Health risk assessment of PCE emissions from dry cleaning activities in France

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HEALTH RISK ASSESSMENT OF PCE EMISSIONS FROM DRY CLEANING ACTIVITIES IN FRANCE

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ABSTRACT

Tetrachloroethylene (PCE) is a solvent used mostly in the dry-cleaning and metal degreasing industries in Europe.

Neurological and renal effects are the main non-cancer human health effects caused by chronic inhalation exposure of PCE. PCE is suspected to be probably carcinogenic to humans by IARC.

During dry-cleaning processes, people are likely to be exposed to the chemical in a variety of ways because PCE emissions are not currently regulated in France. Exposed persons include workers, residents living in co-location with dry-cleaning establishments and the general population.

This paper presents a literature review assimilating human exposure data to assess public health risk from dry-cleaning emissions. At the average indoor air level of 2 mg/m^3, there is concern for health risk to co-located residents living above dry cleaning establishments. A personal exposure of 15 $\mu g/m^3$ of PCE should not cause adverse effects on the health of normal population.

INDEX TERMS

PCE, dry cleaning, risk assessment, public health.

INTRODUCTION

The European Union directive UE/13/1999 concerning the reduction of the emissions of volatile organic compounds requires a special limit value to regulate atmospheric PCE emissions of dry cleaning activities in European countries. PCE (CAS 127-18-4) is currently the main solvent used in dry cleaning processes in Europe.

To formulate national regulations necessary to comply with this directive, the French environment ministry asked INERIS to assess health risks associated with PCE exposure. A preliminary study was carried out from available data in scientific literature to analyze the need to conduct exposure surveys to refine the associated health risks at a national level.

METHOD

The methodology used is based on the human risk assessment process formalised in 1983 by the National Research Council (NRC) of the American National Academy of Sciences (NAS). It aims, within a structured and transparent framework, at providing a decision-tool for risk managers to assess the risks connected with environmental sources of exposure.

For health risk assessment, the NAS describes a four-step paradigm. For each step, the relevant and scientifically reliable information is evaluated. In addition, the related uncertainties are described.

a) Hazard identification - determination of whether a particular chemical is or is not causally linked to specific health effects,

b) Dose-reponse assessment, the determination of the relation between the magnitude of exposure and the probability of occurrence of the health effects in question,
c) Exposure assessment, the determination of the extent of human exposure before or after application of regulatory controls
d) Risk characterisation, the description of the nature and magnitude of human risk including related uncertainty.

In France, the guidelines for health risk assessment have been published by the National Institute for Public Health Surveillance (InVS, 2000) and the National Institute for Industrial Environment and Risks (INERIS, 2001) within the framework of the French regulation of industrial activities with environmental impact.

RESULTS

HAZARD IDENTIFICATION (ATSDR, 1997), (INERIS, 2000)

Inhalation is the most significant route for human exposure to PCE.

In humans, PCE is known to be toxic to central nervous system and kidneys (such effects were observed in dry cleaning workers following chronic inhalation of PCE). Several cases of human acute intoxication by inhalation are reported following the use of coin-operated dry cleaning machines in France (Garnier and Bédouin, 1996).

Carcinogenic effects of PCE are also suggested by numerous epidemiological studies, but are not clearly established. The International Agency for Research on Cancer has classified PCE as a Group 2A carcinogen (probably carcinogenic to humans) on the basis of experimental data (kidney tumours in male rat, hepatic tumours in mice and possibly mononuclear cell leukaemia in rats) and epidemiological data (oesophageal and cervical cancers and non-Hodgkin's lymphoma) (IARC, 1995).

Some studies reported the existence of spontaneous abortions among women exposed to PCE in the workplace. Human data remains however inconclusive regarding PCE potential to cause developmental and reproductive effects.

Available animal data indicate that PCE itself is not mutagenic but some PCE metabolites have been shown to be mutagenic (perchloroethylene epoxide, trichloroacetaldehyde...).

DOSE-REPONSE ASSESSMENT

The manner in which dose-reponse relationships are expressed mainly depends on the endpoint of concern for human health. A key distinction between cancer and other toxicological effects is that most carcinogens are generally assumed to have no dose threshold i.e. no exposure level below which a significant adverse effect is not expected to occur).

This leads to use two different estimates to assess dose-reponse :

- Reference concentration for the chronic non-cancer effects to estimate daily exposure to human population including sensitive subgroups that is likely to be without appreciable risk of adverse effects during a lifetime,
- Inhalation « unit risk » for the chronic cancer effects to estimate the chemical's carcinogenic potency through the upperbound excess lifetime risk per $\mu g/m^3$ average daily inhaled.

In this way, for non-carcinogenic effects, two reference concentrations have been derived for chronic inhalation exposure to PCE, based on the effects observed among workers exposed to PCE at their workplace :

- WHO (WHO 2000) proposes an air quality guideline value of 0,25 mg/m^3 for critical effect on kidney.

- ATSDR (ATSDR 1997) recommends a chronic Minimum Risk Level of 0,28 mg/m^3 for neurotoxic effects.

For the carcinogenic effects, epidemiological data are not sufficient to develop a dose-response relationship. The animal data, therefore, are the only source to approach the carcinogenic risk in humans.
Hazard assessment shows that there exists an uncertainty regarding the relevance in man of PCE carcinogenic mechanism of action in animal. Indeed, the effects observed in animal seem to be species-specific and humans would probably be more sensitive than the rodents.

However, two American organizations have assessed PCE carcinogenic dose-response relationship on the basis of the results of the National Program of Toxicology (NTP) of 1986.
The California EPA (CalEPA, 1999) has derived a unit risk of $5,9.10^{-6}$ $(\mu g/m^3)^{-1}$ in 1992 from male mouse hepatocellular adenoma and carcinoma incidence data using a linearized multistage procedure and PBPK model dose adjustment.
The federal Environmental Protection Agency (US EPA, 1998) has defined a provisional unit risk value of $7,1.10^{-7}$ $(\mu g/m^3)^{-1}$ from mice liver adenomas and/or carcinomas and rat mononuclear cell leukaemia incidence data using a linear-at-low-doses approach.
Toxicity values for use in PCE risk assessment are shown in table 1.

Table 1. Chronic toxicity values for PCE risk assessment

Organization name	Toxicity value name	Toxicity value	Critical organ or effect	Species	Key study
WHO, 2000	Air quality Guideline 1 year	0,25 mg/m^3	Renal	Human occupational study (10 years, mean exposure level 100 mg/m^3)	Mutti et al., 1992
ATSDR, 1997	Chronic Minimum Risk Level	0,28 mg/m^3	Nervous central system	Human occupational study (10 years, mean exposure level 100 mg/m^3)	Ferroni et al., 1992
US EPA, 1998	Unit risk	$7,1.10^{-7}$ $(\mu g/m^3)^{-1}$	Liver adenoma and carcinoma Mononuclear cell leukaemia	Mouse and rat, 2 years	NTP, 1986

EXPOSURE ASSESSMENT
The populations potentially exposed to PCE emissions from dry cleaning activities (Figure 1) include workers and the general population, with specific sub-populations for the latter (individuals who are residing in apartment buildings co-located with PCE dry-cleaning facilities, people working near drycleaners, coin-operated dry cleaning machines users, infants nursed by mothers working in a dry cleaning plants; families of workers...).

In this paper, only general population (non-worker) exposure is presented for inhalation specific pathway which appears most relevant to PCE kind of emissions.
Chronic inhalation exposure is examined in our study as to determine the probability of occurrence of long-term effects. In this way, when available, central tendency (median or average) and high-end exposure descriptors were used to show the variability of estimated exposure.

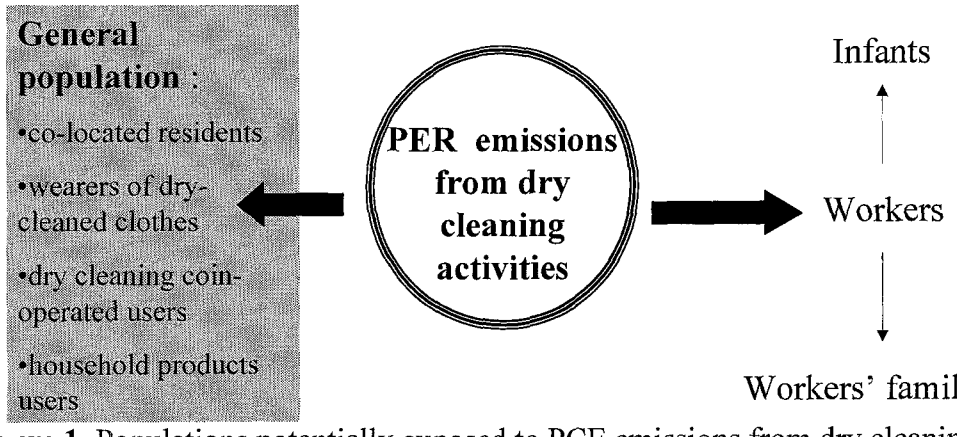

Figure 1. Populations potentially exposed to PCE emissions from dry cleaning activities

Analysis of literature shows that on one hand no French exposure data were to be found and that on the other hand monitoring studies for which appropriate PCE exposure data were available mainly focused on co-located residents and general people exposure.

Exposure received by co-located residents has been monitored by several studies. Two studies were chosen for use in exposure assessment: Fast (1992), quoted by EPA (1998), measured a median concentration of 2,2 mg/m^3 (90^{th} percentile: 17,8 mg/m^3) and Garetano (2000) reported a mean concentration of 2 mg/m^3 (range 0,47-4,2) in 12 residential sites of New Jersey. The value of 2 mg/m^3 was thus retained as average concentration of exposure with the high-end estimate of 17,8 mg/m^3.
To calculate inhaled concentrations, it was assumed that exposed individuals live 20 hours/day in their apartments, 365 days/year for 30 years.

With regard to the general population exposure, data were chosen from the Total Exposure Assessment Measurement (TEAM) study (Wallace 1991). This study was carried out at four sites in the USA and reported 24 hours concentrations of PCE from about 1000 personal samples. Personal sampling over a 24 hours period allowed to reflect exposure consequent to a variety of exposure patterns. The arithmetic mean exposure was 15 $\mu g/m^3$.
In this study, this scenario exposure is assumed to occur over an individual's entire lifetime, so duration of exposure is 24 hours/day, 365 days/year for 70 years

Exposure estimates used in our risk assessment are summarised in table 2. To assess cancer risk, exposure estimates must be averaged over a lifetime as to be compatible with cancer risk values.

Table 2: Estimated exposure received by populations studied

Population scenario	Co-located residents	General population
PCE average concentration in air (high-end)	2 mg/m^3 (17,8 mg/m^3)	15 $\mu g/m^3$
Average daily concentration inhaled (high-end)	1,67 mg/m^3 (14,8 mg/m^3)	15 $\mu g/m^3$
Lifetime Average daily concentration inhaled (high-end)	715 $\mu g/m^3$ (6,3 mg/m^3)	15 $\mu g/m^3$

RISK CHARACTERIZATION

Two expression of risk are widely used. Cancer risk estimates are expressed as the incremental probability of developing a cancer for an individual over a lifetime of exposure to the chemical. Cancer excess risk is calculated by multiplying the estimated exposure level by the reference risk value.

For toxic effects other than cancer, the expected human exposure considered is compared to the reference concentration value. The comparison is expressed as a ratio called Hazard Quotient. Hazard Quotient values above 1 are considered less likely to be free of adverse effects.

The following tables present calculated risk for non-cancer (table 3) and cancer effects (table 4).

Table 3: Non cancer risk from inhalation of PCE

Exposed population	Co-located residents	General population
Average daily concentration inhaled (high-end)	1,67 mg/m^3 (14,8 mg/m^3)	15 $\mu g/m^3$
Hazard Quotient range for renal effects	6,2 - 52,8	0,06
Hazard Quotient range for neurological effects	6,8 - 59,2	0,06

Data shown in table 3 indicate that there is concern for non-cancer risk to co-located residents living above dry cleaning establishments. For the general population, there is not any particular concern of non-cancer risk for a lifetime inhalation exposure at the average daily level of 15 $\mu g/m^3$ measured in the TEAM study.

Table 4: Cancer risk from inhalation of PCE

Population scenario	Co-located residents	General population
Lifetime Average Daily Concentration inhaled (high-end)	715 $\mu g/m^3$ (6,3 mg/m^3)	15 $\mu g/m^3$
Risk index range	5.10^{-4} -4,4.10^{-3}	1.10^{-5}

Data in table 4 for co-located residents show that upperbound lifetime excess cancer risk is higher than 10^{-5}, the reference risk value recommended by WHO. For the general population, the individual health risk calculated is around the reference risk value.

DISCUSSION

PCE health risk quantification is based on available toxicity and exposure data which have gone through assumptions and professional judgements. Risk characterization should therefore describe strength and weakness of data as well as uncertainties embodied in the assessment as to see to what extent risk conclusions are realistic.

Concerning PCE toxicity, non-cancer effects are quite well known even if there is still a lack of knowledge in the human data for development and reproductive toxicity. The main uncertainty relies on the relevance of animal cancer studies to human cancerogenicity. Moreover, it is not clear if human cancer dose-reponse is best fitted by the linear at low dose approach used by US EPA.

Regarding human exposure, as no French data are currently available, foreign studies had to be used to asses PCE health risk. Available monitoring studies do not cover the entire population exposure scenario such as coin-operated dry-cleaning machine customers so this risk assessment is not comprehensive.
Risk conclusions are based on a limited number of exposure estimates. It is not known how well they represent French exposures since variation in the machines type (vented or nonvented transfer or dry-to-dry), maintenance and control operations, sampling duration, season and location may influence exposure levels reported.

CONCLUSION AND IMPLICATIONS

On the basis of a first literature review, PCE health risk assessment shows that there is a health risk concern for non-cancer and cancer effects among residents living in co-location with dry-cleaning establishments. Co-located residents could be even more at risk since they experience general public ways of exposure such as wearing dry-cleaned clothes or using households products containing PCE. The general population lifetime exposure to PCE 15 $\mu g/m^3$ is safe but should remain at public health policy watching in view of the number of exposed persons.
This work has led the INERIS to propose to the French Environment Ministry to carry out an exposure survey near dry-cleaning establishments located in a shopping centre and near coin-operated dry-cleaning facilities located in a residence building. These measures will make it possible to reassess the health problem in the French context.

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