

Annex XV Report

Proposal for identification of a substance as a CMR cat 1 or 2, PBT, vPvB or a substance of an equivalent level of concern

Substance Name: TRICHLOROETHYLENE

EC Number: 201-167-4

CAS Number: 79-01-6

It is proposed to identify the substance as a CMR according to Article 57 (a).

Submitted by: FRANCE

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PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: TRICHLOROETHYLENE

EC number: 201-167-4

CAS number: 79-01-6

- *It is proposed to identify the substance as a CMR according to Article 57 (a) according to the following argument.*

Summary of how the substance meets the CMR (Cat 1 or 2), PBT or vPvB criteria, or is considered to be a substance of an equivalent level of concern

According to Article 57 of Regulation 1907/2006 (the REACH Regulation), substances meeting the criteria for classification as carcinogen (category 1 or 2) in accordance with Directive 67/548/EEC may be included in Annex XIV. Trichloroethylene has been classified as a carcinogen (Carc. Cat. 2) according to Directive 67/548/EEC by Commission Directive 2008/58/EC amending, for the purpose of its adaptation to technical progress, for the 28th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

This classification as Carc.Cat. 2 was included in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008.

The corresponding classification in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) will be Carc. 1B.

Registration number(s) of the substance or of substances containing the substance:

Not relevant

PART I: JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

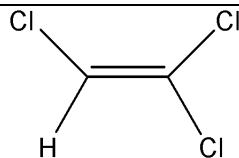
1.1 Name and other identifier of the substance

Chemical Name:	Trichloroethylene
EC Number:	201-167-4
CAS Number:	79-01-6
IUPAC Name:	1,1,2-trichloroethene

Synonyms for Trichloroethylene: Acetylene trichloride, Ethinyl trichloride, Trichloroethene, TRI, TRIC, 1-Chloro-2,2-dichloroethylene, 1,1,2-Trichloroethylene, Trilene, Triklone® , Trimar.

Industrial abbreviations include trichloroethylene, trichlor, Trike, Tricky and trichloroethylene.

1.2 Composition of the substance

Chemical Name:	Trichloroethylene
EC Number:	201-167-4
CAS Number:	79-01-6
IUPAC Name:	1,1,2-trichloroethene
Molecular Formula:	C ₂ HCl ₃
Structural Formula:	
Molecular Weight:	131.39 -131.5 (131.5 used in this assessment)
Typical proportion %	> 99.9 % w/w
Real proportion (range) in %	-

1.2.1 Impurities

Information extracted from EU-RAR

Tetrachloroethylene	<0.03%
1,1-dichloroethene	<0.01%
1, 1, 1-Trichloroethane	<0.01%
Chloroform	<0.01%
Carbon tetrachloride	<0.005%
Dichloromethane	<0.001%
Bromodichloromethane	< 0.1%
Water	trace

1.2.2 Additives

The stated additives present in trichloroethylene available from various suppliers included the following (% w/w) (EU-RAR)

1-Methylpyrrole	0.02 - 0.022
Diisopropylamine	< 0.005%

1.3 Physico-Chemical properties

Table 1 Summary of physico-chemical properties

REACH ref Annex, §	Property	Value	Comment/reference
VII, 7.1	Physical state at 20 C and 101.3 KPa	Colourless non flammable liquid with a characteristic odour detectable at around 20 to 30 ppm resembling that of chloroform.	EU-RAR 1.3.1
VII, 7.2	Melting / freezing point	-84 to -87 °C according to source	EU-RAR 1.3.2
VII, 7.3	Boiling point	85.9 to 88 °C according to source	EU-RAR 1.3.3
VII, 7.5	Vapour pressure	78.7 to 86 hPa at 20°C according to source	EU-RAR 1.3.5
VII, 7.7	Water solubility	according to source 1 to 2.85 g.l ⁻¹	EU-RAR 1.3.6
VII, 7.8	Partition coefficient n-octanol/water (log value)	2.29 to 2.98 according to source	EU-RAR 1.3.7
IX, 7.16	Dissociation constant	No information found	

2 MANUFACTURE AND USES

Information on uses are summarised in the second part of this dossier (Part II: Information on uses, exposure, alternatives and risks).

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex VI of Regulation (EC) No 1272/2008

According to Article 57 of the REACH Regulation, substances meeting the criteria for classification as carcinogenic (category 1 or 2) in accordance with Directive 67/548/EEC may be included in Annex XIV. The classification of trichloroethylene according to Directive 67/548/EEC was updated by the 28th Adaptation to Technical Progress (28th ATP; Commission Directive 2008/58/EC¹) as follows:

Index Number: 602-027-00-9

Carc. Cat. 2; R45 (May cause cancer)

Muta. Cat. 3; R68 (Possible risk of irreversible effects)

Xi indicates 'irritant'; R36/38 (Irritating to eyes/skin)

R67 (Vapours may cause drowsiness and dizziness)

R52-53 (Harmful to aquatic organisms, May cause long term adverse effects in the aquatic environment)

S sentences: 53-45-61

In addition, Note 6 applies to the labelling of preparations that contain trichloroethylene; such preparations have to be assigned R67 if they meet the appropriate criteria.

This classification has been included in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008² by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation 1272/2008 accordingly:

Carc. 1B H350

Muta. 2 H341

Eye Irrit. 2 H319

Skin Irrit. 2 H315

STOT SE 3 H336

Aquatic Chronic 3 H412

3.2 Self classification(s)

Not relevant

¹ COMMISSION DIRECTIVE 2008/58/EC of January 2001 amending, for the purpose of its adaptation to technical progress, for the 28th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

² Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

4 ENVIRONMENTAL FATE PROPERTIES

Not relevant for this proposal

5 HUMAN HEALTH HAZARD ASSESSMENT

Information is available for consultation in the European Risk Assessment Report (EU-RAR) (ECB, 2004).

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.2 Acute toxicity

See EU-RAR (ECB, 2004)

5.3 Irritation

See EU-RAR (ECB, 2004)

5.4 Corrosivity

See EU-RAR (ECB, 2004)

5.5 Sensitisation

See EU-RAR (ECB, 2004)

5.6 Repeated dose toxicity

See EU-RAR (ECB, 2004)

5.7 Mutagenicity

See EU-RAR (ECB, 2004)

5.8. Summary and discussion of mutagenicity

See EU-RAR (ECB, 2004)

5.9 Carcinogenicity

See EU-RAR (ECB, 2004)

5.10 Summary and discussion of carcinogenicity

See EU-RAR (ECB, 2004)

5.11 Toxicity for reproduction

See EU-RAR (ECB, 2004)

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

See EU-RAR (ECB, 2004)

7 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this proposal

8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

Not relevant for this proposal

PART II: INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

Considering the general approach used by ECHA to develop the priority setting³, where the 'regulatory effectiveness' of including the substance into the authorisation process should also be taken into account, we would like to mention decisions taken at the Risk Reduction Strategy Meeting (RRSM) for trichloroethylene that took place in 2006. Transitional measures as a Voluntary Agreement were agreed as the most effective means of achieving the desired objective in the timeframe of REACH. This is because REACH was planned to come into force in Spring 2007 (ECB, 2010). It was foreseen that even if trichloroethylene was to be the highest priority for authorisation under REACH, it was unlikely that such an authorisation could be agreed and come into effects until at least Autumn 2009, and such an authorisation would have to include a transitional period of at least 3 years to enable users to make the necessary changes, postponing the legislative action at EU level not before 2012 at the earliest (ECB, 2010).

Also big efforts have been produced to reduce uses and exposure to trichloroethylene, some data produced here, show that exposure still exist (see paragraph 2). We therefore recommend pursuing the efforts in order to ensure a safe use of trichloroethylene by including it in the priority list for inclusion in Annex XIV.

1 INFORMATION ON USES

1. Production methods

Trichloroethylene is a chlorinated hydrocarbon solvent, known as a clear non-flammable liquid with a sweet smell. Most of the trichloroethylene produced is derived from ethylene by chlorination over a ferric chloride catalyst to produce 1,2-dichloroethane. 1,2-dichloroethane (ethylene dichloride) is chlorinated or oxychlorinated using various catalysts (Nielsen IR and Howe PD, 1992). Ethylene dichloride, produced by the chlorination of ethylene, may be further chlorinated to trichloroethylene at 280-450°C using catalysts such as potassium chloride, aluminium chloride, Fuller's earth, graphite, activated carbon or activated charcoal as various forms of porous carbon.

Trichloroethylene can be prepared via oxychlorination of ethylene dichloride in a pressurised reaction at temperatures of about 425°C, using catalysts such as mixtures of potassium and copper chlorides. Oxychlorination is used to produce tetrachloroethylene and trichloroethylene at the same facility (crude production figures may therefore include both chemicals). The resulting trichloroethylene/tetrachloroethylene mixture is separated by distillation.

Trichloroethylene and tetrachloroethylene are also produced from the oxychlorination of recovered residues derived from vinyl chloride monomer (VCM) manufacture.

³ http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf

Trichloroethylene is also produced by the catalytic hydrogenation of tetrachloroethene (BUA, 1994). A specially activated copper-palladium catalyst on a carrier material is used in the gas phase at temperatures up to 250°C.(ECB, 2004)

An alternative process, in use in Europe since 1986, starts from Perchloroethylene uses catalytic hydrogenation. (ECSA and EUROPEAN CHLORINATED SOLVENT ASSOCIATION, 2010)

2. Use

Trichloroethylene is commonly used as a metal degreaser, and solvent for a variety of organic materials. When it was first widely produced in the 1920s, trichloroethylene's major use was to extract vegetable oils from plant materials such as soy, coconut, and palm. Other uses in the food industry included coffee decaffeination and the preparation of flavoring extracts from hops and spices. It has also been used for drying out the last bit of water for production of 100% ethanol. From the 1930s through the 1970s, both in Europe and North America, trichloroethylene was used as a volatile gas anesthetic and as an inhaled obstetrical analgesic in millions of patients. Trichloroethylene was used in place of earlier the anesthetics chloroform and ether in the 1940s, but was itself replaced in the 1950s by the newer halothane, which allowed much faster induction and recovery times. Marketed in the UK by ICI under the trade name Trilene it was coloured blue (with a dye called waxolene blue) to avoid confusion with the similar smelling chloroform. It has also been used as a dry cleaning solvent, although replaced in the 1950s by tetrachloroethylene (also known as perchloroethylene).Being a substitute for benzene, trichloroethylene use as metal degreaser increased significantly in the fifties (InVS and Goupe de travail Matgéné, 2009). In the seventies, the suspicion on its carcinogenicity led trichloroethylene to be replaced by the 1,1,1-trichloroethane, thought less toxic for degreasing activities. After use of 1,1,1-trichloroethane was forbidden in 1995 (except for dispensation), trichloroethylene again is used for degreasing activities, also not at the same level than in the seventies due to its new classification by IARC from carcinogen of category 3 to 2A. Since then, its use decreases.(InVS and Goupe de travail Matgéné, 2009)

Trichloroethylene is also used in adhesives, for synthesis (chemical intermediate) in the chemical industry and as a solvent for various products, including insecticides and waxes. It is (or has been) used in the leather and textile processing industries and in the paint, lacquers and varnishes industry.

Figure 1 provides a summary of the key uses of trichloroethylene and key stages in the supply chain. The main uses are as a feedstock and in metal degreasing. Whereas feedstock use is often supplied directly by the producers of trichloroethylene (and is site-limited in some cases), other uses - particularly metal degreasing - are often supplied through one or more different links in the supply chain, including:

- Companies that store and repackage trichloroethylene, providing the product to markets requiring particular quantities (e.g. drums) or to markets in particular locations; Companies that add stabilisers to trichloroethylene in order to reduce photochemical or thermal decomposition; and
- Recycling companies that collect and recover trichloroethylene by distillation, particularly for use in metal degreasing.

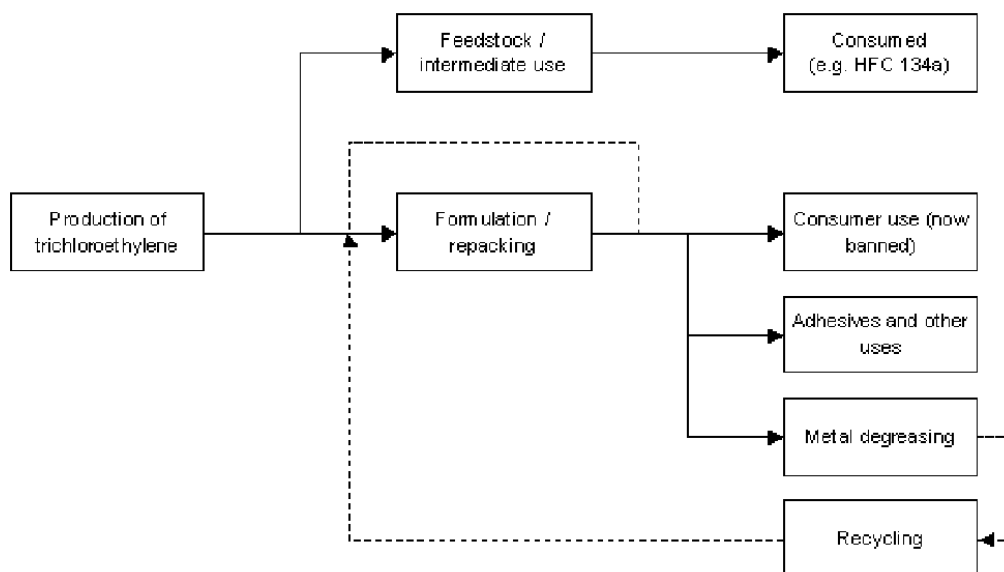


Figure 1: summary of the key uses of trichloroethylene

The major use of trichloroethylene is for hot vapour degreasing of metal parts.

Table 2 summarises uses of trichloroethylene sold into the EU market in 1996 and in 2003. As can be seen from this table, use in metal degreasing and adhesives has decreased significantly in both percentage and absolute terms over recent years, whereas use as an intermediate has increased in both absolute and percentage terms. Use as an intermediate is therefore expected to comprise the majority of the current EU market at present, whereas use in metal degreasing was previously the greatest application. (DEFRA, 2005; ECB, 2010)

Table 2: Uses of Trichloroethylene Sold into EU Market in 1996 and 2003
Use Percentage of Sales, 1996 Percentage of Sales, 2003 (DEFRA, 2005; ECB, 2010)

Use	Percentage of Sales, 1996	Percentage of Sales, 2003
Metal degreasing in vapour degreasers	52%	28%
Adhesives	6%	3%
Consumer uses	4%	0%
Others	2%	2%
Feedstock (intermediate)	37%	67%
Total	100% (approx. 122,000 tonnes)	100% (approx. 96,000 tonnes)

Others include extraction, leather preparation, pharmaceuticals.
 Source: ECB (2004, 2004a).

Table 3 represents the results of an inventory performed in France by INRS in 2005 on a sample of 2000 companies belonging to 30 primary activity sectors for their french consumption of trichloroethylene by activity sectors : (Gasztowtt B. *et al.*, 2008)

Table 3: French consumption of trichloroethylene by activity sectors

	Distribution of the French consumption of Trichloroethylene by activity sector
Smelting	61%
Metallurgy	8,1%
Adhesive glue and gelatine manufacturer	7,8%
Manufacturer of (domestic) electrical appliance, electric and electronic compounds: eg. Degreasing before welding	7,7%
Steeling industry : solvent for surface degreasing during optic evaluation	3.9%
Rubber industry: degreasing before sticking rubber	2,8%
Weapons and ammunition manufacturer: degreasing	2,6%
Maintenance mechanic, boiler work	2,5%
Coating, decolletage	1,1%
Paint and varnish manufacturer (formulation for scouring agent for painting)	1,6%
Plastic, polymer industry	0,3%
Industry paper and cardboard : cleaning of certain blades	<0.1%
Perfume, Soap and bath toilet products manufacturer: use as a detergent	0,03%
Pharmaceuticals production	0,01%
Leather dressing and preparation	0%, 0,2t/year
R&D for pharmaceutical development	0%, 0,03t/year
Motoring, automobile industry	
Aerospace industry	
Furniture and fixation industry	
Transport equipment	

1.1.1 Chemical Intermediate

Approximately 75% of the total trichloroethylene production goes into intermediate applications. High-purity grades of trichloroethylene are used as a feedstock in the synthesis of the refrigerant 1,1,1,2-tetrafluoroethane (HFC-134a, a HFC) together with other CFC substitutes such as 1-chloro-2,2,2-trifluoroethane (HCFC-133a, a HCFC) compound used to manufacture the anaesthetic 'halothane'). In this process, the trichloroethylene molecule is destroyed to form the new fluorinated compound. It also is used in the production of such chlorinated end products as polychlorinated aliphatics and flame-retardant chemicals. In polyvinyl chloride (PVC) manufacture, trichloroethylene is used as a molecular-weight control agent or a chemical process intermediate. It has been used worldwide for more than 70 years.(HSIA, 2010) The demand for trichloroethylene for this use has significantly increased after the Montreal Protocol where the use of CFCs was phased out. Other applications include use as an intermediate in the production of pentachloroethane (ECB, 2004). In some cases, use as an intermediate in production of other chemicals (e.g. HFC-134a) takes place in the same location as production of trichloroethylene (though not necessarily by the same company). (DEFRA, 2005)

1.1.2 Solvent

Contrarily to the use as an intermediate the use as a solvent shows a strong decline. This is due to on-going substitution of trichloroethylene by alternative products and technologies,

- conversion to closed systems in surface cleaning minimizing solvent emissions and reducing solvent consumption.
- maximizing the lifetime in closed systems through service concepts offering solvent maintenance including solvent monitoring and stabilization adjustments.
- use of Closed loop Safety containers with vapour return connections avoiding emissions during filling³. A major producer (Dow Europe GmbH and its affiliated companies/SAFECEM Europe GmbH) has ceased as of April 2009 the supply of trichloroethylene in drums in Western Europe and this approach is being evaluated for all of Europe.

The Solvents Emissions Directive (SED) and anticipation of REACH as well as the of voluntary industry commitments and specific programs of producers e.g. CHEMAWARETM (www.CHEMAWARE.org) for knowledge sharing and awareness raising and the active conversion program to closed loop safety containers reinforced the trend to conversion to closed systems or substitution. Due to the use of closed systems resp. substitution to other solvents the trichloroethylene consumption into solvent applications is expected to drop an additional 60% compared to 2006 consumption. In 2007 the trichloroethylene solvent use accounted for about 25% of trichloroethylene production in the EU and intermediates 75%. This is an inversion of the trichloroethylene use pattern in the 1980s when trichloroethylene was used up to 75% as solvent and intermediate use was only 25% of the EU trichloroethylene production.

In the pharmaceutical sector, trichloroethylene is used according to US Pharmacopoeia in order to detect its presence in active pharmaceutical ingredients using the method USP <467> OVI (Organic Volatiles Impurities) called now USP<467> RS (Residual Solvents). The volume used are really low (around 500 mL/y).

Metal Cleaning/Degreasing

Trichloroethylene is used as an industrial solvent, primarily for vapour degreasing and cleaning of metal parts. More specifically, it is used for the removal of substances such as oils, greases, waxes and buffering compounds, or soils. After the Montreal Protocol in 1995 it has also been used as a replacement for 1,1,1-trichloroethane that has been largely phased out.

Among the properties that have contributed to trichloroethylene's wide acceptance as a metal cleaner and degreaser are the following:

- low flammability (no flash point)
- high solvency
- non-corrosiveness
- high stability
- low specific heat
- low boiling point
- low latent heat of vaporization

Trichloroethylene's advantages for metal cleaning include the ability to degrease more thoroughly and several times faster than alkaline cleaners, and its compatibility with smaller equipment that consumes less energy. Trichloroethylene is an important solvent for degreasing aluminium and for cleaning sheet and strip steel prior to galvanizing. Trichloroethylene also is used for cleaning liquid oxygen and hydrogen tanks. (DEFRA, 2005; HSIA, 2010)

Commercial trichloroethylene formulations include a stabilizer system to help prevent solvent breakdown caused by contaminants such as acids, metal chips and fines, and exposure to oxygen, light, and heat.

As can be seen from table 4, the rate at which solvent is applied varies very significantly amongst companies, which provided information based on consumption in litres per square metre and some in litres per tonne. (DEFRA, 2005)

Table 4: Distribution of specific solvent consumption

	25% of companies use less than	50% of companies use less than	75% of companies use less than
Responses (in litres/m ²)	0.4	8	40
Responses (in litres/t)	8.1	53.3	174

Closed systems, including closed supply and take-back systems in safety containers (like SAFE-TAINER™ system⁴) are today Industry Standard and commonly used in Germany, Austria and Switzerland due to stringent national legislation enforced prior to SED (e.g. German 2.BImSchV⁵). In remaining Europe compliance with the European Solvent Emission Directive (SED) includes a consumption cut-off limit of 1 t/yr for its validity. This leaves surface cleaning applications with <1 t/yr consumption exempted from the need to convert to closed systems. To close the 1t/yr regulatory gap and as an additional risk management measure, producers of trichloroethylene have signed the trichloroethylene Charter to implement the Industry Self Commitment to only deliver trichloroethylene for surface cleaning after December 31, 2010 into closed equipment. Trichloroethylene producers are strongly committed to this trichloroethylene Charter as an essential contribution to increase the safe use of trichloroethylene and its sustainability: After December 31, 2010 customers using open cleaning machines for metal cleaning will no longer be supplied with trichloroethylene by the European manufacturers of Trichloroethylene.(ECSA, 2010) Implementation of SED, requiring conversion to closed systems, substitution of trichloroethylene or ceasing cleaning is progressing but not yet fully finalized in all regions of the EU.

The benefit of conversions to closed systems and impact on worker exposure has been analysed by a thesis done at the poly-technical University (ETH) of Zürich (Grote J, 2003). Subject of the thesis was the development of exposure levels and the number of peoples exposed as function of legislative as well as equipment technology developments related to

⁴ SAFE-TAINER™ trademark system is an example of such a closed supply, use and take-back system offer by SAFECHEM Europe GmbH

⁵ The German 2.BImSchV forced either substitution or the use of closed systems for any volume of halogenated solvent used

the German market. The thesis concluded that as a result of automated closed systems and solvent substitution, the estimated exposure of worker in the near range of closed systems dropped to below 10 ppm, with more sophisticated closed machines below 5 and with best available technology closed machines below 2 ppm. The trichloroethylene concentration in the far range of the cleaning equipment dropped to near or below the detection limit of the monitoring method (1ppm). As a result the estimated number of potentially exposed workers dropped significantly to 500 - 1000. For Germany, this represents more than a 95% reduction in workers potentially exposed to trichloroethylene. The German 2.BImSchV has required closed machines for surface cleaning ~10 years prior to the SED. Since the SED together with the voluntary industry commitment leads to the same requirements on the use of closed machines as the 2.BImSchV, the German experience on the use of trichloroethylene in surface cleaning can be taken as a model. It is expected that by beginning of 2011, once SED and the voluntary industry commitment are fully implemented, all of the EU will be converted to the same equipment technology that is already used successfully in Germany to minimize worker and environmental exposure. (ECSA, 2010)

Adhesives

Trichloroethylene is used as a solvent in certain adhesives due to the combination of its low flammability and drying time. Approximately 1% of trichloroethylene production is used in this application. Trichloroethylene based adhesives have historically been commonly used across a wide range of industrial applications. Additionally, trichloroethylene is often used as a cleaner provided with the adhesive. There were estimated to be 10-15 producers of adhesives containing trichloroethylene in the UK at the time the risk assessment was produced (ECB, 2004). These adhesives are exported (~50% of the produced adhesive). More recent information provided by the producers of trichloroethylene for this risk reduction strategy (DEFRA, 2005) suggests that there are now only a small number of adhesives formulators still using trichloroethylene, with the main use associated with:

- i) the repair of conveyor belts in mines (~0.25% of trichloroethylene production). In underground mining, non-flammable solvents are essential.
- ii) The adhesion of rubber coatings onto vessel walls (~0.2% of trichloroethylene production). Exposure control is realized through controlled venting of the vessels and additional protective respiratory equipment if needed.

Information provided by the Association of European Adhesives Manufacturers in 2004 confirms this view: discussions with one of the largest European adhesive manufacturers indicated that there is generally no trichloroethylene used anymore in adhesives production for products sold to the general public or to industry. Historical applications have been replaced through use of other solvents and new product generations based on aqueous products.

The formulation of the adhesives occurs under industrial conditions in a closed batch process. The use of the special adhesives in mines and in rubber coating, are the only uses where closed systems are not suitable. (DEFRA, 2005)

Miscellaneous

Trichloroethylene is used as a solvent in some aerosol formulations, and as a low temperature heat-transfer medium. Other applications of trichloroethylene include its use as a solvent in the metal processing, electronics, printing, pulp and paper, and textile industries.(HSIA, 2010) It has also been reported for:

- asphalt testing: Trichloroethylene is the solvent listed in national analytical standard procedures. It serves to remove the bitumen fraction of asphalt probes liberating the gravel fraction for particle distribution analysis. Closed analytical equipment has been developed and is used in the testing laboratories as typical risk management measure to minimise exposure during the analytical process.
- wool scouring: The wool scouring process is similar to dry-cleaning. New installations for washing with chlorinated solvents avoid groundwater contamination and are fitted with closed-loop systems to minimize air-stream exhaust to the outside environment. Under these conditions (minimize losses), prevent potential contamination of groundwater from diffuse pollution and accidents), the IPPC document of best available techniques for the textile industry determines wool scouring with a chlorinated solvent (PER and TRI) as best available technique. The solvent process has significant advantages over the water-based scouring techniques which employs 10-15 litres of water per kilogramme of greasy wool processed and comparatively larger energy demands and heavily loaded waste water generation. The solvent process also enables pesticide-free clean wool as pesticides partition strongly to the solvent and are removed with the grease
- high-tech ceramic goods production: trichloroethylene is used as a solvent to dissolve very specific binders used to keep the green ceramic mass in shape and control shrinking during burning. The trichloroethylene is evaporated during the drying process of the applied green ceramic mass. Closed equipment and trichloroethylene recovery re-use as a solvent from exhaust air is employed
- process solvent solvent: trichloroethylene is used as a process solvent in the production of some pharmaceutical products. These are fully-closed processes with recovery of trichloroethylene as solvent for re-use.
- heat transfer fluid: trichloroethylene is used as a heat transfer medium in the closed secondary heat transfer in industrial climate controlled installations such as wind tunnels in the automotive and aeronautic industry.[3]

All these uses are in closed systems or closed system use is well progressing. Other open applications, like solvent in paints, solvent in stone treatment are not of relevance anymore today.

A significant tonnage of trichloroethylene is ascribed to direct use by consumers. The only consumer use identified is for spot cleaning of fabrics to remove stains. It is also reported to have been used as a food extractant in Spain, but no details have been obtained for this application. The advent of triacetate fibres in the 1950s led to the replacement of trichloroethylene with tetrachloroethylene in dry cleaning machines, as the latter has a milder solvent action. Therefore there is either little or no use of trichloroethylene as a dry cleaning solvent in the EU. Trichloroethylene is understood to be used (or to have been used) as a solvent carrier for bitumen coatings, in solvent based phosphating systems, for textile desizing scouring, in leather preparation, the pharmaceutical industry and as a heat transfer agent. Trichloroethylene has also been used as a carrier solvent for pesticides, printing inks, varnishes and paints, as an anaesthetic, and as a solvent for waxes, fats, resins and oils. The

information obtained suggests that it is no longer used for these applications but the extent to which it is so used within the EU has not been established. (ECB, 2004)

3. End products potentially containing trichloroethylene

There are still places where trichloroethylene can be found as a solvent to be used. Some consumer products can contain trichloroethylene such as corrective liquids for typing machine, the paint removers, the adhesives, the stain-removers and the liquids for carpet cleaning, only at concentrations of 0.1% w/w or above, as trichloroethylene is a Category 2 carcinogen. The net effect will be negligible human exposure via consumer products. (Gasztowtt B. et al., 2008)

4. Transport and Storage

At the UK manufacturing site, trichloroethylene is piped to the packing area where it is then metered into road tankers (750 to 9000 litres) and bulk-tankers in loads from 12 – 23 tonnes, or into 20 and 210 litre drums for transport.

Drums are mild steel without lining or coating. Tankers are mild steel or stainless steel. The trichloroethylene is then transported to users or to chemical distributors who may repackage before selling on to their customers.(ECB, 2010)

In general, industry has implemented voluntary risk management measures:

- Delivery, transport, handling and storage of trichloroethylene via a closed loop system by the use of closed loop safety containers (e.g. SAFE-TAINER™) with vapour return line. A major producer has ceased supply of trichloroethylene in drums as of April 2009 in Western Europe. This approach is being evaluated for all of Europe.
- Solvent Services including monitoring and re-stabilization to enhance the lifetime of the solvent and reduce solvent consumption. These services meet the demand of modern vapour degreasing machines which include internal solvent recycling through distillation.
- Waste-take back in closed loop safety containers.(ECSA, 2010)

2 INFORMATION ON EXPOSURE

Most significant exposures to trichloroethylene occur in the workplace. Throughout the EU, the total number of workers exposed during manufacture and packing has not been established. It is understood that approximately 75 persons (including maintenance operators) are exposed to trichloroethylene during its UK manufacture and transport through the manufacturing plant. The number exposed does not include outside contractors (such as electricians) who might be working on the plant, which could be up to 60 workers. (ECB, 2010)

Overall, assuming similar numbers of workers are exposed at each of the 4 manufacturing plants it is estimated that 400-700 workers (including maintenance personnel and contractors) are exposed during manufacture and packing of trichloroethylene.(ECB, 2010)

Increased potential for exposure may be encountered by the following workers:

- dry cleaners
- mechanics
- oil processors
- printers
- resin workers
- rubber cementers
- shoe makers
- textile and fabric cleaners
- tobacco denicotinizers
- varnish workers

2.1 Exposure limits

The American Conference of Governmental and Industrial Hygienists (ACGIH) recommends 100 ppm in air as so exposure limit for an 8-hour workday. NIOSH recommends that peak exposure never exceed 150 ppm. It is important to note that these values are based upon information derived from acute, high-level exposure incidents, not long-term, low-level exposures.(Pactox, 2010).

Lauwerys has suggested a "Tentative Maximum Permissible Level" for TCA in the plasma of 50 ppm, designed to keep total uptake of trichloroethylene below levels found to be safe in resting volunteers. Impairment of some central nervous system functions can be found in exposure around 50 ppm (Grandjean E. *et al.*, 1955), although some investigators have not been able to detect such adverse effects (17-18). Again, workers doing strenuous exercise or who have significant skin contact may well be at risk even if they are exposed to "legal" levels of trichloroethylene.

The German Research Society has published a recommendation for a "Biological Tolerance Value" for trichloroethanol concentration in the blood, aimed at assuring that exposures to trichloroethylene in the air are kept under 50 ppm. Their recommendation is that the trichloroethanol blood level drawn at 5:00 p.m. on Friday afternoon ("end-of-shift/end of week" specimen) be kept under 5 mg/liter (Pactox, 2010).

The EU Scientific Committee for Occupational Exposure Limits (SCOEL) recently proposed a new Occupational Exposure Limit (OEL) (8-hour TWA) for trichloroethylene of 10 ppm with a Short-Term Exposure Limit (15 min) of 30 ppm. SCOEL recognised in its new evaluation of the toxicological database that a threshold exists for the carcinogenicity of trichloroethylene. Closed surface cleaning equipment is able to meet these values (Grote J, 2003). A major trichloroethylene producer in Europe has introduced an internal exposure limit of 5 ppm which is communicated to end users via the Safety Data Sheets.

Table 5: Occupational Exposure Limits (OELs) for trichloroethylene in the EU (ECB, 2010)

Country	8-hour TWA		STEL mg/m ³	STEL ppm
	mg/m ³	ppm		
UK	550	100	820	150
Austria	270	50	1080	200
Belgium	269	50	1070	200
Denmark	160	30		
Eire	535	100	802	150
Finland	160	30	240	45
France	405	75	1080	200
Netherlands	190	35	538	100
Sweden	50	10	140	25

OELs are based on the information available at the time of the limit setting, which varies from country to country – see table above.

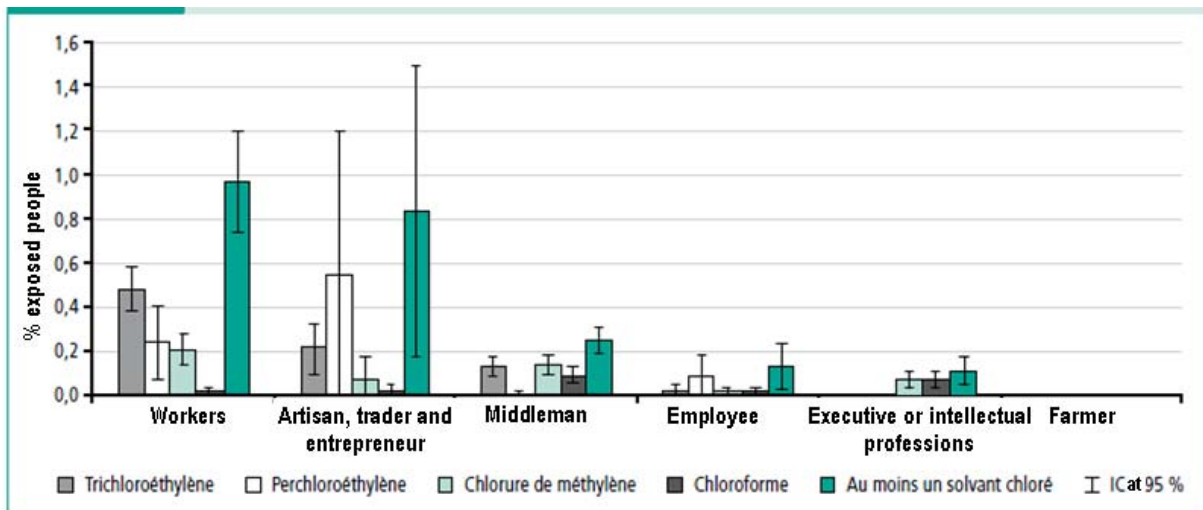
However, the interpretation of specific OELs needs to be viewed within the framework (legal or advisory) in which each OEL sits.

2.2 Exposure measurements

Occupational exposure to trichloroethylene in the U.S. has been identified in various degreasing operations, silk screening, taxidermy, and electronic cleaning. The National Institute for Occupational Safety and Health (NIOSH) conducted a survey of various industries from 1981 to 1983 and estimated that approximately 401,000 U.S. employees in 23,225 plants are potentially exposed to trichloroethylene. Time-weighted average concentrations from personal monitoring ranged from 1.2 to 5.1 ppm at individual industrial sites where trichloroethylene was used (ATSDR, 1997); (Wu C. and Schaum J., 2000).

In France, and as shown figure 2, chlorinated solvent exposures are low. However, trichloroethylene is the chlorinated solvent for which there is, in the active population, the highest percentage (0.30%) of male exposed whereas a few women are exposed (0.02%). (InVS and Goupe de travail Matgéné, 2009)

Figure 2: Exposition prevalence to chlorinated solvent in 2007 for various occupational categories.



2.2.1 Envirowise study, UK, 1996

In 1994, HSE inspectors carried out a survey of vapour degreasing operations in UK factories. Detailed examinations of 120 degreasers using trichloroethylene showed that over 93% of the degreasers were traditional open-topped types. Some were provided with lids, covers and hoists. The survey concluded that the design of the degreasing plant had a number of problems that resulted in excessive solvent use, environmental and safety problems (due presumably to exposure to solvents) and increased costs. The types of problems noted are detailed in Table 6.(DEFRA, 2005)

Table 6 Design feature needing improvement(DEFRA, 2005)

Design feature	Degreasers needing improvement
Inadequate rim ventilation	67%
Hoist speed too fast	63%
Sited in potential draughts	60%
Inadequate topping-up method	60%
Inadequate freeboard ratio	51%
Unsuitable lid or no lid at all	36%

Source: Envirowise (1996).

Since this information was collated, significant improvements have been and are being made within the metal degreasing industry in order to comply with various pieces of legislation, particularly the Solvent Emissions Directive. Therefore, the above information is not likely to be representative of degreasing machines currently in use in the UK and also may not historically be true of machines in other countries.(DEFRA, 2005) The number of open type machines is now estimated to be significantly lower than when the above survey was undertaken, with companies using machines that enable compliance with relevant legislation.

There is good evidence that use of trichloroethylene is decreasing and also that emissions are decreasing (see Table 7 which presents emissions reported from large sites under the ‘pollution inventory’ in the UK). This is to be expected, given that there is a range of legislation that has been introduced in recent years relating to use and emissions of substances such as this.(DEFRA, 2005)

Table 7 Reportable Air Emissions of trichloroethylene in England and Wales 1999-2003 (t)

1999	2001	2003
1,198	685	632

Source: Environment Agency (2004). Includes only sites reporting emissions of more than 1 tonne per year.

However, emissions of trichloroethylene have remained very significant within the EU in recent years. For example, sites reporting emissions for the European Pollutant Emissions Register emitted over 2,000 tonnes in 2001, as shown in Table 8.(DEFRA, 2005)

Table 8 Emissions Reported to EPER for 2001 (tonnes)(DEFRA, 2005)

Country	Number of Sites	Emissions (t)
Finland	1	12
Sweden	1	9
Belgium	5	50
Spain	3	81
Italy	1	5
UK	24	413
Portugal	1	60
Denmark	1	3
France	69	2,071
Total	106	2,704

Source: EEA (2004).

It should be noted that the UK emissions for 2001 do not agree with those from the UK Pollution Inventory in Table 7. These data also exclude a large number of sites (perhaps indicating why the numbers for France and the UK are higher than for other countries). However, they are useful in providing an indication of the emissions currently occurring across the EU. These data should be used with caution given that the EEA (2004) has indicated that not all countries submitted full data sets and because there were problems reported with emissions estimation methodologies.(DEFRA, 2005)

As shown in figure 3, there were a significant number of sites emitting more than this in 2001 (around 60 sites based only on those reporting to the EPER). However, this does not take into account reductions that may have been achieved at these sites between 2001 and the current time, as well as up to 2007 when the Solvent Emissions Directive must be fully implemented. Nor does it take into account the actual environmental concentrations (if dilution is sufficient, the PNEC may not be exceeded even if the emissions are greater than those for the realistic worst case site).

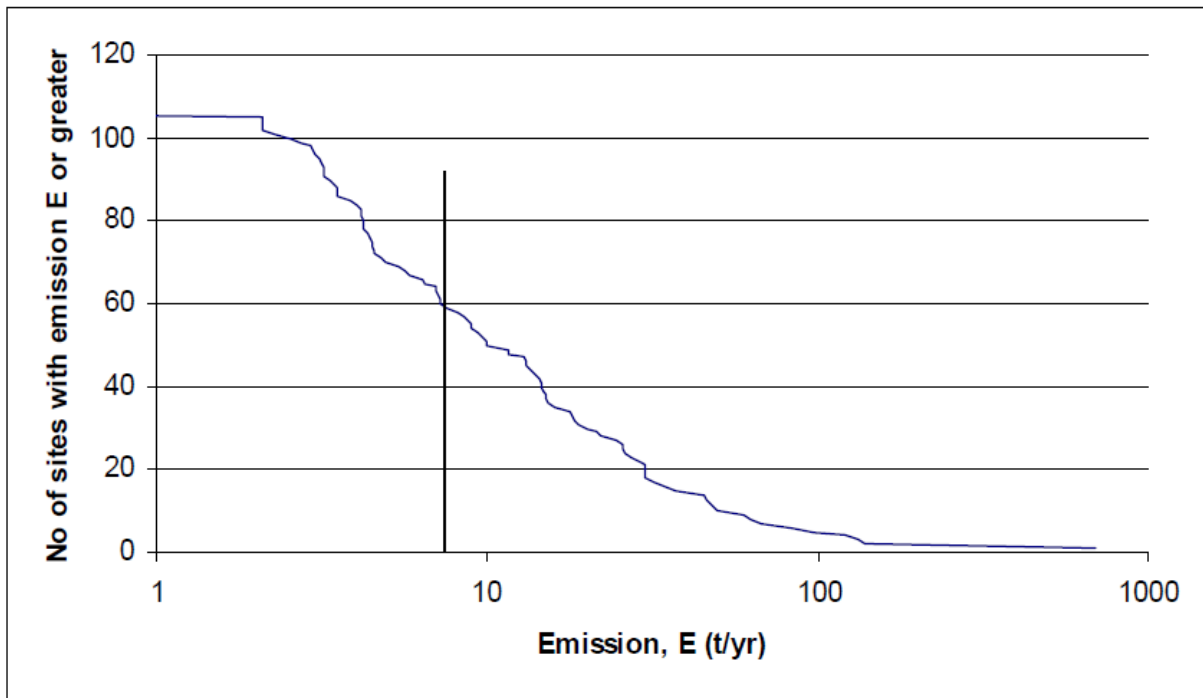


Figure 3: Number of site for a given emission quantity (t/year)

2.2.2 Colchic study, France, 2002-2008

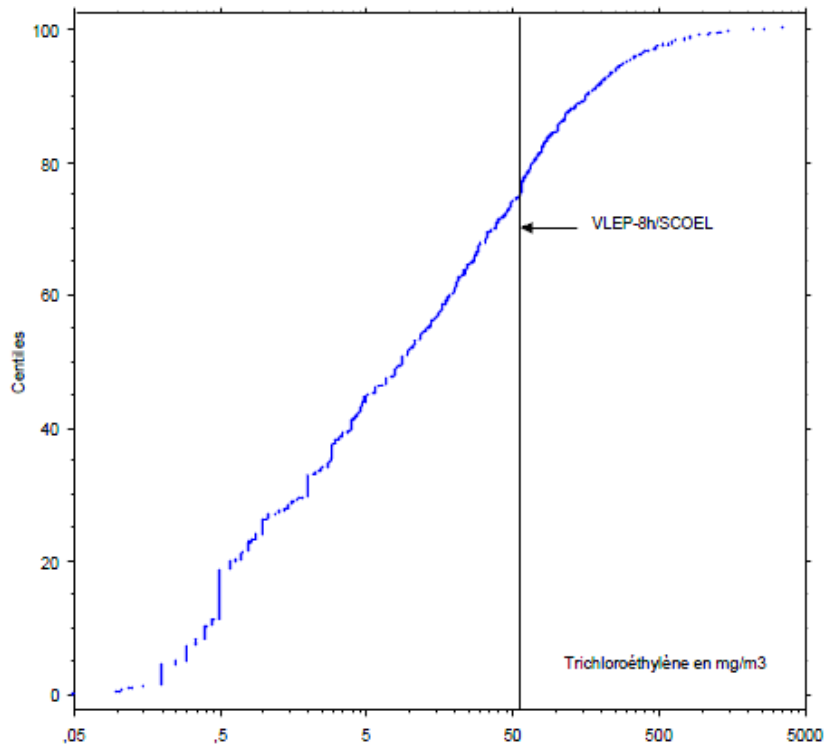
In France, a huge study has been performed from 2002 to 2008 where 1 396 measures have been performed in 152 factories or business during 193 interventions. (INRS and Raymond VINCENT, 2009) These measures have been performed by individual sampling (n=726) or by active or passive vapour trapping systems most frequently on activated charcoal (n=623). Concentration of trichloroethylene was determined after desorption with CS₂ eluant by quantification using chromatography analysis (GC-FID). Level of exposure to trichloroethylene was determined using the 8 hours exposure measures (n=740) as short term measures did not allow performing statistic analysis.

Global Analysis

Table 9: Statistics on the 8 hours-exposure measures to trichloroethylene for period 2002-2008 (mg/m³).

Type of exposure	Number of results	Arithmetic mean	Geometric mean	Median	range	Percentiles		
						25	75	90
8 hours	740	74.9	8.4	9	0.05-3535	1	58	168

Figure 4: Cumulative frequencies of exposure measures – 8 hours

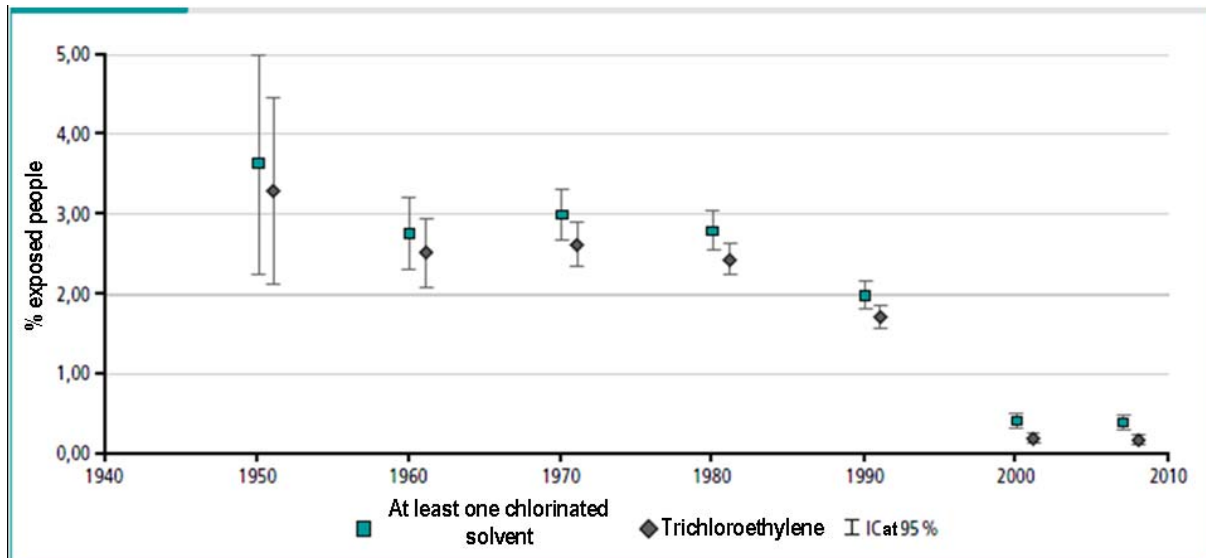


The graph (figure 4) above shows that 25.9% of the results exceed the VLEP-8h proposed by SCOEL of 54 mg/m³ (10ppm).

Trend of the exposure between 2002 et 2008(INRS and Raymond VINCENT, 2009)

Analysis of the data does not show significant evolution of the exposure between 2002 – 2008, as presented within the INVS paper (figure 5)(InVS and Goupe de travail Matgéné, 2009):

Figure 5: Evolution of the exposition prevalence to at least one chlorinated solvent and to trichloroethylene



Life-span chlorinated solvent exposure prevalence evolution are due to drastic decreases in the use of these solvents in the nineties (InVS and Goupe de travail Matgéné, 2009)

Exposure by activity sectors

During 2002-2008, exposure measurement for trichloroethylene took place in 33 different activity sectors from the 88 NAF inventories (NAF is the French equivalent of EU NACE, the coding system for trade sectors). The places where measures were made belong to 6 main trade sectors (table 10):

Table 10: Statistics on exposure (mg/m³) for various trade sectors.

Trade sector	Results number	Arithmetic mean of exposure (mg/m ³)	Geometric mean of exposure (mg/m ³)	Median	Scope	Percentiles		
						25	75	90
Manufacture metal products, except machinery and equipment (NAF 25)	215	108,3	24.9	35	0.0-3535	8.6	94	236
Printing and reproduction (NAF18)	91	9.7	1.9	1	0.2-240	0.5	9.6	19.4
Manufacture of rubber products and plastic (NAF22)	85	55.5	13.3	14.1	0.5-434	3.1	75.5	191
Manufacture computer, electronic and optical products (NAF26)	38	5.3	1.6	1.3	0.1-93.5	0.6	2.8	8.9
Manufacture of electrical equipment (NAF27)	23	0.5	0.3	0.2	0.2-4	0.2	0.5	1
Chemical industry (NAF20)	14	33.9	10.6	18.6	0.1-103	3.5	54	85.9
Other sectors	274	94.3	8.3	8	0.05-2615	1.1	54.3	215

This analysis shows that metallic product manufacture is the trade sector with the highest exposure to trichloroethylene. There are other sectors where measures were above the VLEP-8h proposed by the SCOEL. However, the number of available measures was not important enough to perform statistics.

2.2.3 OQAI measures, France, 2003-2005

This campaign allows having data on the concentration existing for human through its environment. Figure 6 displays the distribution of the concentration found in the main bedroom measured in 541 accommodations from 2003 to 2005 (passive sampling for 7 days) balanced and extrapolated taking into account variables from the OQAI sample and data from the overall accommodations.

Figure 6: Trichloroethylene concentration in the main bedroom

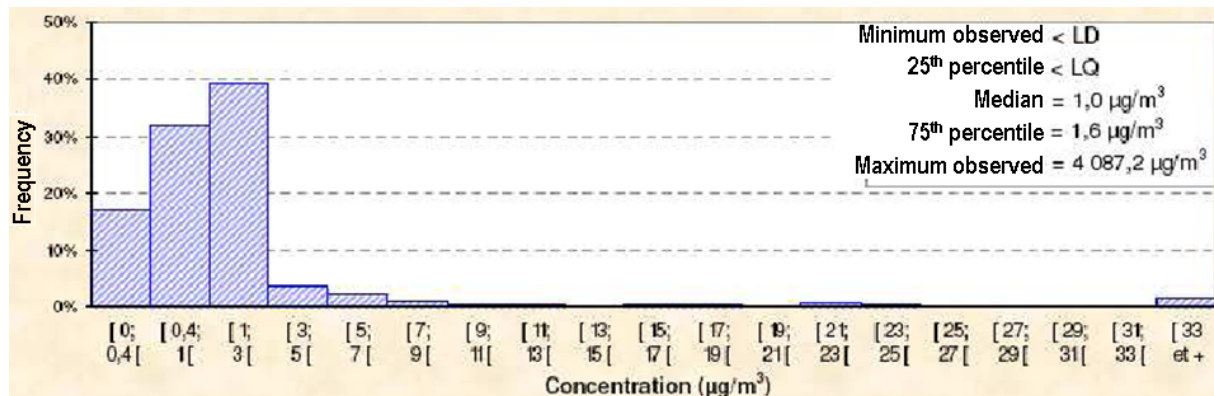
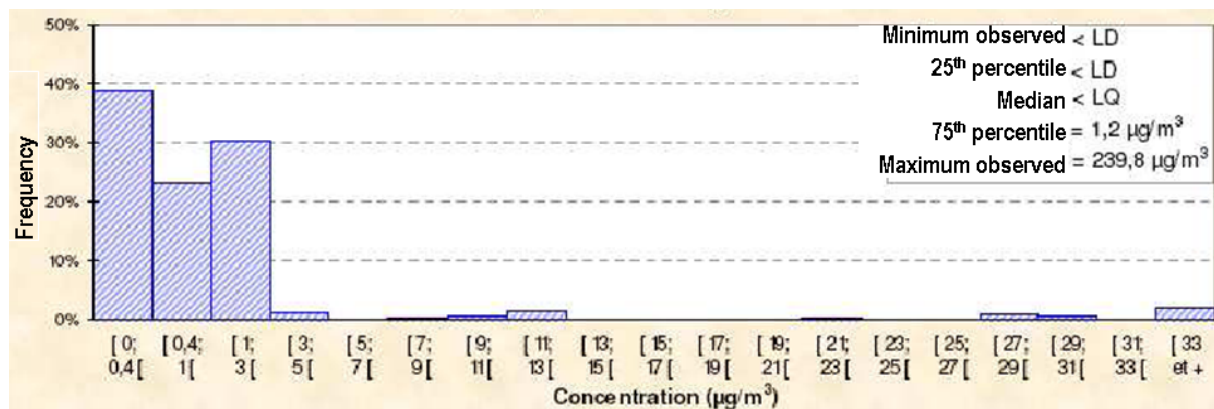


Figure 7 displays the distribution of the concentration found in the 139 garage measured 2003 to 2005 (passive sampling for 7 days) balanced and extrapolated taking into account variables from the OQAI sample and data from the overall accommodations.

Figure 7: Trichloroethylene concentration in the garage communicating with accommodation



These measures were compared with data provided by the literature in table 11

Table11: Summary of the literature data for concentration of trichloroethylene in accommodations

Study description	Values ($\mu\text{g.m}^{-3}$)	Source
750 accommodations in 10 Canadian provinces (1991)	mean = 1,4 (max. = 165)	[OMS 2005]
Accommodations in Shimizu (Japon). Sampling of 24 hours (2000 – 2001)	Summer (n=25) Geo. mean = 0,22 Percentile 10 = 0,10 Percentile 90 = 0,78 Winter(n=21) Geo. mean = 0,36 Percentile 10 = 0,22 Percentile 90 = 0,67	[Ohura 2006]
30 Accommodations in Mexico Sampling of 24 hours (1998 – 1999)	Percentile 90 = 0,7 Max = 0,9 25 % de logements > 0,52	[Serrano-Trespacios, 2004]
New York (n= 46) et Los Angeles (n= 41) logement étudiants Prélèvements de 48 heures (1999 – 2000)	Means : NY (winter) = 1,1 NY (summer) = 0,3 LA (winter) = 0,2 LA (autumn) = 0,2	[Sax 2004]
Mean scenario OMS	Mean = 1,4	[OMS, 2005]
Accommodations of Minnesota (n= 101) Sampling of 6 days 1997	Mean = 0,6 Percentile 25 = 0,4 Percentile 95 = 1,1	[Adgate 2004]
Residences of 6 european town (Athènes (43), Bâle (47), Oxford (40), Helsinki (192), Milan (46), Prague (48)) (n _{tot} = 416) Passive sampling (1996-1997)	n=146 median = 0,8 mean arithm. = 11,5 maximum = 3126 For each town Helsinki : Moy=1 ; Max = 41 ; Med = 0,69 Athenes : Moy=4,70; Max = 76,8 ; Med = 1,03 Bâle : Moy=0,93; Max=5,3 ; Med = 0,71 Milan: Moy =88,79; Max=3126 ; Med = 8,56 Prague: Moy=4,04; Max= 95,8 ; Med =0,88 Oxford : Moy= 2,25; Max=29.5 ; Med= 1,35	EXPOLIS : www.ktl.fi
OQAI Pilot Campain (2001) Sampling of 7 jours. 90 accomodations	Median=0.9	[Mosqueron 2004a et b]

The data, even at the world level, are homogenous with an average between 1 to 2 $\mu\text{g.m}^{-3}$ with some data far above in case of abnormal situations. Detection limits were not always available but seems variable depending on the labs. Periods of study are given when available.

A study performed by Atmosf'air Bourgogne and the French national school for public health in 2002/2003 for measuring the volatile organic compounds (VOCs) concentrations was

performed in various public places by placing passive collectors for 1 week. In schools (3 different measures) concentrations were smaller than 1,0 $\mu\text{g.m}^{-3}$ except one measure at 7,0 $\mu\text{g.m}^{-3}$ (Mosqueron L., 2004a; Mosqueron L., 2004b). This campaign took also place in a cafeteria, a cinema, a train station, a bar, a day care, a MJC (community arts centre / youth club), a town hall and a sport center. Concentrations were below 1 $\mu\text{g.m}^{-3}$ instead of the cinema where the concentrations measured were 138 and 157 $\mu\text{g.m}^{-3}$ associated with the use of a solvent for cleaning up the chewing-gums.

In the BASE (Building Assessment Survey and Evaluation) study performed in the USA, trichloroethylene was detected in 40 to 61% of the measures performed in 56 offices with concentration varying from 0,2 et 18 $\mu\text{g.m}^{-3}$ (Girman J-R. *et al.*, 1999). In a car during rush hour (2 measures) and in public transport (8 bus, 8 measures/bus) concentration was respectively of 0,7 $\mu\text{g.m}^{-3}$ (\pm 0,8 $\mu\text{g.m}^{-3}$) and 0,6 $\mu\text{g.m}^{-3}$ (\pm 0,6 $\mu\text{g.m}^{-3}$) ; in the afternoon, they were respectively of 0,5 $\mu\text{g.m}^{-3}$ (\pm 0,1 $\mu\text{g.m}^{-3}$) and 0,5 $\mu\text{g.m}^{-3}$ (\pm 0,4 $\mu\text{g.m}^{-3}$) (study performed in Detroit, Michigan (Batterman SA *et al.*, 2010)).

Based on OQAI data, the median concentration measured outside (passive collector) are below the detection limit (1 $\mu\text{g.m}^{-3}$). Table 12 gives the data provided in the literature:

Table12: Summary of the literature data for concentration of trichloroethylene in external environment

Study description	Values ($\mu\text{g.m}^{-3}$)	Source
Canadian towns, annual mean	Toronto (1984-1985) : 1,9 Montréal (1984-1985) : 0,7 Sarnia (1 month 1983) : 1,2 Vancouver (1 month 1983) : 1,0	[OMS 2005]
Canadian towns, max values	Toronto (1984-1985) : 8,6 Montréal (1984-1985) : 1,7 Sarnia (1 mois 1983) : 3,6 Vancouver (1 mois 1983) : 3,4	[OMS 2005]
115 measure stations placed in 14 states (USA, 1998)	0,88 [0,01 – 3,9] P90 = 1,76	[OMS 2005] [US-EPA 2001]
External air mean concentration 1985-1998 the US	Rural : 0,42 Urban : 1,26 Sub-Urban : 1,61 Commercial : 1,84 Industrial : 1,54	[OMS 2005]
European town	Means : 0,8 – 18,5 Extremes : 0,04 – 64,1 Athènes : 9,9 (48 h) Bâle : 0,6 (48 h) Milan : 3,7 (48 h) Prague : 5,4 (48 h)	[OMS, 2005] [European commission, 2005]

Here again, data are homogeneous worldwide with a gradient from the non polluted environment 0,003 – 0,1 $\mu\text{g.m}^{-3}$ < countryside 0,002 – 6 $\mu\text{g.m}^{-3}$ (mainly < 1) < industry and proximity from the emission source 0,3 – 30 $\mu\text{g.m}^{-3}$ (mean < 10). Urban sides display concentration between 1 and 2 $\mu\text{g.m}^{-3}$ with values going up to 10 $\mu\text{g.m}^{-3}$ during short periods or particular places.

The different measures give an estimation of the mean exposure for the population at $1 \mu\text{g}\cdot\text{m}^{-3}$.

2.2.4 The CDC campaign, Canada, 2007

Levels of halogenated solvents in blood reflect recent exposure. In the NHANES 2003-2004 subsample, blood levels of trichloroethene and dichloromethane were generally not detected as they were also detected infrequently in previous U.S. surveys.

Population studies in Italy and Germany have reported multifold higher tetrachloroethene and trichloroethene blood levels than the U.S. surveys (Brugnone F. et al., 1994).

Comparatively higher blood levels of tetrachloroethene and trichloroethene have been noted for urban and industrial residential settings than for rural settings (Barkley J. et al., 1980; Begerow J. et al., 1996).

Residing near dry-cleaning facilities or storing recently dry-cleaned clothes at home can contribute to increased blood tetrachloroethene levels. (CDC, 2010)

2.2.5 Exposure evaluation methodologies:

Uptake and Metabolism (Pactox, 2010)

About 30 to 50 percent of the inhaled vapor of trichloroethylene is absorbed by the lungs during inhalation of the vapor. (Monster A.C.1984). The absorption of the solvent can increase by a factor of 2 or 3 during exercise (Vesterberg O. and Astrand I., 1976). Skin contact is also an efficient route of exposure (Sato A. and Nakajima T., 1978).

Trichloroethylene is metabolized more than most of the other chlorinated solvents. Up to 90% of an inhaled dose is metabolized. It is first converted to an epoxide, then to chloralhydrate ("knock-out drops"), and finally to trichloroethanol or Trichloroacetic acid (TCA). Trichloroethylene is stored in the fat; thus, repeated exposures give rise to higher levels of the solvent and its metabolites than do single exposures (Ertle T. et al., 1972; Fernandez J.G. et al., 1977; Savolainen H., 1981).

Trichloroethylene itself is eliminated fairly rapidly from the bloodstream. Within 5 days of industrial exposure, blood levels are under 10-ppb (Monster A.C. et al., 1979). Within 3 days of a single 6-hour exposure, blood levels drop below 20-ppb (Muller G. et al., 1974). However, after repeated exposures, the half-life of the trichloroethylene in the blood is longer.

Biological Monitoring (Pactox, 2010)

Trichloroacetic Acid in Plasma

Due to its efficient binding to serum albumin, trichloroacetic acid has a half-life in the blood of about 3 days; this is longer than the half-life of the parent compound (Monster A.C.1984).

This graph of TCA levels in plasma indicates that the levels rise with repeated exposure to trichloroethylene. It is important to note that alcohol interferes with the metabolism of trichloroethylene to TCA. Thus, in a person who has been drinking alcohol, a low TCA level cannot be used to rule out an overexposure to trichloroethylene. Moreover, this metabolism is variable in between individuals and some persons from the Japanese population have a limited capacity to metabolize trichloroethylene to TCA. Exposure levels nearing 100 ppm in air appear to saturate their metabolism (Ikeda M., 1977). Adoption of this BEI for urinary TCA would likely require that concentrations

of trichloroethylene in air be kept well below 100 ppm. Owever, Droz has argued that urinary TCA is a fairly insensitive index of overexposure to trichloroethylene (Droz P.O. and Fernandez J.G., 1978) and therefore proposed to measure it in urine.

Trichloroethanol in Urine (Pactox, 2010)

Droz has proposed a fairly sensitive way of determining overexposure to trichloroethylene by measuring trichloroethanol in urine both before a shift starts and the next morning (Droz P.O. and Fernandez J.G., 1978). Comparing these two levels gives a very specific determination of the average airborne trichloroethylene concentration during the shift.

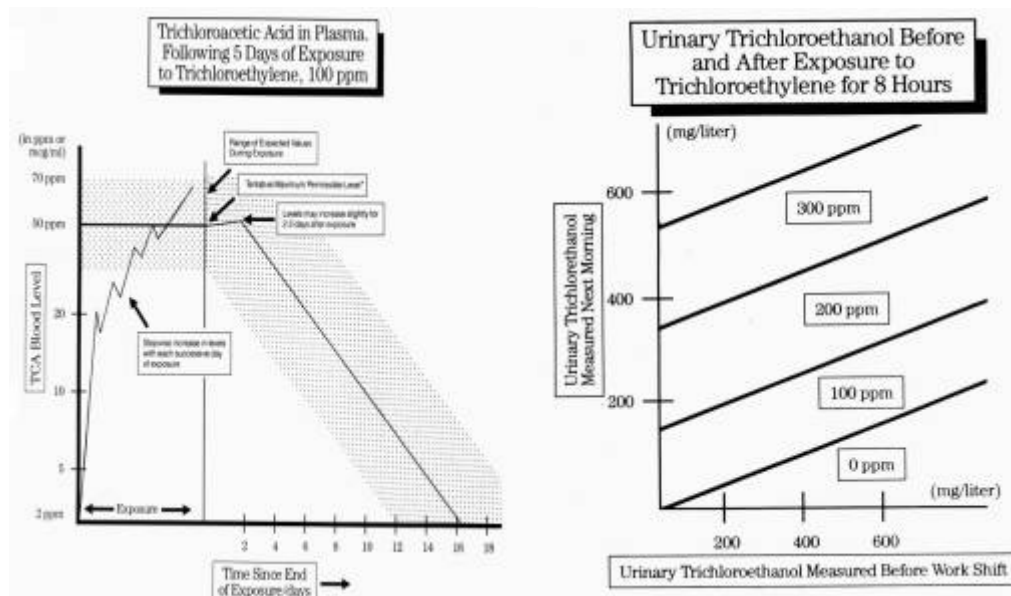


Figure 9 & 10

2.3 Exposure to trichloroethylene from production and use (ECB, 2004)

Releases of trichloroethylene may be from point or diffuse sources. Point source releases of trichloroethylene may occur from production and handling of trichloroethylene and through its use as a chemical intermediate. Trichloroethylene has a wide dispersive use and it is likely that the majority of trichloroethylene used will be released to the environment (excluding that which is used as an intermediate). Due to its high volatility, a majority of the trichloroethylene produced will be released in the atmosphere (60 à 90 %). The major release is likely to be to the atmosphere where trichloroethylene has a lifetime of about one week and so is not likely to enter the stratosphere (see Section 3.1.2.1.1). There will be a smaller release to the aquatic environment. For the purposes of this assessment, a release of 90% to air and 10% to water is assumed where no other information is available.

A review of air emission factors by the US EPA (1988) gives an emission factor for release of trichloroethylene during production (general process) of 2.07 kg/tonne trichloroethylene produced. The same report also gives an emission factor for release of trichloroethylene during production of trichloroethylene and tetrachloroethylene by oxychlorination of 0.082 kg/tonne produced.

Site-specific information has been provided by European producers regarding release of trichloroethylene to the air during production. The largest single release is 879 tonnes/year, which corresponds to 2.93 tonnes/day over 300 days. This value includes emissions from processing as an intermediate as well as from production, but these cannot be separated. This release will also be used as the emission to the regional environment, as 2.41 tonnes/day over 365 days. The sum of the emissions from the other sites, 78 tonnes/year, will be used for the continental emissions. The releases are shown in table 13.

Site-specific information has also been provided by companies which produce trichloroethylene regarding release of trichloroethylene to the aquatic compartment during production. Based on the information from various sources, emission factors to water range from $6.4 \cdot 10^{-4}$ to 0.047 kg/tonne for larger plants (>10,000 tonnes). One higher factor was estimated for a small site at 0.83 kg/tonne.

Other releases of trichloroethylene will be from its use as a metal degreasing agent, in adhesives and as a solvent. These releases are likely to occur from many different sites and so this is a diffuse release on a regional scale. Exposure during use is likely to be much higher than exposure due to production and handling. Emissions from the use of trichloroethylene as an intermediate are also estimated. Release from recycling has not been considered although plants for waste elimination are probably contributing to release into atmosphere, in soil and waste water.

The European inventory of the air pollution emissions reports that 2 704 tonnes of trichloroethylene was released into the atmosphere in 2001: 854 tonnes from the metal industry, 654 tonnes from the surface treatment plants and 34 tonnes from the waste elimination and recycling plants. In Metropolitan France, the emission of trichloroethylene was estimated at 2 400 tonnes for 2006.

It has previously been estimated that western European emissions to air due to end use (degreasing, adhesives, consumer and “other” uses) of trichloroethylene are 60% of total consumption (CEFIC, 1986). The fate of the remaining trichloroethylene is not clear. It may be incinerated or released into other environmental media but it is also possible that it may be recycled.

Process	Compartment	Local	Regional	Continental
		Release (kg/day)	(kg/day)	(kg/day)
Production	Air	2,930	2,410	214
	Water	Site-specific basis	13.7	10.9
Manufacture of other substances	Air	67	55	68
	Water	6.7	5.5	6.8
Handling (formulation as a solvent)	Air	400	329	627
	Water	0.25	0.21	0.32
Metal degreasing	Air	42	10,898	98,083
	Water	4.6	1,211	10,898
Formulation of adhesives	Air	8.3	68.5	406
	Water	1.0	8.2	49
	Soil	1.67	13.7	81
Use of adhesives	Air	19	1,899	17,088
Formulation of consumer products	Air	3.85	32	285
	Water	0.46	3.8	34
	Soil	0.77	6.3	57
Consumer products: use	Air	0.58	1,139	10,253
	Water	0.064	127	1,139
Others	Air	0.29	570	5,126
	Water	0.032	63	570
Total	Air		17,400	132,150
	Water		1,432	12,708
	Soil		20	138

Table 13: Environmental releases of trichloroethylene

3 INFORMATION ON VOLUMES

3.1 Production volumes (ECB, 2010)

Trichloroethylene in the environmental compartments are exclusively anthropogenic[21] Historically, European production has been between 51,000 and 225,000 tonnes per year (According to the IUCLID data provided in 1995 from the risk assessment), with four (or five depending of the source) companies producing trichloroethylene in the EU (ECB, 2004). Since the mid 1970s, the use of trichloroethylene has declined by over 50% due to improved operating conditions leading to better solvent recovery and the use of other chlorinated solvents for metal cleaning. Hence, a considerable proportion of the reduction in production has been due to improved management practices, increased solvent recycling and waste management.

Due to industry rationalization and consolidation over the last few decades, the number of European trichloroethylene producers declined from > 10 in 1984 to 2 in 2009. Information from the European Chlorinated Solvents Association (ECSA) indicates that production of trichloroethylene in the European Union (EU) was 138,000 tonnes per annum in 1996. However, there are also a number of agents acting as distributors for smaller amounts of

imported trichloroethylene. There are considerably more companies listed as suppliers (i.e. all vendors, including distributors) in the IUCLID datasheet for the substance (ECB, 2000). A list of these companies by country is shown in the table 14.(DEFRA, 2005)

Table 14: List of suppliers by country

Country	Number of Companies
Austria	1
Belgium	1
France	1
Germany	5
Italy	2
Netherlands	5
UK	1

Source: ECB (2000). The current number of suppliers is believed to be different compared to when this information was compiled.

Another source indicates that it is produced and used in large quantities within the European Union (total production in the EU was around 100,000 tonnes in 2003) (DEFRA, 2005) . There are currently two companies producing trichloroethylene in the EU, a reduction from the 5 producers in the 15-country EU in 1996. European production of trichloroethylene is between 100,000 and 150,000 tonnes/annum. Production figures supplied by the European Chlorinated Solvents Association (ECSA) indicated that there has been a decline in the production and use of trichloroethylene over a number of years.

Information on the balance between production and imports is not available. A few companies also recycle a relatively small amount of trichloroethylene.

There are a number of agents acting as distributors for smaller amounts of imported trichloroethylene. A few companies also recycle a relatively small amount of trichloroethylene. In 2008, importation of trichloroethylene in France consisted in 14368 tonnes whereas exportations consisted in 220 tonnes (source: Direction générale des douanes). Annual consumption in 2005 was estimated in France at 3857 tonnes.

3.2 Volume per use

However, there has also been a reduction in consumption (use) of trichloroethylene, especially in solvent degreasing. The majority of produced trichloroethylene goes into intermediate applications today (ca. 80%) The use of trichloroethylene as solvent dropped by 85% from 1984 until 2006, with a further estimated decline of 60% from 2006 until 2010. 184000 mt of trichloroethylene were used as solvent in 1984. The consumption dropped to 25000 mt in 2006. This continuous decline is related to: stricter regulation, the reclassification of trichloroethylene in 2002, the use in closed systems and further industry risk reduction measures such as voluntary industry commitment and closed loop systems (see below). (ECSA, 2010) Of the 138,000 tonnes produced per annum in 1996, 77,000 tonnes were sold into the EU for uses other than as a chemical intermediate (see below). The remaining 61,000 tonnes were either exported or used as an intermediate, but no breakdown between export and intermediate use is available for 1996. EU estimated production in 2000 was 74 000 tonnes per annum; EU sales for 2005 were around 23 000 tonnes. In Germany, where a stringent

emission control law (2.BimSchV) was put in place a few years ago, sales of trichloroethylene reduced from 16,000 tonnes in 1991 to 5,200 tones in 2000 (European Chlorinated Solvent Association). More recent information (personal communication, ECSA, 2001) indicates a similar level of sales within the EU to that for 1996, with use as an intermediate of ~45,000 tonnes.

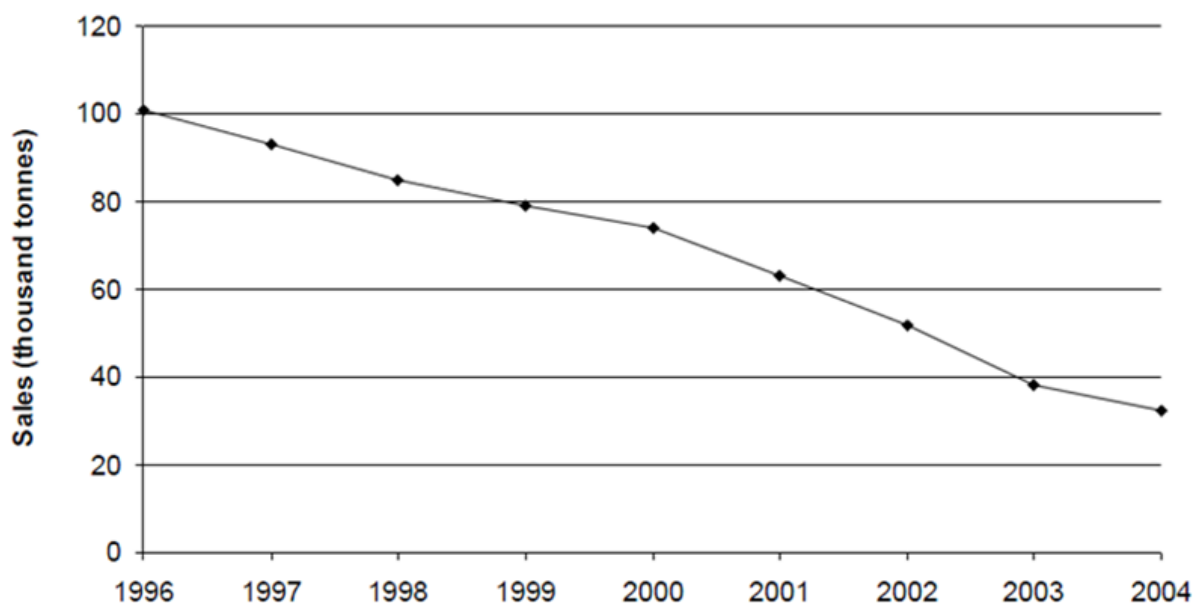
The reduction of sales is also believed to have been compounded more recently by the revised classification of the substance as a category 2 carcinogen. Western European sales in 2003 were only 38,000 tonnes and were 32,500 tonnes in 2004, significantly lower than sales in the recent past. The average annual change from 1998-2003 is -14.9% as given by ECSA in 2004 (DEFRA, 2005).

Table 15 Western European Sales for Trichloroethylene

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004
TRI (kt)	101	93	85	79	74	63	52	38	33

Source: ECSA (2004, 2005).
Excludes sales for use as an intermediate. Data have been rounded.

Figure 11 Trend in Sales of Trichloroethylene 1998-2004 (ECSA, 2004 and 2004a)



Sales of trichloroethylene onto the EU market excluding quantities used as a feedstock/intermediate are worth circa €32-42 million based on sales in 2003 and 2004. The quantity sold for use as an intermediate in 2003 was 65,000 tonnes, with an associated value of €72 million per year, assuming the price is the same as that sold for other uses (in reality, the market may be worth slightly less than this given that larger quantities are likely to be used at each site in manufacture of other chemicals). Total sales in the EU could thus be worth just over €100 million per year.(DEFRA, 2005)

4 INFORMATION ON ALTERNATIVES

A survey has been performed in France by AFSSET to evaluate the capability of substituting the most problematic CMRs (Gasztowtt B. *et al.*, 2008). It is based on listing the success and pitfalls of the substitutions performed for various CMRs in which trichloroethylene. The sample of the industries questioned has been selected to have at least 20 industries by trade sectors. If more than 34 industries were registered for a trade sector, 60% were randomly selected by trade sectors, otherwise, 100% of the registered industries selected for constituting the sample of the trade sector. The sample was therefore representing 45 trade sectors with a total of 3643 industries. Industries were questioned by email, mail, web or phone calls. A total of 12,1% answers was obtained.

Seventy-two industries declared using (n=30)/ having used (n=30) trichloroethylene, 3 did not know if they had stopped, 9 did not answer. Industries declared having performed research for substituting trichloroethylene in 73% (n=46). These research led to substitution in 74,5% of the cases (n=35) (Gasztowtt B. *et al.*, 2008).

4.1 Products and processes for substitution in the literature

4.1.1 Cleaning and degreasing of metal parts

Trichloroethylene is a strong solvent like many other organic solvents. It is a degreaser considered versatile, convenient to use because it is nonflammable.

The alternative products or processes are identified based on their capabilities to interact with the product to be easily removed and cleaned. There are several alternatives for degreasing metals such as alkaline cleaners or new products based on terpenes, not very volatile aliphatic hydrocarbons, glycol ethers or N-methylpyrrolidone. Other methods for degreasing involve water pressure, fluid supercritical, electrolysis and abrasive blasting of various kinds. These various products and processes are described in the following paragraphs. (Gasztowtt B. *et al.*, 2008)

Different methodologies or systems are described in the Cleantool database, a Europe wide database for parts cleaning, metal surface cleaning, component cleaning and degreasing, based on real processes in numerous European companies. These processes together with involved agents and equipments have been developed in small and large European enterprises and are being applied regularly. They represent reliable daily practice. The project advisory boards, consisting of long standing cleaning specialist, consider them as good/best solution for the respective cleaning requirements. When searching for processes you can choose selection criteria meeting your individual needs, and you have the possibility to evaluate the listed processes according to your individual point of view. (Kooperationsstelle Hamburg *et al.*, 2010)

Products

Organic/ Biological degreasing

Biological degreasing is a system based on biodegradable tensides and micro-organisms. They are cleaning processes using microorganisms to break down the dirt. The objects are washed in an aqueous solution. The contaminants are dissolved in the washing liquid, which is separated from the metal objects. Nutrient salts are added to activate micro-organisms, which are non pathogenic agents. Natural hydrocarbons are then degraded by the micro

organisms. Finally, the tenside washing liquid can be reused. All water-soluble tensides (preferably biodegradable) can be used in the new process. The pH is kept between 8.5 and 9.4, with a temperature ranging between 20-80°C, preferably 30-40°C, and the oil content between 50-500 mg/liter. Many lipophilic bacteria are capable remove fats and oils (eg Pseudomonas, Enterobacteriaceae or Micrococcus). They convert complex molecules into substances less dangerous such as carbon dioxide and water. These bacteria are grown and used for biological cleaning continuously. As in the traditional aqueous cleaning, the oils and fats are separated from the surface of the workpiece using surfactants and emulsifiers and fall in the degreasing bath.

An evaluation performed by the U.S. EPA of one of those systems, namely the BioClean System shows that it provides an environmental benefit by eliminating the need for alkaline bath disposal, thereby extending the bath life and reducing the amount of liquid and solid wastes produced by the cleaning operation. The economic benefit associated with this technology is low operating and maintenance labor and reduced chemical costs, and a payback period of less than a year (0.6 yrs). As with any technology selection, the end user must select appropriate cleaning equipment and chemistry for a process that can meet their associated environmental restrictions, productivity, and cleaning requirement.(U.S.EPA, 2000) Other methodologies or systems are described in the Cleantool database (Kooperationsstelle Hamburg *et al.*, 2010).

Degreasing industrial aqueous parts washer

A degreasing agent includes a mixture of trisodium phosphate, sodium silicate, sodium carbonate, sodium dodecyl benzene sulphonate, sodium hydrosulphite and octyl-phenol-polyoxyethylene ether. The degreasing agent may maintain degreasing effect for longer period of time. In addition, the metal product cleaned by the degreasing agent has a low cleaning inferior rate. The lessiviel products are non volatile at room temperature. However, they can be irritating to corrosive for skin, eyes and respiratory tract.

Non halogenated solvent

While a change of this type reduces the problems of inhalation and vapor and skin contact toxicity it increases the fire hazard since the non halogenated solvents are readily flammable and their vapour can produce explosive mixtures. They have to be used in ventilated rooms. There are different types of non-halogenated solvent:

- oxygen solvents: glycol ethers, esters (suitable for all metals except zinc, cadmium, lead and alloys. They can be used only cold (apart from diesters that can be used at temperatures below 30 ° C flash point). Ethyl lactate is a hydroxy ester found naturally in apples, citrus, pineapple and cocoa as well as several bread and alcoholic beverages. It is soluble in water and many organic solvents. Liquid fuel, ethyl lactate (LE) is slightly toxic to humans and environment. Coming from a renewable resource, slightly more volatile than alcohol benzyl, it is less damaging to the environment, and can replace trichlorethylene, probably carcinogenic for degreasing parts and surfaces metal.), ketones (suitable for all metals except zinc, cadmium, aluminum and alloys. They are used at cold temperatures. They are incompatibility with strong oxidants such as chromates.), alcohols (suitable for all metals, used only

at cold temperatures. These are flammable solvents which can pose a safety risk and need to be handled appropriately. Recycling within the cleaning equipment is less efficient due to lower recycling performance because separation of oils from the solvent becomes much less effective. This leads to reduced overall cleaning performance and potentially increased waste and costs. They can be added in other solvents to increase their solvent and drying capabilities).

- hydrocarbons: aliphatic and cycloaliphatic (are used either pure or with oxygenated solvents (alcohols, glycol ethers) to increase the solvating capability. They are suitable for all metals except zinc, cadmium and their alloys and can be used at cold or warm temperature. It is necessary that the degreasing temperature is smaller than 30 ° C above their flashpoint. In case of slow oxidation of these hydrocarbons, there acid formation is incompatible with lead, magnesium, zinc, cadmium and alloys.) , terpenic hydrocarbons (suitable for all metals except zinc, aluminum and their alloys. Used in cold or hot engine.), aromatic hydrocarbons. These are flammable solvents which can pose a safety risk and need to be handled appropriately. Recycling within the cleaning equipment is less efficient due to lower recycling performance because separation of oils from the solvent becomes much less effective. This leads to reduced overall cleaning performance and potentially increased waste and costs.
- A3 solvents (non-chlorinated petroleum products whose flashpoint is higher than 55 ° C. or oxygenated solvents. They dissolve out mineral and vegetable oils, fats, emulsions, grinding residue.).
- N-methyl 2-pyrrolidone (NMP): the physico-chemical properties of this lactam allows to use it for multiple uses. It is a strong solvent (Kauri-butanol > 300) which dissolves many polymers and the same scale. It is completely soluble in water, alcohols, ethers, ketones, and aromatic or chlorinated hydrocarbons. It is a solvent for many polymers. The NMP may include replacing the dichloromethane in the paint stripping on the metal and wood, 1,1,1-trichloroethane, trichlorethylene and PERC in the metal degreasing and CFCs in the cleaning circuit modules printed. It is classified reprotoxic category 2, may cause harm to the unborn child.

Halogenated solvents

Some are classified CMR and under the VOC directive. They should be avoided when technically possible or used with a vacuum. The use of chlorinated solvents classified as suspected carcinogens C3 (such as perchlorethylene, dichloromethane or methylene chloride) should be avoided wherever possible although they are really similar to trichlorethylene based on their technical characteristics such as flammability, high solvent power, a wide range of compatibility material and excellent drying properties and recycling, making them easy substitute for trichloroethylene.

- Perchlorethylene provides lower volatility and thus has the advantage of minimizing emissions in closed equipment. On the other hand, it has a lower

solvent power and must normally be used at higher cleaning temperatures to clean as strongly as trichloroethylene. This can create problems for mechanical or metal parts, sensitive to certain fluids or temperature. It has higher boiling point and the lower solvency power. Moreover, this substance is also identified as hazardous for water. Its substitution is also encouraged.

- Methylene chloride exhibits excellent cleaning properties, already at low temperature, which is interesting for cleaning parts sensitive to temperature. However, its high volatility requires the use of special equipment in order to control emissions.

Halogenated substitutes (fluorinated type Hydrofluorocarbons ether HFE, Hydrofluorocarbons or hydrofluoroalkanes HFA) can be used either pure or with alcohols or halogen. They are suitable for all metals, and are used to hot machine. The initial mixture may become flammable in case of evaporation of decafluoropentane or of hydrofluoroether. They are used for cleaning electronic components (eg PCB containing sensitive components). Hydrofluorocarbons (HFCs) and hydrofluorocarbon ethers or hydrofluoroethers (HFCE) are very expensive and have only very limited solvent power. They can potentially participate to global warming. The 1-bromopropane is a derivative of halogenated aliphatic hydrocarbons and was popular in industry in the early 2000s as an ideal replacement of TCA, banned to protect the ozone layer. Very few technical changes are needed to replace chlorinated solvents in degreasing equipment steam metal parts. From a strictly technical standpoint, the fact remains that the use of 1-BP requires tight control of the level of stabilizer and pH to ensure optimal conditions. But this was also true for the chlorinated solvents such as trichloroethylene. Control emissions, important for health and environmental reasons, are also essential to prevent the loss of an expensive solvent. Finally, it has been classified as toxic and reproductive toxicity category 2 (may impair fertility).

Processes

Supercritical carbon dioxide

When a substance is in the gaseous state at room temperature, such as carbon dioxide and light hydrocarbons, it can act as solvents if it is used at temperatures and pressures above their critical points. Supercritical fluids have the following characteristics: a high density, same viscosity and dissemination than gas, ability to penetrate tiny pores and cracks, dissolution power proportional to pressure. The supercritical carbon dioxide is an excellent solvent for dirt such as oil, esters, silicones, perfluoroethers, triazines substituted halocarbon, organosilicon, chlorotrifluoroethylene. In the other hand, this method is not suitable for high density polyethylene, crosslinked resins such as epoxy or phenolic compounds, rust, scale, lint, dust, ionic dirt, nor salts.

In its supercritical state, carbon dioxide acts as a solvent and was judged capable of cleaning components adequately without creating any environmentally harmful emissions.

Table 16: Comparison of operating costs – carbon dioxide washing versus trichloroethylene washing

		Carbon dioxide	Trichloroethylene
Power consumption	kWh per kg components	0.3	1.0
Chemical consumption	kg per kg components	0.15	0.05
Cost of chemicals	SEK per kg components	1.0	0.6
Waste	litres per year	100 ¹⁾	1000 ²⁾

1) Oil

2) Oil + trichloroethylene

Compared with trichloroethylene degreasing, the carbon dioxide system has slightly lower energy costs but higher costs as regards the degreasing agent. However, as waste disposal costs are lower and the equipment requires considerably less staff supervision, the operating cost of the carbon dioxide system should be lower. As the investment cost is high, total treatment cost could be comparatively higher for carbon dioxide plants. Carbon dioxide degreasing gives excellent results – components are cleaner than when degreased with trichloroethylene. There are other methods which would also give a satisfactory degree of cleaning. Washing in petroleum ether is one possibility, but this has the disadvantage of a considerable risk of fire and explosion. The carbon dioxide system has a low risk of fire and explosion. A further additional benefit is that there is little danger of personnel being exposed to harmful substances. All in all, carbon dioxide washing may involve slightly higher washing costs than the traditional trichloroethylene method but, at the same time, the washing results should always be better and the carbon dioxide system is friendlier to the environment. (IVL Swedish Environmental Research Institute, 2000)

Plasma cleaning for submarine purposes or vacuum-free plasma cleaning/activation

A plasma is an electrically charged gas, composed of ionized atoms, electrons, free radicals and neutral species. The workpiece is exposed to cold plasma with oxygen at low pressures for small duration. Following a chemical reaction with free radicals, organic dust is transformed into vapour and carbon dioxide based on a "cold combustion" process. The main limitation is that dirt layer has to be very thin. Therefore, this process can be used as the final step of cleaning following a first step of cleaning by water. According to the Cleantool website, plasma cleaning has many advantages: it provides a very effective cleaning, reduces material consumption, it allows delicate part to be treated gently, it is capable of removing stable chemical, plasma reaches the most complex geometries such as micro-channels without further preparation. It is even possible to infiltrate the porous substrates, no thermal or mechanical stress is exerted on the substrate, and impact on the user and the environment are minimized. (Kooperationsstelle Hamburg *et al.*, 2010)

Plasma treatments are used to clean and to modify the surfaces of materials such as polymers, textiles, ceramics and metals. Different plasma treatments are available to produce surface properties that are either ultra-clean, highly activated (as a pre-treatment prior to bonding, painting/printing or gluing), hydrophobic, oleophobic, or hydrophilic.

Plasma treatments are fast, clean, repeatable and low cost.

Laser cleaning

There are two applications displayed in the cleantool database: Laser cleaning of vulcanising tools and moulds and of brake linings before powder coating (integrated in production line) (Kooperationsstelle Hamburg *et al.*, 2010)

According to a company specialized in cleaning technologies, desoxidation and laser cleaning are used for removing pollutants such as grease or oil. It is based on the interaction between a high power laser and instant pollutant. This technique is easy to use, has little effluent treatment, only a powder is recovered and processed by filters, it has no abrasive action and therefore does not alterate the base metal, the more complicated geometries can be treated and finally can remove precise thick layers . With the pulsed laser radiation varnishes are removed without further additives or aids layer for layer. Thus a selective (for example only the finish coating will be removed, the primer remains on the substrate) or a complete depainting (up to the substrate) can be achieved.

Ultrasonic degreasing

This technique is used by companies specialized in surface treatment and consist using ultrasonic waves at very high frequency. It can get through aqueous alkaline solvents, acids or organic solvents. The passage of these ultrasound waves through the liquid medium creates microscopic cavitation bubbles. (Kooperationsstelle Hamburg *et al.*, 2010) Previous evaluation showed that the system is extremely effective at removing the carbon deposits but is quite expensive. The assessment indicated that the installation of a new ultrasonic cleaning bath and the use results in an attractive of <3.3 years depending on the cost for handling, treatment and disposal of the spent alkaline cleaner and spent rinse.

Cleaning by blowing

This cleaning process removes stubborn dirt. It consists in projecting the cleaning solution through nozzles on the surface of parts to be cleaned. This method uses mainly aqueous solutions, and more rarely organic solvents. The pressure at which the solution is applied may vary from 14 kPa to 13 800 kPa. In general, the higher the spray pressure is, more the technique is efficient in removing dirt from a surface metal. The products used are neutral or alkaline cleaners and hydrocarbons. But due to their explosive properties, hydrocarbon solvents are not used often.

Sandblasting with compressed air

This technique consists in using many different projectiles propelled at high speed on the metal part. The kinetic energy removes the fat deposits. The airflow energy is between 200 and 300 kPa depending on the surface to be cleaned (material and dirtyness). Dusts produced must be sucked and filtered because they can be harmful to health.

Cleaning processes using dry ice.

There is four applications displayed in the cleantool database: Blasting of ship's hull using CO₂ ice pellets, Cleaning of spot welding robots with CO₂ pellets, Snow blasting of relays, CO₂ particle blasting of moulds in an aluminium casting factory(Kooperationsstelle Hamburg *et al.*, 2010).

This process does not produce residue nor effluent, in contrast to techniques using projectiles shot, sand or glass beads as cleaning agents. This cleaning process uses cryogenic CO₂ pellets (dry ice pellets) at temperature of -78.5 ° C threw under high pressure. It is a nonabrasive technique. The pellet transforms in gas on impact. The firing pressure is adjustable between 2 and 16 bars. According to the website Cleantool, this technique removes grease and oils. It is recommended to test the technique, size of the pellets and pressure before using it in order to avoid damaging the surface being cleaned. Exposed workers must wear personal protection.

Salt bath cleaning

Elimination of fats and oils can be carried out in a salt bath warmed at 200 ° C to 650 ° C. At that temperature, a thermochemical reaction between the liquid salt and dirt occurs. Degreasing is fast and meticulous and the length of wash cycles can vary from seconds to minutes. This degreasing process is always followed by a rinsing cycle to cool the parts and remove residual salts (Kooperationsstelle Hamburg *et al.*, 2010).

High pressure degreasing

High-pressured gases are increasingly used to replace certain solvents for cleaning metallic particles and dust. However this process is rather ineffective against microscopic particles. Several gases can be used for such cleaning: helium, neon, argon, krypton, xenon, air, carbon dioxide, nitrogen and HCFC-22.

High pressure water

This type of degreasing suites particularly for cleaning machines stainless steel or cast iron. Detergent can be added at low concentration (few ppm) to enhance cleaning capability. Small amount of Polyacrylate or polyacrylamide can be added to enhance the cutting ability of the jet. It is preferable to use demineralised or deionised water. In the Cleantool database, one application is registered as cleaning reels from die cutting by high pressure water jet (in line). Reels from die cutting made of stainless steel, copper alloys or tinned copper are cleaned from punching oils and tin flitter in a high-pressure water-jet (integrated in production line) using only tap water; thereafter application of plastic or welding (Kooperationsstelle Hamburg *et al.*, 2010). Aqueous systems have the disadvantage of much higher energy demand, if dry parts are required, and non-universal material compatibility (combined cleaning of different materials is restricted).

Electrolytic degreasing line

Electrolysis allows cleaning parts in an alkaline bath consisting of caustic soda, wetting agents, polishing salts, dispersants and other chemicals. A DC 3-12 volts is applied, the workpiece acting as cathode. The colloidal particles of fat, negatively charged, are rejected, and the hydrogen produced exerts a degreaser. If the piece serves as the anode, oxygen is released and the scrap metal are repelled. Nickel and its alloys must always be scoured by acting as a cathode. This type of degreasing is always followed by a rinsing step.

Thermal vacuum degreasing

The thermal vacuum degreasing is a very simple process by which parts are heated under vacuum in a tank. It is efficient and gives a particularly neat finish. In theory, it is possible to create empty vacuum sufficiently high to allow the oil removal at room temperature. In practice, however degreasing occurs at temperatures from 93 to 204 ° C and at pressures of 13 Pa to 13 kPa. Aluminum-based sheets or parts, such as formed aluminum assemblies contaminated with forming die lubricants, are cleaned by a solventless, thermal degreasing process at controlled temperature (about 300°-400° F.), and in specified atmospheres (reactive gas which is at least at atmospheric pressure) prior to brazing. The organic contaminates on the aluminum-based sheet or part are reacted with the reactive gas (air or oxygen) and removed from the surface of the sheet or part without disruption of the underlying protective oxide layer. Subsequent brazing is thereby facilitated.

The thermal vacuum oiling does not distinguish between dirt, but is useful for cleaning parts from cutting, machining or stamping and in preparation for coating and heat treatment. This method is very effective against dirt that does not evaporate easily, such as welding flux and solid lubricants such as molybdenum disulfide.

How to choose which product or which process?

As described above, there is plenty possibilities for substitution and it is impossible to state categorically what technology is best. It depends on the application, the parts to be cleaned, the products to be removed, the type of soiling, the degree of cleanliness required, the variability of parts to clean, etc. For example, to clean parts between processing steps based on the water (the electroplating, for example), aqueous systems may be the best, since parts will be put into water after degreasing, not requiring any drying step, which requires much energy to remove water. But when the process requires very clean and dry surfaces (for recovery and hardening of surfaces, for example) and in the presence of a range of different metals, orifices in a cul-de-sac, cracks and holes, or a lot of residual oil to clean, chlorinated solvents are usually the best solution, because they are compatible with most materials, they have strong cleaning power, are easy to dry, leaves no residual film and are easily recycled by distillation.

4.1.2 Fabric cleaning

Organic / biological degreasers are recommended for cold stain tissue removal and cold fabric cleaning. Non-halogenated solvents and A3 solvents can be used as non-chlorinated petroleum products whose flashpoint is higher 55 ° C. They dissolve out the oils and fats including mineral and vegetal oils, emulsions, grinding residue. They are used to remove coldly stain on fabrics.

4.1.3 Asphalt cleaner in public works

Trichlorethylene is used for its solvent properties, as an asphalt cleaner mainly in public works activities for cleaning gear and construction equipment after use. There are other solvents that are equivalent properties in terms of efficiency allowing easy substitution:

- agrosolvents: Fatty acids esters from vegetable oils can be used to eliminate traces of tar or to liquefy bitumen. These products have the advantage of having a low volatility and are not classified. However, they can be irritating if their use is prolonged or sensitizers if containing terpenes.
- Hydrocarbons: light petroleum hydro-treated distillates (such as odorless white spirit), and naphtha heavy aromatic solvent, can be used to remove traces of tar or liquefy bitumen. They can be flammable and their vapors are narcotics. Note: The hydrocarbons are not classified as carcinogenic if they proved to content benzene below 0.1% by weight. Fuels (gasoline and diesel) should not be used in the activities of tar from.

4.2 Availability, benefits of these substitutions

ESCA (European Chlorinated Solvent Association) claims that *“an increasing number of alternatives [to trichloroethylene] are now available. However, these alternative solvents can also be hazardous to health, and without appropriate solvent management, a switch from trike to these solvents may simply expose operators to different dangers. The use of alternatives should be properly assessed, taking into account all considerations”* based on a report published by Envirowise in 2002. They also declare that *“Aqueous technology is the best environmentally speaking to produce clean but wet metallic parts, thus solvent cleaning should not be used when an aqueous treatment is following the cleaning step (that is already the case and the best available technology (ACRU6) does not reach the level of the studied aqueous technology. To produce clean and dry metallic parts, solvent technology is the best environmentally speaking, even without an activated carbon recovery unit; thus in cases where the metallic part needs to be dry for the following treatment (e.g.coating), a solvent cleaning should be used.”* (DEFRA, 2005)

The Envirowise study proposes other alternatives than different solvents. They compare the advantages and disadvantages of the principal cleaning techniques:

⁶ Active carbon recovery unit.

Cleaning method	Advantages	Disadvantages	Section
<i>Mechanical</i>	<ul style="list-style-type: none"> Low cost, particularly if using brushes rather than fully enclosed systems. May avoid the need for solvents. 	<ul style="list-style-type: none"> Only line-of-sight is cleaned. Waste disposal costs may be high. Difficult to re-use media when removing oil or grease. May affect the component surface. 	4
<i>Organic solvent</i>	<ul style="list-style-type: none"> Effective at dissolving oils and greases. All parts of the component are cleaned. Load is dry on leaving plant. 	<ul style="list-style-type: none"> Risks to health, safety and the environment. Governed by strict legislation. Special waste generated, which is expensive to dispose of. Solvent losses may occur through evaporation. Plant needs to be maintained and cleaned regularly. 	5
<i>Aqueous</i>	<ul style="list-style-type: none"> Lower operating costs than vapour degreasing. All parts of the component are cleaned. Water can often be re-used or recycled. Less hazardous to human health and the environment than organic solvent cleaning. 	<ul style="list-style-type: none"> Effluent treatment costs may be high. Components may be wet and require drying on completion. This may increase costs. Certain chemicals may corrode machinery and components. 	6
<i>Biological</i>	<ul style="list-style-type: none"> Low operating temperature means lower operating costs than vapour degreasing. All parts of the component are cleaned. Solution can be disposed of directly to sewer. Biological surfactants, which make use of micro-organisms, do not need replacing. Less hazardous to human health and the environment than organic solvent cleaning. 	<ul style="list-style-type: none"> Only suitable for hydrocarbon contamination. May take longer than traditional degreasing techniques. Enzyme cleaners require replenishing. Components may be wet and require drying on completion. This may increase costs. 	7

Table 17: Comparison of the substituting methods

Both Envirowise report (2004) and ESCA claim (1996) are old and we have shown that the substitution technologies are increasing, evolving and developing fast as this is a growing field due to legislative pressure. A lot of technologies have been developed recently giving plenty of possibilities for substituting trichloroethylene depending on the context and technical specificities. If the cost still high for some of them, their generalization will automatically lead to a decrease of the prices.

5 RISK-RELATED INFORMATION

5.1 Risks associated to exposure (ECB, 2010)

The classification of trichloroethylene as a Category 2 carcinogen and a Category 3 mutagen raises issues about the risk of either or both these effects at environmental exposure levels. However, the predicted regional and environmental exposures are very low. Therefore, any residual risks of mutagenicity and/or carcinogenicity are likely to be very low. Moreover, this risk has been further reduced by the impact of the Carcinogens Directive, the Integrated, Pollution, Prevention and Control Directive and the Solvent Emissions Directive.

The risk reduction strategy concluded that for sites producing trichloroethylene, and using the substance as an intermediate, the most appropriate action would be to ensure that under the Integrated Pollution Prevention and Control regime regulators take into account the conclusions of the environmental risk assessment in developing emission limits for sites.

For metal degreasing, it was concluded that there would be no need for further risk reduction measures once all the requirements of the Solvent Emissions Directive were fully implemented by 2007.

In relation to sites undertaking 'formulation' or repackaging of trichloroethylene in significant quantities, it was concluded that there were insufficient information to determine whether existing risk reduction measures are sufficient. Therefore, it was concluded that the most appropriate strategy would be to ensure that appropriate emissions monitoring is undertaken for the largest sites carrying out this activity (smaller sites are not expected to pose unacceptable environmental risks); and, for Member States to introduce legally binding limits on emissions if current emissions are still found to pose an unacceptable risk to the environment.

The potential combined exposure is dominated by the occupational exposure. Thus, the conclusions of the risk characterisation for combined exposure reflect those reached for workers.

5.2 General existing Measures applying to carcinogens (ECB, 2010)

There is a range of existing measures in place that serve to significantly reduce the risks associated with trichloroethylene, particularly when compared to the situation several years ago upon which the risk assessment report was based.

As indicated above, there is a general trend away from the use of trichloroethylene. The revised classification and labelling for the substance as a Category 2 carcinogen, resulting in increased legislative requirements, drive this trend. The classification was adopted in Annex I of the Dangerous Substances Directive in June 2001. The proposed change in classification to a Category 2 carcinogen was included in the 28th ATP to the Dangerous Substances Directive (adopted in June 2001) and implemented in Member States on 30 July 2002. In addition, Note 6 applies to the labelling of preparations that contain trichloroethylene; such preparations have to be assigned R67 if they meet the appropriate criteria.

This has implications for how the chemical is handled in terms of both worker and consumer legislation. This will lead to a higher degree of control compared with previous practices.

The Carcinogens Directive now imposes a strong regime on the use of trichloroethylene. Under the Directive, substitution should be considered first. Where it is neither technically possible to replace the carcinogen by a less dangerous substance, nor to manufacture or use the substance in a closed system, the employer has to ensure that the level of exposure of workers is reduced to a level that is as low as is technically possible. The Directive sets out a series of strict measures that should be applied to achieve this. (ECB, 2010)

5.3 EU Worker Legislation (ECB, 2010)

Trichloroethylene-specific regulations for the protection of the safety and health of workers do not exist at European level. The risks arising from exposure to trichloroethylene are regulated at European level by general regulations for occupational safety and health.

The following Directives are of relevance:

- Framework Directive (89/391/EC as amended) on the introduction of measures to encourage improvements in the safety and health of workers at work.
- Chemical Agents Directive (98/24/EC) on the protection of workers from risks related to the exposure to chemicals at work.
- Carcinogens and Mutagens Directive (2004/37/EC) on the protection of workers from the risks related to exposure to carcinogens and mutagens at work.
- Personal Protective Equipment Directive (89/656/EEC) on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).
- Safety Data Sheet Directive (91/155/EEC) (last amended by Directive 93/112/EEC), sets out requirements to ensure that information on chemical hazards is communicated through the supply chain using safety data sheets.
- Pregnant Workers Directive (92/85/EC as amended) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast-feeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC). This Directive places a duty on the employer to temporarily introduce measures for a pregnant or breastfeeding worker to avoid exposure to risk through adjustment of working conditions, granting leave or moving the employee to another job.
- Young Persons Directive (94/33/EC) imposes a requirement on employers to prohibit young people from working with carcinogenic substances.

These Directives impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the risks to human health from chemicals in the workplace are limited.

The Chemical Agents Directive requires employers to identify any hazardous chemical agents in the workplace, assess the risks and suggests a hierarchy of preventative measures to minimise the risks.

As the classification for trichloroethylene was amended to Category 2 in 2001, the Carcinogens Directive now plays a central and important role in its control of use in the

workplace. The controls required under this Directive are more stringent compared with the general provisions of the Chemical Agents Directive, under which trichloroethylene was previously controlled.

Based on a determination and assessment of risks by the employer, the Carcinogens Directive provides a step-by-step approach for risk control. Under this approach, replacement of the substance should be considered first. Where it is neither technically possible to replace the carcinogen by a less dangerous substance, nor to manufacture or use a substance in a closed system, the employer has to ensure that the level of exposure of workers is reduced to as low as is technically possible. The Directive sets out a series of strict measures to achieve this aim.

This series of measures includes:

- the limitation of the quantities of a carcinogen at the place of work
- keeping as low as possible the number of workers exposed or likely to be exposed
- the design of appropriate work processes
- engineering control measures
- methods for the elimination of carcinogens at source.

Further requirements of the Carcinogens Directive are:

- the use of existing appropriate procedures for the measurement of carcinogens
- the application of suitable working procedures and methods
- the use of collective and/or individual protection measures (where exposure cannot be avoided by other means)
- the provision of information for workers - provisions are made for employers to ensure that workers receive sufficient information and appropriate training and provisions
- employers shall establish arrangements for carrying out relevant health surveillance of workers
- the Directive also contains the possibility to set exposure limit values

5.4 EU Environmental legislation, emission measures(ECB, 2010)

The Solvent Emissions Directive (1999/13/EC) is causing a significant reduction in use and emissions of trichloroethylene in metal cleaning due to the requirements to phase out the substance where feasible and to impose limits upon emissions to atmosphere; in practice by the use of closed systems. Cleaning systems consuming more than 1t/yr of trichloroethylene are within scope of the Directive. (ECB, 2010)

The metal finishing industry is characterised by a large number of small companies: Almost half the companies responding to an Envirowise questionnaire have fewer than 20 employees. 38% of companies have an annual turnover of less than £1 million (Envirowise, 1997). Based on previous work undertaken for Defra by Entec (2002) for the UK Government, the surface cleaning sector is not a well defined sector but covers a wide range of operations and sizes of company. The number of installations expected to be covered by the SED is estimated at 4,600 (with 6,000 processes). Of the 4,600 installations affected in the UK, an estimated 1,840 (40%) were already regulated under the control of local authorities prior to introduction of the SED. The number of new installations affected by the SED in the UK was estimated to

be approximately 2,760. Overall costs of compliance for the surface cleaning sector were estimated at £18.8 million (€26 million) per annum, a significant proportion of the overall costs of SED for the UK. This gives an average cost per installation of just over £5,000 (€7,000) per annum. It is estimated that the average cost per installation is £3,000 (€4,200) for solvent consumption of 1-5tpa; £5,200 (€7,200) for consumption of 5-10 tpa; and £6,500 (€9,100) for greater than 10 tpa.(DEFRA, 2005)

In addition, the Integrated Pollution Prevention and Control regime (1996/61/EC) is imposing additional controls on emissions, potentially including specific emission limits for trichloroethylene. [1]

5.5 EU Consumer legislation (ECB, 2010)

The risks arising from consumer exposure to trichloroethylene are regulated at European level by the 25th amendment to the Marketing and Use Directive (76/769/EC). This directive prohibits the consumer use of substances classified as Category 1 or 2 carcinogen, mutagen or reproductive toxin (CMRs). The 14th amendment to the Marketing and Use Directive (96/60/EC) set out the principles for this consumer protection and imposes on the Commission an obligation to add additional CMRs to the Marketing and Use Directive no later than 6 months after the publication of the new CMR classifications. The 28th Adaptation to Technical Progress (ATP) to the Dangerous Substances Directive included trichloroethylene and was published in June 2001.

The inclusion of trichloroethylene in the Marketing and Use Directive means that its use in consumer products would not be permitted if the product contained at or more than 0.1% w/w of trichloroethylene.

In France, the order of April 30, 2009 concerning the conditions for marketing construction and decoration products containing carcinogens, mutagens or toxic to reproduction category 1 or 2 (JO of 28 May 2009) stipulates that these products can be put on the market only if they emit less 1 µg.m⁻³ trichloroethylene (exposure concentration calculated from the specific emission factor measured in chamber emission test according to ISO 16000, 28 days after product packaging).

5.6 National Legislation

5.6.1 Sweden (ECB, 2010)

Sweden has national legislation on trichloroethylene that came into force on 1st January 1996. This regulates the use of trichloroethylene for all professional uses. The measure imposes a ban with the possibility for exemption on application to the Swedish National Inspectorate.

An exemption can only be granted if it can be shown that:

1. the applicant continuously searches for alternatives;
2. no practicable alternative is available to meet the needs of the applicant, and;
3. the use does not lead to unacceptable exposure.

As from May 2001, there have been over approximately 150 exemptions issued in Sweden, which mainly involve metal degreasing operations and to a lesser extent the vulcanisation of conveyer belts. Some of the reasons for allowing exemptions are:

- Safety reasons; the object needs to be absolutely clean, e.g. objects coming into direct contact with oxygen, which might lead to an explosion. When vulcanising rubber inside tanks etc., the use of a flammable solvent is not allowed.
- The objects are made of various materials and have complicated shapes, which might make it difficult for a water-based solution to reach all cavities and to evaporate during the drying phase.
- Time is required to carry out changes in the operation process to enable the use of an alternative.
- Difficulties in finding alternatives in the pharmaceutical industry and the time consuming process to approve a change in the process in all markets where the pharmaceutical preparation is sold.

There are certain derogations to this restriction of the use trichloroethylene - for professional use of trichloroethylene for analytical purposes and within the area of research and development.

5.6.2 Denmark(ECB, 2010)

In Denmark, trichloroethylene is listed as an undesirable substance and is subject to a tax to discourage its use.

5.6.3 Germany(ECB, 2010)

In Germany a stringent emission control law (2.BimSchV) was introduced. This has affected the amount of trichloroethylene used. The quantities of trichloroethylene decreased from 30,000 t in 1986 to 11,000 t in 1991 (West Germany only) and from 16,000 t in 1991 to 5,200 t in 2000 (all Germany) (ECSA).

Since 1986, Germany is regulating the emissions of halogenated solvents in industrial surface cleaning uses (2.BImSchV). This has led to the development of modern sealed surface cleaning equipment with internal solvent recycling reducing the solvent consumption by up to 90% (1). Such sealed machines are today Industry Standard in Germany. Since 2007 all installations consuming >1t/yr have to comply EU wide with the European Solvent Emission Directive (SED,1999/13/EC). This directive is setting emission limits, which for fulfillment request users to apply closed equipment.

Restrictions: Consumer uses are prohibited EUwide, due to trichloroethylene classification as a carcinogen. A national ban of the use of trichloroethylene as a solvent is active in Sweden restricting its use to those users having been granted a time limited authorization. Contrary to the German approach to force users to apply closed systems but not ban TRI, the Swedish approach failed to reduce consumption and exposure of workers in the same extend as in Germany (ECSA, 2010)

5.7 The existing legislative framework and its gaps

The main health effects of mutagenicity and carcinogenicity largely dominate the risk characterisation for all exposure scenarios for workers. The main potential source of exposure for workers is during metal cleaning activities.

The evidence provided in the environmental and human health risk reduction strategies indicates how existing legislation is decreasing use, increasing substitution and driving a greater movement towards closed cleaning systems. This is particularly true for operations where more than 1 tonne/year of trichloroethylene is consumed, bringing the operation into scope of the Solvent Emissions Directive. The combination of existing environmental, occupational health and supply legislation should provide an effective framework for limiting the risks to workers from exposure to trichloroethylene where more than 1 tonne/year is consumed in the cleaning operation.

Anecdotal evidence indicates, however, that there are significant numbers of cleaning operations in the EU that currently consume trichloroethylene at amounts below the Solvent Emissions Directive threshold of 1 tonne/year. This number may increase as other operators reduce their consumption to fall out of scope of the Directive. Many of these operations are likely to be run by small and medium sized enterprises. It is estimated that between 60 and 70% of all metal cleaning operations in the UK use less than 1 tonne of trichloroethylene per year. To complete the partial framework for workers in enterprises where less than 1 tonne/year is consumed, the existing legislative controls have been reinforced by a voluntary industry agreement to restrict the sale of trichloroethylene solvent products to downstream users who undertake to use the product in closed systems. Under REACH, it can be proposed that authorisation or total exemption could be granted to use of trichloroethylene for metal cleaning proven to take place only within closed systems if no other substitute worth trichloroethylene.

It should be noted that industry has implemented voluntary risk management measures including training and consultancy. If trichloroethylene is handled correctly using available tools, there should be little risk of over-exposure. Standard Personal protection Equipment (PPE) for handling chemicals is recommended, such as safety glasses or goggles, depending on the task at hand, and appropriate chemical resistant gloves. If there is a potential to exceed existing exposure limits, respiratory protective equipment is recommended; Depending on the operation, this may include positive-pressure supplied-air. (ECSA, 2010)

This section shows that a lot of measures already apply to trichloroethylene, as for all the classified CMRs. In the particular case of trichloroethylene, voluntary agreements and other directive apply: there is a multitude of measures applying.

However, it has been shown that human, consumer, and worker are still exposed often at low level and in rare situations. In most of the cases, this exposure could be eliminated by using one of the main substitution product or process available. Identification of trichloroethylene as a SVHC for inclusion into annex XIV may contribute to reach this objective. It will also allow simplifying and harmonising the practices regarding this chemical at the European level.

OTHER INFORMATION

1 GROUPING APPROACH

2 CONSULTATION OF INDUSTRY

Industry was consulted numerous times, for example during the French prioritisation work of SVHC in 2009 and for the work regarding substitution in 2008.

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