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

ANNEX XV RESTRICTION REPORT

SUBMITTED BY: United Kingdom
DATE: 30th November 2008

SUBSTANCE NAME: Tetrachloroethylene
IUPAC NAME: Tetrachloroethene
EC NUMBER: 204-825-9
CAS NUMBER: 127-18-4

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A. Proposal

A.1 Proposed restriction(s)

No restrictions on the manufacture or use of tetrachloroethylene are currently proposed. This view may have to be revised depending on the outcome of the discussion of the proposed Indicative Occupational Exposure Limit Value (IOELV) (see sections B.5.1 and B.9.1.4.3).

A.1.1 The identity of the substance(s)

Chemical Name:	Tetrachloroethylene
EC Number:	204-825-9
CAS Number:	127-18-4
IUPAC Name:	Tetrachloroethene

A.1.2 Proposed risk management measures for occupational uses

- Establish an Indicative Occupational Exposure Limit Value (IOELV) and Biological Limit Value (BLV) for tetrachloroethylene (a long-term and short-term IOELV and BLV are currently under discussion within the EU).
- Implementation of risk management measures (RMMs) following registration of tetrachloroethylene under REACH

A.1.3 Proposed risk management measures for consumer uses

- Implementation of RMMs following registration of tetrachloroethylene under REACH
- Bulky materials (>20 kg) should be aired for 24 hours and steam-pressed before being returned to the consumer.

A.2 Background to the transition dossier

A.2.1 Human Health

The hazards and risks associated with tetrachloroethylene have been evaluated and agreed under the Existing Substances Regulations (ESR) (793/93/EEC). The human health risk assessment report (RAR) was agreed by the Technical Committee for New and Existing Substances (TCNES) in 2008.

When a conclusion (iii) was assigned under the ESR a risk reduction strategy was developed. A conclusion (iii) denotes that further risk management measures are required to control the risk. As ESR has been repealed by REACH (Registration, Evaluation and Authorisation of Chemicals) an Annex XV Restriction document has to be developed for this transitional substance. This Annex XV report **only** examines those human health scenarios that were assigned a conclusion (iii) following the update to the RAR in 2008. This Annex XV report **will not** revisit any other conclusions made in the RAR. The RAR concluded that:

1. Workers

There is a need for reducing the risks (conclusion iii) from tetrachloroethylene because of the following human health effects:

- acute toxicity, eye and respiratory tract irritation, carcinogenicity and reproductive toxicity during the manufacturing and packaging of tetrachloroethylene, recycling of tetrachloroethylene, dry-cleaning, metal degreasing and other uses (engineering and laboratory work).
- repeated dose toxicity during dry-cleaning, metal degreasing and other uses (engineering and laboratory work).

2. Consumers

There is a need for reducing the risks (conclusion iii) from tetrachloroethylene because of the following human health effects:

- acute toxicity and eye and respiratory tract irritation during foreseeable misuse of coin-operated dry-cleaning machines and properly used coin-operated dry-cleaning machines.
- reproductive toxicity from exposure arising after bulky materials are taken back into use following dry-cleaning, and foreseeable misuse of coin-operated dry-cleaning machines.

3. Man via the environment

There are no human health effects that lead to a conclusion (iii) for man via the environment. Therefore, no further risk management activity under REACH is required.

4. Combined exposure

There are no human health concerns that lead to a conclusion (iii) for combined exposure. Therefore, no further risk management activity under REACH is required.

A.2.2 Environment

The environmental RAR for tetrachloroethylene was agreed in 2001 and the environmental Risk Reduction Strategy was agreed in 2005. Therefore, there are no outstanding hazards or risks for the environment that need to be considered in this Annex XV report.

B. INFORMATION ON HAZARD AND RISK

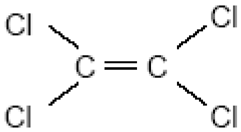
B.1 Identity of the substance(s) and physical and chemical properties

B.1.1 Name and other identifiers of the substance(s)

Chemical Name: Tetrachloroethylene
EC Number: 204-825-9
CAS Number: 127-18-4
IUPAC Name: Tetrachloroethene

B.1.2 Composition of the substance(s)

Molecular formula: C_2Cl_4

Structural formula: 

Molecular weight: 165.85

Impurities: The purities of tetrachloroethylene quoted in IUCLID, where stated, were all > 99 – 100%.

The significant impurities (where stated) comprised some or all of the following:

1,1,1-Trichloroethane < 100 mg/kg (< 0.01% w/w)
Carbon tetrachloride < 50 mg/kg (< 0.005% w/w)
Dichloromethane < 2 mg/kg (< 0.0002% w/w)
Other chlorinated solvents < 150 mg/kg (< 0.015% w/w)
Trichloroethylene < 50 mg/kg (< 0.005% w/w)
Water < 50 mg/kg (< 0.005% w/w)

Given the nature of the production and isolation methods, the purity is likely to be as high as stated. The impurities present vary according to the plant and production method.

Additives: The stated additives from suppliers included a selection of the following (% w/w unless otherwise stated), which are added as stabilizers:

2,3-epoxypropyl isopropylether 0.3
2,6-bis(1,1-dimethylethyl)-4-methylphenol < 0.01
2,4-di-tert-butylphenol < 0.005
4-methylmorpholine < 0.01
Di-isopropylamine < 0.05
Tert-amylphenol < 20 ppm
Tert-butyl-glycidylether < 0.5

B.1.3 Physico-chemical properties

The physico-chemical information outlined below is from the RAR. For those physico-chemical properties where a value (as required by this Annex XV report) is not detailed in the RAR then this is indicated as ‘not available’.

REACH ref Annex, §	Property	IUCLID section	Value	Comment
VII, 7.1	Physical state at 20 ˚C and 101.3 KPa	3.1	Colourless, mobile liquid with "ethereal" odour that is detectable at around 27 ppm (183 mg/m^3)	
VII, 7.2	Melting / freezing point	3.2	-22.0 to -22.7 ^oC	
VII, 7.3	Boiling point	3.3	121.2 ^oC	
VII, 7.4	Relative density	3.4 density	1.623 at 20 ^oC	
VII, 7.5	Vapour pressure	3.6	1.9 kPa at 20 ^oC	
VII, 7.6	Surface tension	3.10	No information	
VII, 7.7	Water solubility	3.8	~149 mg/l at 20 ^oC	
VII, 7.8	Partition coefficient n-octanol/water (log value)	3.7 partition coefficient	2.53	
VII, 7.9	Flash point	3.11	No flash point under normal test conditions	SCHER Risk Assessment document
VII, 7.10	Flammability	3.13	Not available	
VII, 7.11	Explosive properties	3.14	Not explosive	
VII, 7.12	Self-ignition temperature		There are no data indicating that it undergoes autoignition	
VII, 7.13	Oxidising properties	3.15;	Not considered as an oxidising agent but can oxidise in presence of air and light	
VII, 7.14	Granulometry	3.5	N/a – substance is a liquid	
IX, 7.15	Stability in organic solvents and identity of relevant degradation products	3.17	Miscible with alcohol, ether, chloroform and benzene.	
IX, 7.16	Dissociation constant	3.21	Not available	
IX, 7.17	Viscosity	3.22	0.891 $N.m^-2.s$ at 20^oC	
	Auto flammability	3.12	N/a	
	Reactivity towards container material	3.18	Not available	
	Thermal stability	3.19	Not available	
	Vapour density		5.8 (Air=1)	
	Saturated vapour concentration		25,000 ppm (169,500 mg/m^3) at 20^oC	
	Odour recognition		~180 mg/m^3	
	Conversion factors		1 mg/m^3 = 0.147 ppm at 25^oC 1 ppm = 6.78 mg/m^3 at 25^oC	

B.2 Manufacture and uses

B.2.1 Manufacture and import of a substance

The following details have been taken from the RAR:

B.2.1.1 PRODUCTION

B.2.1.1.1 Production volume and capacity

According to the European Chemicals Bureau (ECB) by the year 2000 tetrachloroethylene was produced in 8 European Union (EU) countries - Austria, Belgium, France, Germany, Italy, the Netherlands, Spain and the United Kingdom (UK). Germany had the highest number of manufacturers, a total of 5. More recent information from the European Chlorinated Solvents Association (ECSA) states that since 2005 only 4 manufacturers produce tetrachloroethylene. Tetrachloroethylene produced by companies in the EU may be used internally by the company, sold onto the EU market, or exported from the EU. The manufacturers supply directly to the end-user or via distributors.

The total production capacity in the EU is in the range of 100,000 - 150,000 tonnes per annum (tpa), with actual production reported as 148,074 tpa in 2004. Plant capacities vary and are typically in the range of 10,000-50,000 tpa (a large scale plant would have a capacity in the range of 50,000-100,000 tpa). Sales of tetrachloroethylene in 1994 were reported as 78,000 tonnes and exports as 56,000 tonnes, the remainder being used by the chemical industry as an intermediate. Sales in the EU 25 countries plus Norway, Switzerland and Turkey totalled 56,000 tonnes in 2005. These figures have fallen since 1999 apparently due to more efficient dry-cleaning processes, greater recycling, use of enclosed systems and other good practices.

There are a number of companies in the UK that re-cycle small quantities of used tetrachloroethylene from a variety of industries. This is usually re-sold to the engineering industry for use in metal degreasing.

B.2.1.1.2 Production methods

Tetrachloroethylene may be produced by oxychlorination, chlorination and/or dehydrochlorination reactions of hydrocarbons or chlorinated hydrocarbons. The most common methods of production reported are the chlorination of propylene and the oxychlorination of 1,2-dichloroethane (Brooke *et al*, 1993). Carbon tetrachloride is also produced via the chlorination of propylene route, and the amounts produced are dependent upon the reaction conditions employed. Due to controls on the production and use of carbon tetrachloride, the current reaction conditions are likely to favour the production of tetrachloroethylene. Trichloroethylene and tetrachloroethylene are both produced by the oxychlorination of 1,2-dichloroethane route, and by varying the reaction conditions the amounts produced of either compound can be varied. Production is carried out in closed systems, limiting human and environmental exposure under normal operating conditions.

B.2.2 Uses

B.2.2.1 Workers

The occupational uses of tetrachloroethylene identified in Table 2.1 are those that were assigned a conclusion (iii) in the RAR. A total of 148,074 tpa of tetrachloroethylene was manufactured in 2004 and 119,000 in 2003. The information on tonnage for the uses assigned a conclusion (iii) for human health is presented in Table 2.2.

Table 2.2 Production, use and sales of tetrachloroethylene for 2004 (2003)

Application	Percentage of production volume	Percentage of Sales	Tonnes per annum (x 1000)
Dry cleaning agent	17.5 (19)	49 (43)	26 (23)
Metal cleaning agent	11 (13)	30 (30)	16 (16)
Other and unknown	7 (12)*	21 (26)	1.6 (1)

Source: Environmental Risk Reduction Strategy (RRS, 2005)
*Excludes exports, which accounts for 47 (39) %

The RAR classed 'Other uses' as those where tetrachloroethylene was used in engineering and laboratory work. In addition, the RAR outlined some minor uses of tetrachloroethylene, these were:

- Spot stain removal during the production of textile fabrics;
- Use in some spot stain removers;
- In paint removers;
- In heat transfer media;
- In the preparation of photo-polymer plates;
- As a solvent in paints;
- Degreasing of electrical components during refurbishment, and
- Degreasing of chamois leathers.

No information on the exact tonnage of tetrachloroethylene used in these industries has been provided.

B.2.2.2 Consumers

The only direct consumer use of tetrachloroethylene identified in the RAR which was assigned a conclusion (iii) was its use in coin-operated dry cleaning machines. The RAR noted that there were an estimated 200 to 250 public coin operated machines available through public launderettes in the UK. No figures were available for the number of coin-operated dry-cleaning machines in other Member States.

One indirect exposure to tetrachloroethylene was identified as giving cause for concern (a conclusion (iii) was assigned) for consumer exposure. Professionally dry cleaned bulky materials (e.g. 20 kg curtains) that are hung up in the home could result in a consumer inhaling the residual solvent from dry cleaned items.

B.3 Classification and labelling

B.3.1 Classification in Annex I of Directive 67/548/EEC

Classification: Carcinogen category 3: R40; N: R51/53

Labelling: Xn, N; R40, 51/53; S23-36/37, 61

Carcinogen category 3 indicates a substance which causes concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

R40 indicates 'Limited evidence of a carcinogenic effect'
R51 indicates 'Toxic to aquatic organisms'
R53 indicates 'May cause long-term adverse effects in the aquatic environment'
S23 states 'Do not breathe gas/ fumes/ vapour/ spray' (specified by the manufacturer)
S36/37 states 'Wear suitable protective clothing and gloves'

B.3.1.1 Proposed classification

Following information within the RAR a change to the above classification was proposed. This proposal (outlined below) was agreed within the EU's Classification and Labelling Group. The European Chemicals Bureau (ECB) suggested that tetrachloroethylene be discussed with the European Commission's Environment General Directorate with a view to agreeing a proposal to put forward into a future ATP (Adaptation to Technical Progress). At present no further action has occurred on this matter.

Classification: Carcinogen category 3: R40; Xi: R38, R67; N: R51/53

R38 indicates 'Irritating to the skin'
R67 indicates 'Vapours may cause drowsiness and dizziness'

B.3.2 Classification in classification and labelling inventory/Industry's self classification(s) and labelling

As this is a transitional substance no industry classification and labelling has been carried out.

B.4 Environmental fate properties

This Annex XV (transitional) report is only concerned with those human health scenarios that were assigned a conclusion (iii) in the RAR.

B.5 Human health hazard assessment

The full toxicological assessment of tetrachloroethylene is detailed in the RAR. The final document has yet to be published. However, a draft version of the document is available on the ECB website (http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/RISK_ASSESSMENT/DRAFT/R021_0712_env_hh.pdf).

B.5.1 Derivation of DNEL(s)/DMEL(s) or other quantitative or qualitative measure for dose response

The purpose of this transitional dossier is to develop risk reduction strategies for exposure situations for which conclusion (iii) was reached in the RAR. Therefore, derived no effect levels (DNELs) will be calculated for the health endpoints and routes of exposure that are relevant to the exposure situations of concern identified in the RAR. The UK notes that the European Commission's Scientific Committee on Occupational Exposure Limits (SCOEL) has recommended IOELVs of 20 ppm (8-hour time-weighted average (TWA)) and 40 ppm (15-minute reference period) for tetrachloroethylene. This recommendation is currently undergoing public consultation and the consultation period ends in January 2009 (SCOEL, 2008). The Chemical Safety Assessment (CSA) Guidance (Appendix R.8-13) states that EU IOELVs may take the place of the worker-DNEL short-term inhalation and worker-DNEL long-term inhalation where the current scientific information supports the IOEL. Following this principle, the UK proposes to use these values as a benchmark against which to judge the adequacy of workplace risk management measures (RMMs) to control airborne exposure to tetrachloroethylene. If this value changes as a result of consultation, the revised value will be taken into account in registration dossiers and may result in the conclusions presented within this Annex XV dossier having to be revised. The UK has, however, derived DNELs to assess worker dermal exposure and consumer exposure by the inhalation and dermal routes.

B.5.1.1 Overview of dose descriptors

The human health endpoints for which concerns have been identified in the RAR are:

- acute toxicity (CNS depression)
- skin, eye and respiratory tract irritation
- repeat dose toxicity
- carcinogenicity
- developmental toxicity

The dose descriptors that were identified in the RAR for these endpoints are summarised in Table 5.1 below. In relation to skin irritation as a result of direct contact with liquid tetrachloroethylene, the available data do not provide sufficient information to characterise the dose-response relationship for this effect. It is therefore not possible to derive a DNEL or derived minimum effect level (DMEL) for this endpoint. In accordance with the CSA guidance (Chapter R8, P122 and Part E, table E 3.1) the classification R38 (*Irritating to skin*) recommended to be assigned to tetrachloroethylene in the RAR will be used to identify suitable risk management measures for worker and consumer scenarios of concern.

Table 5.1 Dose descriptors identified in the RAR for endpoints of concern

Endpoint	**Quantitative dose descriptor or other information on potency**		**Associated relevant effect**	**Remarks on the study**
	Local effect	**Systemic effect**		
Acute toxicity				
Inhalation		NOAEC 106 ppm (1 hour)	CNS depression	Human volunteer data
Irritation/corrosivity				
Eye	NOAEC 106 ppm (1 hour)		Eye and respiratory tract irritation from airborne vapour	Human volunteer data
Respiratory tract				
Repeated dose toxicity (sub-acute/sub-chronic/chronic)				
Oral		LOAEC 390 mg/kg/day	Kidney damage	78 week gavage bioassay in mouse, dosing on 5 days per week.
Inhalation (human)		NOAEC 25 ppm (8-hour TWA)	No clear evidence for repeated dose effects at exposure levels up to 25 ppm.	Obtained from epidemiological data including general health surveys and studies looking specifically for potential liver, kidney and neurological effects.
Inhalation (animal)		LOAEC 100 ppm	Lung congestion and kidney damage	2 yr bioassay in the mouse, exposure 6 hours per day, 5 days per week.
Carcinogenicity				
Inhalation		200 ppm (LOAEC)	Kidney toxicity and hyperplasia	2 yr bioassay in the rat, exposure 6 hours per day, 5 days per week. At the LOAEL a low incidence of hyperplasia (3/49) was seen in the kidneys of males only. At the next dose, 400 ppm, a low incidence of kidney tumours was reported in males only (2/50).
Developmental toxicity				
Inhalation		100 ppm (NOAEC)		2-generation study in the rat, exposure 6 hours per day, 5 days per week.

B.5.1.2 Exposure situations for which risk reduction strategies are required

In the RAR, conclusion (iii) was identified for the following exposure situations:

Workers: Manufacture and packaging
Recycling used tetrachloroethylene
Dry-cleaning
Metal degreasing
Others (including laboratory and engineering work)

The pattern of exposure for these uses includes short-term peak exposure by the inhalation and dermal routes and long-term repeated exposure by the inhalation and dermal routes. Short and long-term exposure by the inhalation route will be assessed by comparison with the IOELVs recommended by SCOEL. In the case of short-term peak dermal exposure, there are no measured or modelled data from which to characterise this type of exposure therefore the potential for systemic toxicity to arise following dermal exposure will be assessed by comparison to the long-term dermal DNEL. As indicated previously, it is not possible to derive a DNEL/DMEL for local irritation. Appropriate risk management measures will be identified based on the recommended R-phrase for this endpoint.

The following values will be used to assess worker inhalation exposure:
Short-term – 40 ppm (15-minute reference period)
Long-term – 20 ppm (8-hour TWA)

The following worker DNEL will be calculated:

Worker-DNEL long-term for dermal route

Consumers: Use of coin-operated dry-cleaning machines
Back-in-use exposure from dry-cleaned bulky materials

The pattern of exposure for these uses includes short-term peak exposure by the inhalation and dermal routes and prolonged exposure to residual tetrachloroethylene evaporating out of bulky items by the inhalation and dermal routes. Long-term repeated exposure is unlikely for consumers. No regulatory benchmarks have been proposed for consumer exposure therefore short-term and prolonged inhalation exposure of consumers will be 'assessed' based on a comparison with short and long-term DNELs respectively. In the case of short-term peak dermal exposure, there are no measured or modelled data from which to characterise this type of exposure, therefore all dermal exposure will be assessed by comparison to the long-term dermal DNEL. As for workers, risk management measures for local dermal effects will be identified based on the recommended R-phrase for this endpoint.

The following consumer DNELs will be calculated:

Consumer-DNEL short-term for inhalation route
Consumer-DNEL long-term for inhalation route
Consumer-DNEL long-term for dermal route

Man via the environment: No concerns were identified

B.5.1.3 Workers

B.5.1.3.1 Worker DNEL long-term dermal route

Tetrachloroethylene has the potential to be absorbed across the skin and there is the potential for adverse systemic effects to arise as a result of skin exposure. No studies have been undertaken by the dermal route to characterise the dose-response relationship for systemic effects therefore it will be necessary to obtain a long-term dermal DNEL by extrapolation. The RAR concluded that long-term repeated exposure to tetrachloroethylene has the potential to cause adverse effects in the kidneys. Effects were also seen in the lungs of mice inhaling tetrachloroethylene, but this is considered to be a route specific effect and will not be taken into consideration for deriving a dermal DNEL. There are also concerns for carcinogenicity and for developmental toxicity. Dose descriptors for these effects have been identified from studies in animals. It has also been possible to identify a human dose descriptor for systemic effects following repeated exposure from epidemiological studies. The available human data relating to carcinogenicity and developmental toxicity do not provide sufficient information to allow human dose descriptors to be identified for these endpoints. Since the dose-response relationship and evidence base for each endpoint is different it is not clear which is the critical endpoint for risk assessment of long-term repeated exposure. It will therefore be necessary to calculate separate endpoint specific DNELs for each effect based on animal and human data (where a robust dose descriptor is available) to identify the critical long-term DNEL.

B.5.1.3.1.1 Dermal DNEL derived from the human NOAEC for repeated exposure

A large body of epidemiological studies are available including general health surveys of workers repeatedly exposed to tetrachloroethylene and studies looking specifically for potential liver, kidney and neurological effects in workers. There was no clear evidence from any study for repeated dose effects at concentrations up to 25 ppm (173 mg/m^3) (8-hr TWA). This value was therefore adopted in the RAR as a human NOAEC. Since this dose descriptor relates to inhalation exposure it is necessary to identify the corrected dose descriptor for the dermal route. The NOAEC of 173 mg/m^3 equates to an internal body burden of 25 mg/kg/day (assuming 100% absorption by the inhalation route, that a worker engaged in light activity inhales 10 m^3 over 8 hours and has a body weight of 70kg). A dermal absorption value of 50% has been obtained for liquid tetrachloroethylene.

The corrected starting point is therefore:

25 x 100/50 = 50 mg/kg/day

Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects based on the human NOAEC for repeated exposure		
Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	3	The dose descriptor reflects findings from a number of epidemiological studies covering in total hundreds of workers from several nationalities. This data therefore addresses some sources of human variability. On this basis a factor of 3 is appropriate to take account of remaining intraspecies variability within the worker population.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure because the epidemiological data relate to long-term exposure.
Dose response and endpoint specific/severity issues	1	There is no clear evidence for repeated dose effects in humans at exposure levels up to 25 ppm. The dose-response relationship for specific health endpoints above this concentration is uncertain. This is mainly due to difficulties in interpretation of the available studies rather than any consistent evidence for adverse effects. On this basis, the NOAEC that has been identified can be considered to be reliable. Application of a factor to take account of uncertainties in the dose-response relationship above the NOAEC is not justified.
Quality of database	1	In the RAR deficiencies have been identified in the reporting and/or conduct of many of the epidemiological studies making interpretation of the epidemiological data difficult. One key issue with many studies is the lack of a control group to allow meaningful evaluation of any effects that have been noted or the poor characterisation of the control group. Since the NOAEC was identified on the basis of an absence of reported effects, it is likely to be a conservative estimate. In this situation, application of an assessment factor to address deficiencies in the quality of the data is not justified.
Overall assessment factor: 3		
Endpoint specific DNEL: 50/3 = 16.7 mg/kg/day		

B.5.1.3.1.2 Dermal DNEL derived from animal LOAEC for repeated exposure

There are two possible starting points to derive a dermal DNEL for the effects of repeated exposure. A LOAEC of 100 ppm (690 mg/m^3) obtained from a 2-year inhalation study in the mouse and a LOAEL of 390 mg/kg/day obtained from a 78-week oral gavage study also in the mouse. Both studies are of good quality and reflect lifetime exposure for the mouse. For consistency with the approach taken for risk characterisation in the RAR, the LOAEC of 690 mg/m^3 will be chosen as the starting point.

It is necessary to convert this airborne concentration to an equivalent dermal dose. For a 6-hour exposure, the LOAEC of 690 mg/m^3 will give rise to an internal body burden in the mouse of 348 mg/kg/day (assuming 100% absorption and that a mouse inhales 0.504 m^3 over 6 hours[1]). A worst-case dermal absorption value of 50% was obtained in the RAR for tetrachloroethylene in liquid form.

The corrected starting point is therefore:

348 x 100/50 = 696 mg/kg/day

Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects based on the animal LOAEC for repeated dose toxicity		
Uncertainties	**AF**	**Justification**
Interspecies differences	17.5	The dose descriptor is obtained from an inhalation study in the mouse. It is therefore necessary to apply an allometric scaling factor of 7 to take account of differences in basal metabolic rates between animals and humans. There are no data for tetrachloroethylene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis a default factor of 2.5 to account for other species differences will be applied. The factor to take account of interspecies differences is therefore 17.5.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to tetrachloroethylene in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies variability.
Differences in duration of exposure	1	The dose descriptor was obtained from a lifetime study in the mouse. The DNEL is to be used to assess long-term repeated exposure in workers. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	3	The dose descriptor is a LOAEC. Effects reported include concentration related increases in the incidence of renal tubular cell karyomegaly in males (control 4/49; 100 ppm 17/49; 200 ppm 46/50) and females (control 0/48; 100 ppm 16/49; 200 ppm 38/50), the presence of renal tubular casts in males (control 3/49; 100 ppm 9/49; 200 ppm 15/50) and females (control 4/48; 100 ppm 4/49; 200 ppm 15/50) and congestion in the lungs

[1] Default respiratory volume data for the mouse are not available in the CSA guidance. Based on the standard respiratory volume of 0.2 l/min/kg for humans quoted in the CSA guidance (chapter R8, table R8.2), and using an allometric scaling factor of 7, the standard respiratory volume for the mouse can be calculated to be 1.4 l/min/kg. Hence a mouse would inhale 0.504 m^3/kg bw over 6 hours.

		in males (control 1/49; 100 ppm 8/49; 200 ppm 10/50) and females (control 1/48; 100 ppm 5/50; 200 ppm 6/50). The dose-response relationship suggested by these incidences is not thought to be excessively shallow and hence it is estimated that the NOAEC is likely to be within a factor of 3 of the LOAEC. On this basis an assessment factor of 3 will be adequate.
Quality of database	1	The key study was part of a series of mouse studies conducted to modern regulatory standards. A similar series of studies is available for the rat. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 262.5		
Endpoint specific DNEL: 696/262.5 = 2.65 mg/kg/day		

B.5.1.3.1.3 Dermal DNEL derived from the animal LOAEC for cancer

In mice and female rats there was no evidence for tumours that are relevant to human health. A low incidence of kidney tumours has been reported in male rats (2/50) exposed to 400 ppm tetrachloroethylene in a 2-year bioassay (exposure 6 hours per day, 5 days per week). No kidney tumours were observed at 200 ppm in this study but 3/49 male rats exhibited renal tubular hyperplasia which is a possible precursor to cancerous lesions. The mechanism leading to the formation of these kidney tumours has not been fully elucidated but it is considered that renal tumours are only likely to occur under conditions of sustained renal toxicity and associated cell proliferation. On this basis, a threshold based assessment approach is appropriate. The dose descriptor used in the RAR for cancer is the LOAEC of 200 ppm (276 mg/m^3) for renal tubular hyperplasia.

It is necessary to convert this airborne concentration to an equivalent dermal dose. For a 6-hour exposure, the LOAEC of 1380 mg/m^3 will give rise to an internal body burden in the rat of 80 mg/kg/day (assuming 100% absorption and that a rat inhales 0.29 m^3/kg bw over 6 hours (CSA guidance, chapter R8, table R8.2)). A worst-case dermal absorption value of 50% was obtained in the RAR for tetrachloroethylene in liquid form.

The corrected starting point is therefore:

1380 x 100/50 = 2760 mg/kg/day

Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects based on the animal LOAEC for cancer		
Uncertainties	**AF**	**Justification**
Interspecies differences	10	The dose descriptor is obtained from an inhalation study in the rat. It is therefore necessary to apply an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for tetrachloroethylene to quantify other differences between animals and

		humans that could affect interspecies extrapolation. A default factor of 2.5 to account for other species differences will be applied. The factor to take account of interspecies differences is therefore 10.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to tetrachloroethylene in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies variability.
Differences in duration of exposure	1	The dose descriptor was obtained from a lifetime study in the rat. The DNEL is to be used to assess long-term repeated exposure in workers. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	3	Although the dose descriptor is a LOAEC, the effect seen at this LOAEC is hyperplasia not cancer and was only seen in a small proportion of animals (3/49). Cancerous lesions were only seen at the top dose in this study (400 ppm) and only in a small proportion of animals (2/50). Based on this information the NOAEC for hyperplasia is likely to be within a factor of 3 of the LOAEC and hence a factor of 3 will be applied.
Quality of database	1	The key study was conducted to modern regulatory standards and was adequately reported. On this basis the quality of the database is not considered to contribute uncertainty and it is therefore not necessary to apply an additional factor.
Overall assessment factor: 150		
Endpoint specific DNEL: 2760/150 = 18.4 mg/kg/day		

B.5.1.3.1.4 Dermal DNEL derived from the animal NOAEC for developmental toxicity

A NOAEC of 100 ppm (690 mg/m^3) has been identified for developmental toxicity (2-generation study in the rat, exposure 6 hours per day, 5 days per week). It is necessary to convert this airborne concentration to an equivalent dermal dose.
The NOAEC of 690 mg/m^3 for a 6-hour daily exposure would give rise to an internal body burden in the rat of 200 mg/kg/day (assuming 100% absorption by the inhalation route and that a rat inhales 0.29 m^3/kg over 6 hours (CSA guidance, chapter R8, table R8.2)). A worst-case dermal absorption value of 50% was obtained in the RAR for tetrachloroethylene in liquid form.

The corrected starting point is therefore:

200 x 100/50 = 400 mg/kg/day

Assessment factors and DNEL calculation for worker DNEL long-term dermal systemic effects based on the animal NOAEC for developmental toxicity		
Uncertainties	**AF**	**Justification**
Interspecies	10	The dose descriptor is obtained from an inhalation

differences		study in the rat. To use a value extrapolated from a rat inhalation study to assess dermal exposure in humans it is necessary to apply an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for tetrachloroethylene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis a default factor of 2.5 to account for other species differences will also be applied giving an overall assessment factor of 10.
Intraspecies differences	5	There are no data to quantify variability in susceptibility to the effects of long-term exposure to tetrachloroethylene in the human population. The default factor of 5 for workers will therefore be used to take account of intraspecies differences.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	1	The dose descriptor is a NOAEC. At higher exposure levels in one study slight developmental delay was reported (at 250 ppm), apparently in the absence of maternal toxicity. At 300 ppm in a separate study there was a marginal increase in the numbers of resorptions associated with slight maternal toxicity in rats and a slight developmental delay in the absence of convincing maternal toxicity in mice. In contrast, other studies provided no evidence for developmental toxicity in the presence of maternal toxicity at levels of around 500 ppm in rats and rabbits and 900 ppm in rats. The uncertainty in relation to the dose-response relationship at concentrations above the NOAEC does not affect the reliability of the NOAEC that has been identified and therefore application of an additional factor is not justified.
Quality of database	1	Although there are uncertainties in the interpretation of many studies examining the potential for developmental toxicity at concentrations above the NOAEC, the NOAEC itself has been obtained from a thorough 2-generation study conducted to modern regulatory standards. In this situation, application of an assessment factor to address deficiencies in the quality of the data is not justified.
Overall assessment factor: 50		
Endpoint specific DNEL: 400/50 = 8 mg/kg/day		

B.5.1.3.1.5 Selection of worker-DNEL long-term dermal

Endpoint specific DNELs have been calculated for repeated dose toxicity using both human and animal data and for cancer and developmental toxicity using animal data. It is therefore necessary to identify which of these DNELs is the critical DNEL for assessing long-term dermal exposure of workers.

Considering first the endpoint of repeat dose toxicity, the endpoint specific DNEL that has been derived from the animal LOAEC (2.65 mg/kg/day) is lower than the DNEL that has been derived from the human NOAEC (16.7 mg/kg/day). This is likely to be due to the need to use more conservative assessment factors when a LOAEC is used as the starting point and because of the need to take account of possible differences in susceptibility between animals and humans. Given that the extensive human data do not provide evidence for adverse effects in the kidneys it may be the case that humans are not more susceptible than animals. It therefore seems most appropriate to use the DNEL derived from human data as the endpoint specific DNEL for effects from repeated exposure.

In relation to the endpoint of cancer, the endpoint specific DNEL for kidney cancer based on animal data (18.4 mg/kg/day) is higher than the endpoint specific DNELs for repeated dose toxicity suggesting that cancer is a less sensitive endpoint than repeated dose toxicity. This is consistent with the view that kidney cancer will only arise as a result of sustained kidney toxicity, and therefore it seems appropriate to refer to the endpoint specific DNEL for repeated dose toxicity as a basis for the risk assessment of both repeated dose effects and cancer. Noting that the endpoint specific DNEL for repeated dose toxicity derived from human data should take precedence over the DNEL based on animal data, it is proposed that the endpoint specific DNEL based on human data should be used for risk assessment of repeated dose toxicity and cancer endpoints.

There is also a concern for developmental toxicity. It has not been possible to derive an endpoint specific DNEL based on human data for this endpoint and there are no data to indicate whether humans would be more or less susceptible than animals for this endpoint. On this basis, it is difficult to justify the use of the higher DNEL value obtained for repeated dose toxicity from human data (16.7 mg/kg/day) in preference to the DNEL value of 8 mg/kg/day that has been obtained for developmental toxicity. Developmental toxicity is therefore identified as the critical health endpoint for risk assessment of long-term worker dermal exposure.

The worker DNEL long-term dermal route is therefore 8 mg/kg/day.

This DNEL does not address the potential for skin irritation. The risk characterisation will consider whether specific RMMs are needed for this endpoint.

B.5.1.4 Consumer

B.5.1.4.1 DNEL short-term for inhalation route

Peak airborne exposure to tetrachloroethylene vapour causes both local and systemic effects. It is therefore necessary to calculate DNELs for both types of effect to determine which will be the critical health endpoint for the risk assessment of short-term exposure.

B.5.1.4.1.1 Short-term inhalation DNEL based on local effects (eye and respiratory tract irritation from the vapour)

The dose descriptor is the NOAEC of 106 ppm obtained from human volunteers exposed for 1 hour. Irritation is a concentration specific effect. It is not necessary to modify the dose descriptor to take account of differences in breathing rates between volunteers at rest and consumers who may also be at rest. It is also not necessary to modify the dose descriptor to take account of the difference in dose that will be obtained from the 1-hour exposure of test subjects and the 15-minute reference period for the short-term DNEL. The starting point is therefore 106 ppm.

Assessment factors and DNEL calculation for consumer-DNEL short-term inhalation local effects		
Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	3.16	There are no data to quantify variability in susceptibility to the irritant effects of tetrachloroethylene in the human population. Since irritant effects relate to the concentration at the target site it is not necessary to apply a factor to take account of toxicokinetic differences. In relation to toxicodynamic differences, the International Programme on Chemical Safety (IPCS) recommends a factor of 3.16 to account for differences within the human population (IPCS, 2005). This factor will be used here.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	1	The starting point is a NOAEC. Slight persistent stinging in the eyes and mild nasal irritation was reported at the next higher concentration tested (216 ppm for 2 hours) indicating that the dose-response relationship is not steep. A factor to take account of uncertainties in the NOAEC is therefore not justified.
Quality of database	1	The quality of the database for this endpoint is adequate. A range of concentrations and exposure durations were tested in the key study and the results were internally consistent and were supported by results obtained in a second human volunteer study conducted by a separate group of researchers. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 3.16		
Endpoint specific DNEL: 106/3.16 = 33.5 ppm		

B.5.1.4.1.2 Short-term inhalation DNEL based on systemic effects (CNS depression)

The dose descriptor is the NOAEC of 106 ppm obtained from human volunteers exposed for 1 hour. CNS depression is a dose-specific effect. It is not necessary to adjust the NOAEC to take account of differences in breathing rates between volunteers at rest and consumers who may also be at rest. Since the short-term inhalation DNEL has a 15-minute reference period it is necessary to convert the 1-hour NOAEC to the equivalent dose that would be inhaled over a 15-minute period. This is done using the modified Haber's rule $C^n t = k$ (CSA guidance, Chapter R8, Appendix R8-8, page 108) where 'C' is the concentration, 't' is the exposure time, 'n' is a regression coefficient and 'k' is a constant. It is not possible to determine an appropriate value for 'n' from the available data, therefore the default value of 3 to extrapolate from a longer to shorter exposure period will be used.

$\sqrt[3]{(106^3 \times 4)} = 168$ ppm

The corrected starting point is 168 ppm (15-minute TWA)

Assessment factors and DNEL calculation for consumer DNEL short-term inhalation systemic effects		
Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	10	There are no data to quantify variability in susceptibility to the CNS depressant effects of tetrachloroethylene in the human population. In the absence of substance specific data the default factor of 10 (general population) will be used to take account of differences in susceptibility between consumers.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	1	The starting point is a NOAEC. Dizziness and drowsiness were reported by some volunteers (numbers not reported) exposed to 216 ppm for 2 hours and impaired motor co-ordination was also reported in volunteers exposed to 280 ppm for up to 2 hours. In a separate study, 25-40% of participants reported headache, drowsiness and light-headedness with exposure to 100 ppm for 7 hours. These data support the conclusion that 106 ppm can be regarded as a NOAEC for a 1 hour exposure. A factor to take account of uncertainties in the NOAEC is therefore not justified.
Quality of database	1	The quality of the database for this endpoint is adequate. The key study is a human volunteer study the results of which show a dose-related trend for increasing severity with increasing dose. The results of the key study are supported by data from a second

		human volunteer study conducted by a separate group of researchers. This consistency provides confidence in the reliability of these studies. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 10		
Endpoint specific DNEL: 168/10 = 17 ppm		

B.5.1.4.1.3 Selection of consumer-DNEL short-term inhalation

A DNEL of 33.5 ppm was calculated for eye and respiratory tract irritation compared to a DNEL of 17 ppm for CNS depression. CNS depression is therefore identified as the critical health effect for the risk assessment of short-term inhalation exposure.

<u>The consumer DNEL short-term inhalation route is 17 ppm (15-minute TWA)</u>.

B.5.1.4.2 Consumer-DNEL long-term for inhalation route

Developmental toxicity was identified as the critical health endpoint for long-term dermal exposure to workers. However, this assessment did not consider the potential for adverse effects in the lungs since this was only seen in long-term repeated inhalation studies in the mouse. In the case of tetrachloroethylene, long-term repeated exposure is not anticipated in the consumer use scenarios for which conclusion (iii) was reached. The exposure pattern is one of prolonged exposure to tetrachloroethylene as it evaporates from back in use bulky items and such exposure will predominantly occur on the first day back in use. On this basis, rather than use data from long-term repeated exposure studies which do not seem relevant to the consumer exposure pattern, the UK has derived 24-hour DNELs for short-term irritation and CNS effects to confirm that these endpoints are less sensitive than developmental toxicity.

B.5.1.4.2.1 Long-term inhalation DNEL for consumers based on local effects (eye and respiratory tract irritation from the vapour)

The dose descriptor used to assess the potential for local effects in consumers following short-term peak exposure was a NOAEC of 106 ppm obtained from human volunteers exposed for 1 hour. In a separate study, mild nasal irritation was reported by some volunteers exposed to 100 ppm for 7 hours. The irritation developed within 2 hours of the start of exposure and usually subsided before the end of the 7-hour exposure period; 100 ppm will therefore be regarded as a LOAEC for respiratory tract irritation from prolonged exposure. This will be used as the starting point to derive a DNEL for prolonged consumer exposure. Irritation is a concentration specific effect. It is not necessary to modify the dose descriptor to take account of differences in breathing rates between volunteers at rest and consumers who may also be at rest. It is also not necessary to modify the dose descriptor to take account of the difference in dose that will be obtained from the 7-hour exposure of test subjects and the 24-hour reference period for the long-term DNEL for consumers. The starting point is therefore 100 ppm.

Assessment factors and DNEL calculation for consumer-DNEL long-term inhalation local effects		
Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	3.16	There are no data to quantify variability in susceptibility to the irritant effects of tetrachloroethylene in the human population. Since irritant effects relate to the concentration at the target site it is not necessary to apply a factor to take account of toxicokinetic differences. In relation to toxicodynamic differences, the IPCS recommends a factor of 3.16 to account for differences within the human population (IPCS, 2005). This factor will be used here.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	3	The starting point is a LOAEC. Not all volunteers reported irritation and in those who did, the effect usually subsided before the end of the 7-hour exposure. On this basis, the effects at 100 ppm are considered to be mild and it is likely that the threshold for irritation from prolonged exposure lies close to 100 ppm. A factor of 3 is therefore sufficient to address uncertainties in the dose-response relationship.
Quality of database	1	The quality of the database for this endpoint is adequate. A range of concentrations and exposure durations were tested in the key study and the results were internally consistent and were supported by results obtained in a second human volunteer study conducted by a separate group of researchers. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 9.48		
Endpoint specific DNEL: 100/9.48 = 10.5 ppm		

B.5.1.4.2.2 Long-term inhalation DNEL for consumers based on systemic effects (CNS depression)

The dose descriptor used to assess the potential for CNS depression in consumers following short-term peak exposure was a NOAEC of 106 ppm obtained from human volunteers exposed for 1 hour. In a separate study, 25-40% of participants reported headache, drowsiness and light-headedness with exposure to 100 ppm for 7 hours. Given the longer duration of exposure in the second study, it is considered more appropriate to use this LOAEC as the starting point to derive a DNEL for prolonged consumer exposure. CNS depression is a dose-specific effect. It is not necessary to adjust the NOAEC to take account of differences in breathing rates between volunteers at rest and consumers who may also be at rest. Since the long-term inhalation DNEL has a 24-hour reference period it is necessary to convert the 7-hour LOAEC to the equivalent dose that would be inhaled over a 24-hour period. This adjustment will be done using the modified Haber's rule $C^n t = k$ (CSA guidance, Chapter R8, Appendix R8-8, page 108). In this case, the default value of 1 to extrapolate from a shorter to longer exposure period will be used.

100 x 7/24 = 29.2 ppm

The corrected starting point is 29.2 ppm (24-hour TWA)

Assessment factors and DNEL calculation for consumer DNEL long-term inhalation systemic effects		
Uncertainties	**AF**	**Justification**
Interspecies differences	-	The starting point is obtained from human data so it is not necessary to apply a factor to take account of interspecies differences.
Intraspecies differences	10	There are no data to quantify variability in susceptibility to the CNS depressant effects of tetrachloroethylene in the human population. In the absence of substance specific data the default factor of 10 (general population) will be used to take account of differences in susceptibility between consumers.
Differences in duration of exposure	1	It is not necessary to apply a factor to take account of duration of exposure.
Dose response and endpoint specific/severity issues	3	The starting point is a NOAEC. In the key study, not all participants reported symptoms of CNS depression following 7 hours exposure to 100 ppm. In a separate study, dizziness and drowsiness were reported by some volunteers (numbers not reported) exposed to 216 ppm for 2 hours and impaired motor co-ordination was also reported in volunteers exposed to 280 ppm for up to 2 hours. A NOAEC of 106 ppm was identified for a 1 hour exposure. These data support the view that the NOAEC for CNS depression following a 7-hour exposure is likely to be close to this LOAEC. A factor of 3 is considered sufficient.
Quality of database	1	The quality of the database for this endpoint is adequate. The key study is a human volunteer study the results of which show a dose-related trend for increasing severity with increasing dose. The results of the key study are supported by data from a second human volunteer study conducted by a separate group of researchers. This consistency provides confidence in the reliability of these studies. It is therefore not necessary to apply a factor to take account of deficiencies in the quality of the data.
Overall assessment factor: 30		
Endpoint specific DNEL: 29.2/30 = 1 ppm (rounding to the nearest whole number)		

B.5.1.4.2.3 DNEL derived from the animal NOAEC for developmental toxicity

From the animal data a NOAEC of 100 ppm (2-generation study in the rat, exposure 6 hours per day, 5 days per week) was identified. Since animals were exposed for 6 hours per day whereas consumers may be exposed for up to 24 hours per day it is necessary to adjust the starting point for workers by a factor of 0.25 to take account of differences in the dose that will be obtained over the daily exposure period.

The corrected starting point is therefore:

100 ppm x 0.25 = 25 ppm

Assessment factors and DNEL calculation for consumer DNEL long-term inhalation		
Uncertainties	**AF**	**Justification**
Interspecies differences	2.5	The dose descriptor is obtained from an inhalation study it is therefore not necessary to apply an allometric scaling factor to take account of differences in basal metabolic rates between animals and humans. There are no data for tetrachloroethylene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis the default factor of 2.5 to account for other species differences will be applied.
Intraspecies differences	10	It is necessary to apply a factor to take account of variability in the human population. There are no data to quantify variability in susceptibility to the effects of long-term exposure to tetrachloroethylene in the human population. The default factor of 10 for consumers will therefore be used.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	1	The dose descriptor is a NOAEC. At higher exposure levels in one study slight developmental delay was reported (at 250 ppm), apparently in the absence of maternal toxicity. At 300 ppm in a separate study there was a marginal increase the numbers of resorptions associated with slight maternal toxicity in rats and a slight developmental delay in the absence of convincing maternal toxicity in mice. In contrast, other studies provided no evidence for developmental toxicity in the presence of maternal toxicity at levels of around 500 ppm in rats and rabbits and 900 ppm in rats. The uncertainty in relation to the dose-response relationship at concentrations above the NOAEC does not affect the

		reliability of the NOAEC that has been identified and therefore application of an additional factor is not justified.
Quality of database	1	Although there are uncertainties in the interpretation of many studies examining the potential for developmental toxicity at concentrations above the NOAEC, the NOAEC itself has been obtained from a thorough 2-generation study conducted to modern regulatory standards. In this situation, application of an assessment factor to address deficiencies in the quality of the data is not justified.
Overall assessment factor: 25		
DNEL: 25/25 = 1 ppm		

B.5.1.4.3 Selection of consumer-DNEL long-term inhalation

The endpoints of irritation, CNS depression and developmental toxicity are considered relevant for prolonged exposure of consumers to residual tetrachloroethylene evaporating out of bulky materials. Endpoint specific DNELs of 10.5 ppm, 1 ppm and 1 ppm have been derived for irritation, CNS depression and developmental toxicity respectively. The endpoint specific DNELs for CNS depression and developmental toxicity are the lowest therefore these endpoints are identified as the critical health endpoints for risk assessment of long-term consumer inhalation exposure.

The consumer DNEL long-term inhalation route is therefore 1 ppm.

B.5.1.5 Consumer-DNEL long-term for dermal route

Tetrachloroethylene has the potential to be absorbed across the skin and therefore there is the potential for adverse systemic effects to arise as a result of skin exposure. No studies have been undertaken by the dermal route to characterise the dose-response relationship for systemic effects therefore it will be necessary to obtain the long-term dermal DNEL by extrapolation. Since developmental toxicity has been identified as the critical health endpoint for long-term dermal exposure of workers, this endpoint will also be the critical endpoint for long-term dermal exposure of consumers. The consumer-DNEL long-term dermal route will therefore be based on the animal NOAEC of 100 ppm (690 mg/m^3) for developmental toxicity obtained from a 2-generation study in the rat (exposure 6 hours per day, 5 days per week).

The NOAEC of 690 mg/m^3 for a 6-hour daily exposure would give rise to an internal body burden in the rat of 200 mg/kg/day (assuming 100% absorption by the inhalation route and that a rat inhales 0.29 m^3/kg over 6 hours (CSA guidance, chapter R8, table R8.2)). A worst-case dermal absorption value of 50% was obtained in the RAR for tetrachloroethylene in liquid form.

The corrected starting point is therefore:

200 x 100/50 = 400 mg/kg/day

Assessment factors and DNEL calculation for consumer DNEL long-term dermal		
Uncertainties	**AF**	**Justification**
Interspecies differences	10	The dose descriptor is obtained from an inhalation study in the rat. To extrapolate this value to the dermal route it is necessary to apply an allometric scaling factor of 4 to take account of differences in basal metabolic rates between rats and humans. There are no data for tetrachloroethylene to quantify other differences between animals and humans that could affect interspecies extrapolation. On this basis the default factor of 2.5 to account for other species differences will also be applied giving an overall assessment factor of 10.
Intraspecies differences	10	It is necessary to apply a factor to take account of variability in the human population. There are no data to quantify variability in susceptibility to the effects of long-term exposure to tetrachloroethylene in the human population. The default factor of 10 for consumers will therefore be used.
Differences in duration of exposure	1	The dose descriptor was obtained from a 2-generation study in the rat. It is therefore not necessary to apply a factor to take account of differences in duration of exposure.
Dose response and endpoint specific/severity issues	1	For the reasons discussed in the derivation of the worker-DNEL long-term inhalation above it is not necessary to apply a factor to take account of uncertainties in the dose-response relationship.
Quality of database	1	For the reasons discussed in the derivation of the worker-DNEL long-term inhalation above it is not necessary to apply a factor to take account of issues in the quality of the database.
Overall assessment factor: 100		
Endpoint specific DNEL: 400/100 = 4 mg/kg/day		

The consumer DNEL long-term dermal route is therefore 4 mg/kg/day.

This DNEL does not address the potential for skin irritation. The risk characterisation will consider whether specific RMMs are needed for this endpoint.

B.5.1.6 Summary of critical DNELs

	Worker	**Consumer**
DNEL short-term inhalation	40 ppm (15-minute reference period) (275 mg/m^3)	17 ppm (15-minute reference period) (115 mg/m^3)
DNEL long-term inhalation	20 ppm (8-hour TWA) (138 mg/m^3)	1 ppm (24-hour TWA) (7 mg/m^3)
DNEL long-term dermal	8 mg/kg/day (560 mg/70 Kg/day)	4 mg/kg/day (280 mg/70 Kg/day)

B.6 Human health hazard assessment of physico-chemical properties

A conclusion (ii) for the human health assessment of physico-chemical properties was assigned in the RAR.

B.7 Environmental hazard assessment

This transitional dossier only considers the conclusion (iiis) related to human health. Therefore, this transitional dossier does not take account of the environmental assessment, which was previously agreed.

B.8 PBT and vPvB assessment

This transitional dossier only considers the conclusion (iiis) related to human health. Therefore, this transitional dossier does not take account of the persistent, bioaccumulative and toxic (PBT) and persistent and very bioaccumulative (vPvB) assessment, which was previously agreed.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of existing legal requirements

The legislative requirements, outlined below, are those that are related or currently impact on human health exposure scenarios that were assigned a conclusion (iii) in the RAR.

B.9.1.1.1 Regulation 1907/2006 (REACH)

REACH (Registration, Evaluation, Authorisation (and Restriction) of Chemicals) will require those companies that manufacture and/or import chemicals in to EU to register them with the European Chemicals Agency (ECHA) in Helsinki. REACH will require these registrations to be supported by data on the substance. The amount and type of data that will be required increases with increasing tonnage.

Registration requires manufacturers and importers to submit:

- a technical dossier, for substances in quantities of 1 tonne or more, and
- a chemical safety report, for substances in quantities of 10 tonnes or more.

The **technical dossier** should contain information on the properties, uses and on the classification of a substance as well as guidance on safe use.

The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes should document the hazards and classification of a substance and the assessment as to whether the substance is PBT or very vPvB. When the substance is classified as dangerous or as a PBT or VPvB then the CSR should also describe exposure scenarios. Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their life-cycle and how the manufacturer or importer controls, or recommends to the user how to control exposures to humans and the environment. The exposure scenarios must include the appropriate risk management measures (RMMs) and operational conditions (OCs) that, when properly implemented, should ensure that the risks from the use of the substance are adequately controlled. Exposure scenarios should be developed to cover all “identified uses” which are the manufacturers’ or importers’ own uses, and uses that are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment. Relevant information from the exposure scenarios will need to be annexed to the safety data sheets (SDS) that will be supplied to downstream users and distributors.

As all those who manufacture tetrachloroethylene in the EU do so in quantities of at least 10 tpa, a CSR will need to be provided by the manufacturer or importer. In addition, as tetrachloroethylene is classified as a dangerous substance, exposure scenarios demonstrating that exposures are below the DNEL will need to be submitted. When a DNEL cannot be derived, (as outlined in Section 5.1) substances should be assigned to a hazard category for a more qualitative assessment.

The progressive implementation of REACH will have implications for the management of workplace exposure in the EU. Suppliers of substances that fall within the remit of REACH will have to demonstrate that exposures associated with identified uses are less than the DNEL (i.e. that the substance is adequately controlled), and will have to provide information on the measures that should be in place to control exposure (detailed in the CSR and passed onto the supply chain in the SDS).

B.9.1.1.2 Workplace Legislation

The key pieces of EU legislation that govern workplace health and safety are the Framework Directive (89/391/EEC) and its daughter directives including the Chemical Agents Directive (98/24/EC) (CAD). The Framework Directive outlines general principles for the management of workplace health and safety for all workplace hazards. CAD describes specific measures to be taken in relation to the control of chemical hazards. It requires employers to assess the risks to worker health and safety posed by chemical agents in the workplace and to take the necessary preventative measures to minimise those risks by:

- substitution of a hazardous process or substance with a process or substance which presents no or lower hazards to workers;
- designing work processes and engineering controls to minimise the release of a hazardous chemical agent;
- applying collective protection measures at the source of the risk e.g. adequate ventilation and appropriate organisational measures;
- where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Employers should always, by preference, try to prevent exposure. Where it is not possible to do this, they must control exposure adequately by all routes. The

Directive outlines a priority order (as above) in which risk management measures should be applied.

B.9.1.1.3 Occupational Exposure Limit Values

The EU has developed a programme for protection of workers against risks from dangerous substances. Its objectives are:

- to prevent or limit the exposure of workers to dangerous substances at workplaces; and,
- to protect the workers that are likely to be exposed to these substances.

Setting occupational exposure limits is an essential part of this strategy, which is endorsed under the following directives:

- Council Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work;
- Council Directive 98/24/EC on the protection of the health and safety of the workers from the risks relating to chemical agents at work (the "Chemical Agents Directive");
- Commission Directive 2000/39/EC establishing a first list of IOELVs (for 63 agents);
- Commission Directive 2006/15/EC establishing a second list of IOELVs (for 33 agents), and
- Council Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (the Carcinogens and Mutagens Directive).

SCOEL provides scientific advice to the European Commission to underpin regulatory proposals on exposure limits for chemicals in the workplace. Its mandate is to examine available information on toxicological and other relevant properties of chemical agents, evaluate the relationship between the health effects of the agents and the level of occupational exposure, and where possible recommend values for occupational exposure limits which it believes will protect workers from chemical risks. SCOEL may recommend IOELVs, which can be supplemented by further notations and information such as routes of absorption, as:

- Eight-hour time-weighted average (8hr-TWA);
- short-term exposure limits (STEL); and/or
- biological limit values (BLVs).

SCOEL aims to give health-based OELs that can be recommended when the available scientific data suggest that a clear threshold value can be identified for the adverse effects of the substance in question. For some adverse effects (in particular respiratory sensitisation and genotoxicity i.e. damage to genes), it is currently impossible to identify such limits. In these cases, SCOEL can recommend a pragmatic OEL, which is established on the basis of data on dose and risk.

The European Commission uses the scientific advice from SCOEL to make proposals for IOELVs. Limits based solely on scientific considerations are considered as adaptations to technical progress, and are incorporated in proposals for Commission directives within the framework of CAD and are indicative. Limits that take account also of socio-economic and technical feasibility factors are included in proposals for Council directives under either CAD or the Carcinogens and Mutagens Directive and are binding.

B.9.1.1.4 Classification and Labelling

Harmonised rules for classification and labelling are outlined in Council Directive 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Preparations Directive). These Directives will continue alongside the EC Classification, Packaging and Labelling (CLP) Regulations through the transitional period up to 1 June 2015. The CLP Regulation is expected to come into force in January 2009.

The main objective of these directives is to communicate intrinsic hazardous properties of substances through classification and labelling. The Directives outline the classes of substances or preparations that are considered to be dangerous e.g. sensitisers. The Directives also outline the hazard symbols, risk and safety phrases and labelling and packaging requirements that should be adhered to when a substance is considered to be dangerous.

B.9.1.1.5 Directive 1999/13/EC (Solvent Emissions Directive)

Directive 1999/13/EC requires Member States of the EU to implement controls on the emissions of volatile organic compounds (VOC), which includes tetrachloroethylene. The two major disperse use areas for tetrachloroethylene, dry cleaning and metal cleaning, are both identified in the Directive and it is now a requirement of European law that people using tetrachloroethylene for dry cleaning and metal cleaning hold a permit to do so and are competent and qualified. For dry cleaning, a zero emission threshold applies so all dry cleaners are subject to the Solvent Emissions Directive (SED). Dry cleaning equipment is required to meet an emission rate of 20 g of tetrachloroethylene for every kilogram of product cleaned and dried.

For surface cleaning, there are emission limit values for the concentration in waste gas (for all emitted compounds together) and limits to the fugitive emissions as a percentage of the solvent input. These vary with the quantity of solvent used on site each year. In each area, new equipment must meet this standard on installation, while existing equipment had to be brought up to the standard by 2007 (if more than 1 tpa tetrachloroethylene is used). Stack emissions of tetrachloroethylene must be limited to 20 mg/m^3 at any time.

B.9.1.1.6 Other Environmental legislation related to tetrachloroethylene

Tetrachloroethylene was one of the 36 substances in Annexe 1A of the Hague Declaration (ECSA, 1995) which were cited as requiring a 50% reduction in both air and water emissions in the period 1985 to 1995. The Hague Declaration focuses on chlorinated solvents as they are more likely to persist in the environment than hydrocarbon and oxygenated solvents, due to their density and relative insolubility in water. Emissions to air of trichloroethylene, tetrachloroethylene and 1,1,1-trichloroethane in Western Europe had reduced by 55% between 1985 and 1995, exceeding the target set by the Hague Declaration. This reduction was principally a result of better solvent management and the use of closed cycle processes.

In addition to the Hague Declaration, the United Nations Economic Commission for Europe called for a 30% reduction in the emissions to air of chlorinated solvents, including tetrachloroethylene, over the period 1988 to 1999.

Tetrachloroethylene is one of the chemicals identified by the Commission of the European Communities as being a List I compound under the Dangerous Substances Directive (76/464/EEC) requiring environmental monitoring. A daughter directive, 86/280/EEC, has set limit values for the emission of tetrachloroethylene from industrial plants.

As an organohalogen compound, tetrachloroethylene is a List I substance under the Groundwater Directive (80/68/EEC) and as such must be prevented from reaching groundwater.

B.9.1.2 Other controls on tetrachloroethylene

ECSA began a programme of voluntary activity in 1992 aimed at developing ‘Charters of Co-operation’ with end user and distributor associations throughout Europe. These Charters stated four key aims (ECSA, 1995):

I. To identify the routes towards maximising the practical reduction of emissions within the relevant industry.
II. To encourage recovery, recycling and re-use schemes and to ensure that proper waste disposal practices are followed.
III. To set up a voluntary auditing scheme which allows progress to be assessed.
IV. The establishment of Best Available Techniques; that is approaches which are technically feasible in practical industry use (not just in principle) and which are economically feasible.

As outlined in the RAR for tetrachloroethylene, since the programme began fourteen charters have been signed in six countries. Charters are in place in the UK and French metal finishing, surface cleaning and engineering industries. There is a Charter with the European Federation of Dry Cleaning Trade Associations and agreements with local associations in the UK and Italy. Charters are in place with the distributor associations in France, Italy, Germany, Belgium and the Netherlands. The latest of these was signed in April 1995 with the Dutch national trade association of chemical distributors, the Verbond van Handelaren in Chemische Produkten. The benefits of these Charters are already being seen. The French Fédération des Industries Mécaniques has noted an annual reduction in solvent use of around 10%. The UK Metal Finishing Association has surveyed its

35 members and found significant reduction in solvent use. The Comité International de la Teinture et du Nettoyage has confirmed the trend towards closed cycle-dry cleaning machines, which has led to a reduction in the use of tetrachloroethylene.

B.9.1.4 Summary of effectiveness of the implemented risk management measures

B.9.1.4.1 REACH (1907/2006)

As REACH is a European Regulation, it should be an effective legal instrument to aid tetrachloroethylene risk reduction. REACH requires manufacturers and importers to assess the risks that arise from the manufacture and/or use of their substances and to pass this information down the supply chain. The information supplied to downstream users will include improved information on the hazards plus improved information on risk management in the exposure scenario if one is required. As tetrachloroethylene is classified as dangerous (see section B.3.1), and is manufactured in quantities ≥10 tpa (see section B.2.1.1.1), such information will become available to the user.

This improved information will filter through to the end user after the substance has been registered. As tetrachloroethylene is manufactured by companies in >1000 tpa the information should be available from December 2010. Thus, the information should be available to downstream users via extended safety data sheets in just under 2 years time.

B.9.1.4.2 Chemical Agents Directive (98/24/EC)

The application of the principles of ‘good practice’, as outlined by CAD, should ensure an effective reduction in exposure of people to chemical substances in the workplace.

As much of the work when manufacturing tetrachloroethylene is done with closed systems it is clear that industry have used the principles of CAD to reduce exposure. However, in other situations (e.g. the use of tetrachloroethylene in open-top solvent baths in manual metal degreasing) further consideration needs to be given to the principles outlined in CAD. To ensure CAD is effective in all occupational situations industry should ensure that they examine each potential exposure in each occupational setting and consider the principles of good practice (as outlined in B.9.1.1.1). Effective compliance by employers of the requirements of CAD should further help reduce exposures.

B.9.1.4.3 Indicative Occupational Exposure Limit Values

An IOELV is an important tool in exposure control in the workplace. An IOELV provides a ‘benchmark’ against which employers can assess the effectiveness of the measures in place to control exposure. In the absence of air monitoring, employers can have no confidence that exposures have been controlled to appropriately low levels and, should employees become ill, they have no evidence to demonstrate an adequate control regime. Although workplace monitoring can be undertaken in the absence of an IOELV, the significance of the concentrations measured/found is often unclear.

At present, there is no EU-wide IOELV for tetrachloroethylene, however some Member States have set their own long-term (8-hr TWA) and short-term limits (see Table 9.1).

Table 9.1 Current National occupational exposure limits within the EU (http://bgia-online.hvbg.de/LIMITVALUE/WebForm_ueliste.aspx)

Member state	Limit value – 8-hr TWA		Limit value – Short-term	
	ppm	mg/m^3	ppm	mg/m^3
Austria	50	345	200	1380
Belgium	25	162	100	695
Denmark	10	70	20	140
France	50	335	-	-
Hungary	-	50	-	-
Poland	-	60	-	-
Spain	25	172	100	689
Sweden	10	70	25	170
United Kingdom	50	345	100	689

As discussed in Section B.5.1, SCOEL have proposed an 8-hr TWA of 20 ppm (equivalent to 138 mg/m^3) and a short-term exposure limit of 40 ppm (equivalent to 275 mg/m^3) (SCOEL, 2008). As can be seen in Table 9.1, most Member States are currently working to limits higher than those proposed by SCOEL.

As discussed above, for an IOELV to be effective industry sectors must be able to achieve the reduction in exposures to at least meet the IOELV. Information from the RAR and in Tables 9.2 and 9.3 indicate that industry sectors are already achieving exposures which are below the proposed IOELV.

In addition, to 8-hr TWA and a short-term exposure limit SCOEL have also proposed a BLV as tetrachloroethylene is readily absorbed following inhalation, ingestion or through the skin. SCOEL have proposed a BLV of 0.4 mg/l of whole blood, at a sampling time prior to the last shift of the work week (16 hours after the last preceding shift).

SCOEL has also recommended a “Sk” (skin) notation for tetrachloroethylene.

B.9.1.4.4 Classification and Labelling

When substances and preparations are properly classified and labelled the potential hazards are identified and appropriate risk management measures are communicated on labels and in safety data sheets to those handling the substance or preparation. As the classification and labelling of tetrachloroethylene have been agreed and are listed in Annex I to Directive 67/548/EEC (as outlined in section 3.1) then effective communication of the hazards, risks and risk reduction measures should occur. However, as the proposed amendment to the classification of tetrachloroethylene has yet to be agreed some hazards may not be fully communicated.

B.9.1.4.5 Solvent Emissions Directive

The view of both regulators and industry stakeholders is that SED has already had an effect in decreasing the amount of chlorinated solvents (including tetrachloroethylene) produced and used and that the trend is likely to continue (HSE, 2002 and EuroChlor, 2007). Following consultation for the environmental risk reduction strategy companies using trichloroethylene for metal degreasing suggested to the UK that emissions could be adequately controlled by using enclosed degreasing systems, substituting trichloroethylene or using aqueous systems. These measures are consistent with the SED. Tetrachloroethylene is a less hazardous and less volatile substance than trichloroethylene and applying similar controls to those applied to trichloroethylene in the same work scenarios can be expected to be at least equally manageable and effective.

B.9.2 Manufacturing and Packaging

Introduction

Tetrachloroethylene is manufactured according to the information given in Section B.2.1.1.2.

Exposure values

In the RAR a reasonable worst case (RWC) 8-hr TWA of 10 ppm (68 mg/m^3) was used in the risk characterisation. This value was derived from the analysis of industry data of 837 samples from a three and half year period from January 1991. A total of 81 % of exposures were below 1 ppm (7 mg/m^3), only 8 results were found to be in excess of 10 ppm (68 mg/m^3), with two results being above 100 ppm (680 mg/m^3). The typical value of 0.5 ppm (3.4 mg/m^3) was based on 298 samples from a packing area within a manufacturing plant.

As there were no measured data, the RWC and typical short-term exposure values were determined by multiplying the long-term values by 3.

No measured data were available to determine dermal exposures; therefore exposures were modelled using EASE. This gave a RWC of 1 mg/cm^2/day (intermittent contact and non dispersive use) with an assumed exposed surface area of 210 cm^2. A typical (incidental contact and non-dispersive use) dermal exposure value of 0.1 mg/cm^2/day with an assumed exposed surface area of 210 cm^2 was also derived.

Following a consultation exercise with industry in 2008 for the development of this Annex XV dossier, new exposure data were provided. These data have allowed the inhalation exposure values in the RAR to be revised. Data were submitted from the 4 manufacturers (covering 5 plants) of tetrachloroethylene and a packaging company within the EU.

The new data (summarised in Annex I) cover long-term inhalation exposures (8-hr TWAs) from 2002 to 2008. The submitted data (totalling 1484 samples) indicate that exposures are, in general, lower than those given in the RAR. Operators and maintenance staff were found to be exposed to the highest levels of tetrachloroethylene in the workplace (see Annex I, Table A1.9). Judgement was used to determine the exposure values for use in characterising the risk for the manufacturing and packing industry (see Annex I, Table A1.118 and Table 9.2).

As no short-term inhalation data are available, the short-term inhalation exposure figure has been determined by multiplying the long-term exposure value by 3 (as carried out in the RAR).

No new measured dermal data have been provided so the dermal exposure values outlined in the RAR will be used in this Annex XV report (see Table 9.2).

Table 9.2 Revised RWC and typical exposure values for manufacturing and packaging

Exposure	**Typical exposures**		**RWC exposures**	
	ppm	**mg/m^3**	**ppm**	**mg/m^3**
Inhalation				
Long-term (8-hr TWA)	1	7	4	27
Short-term (15-min)	3	20	12	81
Dermal				
	mg/kg/d*		**mg/kg/d***	
Long-term	0.3		3	

*Based on a 70kg adult

B.9.3 Uses of tetrachloroethylene

B.9.3.1 Occupational scenarios

B.9.3.1.1 Recycling of tetrachloroethylene

Introduction

The RAR stated that there were only a small number of companies in the EU who recycle used tetrachloroethylene and consequently the number of workers potentially exposed during this process is relatively low. The RAR concluded that the type of tasks undertaken in recycling is similar to those in manufacture of tetrachloroethylene i.e. sampling and packing. The largest company recycling tetrachloroethylene in the UK estimates that it processes approximately 870 tpa, with fewer than ten workers potentially exposed.

Exposure values

The RAR concluded that tasks carried out during recycling were similar to those during manufacturing. Therefore, the exposure values calculated in the RAR for manufacturing were used as representative of exposures that may be seen in recycling.

No new information has been provided on exposures seen in recycling from that discussed in the RAR. However, as the RAR concluded that tasks carried out during recycling were similar to those seen in manufacturing, the new exposure values for manufacturing and packaging outlined in Table 9.2 will be used as representative of exposures currently seen in the recycling industry.

B.9.3.1.2 Use in dry cleaning

Introduction

As stated in the RAR, in 1991 there were close to 60,000 dry cleaning establishments in the EU. According to this report there were 20,000 dry cleaning units in Italy, 9,000 in France, 6,400 to 6,950 in the UK, 6,600 in Spain, 6,600 in West Germany, 3,500 in Greece, 1,000 in Denmark, 1,000 in Portugal, 840 in the Netherlands, 800 in Ireland, 450 in Belgium and 50 in Luxembourg. More than 90% of European units used tetrachloroethylene as the dry-cleaning agent, although the southern European countries used more white spirit for dry-cleaning than those in the north.

In 1994, tetrachloroethylene accounted for approximately 90% of the total solvent used by the dry cleaning industry within the EU. Small quantities of other solvents such as 1,1,2-trichloro-1,2,2-trifluoroethane (R113), 1,1,1-trichloroethane, trichloroethylene and white spirit were also used. However, the production of the first two of these alternative solvents is now prohibited under the Montreal Protocol.

Exposure values

In the RAR the long-term typical and RWC exposure values were derived from 4147 samples supplied by industry (1994 to 2003) plus information from within the UK's National Exposure Database (NEDB). Taking all the information into account the values were determined using professional judgement. A typical exposure value of 8 ppm (54 mg/m^3) and a RWC value of 30 ppm (equivalent to 203 mg/m^3) were used in the risk characterisation.

As no measured data were supplied the RWC and typical short-term exposure values were determined by multiplying the long-term values by 3.

No measured data were available to determine dermal exposures. Therefore exposures were modelled using EASE to give a RWC of 1 mg/cm^2/day (direct handling with intermittent contact) with an assumed exposed surface area of 840 cm^2. To obtain a typical exposure value again the EASE model (direct handling with intermittent contact) was used. A typical dermal exposure value of 0.5 mg/cm^2/day with an assumed exposed surface area of 840 cm^2 was obtained.

Following a consultation exercise with industry during the development of this Annex XV dossier new long-term inhalation monitoring data were submitted. Two large companies who operate many dry cleaning establishments in the UK submitted data. Company 1 submitted data covering 2005 (69 samples covering 34 different dry cleaning establishments), 2006 (52 samples covering 27 sites) and 2008 (5 samples covering 2 sites). Company 2 supplied 673 long-term exposure samples for 2008 covering 244 different dry cleaning establishments. A summary of the monitoring data from both companies can be found in Annex II.

The monitoring data from 2008 only (678 samples) has been used to determine the typical and long-term inhalation results (see Table 9.3). The data from 2005 and 2006 have not been included in the analysis as the personal exposure monitoring took place before the introduction of the requirements of the SED. In 2007, the SED required that equipment for dry cleaning meets an emission rate of 20 g of tetrachloroethylene for every kilogram of product cleaned and dried. Therefore, only the results in 2008 take into account the human health exposures that still occur after the requirements of the SED have been met. It is worth noting that the exposure value derived from the new data for typical exposures is the same value that was used for characterising the risk in the RAR.

No new short-term exposure data was provided by industry. Therefore, following the approach outlined in the RAR, the short-term value has been derived by multiplying the long-term values by 3 (see Table 9.3).

No new measured dermal data have been provided so the dermal exposures outlined in the RAR will be taken forward to the risk characterisation (see Table 9.3).

Table 9.3 Revised RWC and typical exposure values for dry cleaning

Exposure	**Typical exposures**		**RWC exposures**	
	ppm	**mg/m^3**	**ppm**	**mg/m^3**
Inhalation				
Long-term (8-hr TWA)	8	54	17	115
Short-term (15-min)	24	163	51	346
Dermal				
	mg/kg/day*		**mg/kg/day***	
Long-term	6		12	

*Based on a 70kg adult

B.9.3.1.3 Use in metal degreasing

Introduction

Tetrachloroethylene can be used in the vapour, boiling liquid, or ultrasonic cleaning of metalwork in the engineering industry. Due to its higher boiling point tetrachloroethylene can be more effective than other solvents in removing persistent deposits.

In vapour degreasing, the solvent which is contained in a specially designed tank is heated to its boiling point to produce a controlled solvent vapour zone. The article to be degreased is placed in a cage that is then mechanically immersed into this vapour zone, the vapour condensing on the metal surface. The condensed solvent runs off the metal, washing away the impurities. The metal dries when it reaches the temperature of the vapour. The cage is lifted above the cooling coils (which prevent the vapour escaping) into the "free board" area where the liquid tetrachloroethylene flashes off. The two most common methods of controlling exposure are enclosure and lip extraction. Operators can be exposed as a result of; incorrect siting of the plant, excessive drag out, due to incorrect operation, inadequate plant maintenance, overloading of equipment and incorrect jigging of work, leading to solvent trapping. Occupational exposure can also occur during the cleaning out of degreasing plants. The degreasing process can range from fully automated to manual and there will be a range of working practices depending on the nature of the business that is using degreasing. The number of degreasing units in the EU which use tetrachloroethylene is not known.

Exposure values

Although, there were some measured data for long-term inhalation exposure data available within the RAR the EASE model was used because the measured data were from totally enclosed machines. The results from the industry data, which were from 52 samples, showed 8-hr TWAs of 3.9 ppm (equivalent to 26 mg/m^3) as a RWC and 0.5 ppm (3.4 mg/m^3) as a typical exposure. However, the EASE model was seen as more representative of manual degreasing, using an open bath with lip extraction. The parameters were non-dispersive use with LEV. Typical long-term exposure was assumed to be 10 ppm (equivalent to 68 mg/m^3) and the RWC to be 20 ppm (equivalent to 138 mg/m^3).

As no measured data were provided the RWC and typical short-term exposure values were determined by multiplying the long-term values by 3.

No measured data were available to determine dermal exposures. Therefore exposures were modelled using EASE to give a RWC of 1 mg/cm^2/day (direct handling with intermittent contact) with an assumed exposed surface area of 840 cm^2. To obtain a typical exposure value again the EASE model (direct handling with intermittent contact) was used. A typical dermal exposure value of 0.5 mg/cm^2/day with an assumed exposed surface area of 840 cm^2 was obtained.

During the development of this Annex XV dossier a request was made to the metal degreasing trade association for any newer exposure data. No measured data were provided. Therefore the exposure values agreed within the RAR (outlined in Table 9.4) will be taken forward to the risk characterisation.

Table 9.4 Reasonable worst case (RWC) and typical exposure values for metal degreasing

Exposure	Typical exposures		RWC exposures	
	ppm	mg/m^3	ppm	mg/m^3
Inhalation				
Long-term (8-hr TWA)	10	68	20	138
Short-term (15-min)	30	204	60	408
Dermal				
	mg/kg/d*		mg/kg/d*	
Long-term	6		12	

*Based on a 70kg adult

B.9.3.1.4 Other occupational uses of tetrachloroethylene

Introduction

The RAR reported that there are a number of other smaller uses of tetrachloroethylene in the EU.

During the production of textile fabrics from synthetic and natural sources, lubricants are added to facilitate the knitting or weaving of yarns. A water/detergent cleaner is usually used to remove the lubricants. However, they can also be removed in continuous open width solvent scouring machines, which use tetrachloroethylene. Textiles can also be scoured in washing machines utilising tetrachloroethylene, in a process similar to dry cleaning.

Tetrachloroethylene also has a number of other minor uses. These include use in some spot stain removers; in paint removers; in heat transfer media; in a mixture with n-butanol to wash away the developer in the preparation of photo-polymer plates; in oil refineries for regeneration of catalysts; as a solvent in paints; to degrease electrical components during refurbishment, this process being very similar to metal degreasing; and on a small scale to degrease chamois leathers. These uses are thought to be in decline (Personal Communication (ECSA), 2001).

Exposure values

A limited amount of long-term inhalation exposure measured data was included in the RAR from a number of industries in Finland (22 samples) and within the UK's NEDB (12 samples). The industry tasks include laboratory work, machine cleaning, cleaning of offset printing machines, printing, electrical engineering and disposal of chemical waste. EASE was also used to determine typical (non-dispersive use and direct handling with dilution ventilation) and RWC long-term inhalation exposures (non-dispersive use and uncontrolled direct handing). The long-term exposure values seen in the Finnish data were in the same range as that predicted by EASE. A RWC value of 20 ppm (equivalent to 138 mg/m^3) and a typical value of 10 ppm (equivalent to 68 mg/m^3) were used in the risk characterisation.

As no short-term exposure data was provided the RWC and typical short-term exposure values were determined by multiplying the long-term values by 3.

No measured data were available to determine dermal exposures. Therefore exposures were modelled using EASE to give a RWC of 1 mg/cm^2/day (non-dispersive use and direct handling with intermittent contact) with an assumed exposed surface area of 840 cm^2. To obtain a typical exposure value again the EASE model (direct handling with intermittent contact) was used. A typical dermal exposure value of 0.5 mg/cm^2/day with an assumed exposed surface area of 840 cm^2 was obtained.

Following a consultation exercise for the development of this Annex XV dossier further information was requested on these 'other uses'. No measured data or information on how tetrachloroethylene was used in these industries was provided. However, ECSA provided an update on what other industries tetrachloroethylene is used in. ECSA noted that the following uses of tetrachloroethylene were either 'unknown' to them or were 'very unlikely':

- as a solvent in paints
- in the preparation of photo-polymer plates
- in heat transfer media
- in paint removers
- spot stain removal during the production of textile fabrics.

ECSA noted that there could be minor uses of tetrachloroethylene in the following industries:

- use in spot stain removers
- degreasing of electrical components during refurbishment.
- in oil refineries for regeneration of catalysts

The uses considered by ECSA as 'unknown' or 'very unlikely' will not be considered further within this Annex XV dossier as tetrachloroethylene is unlikely to be used in these industries.

The use of tetrachloroethylene in spot stain removers and degreasing of electrical components was previously considered in the RAR. Therefore, the exposure values (see Table 9.5) used in the RAR will be used to in the risk characterisation. However, the use of tetrachloroethylene in oil refineries for regeneration of catalysts was not considered within the RAR, therefore a risk assessment has been carried out (see section B.9.3.1.5).

Table 9.5 Reasonable worst case (RWC) and typical exposure values for use in spot stain removal and degreasing of electrical components

Exposure	Typical exposures		RWC exposures	
	ppm	mg/m^3	ppm	mg/m^3
Inhalation				
Long-term (8-hr TWA)	10	68	20	138
Short-term (15-min)	30	204	60	408
Dermal				
	mg/kg/d*		mg/kg/d*	
Long-term	6		12	

*Based on a 70kg adult

B.9.3.1.5 Regeneration of catalysts in oil refineries

Introduction

Two major companies in the oil industry confirmed that this use was ongoing. Further details obtained from them clarified that catalyst regeneration (to replace chloride leached out of the catalyst during the oil refining process) is a continuous closed system process involving limited exposure opportunities relative to manufacturing and packaging. The tasks carried out in this process are similar to those performed during manufacturing, although the volumes handled and frequency/duration of tasks with the potential for exposure is expected to be significantly less. The reported use volumes were 15 – 96 litres per day (about 11 - 47 tpa) of tetrachloroethylene delivered via an automated closed dosing facility. The quantity of tetrachloroethylene used within the entire EU petroleum industry for catalyst generation is not known.

The dosing volume of tetrachloroethylene required for catalyst regeneration is dependent on the volume throughput of the oil refining facility. Tetrachloroethylene is generally supplied via 216 litre drums or via an intermediate bulk container (IBC). From the transport container the tetrachloroethylene is pumped to a buffer vessel. From there it is dosed to the plant via a closed system. Specialised drums fitted with hose connections for enclosed transfer to the dosing vessel are used in newer installations. In some older systems, filling of the dosing/pre-feed vessel may be via a separate pumped connection, which is then directly fed into the process via a closed system. This is reported to be a simple and quick operation to perform. Maintenance of the facilities is performed according to existing permit to work controls.

Exposure values

As the tasks carried out are similar to those performed during manufacturing, the new exposure values for manufacturing outlined in section B.9.2 (Table 9.2) will be used as indicative for this scenario. It is noted that actual frequency and duration of tasks involving exposure to tetrachloroethylene during this operation are expected to be significantly less than for its manufacture, and therefore these exposure values may be considered to be conservative.

B.9.3.2 Consumer Uses

B.9.3.2.1 Use of coin-operated dry cleaning machines

Introduction

According to the RAR there were about 200 to 250 coin-operated machines in the UK alone, which generally produced higher exposures to tetrachloroethylene than their professionally used counterparts. The higher exposures may occur because the machines operate on fixed cycles that are inappropriate for some of the purposes for which they are used, are poorly maintained and unreliable, or simply are overloaded. Any of these scenarios could constitute foreseeable misuse. The highest exposures are found where thick, bulky materials such as duvets and sleeping bags are dry-cleaned. Residual tetrachloroethylene levels can therefore be very high when bulky items are removed from machines.

Following the introduction of SED, the use of coin-operated dry cleaning machines ceased in the UK on the 31st October 2007 (http://www.defra.gov.uk/environment/ppc/localauth/pubs/newsletters/pdf/update3-0607.pdf). Following consultation with industry the ECSA noted that 'To [their] knowledge coin-operated machines were used only in France some 10-15 years ago, and they should have been phased out since then. ECSA does not support this type of operation.' (personal communication, 2008a). France confirmed that coin-operated dry cleaning machines have been forbidden since 2nd May 2002 (personal communication, 2008b). To check that no coin-operated dry cleaning machines where in use within the rest of the EU the UK CA sent an email to representatives of all EU Governments (personal communication, 2008c). A total of 8 other Member States (including Austria, Cyprus, Denmark, Estonia, Germany, the Netherlands, Slovakia and Sweden) responded and confirmed that coin-operated machines were no longer used in these countries. No Member State responded that coin-operated dry cleaning machines were in operation within their country.

Conclusion

On the evidence from 10 Member States it is considered that the use of coin-operated machines has ceased within the EU. As coin-operated dry cleaning machines are no longer available in the EU then no consumer exposure can occur via this scenario. Therefore, consumer exposure from the use of coin operated dry cleaning machines will not be considered further within this Annex XV report.

B.9.3.2.2 Consumer exposure from back-in-use bulky materials

Introduction

A model scenario was developed within the RAR to examine a consumer being exposed following the return of bulky (20 kg by weight) dry-cleaned materials (curtains) to them. The RAR considered that dry cleaning of 20 kg curtains, was a rare event i.e. on average they would be dry cleaned once every seven years.

Exposure values

The scenario discussed within the RAR considers a Tier 1 approach to estimating exposure from freshly dry-cleaned curtains. The Tier 1 approach considers that a person would be exposed to a maximum of **36 mg/m^3** (5.3 ppm) tetrachloroethylene following the return of bulky materials. The exposure scenario is outlined below for information purposes only:

> Assuming 20 kg of dry-cleaned curtains have a maximum residual tetrachloroethylene weight of 18 g (20 kg x 0.9 g/kg) and that 30% of this is volatilised in the first 24 hours (Kurz, 1995) then 5.4 g tetrachloroethylene is released over 24 hours. Assuming that a flat of 4 rooms (for 4 curtains of a maximum of 5 kg each for a total of 20 kg) has a volume of 150 m^3 (a flat of 60 m^2 with a ceiling height of 2.3 m), with minimal air change, then the tetrachloroethylene concentration would be a maximum of **36 mg/m^3** (see Table 9.6).
>
> An occupant of the room, breathing at a rate of 0.83 m^3 per hour (EC default value) would inhale a maximum of 720 mg tetrachloroethylene in 24 hours (equivalent to 10 mg/kg bw for a 70 kg individual). In reality, the inhaled amount would be much less than this, because this calculation assumes that the tetrachloroethylene is distributed evenly and that the air levels do not fall; absorption of tetrachloroethylene by the occupants and air changes within the room would reduce the airborne concentration and the inhaled amount.

A further Tier has been generated within this Annex XV dossier. This further tier (Tier 2) has been developed based on the approach outlined above and agreed within the RAR. The Tier 2 exposure scenario (described below) assumes that the curtains are aired for 24 hours within the dry cleaning establishments and steam pressed prior to being returned to the consumer.

> Assuming 20 kg of dry-cleaned curtains have a maximum residual tetrachloroethylene weight of 18 g (20 kg x 0.9 g/kg) and that 30 % of this is volatilised in the first 24 hours (Kurz, 1995) then 5.4 g tetrachloroethylene is released over the first 24 hours within the shop. This results in 12.6 g of residual tetrachloroethylene remaining on the curtains. If the curtains are stream pressed this can reduce the residual tetrachloroethylene by between 5-15 times (Weber, 1992). Assuming a conservative approach (reduction by 5 times) this would result in 2.52 g of residual tetrachloroethylene being present on the curtains when they are taken home by the consumer. If 30 % of this is volatilised in the next 24 hours then 0.756 g of residual tetrachloroethylene would be released.
>
> Assuming that a flat of 4 rooms (for 4 curtains of a maximum of 5 kg each for a total of 20 kg) has a volume of 150 m^3 (a flat of 60 m^2 with a ceiling height of 2.3 m), with minimal air change, then the tetrachloroethylene concentration would be a maximum of **5.04 mg/m^3** (0.7 ppm).

The exposure values (see Table 9.6) are considered to be conservative as they assume that the exposure levels would remain constant over time i.e. there would be no drop in the level of tetrachloroethylene over time. The exposure scenarios also assume that there are minimal changes of air within the flat.

Table 9.6 Reasonable worst case (RWC) long-term inhalation exposure to back-in-use bulky materials

Exposure*	RWC exposures (mg/m^3)	
	Tier 1	Tier 2
Long-term inhalation (8-hr TWA)	36	5.04

*Exposure via the dermal route has not been calculated as this route was not considered within the RAR

B.10 Risk characterisation

B.10.1 Human health

According to REACH, if exposure is less than the relevant DNEL (i.e. the risk characterisation ratio (RCR) <1) then the risk is adequately controlled. If exposure is greater than the relevant DNEL (i.e. RCR >1) then the risk is NOT controlled. The RCR for combined exposure is calculated by adding the relevant inhalation and dermal RCRs together and if they are <1 then the risk is adequately controlled.

B.10.1.1 Manufacturing and Packaging

The RWC and typical RCRs for the manufacture and packaging of tetrachloroethylene are presented in Table 10.1.

Table 10.1 Risk characterisation ratios for inhalation, dermal and combined exposures during manufacture and packaging of tetrachloroethylene

REASONABLE WORST CASE EXPOSURES	RCR (RWC Exposure / 15 min short term DNEL (mg/m^3))	RCR (RWC exposure / 8h TWA DNEL (mg/m^3))
RCR for inhalation	81 / 275 = 0.29	27 / 138 = 0.20
RCR for dermal	---	3 / 8 = 0.38
RCR for combined exposure	---	0.2 + 0.38 = 0.58

TYPICAL EXPOSURES	RCR (Typical Exposure / 15 min short term DNEL (mg/m^3))	RCR (Typical exposure / 8h TWA DNEL (mg/m^3))
RCR for inhalation	20 / 275 = 0.07	7 /138 = 0.05
RCR for dermal	---	0.3 / 8 = 0.04
RCR for combined exposure	---	0.05 + 0.04 = 0.09

Conclusion

The risk characterisation indicates that the risk (for both typical and RWC exposures) from manufacture and packaging of tetrachloroethylene in relation to concerns for acute toxicity, eye irritation, respiratory tract irritation, carcinogenicity and reproductive toxicity are low taking into account the current risk management measures (RMMs) outlined in the RAR. Therefore, no further RMMs are proposed in this Annex XV dossier.

The proposed classification for tetrachloroethylene states that an R38 risk phrase ('Irritating to the skin') is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

B.10.1.2 Workers

B.10.1.2.1 Recycling of tetrachloroethylene

As discussed in Section B.9.3.1.1 the exposure values for recycling tetrachloroethylene are from those obtained during the manufacture and packaging. As can be see from Table 10.1 the RCRs for typical and RWC exposures are acceptable (RCR <1) taking into account the current RMMs outlined in the RAR. Therefore, no further RMMs are proposed in this Annex XV dossier.

The proposed classification for tetrachloroethylene states that an R38 risk phrase ('Irritating to the skin') is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

B.10.1.2.2 Dry Cleaning

The RCRs for typical and RWC exposures for the use of tetrachloroethylene in dry cleaning are presented in Table 10.2.

Table 10.2 Risk characterisation ratios for inhalation, dermal and combined exposures during the use of tetrachloroethylene in dry cleaning

REASONABLE WORST CASE EXPOSURES	**RCR (RWC Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (RWC exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	346 / 275 = **1.3**	115 / 138 = 0.83
RCR for dermal	---	12 / 8 = **1.5**
RCR for combined exposure	---	0.83 + 1.5 = **2.33**

TYPICAL EXPOSURES	**RCR (Typical Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (Typical exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	163 / 275 = 0.6	54 / 138 = 0.39
RCR for dermal	---	6 / 8 = 0.75
RCR for combined exposure	---	0.39 + 0.75 = **1.14**

Conclusions

The RCRs for RWC exposures indicate that long-term inhalation exposure is adequately controlled (RCR <1). However, the RCRs for RWC exposures for short-term inhalation, dermal and combined exposures are not adequately controlled (RCRs >1). For typical exposures the only cause for concern is the risk from combined exposure. To control typical and RWC exposures, further RMMs need to be considered.

The long-term inhalation exposure values used to determine the typical and RWC exposures are from UK industry in 2008. These exposure values take into account the requirements outlined in the SED, which requires that all dry cleaning machines meet maximum overall emissions to air of 20 g/kg of textile cleaned by the 31st October 2007. Therefore, it is unlikely that the requirements of the SED will impact further to reduce human health exposures.

Currently, within the UK, the dry cleaning industry is working to a long-term exposure level of 50 ppm (345 mg/m^3) and a short-term exposure level of 100 ppm (689 mg/m^3). It is clear that the RWC and typical short-term and long-term exposure values (see Table 10.2) are below these current Workplace Exposure Limits (WELs). In fact, for typical and RWC long-term inhalation exposures are already below the limit proposed by SCOEL. Typical short-term inhalation exposures are already below the limit proposed by SCOEL. However, for RWC short-term inhalation exposures the values seen are higher than the limit proposed by SCOEL. What the results show is that it is possible for adequate control to be achieved for the majority of uses and majority of users. Therefore, if the principles and hierarchy of control as outlined by CAD are followed for the vast majority of workers the risk will be adequately reduced. To ensure that this occurs, compliance with CAD needs to take place.

No industry data were provided on the dermal exposures seen within the dry cleaning industry therefore the EASE model was used to estimate exposures. The RCR for typical dermal exposure show that the risks are adequately controlled. However, the dermal exposures are contributing a higher proportion of the risk to the combined RCR. In addition, the RCRs for RWC exposures indicate that dermal exposures are too high (RCR >1). The RWC inhalation data from 2008 compared to those within the RAR show a drop in tetrachloroethylene levels by about half. It is likely that the reduction in levels of tetrachloroethylene in the air (as can be seen by a reduction in exposure values) will also have an impact on dermal exposures by reducing the amount of tetrachloroethylene landing on the skin and surfaces. Part of this reduction could have been as a result of improved technology to meet the requirements of SED. In addition, it is known that EASE tends to over-estimate dermal exposures. However, how much lower dermal exposures would be in the dry cleaning industry to that estimated in the RAR is difficult to quantify as no actual measurements have been provided. If dermal exposures were lower than those estimated within the RAR (as they are likely to be as a result of the SCOEL proposals for inhalation) then this would also impact on the RCRs seen for combined exposure. In addition, the SCOEL proposal for a BLV will ensure that dermal exposures (in addition to inhalation exposures) are adequately controlled to a safe level. Therefore, if the principles and hierarchy of control as outlined by CAD are followed for the vast majority of workers the risk will be adequately reduced. To ensure that this occurs, compliance with CAD needs to take place.

As well as the introduction of an 8-hr TWA, short-term IOELV and BLV which will aid in the reduction of exposures, industry have to submit their REACH registration dossier plus CSR by December 2010, assuming they have pre-registered the substance. As tetrachloroethylene is classified as dangerous industry will need to carry out exposure scenarios (to include its use in dry cleaning). The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1). In order to do this, it is recommended that industry supply, as part of their REACH registration dossier, adequate dermal exposure data for those working in dry cleaning to ensure that exposures are lower than those estimated within this Annex XV report.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

B.10.1.2.3 Metal Degreasing

The RCRs for typical and RWC exposures for the use of tetrachloroethylene in metal degreasing are presented in Table 10.3.

Table 10.3 Risk characterisation ratios for inhalation, dermal and combined exposures during the use of tetrachloroethylene in open metal degreasing

REASONABLE WORST CASE EXPOSURES	**RCR (RWC Exposure / 15 min short term DNEL (mg/m³))**	**RCR (RWC exposure / 8h TWA DNEL (mg/m³))**
RCR for inhalation	408 / 275 = **1.5**	138 / 138 = **1.0**
RCR for dermal	---	12 / 8 = **1.5**
RCR for combined exposure	---	1.0 + 1.5 = **2.5**

TYPICAL EXPOSURES	**RCR (Typical Exposure / 15 min short term DNEL (mg/m³))**	**RCR (Typical exposure / 8h TWA DNEL (mg/m³))**
RCR for inhalation	204 / 275 = 0.74	68 / 138 = 0.5
RCR for dermal	---	6 / 8 = 0.75
RCR for combined exposure	---	0.5 + 0.75 = **1.25**

Conclusion

The risk characterisation indicates that there is a risk from all RWC exposures (RCR >1) when manual degreasing takes place. Typical exposures are within acceptable levels for inhalation and dermal exposures. However, the typical combined (inhalation and dermal) exposure is above acceptable levels and therefore, further RMMs need to be considered that will decrease the level of worker exposure to tetrachloroethylene in both typical and RWC scenarios.

The use of tetrachloroethylene in metal degreasing is also subject to SED where a maximum emission of 20 mg/m^3 at any time for stack emissions should have been met by 31st October 2007. ECSA (personal communication, 2001) reported that only the modern metal degreasing machines (namely Type III and IV machines – these are enclosed machines fitted with refrigeration, activated carbon and closed loop drying) are capable of achieving these limits. In addition, ECSA reported that by 2007 all machines that use tetrachloroethylene for metal degreasing will be enclosed. ECSA noted that all the metal degreasing machines in Germany have been type III or IV from 2001.

Despite the UK requesting from industry new information on exposure and machines that are still in-use, nothing was provided. Therefore, it is difficult to quantify if there has been a reduction in inhalation and dermal exposures in the workplace as a result of the requirements of SED. However, if compliance with SED was occurring throughout Member States and only Type III or IV machines are available, then it is the UK's view that exposures would be less than those seen in Tables 9.4 and Table 10.3.

As outlined above, no new information was provided during the development of this Annex XV report on exposure measurements. However, there are measured data (52 samples), which were supplied by 9 German companies within the RAR. These German companies all used totally enclosed metal cleaning systems, which automate both operation and maintenance as much as possible, including a closed cleaning chamber, totally enclosed solvent charging and discharging, and solvent reclaim prior to opening. Within the survey a wide range of parts were cleaned and the RAR concludes that the exposures can be viewed as 8-hr TWA. The results of the analysis show a range from non detectable (LOD 0.1 ppm) to 3.9 ppm 8-hr TWA (26.4 mg/m^3), with a geometric mean of 0.5 ppm 8-hr TWA (3.39 mg/m^3).

The dermal exposures detailed in Table 10.3 assume that there are open metal cleaning systems. However, if the systems are enclosed as required by SED then dermal exposures should be equivalent to that seen in the manufacture and packaging of tetrachloroethylene (which is also carried out in a closed system).

Using the figures for typical (3.39 mg/m^3) and RWC (26.4 mg/m^3) inhalation exposures from the German companies and the dermal exposures for manufacturing and packaging of tetrachloroethylene (RWC exposure = 3 mg/m^3 and typical exposure = 0.3 mg/m^3) the RCRs would be as detailed in Table 10.4.

Table 10.4 Risk characterisation ratios for inhalation, dermal and combined exposures during the use of tetrachloroethylene in enclosed metal degreasing systems

REASONABLE WORST CASE EXPOSURES	**RCR (RWC Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (RWC exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	78 / 275 = **0.28**	26 / 138 = 0.19
RCR for dermal	---	3 / 8 = 0.38
RCR for combined exposure	---	0.19 + 0.38 = 0.57

TYPICAL EXPOSURES	**RCR (Typical Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (Typical exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	9 / 275 = **0.03**	3 / 138 = 0.02
RCR for dermal	---	0.3 / 8 = 0.04
RCR for combined exposure	---	0.02 + 0.04 = 0.06

It is clear that in order to meet the requirements of SED (when using more than 1tpa tetrachloroethylene) industry should be using enclosed machines and that this reduces human exposure considerably for both RWC and typical exposures. Therefore, where an individual metal degreasing plant is using a well maintained enclosed metal degreasing machine no further RMMs are required.

However, there are still likely to be many small companies carrying out metal degreasing (i.e. they use less than 1 tpa tetrachloroethylene) where SED does not apply and therefore could be using type I (fully emissive open top machine) or type II (full emissive open top machine with or without activated carbon filter that is enclosed) machines. Therefore the RCRs in Table 10.3 are likely to be relevant for these smaller industries.

For typical exposures in manual metal degreasing it is important that both inhalation and dermal exposures are reduced. What the results show is that it is possible for adequate control to be achieved for the majority of uses and majority or users. Therefore, if the principles and hierarchy of control as outlined by CAD are followed for the vast majority of workers the risk will be adequately reduced. To ensure that this occurs, compliance with CAD needs to take place. These smaller industries should consider substituting tetrachloroethylene, enclosing the process, ensuring LEV is present over the bath or that appropriate personal protective equipment (PPE) is worn when carrying out metal degreasing processes.

As well as the introduction of a short-term IOELV, long-term IOELV and a BLV which should aid in the reduction of exposures, industry has to submit their REACH registration dossier and CSR (as tetrachloroethylene is manufactured in >10 tpa) under REACH by December 2010, assuming they have pre-registered the substance. As tetrachloroethylene is classified as dangerous then industry will need to carry out exposure scenarios (to include its use in metal degreasing). The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1). In order to do this, it is recommended that industry supply, as part of their REACH registration dossier, adequate dermal exposure data for those working in the metal degreasing industry (with type I or II machines) to ensure that exposures are lower than those estimated within this Annex XV report. If the iterative process indicates that exposures are still too high (RCR >1) then the exposure scenario should specify that tetrachloroethylene should only be used in Type III or IV metal degreasing machines. As the exposure scenarios will be described by 1 December 2010 the requirements of these scenarios will therefore have started to filter to downstream users in just over 2 years. Once a user has received the extended safety data sheet they have a maximum of 12 months to implement the measures described in the extended safety data sheet (Article 39.1). This suggests that all users of tetrachloroethylene should be in possession of information on appropriate RMMs for their use and should have taken steps to implement appropriate measures within 3 years.

The proposed classification for tetrachloroethylene states that an R38 risk phrase ('Irritating to the skin') is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

B.10.1.2.4 Minor uses (all minor uses except catalyst regeneration)

The RCRs for typical and RWC exposures for the use of tetrachloroethylene in spot stain removers and degreasing of electrical components are presented in Table 10.5.

Table 10.5 Risk characterisation ratios for inhalation, dermal and combined exposures during the use of tetrachloroethylene in spot stain removal and degreasing of electrical components

REASONABLE WORST CASE EXPOSURES	**RCR (RWC Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (RWC exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	408 / 275 = **1.5**	138 / 138 = **1.0**
RCR for dermal	---	12 / 8 = **1.5**
RCR for combined exposure	---	1.0 + 1.5 = **2.5**

TYPICAL EXPOSURES	**RCR (Typical Exposure / 15 min short term DNEL (mg/m^3))**	**RCR (Typical exposure / 8h TWA DNEL (mg/m^3))**
RCR for inhalation	204 / 275 = 0.75	68 / 138 = 0.49
RCR for dermal	---	6 / 8 = 0.75
RCR for combined exposure	---	0.49 + 0.75 = **1.24**

Conclusion

The RCRs for RWC exposure show that the risks from dermal, inhalation and combined exposures are of concern (>1). However, the typical inhalation (short-term and long-term) and dermal exposures show that the risk is adequately controlled. The risk of typical combined exposure is of concern (RCR >1). Therefore, further RMMs need to be considered.

Without details on the processes carried out in these industries and the likely exposures it is difficult to specify relevant RMMs. The likelihood is that degreasing of electrical components will follow a similar process to that seen in metal degreasing and therefore exposures could be equivalent to those seen in Tables 10.3 and 10.4. In addition, spot stain removal is undertaken within the dry cleaning industry before clothes are placed in the machine and therefore typical exposures could be similar to those seen in Table 10.2. If these uses are supported in the REACH registration dossier then further information will be provided that should clarify exposures within these 'other' industries. The type of information required should include information on the process, the number of workers exposed and any measured inhalation and dermal exposures. As tetrachloroethylene is a high tonnage substance (>1000 tpa) then the registration dossier and CSR needs to be submitted to ECHA by June 2010. As tetrachloroethylene is classified as dangerous then industry will need to carry out exposure scenarios (to include its use in metal degreasing), which will be based on the information outlined above. The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1).

The proposed classification for tetrachloroethylene states that an R38 risk phrase ('Irritating to the skin') is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

B.10.1.2.5 Regeneration of catalysts in oil refineries

As discussed in section 9.3.1.5 the regeneration of catalysts with tetrachloroethylene is a similar process to that carried out in manufacture and therefore the RCRs in Table 10.1 are relevant to this use.

Conclusion

As the RCRs indicate that the RWC and typical exposures are adequately controlled no further RMMs are recommended within this Annex XV report other than those already in place within the industry (i.e. enclosed system).

B.10.1.3 Consumer use

B.10.1.3.2 Consumer exposure from back-in-use bulky materials

The RCRs for typical and RWC exposures for back-in-use of bulky materials are presented in Table 10.6.

Table 10.6 RCRs for consumer exposure to back-in-use bulky materials

REASONABLE WORST CASE EXPOSURES*	Tier	Risk Characterisation Ratios 8h TWA (mg/m^3)
RCR for inhalation	Tier 1	36 / 7 = **5.1**
	Tier 2	5 / 7 = 0.71

* A risk characterisation ratio for dermal (and therefore combined) exposure has not been calculated as the dermal route of exposure was not considered within the RAR

Conclusion

The Tier 2 results indicate that exposure to consumers can be adequately controlled to an acceptable level by professional dry cleaning establishments airing and steam pressing bulky (≥20 kg) materials before returning them to their customers (consumers). It should be noted that airing materials in dry cleaning establishments could increase the amount vapours in the workplace and may cause practical problems for some dry cleaning establishments as space can be at a premium. These bulky materials are dry-cleaned very rarely and therefore they may be best cleaned (and therefore steam pressed and aired) 'at a specialised unit using appropriate equipment' (Pers. comm., 2008d). In addition, the European Dry Cleaning Association noted that a reduction similar to that achievable by airing and steam-pressing could be achieved by 'drying them more properly in the machine. This prevents odours coming into the environment unnecessarily by hanging them out into the open air. Modern machine technology has proved that an extra 4 minutes drying time is more efficient in case of bulky materials. Furthermore, to install a device that the machine only opens when the rest solvent in the machine is within the limits is also feasible in certain situations' (Pers. comm., 2008e).

In order to ensure that dry cleaning operators follow this advice it should be written onto the label and/or associated leaflet of the tetrachloroethylene supplied to dry cleaning shops. It should also be added to the registration dossier, CSR and exposure scenarios developed for REACH. Suppliers should ensure that the dry-cleaners they supply are aware of these requirements at the point of sale and/or delivery. In addition, it is recommended that the manufacturers of tetrachloroethylene should prepare an article outlining the new proposals for publication in the major dry cleaning journals/newsletters across the EU. The UK CA suggests that this is done within 3 months of the decision being published on ECHA's website.

The proposed classification for tetrachloroethylene states that an R38 risk phrase ('Irritating to the skin') is appropriate. If this classification is formally accepted then consumers should be protected from the possible hazard. However, consumers will receive the dry-cleaned bulky materials which will contain a significant reduction in tetrachloroethylene (due to airing and steaming) from the dry cleaning establishment. In addition, the curtains (bulky materials) are normally wrapped in plastic to protect them. Therefore, the contact time between the consumer and the bulky material will be low i.e. they will only handle the material when they remove it from the packaging and hang the curtains. As this is considered to be a rare event (once every 7 years) then the risk of irritation to the skin from this scenario is considered to be low.

B.10.2 Environment

Not applicable as this Annex XV report is concerned with that conclusion (iiis) within the RAR for human health.

B.11 Summary on hazard and risk

Given the risks associated with tetrachloroethylene the risk management proposals outlined below are considered to be proportionate.

<u>Manufacturing and packaging</u>

The risk characterisation indicates that the risk (for both typical and RWC exposures) from manufacture and packaging of tetrachloroethylene in relation to concerns for acute toxicity, eye irritation, respiratory tract irritation, carcinogenicity and reproductive toxicity are low taking into account the current risk management measures (RMMs) outlined in the RAR. Therefore, no further RMMs are proposed in this Annex XV dossier.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

<u>Recycling of tetrachloroethylene</u>

The risk characterisation indicates that the risk (for both typical and RWC exposures) from recycling tetrachloroethylene in relation to concerns for acute toxicity, eye irritation, respiratory tract irritation, carcinogenicity and reproductive toxicity are low taking into account the current risk management measures (RMMs) outlined in the RAR. Therefore, no further RMMs are proposed in this Annex XV dossier.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

<u>Use in dry cleaning</u>

The RCRs for RWC exposures indicated that long-term inhalation exposure is adequately controlled (RCR <1). However, the RCRs for RWC exposures for short-term inhalation, dermal and combined exposures are not adequately controlled (RCRs >1). For typical exposures the only cause for concern is the risk from combined exposure.

The introduction of the SCOEL proposals of 20 ppm (equivalent to 138 mg/m^3) for long-term exposures and 40 ppm (equivalent to 275 mg/m^3) for short-term exposures should ensure that there is a reduction in inhalation exposures below these limits. In fact, for typical and RWC long-term inhalation, exposures are already below the limit proposed by SCOEL. Typical short-term inhalation exposures are already below the limit proposed by SCOEL. What the results show is that it is possible for adequate control to be achieved for the majority of uses and majority or users. Therefore, if the principles and hierarchy of control as outlined by CAD are followed for the vast majority of workers the risk will be adequately reduced. To ensure that this occurs, compliance with CAD needs to take place.

The RCR for typical dermal exposure show that the risks are adequately controlled. However, the dermal exposures are contributing a higher proportion of the risk to the combined RCR. In addition, the RCRs for RWC exposures indicate that dermal exposures are too high (RCR >1). It is likely that the reduction in tetrachloroethylene levels in the air will also have an impact on dermal exposures by reducing the amount of tetrachloroethylene landing on the skin and surfaces. However, how much lower dermal exposures would be in the dry cleaning industry to that estimated in the RAR is difficult to quantify as no actual measurements have been provided. If dermal exposures were lower than those estimated within the RAR (as they are likely to be as a result of the SCOEL proposals for inhalation) then this would also impact on the RCRs seen for combined exposure. In addition, the SCOEL proposal for a BLV will ensure that dermal exposures (in addition to inhalation exposures) are adequately controlled to a safe level. It is therefore proposed that industry follow the principles of CAD to ensure that dermal exposures are reduced when working with tetrachloroethylene in the dry cleaning industry.

As well as the introduction of a short-term IOELV, long-term IOELV and the BLV will aid the reduction in exposure, industry has to submit their REACH registration dossier plus CSR by December 2010 (assuming they have pre-registered the substance). As tetrachloroethylene is classified as dangerous then industry will need to carry out exposure scenarios (to include its use in dry cleaning). The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1). In order to do this, it is recommended that industry supply, as part of their REACH registration dossier, adequate dermal exposure data for those working in dry cleaning to ensure that exposures are lower than those estimated within this Annex XV report.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

<u>Use in metal degreasing</u>

Where tetrachloroethylene is used in enclosed metal degreasing machines (with refrigeration, activated carbon and closed loop drying) exposures (RWC and typical) are low and the risks are adequately controlled.

Where tetrachloroethylene is used for metal degreasing in emissive open top machines, the typical inhalation and dermal exposures are adequately controlled. However, the combined exposure gives cause for concern. For these industries it is possible for adequate control to be achieved for the majority of uses and majority or users. Therefore, if the principles and hierarchy of control as outlined by CAD are followed for the vast majority of workers the risk will be adequately reduced. To ensure that this occurs compliance with CAD needs to take place. However, to ensure that the combined exposures these smaller industries should consider substituting tetrachloroethylene, enclosing the process, ensuring LEV is present over the bath or that appropriate PPE is worn when carrying out metal degreasing processes.

As well as the introduction of a short-term IOELV, long-term IOELV and BLV which should aid in the reduction of exposures, industry has to submit their REACH registration dossier and CSR (as tetrachloroethylene is manufactured in >10 tpa) under REACH by December 2010, assuming they have pre-registered the substance. As tetrachloroethylene is classified as dangerous then industry will need to carry out exposure scenarios (to include its use in metal degreasing). The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1). In order to do this, it is recommended that industry supply, as part of their REACH registration dossier, adequate dermal exposure data for those working in the metal degreasing industry (with type I or II machines) to ensure that exposures are lower than those estimated within this Annex XV report. If the iterative process indicates that exposures are still too high (RCR >1) then the exposure scenario should specify that tetrachloroethylene should only be used in Type III or IV metal degreasing machines. As the exposure scenarios will be described by 1 December 2010 the requirements of these scenarios will therefore have started to filter to downstream users in just over 2 years. Once a user has received the extended safety data sheet they have a maximum of 12 months to implement the measures described in the extended safety data sheet (Article 39.1). This suggests that all users of tetrachloroethylene should be in possession of information on appropriate RMMs for their use and should have taken steps to implement appropriate measures within 3 years.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

Other occupational uses of tetrachloroethylene

The RCRs for RWC exposure show that the risks from dermal, inhalation and combined exposures are of concern (>1). However, the typical inhalation (short-term and long-term) and dermal exposures show that the risk is adequately controlled. The risk of combined exposure is of concern (RCR >1). Therefore, further risk management measures are required.

Without details on the processes carried out in these industries and the likely exposures it is difficult to specify relevant RMMs. The likelihood is that degreasing of electrical components will follow a similar process to that seen in metal degreasing and therefore exposures could be equivalent to those seen in Tables 10.3 and 10.4. In addition, spot stain removal is undertaken within the dry cleaning industry before clothes are placed in the machine and therefore typical exposures could be similar to those seen in Table 10.2. If these uses are supported in the registration dossier the further information will be provided that should clarify exposures within these ‘other’ industries. The type of information required should include information on the process, the number of workers exposed and any measured inhalation and dermal exposures. As tetrachloroethylene is a high tonnage substance (>1000 tpa) then the registration dossier and CSR needs to be submitted to ECHA by June 2010. As tetrachloroethylene is classified as dangerous then industry will need to carry out exposure scenarios (to include its use in metal degreasing), which will be based on the information outlined above. The development of exposure scenarios is an iterative process and requires industry to show that exposures are below the DNEL (i.e. an RCR <1).

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

Regeneration of catalysts in oil refineries

The risk characterisation indicates that the risk (for both typical and RWC exposures) from regeneration of catalysts in oil refineries in relation to concerns for acute toxicity, eye irritation, respiratory tract irritation, carcinogenicity, reproductive toxicity and repeated dose toxicity are low taking into account the current RMMs outlined in the RAR. Therefore, no further RMMs are proposed in this Annex XV dossier.

The proposed classification for tetrachloroethylene states that an R38 risk phrase (‘Irritating to the skin’) is appropriate. If this classification is formally accepted then suitable gloves should be worn by workers when there is the potential for exposure to the skin.

Consumer use of coin-operated dry cleaning machines

According to the information provided no coin-operated dry cleaning machines are in operation within the community and therefore no further RMMs are required within this Annex XV report.

Consumer exposure from back-in-use bulky materials

To ensure that consumers are adequately protected from freshly-dry cleaned bulky (20 kg or more) materials professional dry cleaning establishments should ensure that any bulky materials (≥20 kg) are aired for 24 hours and steam pressed before they are returned to the customer (consumers). It should be noted that airing materials in dry cleaning establishments could increase the amount vapours in the workplace and may cause practical problems for some dry cleaning establishments as space can be at a premium. These bulky materials are dry-cleaned very rarely and therefore they may be best cleaned (and therefore steam pressed and aired) 'at a specialised unit using appropriate equipment' (Pers. comm., 2008d). In addition, the European Dry Cleaning Association noted that a reduction similar to that achievable by airing and steam-pressing could be achieved by 'drying them more properly in the machine. This prevents odours coming into the environment unnecessarily by hanging them out into the open air. Modern machine technology has proved that an extra 4 minutes drying time is more efficient in case of bulky materials. Furthermore, to install a device that the machine only opens when the rest solvent in the machine is within the limits is also feasible in certain situations' (Pers. comm., 2008e).

As the dry-cleaning of bulky-materials is considered to be a rare event and the levels of residual tetrachloroethylene are likely to be low the risk of skin irritation is considered to be small.

In order to ensure that dry cleaning operators follow this advice it should be written on the label and/or associated leaflet of the tetrachloroethylene supplied to dry cleaning shops. It should also be added to the REACH registration dossier, CSR and exposure scenarios developed for REACH. Suppliers should ensure that the dry-cleaners they supply are aware of these requirements at the point of sale and/or delivery. In addition, it is recommended that the manufacturers of tetrachloroethylene should prepare an article outlining the new proposals for publication in the major dry cleaning journals/newsletters across the EU. The UK CA suggests that this is done within 3 months of the decision being published on ECHA's website.

C. AVAILABLE INFORMATION ON ALTERNATIVES

Information on alternative substances and techniques has been provided for dry cleaning and metal degreasing. As, no community wide action is proposed no consideration of the acceptability of these alternatives will take place.

C.1 Identification of possible alternative substances and techniques

A full assessment of the human health risks of potential substitutes is not possible as there are limited data available with which to carry out a full appraisal. Most of the data presented below was also obtained from internet searches and material safety data sheets on websites.

Scenario	Substance/Technique	Comments
Dry Cleaning	Hydrocarbons	All hydrocarbon solvents used in dry cleaning consist of aliphatic hydrocarbons. Inherent properties of petroleum-based solvents include high flammability, volatility and odour. Toxicity varies by compound. All of the solvents are volatile organic compounds (VOCs) and flammable. The machines predominately used for petroleum solvents are closed-loop machines equipped with primary control. They require longer processing times than tetrachloroethylene and thus use more energy. In addition, tests have indicated that they do not clean as well as

		tetrachloroethylene (Pers. Comm., 2008d).
	Decamethylcyclopentasiloxane (Trade Name: Green Earth®) CAS: 541-02-6	Decamethylcyclopentasiloxane (D5) or volatile methyl siloxane is an odourless, colourless liquid that has many consumer and industrial applications. D5 solvent is mostly being used in hydrocarbon machines. Although, Green Earth is used in some converted tetrachloroethylene machines, the manufacturer does not recommend this option. In order for tetrachloroethylene machines to be converted, the following assemblies must be installed by the manufacturer: filtration system; temperature control sensors; pre-water separator filter; water separator; and electrical control panel. Green Earth Cleaning, who distributes the solvent, recommends the purchase of new GreenEarth machines from their approved machine list. D5 has a higher flash point than hydrocarbon and is a less aggressive cleaner than tetrachloroethylene. Because of the latter, the cleaning cycle time is longer than that for tetrachloroethylene and hydrocarbon. It is not classified as a VOC. Information from the European Dry Cleaning Trade Association (Pers. comm., 2008d) indicated that it is likely to be dangerous to the environment and one of the Nordic countries is seeking to substitute it.
	Propylene glycol ethers (examples are propylene glycol t-butyl ether (CAS: 57018-52-7) and dipropylene glycol tert-butyl ether (CAS: 132739-31-2). These have been used under the trade name Rynex® Cleaning.	It can be used in most hydrocarbon machines without modifications. Converting tetrachloroethylene machines to use Rynex is not recommended by the solvent manufacturer and what is more this is not a cost effective strategy. Some advocates consider that Rynex is the best alternative from a cleaning standpoint as it removes both solvent and water soluble components. Glycol ether is an aggressive cleaner and does not require spotting. However, water separation is difficult and the cycle time is long. A hybdrid-technique (Solvair) uses glycol ethers with carbon dioxide for dry cleaning. Information from the European Dry cleaning Trade Association (Pers. comm., 2008d) indicates that a large expensive machine is needed and only becomes viable when it is possible to have a large throughput.
	Traditional/Professional wet cleaning	Professional Wet Cleaning is different to commercial laundering in several aspects. Wet cleaning uses computer-controlled washers and dryers with detergents that have been specially formulated for the process. The washers used in wet cleaning use a frequency-controlled motor to control the rotation of the wash drum. As a result, a gentle wash action is produced and smoother acceleration and deceleration can be created. The wash program software can determine the appropriate combination of time, water level, water temperature, extraction, and drum rotation

		when manual operation is not desired. Washers are also designed to mix water with cleaning agents prior to entering the drum. Wet cleaned garments must be carefully dried in preparation for finishing. Wet cleaning generally takes about 45 minutes from wash through drying, not including the finishing time. The dryers used in wet cleaning are based on humidity and are able to end the cycle when the desired humidity level in the garments has been achieved. Wet cleaning systems may also be gentler on buttons and ornamental pieces on clothing.
	Green Jet®	The Green Jet machine cleans and dries garments in a single computer-controlled unit. The machine is designed to receive a full 45 pound load of garments. It then dehydrates the garments to remove humidity and reduce surface tension, which allows mechanical action and pulsating air jets to dislodge and remove non-soluble soil from the garments. This soil is then collected in a lint chamber. Next, a pre-determined amount of water-based cleaning solution is injected through air jet nozzles to re-hydrate the fabric. After about a pint of solution has been injected, heavy felt pads attached to the ribs and the cylinder absorb the soluble soil. After the cleaning process, the unit goes into a conventional dry cycle and then a cool-down cycle.
	Carbon dioxide	Carbon dioxide and detergent are used for cleaning. It is a non-aggressive cleaner with a short cycle time; however, the equipment is very expensive. It is mainly favoured in the USA where grants are available to industry agreeing to change to using it. Carbon dioxide (CO_2) cleaning is a process that has been developed for use by commercial and retail dry cleaners. CO_2 is a non-flammable, non-toxic, colourless, tasteless, odourless naturally-occurring gas that, when subjected to pressure, becomes a liquid solvent. The liquid CO_2 cleaning machines have a configuration which is similar to a solvent machine. The system is closed loop and comes equipped with a cleaning chamber, storage unit, filtration, distillation, and lint trap. Washing, vapour recovery, and drying are all performed in the cleaning chamber. Liquid CO_2 and detergent are circulated through the clothes via jets inside the chamber. The jets are placed such that fluid impact upon the clothes results in rotation. Next, the CO_2 is pulled out to prevent the dirt from being re-deposited on the clothing. At the end of the cycle (35-40 minutes), the pressure is released and the CO_2 returns to a gaseous state, with dirt and substances removed from the clothing (the dirt and debris end up in the bottom of the tank). Cooling and drying of the clothes occurs as the liquid CO_2 evaporates. The CO_2 used in this process is an industrial by-product from existing operations, primarily

		anhydrous ammonia (fertilizer) production. There is no net increase in the amount of CO_2 emitted; therefore, this process does not contribute to global warming. Tests have indicated that CO2 did not clean properly (or at all) and needed to put through a wet clean process as well (Pers. comm., 2008d). A hybdrid-technique (Solvair) uses glycol ethers with carbon dioxide for dry cleaning.
	n-propyl bromide (n-PB) CAS: 106-94-5 Trade name: DrySolv	This solvent is currently being considered as an alternative substance to tetrachloroethylene in dry cleaning. However, n-PB is classified as a toxic substance. It is reprotoxic (R60, R63), irritant to eyes, respiratory tract and skin (R36/37/38), highly flammable (R11) and harmful (R48/20) such that it can cause serious damage to health by prolonged exposure through inhalation.
	Cold Water Cleaning System	Cold water cleaning systems (washer and dryer) can wash and dry all fabrics including fine fabrics. It is claimed to use 100% water and biodegradable detergents to clean garments. Garments are washed in chilled water which is expected to minimize shrinking and may leave the use of tensioning equipment at the discretion of the dry cleaners.
	Propylene glycol-ether-based solution (Trade Name: Impress™ Dry Cleaning System)	It is compatible with hydrocarbon machines. As with any hydrocarbon or glycol ether is considered a VOC.
	Mixture of normal-, iso-, and cyclo-paraffins (Trade Name: Hydroclene Fluids)	It is a complex solvent with the ability to dissolve a broad range of strains.
Metal Degreasing	Decafluoropentane (CAS 138495-42-8), dichloroethylene (CAS 156-60-5) based formulations and cyclopentane (CAS 287-92-3) may be also be included. (Trade Name: Vetrel® solvents)	This range of solvents is claimed to be superior in terms of its versatility and safer hazard profile than the chlorinated solvents such as tetrachloroethylene.
	D-Greeze™ products Kleeneze™ and D-Zolve™ products	This is a range of products that claim to outperform chlorinated solvents in terms of efficacy, safety and economy.
	n-propyl bromide CAS: 106-94-5	See dry cleaning alternatives
	isoparaffinic hydrocarbons (CAS 64741-65-7). (Trade Name: Accepta 3548)	It is an odourless solvent cleaner and has been used as a substitute for 1,1,1-trichloroethane.
	Airless™ cleaning systems	These are automated distillable solvent cleaning systems where the process occurs in a vacuum chamber. The systems are closed-loop, self-contained systems that alleviate most of the problems associated with open-top systems including start-up solvent loss, ventilation loss, and poor cleaning performance.
	Enzyme cleaners	One company claims to have designed a robust, high operating temperature aqueous degreasing enzyme with a long sump life (months). Details of

		the preparation, Enzyme AZY, are limited but it is claimed to have the degreasing performance of trichloroethylene and is able to remove extremely heavy neat chlorinated oils, drawing oils, hydraulic oils and machine coolants.
	Ultrasonic cleaning	High frequency sound waves applied to the liquid cleaning solution generate zones of high and low pressures throughout the liquid. These pressures and temperatures loosen contaminants and perform the actual scrubbing of the ultrasonic cleaning process. Existing tanks can be modified to use ultrasonic cleaning.
	Automated Aqueous Cleaning	Automated cleaners use aqueous cleaning solutions instead of solvents for cleaning, thereby substituting the hazardous solvent waste stream with a much less hazardous wastewater stream. These automated machines also have features for recovering and recirculating cleaning fluids. Instead of immersion, the automated aqueous washer sprays an aqueous solution across the parts to remove oil and debris. Parts travel through a series of chambers, each with different concentrations of cleaning and rinsing solutions. Excess sprayed solution is recovered and reused.
	Aqueous Power Washing	Parts to be cleaned are placed inside the power washer unit on a turntable. As the turntable rotates, the parts are blasted from all angles with water at high-pressure and elevated temperature. The force of the spray jets, the heat, and the detergent combine to strip oil, grease, carbon, etc. The cycle time varies from 1 to 30 minutes depending on the type of part.
	Vapour Storage Technology	This uses an air lock and airtight equipment to temporarily store solvent vapours from an existing vapour degreaser and return the vapours for reuse. The air lock is used when moving parts into and out of the cleaning chamber. After being cleaned in the vapour degreaser, the parts are moved back into the air lock. The solvent laden air in the air lock is then cooled and circulated through a bed of adsorbent until the desired solvent concentration is reached in the air lock (depending on the design and the number of adsorbent beds used). The parts are then removed, and the air lock can be reloaded for the next cleaning cycle. Next, the adsorbent bed is thermally desorbed by circulating heated air from the air lock through the bed and back to the air lock. The new parts are then moved into the cleaning chamber, and the process is repeated.
	Vacuum Furnace	A vacuum furnace uses heat and vacuum to vaporise oils from parts. The cycle time depends on the mass of the load and the vapour pressure of the oil being removed. Most equipment is closed to eliminate emissions, and to facilitate backfilling the chamber with nitrogen and/or air to cool the parts prior to removal.
	Laser Cleaning	Short pulses of high-peak power laser radiation are used to rapidly heat and vaporize thin layers

		of material surfaces. These layers of surface material form a dense cloud of hot vapours that will condense and re-contaminate the surface if not removed immediately. To prevent recontamination, the vapours are removed by entrainment into a flowing gas stream. Laser cleaning must be carried out in an inert gas environment to avoid further contamination.
	Plasma Cleaning	Plasma cleaning has been used since 1968, when it was found to be effective in guidance system component cleaning. Plasma cleaning works by the same principles as etching. If an inert gas is used, the ions and neutrals in the plasma bombard the surface to be cleaned and physically remove the contaminant film molecule by molecule. By using a reactive gas in the plasma, the bombarding ions also may react with the contaminants and form gaseous species that evaporate from the surface. For energetic ions, the process known as reactive ion etching is used in microfabrication as well as in cleaning. Experiments have shown that plasma cleaning is more effective than solvent cleaning, but is relatively slow.

C.2 Availability of alternatives

All the alternatives listed in C.1, except those listed below, are currently in use and available, in most cases from several suppliers.

Scenario	Substance/Technique	Comments
Dry Cleaning	Resolv™ Dry Cleaning System	This is a relatively new technique that is available, though supply and support maybe limited.
	Impress™ Dry Cleaning System	This technique is in development.
Metal Degreasing	Laser Cleaning	This is a more specialised technique that is likely to be more costly and less widely available than the others listed here.
	Plasma Cleaning	This is a more specialised and limited technique that is likely to be more costly and less widely available than the others listed here. Though there are suppliers, their abundance in the EU is not known.

C.3 Human health risks related to alternatives

Information on the human health hazards, where available, is detailed in Section C.1.

C.4 Environment risks related to alternatives

The present dossier considers only the human health concerns identified in the RAR (conclusion iii). Any alternative substance or technique that presents environmental risks will require an adequate environmental risk assessment, which is beyond the scope of the present Annex XV report.

D. JUSTIFICATION FOR ACTION ON A COMMUNITY-WIDE BASIS

Not applicable as no further action on a community-wide basis is proposed.

E. JUSTIFICATION WHY A RESTRICTION IS THE MOST APPROPRIATE COMMUNITY-WIDE MEASURE

Not applicable as no restriction is proposed.

F. SOCIO-ECONOMIC ASSESSMENT OF PROPOSED RESTRICTION(S)

Not applicable as no restriction is proposed

G. STAKEHOLDER CONSULTATION

Industry

Johnson Cleaners
Persil Cleaners
Timpson Cleaners
Morrisons Dry Cleaners
Dow
Solvay
Ineos Chlor Ltd
Shell
BP
Exxon Mobil

Member States

All EU Member States were contacted for information on at least some aspect in the preparation of this dossier.

Trade Associations & other bodies

Euro Chlor
European Chlorinated Solvents Association
European Chemical Industry Council (Cefic)
Guild of Cleaners and Launders (Gcl.org.uk)
Textile Services Association
European Engineering Industries Association (Orgalime)
European Dry-Cleaners Organisation (CINET)
Occupational Safety and Health Administration
Surface Engineering Association
European Solvent Recyclers Group (ESRG)
European Fluorocarbons Technical Committee (EFCTC)
The Society of Laundry Engineers and Allied Trades Limited (SLEAT)

H. Other information

No other information is to be added to this Annex X report.

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ANNEX I - NEW DATA FROM MANUFACTURING AND PACKAGING COMPANIES SUBMITTED IN 2008

Exposure data measured during manufacturing and packaging of tetrachloroethylene was submitted by 5 companies. This data is summarised below:

Company 1: Manufacturer of tetrachloroethylene

Company 1 provided the summarised results of 823 personal exposure measurements (taken between 2002 – 2007 at its manufacturing site) for operating and maintenance workers plus 58 personal exposure measurements for laboratory workers (2004 - 2007). Monitoring was carried out over a full shift (12 hours or nominal 8 hrs). The results as presented by Company 1 are outlined in Table A1.1 and are expressed as 8 hr TWA in ppm.

Sampling/Analysis

Atmospheric tetrachloroethylene was collected on a thermal desorption tube packed with a suitable adsorbent (chromosorb for tetrachloroethylene). The tube was attached to a diffusion head and then as close as is reasonably practicable to the breathing zone of the wearer.

Tetrachloroethylene collected on the exposed thermal desorption tube is desorbed on an Automatic Thermal Desorber (ATD-400). The desorbed gas is passed into a gas chromatograph (GC) that is calibrated against standard solutions of varying concentrations of tetrachloroethylene, analysed and the results processed using a chromatography data handling software package.

Table A1.1 Inhalation exposure measurements carried out at Company 1

Workgroup	Year	No. of samples	Mean 8-hr TWA (ppm)	Maximum recorded value (ppm)	Notes
Operations & Maintenance	2002	175	0.6	28.5	This workgroup includes monitoring of personnel working in production, tanker loading and effluent treatment.
	2003	141	0.5	21.5	
	2004	144	0.4	19.7	
	2005	143	0.2	2.9	
	2006	111	0.4	10.6	
	2007	109	1.4	100.7	
Laboratory	2002	6	0.1	0.1	This workgroup includes monitoring of personnel working in the two main site laboratories.
	2003	20	2.4	29.1	
	2004	17	0.2	0.5	
	2005	12	0.1	0.2	
	2006	14	0.1	0.5	
	2007	15	0.2	0.6	

As seen in Table A1.1, in 2007 the maximum recorded value was 100.7 ppm. Of the 109 samples taken during the year it was the only recorded value above 50 ppm. Although, a follow-up investigation of the result was undertaken it proved to be inconclusive and the levels found were reported to be low. The data indicated that only one other sample in 2007 had a concentration above 25 ppm, though the value of this sample was not specified. The remaining samples in 2007 (107) were below 5 ppm. Therefore, this result (100.7 ppm) is considered to be an outlier. As only the mean results were provided it is likely that this outlier will have an impact on the overall inhalation exposure values seen in the industry for that year. Therefore, the values from 2007 will not be considered in determining the typical and RWC exposure values for manufacture and packaging.

It was reported that at least 98% of all the samples in each year for operators and maintenance staff were below 5 ppm (one tenth of the country's Workplace Exposure Limit). For the laboratory workers all results for 2003 – 2007 were below 5 ppm. In 2002, a total of 2 of the 20 measured samples were above 5 ppm.

The data used in determining the typical and RWC exposure values are outlined in Table A1.2.

Table A1.2 Summary of Company 1 data

Workgroup	Period (year)	No. of samples	Mean 8-hr TWA (ppm)	Maximum 8-hr TWA (range over period) (ppm)
Operations & Maintenance	2002-6	714	0.2 -0.6	2.9 - 28.5
Laboratory Workers	2004-7	84	0.1 – 2.4	0.1 – 29.1

Company 2: Manufacturer of tetrachloroethylene

Another manufacturer reported the results of 150 personal exposure inhalation measurements (taken between April 2003 – April 2008 at its manufacturing site).

The duration of sampling ranged from 255 – 965 minutes. The lowest measurement was 0.021 ppm. A limit of detection was not stated, therefore, for the purposes of calculating the median and RWC exposures for these data, samples that did not detect any tetrachloroethylene were assigned a value of 0.01 ppm, equal to half the lowest measured value.

No information was provided on the sampling method or the analytical technique undertaken by the company to gather the exposure values.

Table A1.3 Company 2: Summary of inhalation exposure measurements

Year	Function	Number of samples	Range (8-hr TWA ppm)	Sample Time Range (mins)	Notes
2003	Operator	30	ND – 4.6	300-965	28 samples = 'ND'
	Maintenance Instrument technician	6	ND	408-480	
	Lab technician / Research & Development	4	ND	405-465	
	Maintenance Mechanics	5	ND	425-480	
	Coordinator	4	ND	445-475	
	Supervision Administration	4	ND	450-495	
2004	Operator	1	-	428	
2005	Operator	1	ND	380	
	Coordinator	2	ND	270-390	
2006	Operator	38	ND–1.8	255-633	34 samples = 'ND'
	Maintenance Instrument technician	2	ND	365	
	Lab technician / Research & Development	4	ND	365-477	
	Maintenance Mechanics	4	ND	360-400	
	Maintenance Electrician	1	ND	420	No other measurements for this job in 2003- 2008
	Coordinator	1	ND	390	
	Supervision Administration	1	0.22	360	
	Logistic Workers	1	0.19	255	
2007	Operator	30	0 – 0.59	260-470	24 samples = 'ND'
	Maintenance Instrument technician	2	ND	285	
	Lab technician / Research & Development	1	ND	325	
	Maintenance Mechanics	4	0 – 1.8	320-440	2 samples = 'ND'
2008	Operator	4	0 – 0.06	315-390	

'ND' - not detected.

Table A1.4 Company 2: Summary of inhalation exposure measurements

Function	Number of samples N	Median 8-hr TWA (ppm)	90th Percentile 8-hr TWA (ppm)
Operator	104	0.01	0.02
Maintenance instrument technician	10	0.01	0.01
Lab technician / Research & Development	9	0.01	0.01
Maintenance Mechanics	13	0.01	0.16
Coordinator	7	0.01	0.01
Supervision administration	5	0.01	0.02
Maintenance Electrician	1	ND*	-
Logistics Worker	1	0.19*	-
Overall	153	0.01	0.02

* - only a single measurement was provided for these workers. The values shown are the raw data reported and are included in the overall values calculated.

Table A1.4 shows that the median exposure for different workers was 0.01 ppm. The 90th percentile values, however, range from 0.01 ppm to 0.16 ppm.

Company 3: Manufacturer of tetrachloroethylene

The following data, presented below, are as provided by a further manufacturer of tetrachloroethylene. No details of sampling methods and analytical procedures were provided.

Table A1.5 Company 3: Summary of inhalation exposure measurements (2008)

Position	Type	Duration (mins)	Minimum (ppm)	Mean (ppm)	Maximum (ppm)	Number of measurements
Chemist in production	personal sampling	340	0.07	0.26	0.58	19

Company 4: Manufacturer of tetrachloroethylene

Another manufacturer of tetrachloroethylene provided 8-hr TWA exposure information from two manufacturing sites (see Table A1.6 and Table A1.7). The information in tables A.1.6 and A.1.7 are summarised as provided by company 4. For both sites, no details of sampling or analytical methods were provided.

Plant 1

Table A1.6 Company 4: Summary of inhalation exposure measurements for Plant 1

Function	Year	No. of Measurements	Mean Exposure 8-hr TWA (ppm)
Operator	2003	8	0.25
	2004	21	0.25
	2005	8	0.25
	2006	8	0.25
	2007	18	0.05
Maintenance Operator	2003	17	0.25
	2004	28	0.25
	2005	9	0.25
	2006	9	0.25
	2007	30	0.05

Overall the mean tetrachloroethylene exposures for both groups of workers are similar and range from 0.05 – 0.25 ppm.

Plant 2

The information outlined in Table A.1.7 is as presented by the company. A SEG was defined by the data provider as a group of workers with the same general exposure profile because of the similarity and frequency of the tasks performed, the materials and processes used and the similarity of the way they are used. Though the job titles (that included installation mechanics, service engineers or team leaders) were stated, the precise details of the tasks performed by the different SEGs were not provided.

No details of sampling methods and procedures were provided.

Table A1.7 Summary of the inhalation exposure measurements carried out at Company 4, Plant 2

Exposure Group	Year	Number of Measurements	Mean Exposure 8-hr TWA (ppm)	90th Percentile Value 8-hr TWA (ppm)
SEG 1	2002	9	1.48	3.17
SEG 2		9	0.95	1.88
SEG 3		9	0.48	0.96
SEG 1	2003	6	0.64	1.55
SEG 2		6	0.3	0.73
SEG 3		5	0.4	1.31
SEG 4		6	0.21	0.51
SEG 5		12	1.46	3.17
SEG 6		6	0.5	1.04
SEG 2	2004	6	0.128	1.73
SEG 3		6	0.343	0.85
SEG 4		6	0.075	0.13
SEG 7		6	0.241	0.46
SEG 2	2005	13	0.33	0.67
SEG 3		6	0.79	1.97
SEG 4		6	0.09	0.18
SEG 7		6	0.56	1.10
SEG 2	2006	6	0.75	1.45
SEG 3		6	0.2	0.46
SEG 4		6	0.064	0.10
SEG 7		6	0.355	0.63
SEG 2	2007	6	0.26	0.69
SEG 3		6	1.51	4.41
SEG 4		6	0.09	0.15
SEG 7		6	0.39	1.04

For the 25 means (representing 171 samples) in Table A1.7, the mean exposure values ranged from 0.064 – 1.51 ppm (0.4 – 10 mg/m^3). The 90th percentile values ranged from 0.1 – 4.41 ppm (0.68 – 29.9 mg/m^3).

Company 5: Packing of tetrachloroethylene

A drumming contractor to a member company of ECSA submitted the following information.

Following manufacture at an EU manufacturing plant, tetrachloroethylene is transferred by road tanker to a sub-contracted packing facility where it is transferred to a stock tank and then packed from the stock tank into drums. Drum filling is a semi-automatic operation where the required volume of solvent is automatically weighed via a feed pipe placed in the drum by the operator. Exhaust ventilation is used at the filling point. Occupational exposure can also occur during road tanker filling and discharge, however, this will be minimal, as the driver does not remain at the filling or discharge point. Approximately eighteen workers are potentially exposed to tetrachloroethylene on the packing facility (excluding drivers). The results of routine personal air sampling during this process are given in Table A.1.8. No other details (such as the duration of sampling and how the sampling was conducted) were provided.

Table A1.8 Exposure to tetrachloroethylene during packing from 1999 to 2007 (8-hour TWA)

Operation/job	Number of samples	Mean exposure ppm	Maximum exposure ppm
Packing	78	1.5	14

The company reported that for the period 1999 to 2007, 61% of exposures were below 1 ppm and 98% were below 10 ppm.

Summary of the data in the manufacturing and packing industry

Table A1.9 Summary of exposure data with calculated means for manufacturing and packaging

Data Provider	Workgroup	Date	No. of samples	Mean Exposure 8-hr TWA (ppm)	Maximum exposure 8-hr TWA (range over period) (ppm)
Company 1	Operations & Maintenance	2002-6	714	0.2 -0.6	2.9 - 28.5
	Laboratory Workers	2004-7	58	0.1 - 0.2	0.2 – 0.6
Company 3	Chemist in production	2008	19	0.26*	0.07 - 0.58*
Company 4 – Plant 1	Manufacturing & maintenance	2003-7	156	0.05 – 0.25	-
Company 4 – Plant 2	Manufacturing & maintenance	2002-7	171	0.06 – 1.51	0.1 – 4.41**
Company 5	Packing	1999-2007	78	1.5*	14*

*Not 8-hr TWA value
**Not the maximum exposure value but the 90th percentile.

Table A1.10 Summary of median and 90th percentile exposure data for manufacturing and packaging

Data Provider	Workgroup	Date	Number of samples	Median exposure (ppm)	90th percentile exposure (ppm)
Company 2	Manufacturing & maintenance	2003 - 8	153	0.01	0.02

Conclusion

As can be seen from Tables A.1.9 and A.1.10 some of the exposure sample values represent 8-hr TWAs but some appear to be related to the specific exposure times. Therefore, the exposure values from the different manufacture and packaging sites are not directly comparable. Therefore, judgement is needed to determine the typical and RWC inhalation exposure values. A long-term typical value of 1 ppm (as only 3 mean values from company 4 were higher than this) is seen as representative of typical exposures and 4 ppm (as only 1 90th percentile from company 4 and 1 maximum value from company 1 are higher than this) is considered to be representative of RWC exposures.

In the absence of acute inhalation data, the approach taken in the RAR of using 3 times the long-term exposure will be used.

The exposure values taken forward to the risk characterisation is outlined in Table A1.11.

Table A1.11 Exposure values to be used in risk characterisation

Inhalation exposures	Typical exposures		RWC exposures	
	ppm	mg/m^3	ppm	mg/m^3
Long-term (8-hr TWA)	1	7	4	27
Short-term (15-min)	3	20	12	81

ANNEX II - NEW EXPOSURE DATA FROM THE DRY-CLEANING INDUSTRY SUBMITTED IN 2008

Company 1: Exposure data (2005 – 2008)

Results of personal sampling in the form of raw data were provided from 63 sites with a total of 195 samples. No further details about the sampling and analytical methods were provided (see Table A2.1).

Table A2.1 Company 1: Exposure data (2005 – 2008)

Year	Dry-cleaning sites	Number of Samples	Exposure Times (hrs)		Typical Exposure (Median 8-hr TWA) (ppm)	RWC (8-hr TWA)* (ppm)
			Range	Median		
2005	34	69	4 – 16.5	8:00	5.2	17.7
2006	27	52	3 – 12	7:30	3.0	12.4
2008	2	5	7 – 9	9:00	14.0	28.6

* 90^{th} percentile value.

The overall median 8-hr TWA for company 1 is 3.5 ppm. The 90^{th} percentile 8-hr TWA is 14.3 ppm.

Company 2: Exposure data (2008)

Results of personal sampling were provided in the form of raw data from 20 regions, totalling 244 sites and 673 samples. Tetrachloroethylene was measured using a passive dositube (Gastec Sampling Tube system; tube 133D). No further information was provided on the sampling technique. The results are presented in Table A2.2.

The numbers are presented as TWAs (ppm), from samples taken over a period in excess of 3 hours and normally between 6 and 8 hours.

Table A2.2 Company 2: Exposure data (2008)

Month	Number of Samples	Typical Exposure (Median 8-hr TWA) (ppm)	RWC (8-hr TWA)* (ppm)
Feb	239	9.0	19.0
Apr	226	8.0	17.0
Jun	208	7.0	15.0

* 90^{th} percentile value.

The overall median for the data in Table A2.2 is 8.0 ppm. The 90^{th} percentile value is 17.0 ppm.

Analysis of Pooled 2008 Data from company 1 and company 2

As the Solvent Emissions Directive (SED) came fully into effect in 2007 the dry cleaning exposure data from 2008 (which should take account of the implemented requirements of the SED on tetrachloroethylene) from companies 1 and 2 have been combined. The results indicated that for 2008 only (based on 678 samples) there is a median 8-hr TWA of 8 ppm and a 90th percentile value of 17 ppm.

On examination of the entire data set from 2005 to 2008 the median and RWC exposures have remained reasonably constant over this time period. Therefore, the values used in the risk characterisation will be refined to 17 ppm as a RWC and 8 ppm for typical exposure.

In the absence of acute inhalation data, the approach taken in the RAR of using 3 times the long-term exposure will be used.

The exposure values taken forward to the risk characterisation are outlined in Table A2.3.

Table A2.3: Exposure values to be used in risk characterisation

Inhalation exposures	Typical exposures		RWC exposures	
	ppm	mg/m^3	ppm	mg/m^3
Long-term (8-hr TWA)	8	54	17	115
Short-term (15-min)	24	163	51	346

GLOSSARY

ATP	Adaptation to Technical Progress
BLV	Biological Limit Values
CA	Competent Authority
CAD	Chemical Agents Directive (98/24/EC)
CEFIC	European Chemical Industry Council
C & L	Classification and Labelling
CNS	Central Nervous System
CO_2	Carbon Dioxide
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
D5	Decamethylcyclopentasiloxane
DMEL	Derived Minimum Effect Level
DNEL	Derived No Effect Level
DPNB	Dipropylene Normal Glycol Butyl Ether
EASE	Estimation and Assessment of Substance Exposure
EC	European Community
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECSA	European Chlorinated Solvents Association
ESR	Existing Substances Regulations
EU	European Union
GC	Gas Chromatograph
GESTIS	GESTIS-Substance Database maintained by BGIA
HSE	Health & Safety Executive
IBC	Intermediate Bulk Container
IPCS	International Programme on Chemical Safety
IOELV	Indicative Occupational Exposure Limit Value
IUCLID	International Uniform Chemical Information Database
LEV	Local Exhaust Ventilation
LOD	Limit of Detection
LOAEC	Lowest Adverse Effect Concentration
Min	Minute(s)
NEDB	National Exposure Data Base at HSE in UK
NOAEC	No Observed Adverse Effect Concentration
n-PB	N-Propyl Bromide (1-bromopropane)
OEL	Occupational Exposure Limit
OC	Operational Control
PBT	Persistent, Bioaccumulative and Toxic substance
PPE	Personal Protective Equipment
ppm	Parts per million
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC No. 1907/2006)
RMM	Risk Management Measure
RWC	Reasonable Worst Case
SCHER	Scientific Committee on Health and Environmental Risks
SCOEL	Scientific Committee on Occupational Exposure Limits

SDS	Safety Data Sheet
SED	Solvent Emissions Directive
STEL	Short-term Exposure Limits
TCNES	Technical Committee for New and Existing Substances
tpa	Tonnes per annum
TWA	Time-Weighted Average
UK	United Kingdom
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative substance
WEL	Workplace Exposure Limit
w/w	Weight per Weight