Perchloroethylene and PMT Criteria to identify substance as SVHC under REACH

ECSA as a member of Eurochlor supports the aim of assuring high drinking water quality. Ensuring that the sources of our drinking water are secure from any threats caused by chemicals is of the utmost importance. However the approach to establish tailored PMT (persistent, mobile, toxic) criteria and apply them to REACH registered substances in order to consider fulfilling PMT as an equivalent concern under Article 57 as recently suggested by the German UBA is not considered by ECSA as the right tool to improve drinking water quality.

ECSA aligns with the argumentation of CEFIC and the german VCI.

- There is regulation in place for drinking water and ground water.
  The recently initiated Drinking Water Directive – Recast already aims for further harmonize standards and improve drinking water quality in Europe.
  The European Commission adopted on 1 February a proposal for a revised drinking water directive to improve the quality of drinking water and provide greater access and information to citizens. The proposal comes as a result of the REFIT evaluation, the implementation of the Commission's response to the European Citizens' Initiative 'Right2Water' and as a contribution to meeting the targets of the Sustainable Development Goals. The proposal updates existing safety standards in line with latest recommendations of the World Health Organisation (WHO) and ensure our drinking water is safe to use for the decades to come. It will empower authorities to better deal with risks to water supply and engage with polluters.
- There is no need for additional criteria under Article 57
- PMT cannot be regarded as equivalent concern for SVHC identification like PBT as there can be enrichment in biota or in the food chain and could cause harmful effects in organisms at the end of the food chain, which is not the case for mobile substances
- PMT criteria could be used for screening and further monitoring of environmentally critical substances, but should not be used as a criterion for SVHC classification
- The criteria as set differ from the criteria set for PBT and are significantly broadened especially for the Toxic criterion, the mobility criterion compares a Koc value with estimated water solubility, which is not a valid approach, proposed threshold for water solubility of 150 µg/L is not sufficiently substantiated
- With the PMT setting as equivalent concern UBA follows purely the hazard based approach defining substances as SVHC as “precautionary principle” and does

not sufficiently consider a risk based approach, based on actual exposure data and modeling.

- Reviewing individual substances on the list of the UBA PMT report in can be demonstrated, that regulation under REACH (SVHC) will not contribute to improving drinking water quality because substances covered are either not subject to the REACH regulation but regulated under other regulatory schemes or their actual uses do not contribute to drinking water pollution.

Example: Tetrachloroethylene, CAS 127-18-4 (Perchloroethylene, PER)

PER is an industrial chemical with a high volume production. Not current volume numbers exist dues to the low number of manufactures in the EU (3), for which statistical data cannot be collected under ECSA. It can be estimated that the EU production of PER is in the range of 60 000 - 80 000 mt/y.

1. REACH Status

   PER has been registered by 7 registrants under REACH, volume band of lead registrant (Blue Cube Netherland B.V.) >1000mt.
   The REACH PER dossier has been evaluated under CoRap in 2012 by Latvia. The outcome of the evaluation has been “No regulatory action needed at EU level based on this evaluation.”

2. All potential exposure routes have been considered for Risk assessment

   All potential exposure routes such as emissions to air, water and soil as well exposure to workers and the general population and indirect exposure man via environment have been considered in the risk assessment carried out for the REACH registration. The risk assessment has been recently reviewed and calculated using the Chesar tool, a dossier update has been re-submitted in November 2017.

3. PMT and PBT Assessment against UBA and REACH criteria

   The PMT criteria as set by UBA in a very stringent way not aligning with the PBT criteria. Only under this specific criteria setting PER can be regarded as a PMT.

   P = Persistence
   The degradation of tetrachloroethylene by various abiotic and biotic processes has been examined in the relevant environmental media.
   Hydrolysis is not expected to be an important removal process for tetrachloroethylene. Half-lives in the range from 8.8 months to several million years have been reported (Dilling et al., 1975; Jeffers et al 1989). Photolysis is

also unlikely to be a significant removal process for tetrachloroethylene in aquatic environments.
Tetrachloroethylene undergoes reactions with hydroxyl radicals in the atmosphere. The calculated half life of tetrachloroethylene due to this reaction is 50 days with an OH radical concentration of 1.5E6 OH/cm3 (AOPWIN, 2000), with an overall OH-rate constant of 8.05E-13cm3/molecule.sec.
Tetrachloroethylene also reacts with ozone, nitrate radicals, hydroperoxy radicals, and chlorine atoms in the atmosphere but are thought to be insignificant atmospheric degradation processes. Overall, tetrachloroethylene is degraded in the atmosphere.
A number of studies have been reported on the biodegradation of tetrachloroethylene. The substance was not biodegraded under the stringent conditions of the modified shake flask closed bottle biodegradation test after 21 days (Mudder, 1982). Tetrachloroethylene does not appear to undergo aerobic biodegradation.
In contrast, data from simulation and screening tests demonstrated that tetrachloroethylene degrades well under specific anaerobic conditions. More than 99% of the tetrachloroethylene was dechlorinated in less than 200 days of incubation under either sulfate-reducing or methanogenic conditions in soil (Pavlostathis SG and Zhuang P, 1993). The conditions and inocula used appear to be important.
Conclusion: PER is persistent according to criteria

M – Mobile
While the limit for water solubility of 150 mg/L is set at 12°C, for PER only a value at 25°C is available (0.015%). This value exceeds the mobility criterion by 1000. The Log Koc is 2.53, hence hence below the limit set by UBA of 4.5
***Conclusion*: PER is mobile according to criteria**

T – Toxic:

(a) Toxic acc. to PBT criteria
EC10 / NOEC >= 0.01 mg/L for marine / freshwater organisms (long-term toxicity):
The acute effect concentrations for all three trophic levels are much higher than the screening criterion of 0.1 mg/l. It can therefore be expected that tetrachloroethylene is not potentially toxic towards aquatic organisms. The chronic effect concentrations for invertebrates and algae were higher than the defined criterion of 0.01 mg/l. Further, tetrachloroethylene is not classified for CMR as category 1 under GHS nor as STOT RE cat 1 or 2. Therefore, tetrachloroethylene does not fulfill the T criteria.
Conclusion: PER is not toxic acc. to criteria

(b) Toxic acc. to PMT criteria

EC10 / NOEC >= 0.01 mg/L for marine / freshwater organisms (long-term toxicity):

The acute effect concentrations for all three trophic levels are much higher than the screening criterion of 0.1 mg/l. It can therefore be expected that tetrachloroethylene is not potentially toxic towards aquatic organisms. The chronic effect concentrations for invertebrates and algae were higher than the defined criterion of 0.01 mg/l.

Substance is classified as carcinogenic (category 2), according to Regulation EC No 1272/2008 (or CLP Regulation)

Conclusion: as category 2 CMR substances are included into the T criteria for PMT PER is toxic acc. to criteria

4. PER regulated under Water Directives

There is sufficient regulation in place to protect PER from drinking water and minimize potential emissions.

Water Framework Directive

The Water Framework Directive 2000/60/EC is an EU directive which commits European Union member states to achieve good qualitative and quantitative status of all water bodies (including marine waters up to one nautical mile from shore) by 2015. THE WFD builds the framework for ground and surface water monitoring and setting of environmental quality standards

DIRECTIVE 2006/118/EC Ground Water Directive

The Ground Water Directive establishes a regime which sets groundwater quality standards and introduces measures to prevent or limit inputs of pollutants into groundwater. The Groundwater Directive complements the Water Framework Directive (WFD) by establishing ground water quality standards and requesting pollution trend studies of existing data and data which is mandatory by the WFD. It requires measures to prevent or limit inputs of pollutants into groundwater. PER is listed in Annex II of the Groundwater Directive, which lists pollutants and their indicators for which Member States have to consider establishing threshold values in accordance with Article 3 of the Directive. PER is listed as one of the

DIRECTIVE 2008/105/EC on Environmental Quality Standards

Member States shall apply the EQS for bodies of surface water in accordance with the requirements laid down in Part B of Annex I ofthe directive. PER is listed under No. 29a in this directive with this addition that this substance is not a priority substance.

Name of substance	CAS number	AA-EQS Inland surface waters	AA-EQS Other surface waters	MAC-EQS Inland surface waters ([3])	MAC-EQS Other surface waters
Tetrachloro-ethylene ([7])	127-18-4	10 µg/l	10 µg/l	not applicable	not applicable

Drinking Water Directive

The Directive laid down the essential quality standards at EU level. PER is listed under Annex I, part B with a limit of 10 µg/l (Sum of concentrations of specified parameters). Member States are not allowed, to set lower standards as the level of protection of human health should be the same within the whole European Union

Germany. List of Water-Endangering Substances 2017
PER is regulated under the above list with resulting in a WGK class of 3.

5. Uses (professional and industrial)

The PER dossier only contains risk assessments on industrial and professional uses. No consumer use has been identified.
The lead and co-registrants have reviewed all existing uses of PER in 2010 and risk assessments have been carried out accordingly. Due to a request of one specific downstream user, who provided details on his production process 3 uses for maskants have been added as exposure scenarios in 2013. In 2017 the REACH dossier has been updated including an assessment of man via environment into the use “Dry Cleaning, professional”.

Below is the list of REACH assessed uses:
- Manufacture
- Formulation or re-packing - Distribution and (re)packing (large scale)
- Formulation or re-packing - Formulation and (re)packing (small scale)
- Use at industrial sites - Use as an intermediate
- Use at industrial sites - Industrial use in dry cleaning
- **Use at industrial sites - Industrial use in surface cleaning**
- Use at industrial sites - Use as a maskant (medium scale)
- Use at industrial sites - Use as a maskant (large scale)
- **Use by professional workers - Professional use in dry cleaning**
- Use by professional workers - Professional use in film cleaning and copying

The by far major downstream uses of PER are industrial use in surface cleaning and professional use in dry-cleaning.

Manufacture/Use as Intermediate
These uses are carried out in sealed systems. There are only 3 manufacturers of PER in Europe. Release to water after treatment is calculated between 6 and 25ppm.

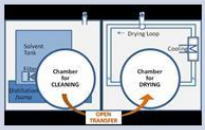
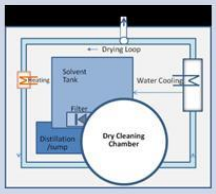
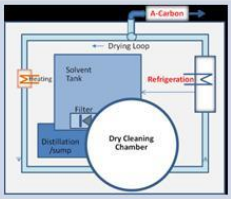
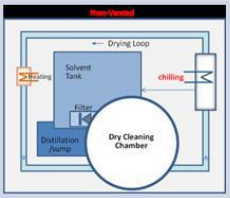
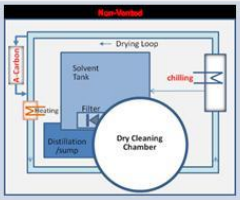
Formulation or repackaging
While the majority of PER is sold by bulk about a 3rd of PER is re-packaged, a small volume is used for re-formulation.
Typical transfer during repacking are made from 24 tons tanks to 200 litre drums. The transfer are made in closed systems with vapour return line between the storage tank and the bulk trucks, which avoids vapour emissions to the atmosphere since the vapour in the pipeline is fed back into the bulk. Repacking is made in ventilated area and exhaust air is treated. There are no emissions to water from this use.

Use in Industrial and Professional Dry-Cleaning
Use of tetrachloroethylene in industrial dry cleaning (including wool scouring, textile cleaning and heat finishing). Includes material transfers, storage and maintenance. The activities take place in rigorously contained system with strict control for manual interventions. Wool scouring is made in an industrial degreasing machine. The release to water is calculated to be 0.05ppm. Industrial dry-leaning is considered a minor use.

Dry cleaning of textiles with tetrachloroethylene has been carried for decades with evolving technologies to reduce exposure at the workplace, as well as minimize emissions to the environment. It can be estimated that there are 30000 – 5000) dry-cleaning machines on the EU market using PER. The Industrial Emission Directive required Member States of the EU to implement controls on the emissions of volatile organic compounds.

Today there are only closed machines on the market (ECSA type III machines and higher). ECSA strongly recommends the use of modern closed equipment of Best Available Technology (BAT). Recommended are 5th generation machines (at least 4th generation should be minimum standard) for dry cleaning equipment.
In Germany legislation requires Type V machines including safety-containers for the transfer of PER.
In the risk assessment of the REACH dossier it has been assumed as a worst case that ECSA type III machines are in use across Europe. These machines continuously recycle the PER used in the washing cycle. The only contact of PER with water is the “contact water” in the machine, the condensed water from the textiles which is captured in a separate tank and should be disposed of as

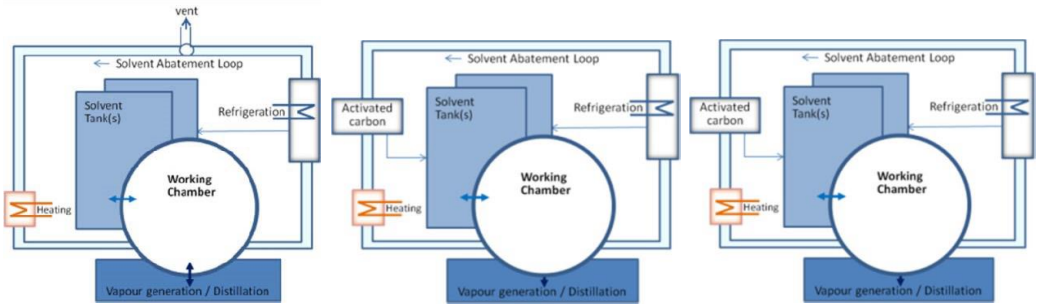
hazardous waste. Hence no release to water is expected only potential indirect release via air. Therefore a worst case calculation has been done in the risk assessment resulting in a release estimate of 7ppm.

1st Gen.: Transfer Machines	**2nd Gen.: Dry-to-dry single equipment, Vented, with water cooling**	**3rd Gen. : Single equip., vented ,refrigerated cooling and external carbon filter**	**4th Gen.: Single equip., not vented, closed loop drying with chilling system for cooling**	**5th Gen.: Single equip., not vented, closed loop drying with chilling system + integrated A-carbon.**
				
Typical total Per consumption: 300-500 g/kg textiles	Typical total Per consumption: 100 to 150 g/kg textiles	Typical total Per consumption: 40 to 80 g/kg textiles	Typical total Per consumption: 20 to 40 g/kg textiles	Typical total Per consumption: < 10 g/kg textiles
	Introduced in the late 1950s	Introduced in the late 1960s	Introduced in the early 1980s	Developed in the late 1980s and introduced in the early 1990s
		Still in use in some EU MS	Designed to enable users to achieve emission limits set by the EU Solvent Emission Directive	Will efficiently achieve residual conc. of 2g/m3 (1) in cleaning chamber after drying and before opening

Industrial use in surface cleaning

Metal degreasing with tetrachloroethylene has been carried for decades with improving technologies to reduce exposure at the workplace, as well as minimise emissions to the environment. The Industrial Emissions directive (2010/75/EC) required Member States of the EU to implement controls on the emissions of volatile organic compounds. In surface cleaning, installation consuming more than 1t/y must meet limits of 20 mg/m3 for stack emissions and 10-15% limits for fugitive emissions depending on the size of the installation. Open machines and enclosed machine are no longer used following the implementation of the IED. The assessment describes metal degreasing in closed machines which are described as ESCA type III and IV machines and uses the requirements of ECSA type III machines as a starting point.

Degreasing machines operating in closed system are not connected to the sewer; therefore there are no direct emissions to wastewater.



Type III Type IV Type V

Use as a maskant

The use as maskant is a minor use estimated to consume around 7 – 10mt per year. Material transfer is done in a closed system. Spraying is done using a robot in an enclosed spray booth. The solvent is captured in carbon beds and recycled. Wet objects are moved by crane or conveyor to a drying room where fumes are captured and recycled. The recommended technology to treat air is activated carbon filters, however other technologies to control emission such as catalytic oxidation (350°C) are also applicable. These systems are not connected to the sewer so there should be no direct emissions to wastewater. A water release factor of 0.09% has been calculated for this use.

Professional use in film cleaning and copying

Film copying and cleaning is a minor use with only few sides left due to witch to digital photography, this use is handled in a closed system. It is estimated that the use consumes only 1-2mt pf PER across EU. Air emitted from the unit is directed to an activated carbon filter. The carbon filter is regenerated once per week with steam, this is the only source for potential release to water. The release factor to water is calculated to be 0.015%.

6. Recycling

Perchloroethylene of the major uses Dry-Cleaning and vapor degreasing is recycled be dedicated recycling companies. Any Per containing residues from spent solvent recycling is sent to industrial waste burners, both being permitted industrial installation with tight emission control and soil&water protection after national and EU law.The PER recycling market has been consolidated in the past years so that one recycling company covers 60-70% of the recycling market. PER can be easily and economically recycled with purities received of recycled PER of 99.9%.

7. Sources for water contamination of PER

Legacy sources

Accidental release
Permitted releases

8. Other potential sources of contamination

   Emissions to air from permitted industrial and professional uses, which may be released to soil and water by rain.