedures had improved (pers. comm. 19th September 2008, Albemarle). Dermal exposure measurements were repeated in 2005 by Albemarle with the analogous substance V6 and resulted in low exposures. PEFRC believe these results illustrate that the implemented hygiene procedures are sufficiently protective (pers. comm. 31st July 2008, PEFRC).

Subsequent to the monitoring documented in the RAR, in an apparent attempt by one TCPP manufacturer to identify appropriate personal protective equipment, glove permeation studies were performed with two types of gloves (Ansell-Edmont Neoprene No. 29-500 and Vygen Plus PVC). The test method was ASTM F1383-99A. The break-through time was > 110 minutes for 4 consecutive days (pers. comm. 31st July 2008, PEFRC).

E.1.2 Possible further risk reduction measures

E.1.2.1 Introduction

This section explores possible mechanisms to reduce the risks posed to workers as a result of dermal exposure to TDPP during the manufacture of TCPP.

The Technical Guidance Document (TGD) on Development of Risk Reduction Strategies (EC, 1998) outlines several possible risk reduction measures. Those related to packaging, distribution and storage are not relevant for the uses of concern in this case, nor are those for waste. **Table E.1** sets out the potential risk reduction measures relevant for manufacturing of TCPP.

Table E.1 Possible Risk Reduction Measures for Manufacture and Professional Use

▪ Control on manufacture ▪ Restrictions on the marketing and use of TCPP in flexible polyurethane foam ▪ Re-design the process itself, or change the substance or material used in it ▪ Safe system of works, such as specified standards of physical containment or extraction ventilation ▪ Application of good manufacturing practise, for example under ISO standards ▪ Classification and labelling ▪ Separation of personnel ▪ Monitoring and maintenance of equipment ▪ Dust suppression methods, such as the use of the substance in tablet or pellet form ▪ Occupational exposure limit and/or air monitoring in the workplace ▪ Accurate hazard information (e.g. safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace ▪ Biological exposure indices and/or biological monitoring of workers ▪ Medical survey of workers ▪ Training ▪ Use of personal protection equipment ▪ Licensing of operator of certain operations ▪ End of pipe control to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise ▪ Limit values for emission and effluent monitoring ▪ Environmental quality standards and/or environmental monitoring

E.1.2.2 Possible further risk reduction measures for the manufacture of TCPP (scenario 1)

Several of the possible risk reduction measures listed in **Table E.1** can immediately be disregarded in the case of the identified risk associated with the manufacture of TCPP. The following measures can be disregarded as they are concerned with environmental exposure:

- End of pipe control to minimise, neutralise or render less harmful any emissions that cannot practicably be avoided otherwise
- Limit values for emission and effluent monitoring
- Environmental quality standards and/or environmental monitoring

Controls on the manufacture of TCPP are not viable as there are other uses of the substance for which there is no concern (e.g. scenarios 2 to 10). This is thought to be the case as appropriate risk reduction measures are in place in scenarios 2 to 10.

A Community-wide restriction on the marketing and use of TCPP would be disproportionate to the risk. The risk associated with the manufacture of TCPP has been identified in the case of reasonable worst case dermal exposure, to workers in industrial settings only. It should be noted that in the case of the reasonable worst case dermal exposure of workers in the remaining nine scenarios, there was no need for risk reduction measures beyond those that are being applied already. This was also the case for the typical dermal exposure of workers in all ten exposure scenarios.

It is therefore recommended that the risk to workers during the manufacture of TCPP can be reduced to an adequate level using technical and/or organisational means. As mentioned above, there are other uses of TCPP for which there is no concern (e.g. scenarios 2 to 10) as appropriate risk reduction measures are in place.

Dust suppression methods (e.g. the use of the substance in tablet or pellet form) are not practical for the manufacture of TCPP. As regards using classification and labelling measures to reduce the risk, Industry have self-classifying TCPP as Xn; R22.

With respect to establishing an occupational exposure limits and/or air monitoring in the workplace, this measure would not be relevant in addressing the identified risk i.e. worker dermal exposure. The biological monitoring of workers would also not be necessary in this instance.

Taking the above into consideration and in light of the fact that the RAR has identified a risk for reasonable worst case dermal exposure of workers, the following risk reduction measures are considered to be appropriate for the manufacture of TCPP:

- Re-design the process itself, or change the substance or material used in it
- Safe system of works, such as specified standards of physical containment or extraction ventilation
- Application of good manufacturing practice, for example under ISO standards
- Separation of personnel
- Monitoring and maintenance of equipment
- Accurate hazard information (e.g. safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace
- Training
- Use of personal protection equipment
- Licensing of operator of certain operations

It is recommended that the culmination of some or all of the above controls on the workplace should be sufficient to reduce the risk to an acceptable level. As a minimum controls such as the safe system of work, the monitoring and maintenance of equipment, accurate hazard information (e.g. safety data sheets), training and the use of personal protection equipment are recommended by the rapporteur to ensure an overall safe system of work.

Medical surveillance of workers may be appropriate, by providing more information about effects of the exposure but would not reduce the risk. The findings of such surveillance may provide assurance that the protective and preventative measures, adopted to control exposure are effective.

As mentioned in **Section E.1.1.1** it is documented in the RAR for TCPP that PPE was not used at the time of when the highest dermal exposure value was recorded during the manufacture of TCPP, where risk was identified. According to the Chemical Agents Directive (98/24/EC) where the nature of the activity does not permit risk to be eliminated by substitution, the employer must ensure that the risk is reduced to a minimum by application of protection and prevention measures. Directive 89/656/EEC requires that PPE shall be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organisation.

Where a risk assessment requires that PPE be used, consideration should be given to the appropriateness of the particular type of PPE during the selection process. Gloves with cotton backs should be avoided as chemical substances can be absorbed by the cotton and lead to continuous contact with the skin. Impervious suits and face masks should be worn where it is deemed necessary to protect against dermal exposure to TCPP.

Hazard information on TCPP should be contained in an up-to-date safety data sheet and should be made available to the operators who have the potential to be exposed to TCPP in the workplace, as required by the REACH Regulation. This obligation to provide information is considered sufficient in principle to provide the recipient with sufficient information for the selection of suitable occupational safety measures.

As there are other uses of TCPP for which there is no concern (e.g. scenarios 2 to 10), it is felt that it should be possible for industries involved in the manufacture of TCPP to ensure that appropriate risk reduction measures are in place in order to ensure a safe system of work for workers.

E.2 COMPARISON OF INSTRUMENTS: RESTRICTION(S) VS. OTHER COMMUNITY-WIDE MANAGEMENT OPTIONS

The measures identified in **Section E.1.2.2,** recommended as possible measures for the management of risks from TCPP will now be assessed against the four criteria of effectiveness, practicality and monitorability. This will be compared to an assessment of a possible Community-wide restriction, carried out first under the same four criteria.

E.2.1 Restriction

A Community-wide restriction on the marketing and use of a substance or preparation can be imposed under Title VIII of the REACH Regulation.

E.2.1.1 Effectiveness

Placing a restriction on the manufacture of TCPP would have a high degree of effectiveness.

E.2.1.1.1 Risk reduction capacity

If a ban were to be imposed and effectively implemented, it is assumed that all associated occupational risks would be eliminated.

E.2.1.1.2 Proportionality

Although a restriction on the manufacture of TCPP would have a high degree of effectiveness, such a measure would be disproportionate to the risk identified in the RAR for TCPP in the case of reasonable worst case dermal exposure for workers. The RAR concluded that there is no concern any of the nine downstream uses of TCPP or for humans via the environment and consumers. There was also no concern for workers exposed to TCPP via the inhalation route. It is felt that the risk to workers can be reduced using an approach that is more proportionate than a Community-wide restriction. This could be through technical and/or organisational means, as required by the existing framework of occupational health and safety legislation (see **Section B.9.1.1**). The effort needed for the appropriate industries to implement a restriction on the manufacture, marketing and/or use of TCPP would be disproportionate to the adverse effects identified in the RAR, that is for reasonable worst case dermal exposure of workers in scenario 1 only.

E.2.1.2 Practicality

In the spirit of ‘Better Regulation’ a restriction should only be recommended where the risk associated with the use of the substance, cannot be reduced using other measures. In the case of the risk identified for reasonable worst case dermal exposure of workers to TCPP, it is felt that the risk can be reduced to an adequate level using technical and/or organisational measures, as required by the existing framework of occupational health and safety legislation.

In addition, if a restriction was placed on the manufacture of TCPP this would mean that this substance would not be available for use in its nine downstream applications. The RAR concluded

that there is no concern regarding exposure to workers in any of these nine exposure scenarios. Therefore imposing a restriction on the manufacture TCPP would not be practical.

E.2.1.2.1 Implementability

In order for a restriction to be implemented at Community level, an Annex XV dossier would have to be developed by the rapporteur, which would then have to be agreed by the Risk Assessment Committee. The timing of such agreement can only be estimated, but would potentially take a number of years before a restriction would be implemented at Community level.

E.2.1.2.2 Enforceability

A restriction could be enforced in the individual Member States, as part of national legislation for REACH enforcement.

E.2.1.2.3 Manageability

Once ECHA or a Member State has submitted an Annex XV dossier for restriction of TCPP, the RAC and SEAC would have overall responsibility to review and provide an opinion on whether or not a restriction is the most appropriate measure to limit the risk. The European Commission will make the final decision on any proposal to restrict TCPP, through the systems laid down in the REACH Regulation. It is felt that the level of Member State resources that would be required to develop and implement a Community-wide restriction would not be proportionate to the risk identified in the RAR. It is also felt that a restriction on the manufacture, marketing and/or use of TCPP would not be manageable for the relevant industries as it would put an end to production involving TCPP.

E.2.1.3 Monitorability

Means by which the European Commission can monitor restrictions using indicators such as concentration of substance in preparations or articles for example are already in place under the current legislative instrument (Marketing and Use Directive 76/769/EEC). Directive will be repealed by Title VIII and Annex XVII of the REACH Regulation on 1st June 2009. After this date, it is expected that the European Commission will continue to identify indicators in order to monitor restrictions listed in Annex XVII of the REACH Regulation.

E.2.1.4 Overall assessment against the three criteria

Although a restriction would be an effective risk reduction measure, it would be disproportionate to the risk identified in the RAR. From the information received from the industry consortium (given in **Section E.1** of this report), it is considered that there are technical and/or organisational measures (e.g. hygiene procedures) available to reduce the risk identified to an adequate level. From the rapporteur's assessment, a restriction on the manufacture of TCPP would not be practical in this case.

E.2.2 Safe system of work, in accordance with occupational health and safety legislation

The following risk reduction options for the manufacture of TCPP are all related to changes in the workplace and safe system of work:

- Re-design the process itself, or change the substance or material used in it
- Safe system of works, such as specified standards of physical containment or extraction ventilation
- Application of good manufacturing practise, for example under ISO standards
- Separation of personnel
- Monitoring and maintenance of equipment
- Accurate hazard information (for example safety data sheets) and/or better delivery of safety information or the provision of warning signs in the workplace
- Training
- Medical surveys
- Use of personal protection equipment
- Licensing of operator of certain operations

As mentioned above, it is recommended that the culmination of some or all of the above controls on the workplace should be sufficient to reduce the risk to an acceptable level. As a minimum controls such as safe system of work, monitoring and maintenance of equipment, accurate hazard information (e.g. safety data sheets), training and the use of personal protection equipment are recommended by the rapporteur to ensure an overall safe system of work.

E.2.2.1 Effectiveness

Overall, it is felt that the measures listed in **Section E.2.2** above will be effective in reducing the risk of dermal exposure to worker to an adequate level. Preventative measures relating to the design and organisation of systems at the workplace, the provision of suitably (maintained) equipment, keeping worker exposure to a minimum, the provision of information and/or training and the use of appropriate hygiene measures are all required under the Chemical Agents Directive 98/24/EC (see **Section B.9.1.1.3.2**). From the information recorded in the RAR for TCPP, it appears that adequate hygiene measures were not being implemented at the relevant industries where exposure monitoring was carried out.

The use of PPE should also be used when the risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures; methods or procedures of work organisation as required by Directive 89/656/EEC (see **Section B.9.1.1.3.3**). From the information recorded in the RAR for TCPP, it appears that adequate PPE was not being used at the relevant industries where exposure monitoring was carried out.

Hazard information relating to TCPP should be supplied to the recipient (e.g. worker or downstream user) of TCPP, in accordance with the REACH Regulation (see **Section B.9.1.1.2**).

Therefore the existing framework of occupational health and safety legislation should be used as a basis to ensure reduction of the exposure to a level that allows adequate control of the identified risk.

E.2.2.1.1 Risk reduction capacity

Establishing a safe system of work during the manufacture of TCPP would result in an adequate degree of effectiveness.

E.2.2.1.2 Proportionality

Establishing a safe system of work is considered a proportionate measure to the risk faced from reasonable worst case dermal exposure of workers to TCPP. The RAR concluded that there is no

concern for any of the nine downstream uses of TCPP or for humans via the environment and to consumers. There was also no concern for workers exposed to TCPP via the inhalation route. It is felt that a 'safe system of work' approach is a proportionate mechanism to address the identified risk to workers. This can be achieved through technical and/or organisational means, using the existing framework of occupational health and safety legislation.

E.2.2.2 Practicality

The above measures to ensure a safe system of work are thought to be relatively easy to implement, except perhaps the re-design of the process itself. If this is not technically feasible, alternative technical and/or organisational measures must be implemented for example, physical containment, regular maintenance of equipment, use of appropriate PPE, etc. Separation of personnel may be practical in ensuring that a limited number of staff is exposed to TCPP. Adequate hygiene procedures should be implemented and strictly adhered to, in the case of employees that have a greater potential of being exposed to TCPP have already revised the hygiene procedures in place, as a consequence of the findings of the RAR for TCPP.

E.2.2.2.1 Implementability

These measures could be implemented very quickly (if they have not been implemented already) at plants engaging in the manufacture of TCPP.

E.2.2.2.2 Enforceability

Establishment of a safe system of work could be enforced in the individual Member States, as part of national legislation for the enforcement of occupational health and safety legislation e.g. the Framework Directive 89/391/EEC, Chemical Agents Directive 98/24/EC, PPE Directive 89/656/EEC and the REACH Regulation.

E.2.2.2.3 Manageability

Establishment of a safe system of work can be managed within the already existing health and safety management system at the industrial sites involved in the manufacture of TCPP. The authorities can use existing health and safety legislation to ensure that a safe system of work is in place, as part of their enforcement programs.

E.2.2.3 Monitorability

Monitoring the implementation and effectiveness of the above recommended safe system of work can be carried out using existing monitoring arrangements, which already exist as part of the health and safety management system at the relevant industrial sites. The relevant industries can implement monitoring systems to ensure that established hygiene procedures are being adhered to. Such systems could range from local inspections, carried out by supervisor's onsite to ensure that hygiene procedures are being adhered to, to exposure monitoring, depending on the scale /resources of the particular site in question. Such monitoring systems should be sufficient to observe whether the risk reduction targets, set by the industry in question have been achieved.

E.2.2.4 Overall assessment against the three criteria

Establishment of a safe system of work through the implementation of a number of measures related to changes in the workplace are considered to be adequate to address the risk identified by the RAR in the case of reasonable worst case dermal exposure of workers to TCPP. It is thought that these measures are proportionate and will be sufficiently effective and practical for addressing the risk. It is also thought that these measures are relatively easy to implement, manage and monitor by the relevant industries and can be enforced by Member State Authorities using the existing framework of occupation health and safety legislation.

E.2.3 Risk Reduction recommendation

Based on the information given in **Section E.1** and **Section E.2** the rapporteur considers that the legislation for workers' protection currently in force at Community level is an adequate framework to limit the risk faced by workers from exposure to TCPP. A restriction would be disproportionate based on the results from the exposure assessments contained in the RAR.

E.3 COMPARISON OF RESTRICTION OPTIONS

Not relevant for this proposal.

E.3.1 Effectiveness

E.3.1.1 Risk reduction capacity

E.3.1.1.1 Effect on human health

E.3.1.1.2 Effect on the environment

E.3.1.1.3 Other effects

E.3.1.2 Proportionality

E.3.1.2.1 Economic feasibility

E.3.1.2.2 Technical feasibility

E.3.1.2.3 Other issues relating to proportionality

E.3.2 Practicality

E.3.2.1 Implementability

E.3.2.2 Enforceability

E.3.3 Monitorability

E.3.4 Overall assessment against the three criteria

E.4 MAIN ASSUMPTIONS USED AND DECISION MADE DURING ANALYSIS

E.5 THE PROPOSED RESTRICTION(S) AND SUMMARY OF THE JUSTIFICATIONS

PART F: SOCIO ECONOMIC ASSESSMENT OF PROPOSED RESTRICTION(S)

As the control measures recommended in this transitional Annex XV dossier do not include recommendations for restrictions on the marketing and use of the substance in question, analysis of alternatives was not performed.

F.1 HUMAN HEALTH AND ENVIRONMENTAL IMPACTS

F.1.1 Human Health impacts

F.1.2 Environmental impacts

F.2 ECONOMIC IMPACTS

F.3 SOCIAL IMPACTS

F.4 WIDER ECONOMIC IMPACTS

F.5 DISTRIBUTIONAL IMPACTS

F.6 MAIN ASSUMPTIONS USED AND DECISIONS MADE DURING ANALYSIS

F.7 UNCERTAINTIES

F.8 SUMMARY OF THE BENEFITS AND COSTS

PART G: STAKEHOLDER CONSULTATION

G.1 LIST OF CONSULTEES

1. Albemarle Corporation
2. ICL-Industrial Products (formerly Supresta)
3. Lanxess Deutschland GmbH
4. BASF
5. Phosphate Ester Flame Retardant Consortium (PEFRC)
6. Danish Ministry of the Environment
7. Ministry of Social Affairs of Estonia
8. Permanent Representative for Cyprus
9. Health and Safety Executive, UK

PART H: OTHER INFORMATION

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