



Study for the strategy for a non-toxic environment of the 7th EAP

Sub-study d : Very Persistent Chemicals



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The views expressed herein are those of the consultants alone and do not necessarily represent the official views of the European Commission.

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Sub-study d: Very persistent chemicals

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ABSTRACT

This sub-study investigates the case for regulating substances solely on the basis of their persistence in the environment. Very persistent (vP) substances may remain in the natural and man-made environments for an indefinite time and eventually reach levels leading to the same type of continuous exposure as occurs with bioaccumulation and to harmful effects to health, environment and natural resources. Such contamination may be poorly reversible or even irreversible, and could render natural resources such as soil and water unusable far into the future.

The sub-study identifies a number of gaps in analytical methods and data generation/availability concerning persistence in chemicals. It also finds gaps in the risk management measures currently used to prevent releases into the natural environment and to control the use of vP chemicals in the technosphere which, among other issues could lead to build-ups in the environment as well as pose problems for the material reuse/recycling streams envisioned for the Circular Economy.

The sub-study argues that in the context of an increasingly resource-constrained world, preserving the usefulness of essential natural and material resources and ecosystem services is important. From the standpoint of public health, environmental protection and economic growth, it thus appears desirable to take a precautionary, hazard-based approach and to prevent and/or minimize all releases of vP chemicals in the future.

EXECUTIVE SUMMARY

The problem

The use and dispersal in the environment of very persistent (vP) chemicals represents a (potential) threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including i.a. vulnerable population groups, wildlife and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the effects are chronic or appear at low concentration levels.

Key findings on very persistent substances

The problem

- A range of very persistent substances, including several groups of halogenated organic compounds, are widely used in different applications, often due to the functionality of the substance.
- Very persistent (vP) substances may accumulate in the environment and man-made materials to levels harmful to human health and natural resources.
- Certain toxic effects (e.g. those occurring at low concentrations or after long periods of low-grade exposure) may take many years to identify, by which time rising concentrations/levels could have already occurred and prove irreversible.
- Highly fluorinated chemicals such as PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea.
- The thousands of new short-chain PFAS marketed by producers as “safer” than the long-chain PFOS and PFOA are also extremely persistent. Evidence of their toxicity and of their presence in the environment is mounting. Known technologies are not able to remove short-chain PFAS from drinking water.
- An estimated 3.5 million sites around Europe are contaminated by hazardous including vP substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to removal of natural resources such as drinking water, soil, land and fish stocks from productive use.

Gaps and inconsistencies in current policy

- Current EU legislation does not provide an adequate way to systematically control substances on the basis of their persistent properties.
- Major gaps in knowledge concerning vP substances are due to lack of a common framework for screening substances for persistence and inadequate requirements for persistence testing and for further testing of health and environment properties if a substance is found to be persistent.
- Evaluation of risks from exposure to vP chemicals during the use phase of products is insufficient, and almost entirely missing in the case of imported products, with a few exceptions covering a limited number of substances in certain product groups such as toys. Product regulations also seldom take account of a substance’s fate at end of product life, which risks build-ups of vP substances in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.
- Criteria for maximum allowable levels of vP substances in food, drinking water and groundwater are needed to ensure that accumulations of vP pollutants in water and soil resources are given sufficient attention.

Concentrations of a vP chemical will tend to build up and can eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to vP chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, some health effects may not become evident until long after exposure.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment, because build-ups of a vP chemical could lead to the same type of continuous exposure as occurs with bioaccumulation¹. Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's propensity for harm. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Once a vP substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products.

The problems related to vP chemicals are particularly challenging in view of a **circular economy** that strives to close the loops by e.g. increasing reuse and recycling of material. If the material is recycled and used again, vP substances may accumulate in recycled materials, leading to increasing concentrations of contaminants in recycled materials, along with increased dispersal and presence of vP chemicals in the technosphere as well as the natural environment.

Testing and identification of persistence in substances. A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. It entails an assortment of supporting information and the need to address gaps and uncertainties².

Moreover, current requirements for testing and test methods to screen and test chemicals for persistence are insufficient³. According to UNEP, only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration⁴.

A major challenge is that testing for multimedia half-lives is time consuming and costly. While chemicals might be screened for persistence potential based on chemical structures and characteristics, no common framework for doing this has been adopted or accepted. As a result, knowledge and/or information available about the persistence of chemicals produced and used as well as about actual quantities and uses of many vP substances is poor.

To be included in the Stockholm Convention on persistent organic pollutants (POPs), a substance must meet the POPs screening criteria for persistence, bioaccumulation, long-range transport potential and

¹ Stephenson, 1977 ; Cousins, I.T., *et al.*, 2016.

² Boethling, R., *et al.*, 2009.

³ Scheringer, M. *et al.*, 2012.

⁴ UNEP 2013.

toxicity. At this point only 26 substances and groups of substances are covered under the POPs Convention, with another three under consideration for future inclusion. Yet as many as 1,200 of the 90,000+ substances on the market today could be potential POPs⁵. The number of substances meeting the POPs criteria for persistence alone is not known, but some 3,000 PFAS alone (a group of highly fluorinated and extremely persistent chemicals) are estimated to be on the market today.

In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.

The highly fluorinated chemicals – especially the per- and polyfluorinated alkyl substances known collectively as PFASs – are very stable and durable, which makes them useful for a broad range of applications. However, scientific tests to determine their degradation half-lives have found almost no degradation during the testing period, meaning they will persist in the environment for hundreds or even thousands of years⁶.

In the 1950s, when highly fluorinated compounds were first commercialised, the focus was on long-chain PFASs -- the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, such as PFOS and PFOA.

Human epidemiological studies have found positive associations between exposure to PFASs and hepatocellular damage affecting liver function in adults, obesogenic effects in females, liver and kidney cancer, low birthweight and reduced length of gestation. Exposures to low levels of highly fluorinated chemicals have also been linked to reduced immune response to routine childhood immunizations⁷.

PFAS are now ubiquitous in the environment. They are capable of long-range transport and found in the biota of remote regions far from any direct source, including in top predators such as polar bears. Studies on Arctic food chains have found indications of bioaccumulability. However, data concerning the specific health effects such exposures may be having on biota is sparse. Links have been found between foetal exposure to PFOA and significant delays in puberty, and between PFAS exposure in general and hepatotoxicity.

Regulatory pressure has led to phase-out of the manufacture and use of long-chain PFAS in Europe and the USA. As a result, many manufacturers have replaced the C-8s with short-chain homologues -- the C-6s and C-4s. PFAS producers argue that the short-chain PFAS are “safer” in that they are not as bioaccumulative as the long-chain PFAS. However, they are just as persistent, and evidence is emerging that the short-chain alternatives are also problematic in terms of risks to health⁸.

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations.

A major source has been the use or spillage of PFAS-containing aqueous film firefighting foam (AFFF); in the EU PFAS-contaminated waters have been documented in the Netherlands, UK, Germany, and Sweden. Groundwater contamination would likely be found in other countries with major airports also, if monitoring were carried out. Discharges from industrial production processes,

⁵ Scheringer, M., *et al.*, 2012.

⁶ Russell, M.H., *et al.*, 2008; Washington, J.W., *et al.*, 2009.

⁷ Grandjean, P., *et al.*, 2015.

⁸ Lerner, S., 2016.

wastewater treatment and landfill leachate are also important sources.

Other groupings of highly persistent substances. **Highly chlorinated substances** form another grouping of chemical compounds that tend to be very persistent and therefore problematic. Many of them are known to be toxic for health and environment. For example, the manufacture and use of polychlorinated biphenyls (PCBs) was banned by the EU and most other industrialised countries some 30 years ago, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health and environmental effects. While concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, since then they have remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources. Types of highly chlorinated substances also of concern include chlorinated paraffins, dichlorodiphenyltrichloroethane (DDT) and unintentionally formed POPs such as dioxins and furans. Other groups of highly persistent substances discussed in the study include **highly brominated substances**, **siloxanes** (D4 & D5), and **organometallics**, e.g., organotin compounds, methyl mercury and tetraethyl lead.

Contamination from vP substances has already had a significant impact on Europe's natural resource base. The use of hazardous substances in industrial production processes over the years has led to some 3.5 million potentially contaminated sites across Europe, with 0.5 million of these considered highly contaminated and needing remediation. Though it is not possible to estimate how many of these sites are contaminated by vP substances, overviews showing contamination of media by specific vPs, including PCDD/Fs⁹, HCHs¹⁰ and PFASs¹¹ do indicate a widespread problem.

In addition to local sources, contamination from vP substances has also been documented in soils away from point sources, e.g. highly fluorinated chemicals (HFCs) have been found at high altitudes because of tendency for long-range transport. Recently, contamination of waters by highly fluorinated chemicals (HFCs) has drawn attention in the USA, where drinking water supplies for 6 million residents were found to exceed national lifetime health advisory limits (70 ng/L) for PFOS and PFOA. While activated charcoal can remove the long-chain HFCs from drinking water, currently available technologies cannot remove the short-chain HFCs. The same type of activities that contaminated groundwater in the USA have also been carried out in the EU, e.g., releases from industrial sites and use of aqueous film firefighting foams at major airports and military bases. But because no EU-wide monitoring for HFCs in water has occurred, it is not known how many similarly contaminated drinking water supplies are to be found around the EU.

The presence of vPs in recycled products will be a particular challenge for the EU's action plan on a Circular Economy aimed at maximizing the use of, and minimizing the waste of, material resources in the economy. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied. The potential for contamination of the 'technosphere' is a serious concern because of the long-term implications for human and ecosystem health.

The Current Policy and Legislative Framework

A number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. For example, the **REACH Regulation** sets criteria for identifying if a substance is persistent, bioaccumulative, and toxic (PBT) or very persistent and very bioaccumulative (vPvB). A PBT or vPvB substance may then be identified as a Substance of Very High Concern (SVHC) under Article 57 and added to the Candidate List for

⁹ Weber, R. *et al.*, 2008.

¹⁰ Vijgen, J., 2006.

¹¹ Rumsby, P.C. *et al.*, 2009; Cousins, I.T. *et al.*, 2016.

eventual inclusion in Annex XIV as subject to authorisation. Alternatively, the substance may be restricted under Annex XVII.

In theory, REACH Article 57(f) might be invoked if evidence can be presented that a vP substance gives rise to an equivalent level of concern as a substance meeting the criteria for PBT/vPvB. But such an approach would also mean an ad hoc, case-by-case approach, which would not be sufficient to address e.g. the 3000+ extremely persistent highly fluorinated substances on the market today. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting. While this provision could in theory also include the particular effect of persistence, to date, neither this provision nor Article 57(f) has been applied to a substance solely on the basis of persistence.

In addition to being persistent, the substances controlled under the 1996 **PCBs Directive**, the 2004 **POPs Regulation** implementing the Stockholm Convention, and the 2008 **Mercury Regulation** are also bioaccumulative and toxic. Similarly, the cut-off criteria for active substances set forth in the 2009 **Plant Protection Products Regulation** (PPPR) and the 2012 **Biocidal Products Regulation** (BPR) also require findings of BT and vB in addition to P or vP. The **Detergents Regulation** is an exception in that it requires surfactants used in detergents to meet biodegradability standards.

The 2011 (recast) **RoHS Directive** is one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. By banning the use of the hazardous substance, the RoHS Directive prevents it from entering the material waste stream, i.e., the technosphere. The Directive targets four metals and two toxic and persistent flame retardants. However, the other persistent flame retardants used extensively in plastic casings of electronic goods are not covered. These other substances are an instance of "regrettable substitution" in that plastics with added flame retardants are often unfit to be recycled. The substance-specific provisions in the other "waste stream directives", e.g. end-of-life vehicles, batteries and packaging materials, play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

Controls over releases of pollutants during manufacturing or production are also not adequate for preventing build-ups of vP substances in the environment. The 2010 **Industrial Emissions Directive** (IED) is aimed at achieving best overall reduction of polluting emissions. This does not take into account the intrinsic quality of persistence which may require measures to prevent any releases of any vP substances in order to avoid build-ups in the environment. The use of emission limit values (concentration levels) set in integrated permits is inappropriate if the need is to prevent build-ups due to any release of a vP substance. Moreover, a vP substance not meeting the additional criteria for BT and vB would not be included in the controls over the industrial facility's emissions.

Systematic environmental monitoring and surveillance of vP substances is also needed in order to track their presence in the environment, including any build-ups, e.g., as part of an early warning system. The so-called WATCH List under the 2000 **Water Framework Directive** is an example of an instrument that could be adapted for such a purpose, though additional analytical methods may be needed to detect the range of vP substances of concern.

Moreover, under almost all of these acts, persistence may be regulated only if bioaccumulability is also present. Hence the EU regulatory system is insufficient for preventing build-ups of vP substances.

An additional gap in the EU regulatory regime is the lack of standards in the **Drinking Water Directive** for PFAS and the other vP substances now showing up in Europe's waters. PFAS have already been found in water resources used for drinking water in Germany, the Netherlands, and Sweden. Without limit values for PFAS in drinking water and EU-wide monitoring for the presence of PFAS in water, the number of other EU residents with drinking water supplies contaminated by PFAS and other chemical substances cannot be known. EU legislation for food contact materials and for

contaminants in food stuffs is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

Identified gaps and inconsistencies in current policy/legislation

The current EU regulatory framework is insufficient for protecting human health and natural resources from risks of exposure due to accumulations of very persistent substances. Four types of gaps were identified:

1. **Gaps in identifying and regulating vP substances.** Testing of chemicals to determine their half-lives is time consuming and costly, and no common framework for comprehensive screening of substances for persistence has been agreed on EU level. REACH does not require data on persistence for low volume substances. Moreover, the role of vP substances in combination effects and cumulative exposures is not adequately considered.
2. **Gaps in regimes to protect the ecosphere from releases of vPs.** Controls over releases of pollutants during manufacturing or production are usually in the form of emission limit values (concentration levels). In the case of vP pollutants, strict controls over any releases may be needed to prevent substances from building up in the environment. Related to this is the lack of controls over vP substances used in certain products, such as in cosmetics or textiles, which will end up being released into the natural environment via e.g. wastewater discharges.
3. **Deficits in controlling vP substances in the technosphere.** In general, product regulations often do not evaluate the risk of a vP during a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy and which could form reservoirs for future exposure.
4. **Deficits in protecting human health and in addressing vP build-ups in the ecosphere.** Systematic monitoring is not carried out to spot the presence and/or build-up of vP chemicals in environmental media and biota, such as humans. For example, the Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so build-ups of vP pollutants in water resources are not given sufficient attention. EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

Conclusions

The traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

Very persistent chemicals released into the environment can render resources such as soil and water unusable far into the future as well as damaging ecosystem services. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams.

For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and pro-active approach and to prevent and/or minimize releases of vP chemicals in the future.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required, and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement –something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

ABBREVIATIONS USED

α-HCH	α -Hexachlorocyclohexane
AFFF	Aqueous film firefighting foam
β-HCH	β -Hexachlorocyclohexane
B	Bioaccumulative
BAT	Best Available Technique
BFR	Brominated flame retardants
BPA	Bisphenol A
BPR	Regulation (EU) 528/2012 concerning the placing on the market and use of biocidal products
BREF	BAT Reference Document
CAS	Chemical Abstracts Service
CEPA	Canadian Environmental Protection Act
CLP	Classification, labelling and packaging or Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CMR	Carcinogenicity, Mutagenicity and Toxicity for Reproduction
CO₂	Carbon Dioxide
CONCAWE	Division of the European Petroleum Refiners Association
CORAP	Community rolling action plan
CP	Chlorinated paraffins
CSA	Chemical Safety Assessment
cVMS	Cyclic Volatile Methylsiloxanes
D3	Cyclotrisiloxane/ examethylcyclotrisiloxane
D4	Cyclotetrasiloxane/ octamethylcyclotetrasiloxane
D5	Cyclopentasiloxane/ decamethylcyclopentasiloxane
D6	Cyclohexasiloxane/ dodecamethylcyclohexasiloxane
DART	Decision Analysis by Ranking Techniques
DDE	Dichlorodiphenyldichloroethylene
DDT	Dichlorodiphenyltrichloroethane
DEPA	Danish Environmental Protection Agency
dl-PBBs	Dioxin-like Biphenyls
EAP	Environment Action Programme
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFOA	European Fuel Oxygenates Association
ELINCS	European List of Notified Chemical Substances
ELV	Emission Limit Value
EU	European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GWP	Global Warming Potential
HBCD	Hexabromocyclododecane
HCB	Hexachlorobenzene
HCH	Hexachlorocyclohexane
HFC	Highly fluorinated chemical substance
HMPD	Directive 2001/83/EC on medicinal products for human use
IARC	International Agency for Research on Cancer
ICCM	International Conference on Chemicals Management
IED	Directive 2010/75/EU on industrial emissions (recast)
INCI	International Nomenclature of Cosmetic Ingredients
IPCC	Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (recast)
IPEN	International POPs Elimination Network
IQ	Intelligence Quotient
KEMI	Swedish Chemicals Agency
LCCP	Long Chain Chlorinated Paraffins
LRTP	Long-Range Transport Potential
M	Mobile
MCCP	Medium Chain Chlorinated Paraffins
MS	Member State
MTBE	Methyl <i>tert</i> -butyl ether
ODS Regulation	Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
OECD	Organisation for Economic Co-operation and Development
P	Persistent
PAH	Polycyclic Aromatic Hydrocarbon
PBB	Polybrominated Biphenyls

PBDD	Polybrominated dibenzo-p-dioxins
PBDF	Polybrominated dibenzofurans
PBDE	Polybrominated Diphenyl Ethers
PBT	Persistent, Bioaccumulative and Toxic
PCB	Polychlorinated Biphenyls
PCDD	Polychlorinated dibenzo-p-dioxins
PCDF	Polychlorinated dibenzo-p-furans
PCN	Polychlorinated Napthalenes
PCT	Polychlorinated Terphenyls
PET	Polyethylene terephthalate
PFASs	Per- and polyfluorinated alkyl substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctane sulphonate
PMT	Persistent, Mobile and Toxic
POPs	Persistent Organic Pollutants
POPs Convention	2001 Stockholm Convention on Persistent Organic Pollutants
POPs Protocol	1998 Aarhus Protocol on Persistent Organic Pollutants
POPRC	Persistent Organic Pollutants Review Committee
PPPR	Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products on the market
PVC	Polyvinyl chloride
QSAR	Quantitative Structure Activity Relationships
RAC	ECHA Committee for Risk Assessment
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RIVM	National Institute for Public Health and the Environment, Netherlands (Rijksinstituut voor Volksgezondheid en Milieu)
RoHS 2	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)
SAICM	Strategic Approach to International Chemicals Management
SCCP	Short Chain Chlorinated Paraffins
SDS	Safety Data Sheet
SVOCs	Semi-volatile organic compounds
SVHC	Substances of very high concern
T	Toxic
TBT	Tributyltin
TBBPA	Tetrabromobisphenol A
TEL	Tetraethyllead
TPhT	Triphenyltin
T2D	Type 2 Diabetes
TEQ	Toxic Equivalent
UK	United Kingdom
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
USSR	Union of Soviet Socialist Republics
UWWTD	Urban Wastewater Treatment Directive
VMPD	Directive 2001/82/EC relating to veterinary medicinal products
vP	Very Persistent
vPvB	Very Persistent, Very Bio-accumulative
WHO	World Health Organization

1 INTRODUCTION

This sub-study focuses on “very persistent” chemical substances, i.e., those substances that are resistant to degradation and therefore will remain in the environment for a long time. One of the most well-known examples of very persistent substances is the grouping of highly fluorinated chemicals, also known as per- and poly-fluorinated alkyl substances, or PFASs. The sub-study aims to provide:

- An overview of the status quo regarding very persistent chemicals, including a description of the most important health and environmental issues relating to very persistent chemicals, according to current knowledge;
- An overview of current legislation and policy measures on the EU level;
- Activities in international and regional organisations as well as Member States and other countries, and of industry and civil society organisations;
- An analysis of the main gaps in relevant legislation and policies;
- A review of ongoing activities aimed at developing alternatives to or substitutes for very persistent chemicals, including non-chemical solutions.

The study considers the following problem:

Problem Statement

The use and dispersal in the environment of very persistent chemicals represents a threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including i.a. vulnerable population groups, biodiversity and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the toxic effects occur at low concentration levels or the do not appear until many years later.

Concentrations of a (very) persistent chemical will tend to build up and eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to very persistent chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of very persistent substances, cases of such damages are highly likely to appear or may even be unavoidable.

The current EU regulatory framework identifies chemicals that combine persistence with bioaccumulation and toxicity (PBT) or high persistence and high degree of bioaccumulation (vPvB) as substances of very high concern (SVHC), which may be subject to authorisation or restriction. However, it is not clear whether EU legislation allows for the possibility to regulate substances based on persistence alone, or whether current requirements for testing and/or test methods to screen and test chemicals for persistence are adequate for identifying those chemicals where persistence is likely to lead to accumulations of concern.

The sub-study’s findings are based on a thorough review of the available literature, including academic articles and reports and stakeholder input obtained through a June 2016 workshop and selected interviews. On the basis of the overview and analysis, the sub-study identifies a number of possible responses in the short, medium and long term, which could contribute to the protection of health and the environment.

The process of fact-finding has also drawn on work carried out in other EU policy processes, notably a project for the European Commission - “Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation”, which includes a case study on ‘Inconsistencies in assessment procedures for PBT and vPvB as properties of concern’. The case study is an ex-post assessment of the coherence and effectiveness of the current regulatory framework. It does not consider ‘persistence’ as a characteristic apart from BT or vB, nor does it look at the scientific literature concerning the health and environmental issues linked to very persistent substances. It therefore complements rather than duplicates this sub-study.

1.1 THE PROBLEM WITH PERSISTENCE

Persistence in chemicals is a desirable quality, as well as an issue of concern. Chemicals that are not readily biodegradable last longer, which can be important for particular applications where durability is a requirement. For various technical or functionality reasons, such chemicals are used widely in a broad range of applications. However, because persistent substances tend not to degrade through natural processes, they may remain in the environment for an indefinite time.

Some stakeholders have questioned why this persistence should be considered a problem, and compared such substances to the stones found in nature. But chemical substances are not like inert stones, fixed to one place. They are molecules and, if persistent, will “have time” to be transported over long distances and reach remote regions in all parts of the world¹². They may accumulate to high levels in the environment and become sources of exposure. If these substances turn out to be toxic at a later point and if exposure levels have become sufficient to cause adverse effects in humans, domestic animals, or wildlife, it may not be possible to reverse their impacts.

Concern about persistence in chemicals is long-standing. One of the earliest warnings dates from 1977¹³:

‘On the face of it there appears little reason to be concerned about a material which, even though present in the environment, is not causing any detectable damage. On the other hand, persistent materials, because of this property, will accumulate in the environment for as long as they are released. Since the environment is not effective at cleansing itself of these materials, they will remain for indefinite periods, which were not recognized at the time of their original release. The problem could become entirely out of control and it would be extremely difficult if not impossible to do anything about it. Materials which are strongly persistent can accumulate to rather high levels in the environment and effects which would not otherwise be important could become so.’

Because of their long half-lives and tendency for bioaccumulation and long-range transport, they can accumulate in remote polar regions, far from their origins. Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk for the environment¹⁴. While many environmental exposures may occur close to the point of origin, such as discharges from industrial plants, in the case of very persistent chemicals the main concern may be exposures that occur far afield. An additional challenge lies in the difficulty to detect/demonstrate harmful effects given the multitude of organisms across ecosystems and the still limited knowledge concerning some toxicological aspects. Because very persistent substances stay around for a long time, their role in such aspects as combination effects, low dose and long term exposure, and sensitivities of certain vulnerable populations may require special attention.

Several of the world’s major threats to the human health and the environment are closely related to this aspect of persistence. For example, the threat to the stratospheric ozone layer comes from ozone-depleting chemicals -- highly persistent fluorinated compounds with a very slow turnover in the atmosphere (see section 2.4 below for more on highly fluorinated compounds). Climate change caused by the increased greenhouse effect of the atmosphere is related to how long the various greenhouse gas compounds remain in the atmosphere. These compounds (F-gases, methane and CO₂) are also more or less persistent, with CO₂ eliminated only through photosynthesis. In both cases, the persistence of the compounds involved means that a very long time is required for “repairing” the environment, if such effects can even be reversed.

¹² Scheringer, M. *et al.*, 2012.

¹³ Stephenson, M.E., 1977.

¹⁴ Mackay, D., *et al.*, 2014.

Unease about the global spread of some types of pollutants, e.g., the persistent organic pollutants (POPs) covered by the Stockholm Convention¹⁵, has led some to identify chemical pollution as one of nine so-called ‘planetary boundaries’ – thresholds beyond which non-linear, abrupt environmental change might occur on a global scale¹⁶.

Scientists have proposed three conditions that must be met at the same time for a chemical or mixture of chemicals to be considered a planetary threat¹⁷:

- (1) The chemical or mixture of chemicals has a disruptive effect on a vital earth system process of which we are ignorant;
- (2) The disruptive effect is not discovered until it is, or inevitably will become, a problem at a planetary scale; and
- (3) The effects of the pollutant in the environment cannot be readily reversed.

The problem of ignorance is an important factor, in that the disruptive effects are not discovered until they already occur on a global scale and are affecting a vital earth system process. In light of this problem of ignorance, the scientists argued for a regulatory approach based on hazard rather than risk, with a focus on persistence seen as particularly important. The depletion of the stratospheric ozone layer because of the production and release of halocarbons was cited as a clear example of a global-scale environmental impact that no one foresaw at the time of the design and initial commercialisation of these substances.

In 2015, the Stockholm Resilience Centre¹⁸, the leading proponent of the planetary boundaries concept, replaced the term ‘**chemical pollution**’ with the term ‘**introduction of novel entities**’, to include other potential human-driven global risks such as the release of plastics, nanomaterials and radioactive materials. Its website notes: *“These compounds can have potentially irreversible effects on living organisms and on the physical environment (by affecting atmospheric processes and climate). Even when the uptake and bioaccumulation of chemical pollution is at sub-lethal levels for organisms, the effects of reduced fertility and the potential of permanent genetic damage can have severe effects on ecosystems far removed from the source of the pollution. For example, persistent organic compounds have caused dramatic reductions in bird populations and impaired reproduction and development in marine mammals...At present, we are unable to quantify a single chemical pollution boundary, although the risk of crossing Earth system thresholds is considered sufficiently well-defined for it to be included in the list as a priority for precautionary action and for further research.”*

If a substance with a rather low or unknown toxicity is very persistent (and particularly if it is volatile or highly mobile), concentration levels will increase over time across the environment, in the different compartments such as air or water, depending on chemical properties. When concentrations reach certain levels, toxic effects will start to appear. If exposure is widespread (geographically and/or in different compartments), the risk for adverse effects increases. Since a multitude of organisms and ecosystems with varying sensitivities will be exposed, it will be hard to predict at what concentrations the effects will appear, but over time the probability of adverse effects will increase. If such an impact is discovered too late to have a disruptive effect on a vital earth system, the effects of the pollutant may be irreversible¹⁹.

The problems related to very persistent chemicals are particularly challenging in view of a circular economy that strives to close the loops by e.g. increasing reuse and recycling of material. Exposure might occur throughout the material cycle, from manufacturing of the chemicals to manufacturing and use of products, during waste management and recycling as well as in connection to use of recycled

¹⁵ UNEP, 2001 (the ‘Stockholm Convention’).

¹⁶ Rockström, J., *et al.*, 2009.

¹⁷ Persson, L.M., *et al.*, 2013.

¹⁸ <http://www.stockholmresilience.org/21/research/research-programmes/planetary-boundaries.html>

¹⁹ Diamond, M.L., *et al.*, 2015.

materials. Even less persistent substances may be persistent if integrated into a material. If they continuously leak, levels will build up in the environment (see section 2.5.5 below on the special case of ‘pseudo-persistence’). If the material is recycled and used again, very persistent substances may accumulate in recycled materials²⁰. If this problem is not properly managed, it might lead to increasing concentrations of contaminants in recycled materials, along with increased dispersal and presence of very persistent chemicals in the technosphere as well as the natural environment.

1.2 IMPACT ON HEALTH AND THE ENVIRONMENT OF VERY PERSISTENT CHEMICALS

Making any generalizations on the health and environmental impacts of very persistent chemicals is a difficult proposition. However, overall, humans, domestic animals, and wildlife are more likely to be exposed to a chemical if it does not easily degrade or is dispersed widely in the environment. The structural characteristics that enable a chemical to persist in the environment can also help it to resist metabolic breakdown in people or wildlife. For example, synthetic chemicals that contain halogen atoms (particularly fluorine, chlorine, or bromine) are often resistant to degradation in the environment or within organisms²¹.

Metals are basic elements and cannot be further broken down in the environment. Because of human activities, some highly toxic metals, such as lead, mercury and arsenic, may accumulate in the environment in ways similar to the accumulations of very persistent substances, leading to increased exposures. For example, lead contamination of air, soil, or drinking water can ultimately result in significant exposures in fetuses, infants, and children, resulting in impaired brain development²². Although this sub-study will focus on synthetic organic chemicals the potential health effects of exposure to certain metal compounds should not be overlooked, as discussed in more detail in section 2.5.3 on organometallics.

The different chemicals that have been classified as persistent or very persistent exhibit a wide range of impacts on health and the environment. For example, the negative health and environmental effects of a number of POPs are well documented. Exposure to the well-studied POPs can lead to serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system²³. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals. The specific health and environmental impacts of the groups of chemicals looked at more closely in this study are discussed in more detail in sections 2.5 and 2.6.

Persistence in itself relates to both health and environmental impacts. In this respect, persistence can be viewed as a factor in exposure and risk. How persistent the chemical or substance is means that the chemical is present longer in the environment and in turn affects present and future routes and rates of exposure. For this reason, persistence of chemicals in the body and/or the environment is considered one of the important factors to take into account when figuring out how to target those combinations of chemicals that pose the highest risk for human and environmental health²⁴.

An illustrative example of this are the highly fluorinated chemicals, more specifically the per- and poly-fluorinated alkyl substances known collectively as PFASs (discussed in greater detail in section 2.4). The highly fluorinated chemicals are anticipated to have long term effects on the environment and health in the foreseeable future due to their extremely persistent nature in the environment, their continued formation from precursor compounds and their continued production in other parts of the world. These chemicals were originally perceived as being inert because the compounds did not break

²⁰ Ionas, A.C., *et al.*, 2014.

²¹ Heath, E. and Kosjek, T., 2012.

²² WHO, 2005b.

²³ Wong, M.H., *et al.*, 2012.

²⁴ SCHER, SCCS, SCENHIR, 2012.

down in the environment. However, the interpretation of human health risks associated with PFASs has changed over time gradually as evidence relating to the effects of persistence and bioaccumulation has emerged²⁵. It is also suggested that the lack of initial evidence was in fact related to their persistence or the compounds' resistance to breakdown, i.e. it was assumed that the compounds were inert and thus would not pose a health risk.

New health risks are also a concern as new evidence for “old” persistent chemicals, e.g., the highly chlorinated persistent organic pollutants (POPs) such as DDT and the PCBs, has emerged. Recently, for example, a substantial volume of research has focused on chemicals with endocrine disrupting properties, and especially on POPs and possible associations with increased risk for Type 2 diabetes (T2D) and obesity²⁶.

1.3 WHY PERSISTENCE ALONE IS A CONCERN

At this point REACH and other EU legal acts regulate persistent chemicals only if other hazardous properties are also present. Article 57 of REACH setting forth the substances that may be included in REACH Annex XIV as subject to authorisation as substances of very high concern (SVHC) specifies three categories where persistence plays a role, i.e.:

- Persistent, bio-accumulative and toxic (PBT)
- Very persistent and very bio-accumulative (vPvB)
- Substances, such as those having PBT or vPvB properties which do not fulfil the criteria set in REACH Annex XIII, but for which there is scientific evidence of probably serious effects to human health or the environment which give rise to an equivalent level of concern. Note that this category can only be applied on a case by case basis and not to a grouping of chemicals of concern.

Thus regulators must show that a substance that is persistent or very persistent in the environment is also bio-accumulative and toxic, or very bio-accumulative in order to put in place controls under EU legislation. But, as section 2.5.2 on siloxanes discusses briefly, it is not straightforward to determine whether a substance is bioaccumulative, and there is a strong possibility of missing substances that should be considered as of very high concern.

More recently, German authorities have argued that the characteristic of mobility (M) should be a criterion giving rise to a level of concern equivalent to bioaccumulability. They have proposed a methodology for determining when a substance registered under REACH should be considered persistent, mobile and toxic (PMT), particularly with respect to protection of water resources used for human consumption²⁷. The concept of mobility is discussed further in later sections.

The degree of persistence means that chemicals can accumulate in the different environmental compartments, and become sources of exposure to substances. As noted earlier, if these substances turn out to be toxic at a later point and if exposure levels have become sufficient to cause adverse effects in humans, domestic animals, or wildlife, it may not be easy or even impossible to reverse their impacts. This may lead to the loss of an important natural resource, and to increased pressures on other resources as well as increased overall pressure on human health and the ecosystems.

It should be noted that one of the 12 principles of Green Chemistry is:

10. Design chemicals and products to degrade after use: Design chemical products to break

²⁵ Grandjean, P., & Clapp, R., 2014.

²⁶ Lee, D. *et al.*, 2014.

²⁷ Kalberlah *et al.*, 2014a.

down to innocuous substances after use so that they do not accumulate in the environment²⁸.

Recent studies have pointed out how persistence alone becomes a concern if accumulations of a substance that lead to exposure are found to be poorly reversible. For example, the widespread use of highly fluorinated firefighting foams in trainings around military and other airports has resulted in contamination of underlying groundwater reserves in those localities. Since highly fluorinated chemicals are known not to degrade for decades or longer, and since exchange of groundwater reserves due to rain or other flows can also take a very long time, drinking water supplies contaminated by such chemicals will become a constant source of exposure, unless substitute drinking water sources are found²⁹.

Once a very persistent substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products³⁰. DDT is another example in that the compound itself is considered to have low toxicity for humans, but when released into the environment its transformation products include the more toxic DDE³¹. Moreover, some health effects may not become evident until long after exposure³².

The question has arisen whether all vP substances are of concern, or whether there might be examples of vP substances which have already accumulated to high levels and still do not induce any impacts. In the research for this sub-study, no such examples came to light. But in the case of vP substances, there will always be uncertainty about whether and when an adverse effect will occur and where, and this uncertainty will never be removed.

The logic is as follows: risk is the ratio of exposure (i.e. concentration in the environment) versus the no-effect threshold. If a substance is very persistent, and assuming that emissions continue at a constant rate, it will attain higher and higher concentration levels in the environment. In this case the risk quotient also increases continuously up to the point that the concentration exceeds the no-effect threshold. This is an inevitable process. When and where the adverse effect occurs will depend on the sensitivity of the species that are exposed.

Accordingly, this sub-study focuses on whether very persistent substances, as well as those substances that combine persistence with mobility, should be regulated.

²⁸ Anastas & Warner, 1998.

²⁹ Cousins, I.T. *et al.*, 2016.

³⁰ EEA, 2001.

³¹ U.S. Dept of Health and Human Services, 2002.

³² Grandjean & Clapp 2014; Rucker, C. & Kümmerer, K., 2015.

2 THE STATE OF PLAY REGARDING THE SUB-STUDY AREA

2.1 DEFINING PERSISTENT AND VERY PERSISTENT

Persistence is normally defined in terms of the biodegradability of a substance or chemical substance in different environmental media or compartments, such as water or soil. In the environment, many chemicals are degraded by sunlight, destroyed through reactions with other environmental substances, or metabolized by naturally occurring micro-organisms. Some chemical substances, however, have features that enable them to resist environmental degradation. They can accumulate in soil and aquatic environments. Substances with properties that enable them to bind strongly to soil particles may stay in the place they were deposited, but other substances may evaporate into air (volatilize) or dissolve in water. These may then migrate considerable distances from where they are released.

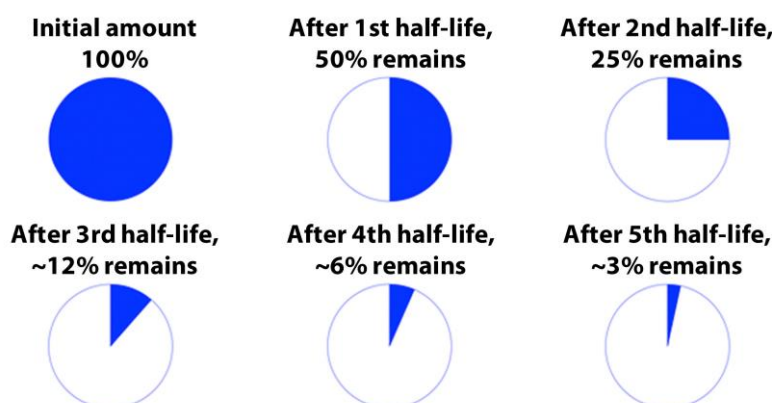
In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.³³ The table below compares the REACH Annex III criteria for persistence to those set by other national and international fora:

Table 1: Degradation half-lives for identification of PBT/vPvB/POP substances

Criteria	PBT (REACH)	vPvB (REACH)	PBT (US EPA)	vPvB (USEPA)	POP (Stockholm Convention)	PBT (OSPAR)
- in marine water	>60 days	>60 days	>60 days	>180 days	>60 days	>50 days
- in fresh or estuarine water	>40 days	>60 days	>60 days	>180 days	>60 days	>50 days
- in marine sediment	>180 days	>180 days	>60 days	>180 days	>180 days	>50 days
- in fresh or estuarine sediment	>120 days	>180 days	>60 days	>180 days	>180 days	>50 days
- in soil	>120 days	>180 days	>60 days	>180 days	>180 days	

A very persistent chemical with a half-life of more than 180 days, or approximately six months, may remain in the environment for much longer than that. The figure below illustrates how a significant amount of a substance may still remain even after a fourth or fifth half-life. If releases of the substance continue, accumulations will occur.

Figure 1: Amounts of a substance remaining after multiple half-lives



³³ Regulation (EC) No 1907/2006.

No criteria have been developed to define when a substance might be considered extremely persistent, i.e., when no evidence of degradation potential has yet been identified, as with some of the highly fluorinated chemicals.

2.2 SCREENING AND TESTING FOR PERSISTENCE

One of the major challenges relating to persistent and very persistent chemicals is that testing multimedia half-lives is time consuming and costly. According to UNEP³⁴, only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration. A number of studies have suggested ways in which chemicals can be screened based on chemical structures and characteristics to estimate their persistence. However, no common framework for doing this has been adopted or accepted. Scheringer et al.³⁵ pointed out the need for concepts and tools that make it possible to screen large numbers of chemicals for persistence.

While a number of studies³⁶ have published lists of priority chemicals, or chemicals of concern, including because of persistence, they differ in their approach and focus, and are based on different criteria, such as the REACH PBT criteria, which do not include long-range transport potential (LRTP); and the POPs criteria under the Stockholm Convention, which do include LRTP³⁷.

A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. A review of the current state of science for POP fate assessment in order to prepare guidance for the development and review of POP risk profiles found that evaluating persistence entailed an assortment of supporting information and the need to address gaps and uncertainties³⁸.

The persistence criterion under REACH is defined in terms of degradation half-lives in water, soil or sediment. Degradation processes that transform a chemical – ultimately into water, CO₂ and salts – include microbial and chemical transformation reactions. In particular, microbial transformation (“biodegradation”) depends strongly on a variety of factors such as type of bacteria, composition of soil, temperature, humidity, presence of other chemicals, adaptation of microbes, etc. For these reasons, results from biodegradation tests are generally highly variable even for the same chemical. This means that the measurement of biodegradation half-lives is a challenging task that involves many uncertainties³⁹.

Established degradation tests include: (i) the test for ready biodegradation (“ready test”), described by OECD guidelines 301; (ii) the test for inherent biodegradability, described by OECD guidelines 302; and (iii) so-called simulation tests, for example as described by OECD guidelines 303⁴⁰. The ready test shows whether or not a chemical is easily biodegraded even under conditions that are not supportive of the biodegradation process. If a chemical passes this test, i.e. is readily biodegradable, its degradation half-life is on the order of 1–10 days. In such cases it can be concluded almost with certainty that the chemical is not persistent. If a chemical does not pass the test, i.e. is not readily biodegradable, its half-life cannot be quantified on the basis of the test result. It can be anything between 20–30 days and many years or even decades.

³⁴ UNEP 2013b.

³⁵ Scheringer, M. *et al.*, 2012.

³⁶ Brown, T.N. & Wania, F., 2008; Walker, J.D. & Carlsen, L., 2002; Muir, D.C.G. & Howard, P.H., 2006; Howard, P.H. & Muir, D.C.G. 2010.

³⁷ Scheringer, M. *et al.*, 2012.

³⁸ Boethling, R. *et al.*, 2009.

³⁹ Brillet, F. *et al.*, 2016.

⁴⁰ OECD, 2001; OECD, 2002; and other tests.

The test for inherent biodegradability is not very common; it applies conditions that are more supportive of the biodegradation process (such as a co-substrate for the bacteria to metabolize) than those of the ready test. If a chemical passes this test, this means that the chemical has at least a potential for biodegradation (this is meant by “inherent biodegradability”) and it may or may not be persistent⁴¹.

The most informative results in terms of biodegradation half-lives are obtained from simulation tests, where the conditions in a sewage treatment plant or soil are simulated. Often these tests are performed with carbon 14 (14C)-labeled chemicals because then all the carbon that was provided in form of the test chemical can be tracked with a Geiger counter and the transformation products on the way from the test chemical to CO₂ may be identified. However, this procedure is time- and labor-intensive and expensive. Under REACH, simulation tests are required only for chemicals manufactured or imported above 100 tonnes per year. For many chemicals where persistence is predicted, e.g., because of chemical structure, no simulation test results are available⁴².

While lower tier tests such as ready and inherent biodegradability tests (OECD 301 and OECD 302 test series) are relatively inexpensive (between €1,500 and €3,200 per test), simulation tests as described above using 14C labeling are expensive and time consuming. The costs associated with these tests depend on the exact test design, and with this caveat the costs are estimated to be between €80,000 and €120,000. The additional cost for synthesis of 14C-labeled test items of around €20,000 to €40,000 should also be considered when estimating the costs associated with these tests⁴³. As mentioned previously, chemicals behave differently under different environmental conditions, so more thorough testing requires not just testing in different media, but simulation of different environmental conditions in these media. The following table gives cost estimates for different simulation studies in different media.

Table 2 Estimated costs associated with multimedia simulation tests⁴⁴

Test type	Estimated cost
OECD 307 study (Aerobic and anaerobic transformation in soil) with 4 different soils and radiolabeled test item:	€88,000
OECD 308 study (Aerobic and anaerobic transformation in aquatic sediment systems) with 2 different water/sediment systems and radiolabeled test item	€109,000
OECD 309 study (Aerobic mineralisation in surface water) with 1 natural water and radiolabeled test item	€55,000

Note that the costs of simulation tests depend strongly on the properties and behaviour of the substance being tested.

Long or very long half-lives are particularly difficult to measure in simulation tests because the test has to be run for many weeks or months. This obviously increases the costs substantially. It also means that the degradation half-lives of (very) persistent chemicals have to be extrapolated from results of a few percent degradation during the time for which a test was run (for example, a three-month long simulation test might result in 6% degradation; because the point in time when 50% are degraded will not be reached, the degradation half-life is calculated on the basis of the partial degradation).

In addition, degradation half-lives can be estimated from field data in cases where a chemical was applied (pesticides such as DDT) or spilled (PCBs) at a given time and its residues in the soil are determined over several years. This is the source of soil degradation half-lives of many POP

⁴¹ OECD, 2009.

⁴² Scheringer, M. *et al.*, 2006.

⁴³ Cost estimates provided by Hydrotex GmbH.

⁴⁴ Cost estimates provided by Eurofins Agrosience Services EcoChem GmbH.

pesticides; these half-lives are often on the order of 10 to 20 years or more. However, this source of information on biodegradation is limited to just a few chemicals that have been monitored over many years, and is not a testing strategy⁴⁵.

Another option is provided by estimation methods that calculate a degradation half-life on the basis of the structure of the test chemical. In particular for (very) long half-lives, this may be the most efficient method for obtaining half-life data. An estimation tool that is often used because it is available from the US EPA website free of charge is BIOWINTM. This method was derived from biodegradation information for 200 chemicals with different structural elements (alkyl chains, amino groups, nitro groups, etc.). For each of these structural elements, a contribution to the degradation half-life is added to the estimate of the chemical's degradability. However, the BIOWIN model tends to catch a range of chemicals, not all of which are persistent.⁴⁶

A number of models that use Quantitative Structure- Activity Relationships (QSARs) exist, such as: KOWWIN, BIOWIN 2, BIOWIN 3, BIOWIN 6, OECD 301 C model and OECD 301 F model. Different combinations of tests can be used to derive estimates of persistence using estimated half-lives⁴⁷.

Current screening methods are based on limited information, and rely on data that is limited to structures and activity. The reliability of QSAR results strongly depends on whether or not the predicted substance is within the applicability domain of the model. The PROMETHEUS study attempted to integrate computer models to provide more accurate results, and the results suggests that integrations of computer models can produce more accurate predictions of persistence⁴⁸.

For a large number of existing substances on the (European) market, potential hazard has never been evaluated, since such an evaluation was not required in the past, or because their market volumes were so small. RIVM in the Netherlands has developed a Persistence/Bioaccumulation score that can be used as a tool to rapidly screen and assess data-poor substances for their potential persistence and bioaccumulation in the food chain⁴⁹. The tool was developed building on previous studies on PBT prioritization and selection and to improve on the set of chemicals, which could be analyzed. The aim of the study was to develop a methodology to screen a large set of chemicals and to identify those substances that show the most POP- or PBT-like properties.

The estimation methods described above could provide a way forward, e.g., for screening of new chemicals to avoid having those that are very persistent from entering the market or reaching high production volumes. They could also be used to cross-check whether the very persistent chemicals already on the market have been identified and the appropriate measures taken. However, no common framework for carrying out such screenings has been adopted or accepted.

A ECETOC task force⁵⁰ that reviewed recent literature linked to the 2011 amendments of Annex XIII of the REACH Regulation (introduction of new information and a 'weight-of-evidence' approach to assess whether a chemical meets the criteria for PBT or is regarded as vPvB) focused on certain aspects of persistence and bioaccumulation assessment. While the task force developed an integrated evaluation strategy, it also recommended further research on other topics where it found the science not sufficiently developed to allow regulatory conclusions to be drawn.

Weight-of-evidence is an approach used to evaluate evidence, where a number of studies exist showing different aspects of the problem, i.e. different exposure routes or where good quality studies

⁴⁵ See section 2.5.1.1 for examples of monitoring of PCBs and PDDE.

⁴⁶ Benfenati, E., *et al.*, 2016; Pizzo, F. *et al.*, 2013.

⁴⁷ Böhnhardt, 2013; Pizzo, F. *et al.*, 2013.

⁴⁸ Benfenati, E., *et al.*, 2016.

⁴⁹ Rorije, E. *et al.*, 2011.

⁵⁰ ECETOC, 2014.

show conflicting results. Relative weights are assigned to different sources of information/studies based on the following factors: quality of the data; consistency of results/data; nature and severity of effects; and the relevance of the information for the given regulatory endpoint. In all cases the relevance, reliability and adequacy for the purpose should be considered. The weight of evidence approach uses expert judgement to assign weights and assess the information.

Weight-of-evidence approaches provide a system for analysis where gaps in knowledge and outright contradictions between information or sources of information exist. Existing weight-of-evidence approaches have been criticized as either too formulaic or too vague, simply calling for professional judgment that is hard to trace to its scientific basis⁵¹. Hypothesis-based weight of evidence—that emphasizes articulation of the hypothesized generalizations, their basis, and span of applicability has been suggested as a way to improve upon weight of evidence approaches⁵².

Given the amount of chemicals that are potentially P or vP, better screening and testing methods are needed. Opportunities for improvement seem to lie between inherent biodegradability tests and simulation tests. There are several areas that should be explored. One is to improve accuracy of QSARs by using multiple *in silico*⁵³ methods as PROMETHEUS has illustrated. Another possibility is to improve the data or to add additional properties to the models that would improve their accuracy in predicting persistence.

2.3 WHICH (GROUPS OF) SUBSTANCES ARE PERSISTENT AND VERY PERSISTENT

The Stockholm Convention covers 26 substances and groups of substances which are acknowledged to meet the screening criteria to be considered persistent organic pollutants (POPs) within the meaning of the Convention. Three additional substances are under consideration for regulation under the Convention.

However, many more substances have been identified that meet the criteria for POPs. For example, a 2008 study⁵⁴ looked at a group of known Arctic contaminants and the extent of their resemblance to other chemicals, to develop a screening methodology that was then used to identify 120 high production volume chemicals out of 100,000 industrial chemicals with structural similarities or with partitioning properties that suggested they were potential Arctic contaminants.

Another study⁵⁵ applied screening criteria for persistence, bioaccumulation, long-range transport potential, and toxicity to a set of 93,144 organic chemicals. In addition to those chemicals already acknowledged as POPs under the Stockholm Convention or under review as POP candidates, another 510 chemicals were identified that exceeded all four criteria but had not been evaluated under the Convention. The study's dataset of substances did not include many pesticides, biocides, and pharmaceuticals. It also did not include siloxanes. Finally, inorganic substances, metallorganic substances and salts were removed from the database before the analysis took place. Because no experimental data on persistence was available for most of the chemicals, data on persistent properties had to be estimated on the basis of chemical structure, using BIOWIN™. Ranges of uncertainty for the chemical property data were used to estimate a lower (190) and upper (1200) bound for the numbers of potential POPs. Of these, 98 percent were halogenated, including the highly fluorinated chemicals.

Within the EU, the European Chemicals Agency (ECHA), Member State and Commission experts collaborate in mass screening, assessing and ultimately in identifying additional substances that are

⁵¹ Rhomberg, L., 2015.

⁵² Lutter, R. *et al.*, 2015.

⁵³ *In silico* is used to refer to a computer-based methodology, as opposed to an *in vitro* (test tube) or *in vivo* (animal)-based test methodology.

⁵⁴ Brown, T.N. & Wania, F., 2008.

⁵⁵ Scheringer, M. *et al.*, 2012.

PBT or vPvB and that should be added to the REACH Candidate List of substances to consider for inclusion in Annex XIV of REACH. The preparatory discussions are held in ECHA's PBT expert group. To date it has provided advice on some 160 substances under review as potentially PBT or vPvB. As of June 2016, 25 substances were evaluated as not PBT or vPvB, 19 were evaluated as appropriate for risk management action, and 10 were deemed potentially PBT but further action was postponed. Reviews were ongoing for the other 106 chemicals. New potential PBT/vPvB substances are added annually to the pool of on-going assessments. From the information available on the ECA website, it was not possible to determine how many substances may be of concern due to persistence alone.

A 2012 study⁵⁶ that screened a set of 95,000 chemicals for P, B and T thresholds as defined in REACH legislation highlighted that uncertainty concerning the number of potential PBT chemicals was particularly due to uncertainty with respect to persistence data.

The first chemicals to be classified as persistent were hydrophobic, or water repelling⁵⁷, including the original set of POPs listed in the Stockholm Convention. However, today a number of chemicals considered hydrophilic, i.e. with an affinity for water⁵⁸, are also recognised as very persistent. With the addition of perfluorooctanesulfonate (PFOS), chlordecone, hexachlorocyclohexane (HCH) isomers and endosulfan, the chemicals addressed by the Stockholm Convention are no longer solely hydrophobic.

While many persistent and hydrophobic compounds can be removed from water by sorption processes in the environment or during water treatment, the hydrophilic substances cannot, and there is a higher likelihood that they might be found in drinking water⁵⁹. Some scientists are therefore arguing that persistent, mobile and toxic (PMT) substances should be considered of equivalent concern as PBT substances⁶⁰. The persistence and mobility of the highly-fluorinated chemicals is discussed below and other persistent hydrophilic compounds are covered in section 2.5.4.

2.4 THE CASE OF HIGHLY FLUORINATED CHEMICALS

Highly fluorinated chemicals (HFCs) have been widely produced and marketed for use since the 1950s. The term is used here to cover the large group of compounds characterised by a fluorine-carbon bond. The persistence of the fluorine-carbon bond means that these chemical compounds are also very stable and durable. They are very efficient surfactants as well, and useful for a broad range of applications, e.g., cosmetics, firefighting foams, food contact materials, inks, medical devices, oil production, pesticide formulations, mining, textiles, apparel, and home furnishings⁶¹.

This case study focuses largely on the per- and polyfluorinated alkyl substances known collectively as PFASs. However, it recognises that other man-made chemicals with this fluorine-carbon bond may also pose problems due to their environmental persistence. In addition to historical uses of PFAS, other significant sources of HFCs may include (bio)degradation of various side-chain fluorinated polymers, and atmospheric degradation of hydrofluorocarbons and hydrofluoroethers⁶². For example, the dominant atmospheric source of trifluoroacetic acid (TFA) -- one of the haloacetic acids found in polar regions that is resistant to degradation -- is from decomposition of the fluorocarbons HFC-134a, HCFC-123, and HCFC-124⁶³.

⁵⁶ Stempel, S. *et al.*, 2012.

⁵⁷ Chandler, D.L., 2013.

⁵⁸ Ibid.

⁵⁹ Reemtsma, T, *et al.*, 2016.

⁶⁰ Ibid.

⁶¹ KEMI, 2015.

⁶² OECD, 2015b.

⁶³ Martin, J.W. *et al.*, 2003.

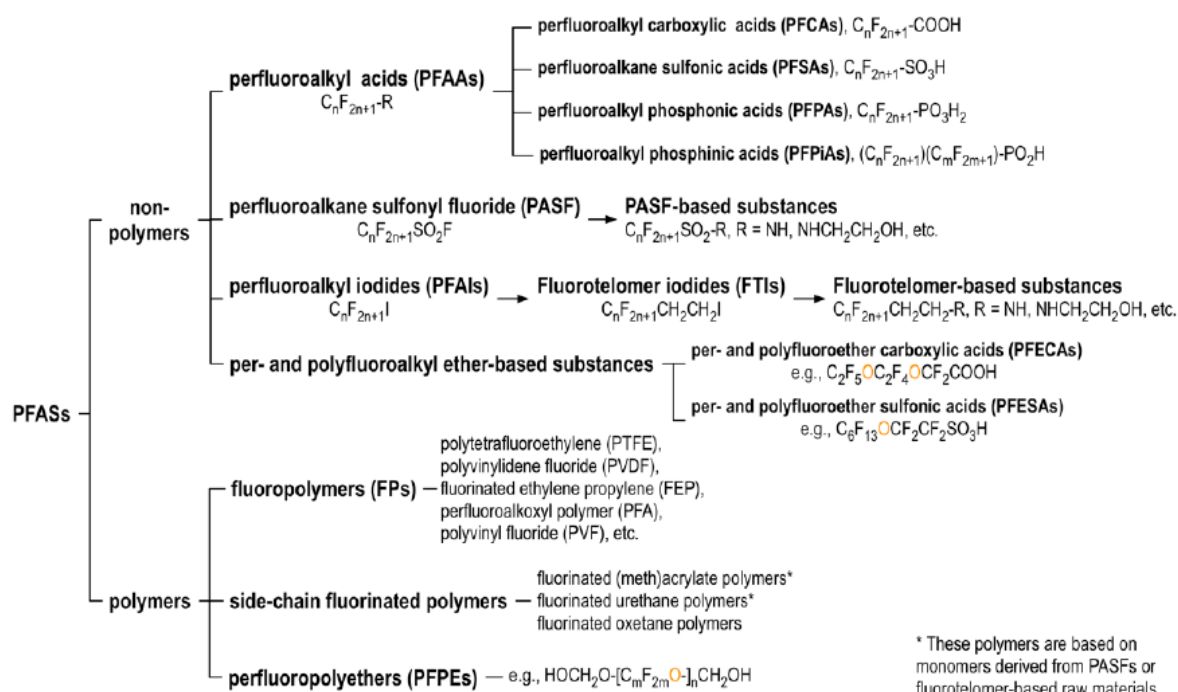
Moreover, as section 1.1 already notes, two of the biggest threats to our global environment are linked to highly persistent fluorinated compounds – the ozone-depleting substances which react chemically with the molecules comprising the stratospheric ozone layer, and the contribution of the F-gases with high Global Warming Potential (GWP) to climate change. In fact, a direct F-gas connection exists in that combustion of some fluorinated polymers is known to release F-gases⁶⁴. This source of F-gases has not yet been taken into account under the Montreal Protocol.

The per- and polyfluorinated alkyl substances (PFAS) are a subgroup of the group of highly fluorinated chemicals, and they are characterised by chains of carbon and fluorine bonds. The focus during the first decades of commercialisation of these compounds was on long-chain PFASs – the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. Of these, PFOS and PFOA were the most widely produced. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, and regulatory pressure has led to phase-outs of their manufacture and use in the USA and Europe.

At the same time, a geographical shift in their manufacture has taken place and the long-chain PFASs are now produced in large volumes in the emerging Asian economies, notably China and India⁶⁵. The concern about harm to human health and the environment due to emissions to the environment of long-chain PFAS is now global, as reflected by the designation of PFOS as a persistent organic pollutant under the Stockholm Convention⁶⁶.

In many cases the long-chain PFAS have been replaced by short-chain homologues -- the C-6s and C-4s. The diagram on the below gives an idea of the many different types of compounds that form part of the overall grouping of PFAS⁶⁷.

Figure 2: Different types of compounds in the grouping PFAS



⁶⁴ Huber, S. *et al.*, 2009.

⁶⁵ OECD, 2015b.

⁶⁶ UNEP, 2001.

⁶⁷ OECD, 2015b, p. 24.

Two statements issued by scientists in the last two years -- the Helsingør Statement⁶⁸ and the Madrid Statement⁶⁹ -- have highlighted the health and environmental risks posed by the highly fluorinated chemicals as a group. The statements emphasise the extreme persistence of the carbon-fluorine bond in nature, and call for regulatory as well as non-regulatory actions to address the risks associated with all highly fluorinated chemicals, including the short-chain PFAS.

The FluoroCouncil, which represents the major producers of per- and polyfluorinated chemicals at global level, has responded to the Madrid Statement by acknowledging the problems of toxicity and bioaccumulability associated with the long-chain PFASs but emphasising that development of the short-chain alternatives had addressed these problems⁷⁰. It has pointed out that the environmental persistence of these compounds is closely related to the stability and durability which makes them useful, and asserted that ‘[d]ecisions on the societal acceptability of strategic materials such as PFASs cannot be wisely made on a single attribute such as persistence’.

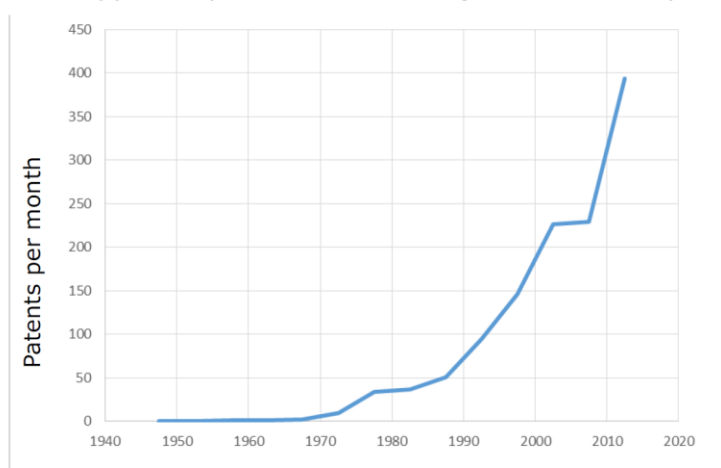
Two types of PFAS chemistries -- fluoropolymers and fluorotelomers – are commercially important. The fluoropolymers are widely used as linings for pipes, valves and tanks for chemical and pharmaceutical manufacturers; as lightweight, durable tubing and hoses for aircraft and land vehicles; and to enable high speed data transfer via communication devices. The fluorotelomer-based polymers provide water and oil repellency and are used in surface finishes for textiles and food packaging, and in firefighting foams.

Some 3,000 PFAS are estimated to be on the global market at this time⁷¹. A large proportion are polymers and therefore exempted from registration under REACH; of the others, only a few are registered. Very little information is available on quantities produced and, for half of all PFAS, almost no information can be found concerning their uses. However, the figure below, which shows how many patents with “perfluor” in the patent text are approved in the USA each month, gives an idea of how the number of uses for perfluorinated substances is burgeoning.

Figure 3: Number of approved patents in US with “perfluor” in the patent text⁷²

PATENT TREND

Number of approved patents in US with “perfluor” in the patent text



⁶⁸ Scheringer, M. *et al.*, 2014a.

⁶⁹ Blum, A. *et al.*, 2015.

⁷⁰ Bowman, J.S., 2015a.

⁷¹ KEMI, 2016.

⁷² Fischer, S., 2017.

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations.

While the environmental and health effects of PFOS and PFOA have been widely studied, many of the thousands of other PFAS still produced and used have been overlooked by researchers, and few control measures set in place. Indeed, the issue of PFAS as a whole has been called “*an intractable, potentially never-ending chemicals management issue that challenges the conventional chemical assessment and management paradigm adopted by society since the 1970s*”⁷³.

Environmental persistence and pathways to the environment

As discussed earlier in this sub-study, the criteria under REACH for determining if a substance is ‘very persistent’ is whether its half-life for biodegradation is shown to be more than 60 days in water, and more than 180 days in sediment or soil⁷⁴. The degradation half-lives of PFASs, where such information is available, indicates a persistence of a totally different magnitude. One study estimated the half-life for PFOS as >41 years⁷⁵, but conceded it could be significantly longer than 41 years, because almost no degradation was observed during the period of the test. Scientists who study these chemicals have estimated that they will persist for hundreds of years⁷⁶.

The evidence available to date indicates that the new short-chained alternatives are also extremely persistent. Some degradation may occur by the chains breaking into smaller molecules but these still have the persistence of the fluorine-carbon bond. A report for the FluoroCouncil concluded that all of the five short-chain alternatives evaluated met the Stockholm Convention’s criteria for persistence – whether as the actual substance evaluated or as their terminal degradation products (PFHxA/PFHx)⁷⁷. Since data on the degradation half-life of perfluorohexanoic acid (PFHxA) in soil, sediment, and water was not available, the Environ study carried out a read-across from degradation studies of PFOA and concluded that PFHxA is not likely to degrade under normal environmental conditions⁷⁸. Other studies also conclude that the perfluorinated parts of fluorinated alternatives, i.e., the short-chained PFASs, will form transformation products that will persist in the environment⁷⁹.

Per- and polyfluorinated alkyl substances reach the environment through a number of routes. According to a Swedish Environmental Protection Agency study, the largest direct point source of PFAS is its use in firefighting foams primarily at airports and military bases⁸⁰. Water supplies with measurable PFAS levels were higher within 1 km of a potential source of PFAS, though PFAS was also found in water supplies far from known point sources. The use of firefighting foams has resulted in widespread contamination of groundwater at airports and military bases⁸¹, including in The Netherlands, Germany, and Sweden. Because PFAS contamination of groundwater near firefighting practice sites has been found so frequently once it is looked for, it is highly likely that similar contamination underlies the commercial or military airfields of the other Member States.

⁷³ Wang, Z., *et al.*, 2017.

⁷⁴ These are also the criteria used under the Stockholm Convention for determining whether a substance is persistent.

⁷⁵ Hekster, F.M. *et al.* 2002.

⁷⁶ Russell, M.H. *et al.*, 2008; Washington, J.W. *et al.*, 2009.

⁷⁷ ENVIRON International Corporation, 2014.

⁷⁸ See also Post, G.B. *et al.*, 2012.

⁷⁹ Hurley, M.D. *et al.*, 2004; Liou, J.S. *et al.*, 2010; Liu, J. *et al.*, 2013.

⁸⁰ Naturvårdsverket, 2016.

⁸¹ Cousins, I.T. *et al.*, 2016.

Why is the persistence of PFASs different from that of other chemicals?⁸²

Typically, the persistence of an organic chemical depends on the interplay of chemical properties (and the underlying chemical structure, which defines the properties), on the one hand, and the environmental conditions, such as intensity of light or presence of certain bacteria, on the other hand. This is why in many cases the persistence of a chemical is not just a certain value, but varies widely depending on the environmental conditions. Of course, there is still an important or even dominant influence of the chemical structure: chemicals that are readily biodegradable such as ethanol or glucose are degradable under virtually all relevant environmental conditions; chemicals such as PCBs that are hard to degrade because of the stability of the carbon-chlorine bond will never be readily biodegradable under any kind of environmental conditions. However, even for PCBs or DDT, in particular when they reside in the soil, there is a wide range of degradation half-lives depending on soil conditions (soil moisture, presence of bacteria, adaptation status of bacteria, presence of other substances that can be metabolized easily by the bacteria and support co-metabolizing of the contaminant, etc.). This is why in some studies on environmental persistence of DDT residues of many years or decades is reported whereas others report faster disappearance. Even for the herbicide, atrazine, there is a study where the authors found atrazine residues in soil samples that were more than 20 years old. Normally, the persistence of atrazine is assumed to be on the order of months.

For PFASs, specifically for perfluorinated carboxylic and sulfonic acids (PFCAs and PFSA), the situation is different. PFCAs and PFSA are so stable that they do not degrade under any environmental conditions. In other words, their persistence does not depend on the environmental conditions; none of the many variable factors that are present in the environment does modify the persistence of PFCAs and PFSA. This is unique and makes PFCAs and PFSA different as a class. This is also why we are fully certain that their persistence is so high: we know that there are no conditions that would lead to an increase in their degradation rates. For other chemicals, we do not have this certainty just because of the influence of environmental factors that modulate the persistence, even for PCBs or DDT. PFCAs and PFSA can be broken down, of course, but only under conditions that are so harsh, e.g. incineration at very high temperatures, e.g. 1,100°C, they do not occur in the normal environment⁸³.

Other PFASs such as fluorotelomer alcohols etc. eventually are transformed into PFCAs or PFSA. This transformation process depends on environmental conditions as described above; it may take a few days, weeks or months. However, in the end they always form a totally persistent acid and that is why they should certainly be included in the persistence assessment in the same way as PFCAs and PFSA.

Wastewater treatment and disposal and treatment of waste are also considered important secondary point sources, along with releases from industrial production processes. Laundering of PFAS-treated textiles or use of personal care products containing PFASs has led to their presence in urban wastewater and in the treated biosolids subsequently used as agricultural soil supplements⁸⁴.

The behavior of the HFCs in the environment is due in part to their physical properties. Many are water-soluble and mobile in soil, thus posing a threat to groundwater. Certain HFCs are volatile, and prone to long-range atmospheric transport. The two most widely studied PFAS -- PFOS and PFOA -- are non-volatile and only moderately water soluble; yet they are found even in remote regions like the European Arctic areas⁸⁵.

Because of the extreme persistence of these substances, concerns have been expressed about whether their releases into the environment might reach concentration levels that could breach so-called 'planetary boundaries' -- a point at which the earth is no longer able to assimilate or degrade a human-released chemical which is discovered only too late to have a disruptive effect on a vital earth system, and the effects of the pollutant cannot be readily reversed⁸⁶. The Helsingør Statement points out that the short-chain PFASs being introduced as alternatives are less efficient from a technical point of view, and therefore larger quantities may be needed to achieve the same performance as the longer chained PFAS, with the potential of increasing the overall load of highly fluorinated chemicals in the environment⁸⁷.

⁸² Personal communication from Martin Scheringer, 21 May 2016.

⁸³ Wang, Z. *et al.*, 2015.

⁸⁴ Ahrens, L. *et al.*, 2011.

⁸⁵ Jahnke, A., 2007.

⁸⁶ Persson, L.M. *et al.*, 2013; Diamond, M.L. *et al.*, 2015.

⁸⁷ Scheringer, M. *et al.*, 2014a.

Health impacts

Human exposure to highly fluorinated chemicals is a growing concern. Significant sources of human exposure to PFAS include drinking water⁸⁸, diet⁸⁹ and household dust⁹⁰. Studies of plants grown in PFAS-contaminated soils and reclaimed water demonstrated that these substances can bioaccumulate, with long chain PFAS tending to stay in shoot or root crops and short chain PFAS moving into leaves and fruits, e.g., lettuce and strawberries⁹¹.

Migration to food from food contact materials⁹² is another concern. A 2017 study carried out by consumer groups in Belgium, Italy, Denmark, Spain and Portugal found that a third of the 65 samples of fast food packaging tested contained high levels of fluorinated compounds⁹³.

Most of the studies of health impacts from highly fluorinated chemicals to date have focused on PFOS and PFOA, the long-chained substances that have been in use since the 1950s, and the evidence of their risks to human health has only been discovered over time⁹⁴. Some of the long-chain PFAS are known to be toxic, as well as bioaccumulative. However, in contrast to persistent chlorinated and brominated compounds, which are lipophilic and bioaccumulate in fatty tissues, the PFAS bioaccumulate in organ and muscle tissues. They have been detected in human blood and breast milk as well as in other biota around the globe. The table below indicates half-lives for selected PFAS in mouse and human serum.

Table 3: Persistence of selected PFAS in mouse and human serum⁹⁵

Serum half-life	PFBS (C4)	PFHxS (C6)	PFOS (C8)	PFBA (C4)	PFHxA (C6)	PFOA (C8)	PFNA (C9)
Mouse	5 hours	30 days	40 days	12 hours	2 hours	20 days	60 days
Humans	28 days	8.5 years	4-5 years	3 days	32 days	3-4 years	unknown

Elevated exposures to PFASs in adults have been linked to hepatocellular damage affecting liver function in adults⁹⁶ and obesogenic effects in females⁹⁷. Fetal exposure to PFAS has been associated with reduced birthweight and length of gestation⁹⁸, as well as reduced immune response to routine childhood immunizations⁹⁹.

Particularly convincing evidence of effects on human health has emerged because of a legal settlement in 2005 with the company Dupont, because of the exposure of some 70,000 persons via drinking water contaminated by discharges from a West Virginia manufacturing facility operated by Dupont. The legal settlement included an obligation to monitor the exposed population. The resulting C8 Health Project Monitoring has gathered epidemiological evidence of associations between PFOA exposures and later age of sexual maturation¹⁰⁰, alterations of thyroid hormone levels among children¹⁰¹, ulcerative colitis¹⁰² and kidney and testicular cancer¹⁰³.

⁸⁸ Post, G.B. *et al.*, 2012; Rahman, M.F. *et al.*, 2014; Eschauzier, C. *et al.* 2012.

⁸⁹ Tittlemier, S.A. *et al.*, 2007.

⁹⁰ Björklund, J. *et al.*, 2009 ; Shoeib, M. *et al.*, 2011 ; Liu, J. *et al.*, 2013.

⁹¹ Higgins, C.P., 2017.

⁹² Begley, T.H. *et al.*, 2008; D'Eon, J.C. *et al.*, 2007.

⁹³ *ENDSEurope*, 10.03.2017.

⁹⁴ Grandjean, P. & Clapp, R., 2014.

⁹⁵ Stynar, M., 2017.

⁹⁶ Gallo, V. *et al.*, 2012.

⁹⁷ Halldorsson, T.I. *et al.*, 2012.

⁹⁸ Fei, C. *et al.*, 2007.

⁹⁹ Grandjean, P. *et al.*, 2012.

¹⁰⁰ Lopez-Espinos, M. *et al.*, 2011.

¹⁰¹ Lopez-Espinos, M. *et al.*, 2012.

¹⁰² Steenland, K., *et al.*, 2013.

¹⁰³ Barry, V. *et al.*, 2013.

While producers of the short-chain alternatives have put forward data showing that they do not pose the same risks to human health and the environment¹⁰⁴, information on the structures, properties and toxicological profiles of the short-chain fluorinated alternatives needed to confirm this reduction in risk is not publicly available¹⁰⁵. However, evidence is emerging that the new short-chain alternatives are also problematic in terms of risks to health. For example, tests carried out using the chemical sold by Dupont as an alternative to PFOA under the name GenX have found numerous health effects in animals, including changes in immune responses, cholesterol levels, reproductive problems and cancer¹⁰⁶. In the meantime, levels of some alternatives or their degradation products in the environment and in human tissues have been rising¹⁰⁷. This implies more frequent exposures.

From an environmental point of view, the widespread occurrence of highly fluorinated substances is also a concern. PFOA has been found in the biota of remote regions where no direct source of PFOA is known, including in top predators such as polar bears¹⁰⁸. Studies on dolphins, caribou and Arctic food chains have found indications of bioaccumulability. On the other hand, PFOA shows low bio-concentration in fish because it is eliminated quickly through the respiratory system of fish due to its high solubility, in contrast to humans where elimination is on the scale of years¹⁰⁹.

Data concerning the specific health effects such exposures may be having on biota is sparse. Female mice exposed as foetuses to low doses of PFOA had significant delays in puberty progress, which is in line with the findings of human epidemiological studies¹¹⁰. Moreover, PFAA exposure in general appears to be linked to hepatotoxicity, i.e. the capacity to injure the liver¹¹¹.

Regulatory and voluntary actions to date

International level

At international level, both the Stockholm Convention and the UNECE POPs Protocol list perfluorooctane sulfonic acid and perfluorooctane sulfonyl fluoride (PFOS) as POPs to be restricted, except for a number of ‘acceptable purposes’ and ‘specific exemptions’ for which production and use may continue. PFOA is among the substances currently under consideration for addition to the Stockholm Convention as a POP¹¹².

In the context of the Strategic Approach to International Chemicals Management (SAICM), the second (2009) session of the International Conference on Chemicals Management (ICCM2) adopted resolution II/5 on “managing perfluorinated chemicals and the transition to safer alternatives”¹¹³. A progress report distributed at the 2012 session¹¹⁴ describes the work carried out since 2009. Most notably, in light of the geographical shift in production of long-chain PFAS from the OECD countries to the emerging Asian economies and to facilitate the participation of all interested governments and stakeholders, the previous OECD PFC Steering Group was replaced by- a global PFC group. Secretariat support is provided jointly by the OECD and UNEP.

In addition to establishing a PFC web portal¹¹⁵, the Global PFC Group has published a consolidated

¹⁰⁴ Bowman, J.S., 2015b.

¹⁰⁵ Scheringer, M. *et al.*, 2014a.

¹⁰⁶ Lerner, S., 2016a.

¹⁰⁷ Ahrens, L. *et al.*, 2011; Glynn, A. *et al.*, 2012.

¹⁰⁸ Vierke, L., *et al.*, 2012.

¹⁰⁹ Ibid.

¹¹⁰ Wang, Z, *et al.*, 2017.

¹¹¹ Wang, Z., *et al.*, 2016.

¹¹² UNEP/POPS/POPRC.11/5 (2015)

¹¹³ SAICM/ICCM.2/15 (2009).

¹¹⁴ SAICM/ICCM.3/18 (2012).

¹¹⁵ www.oecd.org/ehs/pfc.

synthesis paper¹¹⁶, which inter alia summarises scientific evidence on potential adverse effects on humans of PFASs, regulatory approaches to date, and recent developments on alternatives to long-chain PFASs. A survey conducted by the Global PFC Group resulted in a 2015 publication that provides a snapshot of risk reduction approaches for PFASs in selected countries, as well as information about options for risk reduction of PFASs¹¹⁷.

EU level

At EU level, PFOS is restricted under the 2004 POPs Regulation¹¹⁸ implementing the Stockholm Convention, except for a number of ‘acceptable purposes’ and ‘specific exemptions’ for which production and use may continue. PFOA is also under consideration for restriction under the Stockholm Convention.

A few PFASs are regulated under REACH. Annex XVII on Restrictions, Entry 30, restricts substances classified as CMR 1A or 1B from being placed on the market or used as substances, as constituents of other substances or in mixtures for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than the relevant concentration limit. The following PFASs are listed as being toxic to reproduction 1B (R1B)¹¹⁹.

Table 4: HFCs listed as toxic to reproduction (1B) under Annex XVII

REACH Annex XVII	Reason for inclusion & reference to amending legislation
Perfluorooctane sulfonic acid	R – 1B (M14)
Heptadecafluorooctane-1-sulfonic acid;	R – 1B (M14)
Potassium perfluorooctanesulfonate	R – 1B (M14)
Potassium heptadecafluorooctane-1-sulfonate;	R – 1B (M14)
Diethanolamine perfluorooctane sulfonate;	R – 1B (M14)
Ammonium perfluorooctane sulfonate;	R – 1B (M14)
Ammonium heptadecafluorooctanesulfonate;	R – 1B (M14)
Lithium perfluorooctane sulfonate;	R – 1B (M14)
Lithium heptadecafluorooctanesulfonate	R – 1B (M14)
Ammoniumpentadecafluorooctanoate	R – 1B (M25)
Perfluorooctanoic acid	R – 1B (M25)

Under REACH Article 59, substances identified as meeting the Article 57 criteria are to be placed on a candidate list for eventual inclusion in Annex XIV as subject to authorisation. The following highly fluorinated substances are on the candidate list maintained by the ECHA¹²⁰:

Table 5: HFCs on candidate list for Annex XIV

Candidate List	Reason for inclusion
Nonadecafluorodecanoic acid (PFDA) and its sodium and ammonium salts: <ul style="list-style-type: none"> ■ Nonadecafluorodecanoic acid; ■ Decanoic acid, nonadecafluoro-, sodium salt 	Toxic for reproduction; PBT
Perfluorononan-1-oic-acid and its sodium and ammonium salts (PFNA): <ul style="list-style-type: none"> ■ Ammonium salts of perfluorononan-1-oic-acid; ■ Perfluorononan-1-oic-acid; and ■ Sodium salts of perfluorononan-1-oic-acid 	Toxic for reproduction; PBT
Pentadecafluorooctanoic acid (PFOA)	Toxic for reproduction; PBT

¹¹⁶ OECD, 2013.

¹¹⁷ OECD, 2015a.

¹¹⁸ Regulation (EC) No 850/2004, p.7.

¹¹⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:LATEST:EN:PDF> (accessed 17.05.2016).

¹²⁰ <http://echa.europa.eu/web/guest/candidate-list-table> (accessed 17.05.2016).

Note that REACH exempts polymers from registration¹²¹. There is concern that, while the fluoropolymers are true polymers, the side-chain fluorinated polymers and polyfluorinated ethers increasingly found on the market may not be true polymers¹²² and therefore may be falling through the controls set in place under REACH.

The PBT working group coordinated by the European Chemicals Agency (ECHA) is jointly developing a work plan to restrict the use of PFAS in the EU through classification, SVHC/authorisation and restrictions. The network foresees regulating PFAS by utilising methods of grouping¹²³.

For example, Germany and Norway put forward a proposal for restriction of the manufacturing, marketing and use of PFOA (considered a group comprising some 500 substances) for discussion by the REACH committee of Member States in early July 2016. In December 2016 the committee approved a proposed restriction which would ban the use of the chemical in fire-fighting foams and certain other uses three years after the entry into force of the amendment to REACH. It included a number of deferrals for specific products which were less strict than those proposed by Germany and Norway¹²⁴. The proposed amendment is now with the European Parliament and the Council, and is expected to be adopted by the end of April 2017.

Other substance evaluations which are under way or envisioned include:

- **PFHxS** (perfluorohexane sulfonic acid). Sweden has submitted a proposal for identification of this substance as vPvB and to include it on the Candidate List.
- **PFCA C9-C14**. Sweden and Germany are cooperating on preparation of a restriction dossier for PFCAs and their precursors, with submission expected early 2018. The substances are on the Candidate List.
- **PFNA** (perfluorononanoic acid). This is now on the Candidate List. Sweden and Germany are cooperating on the compilation of a dossier proposing a restriction as part of the C9-C14 grouping.

In 2017, the European Food Safety Authority (EFSA) initiated a reevaluation of its 2008 scientific opinion on health impacts of PFOS and PFOA in the food chain¹²⁵. The reevaluation will review the total daily intake (TDI) levels of 150 nanograms per kilogram of body weight per day for PFOS and 1,500 nanograms per kilogram of body weight per day for PFOA established in the 2008 opinion.

Finally, a review of Annex X to the Water Framework Directive (2000/60/EC) led to a 2012 proposal to revise the list of priority substances in the field of water policy and inter alia to include perfluorooctane sulfonic acid and its derivatives (PFOS) as a priority hazardous substance presenting a significant risk to or via the aquatic environment¹²⁶.

National level in Europe

The Swedish Government commissioned the Swedish Chemicals Agency (KEMI) to prepare a national action plan on PFASs, aimed at increasing awareness and reducing use of these extremely persistent chemicals¹²⁷. The first target is to eliminate the use of highly fluorinated substances in

¹²¹ REACH, Article 3.5 defines a polymer as meaning a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

¹²² Posner, S., 2017.

¹²³ Communication from the Danish Environmental Protection Agency.

¹²⁴ "Commission moves forward with PFOA restrictions", *ENDsEurope*, 17.01.2017.

¹²⁵ EFSA, 2008.

¹²⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52011PC0876> (accessed 17.05.2016).

¹²⁷ KEMI, 2016.

firefighting foam, since this has been the main source of releases to the environment of HFCs. Other actions foreseen include facilitation of voluntary measures by companies to reduce use of PFAS in sectors such as textiles and food packaging, and requirements to report to Sweden's product register targeting PFASs.

In Denmark, some efforts have been taken to restrict PFASs both at government and company level. In 2015, the government issued a guideline limit ("advisory ban") on the use of PFASs in paper and cardboard food packaging, with the aim of ultimately turning the guideline into a binding prohibition¹²⁸. In response, the country's largest retailer (Coop) speeded up a commitment it had already made to phase out PFASs. It announced that it would refuse to distribute popcorn products packaged in PFASs-coated cardboard and noted that alternative packaging was available¹²⁹.

Norway enacted regulations in 2013 to restrict the production, import, export or sale of consumer products containing PFOA in consumer products if certain limit values were exceeded. This resulted in a legal reprimand from the European Free Trade Association in the form of a reasoned opinion, which found that the 2013 regulations were an inappropriate unilateral action. As already mentioned earlier in this section, Norway then teamed up with Germany in putting forward a proposal to restrict PFOA at EU level. The proposal is for a total ban on manufacture, marketing and use of PFOA, its salts, and related substances, though a number of derogations would be allowed, e.g., manufacturing and use of short chain alternatives as long as no other alternatives are available, use in semiconductor photolithographic processes, certain photographic coatings, firefighting foams already on the market, etc.

National level elsewhere

The US EPA has targeted PFASs for special action for several decades, starting with PFOS, which has not been reported as manufactured or imported into the UEA since 2002. In 2006, it invited eight companies (Arkema, Asahi, BASF, Clariant, Daikin, 3M/Dyneon, DuPont, Solvay Solexis) to join the PFOA Stewardship Program, under which they committed to achieve, by 2010, a 95 percent reduction in global facility emissions of PFOA to all media; in precursor chemicals that break down to PFOA, and in product content levels. They also committed to work towards elimination of PFOA from emissions and products by 2015¹³⁰, and to submit annual progress reports on their reductions of PFOA.

In 2015, the US EPA proposed 'Significant New Use Rules: Long-chain perfluoroalkyl carboxylate and perfluoroalkyl sulfonate chemical substances', which would require notification of any manufacturing (including importing) of certain long-chain PFACs at least 90 days in advance, in order to provide the opportunity to evaluate the intended use and, if necessary, to protect against potential unreasonable risks by prohibiting or limiting that activity before it occurs. This action is still pending¹³¹.

In the same vein, the US Food and Drug Administration (FDA) issued a rule in 2016 banning the use of three specific perfluoroalkyl ethyl containing food-contact substances (FCSs) as oil and water repellents for paper and paperboard for use in contact with aqueous and fatty foods in the face of new information on the substances' toxicity. The order was in response to a petition filed by the Natural Resources Defence Council and a number of other organisations and came into effect on February 4th, 2016.¹³²

Most recently, in May 2016, the US EPA issued a lifetime drinking water health advisory (HA) for PFOA of 0.07 micrograms per liter based on a reference dose (RfD) derived from a developmental

¹²⁸ TAPPI, 2016.

¹²⁹ Buck, 2015.

¹³⁰ EPA, 2014a; also <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/and-polyfluoroalkyl-substances-pfass-under-tsca> (accessed 19.05.2016).

¹³¹ <https://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2013-0225-0001> (accessed 19.05.2016).

¹³² US FDA, 2016.

toxicity study in mice; the critical effects included reduced ossification in proximal phalanges and accelerated puberty in male pups following exposure during gestation and lactation. It also issued a similar lifetime drinking water health advisory (HA) for PFOS of 0.07 micrograms per liter based on a reference dose (RfD) derived from a developmental toxicity study in rats; the critical effect was decreased pup bodyweight following exposure during gestation and lactation. The guidance recommends that when these two chemicals co-occur at the same time and location in a drinking water source, a conservative and health-protective approach would be to compare the sum of the concentrations ([PFOA] + [PFOS]) to the HA.¹³³ Dozens of US municipalities now find themselves in non-compliance with this advisory standard¹³⁴.

Canada has targeted PFOS for regulatory action since 2006, when it published an assessment of PFOS and concluded that they were entering the environment under conditions that could have immediate or long-term harmful effects on the environment. Regulations adopted in 2008¹³⁵ prohibit the manufacture, use, sale, offer for sale and import of PFOS and products containing PFOS, with certain exceptions (aqueous film forming foam, products manufactured and imported before May 2008; and coatings for photographic films, papers and printing plates). In 2009 Environment Canada issued regulations adding PFOS and its salts to Canada's Virtual Elimination List¹³⁶.

In 2010 it negotiated a voluntary 'Environmental performance agreement respecting PFCAs and their precursors in perfluorochemical products sold in Canada' with four companies (Arkema Canada, Asahi Glass, Clariant Canada and Dupont Canada) which committed them to work toward the elimination of residual PFOA and long-chain PFCAs¹³⁷. The agreement expires in 2015.

Canada's efforts also include a 2015 proposal to amend the 2012 Prohibition of Certain Toxic Substances Regulations to add PFOA and long-chain PFCAs to the regime covering PFOS. The proposed amendments would prohibit the manufacture, use, sale, offer for sale, or import of PFOA and LC-PFCAs, unless present in manufactured items, from the coming into force of the amendments. Use in aqueous film-forming foams (AFFF) used in fire protection applications would still be allowed, as well as a temporary permitted use for these substances in water-based inks and photo media coatings until the end of 2016.¹³⁸

Note that these regulatory efforts are almost all targeted at the long chain PFAS, i.e., the C-8s. While the short chain PFAS are also extremely persistent, to date they have not received equivalent regulatory attention.

Voluntary efforts

The Greenpeace DETOX campaign is an effort to get highly fluorinated chemicals out of brand-name goods. It started by focusing on production and use of PFOS and PFOA in East Asia, particularly by the textile industry as a downstream user. According to Tianjie Ma, head of Greenpeace East Asia's Toxics Campaign, "we are currently working on the textile industry as a downstream user of PFCs. Downstream users have more incentives to change faster than up-stream suppliers of chemicals."¹³⁹

Pressure by Greenpeace has resulted in some 66 brands, retailers and suppliers, including Marks & Spencers, H&M, Zara, Puma, and Adidas, to make the commitment to eliminate all hazardous chemicals from across their entire supply chain and product life-cycle by the year 2020 and, in the short term, to eliminate the worst chemicals, including all per- and poly-fluorinated chemicals as well

¹³³ US EPA, 2016.

¹³⁴ Lerner, 2016b.

¹³⁵ Environment Canada, 2008.

¹³⁶ Environment Canada, 2009.

¹³⁷ <http://www.ec.gc.ca/epe-epa/default.asp?lang=En&n=AE06B51E-1> (accessed 19.05.2016).

¹³⁸ <https://www.ec.gc.ca/toxiques-toxics/Default.asp?lang=En&n=ECD5A576-1> (accessed 19.05.2016).

¹³⁹ ChemicalWatch, 2012.

as alkylphenols. Greenpeace states that their goal is to get the manufacturers to collaborate with their suppliers, rather than to cancel existing contracts. As part of their commitment, the manufacturers have agreed to implement right-to-know, by providing data on discharges to the environment and on chemicals in their products, thereby setting a standard for transparency and accountability across their sector.

In early 2017 GoreTex, a market leader in water repellency technologies, also joined in making a commitment to phase out the use of per- and polyfluorinated compounds in its fabrics¹⁴⁰.

As part of its DETOX campaign, Greenpeace frequently carries out new PFC-relevant research. Its 2015 publication *Footprints in the Snow*¹⁴¹ describes eight expeditions that were organised to some of the most remote places on three continents to take samples of new-fallen snow and water from pristine lakes for laboratory analysis. Evidence of PFC chemicals was found in each location, documenting how PFCs (which do not occur naturally) can travel around the world until they are washed out of the atmosphere in rain or snow. The expeditions were organised to educate the outdoor industry about how use of PFCs in their products ends up contaminating the regions so appreciated by outdoor aficionados.

Another notable effort is the cooperation entitled Zero Discharge of Hazardous Chemicals (ZDHC). In 2011 six major brands, Puma, C&A, H&M, Nike, Ni Ling and Adidas came together to initiate the ZDHC programme aimed at bringing about change across the textile and footwear product industry. The companies have set forth a “joint roadmap” setting out plans to achieve zero discharge of the hazardous chemicals used in all their products by 2020, including the elimination of products associated with PFOA and PFOS by the end of 2012. The ZDHC programme will initially replace C8 chemistry with short-chain alternatives; efforts to find non-fluorinated water- and stain-repellent alternatives are still having only limited success.

As of 2015, a total of 19 global sports, fashion and outdoor brands had joined the ZDHC programme. A number of joint roadmap milestones have now been completed, including

- Manufacturing Restricted Substances List (MRSL)
- Framework for the Prioritisation of Hazardous Chemicals
- Audit Protocol
- Right-to-Know Chemical Disclosure Methodology Research
- Chemical Management Systems Manual
- Chemical Management Training for suppliers in Bangladesh, China, India and Vietnam
- 20 supplier site visits to observe chemicals management and inventory practices and to test influent, effluent and sludge discharges in Bangladesh, China, India, Taiwan and Vietnam
- 25 audits across regions, mills and dye houses in Bangladesh, China, El Salvador, India, Taiwan, Turkey, South Korea and the United States¹⁴².

Outside of the Greenpeace campaign, other manufacturers, retailers and/or commercial users have voluntarily suspended the marketing or use of PFC-containing products, because of their persistence and toxicity. IKEA, Crate & Barrel, and Kaiser Permanente (a major US hospital chain) are among the entities that have committed to eliminating PFCs from the products they sell and/or use.

Most important gaps and deficits with respect to PFAS

The phasing out of emissions of long-chain PFASs by US and European manufacturers has been offset

¹⁴⁰ <http://www.greenpeace.org/international/en/press/releases/2017/Gore-hazardous-PFCs-outdoor-gear-pledge/> (accessed 23.04.2017).

¹⁴¹ Cobbing, M. *et al.*, 2015.

¹⁴² ZDHC, 2015.

by a geographical shift of their manufacture and use to countries in Asia ¹⁴³. This global dimension has implications for the types of actions available to the EU for addressing impacts on health and environment from the PFASs, including the short-chain alternatives. Any action on EU-level should at the same time pave the way for equivalent global measure in the context of SAICM and the Stockholm Convention.

Information concerning the many types of PFAS on the market is incomplete. Efforts to develop inventories of the PFAS manufactured and used since the 1950s have identified a number of sources, but quantification remains difficult due to gaps in data ¹⁴⁴.

Although information on health and environmental impacts of the short-chain alternatives has been provided to regulatory agencies to seek approval of specific uses in the context of new chemical regulatory frameworks, the information available in the public domain is limited. Given the high number of both long chain and short chain PFAS on the market today, it is critical to consider how to apply grouping approaches for regulating these extremely persistent substances.

2.5 OTHER GROUPINGS OF HIGHLY PERSISTENT SUBSTANCES

In the course of the research for this study, a number of groups, including a number of highly chlorinated groupings, were singled out for special discussion below.

2.5.1 Highly chlorinated substances

Background

The pesticide DDT was the first highly persistent organic pollutant (POP) to come to international attention because of its adverse effect on the environment. Though first synthesized in 1873, its insecticidal effect was not recognised until 1939, shortly before World War II. It quickly became widely applied to combat insect-borne diseases, including malaria, for which it is still permitted to be used today. The 1962 publication of Rachel Carson's book *Silent Spring* highlighted how DDT and other organochlorine pesticides affected wildlife, particularly birds. This led to the phase-out of DDT in Europe and North America during the 1970s, followed by bans and/or restrictions on other highly chlorinated organic pesticides in the following decades.

Some chlorinated organic substances are highly lipophilic, tend to accumulate in biological systems, and degrade slowly in the environment, particularly those having a carbon ring structure and multiple chlorine substitution ¹⁴⁵. In contrast to highly fluorinated substances, which tend to be both persistent and mobile, many of the highly chlorinated substances have a low mobility and are mainly adsorbed on soil or other particles. This strongly depends on the degree of chlorination. Though the highly chlorinated compounds with larger molecules will not easily enter the gas phase, they may become adsorbed to small particles which could be found in air.

However, other chlorinated organic chemicals with lesser degrees of chlorine substitution do not have the same physical and chemical properties. For example, chlorinated compounds with smaller molecules like dichlorobenzene may slowly evaporate into the environment. This is also the case for hexachlorocyclohexane (HCH) and hexachlorobutadiene (HCBd). A site in Spain containing 10,000 tonnes of HCH releases HCH to water and to air continuously, in the range of

¹⁴³ OECD, 2015b.

¹⁴⁴ Wang, *et al.*, 2014b

¹⁴⁵ Willes, R.F. *et al.*, 1993.

100 kg/year¹⁴⁶. Similarly, houses near a UK site where HCBd had been disposed were found to have high levels of the substance in their indoor environments¹⁴⁷.

While it is not possible to generalise about the persistence and bioaccumulability of all chlorinated organic chemicals, it is noteworthy that 18 of the 22 chemicals listed for elimination in the Stockholm Convention are highly chlorinated substances.

Table 6: Highly chlorinated substances listed for elimination under the Stockholm Convention

Highly chlorinated POPs listed for elimination	
<ul style="list-style-type: none"> ■ Aldrin ■ Chlordane ■ Chlordane ■ Dieldrin ■ Endrin ■ Heptachlor ■ Hexachlorobenzene ■ Hexachlorobutadiene ■ α-Hexachlorocyclohexane (α-HCH) ■ β-Hexachlorocyclohexane (β-HCH) 	<ul style="list-style-type: none"> ■ Lindane (γ-Hexachlorocyclohexane) ■ Mirex ■ Pentachlorobenzene ■ Pentachlorophenol and its salts and esters ■ Polychlorinated biphenyls (PCBs) ■ Polychlorinated naphthalenes ■ Technical endosulfan and its related isomers ■ Toxaphene

Polychlorinated biphenyls (PCBs)

Polychlorinated biphenyls (PCBs) are a group of highly chlorinated organic pollutants that were mass-produced starting in 1929. PCBs were primarily used in electrical equipment, such as capacitors and transformers, due to their resistance to high temperatures and insulating properties, and over time were also used as ingredients in paints, adhesives, lubricants and PVC plastics. Total global production of PCBs from 1929 to 1988 (not counting China and the USSR) is estimated at 1.5 million tons¹⁴⁸, not a large amount when compared to the 360 million metric tons of bulk organic chemicals estimated to have been produced globally in 2010¹⁴⁹. Though never intentionally released into the environment e.g. as pesticides, the high persistence and mobility of PCBs led to their transport around the world. They are found everywhere on the globe today, including in the polar regions.

PCBs became the target of regulatory action at EU level and in the United States in the mid-1970s, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health effects¹⁵⁰. In the 1980s evidence emerged that PCBs can change during bioaccumulation and biodegradation in the environment, producing concentrations of congeners with higher chlorine content and toxicity than commercially produced PCBs¹⁵¹. Studies of children whose mothers had consumed large amounts of fish from Lake Michigan found that those more highly exposed *in utero* had lower IQ-test scores, difficulties in verbal comprehension and reduced ability to concentrate¹⁵².

A 2010 study of PCB stocks and emissions in the city of Toronto concluded that efforts under the Stockholm Convention to eliminate exposure to PCBs has had only partial success. When their manufacture was banned by most industrialised countries some 30 years ago, concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, but since then have

¹⁴⁶ Fernandez, J. *et al.*, 2013.

¹⁴⁷ Barnes, G., *et al.*, 2002.

¹⁴⁸ EEA, 2001, p. 64.

¹⁴⁹ UNEP, 2013b.

¹⁵⁰ Grossman, E., 2013.

¹⁵¹ EEA, 2001.

¹⁵² Jacobson, J.L., & Jacobson, S.W., 1996.

remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources¹⁵³.

In the past decade, studies have found a relationship between exposure to PCBs and the rise of Type 2 diabetes¹⁵⁴ as well as with obesity. And at least one animal study found that prenatal exposure to low doses of PCBs can change the developing brain in an area involved in metabolism, with some effects apparent even two generations later¹⁵⁵.

The evidence as a whole suggests that, rather than a few individual POPs, background exposure to POP mixtures including organochlorine pesticides and polychlorinated biphenyls – can increase risk for T2D¹⁵⁶. This review of current evidence also examines relationships between POPs and obesity in humans. Evidence from animal studies have shown a link between POPs and obesity. However, results on the relationship between POPs and obesity in human studies have been inconsistent and the study highlights some important gaps in knowledge and suggests that large prospective studies with serial measurements of a broad range of POPs, adiposity, and clinically relevant biomarkers are needed to disentangle the interrelationships among POPs, obesity, and the development of T2D.

Another study based on a National Toxicology program workshop review in the US suggests that collectively the data was not sufficient to show a causal relation between POPs and T2D, and that experimental data are needed to confirm the causality of these POPs, which will shed new light on the pathogenesis of diabetes¹⁵⁷. Both studies highlight a lack of evidence, but suggest that new evidence and uncertainty relating to exposure and risk should be considered by governmental bodies involved in the regulation of persistent, environmental contaminants.

Chlorinated paraffins

Chlorinated paraffins (CPs) are high volume semivolatile organic compounds (SVOCs) with an estimated annual global production volume of more than 1 million tonnes¹⁵⁸. CPs are subdivided according to their carbon chain length into short chain CPs (SCCPs, C10–13), medium chain CPs (MCCPs, C14–17) and long chain CPs (LCCPs, C>17). SCCPs were previously listed under Annex XVII of REACH as well as a Substance of Very High Concern (SVHC). SCCPs were incorporated in the EU POP-Regulation (European Commission 2015)¹⁵⁹ and the entry in Annex XVII of REACH has now been deleted. Thus, SCCPs are now classified as persistent organic pollutants (POP) in the EU. SCCPs are currently under consideration for listing in the Stockholm Convention. MCCP has been included in the Community rolling action plan (CORAP) (ECHA, 2012).

CPs are used for a wide range of industrial applications including flame retardants, plasticisers, as additives in metal working fluids, in sealants, paints, adhesives, textiles, leather fat and coatings¹⁶⁰ and have substituted here PCBs in many open applications¹⁶¹. The chlorination degree of CPs can vary between 30 and 70 wt%. The chlorination degree determines the persistence and higher chlorinated SCCPs meet the criteria for PBT and vPvB under REACH¹⁶².

Levels in Swiss sediments have been found several times higher compared to the peak levels of PCB¹⁶³. In wildlife in China CPs were by far the most abundant contaminant, contributing over

¹⁵³ Diamond, M. *et al.*, 2010.

¹⁵⁴ Lee, D. *et al.*, 2006.

¹⁵⁵ Steinberg, R.M. *et al.*, 2008.

¹⁵⁶ Lee, D. *et al.*, 2014.

¹⁵⁷ Taylor, K.W. *et al.*, 2013.

¹⁵⁸ Tong, X.C. *et al.*, 2009.

¹⁵⁹ Commission Regulation (EU) 2015/2030.

¹⁶⁰ de Boer J. *et al.*, 2010.

¹⁶¹ Fantke, P. *et al.*, 2015.

¹⁶² van Wijk D. & Presow S. , 2011

¹⁶³ Iozza S. *et al.*, 2008.

90% of the total OHCs in snake, toad, and falcon¹⁶⁴. Global CP contamination has been revealed by the WHO human milk study as being comparable to levels of PCBs¹⁶⁵.

One additional concern, which has not been assessed in relation to persistence in the environment, is the formation of degradation products of chlorinated paraffins. For oxidative degradation the chain lengths might be shortened resulting in an increase in mobility. Also, such degradation likely results in hydroxylation and carboxylation resulting also in higher mobility of the molecules of the degradation products. Due to the oxidation and reduction of hydrogen, such degradation could lead to an increase in persistence for further oxidation. Such an increase of persistence has been shown for the degradation of polyfluorinated PFAS to the extremely persistent shorter chain perfluorinated PFAS.

For CPs the possible increase in persistence by degradation needs attention and assessment. Furthermore, the degradation of long and medium chain CPs could result in the formation of persistent molecules with a chain length of less than 13 and associated mobility and possibly bioaccumulation potential and need to be further assessed. The assessment of degradation products is also required under REACH.¹⁶⁶

Unintentionally formed POPs

Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDFs) are particularly highly persistent chlorinated POPs often found in other chemicals as contaminants, i.e., as unintentional by-products of manufacturing processes^{167 168}. Polychlorinated biphenyls (PCBs) and hexachlorobenzene (HCB) may also come to be present as unintentional contaminants formed during a manufacturing process. These unintentional POPs are frequently present in consumer goods, particularly where chemical additives have been used.

PCDD/PCDF are some of the most toxic chemicals known to science. The International Agency for Research on Cancer (IARC) lists certain congeners as class 1 carcinogens, together with PCBs.

The half-lives of PCDD/PCDF and PCBs in soils and sediments are estimated to be between several years to centuries and longer¹⁶⁹. An assessment of PCDD/PCDF congener profiles and levels in a contaminated site in Lampertheim, Germany (where an industrial process operated from 1840 to 1890) found no significant degradation of PCDD/PCDF in affected soils and deposits over the last 120 to 170 years, indicating half-lives of longer than a century for the PCDD/PCDF at this site¹⁷⁰. Another study found PCDD/PCDF present in kaolin/ball clay that had been formed millions of years before, and considered this an indication of their extreme persistence in this environmental setting¹⁷¹.

Important examples of products containing unintentional POPs today include pigments, paints and pesticides¹⁷². For example, in recent years PCBs have been detected in a range of pigments used in

¹⁶⁴ Zhou Y. *et al.*, 2016.

¹⁶⁵ Malisch R., 2012.

¹⁶⁶ In REACH (Regulation (EC) No 1907/2006) it is stated (p. 34) “The PBT/vPvB assessment should normally be carried out for each relevant transformation or degradation product. It is not possible to draw an overall conclusion for the substance if the assessment of persistence has been concluded for one transformation/degradation product and the assessment of bioaccumulation or toxicity for another transformation/degradation product.” and what is relevant is described as “An elevated threshold value should not exceed 10% (w/w) for the total amount of all constituents, impurities, additives and transformation/degradation products with PBT/vPvB properties, and the total amount of these within the manufactured/imported substance should in no case exceed 1 tonne/year.”

¹⁶⁷ Grossman, E., 2013.

¹⁶⁸ UNEP (2015) UNEP/POPS/TOOLKIT/BATBEP/2015/2

¹⁶⁹ Balzer, W. *et al.* 2007, 2008; Ferrario, J.B. *et al.* 2000; Lake, J.L. *et al.* 1992; Nauman, C.H. & Schaum, J.L., 1987 ; Kjeller, L.O. & Rappe, C., 1995 ; Sinkkonen, S. & Paasivirta, J., 2000.

¹⁷⁰ Balzer, W. *et al.*, 2007 ; Balzer, W. *et al.*, 2008.

¹⁷¹ Ferrario, J.B. *et al.*, 2000.

¹⁷² UNEP, 2013; Weber, R. *et al.*, 2008.

consumer products such as paints, plastics, print/magazines or packaging (including food packaging)¹⁷³. Monitoring of the PCB content of pigments imported and used in Japan found PCB levels up to 2000 ppm in some pigments, exceeding the Basel Convention low POPs limit for PCBs of 50 ppm¹⁷⁴.

Chlorinated paraffins (discussed above) may also be a source of unintentional POPs in consumer products such as leather. A recent assessment found that these chemicals can contain high levels of PCDD/F, PCBs and polychlorinated naphthalenes (PCNs)¹⁷⁵. The study estimated that the annual production and use of 1 million tons of chlorinated paraffins could produce some 100 tons of PCB per year, with related contamination of consumer products¹⁷⁶.

In addition to the highly toxic PCDD/PCDFs, polybrominated dibenzo-p-dioxins and dibenzofurans (PBDD/PBDFs) are also of concern, given their similar toxicities¹⁷⁷. PBDD/PBDF are present in brominated flame retardants (BFRs) and products and articles containing BFRs¹⁷⁸, due to their unintentional formation and release throughout the life-cycle of BFRs¹⁷⁹. PBDD/Fs can be formed or released during the production of BFRs¹⁸⁰; during the manufacture of BFR-containing products¹⁸¹; and in the recycling and disposal of BFR-containing polymers¹⁸². A WHO expert panel concluded that PBDD/PBDFs and some dioxin-like biphenyls (dl-PBBs) may contribute significantly to the daily human background exposure to total dioxin toxic equivalents (TEQs)¹⁸³.

Recent studies on unintentional POPs in chemicals and consumer products show their contemporary relevance. For example, the Washington State Department of Ecology recently looked for PCBs in a range of consumer products (packaging, paper products, paint and colorants, caulks and printer inks)¹⁸⁴. Unintentional PCBs were found in most samples. Concentrations were in the ppb level with the highest PCB contamination of 320,000 µg t⁻¹ in a green paint. The study concluded that PCBs found in consumer products may affect people directly through contact with those products.

House dust is an excellent indicator for chemicals in consumer products and other indoor sources and their release and exposure¹⁸⁵. Research in Japan and the US demonstrated high levels and relevance of dioxin-like compounds in house dust with levels of dioxin-like toxicity comparable to fly ash from waste incinerators¹⁸⁶. It is important to note that in the majority of the house dust samples, the known dioxin and dioxin-like compounds (PCDD/PCDFs, PBDD/PBDFs and dl-PCBs) only accounted for a minor fraction (often less than 20%) of total dioxin-like toxicity. What other dioxin-like compounds are present in house dust and the indoor environment remains unknown¹⁸⁷.

A recent survey on dioxins in British food by the UK food authority highlighted that up to 30% of the total dioxin-related toxic equivalents (TEQs) could stem from polybrominated dioxins/furans, and additional 20-50% could come from brominated-chlorinated dibenzo-p-dioxins/furans (PXDD/Fs)¹⁸⁸.

¹⁷³ Anezaki, K. & Nakano, T., 2014; Anezaki, K. *et al.* 2015; Hu, D. & Hornbuckle, K.C., 2010.

¹⁷⁴ Japanese Ministry of Economy, Trade and Industry, 2013.

¹⁷⁵ Takasuga, T. *et al.* 2012a ; Takasuga, T. *et al.* 2012b.

¹⁷⁶ Takasuga, T. *et al.* 2012b.

¹⁷⁷ Behnisch, P.A. *et al.*, 2003; Birnbaum, L.S. *et al.*, 2003; van den Berg, M. *et al.*, 2013.

¹⁷⁸ WHO, 1998; Ebert, J. & Bahadir, M., 2003.

¹⁷⁹ Shaw, S. *et al.*, 2010.

¹⁸⁰ WHO, 1998; Hanari, N. *et al.*, 2006; Ren, M. *et al.*, 2011.

¹⁸¹ Luijk, R. & Govers, H.A.J., 1992; Ota, S. *et al.*, 2009; Ren, M. *et al.*, 2011.

¹⁸² Ebert, J. & Bahadir, M., 2003; Zennegg, M. *et al.*, 2014; Shaw, S. *et al.*, 2010.

¹⁸³ Van den Berg, M. *et al.*, 2013.

¹⁸⁴ Stone, A., 2014.

¹⁸⁵ Butte, W. & Heinzow, B., 2002; Maertens, R.M. *et al.*, 2004; Mercier, F. *et al.*, 2011.

¹⁸⁶ Suzuki, G. *et al.*, 2007 ; Suzuki, G. *et al.*, 2010, Tue, N.M. *et al.*, 2013.

¹⁸⁷ Suzuki, G. *et al.* 2010, Tue, N.M. *et al.* 2013.

¹⁸⁸ Mortimer, D. *et al.* 2013.

Regulations in place

In the EU, PCDD/PCDFs and PCBs are only regulated in food and feed, through legislation establishing residue limits, and for air emissions of industrial sources. No EU-level regulations are in place for control of PBDD/PBDFs or for brominated-chlorinated dibenzo-p-dioxins and furans (PXDD/PXDFs).

The EU REACH framework does not regulate unintentional POPs that may be present in chemical formulations or in consumer products. Unintentional POPs and other residues found in products as a result of cross-contamination (e.g. from using recycled materials in the production of products) are currently also not regulated within REACH.

On national level some regulations exist for restricting some unintentional POPs in products. For example, Germany has limits for chlorinated and brominated PCDD/PCDFs and PBDD/PBDFs for chemicals and products in its *Chemikalien-Verbotsverordnung*¹⁸⁹. In addition, Japan has recently restricted the import of pigments to Japan with PCB levels above 50 ppm¹⁹⁰ -- the Basel Convention's low POPs content which is also the EU limit for PCBs in waste oils. Japan has also established regulatory limits for PCDD/PCDFs in pesticides¹⁹¹.

2.5.2 Highly brominated substances

Organobromine substances are compounds with a number of commercially significant applications. They are used primarily as flame retardants but also as fumigants and biocides, dyes, and certain pharmaceuticals.

The most widely used brominated flame retardants are the polybrominated diphenyl ethers (PBDEs), tetrabromobisphenol A (TBBPA) and hexabromocyclododecane (HBCD). They are used in a wide array of products, including building materials, electronics, furnishings, motor vehicles, airplanes, plastics, polyurethane foams, and textiles.

The total global production of brominated flame retardants increased from 150,000 t/y in 1994 to approximately 360,000 t/y in 2011. The increase in production and consumption has primarily been in Asia¹⁹². The brominated flame retardants account for approximately 20% of the consumption of flame retardants world-wide. Globally, the majority of the brominated flame retardants are manufactured by four major manufacturers, and the substances are manufactured in the EU at one site only¹⁹³, in The Netherlands.

DecaPBDE is one of the most well-understood of the brominated compounds with respect to its environmental fate. Laboratory tests using aerobic and anaerobic soils and sediment have shown a much longer degradation half-life – typically more than one year¹⁹⁴. Bromine is heavier than chlorine and therefore the effect of adsorption is even stronger compared to chlorine. However, since the carbon-bromine bond is weaker compared to the carbon-chlorine bond, the highly brominated compounds degrade easier.

Exposure to brominated flame retardants has been associated with numerous health effects in animals and in humans, including endocrine disruption, immunotoxicity, reproductive toxicity, effects on fetal/child development, and cancer¹⁹⁵. Experiments have found that PBDEs have the potential to

¹⁸⁹ *Chemikalienverbotsverordnung*, 2003.

¹⁹⁰ Japanese Ministry of Economy, Industry and Trade, 2013.

¹⁹¹ Japanese Ministry of Agriculture, Forestry and Fisheries, 2007.

¹⁹² Lassen *et al.*, 2014.

¹⁹³ *Ibid.*

¹⁹⁴ *Ibid.*

¹⁹⁵ Shaw *et al.* 2010

disrupt endocrine systems resulting in effects on thyroid, ovarian and androgen functions. Similarly, HBCD has shown a range of endocrine disrupting and reproductive developmental effects in animals.

A particular concern with respect to bromine-containing plastics is the risk of formation of brominated and mixed brominated/chlorinated dioxins and furans upon incineration. Although emissions from incinerators with modern flue gas controls may be of little concern, many studies have indicated that the emissions of dioxins and furans from fires such as incidental landfill fires and uncontrolled burning of BFR-containing plastics may be significant.

Brominated flame retardants are not the only type of brominated compound of concern. A recent study of house dust using a novel screening method found 549 unique brominated compounds in 23 samples from eight Canadian homes¹⁹⁶. Of the 140 most abundant compounds, only 24 were known brominated flame retardants. Closer investigation of the unknown compounds identified 2-bromo-4,6-dinitroaniline (BNA) – a raw material for synthesizing brominated azo dyes -- as a common motif. In order to confirm that such dyes were the source of the unknown compounds, the scientists analysed snippets of clothing using the same screening method and found similar high concentrations of BNA. Use of a standard, cell-based test showed significant mutagenicity of the BNA-containing house dust.

International and EU regulation has focused on PBBs and PBDEs. Recently HBCD has become subject to authorisation under REACH and listed under the Stockholm Convention on Persistent Organic Pollutants (POPs)¹⁹⁷. Table 5 shows the highly brominated substances listed for elimination under the Stockholm Convention as POPs.

Table 7: Highly brominated substances listed for elimination under the Stockholm Convention

Highly brominated POPs listed for elimination	
■	Hexabromobiphenyl
■	Hexabromocyclododecane (HBCD)
■	Hexabromodiphenyl ether and heptabromodiphenyl ether
■	Tetrabromodiphenyl ether and pentabromodiphenyl ether

The EU has recently amended its Regulation on persistent organic pollutants (POPs), to ban hexabromocyclododecane (HBCD). This substance will now be listed in Annex 1 of the POPs Regulation¹⁹⁸ prohibiting its production, use, import and export.

The RoHS Directive¹⁹⁹ restricts polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) from being used in new electrical and electronic equipment placed on the market. DecaBDE was exempted from the RoHS directive in 2005, but since 2008 Deca-BDE can no longer be used in electronics and electrical applications. However, a number of other brominated flame retardants are frequently added to the plastic casings of televisions and other electronic products, despite findings that this use does not increase fire safety²⁰⁰. Examples of persistent flame retardants of concern used widely in electronics but not covered by RoHS include TBBPA and HBCD.

One legal instrument at the EU level addresses the brominated flame retardants as a group: The Directive on waste electrical and electronic equipment (WEEE)²⁰¹ requires selective treatment and proper disposal for materials and components of WEEE with brominated flame retardants. In addition, the criteria for Nordic ecolabelling for some product groups address all brominated flame retardants as a common class, while the Nordic and EU ecolabelling criteria for many products focus on specific brominated flame retardants or brominated flame retardants assigned specific risk-phrases.

¹⁹⁶ Peng *et al.*, 2016.

¹⁹⁷ Lassen *et al.*, 2014

¹⁹⁸ (EC) No 850/2004.

¹⁹⁹ Directive 2002/95/EC.

²⁰⁰ Shaw *et al.*, 2010.

²⁰¹ Directive 2012/19/EU.

The flame retardant decaBDE, assessed as both PBT and vPvB, was added to REACH Annex XVII in February 2017. Restrictions on its manufacture and use will apply as of 2 March 2019. Deferral periods were granted to aircraft or spare parts for aircraft produced before 2.03.2027 to give the industry “sufficient time to adapt”.

Use of TBBPA is not currently restricted, but was included in EU’s draft Community Rolling Action Plan (CoRAP) for evaluation in 2015. Based on currently available information TBBPA does not meet the REACH PBT criteria as concluded in the risk assessment report from 2008. However, it is possible that it fulfils Article 57(f) as quasi PBT on the basis of its environmental toxicity and persistency.

Restrictions and bans on the use of traditional brominated flame retardants such as PBDE, HBCD and TBBPA have created a market for the use of Novel Brominated Flame Retardants (NBFR). A wide range of alternative BFRs, such as decabromodiphenyl ethane and tribromophenol are increasingly used as replacements, though they may possess similar hazardous properties as the replaced substances. Most information on NBFRs comes from research designed principally to study more “traditional” BFRs, such as PBDEs²⁰². However, their biotransformation in the environment is still poorly understood and data on PBT properties is limited²⁰³. Further research is needed in these areas, in order to avoid the large- scale use of potentially harmful and recalcitrant substances.

Some studies have questioned the relative effectiveness of flame retardants in reducing fire hazards, especially when compared to the potential negative health and environment impacts²⁰⁴. This has been cited as an example of an application where policy makers might well consider if such a use is really needed.

2.5.3 Siloxanes (D4 & D5)

Siloxanes are silicone-based compounds used in cosmetics to soften, smooth, and moisten. They make hair products dry more quickly and deodorant creams slide on more easily. They are also used extensively in moisturizers and facial treatments. Siloxanes can also be found in medical implants, water-repelling windshield coatings, building sealants and lubricants. In recent years these compounds have increasingly been in focus because of their persistence and bioaccumulation²⁰⁵. About 200 siloxanes and siloxane derivatives are listed in the inventory of ingredients used in cosmetic products compiled by the European Commission INCI²⁰⁶. Globally the total consumption of siloxanes is approximately 850,000 tonnes, with Western Europe accounting for about 296,000 tonnes²⁰⁷.

Recent regulatory discussions regarding the environmental and health impact of siloxanes have focused on D4 (cyclotetrasiloxane) and D5 (cyclopentasiloxane). These cyclic volatile methylsiloxanes (cVMS), such as D4 and D5, are commonly used in personal care products and have a strong tendency to partition from water to air. Because of the ongoing discussion in Europe and Canada regarding the potential persistent, bioaccumulative and toxic classification of cVMS a number of monitoring and research programs are being conducted²⁰⁸.

Environmental occurrence and fate

Volatile siloxanes are released into the atmosphere and non-volatile siloxane fluids are released via wastewater and then are directed to wastewater treatment plants. Siloxanes mainly follow the sludge and are either spread on agricultural fields, incinerated or disposed of for landfills. Siloxanes in solids will be disposed of for incineration and are nearly 100% mineralised by this process. Siloxanes are

²⁰² Covaci *et al.* 2011

²⁰³ Steiger *et al.*, 2014; Ezechiáš *et al.*, 2014.

²⁰⁴ Shaw *et al.*, 2010.

²⁰⁵ Rücker, C. & Kümmerer, K., 2015.

²⁰⁶ INCI, 2000.

²⁰⁷ Will, R. *et al.* 2003.

²⁰⁸ Tolls, J., *et al.*, 2009.

resistant to chemical reactions such as oxidation, reduction and photodegradation. As varying information exists, it is not clear whether it is possible for siloxanes to undergo hydrolysis under environmental conditions²⁰⁹.

cVMS have been detected in air, biogas, biosolids, and waste water influent and effluent from waste water treatment plants in many countries²¹⁰. The presence of linear and cyclic cVMS has been detected in urban, background, and Arctic sites, and that concentrations of D3 and D4 are significantly correlated, as are D5 and D6, which suggests different sources for these two pairs of compounds. Elevated concentrations of D3 and D4 on the West coast of North America and at high elevation sites suggest these sites are influenced by trans-Pacific transport, while D5 and D6 have elevated concentrations in urban areas, which is most likely due to personal care product use (ref).

A number of studies have examined fate and different paths of exposure to D4 and D5. Even though there has been some uncertainty expressed regarding bioaccumulation and biomagnification of siloxane in the environment, significant levels of cVMS have been detected in marine animals, with a significant correlation between the fat content and cVMS (ref). Siloxanes D4 and D5 behave differently than other persistent organic pollutants, and how they behave is not yet clearly understood. cVMS are superhydrophobic, and behave differently in relation to bioaccumulation and biomagnification, and better regulatory evaluation requires specially designed test protocols addressing biotransformation and dietary uptake²¹¹.

Regulatory Status

As of April 2017, the ECHA Committees for Risk Assessment (RAC) and for Socio-Economic Assessment (SEAC) have both issued opinions supporting a UK proposal for restricting D4 and D5 in personal care products because of their potential harm to the environment. The RAC assessment identified D4 (octamethylcyclotetrasiloxane) as being persistent, bioaccumulative and toxic (PBT) and D5 (decamethylcyclopentasiloxane) as very persistent and very bioaccumulative (vPvB)²¹². Under the proposed restriction, wash-off personal care products would not be allowed to contain more than 0.1% of D4 or D5. The proposed restriction is pending decision by the Commission.

The UK's proposal for restriction²¹³ concluded that of the measures available under the REACH Regulation, restriction is preferred to authorisation because:

- It provides a more flexible approach to achieve the aims of emission reduction as it can be targeted to those applications that pose the greatest risk (i.e. waste water discharges from relatively minor uses of the substance).
- It is likely to achieve a significant reduction in environmental concentrations more quickly.
- It can cover all relevant parts of the life cycle, including the presence of D5 as an impurity in polymeric products (where relevant) and higher molecular weight homologues like D6.
- It can address the D4 content of D5 (which is relevant as D4 is a PBT substance).
- It will avoid the creation of an unnecessary burden on companies whose products do not lead to significant waste water discharges.

The UK proposal also highlighted that alternative products already exist, and the fact that the manufacturers of personal care products are already substituting this substance indicates that they have (or are developing) effective substitutes²¹⁴.

In Canada, CEPA assessments concluded that cyclotetrasiloxane and cyclopentasiloxane — also

²⁰⁹ TemaNord, 2005.

²¹⁰ Wang, D., *et al.* 2014.

²¹¹ Mackay, D., *et al.* 2015.

²¹² ECHA, 2016

²¹³ ECHA, 2015.

²¹⁴ REACH UK Competent Authority, 2015.

known as D4 and D5 — are toxic, persistent, and have the potential to bioaccumulate in aquatic organisms²¹⁵. In laboratory experiments, exposure to high doses of D5 has been shown to cause uterine tumours and harm to the reproductive and immune systems. D5 can also influence neurotransmitters in the nervous system²¹⁶.

Structurally similar to D4 and D5, cyclohexasiloxane (or D6) is also persistent and has the potential to bioaccumulate. Environment Canada's assessment of D6 concluded that this third siloxane is not entering the environment in a quantity or concentration that endangers human health or the environment, but noted significant data gaps concerning its toxicity²¹⁷. Cyclomethicone is a mixture of D4, D5, and D6 siloxanes.

In January 2009, Environment Canada and Health Canada proposed to add D4 and D5 siloxanes to the List of Toxic Substances pursuant to the *Canadian Environmental Protection Act, 1999* (CEPA), and to develop regulations "to limit the quantity or concentration of D4 and D5 in certain personal care products."²¹⁸ A Notice of Objection was filed by one of the affected stakeholders, and consequently the Minister of Environment appointed a review board of three academic toxicologists. The Board submitted its report in 2011 and concluded that although D5 exceeded regulatory thresholds for persistence and it bioaccumulates; it does not biomagnify and there is no evidence that it is toxic to any organism tested up to the limit of solubility in environmental phases, it will not cause adverse effects in organisms in air, water, or sediment, and that projected future uses will not pose a danger to the environment²¹⁹. Following the review, the restriction for D5 was repealed in 2012, and only D4 remains restricted.

More recent work reviewing organosiloxanes' environmental chemistry²²⁰ highlights that the biological effects research is still in its infancy. In particular, very little research has been done on degradation products and the role of siloxanes in the methylation of mercury and bismuth compounds to highly toxic organometals. Because siloxanes are able to interconvert depending on environmental conditions, it was suggested that it does not make sense to regulate D4 and not D5 as in Canada, but rather oligomeric siloxanes should be considered as a group²²¹.

2.5.4 Organometallics

Organometallics are characterized by having both organic and inorganic moieties, the latter being a metal or metalloid²²². Their level of persistence depends on the chemical structure and how they react in the environment. Organometallics may dissolve and dissociate into the separate organic and inorganic moieties to some extent, or may transform into other products via processes such as ligand exchange, nucleophilic substitution and hydrolysis, oxidation-reduction and photolysis. The relevant compound for the ecological assessment may thus be the original organometallic or a transformation product²²³.

Organometallics can be classified into three groups as presented in Table 8: Organometallics classification. Coordination complexes may be grouped with organometallic compounds due to the covalent bond. Organometallics with heavy metal moieties are some of the most common, and also present the greatest potential harm for human health and the environment.

²¹⁵ Environment Canada and Health Canada, 2008a; Environment Canada and Health Canada, 2008b.

²¹⁶ California Office of Environmental Health Hazard Assessment, 2008.

²¹⁷ Environment Canada and Health Canada, 2008c.

²¹⁸ Environment Canada and Health Canada, 2009.

²¹⁹ Siloxane D5 Board of Review, 2011; Mackay, D., 2015.

²²⁰ Rücker, C. & Kümmerer, K., 2015.

²²¹ *ibid*

²²² Atkins, P. *et al*, 2010.

²²³ OECD, 2015.

Table 8: Organometallics classification

	Organic moiety	Inorganic moiety*	Bond
Organometallic compounds	Carbon	Lead, chromium, cadmium, antimony, arsenic, mercury	Covalent
Organic metal salts	Carbon		Ionic
Coordination complexes	Oxygen, Nitrogen, Sulphur, Phosphorus		Covalent

*This overview focuses on this selection of metals and metalloids.

Routes of exposure to organometallics and their transformation products are multiple and can present a significant hazard to human health. Organometallics can be found in foods due to their usage as food additives or from contamination with industrial byproducts including heavy metal emissions. Moreover, organometallics present in low concentrations in the environment may undergo biomagnification through the food chain, resulting in higher concentrations in some foods such as large fish. Organometallics also have a wide range of applications in consumer products including plastics and surface protectants, as well as in medicine for the treatment of carcinoma and lymphoma, glucose utilisation and inflammation²²⁴.

The half-life of an organometallic may not provide sufficient indication of its persistence due to factors including biomagnification, and the potential to degrade into separate moieties including heavy metals. Organometallics usually stabilize in aqueous and sediment environments, while they typically do not persist in the atmosphere. They can travel in surface and groundwater increasing exposure and the costs of removal. Another consideration regarding the impact on human health and the environment is toxicity. The combination of heavy metals with salts or organic compounds are often more toxic than the heavy metal alone²²⁵.

Several organometallics are of particular concern due to their widespread use and highly adverse impacts on health and the environment. One of the major health and environment catastrophes of the 20th century is linked to the 1920s introduction of tetraethyllead (TEL) in petrol as an anti-knocking agent to improve fuel economy. Despite warnings of the likely health impacts from lead and the availability of a safer alternative fuel additive, it came to be used as a fuel additive around the world. At the high point of its use in the 1970s, some 200,000 tonnes of lead were released into the atmosphere in the EU and USA combined, and some body burdens of lead were of times higher than in pre-industrial times²²⁶. Studies at this time found strong correlations between high levels of lead in children's bones and neurotoxic effects including IQ loss and chronic anti-social behaviour. In 2000, the EU banned the use of leaded petrol in road vehicles and it was phased out in most other industrial countries around the same time. It is still used in some grades of aviation fuel as well as in some developing countries resulting in an estimated 100 tonnes of lead released each year.²²⁷

Organotin compounds are also of concern. They were commonly used in anti-fouling paints and pesticides until their ban in the European Union in January 2008. By that time, numerous studies had documented the leaching of these substances, which are highly toxic to many organisms beyond those they are intended to kill, into the marine and coastal environments²²⁸. The most well-known of these compounds include tributyltin (TBT) and triphenyltin (TPhT). Studies have indicated that TBT disrupts the endocrine system for invertebrates, resulting in higher androgen levels in females, and lower immunity in vertebrates and mammals and possible hearing loss in some mammals.²²⁹

Methylmercury is a well-known transformation product of mercury, through biotic methylation. This process, which typically occurs in oxygen deficient sediments, can transform an organometallic into a

²²⁴ Mudi, S.Y. *et al*, 2015.

²²⁵ Craig, P.J., 2003.

²²⁶ EEA, 2013.

²²⁷ Masiol, M. & Harrison, R.M., 2014.

²²⁸ Cavaleiro, J., 2016.

²²⁹ Segner *et al*, 2003.

methyl organometallic, considered to be one of the most toxic derivatives²³⁰. With a half-life in water of 72 days, it is considered to be very persistent. Today the usage and disposal of mercury is regulated by the Minamata Convention, a global treaty adopted in October 2013²³¹. The treaty's name reflects the disaster that occurred in Minamata, Japan, when thousands of children were born with deformed limbs, mental retardation and muscular spasms, due to the consumption of fish with high levels of methylmercury from waters contaminated by mercury-containing chemical industrial waste.²³² Despite high-profile international attention, methylmercury contamination remains a significant public health concern in Europe. A cost benefit analysis found that the benefits of preventing exposure within the EU include more than 600,000 IQ points a year, translating to an economic benefit between €8,000 million and €9,000 million per year²³³.

Another organometallic whose persistence and consequent impact on public health has been debated is antimony trioxide, which is used in the manufacture of polyethylene terephthalate (PET plastic) and can also be found in some flame retardants applied to clothing, carpets, upholstery and plastics. About 130,000 tonnes of antimony trioxide was produced globally in 2012. Like many metals, antimony is suspected to be carcinogenic and can severely affect the lungs, heart and stomach. The compound can travel through ground and surface waters, and can also be biomagnified through some plant species²³⁴. The EU undertook a risk assessment of the compound in 2008 and concluded that the main concern was potential pulmonary toxicity from exposure in the workplace with less attention to the issue of persistence²³⁵. In Canada, the compound met the criteria for persistence, but the levels being released to the environment were not considered sufficient to present a danger to public health or the environment²³⁶. The United States commenced a review of the compound in 2014 with a focus on the carcinogenic potential²³⁷.

Another interesting case is presented by the widespread usage of some organometallics which degrade into metals, which are elements and inherently not degradable, but may be more toxic when ingested. For example, organoarsenic compounds, which include roxarsone, nitarsone, carbason and arsanilic acid, were used until recently in the United States as feed additives for livestock, though they are not approved for such use in the European Union²³⁸. When waste from animals that consumed these additives is used as fertilizer, the organoarsenic compounds can contaminate soil, surface water and groundwater.²³⁹ Organic forms of arsenic are considered to be less toxic than inorganic arsenic, which is recognized to be a neurotoxin and carcinogenic. However, organoarsenic compounds can be degraded into inorganic forms of arsenic within the animal's digestive system and emitted in their waste²⁴⁰.

A similar example is provided by organocadmium compounds in phosphate fertilizers. While the EU has restricted their use, the United States has not. These compounds may be responsible for excessive levels of cadmium found in whey-based protein shakes. It is postulated that organocadmium from fertilizer-treated grains and grasses is consumed by dairy cows, where the chemical is broken down into cadmium, and then transfers to their milk. In addition to being a carcinogen, exposure to cadmium compounds can adversely affect kidney function, the liver, the central nervous system as well as the respiratory system.

²³⁰ Craig *et al.*, 2003.

²³¹ EEA, 2013.

²³² *Ibid.*

²³³ Bellanger, M. *et al.*, 2013.

²³⁴ Reimann, C. *et al.*, 2010.

²³⁵ ECHA, 2008; Newton, P.E. *et al.*, 2004.

²³⁶ Environment Canada, 2010.

²³⁷ EPA, 2014.

²³⁸ Hileman, B., 2007.

²³⁹ Liu, X., 2013.

²⁴⁰ Sapkota, A.R. *et al.* 2007; Arai, Y. *et al.*, 2003.

The market for new organometallics and applications is projected to grow significantly especially in the Asia Pacific region, where they are sought after as catalysts to accelerate the manufacture of bulk and specialty chemicals²⁴¹. This trend is concerning given that little is known about their health and environmental impacts, how they may transform into other products in the environment, and the potential irreversibility. While minimal growth is expected in Europe in terms of production, this class of chemicals nonetheless poses potential health and environmental risks in the EU due to its mobility and cross-border trade in food and consumer products.

Although guidance for conducting ecological risk assessments of metals exists, there is a need for specific approaches regarding organometallics²⁴². Such guidance could support the development of a regulatory framework in Europe to reduce the risk of exposure to organometallics. In addition, regular monitoring of organometallics under the Water Framework Directive could also provide valuable information regarding exposure²⁴³. Following the *National Action Plan on Micropollutants in the Aquatic Environment*, a large-scale screening study was undertaken in France which included a wide range of micro-pollutants including some organometallics²⁴⁴.

2.5.5 The persistent 'hydrophilics'

The persistent substances that first drew scientific attention due to their health and environmental impacts were hydrophobic and bioaccumulable. But in recent years strong concerns have been raised concerning a number of persistent substances that are hydrophilic, i.e., having a strong affinity for water. Because of their mobility in water, they pose particular threats to the quality of water resources. Some scientists argue that mobility should be considered of equivalent concern to bioaccumulability²⁴⁵.

For example, **Germany's Umweltbundesamt (UBA)** is on record as considering the REACH Regulation and guidelines related to REACH as insufficient to protect water resources from chemical contamination²⁴⁶. It has established precautionary guidance which combines three parameters – persistence (P), mobility (M) and toxicity (T), for the evaluation of potential contaminants of waters used as sources for drinking water²⁴⁷. The methodology is aimed at identifying substances registered under REACH which are emitted by registrants (manufacturers, importers), formulators or other downstream users. The guidance provides a methodology for identifying chemicals which are likely to contaminate water in its raw state. This is defined as untreated water from groundwater or surface water or bank storage water (dune recharges).

The methodology is a tiered assessment that first considers whether environmental emissions may or may not occur²⁴⁸. If environmental releases cannot be excluded, the assessment considers whether the substance is persistent (P). The criteria for the assessment of P follows the REACH-guidance R.11. If yes, the assessment considers whether it is mobile (M). A substance that has the physiochemical properties of P and M, and where annual tonnage figures and uses provided in REACH registration dossiers indicate releases to the environment are NOT low is considered 'critical to raw water'. If the substance is also assessed as toxic as well as persistent and mobile (PMT) and which occurs in raw water is considered as setting up a scenario that "gives rise to equivalent concern" under Article 57f, REACH.

²⁴¹ Grand View Research, 2014.

²⁴² OECD, 2015.

²⁴³ Dulio, V. & Andres, S., 2012.

²⁴⁴ ONEMA, 2012.

²⁴⁵ Reemtsma, T. *et al.*, 2016.

²⁴⁶ http://www.reach-info.de/dokumente/Neumann_Klein_2011_Drinkingwater_REACH_SETAC_Europe_Poster.pdf.

²⁴⁷ Kalberlah *et al.*, 2014a.

²⁴⁸ Kalberlah *et al.*, 2014b.

A 2016 study²⁴⁹ explains that two of the quantifiers of aquatic mobility are water solubility and sorption tendency, both of which are governed by the compound's molecular polarity. The study identifies challenges in predicting aquatic mobility on the basis of sorption behaviour and gives evidence for a current modelling gap for PM substances. It notes that persistent and mobile compounds can pass through wastewater treatment plans as well as drinking water treatment. The limited number of very polar compounds found in groundwater so far does not indicate that only a few such contaminants are present, but that they are rarely searched for and therefore a gap in monitoring for such compounds exists.

Two cases, atrazine and methyl *tert*-butyl ether (MTBE), are described below, to illustrate how persistent hydrophilic compounds behave in the environment and can remain a potential threat to groundwater and drinking water supplies even after controls are in place.

Atrazine

Atrazine is an agricultural herbicide that was used extensively in Europe until the late 1980s, after which its application declined due to restrictions on its use and increasing substitution by less persistent herbicides.²⁵⁰ In the US, where atrazine is currently permitted, it is amongst the top, if not the top, most heavily used pesticide.²⁵¹

Atrazine is highly water soluble²⁵² and is referred to in the scientific literature as a moderately hydrophilic substance.²⁵³ Its affinity for water²⁵⁴ gives it a propensity to penetrate into surface runoff and groundwater.²⁵⁵ The persistence and time that it takes atrazine to leach into groundwater depends on a variety of environmental factors, including: soil and subsoil type, hydrological conditions and aquifer structure.²⁵⁶ Similarly, its persistence in soil depends on soil type, levels of organic matter, soil pH, temperature, clay content, presence of other species, presence of surfactants, surface area and soil structure.²⁵⁷ For example, atrazine is more likely to degrade in soils high in organic matter as the processes facilitating degradation are mostly biological (but also chemical).²⁵⁸

Though atrazine can take years to reach groundwater²⁵⁹, once it has reached an aquifer, it is highly persistent, more so than in soil.²⁶⁰ One study found atrazine to be extremely persistent in stagnant aquifer conditions, with a half-life of 206 to 710 days, posing a high risk of build-up under natural conditions²⁶¹. The same study found that in well recirculated water, the half-life of atrazine was lower at 66 to 106 days. Atrazine also has a propensity for being highly mobile in water, and has been found far from its point source—in fog, ambient air, arctic ice and seawater.²⁶²

Germany and Italy banned atrazine in 1991 due to its detection at consistently high levels in drinking water.²⁶³ It was then banned in Austria, Slovenia, Denmark and Sweden also²⁶⁴, and restricted in other

²⁴⁹ Reemtsma, T, *et al.*, 2016.

²⁵⁰ PAN UK, 2002

²⁵¹ Jablonowski, 2011; Hoshaw, 2016

²⁵² Graymore *et al.*, 2001

²⁵³ Graymore *et al.*, 2001 ; Xu *et al.*, 2014

²⁵⁴ Chandler, 2013

²⁵⁵ Xu, 2014

²⁵⁶ Tappe *et al.*, 2002 ; European Commission, 2009

²⁵⁷ Graymore *et al.*, 2001 ; Mudhoo & Gar, 2011

²⁵⁸ Graymore *et al.*, 2001

²⁵⁹ Jayachandran *et al.*, 1994.

²⁶⁰ Schwab *et al.*, 2006

²⁶¹ Ibid.

²⁶² Jablonowski, 2011

²⁶³ Mergel, 2010

²⁶⁴ Graymore, 2001

EU countries such as France and the UK.²⁶⁵ In 2004, the European Commission Decision 2004/248/EC banned atrazine for use as an active substance in plant protection products, except for a few exemptions for essential uses, due to 'ubiquitous and unpreventable water contamination'.²⁶⁶ The Decision specifically cited the 'large area concentrations' in groundwater exceeding the EU Directive 91/414/EEC limit of 0.1 µg/l for individual pesticides.²⁶⁷ This limit value corresponds to those provided in the Groundwater Directive (2006/118/EC) and Drinking Water Directive (98/83/EC). At its core, the decision was precautionary in that the quality limit of 0.1 µg/l is a precautionary limit and because of the properties of atrazine continued use would lead to exceedance of the limit. The Decision noted the inability to guarantee the 'satisfactory recovery of groundwater quality' in areas exceeding the 0.1 µg/l limit if use continued elsewhere.

Studies on health and environmental impacts of atrazine have been subject to controversy. Though several studies²⁶⁸ have shown adverse effects of atrazine on health and wildlife, others²⁶⁹ have argued that no consistent positive associations can be found across studies, such that no conclusions can be drawn concerning any health or environmental impacts from atrazine. Many of the latter studies have attracted criticism for being funded by atrazine's main manufacturer, Syngenta.²⁷⁰

Some studies have linked atrazine to a range of direct and indirect health impacts in animals or humans, including: endocrine disruption in fish and amphibians²⁷¹, impacts on reproduction and development, and to certain cancers in laboratory rodents, and also in humans, especially when exposure is combined with other agricultural chemicals.²⁷² A particularly well-publicised study²⁷³ found that atrazine chemical castrated and induced feminization in African clawed frogs at low ecologically relevant doses (≥ 0.1 ppb). The author's findings were confirmed in a follow-up study in 2010, and extended across vertebrate classes in 2011²⁷⁴.

A 2009 US EPA-guided study found that atrazine exposure did not have endocrine disrupting effects.²⁷⁵ However, other subsequent studies documented adverse reproductive effects or developmental effects on fish, amphibians at concentrations of around 1 µg/l¹ in water, and on rats at more elevated concentrations.²⁷⁶ On the other hand, according to a 2014 study funded by Syngenta, no consistent positive evidence has come to light of atrazine's impact on pregnancy outcomes in humans, such as: birth defects, small for gestational age birth weight, prematurity, miscarriages, and problems of fetal growth and development²⁷⁷.

Despite these mixed results in the scientific literature, in 2016 California listed atrazine on its Proposition 65 list of toxic chemicals due to its association with reproductive harm.²⁷⁸ The US EPA is currently undertaking a draft ecological risk assessment for atrazine, and will publish a report at the end of 2016 on its human impact.²⁷⁹

Other environmental impacts linked to atrazine are also controversial. On the one hand atrazine has been found to inhibit photosynthesis, resulting in decreased production of algae, periphyton,

²⁶⁵ PAN UK, 2002

²⁶⁶ Sass & Congelo, 2006, p. 260

²⁶⁷ Commission Decision 2004/248/EC

²⁶⁸ Such as Hayes *et al.*, 2002, 2010 and 2011; Rohr & McCoy, 2010.

²⁶⁹ such as Solomon *et al.* 2008, van der Kraak *et al.*, 2014 and Goodman *et al.*, 2014

²⁷⁰ Sass & Colangelo, 2006

²⁷¹ Hayes *et al.*, 2002, 2010 and 2011; Rohr & McCoy, 2010

²⁷² Sass & Colangelo, 2006.

²⁷³ Hayes *et al.*, 2002.

²⁷⁴ Hayes *et al.*, 2011

²⁷⁵ Kloas *et al.*, 2009, cited in Jablonowski, 2011

²⁷⁶ Jablonowski, 2011

²⁷⁷ Goodman *et al.*, 2014

²⁷⁸ Hoshaw, 2016

²⁷⁹ Hoshaw, 2016

phytoplankton and macrophytes, with impacts up the food chain.²⁸⁰ For example, it has been linked to decreases in fish and wildfowl populations in the Chesapeake Bay in the US.²⁸¹ However, other studies (largely industry-funded) have criticized these results and asserted that atrazine poses no significant acute or chronic risks to amphibians or aquatic organisms at environmentally relevant concentrations.²⁸²

Atrazine continues to be detected across Europe decades after its agricultural use stopped. Despite the EU-wide ban in 2004, atrazine and its degradation product desethylatrazine are still the pesticides that are most commonly detected at levels above the EU Groundwater Directive (2006/118/EC) limit of 0.1 µg/l for individual pesticides.²⁸³ A 2010 German study found that atrazine was still the most abundant pesticide in groundwater 18 years after its ban.²⁸⁴ Similar results were found at Germany's Zwischenscholle aquifer, where atrazine remained at largely stable levels close to 0.1 µg/l 20 years on from its ban.²⁸⁵ A 2009 French study of Brevilles Spring found that 8 years after its application was stopped, atrazine was still in spring water at concentrations above the limit for drinking water.²⁸⁶

Certain environmental conditions can contribute to the degradation of atrazine, although its metabolites have different toxicological and degradability profiles, with some being less toxic but more persistent.²⁸⁷ Another study found that the combination of ultrasound (sonolysis) and UV radiation could break down atrazine into less hydrophilic intermediates.²⁸⁸

Nonetheless, atrazine is an example of how persistent hydrophilic substances can remain in water resources for long periods after the source is stopped.

Methyl tert-butyl ether (MTBE)

Methyl *tert*-butyl ether (MTBE) is an aromatic organic chemical used as an octane boosting agent in petrol. MTBE was originally introduced as an alternative to lead based anti-knocking agents (tri-ethyl lead). Production of MTBE started in Europe in 1973 and in 1979 in the US²⁸⁹, and legislation in both the USA (Clean Air Act amendments in 1990) and EU (Fuel Quality Directive) promoted using octane boosters to improve combustion of fuels and limit emissions of volatile organic compounds.

Global MTBE production and consumption peaked in 1999, with total worldwide annual production at about 21.4 million. At this time roughly 3.3 million tonnes of MTBE were produced in the EU and approximately 2.3 million tonnes were used domestically²⁹⁰.

During the 1990s it became apparent that MTBE could render drinking water unfit for consumption because of unpleasant odor and taste at relatively low concentrations. Several cases of contamination of groundwater in the USA²⁹¹ were documented mainly due to leakages in underground containers. The cost of cleaning up leaks and spills was estimated to be in the order of tens to hundreds of millions of dollars and led to several US states restricting or banning the use of MTBE as an additive to petrol²⁹².

MTBE usage bans in the US and Canada led to sharp decreases in global demand for MTBE, from

²⁸⁰ Graymore *et al.*, 2001

²⁸¹ Graymore *et al.*, 2001

²⁸² Solomon *et al.*, 2008 ; Van der Kraak *et al.*, 2014

²⁸³ Eurostat, n.d.

²⁸⁴ Jablonowski *et al.*, 2011

²⁸⁵ Vonberg, D., 2015. N.b. Tappe *et al.*, 2002, also recorded only slightly decreasing levels of atrazine in German aquifers 10 years on from its ban, but noted that this could be in part due to continued illegal application, estimated around 6%.

²⁸⁶ European Commission, 2009

²⁸⁷ Jablonowski *et al.*, 2011

²⁸⁸ Xu *et al.*, 2014

²⁸⁹ ECOTOC, 2003.

²⁹⁰ EEA, 2001.

²⁹¹ EEA, 2001.

²⁹² Ibid.

19.3 million tons in 2000 to 12.1 million tons in 2011. However global demand is expected to grow slowly in the longer term due to increased demand in Asia Pacific and Middle East regions.²⁹³. Demand for MTBE in Europe has remained relatively stable between 2 and 3 million tonnes, though it is being gradually replaced by other octane boosting agents such as ethanol and bio-based additives such as ethyl tert-butyl ether (ETBE)²⁹⁴. Production capacity of MTBE in Europe has decreased to approximately 1.5 million tonnes in 2010²⁹⁵, indicating that it is still a high production volume chemical.

MTBE is persistent. Degradation half-lives in surface waters are dependent on a number of conditions such as current, depth of water and temperature; the estimated half-life for MTBE in rivers ranges from 30 minutes to 52 days and for lakes from 10 to 193 days²⁹⁶. Degradation in ground water aquifers is slow to non-existent under both aerobic and anaerobic conditions. If degraded, the primary degradation product in soil and groundwater is TBA (Tertiary Butyl Alcohol)²⁹⁷. The atmospheric half-lives of MTBE are dependent on atmospheric conditions, and range between 3 and 6 days in summer and winter respectively²⁹⁸. The bioconcentration potential of MTBE is insignificant²⁹⁹.

MTBE is highly soluble in water -- up to 30 times more soluble than other components of petroleum. Unlike many other organic chemicals, MTBE is poorly sorbed to carbon based substrates such as soil. These two physical properties have important consequences for the movement of MTBE in groundwater and the types of remediation technology that are likely to be effective in removing it from contaminated groundwater³⁰⁰.

MTBE is ubiquitous in the environment. Because of its unique properties relating to water solubility, affinity for water (hydrophilic) and mobility, it has been detected in groundwater, drinking water, surface waters such as rivers, lakes and coastal waters, and in wastewater³⁰¹. Unlike other VOCs, storm water runoff and atmospheric transportation are low contributors to water concentrations of this pollutant; higher concentrations of MTBE are usually attributed to point sources such as spills, industrial discharges or illegal dumping of tank washings from tanker ships. The main mechanisms for pollution of groundwater include leaking storage tanks, accidental spillage during production, transportation of and issue of gasoline products in retail filling stations, depots and refineries. While fewer incidents of point source contamination of groundwater have been identified in Europe compared to the United States, cases of contamination from point sources have been documented in Germany, the Netherlands, Denmark and the UK³⁰². Concentrations of MTBE in surface water and groundwater are strongly connected to urban areas, population density and amount of MTBE used in petrol³⁰³.

Risk assessments of MTBE have found limited evidence of risks to human health, especially at levels that are realistic in terms of exposure either through occupational exposure or exposure through the environment³⁰⁴. In fact, the World Health Organization (WHO) decided not to establish a health-based guideline value for MTBE because any such value based on any adverse effects would be significantly higher than the concentration at which it would be detected by odor³⁰⁵.

²⁹³ EFOA, 2016; Merchant Research and Consulting Ltd. 2016.

²⁹⁴ Ibid.

²⁹⁵ CONCAWE, 2012.

²⁹⁶ Rosell, M. *et al.*, 2006.

²⁹⁷ Kjølholt, J. *et al.*, 2014.

²⁹⁸ Kolb, A. & Püttmann, W., 2006.

²⁹⁹ Kjølholt, J. *et al.*, 2014.

³⁰⁰ National Groundwater and Contaminated Land Centre, 2000.

³⁰¹ Rosell, M. *et al.*, 2006.

³⁰² Chisala, B.N. *et al.* 2007: National Groundwater and Contaminated Land Centre 2000; Rosell, M. *et al.*, 2006.

³⁰³ Achten *et al.*, 2001.

³⁰⁴ Finnish Environment Institute, 2002.

³⁰⁵ WHO, 2005a.

More recently, concerns have been raised about the possible endocrine disrupting properties of MTBE, along with the high tonnage/exposure potential of the substance. A substance evaluation of MTBE under REACH is currently underway with France as Rapporteur MS³⁰⁶. A recent weight of evidence approach evaluating endocrine activity using multiple endocrine endpoints concluded that the evidence thus far does not support a direct effect on the endocrine system in terms of the hypotheses tested³⁰⁷. MTBE has also been linked to asthma and Diabetes Type II³⁰⁸, but so far very little research is available on this.

MTBE is not considered as either PBT or vPvB under REACH, because its bioaccumulation potential is considered insignificant. Under the CLP Regulation, MTBE is classified as a flammable liquid (cat. 2) and a skin irritant (Cat. 2). MTBE is not classified with regard to environmental properties. An EU-level indicative Occupational Exposure Limit is in place.

Most EU legislation mentioning MTBE focuses on its use in petrol. Directive 2009/30/EC on the specifications for petrol, diesel and gas oil establishes, among other aspects, the maximum content of MTBE (“ethers containing 5 or more carbon atoms per molecule”) in market fuel at 22 % v/v. Directive 2009/28/EC on the promotion of energy from renewable energy sources establishes a target value for Bio-MTBE in Annex III, according to which 22 % of the energy content in MTBE produced on the basis of bio-methanol (35 MJ/kg) can be considered to originate from renewable resources (the target is for 10 % of total energy used for transportation purposes to be produced from renewable resources in 2020).

Because of concerns related to potential latent health risks, and because its persistence in groundwater and mobility in soil have contributed to water contamination, both academics and regulators have suggested that environmental fate and presence of MTBE in groundwater and drinking water should be closely monitored.

2.5.6 The special case of ‘pseudopersistence’

In terms of regulatory frameworks persistence is defined by the chemicals’ biodegradability measured by their half lives in different media or their long-range transport potential. As explained above, persistence is considered as a factor in exposure and risk. The chemical or substance’s degree of persistence determines how long the chemical is present and in turn affects routes and rates of exposure.

In certain cases, substances that would not be considered persistent because of their relatively short half-lives might nonetheless, because of their continuous release, result in the type of continuous exposure associated with persistent chemicals³⁰⁹.

The term ‘*pseudo-persistence*’ was first coined with respect to traces of pharmaceuticals continuously discharged to the aquatic environment³¹⁰. It is considered misleading in that it does not refer to an intrinsic property of a substance, but rather describes widespread patterns of use or modes of entry into the environment. The term ‘*continuously present*’ has been proposed as being more descriptive and less likely to be misinterpreted as an intrinsic property of a substance³¹¹. Such substances do not need to be persistent in the environment to cause negative effects. The key factor is that their supply is continually replenished, even if their half-lives are short. If this continuous supply of a chemical takes place in an indoor environment or with respect to the aquatic environment, the likelihood of a constant exposure becomes heightened.

³⁰⁶ Kjølholt, J. *et al.*, 2014.

³⁰⁷ Peyster, A. & Mihaich, E., 2014.

³⁰⁸ Saeedi, A. *et al.*, 2016.

³⁰⁹ Mackay, D *et al.*, 2014.

³¹⁰ Daughton & Ternes, 1999.

³¹¹ Mackay, D. *et al.*, 2014.

For example, Bisphenol A (BPA) – a known endocrine disruptor -- is one of the highest volume chemicals produced worldwide³¹². It is a building block of polycarbonate plastics often used for food and beverage storage, as well as a component of epoxy resins that are used to line food and beverage containers. Studies have shown that BPA can leach from these and other products in contact with food and drink, and as a result, routine ingestion of BPA is presumed. This compound is also found in an enormous number of other products that consumers come into contact with daily, and has been detected in the majority of individuals examined. Although many questions remain to be answered concerning the effects of this endocrine disruptor, exposure to BPA is apparently ubiquitous.

Other groupings of so-called ‘pseudo-persistent’ or ‘continuously present’ compounds include certain phthalates, polyaromatic hydrocarbons (PAHs), and other phenols such as perchlorate.

Because ‘*pseudo-persistence*’ is not related to an intrinsic property of a substance, it will not be considered further in this study.

2.6 ACTIVITIES IN INTERNATIONAL ORGANISATIONS AS WELL AS AT NATIONAL LEVEL

A number of recent activities within international organisations are relevant for the governance of POPs and other very persistent substances. In 2015, in the context of the **Strategic Approach to International Chemicals Management (SAICM)**, stakeholders at the fourth meeting of the International Conference on Chemicals Management (ICCM4) adopted a resolution designating environmentally persistent pharmaceutical pollutants as a new emerging policy issue³¹³. Based on a proposal by Peru, Uruguay and the International Society of Doctors for the Environment, the resolution included an invitation to IOMC organisations to “facilitate collaborative action”, to develop a workplan on environmentally persistent pharmaceutical pollutants and to report back on these activities at ICCM5 in 2020.³¹⁴

At ICCM4 stakeholders also discussed other issues of concern including perfluorinated chemicals (PFCs). While no resolutions were adopted on PFCs, an update was given on progress and an information document circulated containing an update on managing PFCs and the transition to safer alternatives, prepared by the OECD and UNEP.³¹⁵ Two representatives called for the proposed workplan for the Global PFC group to address the hazards of short-chained PFCs.³¹⁶

Within the **United Nations Environment Programme (UNEP)**, activities related to POPs are ongoing through the implementation of the Stockholm Convention. At its seventh Conference of the Parties (COP7), Parties agreed to list three additional substances as POPs: hexachlorobutadiene, pentachlorophenol and its salts and esters, and polychlorinated naphthalenes.³¹⁷ This takes the total number of POPs listed under the Stockholm Convention to 26.

The **Persistent Organic Pollutants Review Committee (POPRC)** is charged with examining proposals for listing of additional chemicals under the Stockholm Convention. At the 12th meeting of the POPRC in September 2016 it decided to initiate steps towards listing PFOA in the Convention. It also made recommendations for global bans on short-chain chlorinated paraffins and the flame

³¹² Rubin, 2011.

³¹³ SAICM, 2015, ICCM4 Meeting report

³¹⁴ SAICM, 2015, ICCM4 Meeting report, p 17

³¹⁵ SAICM/ICCM.4/INF/21, cited in SAICM, 2015, ICCM4 Meeting report, p 26

³¹⁶ SAICM, 2015, ICCM4 Meeting report, p 27

³¹⁷ UNEP, 2015, Report of the Conference of the Parties to the Stockholm Convention on Persistent Organic Pollutants on the work of its seventh meeting, UNEP/POPS/COP.7/36

<http://chm.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx>

retardant decaBDE (with certain exemptions), and recommended global action on dicofol³¹⁸. A proposal to list hexachlorobutadiene (HCBD) (an unintentional POP) in Annex C to the Convention was not agreed by the POPRC³¹⁹.

The UNEP continues various monitoring activities on POPs within the context of the Stockholm Convention. Its Global Monitoring Plan (GMP) for POPs collects global data on levels of the 26 POPs listed in the environment and in humans. Its aims include providing globally comparable data on POPs and strengthening in-country capacity for monitoring POPs where this is lacking. The GMP is now implementing the second of its regional projects, which will run from 2016 to 2019, focusing on building in-country capacity for the sampling and analysis of POPs³²⁰.

The **United Nations Globally Harmonised System of classification and labelling of chemicals (GHS)** published its 6th edition in 2015. This included clarification of criteria for some hazard classes, including substances classed as hazardous to the aquatic environment. Persistence, or a 'lack of rapid degradability', in combination with acute toxicity or bioaccumulation potential, qualifies a substance to be classed as a hazard to aquatic ecosystems³²¹. This is based on the fact that persistent substances in water threaten to 'exert toxicity over a wide temporal and spatial scale'³²².

The GHS defines 'rapid degradation' in the aquatic environment as at least 70% degradation of a substance within 28 days (equivalent to a degradation half-life of 16 days).³²³ This can be biotic or abiotic (e.g. hydrolysis). This also applies to a substance's degradation products.³²⁴ Apart from some exceptions, these levels must be achieved within 10 days of the start of the degradation process. Degradability is determined by biodegradability tests (A-F) of OECD Test Guideline 301 for freshwater, and OECD Test Guideline 306 for marine environments.³²⁵ In the absence of these data, a BOD(5 days)/COD³²⁶ ratio of greater than or equal to 0.5 is considered to indicate rapid degradation. However, if a substance fails an OECD test for rapid degradability, it can still be classed as such if rapid degradation in the real environment can be proven.³²⁷

At the national level, **Canada** has progressed action on the management of persistent chemicals. In 2016 the Canadian government launched the third phase (running 2016 to 2021) of its Chemicals Management Plan, to address the remaining 1550 priority substances out of the original 4300 chemicals identified as requiring health and ecological assessment on Canada's Domestic Substance List. These include numerous persistent chemicals, for example D3 (hexamethylcyclotrisiloxane) D4 (cyclotetrasiloxane) and persistent chemicals within other groups of substances such as siloxanes and organometallics.³²⁸ This autumn (2016) the government is expected to publish its final screening assessment decisions under the Canadian Environmental Protection Act (1999) of 10 organic flame retardants chosen on the basis of their potential environmental persistence and their potential exposure to consumers and children.

In the **USA** a new chemicals act—the Frank R. Lautenberg Chemical Safety for the 21st Century Act—came into force in June 2016, updating the US Toxic Substances Control Act (TSCA). It includes a specific section on persistent, bioaccumulative and toxic (PBT) chemicals. Under this, PBT

³¹⁸ IPEN, 2016.

³¹⁹ Ibid.

³²⁰ , <http://www.unep.org/chemicalsandwaste/POPs/AnalysisandMonitoring/GMPcopy/tabid/1061031/Default.aspx#> (Viewed 26 September 2016)

³²¹ GHS, 2015, p. 222.

³²² Ibid., p. 222.

³²³ Ibid.

³²⁴ Ibid., p. 223

³²⁵ Ibid., p. 218

³²⁶ Biochemical oxygen demand/ chemical oxygen demand.

³²⁷ GHS, 2015, p. 223

³²⁸ List of Substances in the next phase of the Chemicals Management Plan (CMP) and Two-year Rolling Risk Assessment Publication Plan, viewed 29 September 2016, <http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2A33EEC9-1>

chemicals identified in the 2014 update of the TSCA Work Plan for Chemical Assessments will be subject to ‘expedited action’.³²⁹³³⁰³³¹ According to this ‘fast track’ process, risk evaluation for the substances is not needed, only assessment of their use and exposure, and rules on the substances involved must be proposed within three years of the Act and finalised 18 months later.³³² In the 2014 TSCA Work Plan, 12 out of 89 substances are classed as highly persistent in the environment, but with low bioaccumulation potential.³³³

In 2009, **Japan** amended their Chemical Substances Control Law, bringing in new laws for the classification and regulation of chemicals. Prior to 2009, chemicals were assessed for persistence first (those readily biodegradable were automatically authorized) and then assessed for their bioaccumulability and then toxicity.³³⁴ Since 2009 around 1,000 ‘priority’ chemicals have been identified based on whether they have ‘highly residual properties’. If they are found to have such properties, they are then assessed for their T and B properties. From there they are put into Class I (PBT chemicals) or Class II (PT, but this also includes since 2009 non-persistent chemicals).³³⁵ OECD test guideline 301C for ready biodegradability is the most common test used to assess biodegradation in Japan.³³⁶ The importance attached to biodegradability in testing the environmental fate of chemicals stems back to the original impetus for the Chemical Substances Control Law in 1973, brought in following environmental and health hazards caused by PCBs.³³⁷

2.7 REGULATORY FRAMEWORK RELEVANT FOR VERY PERSISTENT CHEMICALS

2.7.1 International efforts to control vP chemicals

Very persistent chemicals are increasingly a global problem requiring international action, because of the potential for long-range transport as well as internationalized production and trade. The most targeted international instrument for control of persistent substances is the **2001 UN Stockholm Convention on Persistent Organic Pollutants** (POPs Convention)³³⁸, already mentioned in the case study on highly fluorinated substances. The Convention sets forth measures to eliminate or reduce the release of POPs into the environment at the global level.

The Convention lists the chemicals it regulates in three Annexes. As of July 2016, Annex A lists 22 chemicals for which Parties are to take measures to eliminate their production and use. Eighteen of these are highly chlorinated POPs and four are highly brominated POPs (see below).

³²⁹ <https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf>

³³⁰ Those added in 2014 which demonstrate high environmental persistence on this list include: Decabromodiphenyl ethers (DecaBDE); Hexabromocyclododecane (HBCD); 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA); Molybdenum and Molybdenum Compounds; Pentachloro-thio-phenol; Phenol, isopropylated, phosphate (3:1) (IPTPP).

³³¹ https://www.epa.gov/sites/production/files/2015-01/documents/tasca_work_plan_chemicals_2014_update-final.pdf

³³² <https://www.epa.gov/sites/production/files/2016-06/documents/bills-114hr2576eah.pdf>

³³³ See TSCA 2014 Work Plan for Chemical Assessments, viewed 28 September 2016,

https://www.epa.gov/sites/production/files/2015-01/documents/tasca_work_plan_chemicals_2014_update-final.pdf

³³⁴ Ikeda *et al.*, 2001

³³⁵ Naiki *et al.*, 2010

³³⁶ Nabeoka *et al.*, 2016

³³⁷ Ibid.

³³⁸ UNEP, 2001.

Table 9: Substances listed for elimination in the Stockholm Convention

Stockholm Convention substances listed for elimination	
Highly chlorinated POPs	
1.	Aldrin
2.	Chlordane
3.	Chlordecone
4.	Dieldrin
5.	Endrin
6.	Heptachlor
7.	Hexachlorobenzene
8.	Hexachlorobutadiene
9.	α -Hexachlorocyclohexane (α -HCH)
10.	β -Hexachlorocyclohexane (β -HCH)
11.	Lindane (γ -Hexachlorocyclohexane)
12.	Mirex
13.	Pentachlorobenzene
14.	Pentachlorophenol and its salts and esters
15.	Polychlorinated biphenyls (PCBs)
16.	Polychlorinated naphthalenes
17.	Technical endosulfan and its related isomers
18.	Toxaphene
Highly brominated POPs	
19.	Hexabromobiphenyl
20.	Hexabromocyclododecane (HBCD)
21.	Hexabromodiphenyl ether and heptabromodiphenyl ether
22.	Tetrabromodiphenyl ether and pentabromodiphenyl ether

Annex B lists two chemicals (DDT; perfluoro-octane sulfonic acid and perfluorooctane sulfonyl fluoride, or PFOS) that are to be restricted by Parties to the Convention, except for a number of ‘acceptable purposes’ and ‘specific exemptions’ for which production and use may continue. Finally, Annex C covers six unintentionally produced substances, including dioxins and furans, for which Parties must take measures to minimize and, where feasible, eliminate their production and release.

The Convention foresees that additional chemicals will need to be included in its regime if the problem of POPs is to be fully addressed. Four additional substances (DBDE, dicofol, short-chained chlorinated paraffins, PFOA) are currently under review for possible listing in one or more of the annexes.

Adding a new substance to one of the Convention’s three Annexes is not easy. In order for a substance to be designated as a POP, it must be shown to be persistent, bioaccumulative, and toxic, as well as known to travel long distances by various pathways. A proposal for listing a new chemical may be submitted by a party to the Convention, either a State or a regional economic integration organisation such as the EU, at any time. The Persistent Organic Pollutants Review Committee (POPRC)³³⁹ then evaluates the proposals. This process involves *inter alia*, putting together a risk profile and risk management evaluation in consultation with Parties and observers.³⁴⁰

The POPRC then makes recommendations to the Conference of the Parties as to whether the chemical should be listed for elimination (Annex A); restriction (Annex B); or for measures to minimize unintentional production (Annex C). The Conference has the final decision-making power, taking due account of the recommendations of the Committee whether to list the chemical and specifies the potential control measures. Overall, the process can take several years.

The 1998 UNECE Aarhus Protocol on Persistent Organic Pollutants (POPs Protocol)³⁴¹ and the

³³⁹ The POPRC consists of 31 government-designated chemicals assessment experts representing the regions to the Convention: 8 from African states; 8 from Asian and Pacific States; 3 from Central and Eastern European States; 5 Latin American and Caribbean States, and 7 from Western European and other States.

³⁴⁰ Moermond, C., *et al.*, 2012, p. 363.

³⁴¹ http://www.unece.org/env/lrtap/pops_h1.html.

2013 Minamata Convention on Mercury³⁴² should also be noted. Other international efforts include the UNEP-led Strategic Approach to International Chemicals Management (SAICM) and the four International Conferences on Chemicals Management (ICCM) held under its aegis to date³⁴³, already discussed above

2.7.2 The EU regulatory framework for control of vP chemicals

As noted in the Technical Specifications, a number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. The one exception is the **Detergents Regulation**³⁴⁴, which requires surfactants used in detergents to meet biodegradability standards.

The **REACH Regulation**³⁴⁵ is of course the overarching framework, together with the **CLP Regulation**³⁴⁶. It covers all substances placed on the EU market, except for those exempted because other acts apply. As already noted, REACH Annex XIII sets criteria for identifying if a substance is PBT or vPvB. The identification of a substance as PBT or vPvB automatically requires the registrant to carry out an estimate of emissions, to identify and implement measures to minimise emissions, to indicate in the safety data sheet (SDS) that the substance is PBT/vPvB, and to communicate measures for minimizing emissions to downstream users via the SDS³⁴⁷.

REACH also provides for the possibility of control of a PBT or vPvB substance through the mechanism of authorization. Under the REACH system, a compound must first be identified as a Substance of Very High Concern (SVHC) and then added to the Candidate List for eventual inclusion in Annex XIV as subject to authorisation or, alternately, to restrict it under Annex XVII.

While REACH does not explicitly provide for the possibility of controlling a substance on the basis of persistence alone, it might be possible to make a case under Article 57(f) that there is scientific evidence of probably serious effects to human health or the environment giving rise to an equivalent level of concern as a substance meeting the Annex XIII criteria for PBT/vPvB. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting, in which case the manufacturer or importer shall assess the risks associated with such effects on a case by case basis and include a full description in the chemical safety report and a summary in the safety data sheet. To date, neither of these provisions has been applied to a substance because of persistence.

³⁴² <http://www.mercuryconvention.org/Convention/tabid/3426/Default.aspx> .

³⁴³ http://www.saicm.org/index.php?option=com_content&view=article&id=78&Itemid=480.

³⁴⁴ Regulation (EC) No 648/2004 on detergents.

³⁴⁵ Regulation (EC) No 1907/2006 (REACH).

³⁴⁶ Regulation (EC) No 1272/2008 (CLP).

³⁴⁷ Case study on 'Inconsistencies in assessment procedures for PBT and vPvB as properties of concern' (as mentioned in introduction; not yet published, December 2016).

Table 10: PBT/vPvB substances on the Candidate List

PBT/vPvB substances on the Candidate List	
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane	PBT/vPvB
Perfluorononan-1-oic-acid	PBT
Henicosafuoroundecanoic acid	vPvB
Bis(pentabromophenyl) ether (decabromodiphenyl ether) (DecaBDE)	PBT/vPvB
Anthracene	PBT
2-(2H-benzotriazol-2-yl)-4,6-diterpentylphenol (UV-328)	PBT/vPvB
Tricosafuorododecanoic acid	vPvB
Pentadecafluorooctanoic acid (PFOA)	PBT
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	PBT/vPvB
Perfluorononan-1-oic-acid	PBT
Heptacosafuorotetradecanoic acid	vPvB
Ammonium pentadecafluorooctanoate (APFO)	PBT
2-benzotriazo-2-yl-4,6-di-tert-butylphenol (UV-320)	PBT/vPvB
Bis(tributyltin) oxide (TBTO)	PBT
Pitch, coal tar, high-temp.	PBT/vPvB
Pentacosafuorotridecanoic acid	vPvB
5-tert-butyl-2,4,6-trinitro-m-xylene (Musk xylene)	vPvB
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	PBT/vPvB
Anthracene oil	PBT/vPvB
Anthracene oil, anthracene paste	PBT/vPvB
Hexabromocyclododecane	PBT/POP

Note that the **CLP Regulation**, which implements the Globally Harmonised System of Classification and Labelling of Chemicals, does not include the possibility of classification for PBT/vPvB, since these are not part of the GHS. However, the classification “Hazardous for the aquatic environment” (chronic hazard toxicity for organisms such as fish and algae) includes ‘ready degradability’ or ‘potential to bioaccumulate’ as criteria to consider and therefore some aspects of persistence are taken into account.

Several EU acts are aimed at restricting specific chemical substances because of their persistence as well as their toxicity and potential for bioaccumulation. These include the 1996 **PCBs Directive**³⁴⁸, the 2004 **POPs Regulation**³⁴⁹ implementing the Stockholm Convention, and the 2008 **Mercury Regulation**³⁵⁰. As noted earlier, persistence is also a factor with respect to the substances regulated through the 2009 **Ozone-Depleting Substances Regulation**³⁵¹, and the 2014 **F-Gases Regulation**³⁵², both implementing the Montreal Protocol.

The EU regulatory framework relevant for very persistent substances also includes controls over products released directly into the environment, such as the 2009 **Plant Protection Products Regulation** (PPPR)³⁵³, the 2012 **Biocidal Products Regulation** (BPR)³⁵⁴, and the **Directives on medicinal products for human use** (HMPD)³⁵⁵ or **for veterinary use** (VMPD)³⁵⁶. Both the PPPR and the BPR provide that active substances cannot be approved for use in pesticides or biocides if they are found to be PBT or vPvB; however, the BPR foresees the possibility of a derogation, e.g. if the

³⁴⁸ Directive 96/59/EC on disposal of polychlorinated biphenyls and polychlorinated terphenyls.

³⁴⁹ Regulation (EC) No 850/2004 on persistent organic pollutants.

³⁵⁰ Regulation (EC) No 1102/2008 on the banning of exports of metallic mercury and certain mercury compounds.

³⁵¹ Regulation (EC) No 1005/2009 on substances that deplete the ozone layer

³⁵² Regulation (EU) No 517/2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006

³⁵³ Regulation (EC) No 1107/2009 concerning plant protection products.

³⁵⁴ Regulation (EU) 528/2012 concerning biocidal products.

³⁵⁵ Directive 2001/83/EC relating to medicinal products for human use.

³⁵⁶ Directive 2001/82/EC relating to veterinary medicinal products

active substance is needed on the grounds of public health or public interest and no alternatives are available. While both the HMPD and the VMPD provide for Member States to suspend marketing authorisation if necessary to protect human health, only the Directive on veterinary medicinal products permits the refusal of authorisation in order to protect the environment, e.g. on the basis of PBT or vPvB. In addition, as already noted above, the 2004 **Detergents Regulation**³⁵⁷ is the one EU act that regulates substances on the basis of their persistence, by requiring surfactants used in detergents to meet biodegradability standards.

Also important to mention are those acts aimed at controlling processes that result in releases to the environment, including of certain PBT/vPvB substances, during manufacturing or product use. The 2010 **Industrial Emissions Directive** (IED)³⁵⁸ covers 52,000 major industrial installations across the EU. It requires the operation of these installations in accordance with best available techniques (BAT) for the particular industrial process, and as per the emission limit values (ELVs) for hazardous substances set in each installation's integrated permit.

The IED's list of polluting substances to be covered by ELVs includes some groups of persistent substances covered in EU legislation for air and water quality protection, and refers to the CLP Regulation for a general definition of 'hazardous substances'. As explained above, the CLP Regulation includes a classification for 'hazardous to the aquatic environment'. While this includes the criterion of ready biodegradability, it is not equivalent to the criteria for persistence under REACH and it is likely that many vP substances would not be caught, e.g., a vP substance not meeting additional criteria for BT and vB and not specifically listed in the IED would not be included in the controls over the industrial facility's emissions.

The conditions considered best available techniques (BAT) for the industrial processes covered under the IED are defined inter alia on the basis of BAT reference documents (BREFs) developed by stakeholders under the coordination of the Commission's Joint Research Centre. These are aimed at achieving best overall reduction of pollution emitted to the environment and do not take into account the intrinsic quality of persistence which may require special measures to prevent any releases of vP substances in order to avoid build-ups in the environment. As already noted, releases of vP substances not yet determined to be B or T would not be covered. Moreover, the use of ELVs or concentration values is inappropriate for vP substances likely to lead to accumulations in the environment. Another gap is that emissions of vP substances from smaller industrial installations are not covered.

The 1991 **Urban Wastewater Treatment Directive**³⁵⁹ is primarily aimed at reducing the nitrogen content of receiving waters, so as to prevent eutrophication. It includes a general requirement that industrial waste water discharged into sewage systems must be pre-treated to ensure that discharges from treatment plants do not adversely affect the environment. The emerging problem of chemical loads from household chemicals, pharmaceuticals and cosmetics collected via sewerage and which cannot be removed via conventional sewage treatment is not covered.

In addition, several acts are important for their relevance in controlling hazardous substances in the technosphere. Among these is the 2011 (**recast**) **RoHS Directive**³⁶⁰, one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. RoHS requires Member States to prevent the placing on the market of new electrical and electronic equipment (EEE) containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE). The first four substances are metals and hence primary elements, while the last two are POPs used as flame retardants. By banning the use of these substances, they are prevented from entering the material waste stream, i.e., the technosphere. Note that other flame retardants not

³⁵⁷ Regulation (EC) No 648/2004 on detergents.

³⁵⁸ Directive 2010/75/EU on industrial emissions (IPPC).

³⁵⁹ Directive 91/271/EEC concerning urban waste-water treatment

³⁶⁰ Directive 2011/65/EU (RoHS Directive).

covered under RoHS but which are frequently added to the plastic casings of televisions and other electronic products -- such as tetrabromobisphenol A (TBBPA), and hexabromocyclododecane (HBCD) -- are also problematic and an instance of “regrettable substitution” in that plastics with added flame retardants may not be recyclable and in any case the flame retardants should be kept out of recycled material flows. The substance-specific provisions in the other “waste stream directives”, e.g. end-of-life vehicles³⁶¹, batteries³⁶² and packaging materials³⁶³, play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

The 2000 **Water Framework Directive**³⁶⁴, together with the 2008 **Environmental Quality Standards Directive** (EQSD)³⁶⁵, form another essential element of the overall EU regulatory regime. The Water Framework Directive provides for establishment of a list of priority substances, which present a significant risk to or via the aquatic environment, identified on the basis of risk assessment. Within this list, substances that are toxic, persistent and liable to bio-accumulate or which give rise to an equivalent level of concern, are to be identified as priority hazardous substances. The classification of substances as priority substances and priority hazardous substances triggers specific risk management measures. Priority substances should be subject to controls for the progressive reduction of discharges, emissions and losses of the substances concerned. In the case of priority hazardous substances such controls aim at the cessation or phasing-out of discharges, emissions and losses by 2020. Amendment by the EQS Directive has resulted in a list of 45 substances considered priority substances. Within these are 21 substances considered priority hazardous substances, including PBDE, chloroalkanes (C₁₀₋₁₃), DEHP, hexachlorobenzene, PCB, PCP, PAH, PFOS, dioxins, and HBCDD.

Directive 2013/39/EC³⁶⁶ amending the Water Framework and EQS Directives recognises the need for special consideration of substances behaving as ubiquitous persistent, bioaccumulative and toxic (UPBT) substances. Because of long-range transport and their persistence in the aquatic environment, special monitoring requirements may be called for, as well as more stringent emission controls. Substances identified as UPBTs include brominated diphenylethers, mercury and its compounds, polyaromatic hydrocarbons (PAH), tributyltin compounds, perfluorooctane sulfonic acid and its derivatives (PFOS), dioxins and dioxin-like compounds, hexabromocyclododecane (HBCDD) and heptachlor. In addition, the Directive recognises the contamination of soil and water with pharmaceutical residues as an emerging environmental concern. Finally, the Directive sets up a new monitoring mechanism to provide high-quality information on the concentration of substances in the aquatic environment, with a focus on emerging pollutants. This includes a provision for a watch-list mechanism designed to allow targeted EU-wide monitoring of a limited number of substances of possible concern.

Table 11: The WATCH List under the Water Framework Directive

The WATCH List under the Water Framework Directive
<p>The WATCH List established under Directive 2013/39/EU will focus on ten compounds. The first three compounds selected are the pharmaceuticals diclofenac, 17-beta-estradiol (E2) and 17-alpha-ethinylestradiol (EE2). The candidate compounds for the remaining seven positions on this shortlist are: trichlorfon, cyclododecane, imidacloprid, diflufenican, oxadiazon, tri-allate, methiocarb, 2,6-di-tert-butyl-4-methylphenol, thiacloprid, aminotriazole, clothianidin, chromium trioxide, thiamethoxam, 2-ethylhexyl 4-methoxycinnamate, dichlorfuanid, formaldehyde, dimethenamid-P, triphenyl phosphate, acetamiprid, erythromycin, clarithromycin, ciprofloxacin, tolylfluanid, azithromycin and free cyanide³⁶⁷.</p>

³⁶¹ Directive 2000/53/EC on end-of-life vehicles.

³⁶² Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators.

³⁶³ Directive 94/62/EC on packaging and packaging waste

³⁶⁴ Directive 2000/60/EC establishing a framework in the field of water policy.

³⁶⁵ Directive 2008/105/EC on environmental quality standards in the field of water policy.

³⁶⁶ Directive 2013/39/EU amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy.

³⁶⁷ <https://www.gov.uk/government/news/european-commission-publishes-candidate-compounds-for-watch-list-under-water-framework-directive> (accessed 26.09.2016).

While there is surely a need for systematic environmental monitoring and surveillance of vP substances in waters and soils in order to track their presence in the environment, including any build-ups, efforts towards this end are impeded by the lack of analytical test methods and technical standards from producers.

Other relevant EU acts that merit mention include the 1998 Drinking Water Directive³⁶⁸, the Cosmetics Regulation³⁶⁹ and the regulations on food contact materials³⁷⁰ and food safety³⁷¹. While the **Drinking Water Directive** sets 26 chemical parameters in its Annex I, these have not been revised since 1998. A recent evaluation of the Directive³⁷² concluded that these quality standards no longer fully reflect scientific progress, improved risk assessments, changes in behaviors, and environmental pressures. Emerging substances mentioned by the study as in need of drinking water parameters were chromium VI, perfluorinated substances, and nanoparticles. EU legislation on food safety is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

More detailed descriptions of each act are provided in Annex 1 on the regulatory framework relevant for very persistent substances.

2.8 IMPACT ON NATURAL RESOURCES AND THE TECHNOSPHERE.

This section considers the impact that very persistent substances have had on Europe's natural resource base. In the absence of comprehensive information, it relies on the many examples in the literature of contamination of natural resources by persistent chemicals in Europe and elsewhere. They cover environmental media such as groundwater, surface water, soil, sediment and air. Major sources are industrial production of POPs or their precursors, industrial spillages, inadequate waste treatment, agricultural inputs and firefighting foams. However, releases from uses and disposal of consumer products containing vPs, such as pharmaceuticals, cosmetics and textiles treated for water and stain resistance are increasingly problematic also.

In numerous cases resources have been taken out of use because they contain levels of vPs which exceed regulatory limits, such as those set by the Groundwater Directive, or national health authority guidelines. The effects on resources can extend to decades after their production or release due to their inherent properties³⁷³. Levels of vPs below regulatory limits are also well documented throughout Europe and elsewhere. The resulting chronic exposure could in some cases pose a greater risk to ecosystems than acute incidents³⁷⁴.

The contamination of resources with persistent chemicals is of concern for several reasons, including: 1) the inability to use—often scarce—resources for long periods of time, 2) the endurance of vPs in ecosystems even once acute contamination incidents have become dispersed through transfer to other environmental media and long-range transport, and the threats of chronic toxicity therein³⁷⁵, 3) the extremely high costs of remediation of contamination, which often contains rather than destroys or irreversibly transforms the contaminants—as required under the Stockholm Convention³⁷⁶, and 4) the implications for human and ecosystem health of contaminated resources being used in recycling processes, especially in light of the EU's Circular Economy Package (contamination of the 'technosphere').

³⁶⁸ Directive 98/83/EC on the quality of water intended for human consumption.

³⁶⁹ Regulation (EC) No 1223/2009 on cosmetic products.

³⁷⁰ Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food.

³⁷¹ Regulation (EC) No 178/2002 on the general principles and requirements of food law.

³⁷² <http://www.safe2drink.eu/news/final-evaluation-report-available/> (accessed 27.09.2016).

³⁷³ Wilhelm, M. *et al.*, 2010.

³⁷⁴ Giger, W., 2009.

³⁷⁵ *Ibid.*; Pico, Y. *et al.*, 2012.

³⁷⁶ Weber, R. & Varbelow, H.G., 2013.

Several overviews exist of contamination of specific media or by specific vPs, including PCDD/Fs³⁷⁷, HCHs³⁷⁸ and PFASs³⁷⁹. However, few synthesis studies could be found on the state of contamination of various natural resources in Europe by vPs. To address this, this review presents a range of salient cases of contamination of groundwater, surface water, soil and sediment by persistent chemicals, mainly in Europe, including where resources have become unusable as a result³⁸⁰. Finally, it presents a preliminary analysis of the implications of recycling of persistent chemicals through circular economy activities.

2.8.1 Groundwater and surface water

The contamination of groundwaters and surface waters by persistent chemicals has occurred in multiple locations across Europe and elsewhere^{381 382}. Because of hydrological cycles and flooding, contaminated surface waters can filter into groundwater, and become sources of contamination of aquatic food webs³⁸³ and land-based food webs³⁸⁴. Both groundwater and surface water are sources for drinking water, so contamination by persistent chemicals is a major concern.

In particular, the persistence of highly fluorinated chemicals (HFCs) and also of water-soluble organochlorines in groundwater has been documented³⁸⁵. Where concentrations of particular substances have been above regulatory limits, e.g. drinking water or groundwater standards, authorities in several cases have prohibited the consumption of water from contaminated groundwater sources, whilst in others measures such as mixing the water with non-contaminated sources has brought levels of particular substances within regulatory limits³⁸⁶.

Highly chlorinated substances have been involved in several cases of contamination of surface waters in Europe. In Switzerland, fishing from rivers in three Cantons was prohibited due to excessive levels of PCBs (including PCDDs and PCDFs) leaching from local landfill waste³⁸⁷. Industrial waste incineration led to contamination by the same groups of chemicals in Bolsover, UK³⁸⁸. In France, some 550 sites were estimated in 2013 to be polluted by PCBs, prompting various fishing bans between 2007 and 2012³⁸⁹.

Other cases of contamination by PCFF/Fs and PCDE have been documented in rivers in Finland and the Baltic Sea, even though the industrial sources stopped operating in 1984³⁹⁰. In Aragón, Spain, HCH wastes from lindane manufacturing in the 1970s and 1980s deposited at landfills has led to levels of HCH in the Gallégo river that exceed the limit set by the Water Framework Directive³⁹¹, leading to several bans on drinking water³⁹². Surface water was also impacted by organochlorine contamination at the former HCH/DDT production site at Bitterfeld Wolfen in Germany, which operated between the 1950s and 1980s, where total costs of remediation are estimated at EUR700-2000 million³⁹³.

³⁷⁷ Weber, R. *et al.*, 2008.

³⁷⁸ Vijgen, J., 2006.

³⁷⁹ Rumsby, P.C. *et al.*, 2009; Cousins, I.T. *et al.*, 2016.

³⁸⁰ Therefore, whilst this overview is mainly structured according to different media, some overlap occurs due to the fact that many cases involve contamination of several media at the same time because of the exchange of different vPs between air, soil and water.

³⁸¹ See Table Appendix 3.

³⁸² And is now the subject of monitoring programmes and investigation in Germany.

³⁸³ Choi, S. & Wania, F., 2011; Castro-Jiménez, J. *et al.* (eds.), 2007.

³⁸⁴ See for example Holoubek, I. & Klánová, J., 2008; Holoubek, I. *et al.*, 2003.

³⁸⁵ Fawell, J. & Ong, C.N., 2012; Rumsby, P.C. *et al.*, 2009; Götz, R. *et al.*, 2013.

³⁸⁶ See for example: Rumsby, P.C. *et al.*, 2009; Wilhelm, M. *et al.*, 2010.

³⁸⁷ Häner, A., & Urmann, K., 2012.

³⁸⁸ Weber, R. *et al.*, 2008.

³⁸⁹ Soullier, L., 2013 ; Robin des Bois, 2013a.

³⁹⁰ Weber, R. *et al.*, 2008.

³⁹¹ Fernández, J. *et al.*, 2013.

³⁹² Heraldo, 2014.

³⁹³ Wycisk, P. *et al.*, 2012.

A common source of vP contamination of groundwater has been the production and disposal in landfills of pesticides, in particular of HCH (lindane), and other persistent chemicals, including in: Hamburg, Germany³⁹⁴; Bitterfeld-Wolfen, Germany³⁹⁵; Aragón, Spain³⁹⁶; at Spolana Neratovice, Czech Republic³⁹⁷; Schweizerhalle, Switzerland³⁹⁸; in 18 other locations in Switzerland³⁹⁹; and at various sites in the Netherlands⁴⁰⁰. Organochlorines are more water-soluble and therefore pose a particular challenge for groundwater management⁴⁰¹. For example, in Hamburg, Germany, the groundwater below a landfill where HCH/PCDD/PCDF waste was deposited in the 1980s, appears to be permanently polluted, necessitating expensive ‘pump and treat’ activities well into the future⁴⁰². These examples highlight that these substances remain in environmental media and transfer between them long after the source is stopped.

Highly fluorinated chemicals (HFCs) have become an increasingly widespread groundwater and surface water contaminant. In groundwater, they can persist for a very long time after the source is stopped⁴⁰³. A particularly well-documented case of surface water contamination by HFCs, especially PFOA, occurred in 2006 in the Ruhr and Moehne rivers in Germany following the application of contaminated fertiliser on adjacent fields⁴⁰⁴. This affected drinking water supplies of around 40,000 residents, prompting bottled water to be distributed to families with babies and pregnant women. A follow-up investigation in North-Rhine Westphalia identified several cases of contamination in river and ground waters used for drinking water⁴⁰⁵.

A major source of HFC contamination has been the use or spillage of PFASs-containing aqueous film firefighting foam (AFFF)⁴⁰⁶. In Schiphol Airport in the Netherlands in 2008, an accidental release of AFFF led to contamination—mainly by PFOS—of local water, sediment and fish⁴⁰⁷. AFFFs have contaminated ground and surface water around Buncefield Oil Depot, UK⁴⁰⁸; East Anglia in the UK⁴⁰⁹; in several private wells in Cologne in Germany⁴¹⁰; at a number of civilian and military airports in Sweden⁴¹¹; and at Jersey Airport in the UK⁴¹². This has implications for drinking water supplies drawn from groundwater.

For example, in Cologne the City’s Public Health Department prohibited the consumption of well water in 2009⁴¹³ and in Cologne and Jersey affected residents were supplied with bottled water or connected to the mains supply⁴¹⁴. The persistence of these substances in groundwater was demonstrated in Jersey, where PFOS was still being detected two decades on at above 10µg l⁻¹ in some areas⁴¹⁵, and in East Anglia, UK, where the level of PFOS in raw water was around the same level

³⁹⁴ Weber, R. & Varbelow, H.G., 2012 ; Weber, R. *et al.*, 2013 ; Götz, R. *et al.*, 2013.

³⁹⁵ Wycisk, P., P. *et al.*, 2012.

³⁹⁶ Fernández, J. *et al.*, 2012; Morgan, S., 2016.

³⁹⁷ Holoubek, I. *et al.*, 2003a.

³⁹⁸ Giger, W., 2009.

³⁹⁹ Weber, R. *et al.*, 2008.

⁴⁰⁰ Vijgen, J., 2006.

⁴⁰¹ Götz, R. *et al.*, 2013.

⁴⁰² *Ibid.*

⁴⁰³ Fawell, J. & Ong, C.N., 2012.

⁴⁰⁴ Skutlarek, D. *et al.*, 2006; Schaefer, A., 2006; Hölzer, J. *et al.*, 2008.

⁴⁰⁵ Wilhelm, M. *et al.*, 2010.

⁴⁰⁶ Cousins, I.T. *et al.*, 2016.

⁴⁰⁷ Kwadijk, C. *et al.*, 2014.

⁴⁰⁸ Rumsby, P.C. *et al.*, 2009.

⁴⁰⁹ *Ibid.*

⁴¹⁰ Weiß, O. *et al.*, 2012.

⁴¹¹ Norström, K. *et al.*, 2015 ; Naturvårdsverket, 2016; KEMI, 2016; Cousins, I.T. *et al.*, 2016.

⁴¹² Rumsby, P.C. *et al.*, 2009.

⁴¹³ Weiß, O. *et al.*, 2012.

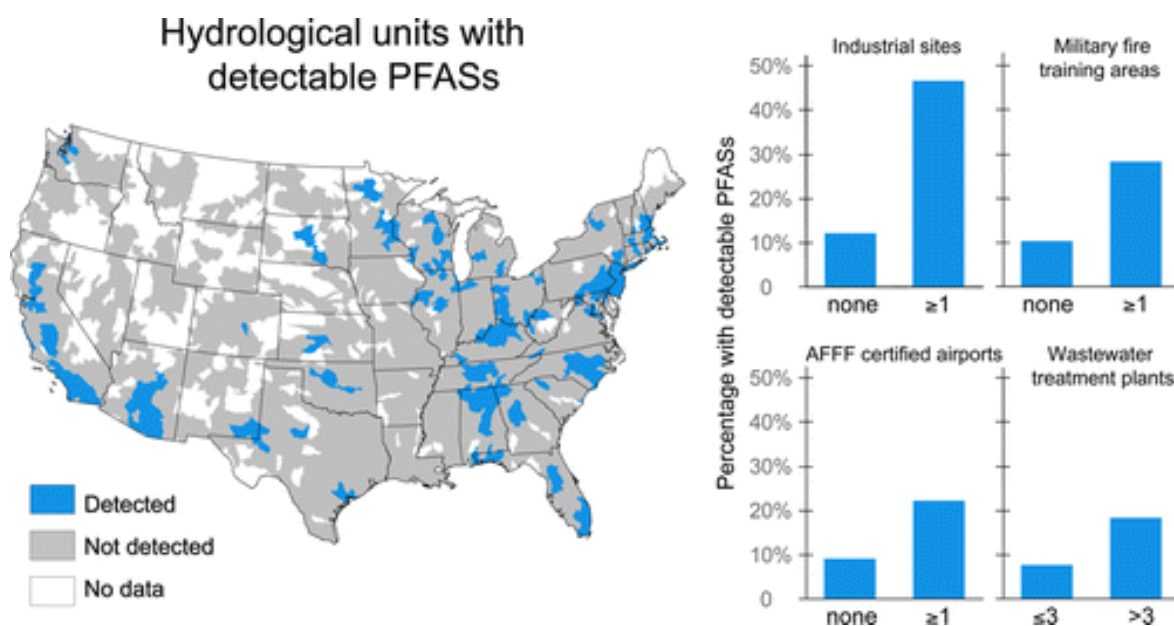
⁴¹⁴ *Ibid.*; Rumsby, P.C. *et al.*, 2009.

⁴¹⁵ Rumsby, P.C. *et al.*, 2009.

approximately three years after the incident⁴¹⁶. The drinking water works in Kallinge, Sweden were shut down following groundwater contamination by HFCs linked to the use of firefighting foam.

Recently, the issue of HFC contamination of surface waters (and groundwater) used as sources of drinking water has become a particular concern in the US. The US EPA monitored PFAS concentrations in 2013-2015 as part of its third Unregulated Contaminant Monitoring Rule program. A review of that data found that drinking water supplies for 6 million U.S. residents exceed the US EPA's May 2016 lifetime health advisory limits (70 ng/L) for PFOS and PFOA⁴¹⁷. Significant predictors of PFAS detection frequencies and concentrations in public water supplies included the number of industrial sites that manufacture or use these compounds, the number of military fire training areas, and the number of wastewater treatment plants. The number of civilian airports with personnel trained in the use of aqueous film-forming foams was also significantly associated with the detection of PFASs above the minimal reporting level.

Figure 4: Areas in the USA where PFAS has been detected in surface or groundwater



No comparable EU-wide monitoring of water resources has been carried out, and the number of drinking water supplies contaminated by PFAS in Europe is not known. However, the range of sources of PFAS indicates that contamination may be widespread. A Dutch study identified waste water treatment plants as a main direct source of PFAS in surface waters and corresponding drinking water, along with landfill leachate and water draining from a nearby military base. In addition, it found that infiltrated rainwater was a significant indirect source, suggesting a widespread diffuse contamination from atmospheric deposition.⁴¹⁸

The presence of persistent substances in surface water and groundwater serves as a reservoir of contamination for aquatic ecosystems, drinking water and human food webs. On this basis, the Association of Waterworks from Central Europe (IAWR) argued that more weight should be placed on persistence and exposure as opposed to toxicity when assessing limits for drinking water⁴¹⁹.

⁴¹⁶ *Ibid.*

⁴¹⁷ Hu, X.C. *et al.*, 2016.

⁴¹⁸ Eschauzier, C., *et al.*, 2013.

⁴¹⁹ Giger, W., 2009.

2.8.2 Soil

The contamination of soils in Europe by vPs covers a variety of sources and substances. The Commission Staff Working Document accompanying the 2006 Thematic Strategy for Soil Protection estimated that because of the use and presence of dangerous substances in many production processes, some 3.5 million sites may be potentially contaminated across Europe, with 0.5 million sites being really contaminated and needing remediation⁴²⁰. In addition to local sources, contamination has also been documented in soils away from point sources, e.g. at high altitudes due to long-range transportation⁴²¹.

In Central and Eastern Europe, contamination has often been related to former pesticide production. Various industrial soils in the Czech Republic are heavily contaminated, most notably the Spolana Neratovice factory, involving HCH compounds, DDT and DDE from production which ceased in 1975, at levels which made it one of the most highly dioxin-contaminated sites in the world in the early 2000s⁴²². In Romania around 200 contaminated soil sites exist (with a potential 2000 more), mainly due to pesticide manufacturing, with an estimated EUR8.5 billion clean-up cost⁴²³. Former pesticide production has also caused soil contamination in Galicia, Spain⁴²⁴; Hamburg, Germany⁴²⁵; Aragón, Spain⁴²⁶; Bitterfeld Wolfen, Germany⁴²⁷; Dielsdorf, Switzerland, which has since been remediated⁴²⁸; and at various sites in the Netherlands⁴²⁹.

Table 11: Costs of cleaning up some very persistent chemicals

Costs of cleaning up very persistent chemicals	
Estimates for addressing organochlorine contamination of natural resources:	
■	Remediation of former HCH/DDT production site at Bitterfeld Wolfen (DE): total est. costs 700-2000 million EUR ⁴³⁰ .
■	Clean-up of 200 Romanian sites contaminated by pesticide manufacturing: 8.5 billion EUR
Estimates for addressing PFAS contamination of drinking water:	
■	Charcoal filtering of water in Uppsala (SE): annual cost 10 million SEK (1 million EUR)
■	New water supply in Ronneby (SE) (population 12,000): 30 million SEK (3 million EUR)
■	Larger new water supplies for Växjö (pop. 63,500) and Alvesta (pop. 15,900): 455 million SEK (45,5 million EUR) ⁴³¹
■	Collection and carbon filtration of the drainage water at one site on Möhne River (DE), with regular exchange of filters: 2 million EUR (initial) ⁴³²
■	Pumping out & treating polluted groundwater at Buncefield (UK) to remove fuel and PFOS: 1 million GBP a year ⁴³³
Options for remediation of fire training ground at Jersey Airport in the Channel Islands ⁴³⁴ :	
■	Removal of the entire Fire Training Ground to a depth of 30 meters and construction of a replacement Fire Training Ground -- total estimated cost of 30 million GBP.
■	Removal of contaminated stone to depth of 10 meters -- total estimated cost of 22 million GBP (at 1999 prices)
■	Removing 2 meters of contaminated soil and placing it on impermeable base, insertion of deep concrete wall to prevent groundwater running through site; and placing concrete cap on an impermeable base and containment of all firewater runoff contaminated with foam -- estimated cost between 3.7 and 4.9 million

⁴²⁰ {COM(2006)231 final} {SEC(2006)620} /* SEC/2006/1165 */

⁴²¹ Holoubek, I. *et al.*, 2013b; Kukučka *et al.*, 2009

⁴²² Ruzicková, P. *et al.*, 2008; Holoubek, I. *et al.* 2003a

⁴²³ Mogos, A., n.d.

⁴²⁴ Concha-Graña, E. *et al.*, 2006

⁴²⁵ Weber, R. & Varbelow, H.G., 2012 ; Weber, R. *et al.*, 2013 ; Götz, R. *et al.*, 2013

⁴²⁶ Fernández, J. *et al.*, 2013; Morgan, S., 2016

⁴²⁷ Wycisk, P. *et al.*, 2012

⁴²⁸ Häner, A., & Urmann, K., 2012

⁴²⁹ Vijgen, J., 2006

⁴³⁰ Wycisk, P. *et al.*, 2012

⁴³¹ KEMI, 2016

⁴³² Wang, Z. *et al.*, 2017.

⁴³³ Ibid.

⁴³⁴ Klein, R., 2013.

Costs of cleaning up very persistent chemicals

GBP (at 2000 prices);

- Doing nothing (considered environmentally and politically unacceptable)

Disposal of foam contaminated firewater runoff or legacy stock is also costly, since these compounds are difficult to destroy. Incineration must be carried out at >1,100°C in special furnaces with scrubbing of the flue gases using calcium carbonate or quicklime to remove the hydrogen fluoride produced.

The contamination of soils in Aragón, Spain related to disposal of HCH waste from lindane manufacturing at two unsecured landfills, recently received attention due to the region's plan to apply for Horizon 2020 funding to clean up the pollution⁴³⁵. The transfer of the waste to secured sites is estimated to cost EUR19 million over three years, along with other annual costs for each site estimated at hundreds of thousands of euros.

Other vPs are also implicated in soil contamination in Europe. In England, PAHs are the most common organic substances that lead to land being categorised as contaminated, with other vPs such as PCBs/dioxins/furans playing a smaller role⁴³⁶. In Wales, Benzo(a)pyrene (a PAH) is the single most common compound leading to land being legally designated as contaminated, accounting for 76% of sites⁴³⁷. Soil contamination has also occurred from the application of agricultural products which contained recycled materials contaminated with vPs. These are discussed in the below section on the impact on the technosphere. Other cases of soil contamination in Europe are summarised in appendix III.

2.8.3 Sediment

In Europe releases of vPs into the environment have also transferred into river, lowland and marine sediment. The release of AFFF at Schiphol Airport in the Netherlands, led to 0.5-14 ng/g dw PFOS being measured in sediment, which remained at similarly high levels compared to the reference location ten weeks following the incident, as well as three years afterwards⁴³⁸. Low levels of PFCs—under regulatory limits—were found in water and sediment in the Albufera Natural Park in Valencia, Spain. However, because they are bioaccumulative and persistent they carry the risk of longer term toxicity, especially as they travel up the aquatic food chain⁴³⁹. In France, high concentrations of POPs in sediment in the Seine river floodplain were the subject of a national Plan of Action on PCBs⁴⁴⁰.

Two surveys of PCBs, DDTs and HCBs in Mediterranean marine sediments found several 'hotspots' of contamination, especially around industrial and urban areas and around the mouths of the main Mediterranean rivers⁴⁴¹. Further, despite a significant decline in emissions in recent decades, the same study found significant amounts of DDT in sediment, highlighting the persistence of these compounds and their transfer across different environmental media.

The contamination of sediment has also been associated with the re-mobilisation of chemicals when flooding occurs. Two notable cases of this were in the Czech Republic in 2002⁴⁴² and in Bitterfeld Wolfen in 2002, around which site there is a 60km² wide lowland containing around 20,000 tons of sediment heavily polluted with POPs, and where the re-mobilisation of sediment presents a major problem⁴⁴³.

⁴³⁵ Morgan, S., 2016

⁴³⁶ UK Environment Agency, 2016

⁴³⁷ Cyfoeth Naturiol Cymru, 2016

⁴³⁸ Kwadijk, C. *et al.*, 2014

⁴³⁹ Pico, Y. *et al.*, 2012

⁴⁴⁰ Lorgeoux, C. *et al.*, 2016 ; République Française, 2008

⁴⁴¹ Gómez-Gutiérrez, A. *et al.*, 2007a, b

⁴⁴² Holoubek, I. *et al.*, 2003

⁴⁴³ Wycisk, P. *et al.*, 2012

2.8.4 Technosphere

The EU's action plan on a circular economy to maximise the use of, and minimize the waste of, material resources in the economy includes "the development of strategic approaches on plastics and chemicals"⁴⁴⁴. A particular challenge will be the presence of POPs in recycled products. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied⁴⁴⁵.

Cases of persistent chemicals being recycled through agricultural inputs had already been documented in Europe and globally. The contamination in Arnsberg Germany in 2006 described above occurred because a fertilizer containing food industry sewage sludges was applied, which was likely contaminated with mislabeled waste⁴⁴⁶. In Decatur, Alabama, in the US, the application of biosolids from wastewater treatment which had received waste from local fluorochemical manufacturing, caused soil, surface water and well water contamination with HFCs⁴⁴⁷. This highlights the risk of persistent chemicals being transmitted from waste water recycling into drinking water and biosolids used in agriculture, especially of HFCs due to their persistence and potential toxicity and their presence in certain cases in large concentrations in sludge⁴⁴⁸. This could become an increasingly important issue in the context of increasing population pressures and circular economy goals which are likely to prompt greater recycling of waters⁴⁴⁹.

Contamination of human food chains has also occurred through recycling of other inputs. A survey of cases of contamination by PCDD/Fs highlighted various cases: 1) in 1998, citrus pulp made from lime deposits from the choline/organochlorine industry caused contamination of meat and dairy products with high levels of PCDD/Fs, 2) the 'Belgian dioxin scandal' in 1999, where chickens, eggs and other animal products were contaminated due to animal feed containing fats mixed with PCB oil, and 3) in 2002, the contamination of animal feed mixture in Europe with high levels of PCDD/Fs from PCP via saw mill dust that had been added to the feed⁴⁵⁰.

Non-food related contamination has also resulted from recycling processes. Recycled paper products including napkins and toilet paper have been shown to contain concentrations of Bisphenol A in the μg range⁴⁵¹. A recent series of studies in Denmark on chemical contaminants in recycled paper and plastics found 157 hazardous chemicals in paper, of which over 50% were persistent and included PCBs. The study results indicated that phasing out of chemicals is the most effective measure for reducing chemical contamination in material flows. However, assuming a recycling rate of 70% of paper in Europe, the time lag between stopping a chemical contaminant such as BPA (commonly found in thermal cash register receipts) before the presence of the chemical in paper products could be considered insignificant was between 10 to 30 years⁴⁵². In the case of PFAS contamination in recycled paper (e.g. from food containers like pizza boxes), since PFAS do not degrade, it will take a very long time indeed to get rid of the organofluorine contamination, even if the deliberate addition of PFAS to paper stopped.

In other cases, sites have been contaminated with PCDD/Fs by waste incineration, secondary metal industries, and the recycling or depositing of certain wastes like electronic or car shredder wastes⁴⁵³. This highlights the importance of addressing the linkages between chemicals legislation and circular economy activities in a range of product recycling activities to prevent acute and chronic exposure to

⁴⁴⁴ European Commission COM(2015) 614 final

⁴⁴⁵ *Ibid.*

⁴⁴⁶ Schaefer, A., 2006

⁴⁴⁷ Lindstrom, A.B. *et al.*, 2011

⁴⁴⁸ Clarke, B.O. & Smith, S.R., 2011

⁴⁴⁹ Loos, R. *et al.*, 2007

⁴⁵⁰ Weber, R. *et al.*, 2008 ; Weber, R. *et al.*, 2013

⁴⁵¹ Liao, C. & Kannan, K., 2011

⁴⁵² Pivnenko, K., *et al.*, 2016

⁴⁵³ Weber, R. *et al.*, 2008

POPs.

3 GAPS AND DEFICITS

On the basis of the literature review and the issues highlighted during the NTE workshop, a number of gaps and deficits in EU policies related to very persistent chemicals have been identified. The section below summarising these gaps and deficits is structured from a life cycle point of view. It first considers gaps in identifying those substances which may be very persistent, in view of their potential impacts on health and the environment. It then looks at gaps in the current system of controls over how these substances reach the natural environment (ecosphere) as well as the technosphere, i.e., through manufacturing processes to uses in products and to recycling and end-of-life disposal. It also considers deficits in policies related to how to address very persistent chemicals once they reach the environment and persist, leading to accumulations, exposures and possible irreversibility.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

3.1 GAPS IN IDENTIFYING AND REGULATING VP SUBSTANCES

1. REACH and other EU legal acts regulate persistent chemicals only if other hazardous properties such as bioaccumulability are also present (except for the 2004 Detergents Regulation). While in theory ‘very persistent’ might be considered as giving rise to an equivalent level of concern under REACH Article 57(f), such an analysis would need to be carried out on a case-by-case basis, and regulation of similar vP substances on the basis of a grouping might not be possible.
2. Testing chemicals to determine their half-lives in the various environmental compartments (water, soil, etc.) is time consuming and costly, and only some 200 chemicals have been fully tested for persistence to date, which is a large information gap.
3. In part because of this gap in analytical methods and data on persistence in chemicals, no common framework for comprehensive screening of substances for persistence has been agreed on EU level.
4. The criteria and methodologies (both testing and screening methods) for identifying substances considered extremely persistent – such as for the highly fluorinated substances – are particularly inadequate. Given that the criteria for vP is for degradation half-lives of >180 days in certain environmental media, other criteria are needed for substances where no evidence of degradation potential could be identified, or when degradation half-lives could be decades to centuries.
5. The role of vP substances in combination effects and cumulative exposure from chemicals is not given adequate consideration.
6. The persistence of a substance’s transformation (including degradation) products are not sufficiently taken into account when that substance’s health and environmental impacts are considered.
7. REACH does not require data on persistence for low volume substances, i.e., substances produced or imported <10 tonnes per annum, and therefore a large information gap continues. For example, the Swedish Chemicals Agency estimates that some 3000 PFAS are on the global market today, yet only a few of these have been registered under REACH⁴⁵⁴ – hence another information gap.
8. Some unintentionally produced vP chemicals, e.g., polybrominated dioxins/furans (PBDD/F) or brominated-chlorinated dioxins/furans (PXDD/F), are not explicitly recognised under the EU regulatory framework, and therefore very little monitoring of human and environmental exposure

⁴⁵⁴ Note that only substances produced or imported in quantities over 100 tonnes per annum have been registered to date. The deadline for registration of substances over 1 tonne per annum is 1 June 2018 at which time the number of registered PFAS will increase.

to these vPs is carried out.

9. International controls of vP substances have not kept pace with globalisation of chemicals industry and downstream product manufacturing.

3.2 GAPS IN REGIMES TO PROTECT THE ECOSPHERE FROM RELEASES OF VPS

A number of gaps have also been identified in the existing controls concerning how very persistent substances may be emitted to the natural environment due to anthropogenic activities, such as releases during manufacturing processes, while being used in products including articles, and due to end-of life disposal.

10. Data is lacking on the quantities of vP chemicals produced and/or emitted to the environment, which makes it very difficult to determine the overall load of vPs released to date.
11. The Industrial Emissions Directive (IED) applies only to major industrial activities, so some vP polluting emissions from smaller industrial activities often lack controls entirely.
12. The IED's list of polluting substances that must be covered by emission limit values in integrated permits cross-refers to the definition of hazardous substances and mixtures under the CLP, which does not include harmonized criteria for persistence, bioaccumulability, or the combinations of PBT or vPvB, so vP substances which do not fall under one of the groups of substances listed in the IED's Annex II will not be covered.
13. The BAT guidance documents developed to define 'best available techniques' for the industrial activities covered under the IED do not sufficiently address the measures needed to control emissions of vP substances.
14. Use of emission limit values is not appropriate in the case of vP substances, where overall limits may be needed to prevent undue loading of the natural environment.
15. Current controls are inadequate to prevent diffuse sources of vP substances from being released into the natural environment, e.g. due to uses of vP chemicals in certain kinds of products, such as in cosmetics or in textiles which will definitely result in releases to the environment due to bathing or laundering, or via discharges from waste water treatment plants or application of sewage sludge to soil. Controls are particularly insufficient concerning uses of vP substances in imported articles.
16. Lack of attention to substances that are both persistent and mobile. Chemical substances with this important and highly problematic combination of properties are not identified and not made subject to risk management measures. This puts surface and groundwater resources at particular risk.

3.3 DEFICITS IN CONTROLLING VP SUBSTANCES IN THE TECHNOSPHERE

17. Information is lacking concerning which vP substances might be used in products, including articles – whether they are produced within the EU or imported.
18. Controls over the use of vP substances in products/articles, including imports, are inadequate and only on a case-by-case basis, e.g., via REACH authorisation or restrictions or in certain product-related legislation such as RoHS.
19. Few mechanisms are in place to control vP substances that may be present in chemical formulations or in consumer articles and which then become recycled material waste streams at the end of product life. A related problem can occur as a result of unintended cross-contamination, e.g. from unintentional POPs in materials that are then recycled.
20. No tracking or monitoring is in place to determine which vPs are present in products, waste and recycled materials. Indeed, vP substances are allowed to be used in various product legislation, such as in food contact materials and as adjuvants in pesticides, cosmetics and pharmaceuticals.
21. Assessments of substances for use in certain products, e.g. cosmetics and food contact materials, focus primarily on limiting exposure to humans during the use/contact/intake of the product and

do not consider emissions occurring during the production or disposal of the product.

22. Few controls are in place over vP chemicals in end-of-product-life materials entering the material re-use/recycling streams and which could form reservoirs for future exposure.

3.4 DEFICITS IN PROTECTING HUMAN HEALTH AND IN ADDRESSING VP BUILD-UPS IN THE ECOSPHERE

23. Systematic monitoring is lacking for the presence and/or build-up of vP chemicals in the environment, including in specific environmental media and biota, e.g. humans.
24. The current EU regulatory regime provides no possibility for intervention/clean-up of reservoirs of contamination by P substances.
25. The Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so accumulations of vP pollutants in water resources are not given sufficient attention. Similarly, the EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

3.5 REASONS FOR GAPS AND DEFICITS

One of the major challenges relating to persistent and very persistent chemicals is that testing including screening for a substance's half-lives in the various environmental compartments such as water and soil is time consuming and costly. A number of studies have suggested ways in which chemicals can be screened based on chemical structures and characteristics to estimate their persistence. However, because the data available on various chemical structures and their biodegradability/persistence is limited, current methodologies for screening chemicals for possible persistence based on this limited information are problematic.

A related challenge concerns the difficulties involved in environmental monitoring, e.g., to detect actual presence/accumulation of chemical substances in the environment or biota. Because producers/importers of chemical substances are not required to provide samples (standards) of their products or analytical methods for their detection, scientists must often play a guessing game to determine which substances are present.

The EU regulatory framework does not allow controls over substances on basis of persistence alone. Legislation to protect the environment from polluting discharges covers substances only if they can be shown to be B and T also. Finally, product regulations often do not evaluate the risk of a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy.

In addition, the traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

3.6 AVAILABLE TOOLS TO RESPOND TO GAPS AND DEFICITS

The gaps and deficits identified in current policy are not new. Member States and stakeholders have to a smaller or larger extent identified the gaps and have developed or are developing measures to address the gaps. The catalogue of available tools listed below comprises a listing of existing measures practiced in Member States and/or by other stakeholders as well as measures described in the reviewed

literature.

The available tools below are grouped according to the four areas of gaps and deficits identified above, i.e., identification of very persistent substances, controls over emissions to the natural environment, controls over vP chemicals in the technosphere, and addressing vP accumulations. The basic starting point for the tools identified is that they contribute to a non-toxic environment by decreasing the human and/or environmental exposure to and dispersal of vP substances. They are aimed at addressing the problems, gaps and deficits identified above, and either go beyond current legal requirements or other aspects of current policy or facilitate the implementation and compliance with legislation.

Care has been taken to consider a range of possible tools to the gaps and deficits identified above, from 'soft' policy responses such as knowledge generation and awareness raising to 'command and control' regulation.

A number of ongoing initiatives within the Commission are currently assessing the performance of chemicals legislation. These include the fitness check of all chemicals legislation except REACH and the REACH review, which are both due in 2017. The results of this study will also provide useful input to those initiatives.

The catalogue of available tools to respond to gaps and deficits identified in this study is a comprehensive inventory of all possible measures identified during the work of this study. The potential impacts of these tools have not been assessed as part of this study. This needs to be done in a further step, taking into account the tools identified in the better regulation agenda.

3.6.1 Tools for gaps in identifying and regulating vP substances

1. Consider substances determined to be vP as giving rise to equivalent levels of concern under REACH Article 57(f), so that they can be added to the REACH Candidate List of substances for possible restriction/authorisation. Note that Article 57(f) can only be applied on a case by case basis so grouping approaches would not be possible.
2. Develop a harmonized framework for comprehensive screening for persistence, for use in identifying priority chemicals and for requiring more rigorous testing of actual environmental media half-lives where indications of lack of biodegradability are found.
3. Improve accuracy of screening results by combining screening methods currently available, such as described in PROMETHEUS, and/or by developing better screening methods.
4. Support development of additional analytical tests for determining half-lives of vP substances, including when a substance is characterised by extreme persistence.
5. Factor in the additional exposure due to a vP substance's persistence in assessing its role in combination effects and cumulative exposure.
6. Set in place drinking water standards to limit presence of vP substances, similar to the current group limit value for pesticides in drinking water.
7. Ensure that the persistence of any transformation or degradation products are considered when a substance is evaluated for health and environmental effects.
8. Automatically oblige industry to perform simulation tests for substances identified through screening as potentially vP.
9. Require registrants of low volume substances (<10 tonnes) to provide data on persistence/biodegradability.
10. Require producers to deliver validated analytical test methods for persistent substances, along with technical or authentic chemical standards, to enable better detection and monitoring of their presence in the environment or technosphere.
11. Apply the grouping approaches possible under REACH more vigorously with respect to vP substances with similar chemical structures, so as to facilitate evaluation, risk assessment and risk management as well as to avoid regrettable substitution.

12. Amend the CLP regulation to include P, vP, PBT, vPvB, M (mobility) and PM as additional hazard categories. This may require work at international level on the GHS framework.
13. Include additional unintentionally produced vP chemicals such as polybrominated dioxins/furans in the EU framework for POPs, as a first step towards a more comprehensive regulatory regime for monitoring of exposure and for setting product safety standards.
14. Consider the possibility of an additional classification for extreme persistence for those chemicals that may not degrade for decades or longer.
15. Encourage more ambitious international implementation of controls over vPs through the Stockholm Convention mechanism.

3.6.2 Tools for gaps in controls for vP emissions to the ecosphere

16. Establish transparent collection of data on quantities of vP substances produced and/or emitted to the environment, in order to better determine overall loads of vPs in the environment.
17. Require all emissions of vP substances to the natural environment from industrial activities to be subject to permit, including those from smaller installations not covered by the current Industrial Emissions Directive (IED).
18. Revise all BAT guidance documents as necessary to take account of all potential releases of vP substances to the environment, and to keep such releases to a minimum.
19. Require the production and/or industrial use of vP substances to take place only in closed systems.
20. Instead of using emission limit values (concentration levels) for controlling vP substances in discharges, set fixed maximum amounts for restricting vP substances released to the environment.
21. Include consideration of the environmental impacts of a vP throughout a product's lifecycle, including any releases of vP substances into wastewater that will result in contamination of UWWT discharges and of sewage sludge applied to land
22. Consider fixed limits at EU level to amounts of vP substances that can be produced/used/released, as per the restrictions in place for ozone-depleting substances, and allocate allowances of substances subject to strict limits via economic instruments such as tradeable permits.
23. Establish [hazard-based] bans on all unessential releases of vP substances to the environment, e.g., use of PFAS-based foams in fire-fighting training.

3.6.3 Tools for deficits in controls for vPs in the technosphere

24. Encourage voluntary bans or restrictions on use of vP chemicals by product designers, manufacturers and retailers.
25. Carry out public awareness campaigns to inform consumers and institutional purchasers (public procurement) concerning vP chemicals in products, including safe disposal at end-of-product life, so that they can make informed choices.
26. Establish labelling of products where vP chemicals are present, and traceability to prevent passing on accumulations of vP chemicals via materials recycling.
27. Establish central registries of products containing vP substances, along with annual statistical data of the volumes of vP substances produced, used and emitted, as part of a comprehensive monitoring system for persistent substances. The registries should include information on the chemical structures, elemental composition, CAS no. and include the possibility for authorities to have access to physical standards in order to set up testing and analysis for the presence of vP substances in the environment as well as the technosphere.
28. Limit the use of persistent substances to certain essential uses which due to technical reasons/functionality absolutely require such persistence.
29. In collaboration with the Member States, establish product standards that balance performance of vP substances against the health and environmental risks of that substance.
30. Set limit values and develop testing methods that can be used to check for/enforce compliance with such product standards.
31. Consider cradle-to-grave producer responsibility for vP substances, from production to its

downstream use in a product or article and the subsequent use phase, through to collection and destruction at the end of the product's useful life.

32. Establish European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances and vP-containing products, at end of their useful product life.
33. Support research to enable the development of better, less persistent alternatives to highly persistent substances used in consumer products.

3.6.4 Tools for gaps in controls over environmental build-ups of vPs

34. Set in place systematic environmental monitoring and surveillance of substances known to be very persistent, including human bio-monitoring and monitoring in e.g. waste streams and products, in order to track their presence and to be aware of any build-up in the environment, e.g., as part of any early warning system.
35. Develop better analytical methods for determining which substances are mobile (M) as well as persistent.
36. Design sampling and monitoring programs to look for contaminated resources where point sources of discharges have been identified, e.g., PFAS contamination of groundwater around all commercial and military airfields as well as landfills.
37. Facilitate environmental and human monitoring of vP substances by requiring producers to provide scientists with standard samples, including information on all transformation products formed upon release into the environment, as is required for pesticides and pharmaceuticals.
38. Develop and maintain inventories of all vP substances produced and used in products or released to the environment as emissions or waste, in order to keep track of overall loads of vPs in the environment.
39. Carry out a comprehensive survey of the overall natural resource base within the EU and its Member States, including inventories of all natural resources already contaminated by vP substances (central registries of contaminated land/water), and develop estimates of the costs of clean-up or of finding alternative resources.
40. Design and implement programs for limiting further contamination and for prioritising clean-up and explore liability and redress mechanisms for funding costs of clean-up.
41. Support development of and knowledge sharing on remediation methodologies/technology.

3.7 INITIAL EVALUATION OF AVAILABLE TOOLS

The following table presents the identified responses measures in a structured manner. The first column lists the gap or deficit addressed by the possible response, and the second column summarises the reason for the gap/deficit. The fourth column lists the possible responses (also identified by number in the third column) for addressing the gap or deficit. The next column characterises or qualifies the possible response by indicating if the response is short (1-2 years), mid (3-5 years) or long-term (over 5 years) and whether the identified response could be implemented through existing regulations or if new legislation would be required. The final column discusses the identified response from a qualitative point of view. This includes consideration of the following points.

- Does the measure spur the development of methods for identification and risk assessment of vP chemicals?
- Does the measure improve the knowledge of and access to information on vP chemicals?
- Does the measure promote the substitution and phasing out of vP chemicals, including the use of grouping approaches?
- Does the measure prevent the release of vP chemicals into the environment or the technosphere?
- Does the measure support the development of a health and environmental monitoring system of vP chemicals?

Table 12: Overview of available tools with respect to very persistent substances

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Identified responses to gaps in identifying & regulating very persistent substances					
Insufficient regulation of very persistent substances (vPs)	REACH requires showing of bioaccumulability in addition to persistence; no recognition of P as hazard category in own right (surfactants an exception)	1	Consider substances determined to be vP as giving rise to equivalent levels of concern under REACH Article 57(f) & add them to Candidate List. Note that Article 57(f) can only be applied on a case by case basis, so grouping approaches would not be possible.	Short-term, implementation; address under REACH	Recognition of vP as equivalent level of concern could happen without amending REACH and would enable better controls of vP substances where needed. The possibility of bringing in additional factors such as mobility (M) in order to get more political support has been put forward.
		11	Apply grouping approaches more vigorously with respect to vP substances with similar chemical structures, so as to facilitate evaluation, risk assessment & risk management, & avoid regrettable substitution	Short-term, implementation; address under REACH	Grouping approaches would lead to faster screening and identification of vPs. While ECHA already facilitates this during its screening processes, there is a need to increase collaboration of assessors of related substances during the assessment stage.
		12	Include P, vP, vPvB and PM (mobile) as hazard categories under CLP Regulation	Mid-term, regulatory; address under CLP	New hazard categories would improve information availability b/c hazards would be identified and communicated
Data gap because only ≈200 chemicals fully tested for persistence to date	Testing chemicals to determine half-lives is costly & time-consuming	4	Develop additional, less costly analytical tests for determining half-lives of vPs	Mid-term, implementation; address under REACH	Better testing methods would spur the identification and risk assessment of vPs, and improve knowledge about them
	Data on persistence for substances <10 tpa not required	9	Require registrants of low volume substances to provide data on persistence/biodegradability	Mid-term, implementation; address under REACH	Filling this data gap would increase the information available concerning numbers of vPs on the market and their uses
Total number of P/vP substances on EU market today is not known	No common framework for comprehensive screening for P/vP agreed at EU level	2	Develop harmonised framework for comprehensive screening for persistence & require more rigorous testing of half-lives where lack of biodegradability is found	Mid-term, implementation; address under REACH	A harmonised framework would facilitate the screening of substances concerning their potential for persistence and improve availability of information
		3	Improve accuracy of screening results by combining screening methods currently available &/or developing better screening methods	Short-term, implementation; address under REACH	This would increase confidence in screening methodologies and facilitate more comprehensive screening of the universe of substances, e.g., in commercial use
	Information lacking on degree of persistence (length of half-lives)	8	Require simulation tests for registered substances identified through screening as potentially vP	Mid-term, implementation; address under REACH	This would enable better understanding of degree of persistence and therefore the potential for occurrences of build-ups in the natural and material environment
Criteria & methodologies for identifying extreme	Analytical difficulties in determining half-lives >180 days	4	Develop additional, less costly analytical tests for determining half-lives of vPs, including when a substance is extremely persistent	Mid-term, implementation; address under	Better testing methods would spur the identification and risk assessment of vPs, including when no evidence of degradation by natural processes is found

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
persistence are lacking		14	Add additional classification for extreme persistence for those substances that may not degrade for decades or longer	REACH Mid-term, implementation; address under CLP or REACH	Better identification of vP substances needed for understanding of potential for build-ups in the natural and material environment
Information gap concerning vP substances' contribution to combination effects/cumulative exposure	Lack of attention to role of vP substances in combination effects/cumulative exposure	5	Factor in the additional exposure due to a substance's persistence in assessing its role in combination effects and cumulative exposure	Short-term, implementation; address under REACH	This would contribute to better knowledge and understanding concerning how continuing exposure because of a substance's persistence could have health and environment impacts
vP transformation products not sufficiently taken into account in looking at environmental impacts	Lack of information on transformation products	7	Require persistence of transformation products to be considered in evaluations of a substance for health &/or environmental impacts	Short-term, implementation; address under REACH	This would contribute to better information concerning the types of health & environmental impacts due to transformation products
Insufficient monitoring of impacts of unintentionally produced chemicals found in some products	EU regulatory framework does not account for all unintentionally produced contaminants	13	Take steps towards a more comprehensive regulatory regime for POPs by including additional unintentionally produced vP chemicals, as a first step towards more inclusive monitoring of exposure & product safety standards.	Mid-term, implementation; address under REACH or POPs	This would support development of better information concerning unintentionally produced contaminants in products, including human and environmental exposure
Inadequate international controls of production & releases of vP substances	International controls of vPs have not kept pace with globalisation of chemicals industry	12	Encourage inclusion of P, vP, vPvB and PM (mobile) as internationally recognised hazard categories under GHS	Mid-term, implementation; address under CLP	Internationally recognised hazard categories for persistence would improve information availability and communication
		15	Encourage more ambitious international implementation of controls through the Stockholm Convention mechanism	Mid-term, implementation; address under POPs	This would bring more vPs under the international POPs regime and contribute to elimination of their production and environmental release
Identified responses to gaps in controls over vP emissions to the natural environment					
Little information on overall loads of vPs released to environment or technosphere to date	Data not collected on quantities of vP chemicals produced/emitted	16	Establish transparent collection of data on quantities of vP substances produced and/or emitted to the environment	Mid-term, implementation; address under REACH	This would increase the availability of information on amounts of vP substances produced, and enable to better determination of overall loads of vPs in the natural environment
		10	Require producers to deliver validated analytical test methods for vPs along with technical standards, to enable better detection and monitoring of their presence	Mid-term, implementation; address under REACH	Scientists & regulators currently have to guess at what to look for. This support from producers would greatly facilitate environmental monitoring for the presence of vPs.

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
Incomplete controls over industrial emissions of vPs	Industrial Emissions Directive (IED) only applies to major installations	17	Require all industrial emissions of vP substances to the ecosphere to be subject to permit, including from smaller industrial installations	Mid-term, implementation; address under IED or other legislation	This would increase awareness of emissions of vPs to the natural environment and enable permitting authorities to set controls where necessary to prevent build-ups in the environment
	Use of emission limit values (ELVs) inappropriate to prevent build-ups of vP loads in environment	20	Establish fixed maximum amounts rather than ELVs (concentration levels) for vPs discharged to ecosphere, in order to avoid accumulations of vPs in the environment	Mid-term, regulatory; address under IED and Water Framework Directive	This would provide legal basis for preventing accumulations of vPs in the environment due to industrial discharges
	Some BAT guidance not adequate for controlling emissions of vP substances	18	Revise BAT guidance documents as necessary for industries utilizing vPs, to minimize all potential releases of vP substances to the environment	Mid-term, implementation; address under IED	Better guidance on best available techniques focusing on those industrial activities where vPs are used, e.g., as biocides, would improve access to information on how to prevent releases to the environment
		19	Require the production and/or industrial use of vP substances to take place only in closed systems	Mid-term, regulatory; address under IED and other legislation	This would provide legal basis for preventing any further discharges of a vP of high concern into the natural environment
Incomplete coverage of vPs in lists of polluting substances covered by IED	IED lists some vPs but only PBT & vPvB as categories	17	Require industrial emissions of all vP substances to the ecosphere to be subject to permit, including from smaller industrial installations	Mid-term, regulatory; address under IED and other legislation	This measure would extend awareness to other vPs not covered by integrated permitting to date and help to prevent their release into the environment
Inadequate controls to prevent vP releases during manufacturing/uses of certain products	Lack of attention to impacts of vPs during product use and end-of-life	21	Ensure consideration of a vP's environmental impacts throughout a product's lifecycle, including possible releases into wastewater that will result in contamination of UWWT discharges and in sewage sludge applied to land	Mid-term, regulatory; address under new legislation	This will lead to better knowledge about the impact of a vP substance throughout its life-cycle, and encourage the substitution and phase-out of vPs where undesirable risks of impacts cannot be otherwise managed
	No legal basis for restricting overall amounts of vPs released to environment	22	Set fixed limits at EU level to amounts of vPs be produced/used/released, as per restrictions in place for ozone-depleting substances.	Mid-term, regulatory; address under new legislation	Fixed limits for production and use of ozone-depleting substances is recognised internationally as an effective measure for preventing releases of ODS; similar limits for certain vP substances would prevent releases where necessary
		22	Allocate allowances for production/use of vPs via economic instruments such as tradeable permits	Mid-term, regulatory; address under new legislation	Economic instruments could promote the substitution and phasing out of vP substances, and minimise releases to the environment
Lack of attention to	Mobility of vPs not	23	Establish [hazard-based] bans on all unessential	Mid-term,	Mobility is increasingly acknowledged as a

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
risk to water resources when substances are P & mobile	recognised as hazard (risk) factor for water resources		releases of vP and mobile substances to the environment, e.g., use of PFAS-based foams in fire-fighting training	implementation; address under REACH	characteristic that can give rise to equivalent concern, particularly with respect to water resources including groundwater. This measure would prevent any unessential releases of PM substances in the interests of protecting water quality
Identified responses to deficits in controls over vPs in the technosphere					
Lack of information on vP substances used in articles, incl. imported articles	No data on what substances used in what products	26	Establish labelling of products where vPs present, together with traceability mechanisms	Mid-term, regulatory; address under REACH	This would improve access to information on vPs in particular products and enable buyers/consumers to make informed choices. Traceability mechanisms would help prevent vP contamination of material recycling streams
		27	Establish central registries of products containing vPs, & collect annual data on volumes of vPs produced, used & emitted, as part of a comprehensive vPs monitoring system	Mid-term, regulatory; address under REACH	Central product registries would improve information on vPs of concern in products and help in determining overall volumes, i.e., loads in the natural environment and ecosphere
	Lack of awareness of vPs & their impact on health & environment	25	Carry out public awareness campaigns to inform consumers and institutional purchasers (public procurement) concerning vP chemicals in products	Short-term; self-regulation	More consumer knowledge and awareness about the potential costs to health and environment from vP substances would lead to more informed choices & promote substitution/phase out of vPs
Few controls over use of vPs in products/articles	No controls on basis of persistence alone	24	Encourage voluntary bans or restrictions on use of vP chemicals by product designers, manufacturers and retailers	Short-term; self-regulation	This identified response would promote the voluntary substitution and phasing out of vPs
		28	Limit uses of vPs to certain essential uses which absolutely require such persistence due to technical reasons/functionality	Mid-term; implementation; address under REACH	Bans on non-essential uses would promote innovation and substitution of less harmful alternatives
	RoHS-type control only for EEE; missing for other products	29	Establish product standards that balance performance of vP substances against the health and environmental risks of that substance	Mid-term, regulatory; address under product legislation	Product standards that balance health and environmental concerns against a substances performance could promote substitution of less harmful alternatives
		30	Set limit values and develop testing methods that can be used to check for/enforce compliance with such product standards	Mid-term, regulatory; address under product legislation	This identified response would support the implementation of product standards aimed at minimising non-essential uses of vP substances
Alternatives to certain vPs with high performance sometimes lacking		33	Support research to enable the development of better, less persistent alternatives vPs used in consumer products.	Mid-term; implementation	The development of better alternatives would promote substitution and phase-outs of vP substances of concern
Lack of mechanisms	No tracking/	26	Establish labelling of products where vPs present,	Mid-term,	Labelling of products would improve access to

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
for preventing vPs contamination of the technosphere	monitoring of vPs in products, waste & recycled materials		together with traceability mechanisms	regulatory; address under product legislation	information on vPs in particular products, while traceability mechanisms would help prevent vP contamination of material recycling streams
	No restrictions on vPs in end-of-product materials entering recycling streams	31	Consider cradle-to-grave producer responsibility for certain vP substances, from production to downstream use in a product and the subsequent use phase, through to collection & destruction at end of product life	Mid-term; regulatory; address under waste legislation	This identified response would help to prevent the release of vP substances into the technosphere
Limited possibilities for safe destruction of vP substances	No requirements for end-of-life destruction of vP substances (market failure)	32	Establish European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances and vP-containing products, at end of their useful product life	Long-term; implementation; address under waste legislation	This response would improve the availability of methods for preventing release and build-up of vP substances in the environment
Identified responses to gaps in controls over environmental build-ups of vPs					
Inadequate protection of groundwater & other raw water resources used for drinking water	Lack of attention to substances both P and mobile, including in monitoring programs	35	Develop better analytical methods for determining which substances are mobile (M) as well as persistent	Short-term; implementation; address under REACH	Better methods for identifying substances that are both persistent and mobile would support risk assessment of vPs and help to prevent releases to the environment
		36	Design sampling and monitoring programs to look for contaminated resources where point sources of discharges have been identified,	Short-term; implementation; address under water quality & soil legislation	Sweden's research into PFAS contamination of groundwater around all commercial and military airfields has set an example here.
Lack of information concerning presence &/or build-up of vPs in environmental media	Inadequate monitoring of vPs in the environment	34	Set in place systematic environmental monitoring and surveillance of vPs, including human bio-monitoring, to track presence and any build-up in the environment, e.g., as part of an early warning system	Short-term; implementation; address under water quality & soil legislation	This response would support the development of a health and environmental monitoring system
	Lack of access to information of vPs and their transformation products	37	Facilitate environmental/human monitoring of vPs by requiring producers to provide scientists with standard samples, including information on all transformation products formed upon release into the environment, as with pesticides & pharmaceuticals	Short-term; implementation; address under REACH	This would improve scientific knowledge of vP substances in the environment, and support the development of a comprehensive monitoring system
		38	Develop inventories of all vP substances produced/used in products or released to the environment as emissions or waste	Mid-term; implementation; address under EPRT	This identified response would support the development of a monitoring system to keep track of overall loads of vPs in the environment
Lack of knowledge concerning extent of	No overview of vP contamination of	39	Carry out a comprehensive survey of the overall natural resource base within the EU and its	Mid-term; implementation;	A better understanding of the extent of vPs contamination of Europe's natural resources and the

Gap / Deficit	Reason for Gap/Deficit	#	Identified Responses	Qualification	Discussion
accumulations of vPs in the environment & related costs	the EU's natural resource base		Member States, including inventories of all natural resources already contaminated by vPs (central registries of contaminated land/water), along with estimates of the costs of clean-up or of finding alternative resources	address under soil or water legislation	costs of remediation would help to inform policy choices
		40	Design and implement programs for limiting further contamination and for prioritising clean-up and explore liability and redress mechanisms for funding costs of clean-up	Long-term; implementation; address under soil or water legislation	This long-term response would aim to prevent spreading of contamination and to protect important natural resources such as water reserves.
		41	Support development of and knowledge sharing on remediation methodologies/ technology.	Mid-term; implementation	This response would help to improve the knowledge base concerning methodologies for clean-up, and act to encourage clean-ups where a priority.,

4 CONCLUSIONS

This sub-study has investigated the case for regulating substances solely on the basis of their persistence in the environment. Substances that are determined to be very persistent (vP) are resistant to degradation. Because vP substances tend not to degrade through natural processes, their use and dispersal in the environment means they may remain there for an indefinite time and eventually reach levels where harmful effects to health and natural resources may occur.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment. Build-ups of a persistent chemical could lead to the same type of continuous exposure as occurs with bioaccumulation. Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's intrinsic hazard leading to harm.

As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process. This uncertainty about the properties of vP chemicals in combination with potentially severe and long term health and/or environmental damages would seem to suggest the need for a precautionary (hazard-based) approach.

In particular, build-ups of persistent chemicals in the environment are not sustainable. Contamination of natural resources with persistent chemicals is not easily reversed, and often continues even after the source of the pollution is stopped. For example, the propensity of persistent hydrophilics to remain in soil and groundwater for long periods of time, even after they cease to be emitted, presents particular concerns for water resources and aquatic ecosystems. Where remediation measures have been implemented, the costs have been extremely high and in many cases have only contained rather than reversed the contamination caused.

The sub-study has identified a number of gaps in analytical methods and data concerning persistence in chemicals. It has also found gaps in the risk management measures in place to prevent releases into the natural environment and to control the use of very persistent chemicals in the technosphere, which could pose problems for the material reuse/recycling streams envisioned as part of the Circular Economy.

On the basis of the research for this sub-study, a wide range of responses to these gaps were identified. It is clear that better screening and testing methods are needed, in order to target those chemicals where persistence is of high concern. There is also a need for various responses concerning very persistent chemicals in products.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement – something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

Very persistent chemicals released into the environment can render resources such as soil and water unusable or requiring expensive and resource demanding purification and remediation measures far into the future. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent

chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams. For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and pro-active approach and to prevent and/or minimize releases of vP chemicals in the future.

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